MEDICAL SUCTION UNIT

OB1000 FA - OB1000 FM

USER MANUAL

CE 0123

MANUFACTURED BY:

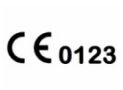
BOSCAROL®

Emergency Medical Systems

INDEX

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 OB1000 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 and performed to the 95/54/EEC European Directive.
	Manufacturer
	Date of manufacture
	The OB1000 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)

EC REP	Authorized Representative in the European Community, if the manufacturer is not resident therein.
	Expiration date
	Do not use if the packaging is not intact
REF	Catalogue ID code
STERILE EO	Sterile device. Sterilization method: ethylene oxide
STERILE R	Sterile device. Sterilization method: ionizing radiation
LOT	Production batch number
SN	Serial number

S.2 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 suction 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.
- Do not make any mechanical and/or electrical modifications to the wall/charging bracket. Replacing any parts thereof, and/or modifying the bracket itself, can seriously affect unit anchoring.
- The OB1000 suction unit does not perform any clinical diagnostics on the patient.
- Il dispositivo non può essere utilizzato per assistere pazienti durante indagini attraverso RMN (risonanza magnetica nucleare).

□ BATTERY

- Before using the suction unit for the first time (and/or upon receiving it), charge the internal battery for at least 24 consecutive hours.
- Keep the device under load even when not in using. Remaining plugged into the vehicle power supply (12 ÷ 15 VDC) does not damage the suction unit but allows maximum autonomy of the battery.
- Failure to regularly recharge the battery will lead to a 'deep discharge' at which time the battery will need to be replaced.

□ 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

Note:

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 device should be checked at least once every 12 months from the authorized service center. Every 24 months an inspection of safety and technical maintenance is required instead. Refer to authorized service centers for planning of inspection. The periodic safety inspection of the device does not fall under warranty.

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 OB1000 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.

OB1000 SUCTION UNIT

INSPECT THE SUCTION UNIT AND ALL PARTS BEFORE USE.
DO NOT ATTEMPT TO USE IF ANY PARTS ARE DAMAGED OR MISSING.

Model BSU210:

1. Suction unit
2. Autoclavable jar
3. Protection filter
4. Angular connector
5. Silicone tube with joint

Model BSU212:

1. Suction unit
2. OB-J jar
3. Disposable bag SERRES®
4. Silicone tube with joint

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 OB1000 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).

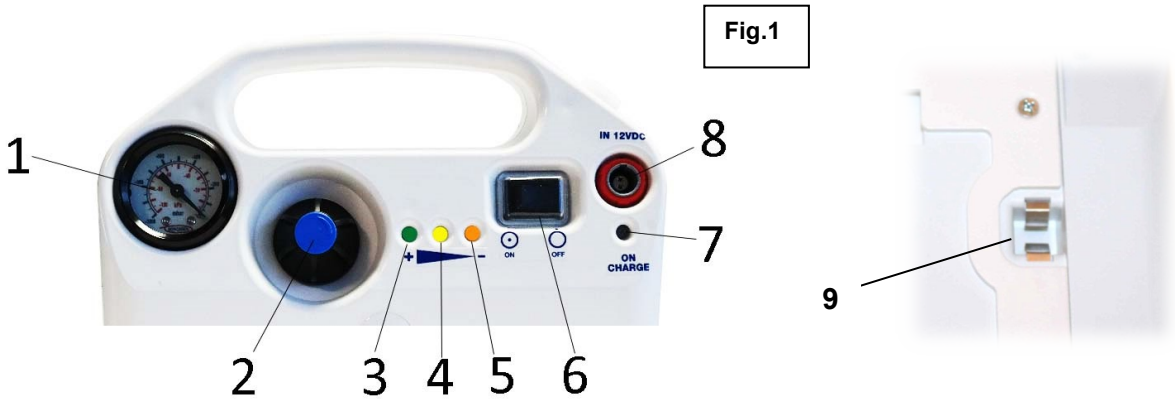
□ Contraindications for use

Do not use the OB1000 for thorax drainage.

□ Controls, operations and control panel

All controls are on the front of the suction unit. The unit can be controlled when fitted on the wall-bracket or in the carrying bag.
To activate the device, press the switch (6), which is protected against infiltration of moisture, splashing of water and other cleansers. Vacuum can be adjusted by turning the knob (2). 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. On the back are two contacts (9) that allow the charging of the device if fitted on the wall bracket. Alternatively, you can use the charging cable plugged into the external 2-pin connector (8).

Fig.1



□ Indicator lights

All lights are placed on the front and display the operation of the device (see Fig1): the autonomy of the battery (3-4-5) and the recharge state (7).

The table below indicates the condition of the LEDs and the relative power of the battery:

LEDS STATUS	BATTERY POWER LEVEL
LED green on (3)	>70% maximum power
LED yellow on (4)	40-50% medium power
LED orange on (5)	**10-20% battery low – the suction unit twill shut down soon**

The indicator for charging ON/CHG (7), placed next to the indicators of autonomy, has two different colors: Yellow indicates that charging is taking place; green indicates that charging is complete. The indicator lights up whenever the device is connected for recharging. If the LED does not light up, there could be a malfunction of internal recharge circuit, lack of power (12 Vdc) or lack of connection of external cable to a power source for 12 Vdc.

WARNING

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 <ON/CHG> LED: it should be on, both during charging and once charging has been completed!
A low battery compromises suction unit function, and thus its use. It's always necessary to recharge the battery after each use. 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).

□ Unit testing

The test 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.

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.

- Disconnect the unit from the wall bracket or from the external charging cable;
- 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;
- Turn on the unit with the switch on the front panel. 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;
- Check the indicator lights for battery power (when the battery is fully charged, all of the lights will be on);
- 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 (orange LED is on).

When finished, compare the results of this test with the value on the table below:

Test – phase	Result	Remedy
Switch the unit on.	The indicator lights for the power and the pump motor switch are on (noise from the motor).	Pump failure and/or battery completely discharged. Recharge the battery and check the indicator light goes green.
Check the battery power.	When the battery is fully charged the green light will be on.	Recharge the unit immediately.
Check the maximum vacuum.	Value range between 700 and 800 mbar (70kPa ÷ 80kPa; 525 ÷ 600mmHg).	Check that the lid on the collection jar is tight and that all connections are secure. Change the disposable liner.
Check the vacuum regulation.	Gauge reading ranges from maximum to minimum.	Check the vacuum connections and/or the regulator (anti-clockwise for minimum vacuum).

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.

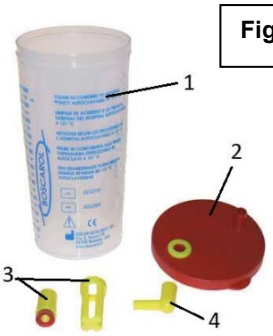
□ Collection jars

The suction unit is marketed with three different types of collection jar:

- OB-J FA autoclavabile collection jar with a capacity of 1000 ml (OB1000 FA)
- OB-J collection jar with a capacity of 1000 ml, with disposable liner SERRES® (OB1000 FM)

□ OB-J FA reusable, autoclavable 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.

□ Protection 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.

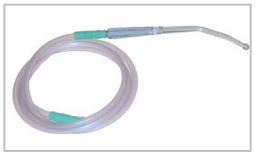
If the suction unit remains unused, it is advisable to replace the filter once a month. The material used in its construction could even be damaged by particular environmental conditions (humidity, heat, cold).
Do not use the suction unit without the protection filter or jar!

□ OB J collection jar with SERRES disposable liner

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.

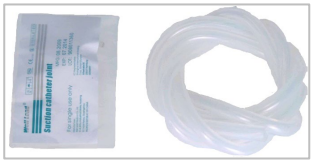
When used in a home environment, the jar can be cleaned using a special cleanser able to guarantee medical device disinfection. The disposable liner can never be emptied and reused. The liner containing the aspirated secretions must be disposed of in compliance with medical doctrine, i.e. as prescribed 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.

□ Power supply and battery charging

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 about 15 consecutive hours. A fully charged battery will provide approximately 45÷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), the wall bracket or optional power supply (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 (12÷15 Vdc) that can provide at least 6A.

Charging cable
BSU855

OB WB wall bracket
BSU810

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 power supply 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.

WARNING

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

□ Battery function test

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

- Recharge the suction unit for at least 15 consecutive hours;
- 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 20 consecutive minutes;
- 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.

MAINTENANCE AND REUSE

□ 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 "Daily test” in page.9.

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 INSTRUCTIONS

□ Cleaning of OB-J FA autoclavable jar

1. Wear gloves and protective clothing.
2. Remove the yellow angular connector with patient tube, 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). The yellow angular connector can be autoclave sterilized.
3. Disconnect the conical connection from the suction unit connector.
4. Loose canister fixing belt.
5. Pull the jar vertically out of the unit.
6. Disconnect the filter from the lid by turning it slightly in its housing.
7. Remove the lid (paying attention to possible contamination with the contents of the jar!). Empty the contents of the jar.

8 – 9 – 10 – 11 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.

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.

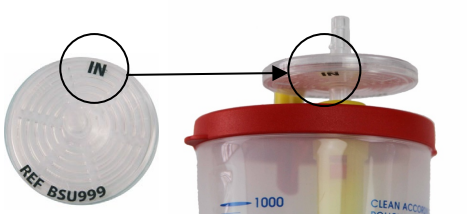
WARNING

- **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.

Replacing he 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.

□ Cleaning of OB-J jar

1. Wear gloves and protective clothing.
2. Disconnect the patient tubing together with the white angular connector for the disposable liner and discard it.
3. Close the “PATIENT” connector with the cap provided on the liner cover.
4. Disconnect the red connection from the suction unit connector.
5. Disconnect silicone tube from the red angular connector on the jar.
6. Loose canister fixing belt and pull the jar vertically out of the unit.
7. Remove the liner from the jar and dispose of it in compliance with current laws and regulations.
8. Disconnect for disposable liner adapter.

9. 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 in page 13 “Decontamination/sterilisation of the collection jar and silicone tubing”.

Reassembly of the jar

Extract a new disposable bag from the packaging, stretch it (picture 1) and insert it into the jar (picture 2). Insert the complete jar into the bag and connect the tube to the suction unit. Activate the suction unit. Close with a finger the connector <PATIENT> and, at the same time, press lightly the bag from the centre of the lid (picture 3). Make sure the bag is completely swollen. Connect the patient tube (Yankauer) to the connector <PATIENT>.

Fig. 1

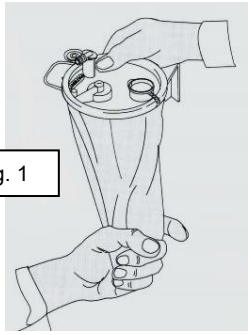


Fig. 2

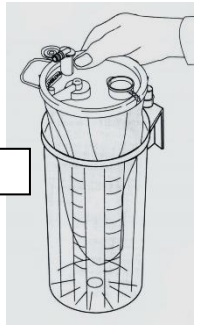
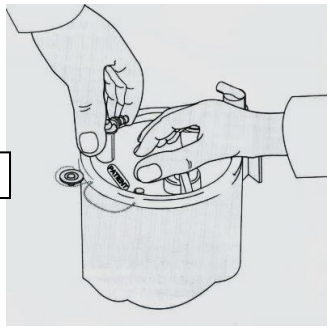


Fig. 3



NOTE

The collecting bag must be inserted into a rigid container of the same size.

Il is strictly forbidden to use defective products!

□ 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. If the above safety devices trip, if they do not reset automatically, contact your authorized service centre or Oscar Boscarol srl.

□ 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
BSU810	Wall bracket OB WB
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
	Parti di consumo
BSU730	Filter for autoclavable jar – 5 pcs
BSU732	Filter for autoclavable jar – 15 pcs
BSU734	Filter for autoclavable jar – 40 pcs
BSU705	Disposable bag - 6 pcs
BSU706	Disposable bag - 12 pcs
BSU707	Disposable bag - 36 pcs
BSU500	OB-J FA autoclavable jar, without protection filter
BSU506	OB-J jar, without disposable liner
126140107191	Yankauer suction catheter
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
	Parti di ricambio
BSU855	External charging cable with cigarette lighter fitting and 2-pole plug
BSU902	Silicone patient tubing - length 130cm
SPS6000	OB-J FA jar without lid
SPS6002	Over-fill valve – 3 pcs
SPS6004	Elbow connector for OB-J FA – 3 pcs
SPS6006	Lid for OB-J fa jar, without protection filter
SPS6011	Red angular connector – 3 pcs
SPS6014	Conical connector – 5 pcs
SPS6023	Silicone tubing 16 cm with conical connector for OB-J FA jar
SPS6021A	Silicone tubing 18 cm with angular connector for OB-J jar
BSU825	Protection bag for OB1000
--	User manual - can be downloaded from 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 SERVICE

No electrical and/or mechanical part of the suction unit OB1000 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 wall bracket.	• Cable damaged. • Damaged wall bracket and/or contacts on the suction unit. • External power source failure (12÷15 Vdc – min. 6A).	• Replace the cable • Replace the wall bracket. • Check the external power source.
The suction unit only works if it is mounted on the wall-bracket or fitted with the external cable.	• Faulty battery.	• Contact an authorized service centre.
The power supply doesn't work properly.	• Faulty power supply.	• Check the Charging LED. If it is on, but the battery is not charged, please refer to authorised service personnel. • Replace the power supply.
The suction unit works, but the battery power indicator lights are off.	• Faulty internal circuit. • Very low battery power.	• Check that the indicator lights work if connected to the wall-bracket or to the external charger cable. If they work, immediately charge the battery for at least 24 hours. • Charge the battery for at least 24 hours.
Suction unit battery life is significantly reduced	• Battery is dead • Internal charge circuit failure	• Replace battery • 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
Vacuum is always at maximum even if the jar is removed.	• Fault on the internal pneumatic circuit.	• Contact an authorized 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 (maximum continuous use 60 minutes)
Electrical requirements:	SELV (12÷15 VDC)
Use of the device in the home environment:	IEC 60601-1-11
Use of the device in the health emergency:	IEC 60601-1-12
Applied part according to IEC 60601-1:	TYPE BF
Insulation rating:	CLASS II
Protection against ingress of liquids and solids (IEC 529):	IP34d
Compliant with general rules in IEC 60601-1:	Compliant with 3rd Edition
Dimensions	
Maximum dimensions:	320 mm (l) x 250 mm (h)x100 mm (p)
Weight:	3,5 Kg max. max. complete with all accessories
Tolerance on all values:	±5%
Technical data	
Nominal suction power:	850mbar (85kPa, 638mmHg) +/-10%
Vacuum regulation:	linear
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:	> 45 minutes ±10% run time
Approximate maximum noise:	65dB
Vacuum gauge precision:	±5%
Battery power indicator precision:	±5%
Power supply	
Running/charging:	12÷15 Vdc (direct current)
Max current load:	70W (max. current 6A)
Battery:	rechargeable hermetically sealed acid type, Capacity 3,2 Ah
Max charge time:	15 hours consecutive

Electrical safety devices:	Internal, not accessible to operator

NOTE

The external direct current power supply must provide at least 6A 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	
Operating temperature range:	0÷50 °C (32÷122 °F)
Charging temperature range:	15÷30 °C (59÷86 °F)
Storage and transport temperature range (packaged unit):	-25÷55 °C (-77÷131 °F)
Storage and transport temperature range (without packaging):	0÷50 °C
Relative humidity for storage, operation and transport (unit without battery):	15–95%, not condensed
Atmospheric pressure for storage and transport:	70–106 kPa (700–1060 mbar)

Operating in the rain

The OB1000 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%

Storage of SERRES products

SERRES products are factory-sterile and should be stored in warm indoor locations. Protect the package from humidity, dirt and dust. Disposable products can be used for 5 years after the date on the label.

Battery charger technical data

Input: 100÷240 Vac 50/60Hz, 1,5A
Output: 14 Vcc 4,25A, 60W

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 OB1000 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 OB1000 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 OB1000 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 OB1000 suction unit is designed for use in the electromagnetic environment specified below. The customer or operator of the OB1000 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 OB1000 suction unit continuously even when power from the mains is out, we recommend powering the OB1000 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 OB1000 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 OB1000 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 OB1000 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 OB1000 suction unit for a period of 24 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 24-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 – N° Q5 042208 0031 Rev. 00 Certifies UNI EN ISO 9001:2015 – N° 50 100 7289 – R.004 Emission: TÜV–SÜD Product service (CE0123) EC Certificate N° G1 042208 0032 Rev. 00
We declare under our sole responsibility that the device (name): *Dichiariamo sotto nostra responsabilità che il dispositivo (nome):*	**MEDICAL SUCTION UNIT** **ASPIRATORE MEDICALE DI SECRETI**
Type: **Tipo:**	**OB1000 FA – OB1000 FM**
UMDNS code:	**15016**
Boscarol code:	**BSU210 – BSU212 – BSU216 - BSU220 – BSU226 – BSU228** **XAS0100 – XAS0104 _ XAS0106 – XAS0108** **XAS0200 - XAS0112 - XAS0150 - XAS0152**
Devices classification (MDD 93/42/EEC – Annex IX) : *Classificazione dispositivo (MDD93/42/CEE – Allegato IX):*	**Class IIa**
Meets all the provisions of the directive MDD 93/42/EEC and subsequent amendments which apply to it. *Soddisfa tutte le disposizioni della direttiva MDD 93/42/CEE e successivi emendamenti che lo riguardano.*	
Applied harmonised standards, national standards or other normative documents: *Norme armonizzate o nazionali applicate, altri documenti normative applicate:*	**ISO 10079-1:2016** **UNI EN 1789:2014** **IEC 60601-1 Ed. 3.0** **IEC 60601-1-11** **IEC 60601-1-12** **ECE-R10**
Conformity assessment procedure: *Procedimento di valutazione della conformità:*	**MDD93/42/EEC, Annex II (Allegato II)**
Notify body: *Organismo di notifica incaric. della valut. della conformità:*	**TÜV – SÜD Product Service GmbH** **CE 0123**

Bolzano, 25.08.2020

DIR/RAQ – Quality Manager
Dr. MARCHETTI BENEDETTA

DIR/CEO
BRAZZO DANIELE

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