BOSCAROL MEDICAL SUCTION UNIT

OB3000

OPERATING INSTRUCTIONS

CE 0123

MANUFACTURED BY:

OSCAR BOSCAROL SRL
Via Enzo Ferrari 29
39100 Bolzano
ITALIA

Tel. +39 0471 932893
Fax: +39 02 57760140

info@boscarol.it
www.boscarol.it

Information about the manufacturer and to the device:

- The Oscar Boscarol apply a quality management system according to the International standards ISO 13485 and ISO 9001
- The medical device OB3000 (in all its configurations) complies with the MDD 93/42/EEC (and subsequent modifications) and bears CE marking (CE 0123 notify body TÜV SUD Italy)
- The medical device meets the essential requirements as described in the Annex I of the MDD 93/42/EEC

Information about these operating instructions:

- This document contains important information for safe, effective, and compliant use
- Use this information to train users and to confirm the training carried out
- The manual cannot be modified (even partially) except for the device manufacturer
- These instructions must always accompany the device. It is advisable to use the electronic version and make it available on operators' PDAs, tablets, and mobile phones

These operating instructions are valid for the following devices:

OB 3000 FA
OB 3000 LINER
OB3000 AVIO FA
OB3000 AVIO LINER

REF CODE:

BSU3000	BSU3001	BSU3020	BSU3021	BSU3000A	BSU3001A	BSU3020A	BSU3021A

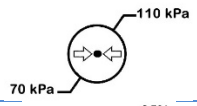
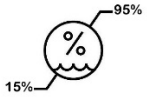
CONTENTS

0. MEANING OF SYMBOLOGY AND PICTOGRAMS

0.1. Symbols used in the Operating Instructions to draw the reader's attention

	Danger: 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 to prevent damages to the device or other items. Activate the correct measures
1.	List of actions: follow the actions step by step
	These operating instructions
	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 OB3000 and OB3000 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)
	The suction unit complies with European Directive 2011/65/EU (RoHS)
	Maintenance service required (refer to the manufacturer and/or to the authorized service centre)

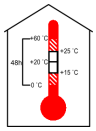
0.2. Symbols used on the suction unit and accessories

	Protection class II (according to the IEC 60601-1 standard)
	Application part Type BF (according to the IEC 60601-1 standard)
	Use suction unit only within indicated temperature range. Using the OB3000 outside these limits may compromise its operation, reduce battery life and cause internal safety devices to trip.
	Limits for use for atmospheric pressure (from 70 kPa to 110 kPa)
	Limits of use for humidity (from 15 to 95 %)
	Please read the Operating Instruction Manual entirely
	Suction unit accessories and/or consumables bearing this symbol are single use, disposable items. Cannot be reused and after use must be discarded and replaced with new ones. The symbol is placed on the consumables
	Indicates the need for the user to consult the instructions for use for important precautionary information, such as warnings and precautions which cannot be displayed on the medical device in question

CE 0123	CE marking compliant with MDD 93/42/EEC for medical devices rated higher than class I
	Manufacturer
	Date of manufacture
	The OB3000 and OB3000 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).
EC REP	Authorized Representative in the European Community if the manufacturer is not resident therein.
	Expiry date
REF	Order number
	Please read the Operating Instruction Manual in other languages available on the web site indicated
	Do not use the device in MR environments
LOT	Production batch number
SN	Serial number
MD	Indicates the item is a medical device
	Follow operating instructions
PATIENT	Connection suction hose/patient (lid of the collect container and to the Serres® liner)
INPUT	On the power adapter indicates the input voltage range accepted
OUTPUT	On the power adapter indicates the output nominal voltage
	Indoor use only
	Direct current
	Alternating current

0.3. Symbols used on battery and recalled also in the Operating Instructions

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 (at least)
REF SPS3500	Battery reference code
	Warning, important notice

	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 suggested conditions (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. Follow European Recycling Plan
	Read the User Manual
	Production batch number

1. INTENDED USE

Name of the device	OB3000 – OB3000 AVIO BOSCAROL SUCTION UNIT
Main use	Suction unit intended to remove secretion, blood and other body fluids, solid pieces of food or tissues in the medical sector
Other use	The device can also be used as pump to evacuate vacuum mattresses and vacuum splints
Medical purpose	Suction of the upper and lower respiratory airways
Part of application in the human body	Upper airways: nose, nasal cavity, throat, mouth Lower airways: larynx, trachea, bronchial system
Type of patients	New-borns, infants, and adults both genders
Application time on the patient	< 60 minutes – Temporary use
 **About the use**	• The suction unit can be used on all types of patients following the correct medical technique • Clearing the lower respiratory tract is to be performed by medical and/or health care professionals trained and authorized for such actions • Clearing the upper respiratory tract is to be performed by medical and/or health care professionals (included paramedical people and rescuers) trained and authorized for such actions • In some Countries, this information must be verified according to the protocols implemented by the local emergency health services
Application site according to the ISO 10079-1:2019	The suction unit OB3000 and OB3000 AVIO can be used in the hospital/clinics, in the practice, accident, and emergency health services, first aid in general, nursing and home care facilities as well as for outdoor application and during transport. The OB3000 AVIO can also be used and recharged in helicopter-ambulances and planes

2. WARNINGS, PRECAUTIONS, AND IMPORTANT INFORMATION

Read carefully

These Operating Instructions have been prepared using simple, easy-to-understand language. If you have difficulty interpreting this document, contact the manufacturer for further clarification.

Phone +39 0471 93 28 93

info@boscarol.it

- 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.
- If suction is performed without the collection jar and/or filter in place, or if it is suspected that substances may have entered in the suction circuit (i.e. in the OB3000 device), immediately contact the nearest service centre or the manufacturer to have the unit serviced.
- Do not spray substances on the device. Before cleaning it, make sure that the intake hole of the suction circuit is closed (affix a piece of tape or connect the tube of the jar).
- 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 and the tools 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.
- Do not modify any mechanical or electrical parts on the wall-bracket. The replacement of parts of wall bracket and / or alteration thereof can seriously affect the safety anchorage of device.
- The user can replace the battery with a new one (only original manufacturer's part), thanks to the appropriate housing provided at the bottom of the device. Always close tightly the red cover on the case (battery bay) to prevent that liquids and other substances entry into the device from outside.
- The OB3000 suction unit does not perform any clinical diagnostics on the patient.
- An overtemperature stop the working of the device to prevents overheating of the batteries.

 **LATEX**	The OB3000 and OB3000 AVIO device is built and produced without the use of latex. However, it is not excluded that throughout the production chain it may have meet latex substances.
	Do not use the device in environments that require magnetic resonance imaging. The device could be dangerous for users and patients

	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the OB3000 and OB3000 AVIO, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
	• Warning: use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally. • Warning: use of accessories, power adapter, transducers, and cables other than those specified or provided by the manufacturer of this medical device could result in increased electromagnetic emissions or decreased electromagnetic immunity of this device and result in improper operation.
 **DEVICE CONTAMINATED**	• Warning: contamination of the device. If you use the suction unit according to these instructions, with the original collect container and bacterial filter the device cannot be oversucked during normal use. Nevertheless, if substances have entered in the device, the unit must be discarded. Sending a contaminated suction unit to the manufacturer, installer or service centre is **strictly forbidden**. The risk of spreading pandemics is high and must be avoided • Any device received in such condition will be rejected and health authorities notified of possible contamination. In this case, the term contaminated means a suction unit that has not been made cleaned of the secretions aspirated from the patient. If the substances aspirated have entered the suction unit, it must be discarded. For Boscarol, 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 it is contaminated and it is possible the risk of infection (application of the international law for the protection of workers where applicable). • If in doubt before sending a device for repair, contact the Boscarol technical service by sending an email to the address info@boscarol.it or by calling the telephone number +39 0471 932893
 **REUSE OF DISPOSABLE PARTS**	• Warning: 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 losing mechanical integrity.
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÷30 Vdc) does not damage the suction unit. • The battery can be replaced by the operator. Contact Oscar Boscarol Srl or send an email to info@boscarol.it to buy a new battery

3. IMPORTANT INFORMATION TO KNOW BEFORE USE OB3000 – OB3000 AVIO

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!

 **PERIODICAL SAFETY INSPECTION**	**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 manufacturing date on the label).
Operator responsibilities	• The OB3000 suction unit is designed for emergency health services and must therefore be ready for use at any time and in any situation. • Always make sure 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 sure that it is out of the reach of children.
 **OVERFILL INTERVENTION**	**WHAT TO DO IN THE EVENT OF INTERVENTION OF THE OVERFILL VALVE?** • Wear protective gloves, splash guard goggles and a mask type FFP2 or FFP3 • Turn off the suction unit and disconnect the silicone hose that goes from the collect container to the device. • Check if the level of the sucked liquids has reached the maximum level in the collect container. • Carefully remove the collect container and store it in a safe place • Empty the bottle safely by first removing the filter (which must be discarded), then the lid. • Empty the collect container and allow for complete cleaning and disinfection (if necessary, sterilization) • Clean and disinfect the device according to what is indicated in these operating instructions

4. CONTRAINDICATIONS (NOT SUITABLE FOR)

 **CONTRAINDICATIONS**	• Low vacuum range e.g. thorax drainage or wound drainages in general • Permanent endoscopic use • Do not use in surgical rooms where the potential equalization is necessary (e.g. heart surgery) • Outside the medical field • Suction of flammable, corrosive or explosive substances • Suction in explosion-hazardous environments

5. SIDE EFFECTS (POSSIBLE DURING SUCTION OPERATIONS)

 **SIDE EFFECTS**	• Bleeding in general in the nasal pharyngeal area. Also throat and tongue. • Damages to the vocal cords • Cardiovascular instability • Side effects caused by vagus nerve stimulation • Tachycardia caused by stress • Choking, nausea, vomiting and coughing • Respiratory tract infection (typical from the hospitals) • Seizures by patients who tend to have cramps
 **SIDE EFFECTS**	Attention: to minimize side effects, it is important to observe what is indicated in these operating instructions

6. THE OB3000 AND OB3000 AVIO MEDICAL SUCTION UNIT

After receiving the device, make sure all parts are present. All Boscarol suction units are ready for use and are assembled except for the antibacterial filter which is placed on the device itself (but not connected to the device).

Package contents for FA type

01 Suction unit complete with battery pack already inserted and ready for use
01 Reusable collect container complete with overfill valve in the lid
01 Antibacterial filter complete with silicone hose
01 Sterile Yankauer catheter (not mounted)
01 Power cable from the SELV voltage (11÷30 Vdc) ready for use
01 Operating instruction in Italian language or English and technical documentation

Package contents for LINER type

01 Suction unit complete with battery pack already inserted and ready for use
01 Reusable collect container complete with SERRES disposable liner already inserted in the collect container
01 Sterile Yankauer catheter (not mounted)
01 Power cable from the SELV voltage (11÷30 Vdc) ready for use
01 Operating instruction in Italian language or English and technical documentation

Depending on the chosen configuration, the device can be equipped with the following accessories:

01 Power adapter suitable for powering and recharging the unit from the main supply
02 Wall bracket complete of power cable for the connection to the SELV voltage (11÷30 Vdc)

6.1. Description of the unit

The OB3000 and OB3000 AVIO are a medical suction device that complies with all reference standards. It can be used in motor vehicles (such as ambulances), 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 (LIPO) with an electronic internal circuit to protect against short circuiting or other failures that could make the unit dangerous.
The battery has undergone specific tests of conformities for aircraft and helicopter transport (IEC 62133 and UN38.3 IATA).
The OB3000 suction unit comes in four basic versions: BSU3000 e BSU3020 and BSU3000 and BSU3020A.

Model BSU3000:

1. Suction unit
2. Autoclavable OB-J FA collection jar 1000 ml
3. Antibacterial filter
4. Elbow connector
5. Silicone tubing to connect the jar to the device.

Model BSU3020:

1. Suction unit
2. Autoclavable OB-J collection jar 1000 ml
3. SERRES disposable liner
4. Elbow connector

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

6.2. Controls, operations, and control panel

All controls are on the front of the suction unit to facilitate its use even when fixed on the wall bracket. 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 kilopascals (kPa) or millimetres of mercury (mmHg). The vacuum gauge is fluorescent and can be seen in the dark. There are two contacts (5) on the backside of the unit that allow the charging and power of the device when it is fixed on the wall bracket. Alternatively, you can use the external charging cable by connecting it to the socket (4) at the lateral side (see picture 2). The charging socket is airtight and fit with two electric poles (Fig. 2).

Fig.1

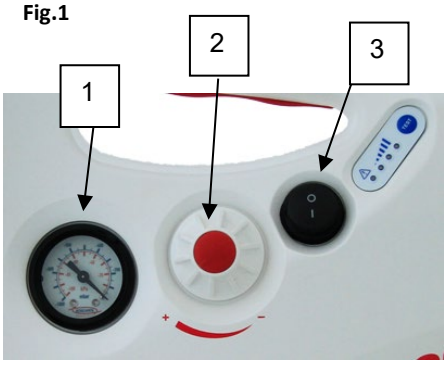
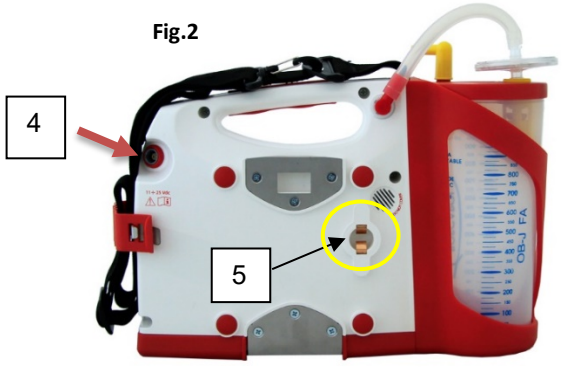


Fig.2



6.3. Indicator lights

The front of the unit holds the lights (LEDs) and battery charge test button (see →). 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 **only** when the power is off, and the unit is disconnected from any external electric sources (wall bracket, power 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 fixed into the wall bracket, plugged to the external power adapter or to the charging cable — 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 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**

BATTERY FULLY DISCHARGED	The suction unit will cut out within **two minutes** of the moment the last green LED starts flashing because the battery is completely discharged!
LOW BATTERY	**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.
ELECTRICAL CONNECTIONS	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!
BATTERY TEST INFO	The insertion of the battery in the device activates a special function to test and verify the charging of it, which will display the autonomy status by lighting the respective LEDs. Charge the battery immediately to ensure its maximum autonomy. To view the battery charge, press the TEST button: to do so, the suction unit must be disconnected from the power adapter, wall bracket or charging cable. A steady yellow light indicates that the battery is fully charged (maximum battery life).

6.4. Periodic OB3000 and OB3000 AVIO suction 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 that 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.

OB3000 AVIO	**For this version of suction unit, the periodic test must be conducted every six months due to the strict conditions of use!**

Daily 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.

6.4.1. Periodical daily test for OB3000 e OB3000 AVIO suction unit

DAILY TEST	• Disconnect the device 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. • Press the test button located near the battery charge LEDs. If all 4 green LEDs are on, the battery is full (running time: approximately 60 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 squeeze the silicone tube connected to the secret bottle (before the filter) or before the connection to the collect container for SERRES® bags. The sound of the pump should change and the reading on the vacuum meter should reach the maximum value (about 800 mbar, 80 kPa, 600 mmHg) in seconds. • While keeping fully squeezed the silicone tubing, turn the vacuum regulator anticlockwise 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 contacts on the back side of the unit (they must be clean and free of stains, oxidation and/or burns). • Fix the device on the wall bracket. If the battery is discharged, the device will start to charge it. If the device is not complete with a wall bracket and the battery is discharged 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. Do not use the suction unit without filter.

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 4 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 or replace the battery with a new one. During these operations, exclude the device from its use
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. Try replacing the battery and, if the problem persists, 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
Check the contacts at the back side of the device	The contacts must be clean and free from oxidation. The metal parts must be free from burning marks.	Clean the contacts with a cloth soaked in ethyl alcohol. In presence of strong burning marks, contact an authorized service centre.

⚠	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.

6.4.2. Semi-annual/annual test for OB3000 e OB3000 AVIO suction unit

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, even if the device has not been opened it is advisable, given it's specific use, to run an electrical safety test according to IEC60601-1 and issue a test summary document available for the user.

SEMI-ANNUAL/ ANNUAL TEST	• Before starting these tests, replace the disposable bag or antibacterial filter. • Mechanic operation of the wall bracket: check its correct fixing, functioning, and sliding of the upper red part without any impediments. After pushing the upper red part, release it and check that the blocking hook returns into the initial position. Check the charging contacts on the wall bracket. • Check the connection of the electric cables to the wall bracket (they should be fixed properly). • 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 12. • 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 (precision ±2,5 % or less). 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 time operation: 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 data plates 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 the correct battery insertion in its compartment and the hermetic closing of the red cover. • Check vacuum gauge function. When the suction unit is off, the needle should be on "0". • Make certain that the strap is stable, intact, and not torn. Slipping of the strap (in nylon) is not permitted. • Check that the collection jars are intact and that there are no cracks that could compromise suction. • Check the screws of the two steel elements at the back side of the device to be fixed tightly. • Before declaring the suction unit compliant with the manufacturer's data plate, run an electrical safety test as per IEC60601-1. Contact the manufacturer or authorized service centre for information on running this test.

CONFORMITY OF THE DEVICE	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 before and after the control. Always keep a copy of the report on the safety test performed with an appropriate, calibrated instrument
WORKING FEATURES	In compliance with ISO 10079-1:2019, the device can operate only in a vertical position and with an inclination angle of no more than 20°. If this limit is exceeded, the overflow valve could intervene by blocking the suction.

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.

6.5. Special automatic functions

The OB3000 and OB3000 AVIO suction unit have 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 faulty, this does not compromise the suction produced by the unit. The microprocessor serves a special 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 expiry 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.

6.6. 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 normal.

6.7. Safety information to protect users, patients and third parties

To prevent undesirable effects always follow the following information:

- Make sure that all accessories are functional and replace defective power adapter or cables. Do not take unnecessary risks: always replace the defective parts to have an always efficient device in case of use and emergency.
- Keep the unit on the wall bracket (in the emergency vehicles) to prevent damages to the user during transport or emergency medical situation.
- Even you do not use the unit recharge the battery once a month. If the device has not been used for a long time, remove the battery, and keep it in a safe place.
- We suggest having another suction unit in case it does not work or break down (e.g. manual suction unit).
- Always remember what is reported in the initial warnings regarding the risks deriving from the effects of magnetic fields (EMC).
- Always select the appropriate level of vacuum according to the patient and the medical guidelines.
- Do not alter or modify the medical device. Serious consequences for the patient and user can occur.
- OB3000 and OB3000 AVIO **isn't a sterile** device and cannot be sterilized except for the collect container.
- Keep children away from hoses and connection cables. Also keep away from fingertip, and other small parts

Risk of infection

- Incorrect use of the device can cause the transmission of even fatal infections.
- Always wear disposable gloves especially if you could come into contact with the sucked fluids.
- Never use components marked disposable more than once. Disposable parts or medical devices are marked as on the figure beside (the number 2 crossed out).
- Never operate the device without the bacterial filter.
- Always disconnect the unit from the power adapter or the SELV source before performing cleaning and disinfection processes.
- Use the power adapter only in dry indoor environments. Do not use main power adapter outdoor!
- Always use only original accessories and original spare parts. Do not try to repair the battery pack or replace with a similar one!
- Assembly, repairs, modifications, and period tests may only be carried out by the manufacturer or authorized persons.

7. OB3000 COLLECTION JARS (AND OB3000 AVIO)

The suction unit is marketed with two different collect containers:

- Suction unit with 1000 ml autoclavable OB-J FA collection jar (OB3000 FA – OB3000 AVIO FA).
- Suction unit with 1000 ml autoclavable OB-J collection jar and SERRES disposable liner (all type of OB3000 devices)

7.1. OB-J FA Collect container

The jar is made of specific transparent plastic (polypropylene medical grade). It includes canister (1), snap-on lid (2), overflow valve (3) and 90° plastic connector (4). The lid allows direct insertion of the filter end provide an overflow valve.
The jar can be sterilized in a conventional steam autoclave at a maximum temperature of 121° C and pressure of 2 bars (200 kPa). The jar must be replaced if it shows any deformation, breaks, or cracks. The collect container (and consequently also the suction unit) 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, then remove the filter to rebalance the pressure inside the bottle.

Collect container LIFETIME	The collect container must be replaced after 30 sterilization cycles or 4 years of use

7.2. Anti-bacterial filter

The filter protects the suction unit 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). The filter is disposable and ***must be replaced after each use***. In case of possible contamination, discolouration and increased resistance to suction replace the filter always.

Anti-bacterial 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 ones, 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, when the suction level decrease or if the colour of the filter changes.

Risk of infection	• Never use the device without the bacterial filter. Please always store at least three spare filters. • Always wear gloves and personal protective equipment when you change the antibacterial filter and empty the collect containers. • Before each use, check that the filter is dry and clean (it must not be of a colour other than white). Change the wet or contaminated filter with a new one. • Never reuse the bacterial filter (disposable item).
Non-use of the suction unit	• If the suction unit remains unused, it is recommended that you remove the filter. Re-insert a new filter before it is reused. The material used to build the antibacterial filter can be sensitive to environmental conditions (humidity, heat, cold). • Do not use the suction unit without the protection filter or collect container!

7.3. OB-J LINER : collection container with disposable SERRES® system

The OB-J jar for SERRES® disposable bags (see Fig. 4) is made of a specific transparent plastic (polypropylene medical grade). It includes a canister (1), adaptor for SERRES disposable bags (2), 90° connector (3) and disposable SERRES® bag (4). The antibacterial 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 bag 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.

Fig. 4

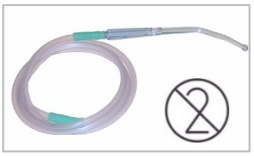
Risk of infection	• Please always store at least three spare SERRES® bag. • Always wear gloves and personal protective equipment when you change the SERRES® bag and dispose it. • Before each use, check that the SERRES® bag has not already been used. Change the contaminated bag with a new one. • Never reuse the disposable SERRES® bag (disposable item).
Non-use of the suction unit	• If the suction unit remains unused, it is advisable to keep the device without the SERRES® bag and insert a new bag when needed or in any case before its reuse. The material used in its construction (the SERRES® bag) could even be damaged by environmental conditions (humidity, heat, cold). • Do not use the suction unit without the bag properly inserted in the collection container!

7.4. Collect container connection

The jar is connected to the suction unit through a silicone tube and a red plastic connector. Insert the connector in the device through the inlet as showed on the picture beside: insert 90° red plastic fitting without straining. This operation is valid for both types of collect container.

7.5. Yankauer catheter (sterile) with integrated suction 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. The rigid suction tip is also spherical and equipped with lateral holes to avoid damaging the tissues during aspiration.

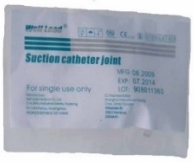


Yankauer PATIENT	The Yankauer suction catheter is a disposable sterile medical device. Never reuse this device which must be disposed of after use on the patient.
	Warning! Do not use sterile medical devices beyond their expiration date or if the package is damaged.
	Always connect the Yankauer suction tube to the side “PATIENT” on the lid of the reusable collect container (FA) or to the “PATIENT side on the SERRES® bag through the white plastic connector.

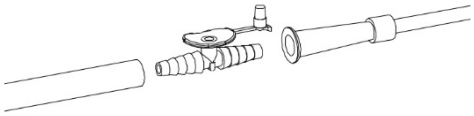
7.6. Silicon suction tube and sterile Fingertip (suction catheter joint)

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 silicone tubing can be sterilised while the finger-tip joint is, instead, disposable.

The finger-tip joint allows the user to control vacuum directly with a finger, without requiring any commands. The disposable devices supplied with the medical suction unit bear labels providing all information needed for proper use.



The Fingertip (also called as suction catheter joint) allows the fixing of standard catheters for aspiration (see the picture beside)



7.7. Warning about the reuse of disposable devices

Disposable medical devices Risk of infection	**Warning**: 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
Disposable SERRES® bag	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!

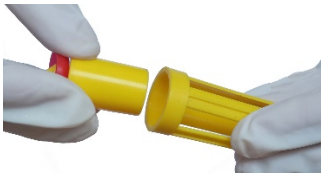
8. CLEANING AND DISINFECTION

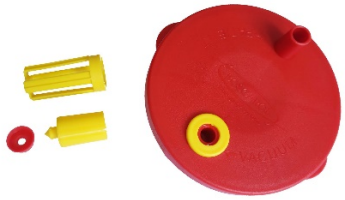
After each use, unplug the suction unit, disconnect the disposable parts, and discard them. Check that the suction unit is intact, check the connection tubing and check for any structural anomalies. Clean and disinfect the suction unit as described below. Replace all single-use, disposable parts with new components and recharge the battery.
Run the daily function test as described under "1.4 Periodic unit testing”. 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.

Risk of infection	Always wear gloves and personal protective equipment when you change the antibacterial filter and empty the collect containers	
DANGER	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.	

8.1. Reuse of the autoclavable OB-J FA collect container

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, the mouth, and the eyes.

Remove the patient tubing together with yellow 90° connector. If the tube is equipped with a Yankauer suction tip, it must be disposed of together with the curved tip (sterile disposable devices). Do not dispose the 90° yellow connector which can be reused and sterilized.	
Disconnect the 90° red connection from the suction unit inlet.	
Pull the jar vertically out of the unit.	
Disconnect the filter from the lid by turning it slightly in its housing and discard it.	
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.	
Remove the overflow valve from the lid.	
Separate all parts of overflow valve.	

Parts composing the lid.	
DANGER	Risk of infection by spilled over secretion. Deadly disease can be transmitted. For this reason, always use suitable PPE and disinfection products as established by the competent authorities.
	Please pay attention to some disinfectants may stain the parts that compose the collect container, even if they cannot damage the chemical properties of the material.

8.2. Cleaning, disinfection and/or sterilisation of the collect container OB-J FA and silicone tubing

The collection container and silicone tubing can be cleaned with non-abrasive cleanser suitable for cleaning medical devices. Alcohol or solvent-based detergents can be used if diluted (follow the instruction of use on the label of the disinfectants). Avoid use of any coloured disinfectants as these may stain the plastic of the jar and stain the silicone tubing, reducing its transparency. After having disposed of the disposable filter and Yankauer suction catheter, complete with tubing, set the reusable parts in hot water (temperature not higher than 60° C to prevent burns to the operators) containing a diluted disinfectant for medical devices. Rinse thoroughly and, if necessary, use a non-abrasive brush to remove any deposits. After washing, dry all parts. Refer to the cleaning and disinfection plan on the following pages. For serious contamination, refer **always** to the provisions of the hospitals and competent authorities
If needed, sterilize the “REUSABLE PARTS” (see above) with steam autoclaves at a maximum temperature of 121°C for max. 15-20 minutes (typical cycle). Do not use autoclaves pressures above 2 bar (200 kPa). The jar should be placed in If needed, sterilize with a steam autoclave at a maximum temperature of 121°C for max. 15-20 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 all parts to cool to ambient temperature. Check that the parts are not damaged, not deformed or broken.

DISINFECTION CYCLE **WARNING**	• **Do not spray liquids on the device. Clean the device with the suction inlet closed. Put a tape or leave the jar connected to the unit.** • Do not use disinfectants based on aldehyde and/or amine to prevent discoloration. • Use disinfectants for the cleaning of medical devices. Before applying to the surface of the device and device collect container, verify in a small part that no damage occurs. • Refer to the trained personnel in the hospitals and clinics. Check for specific disinfecting and cleaning plans and/or protocols for the affected area.
STERILISATION CYCLE **WARNING**	• Never sterilize devices or parts that have not been cleaned before. • Do not put weight on the parts during the sterilisation cycle. • Observe the maximum limits for temperature, pressure, and duration during the autoclave cycle (temperature: 121° C, pressure: 200 kPa, time 15-20 minutes max.). • 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 to prevent loss of vacuum and carryover of fluids. • Comply with the instructions provided by the autoclave manufacturer.

8.3. Reassembling of the collect container OB-J FA and suction silicone tubing connection

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 (red part). Reassemble the jar following the operations used to dismantle it in inverse order.

AFTER CLEANING	**Warning** • Check after each cleaning if the device and its parts are damaged. • If necessary, send the device to the manufacturer or to an authorized centre for review and control • Always, after the reassembling process, perform a function check as described on Chapter 1.4 of these operating instructions • Prepare the device for next use

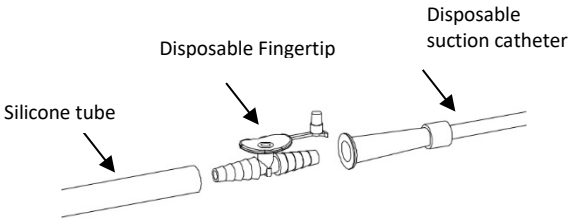
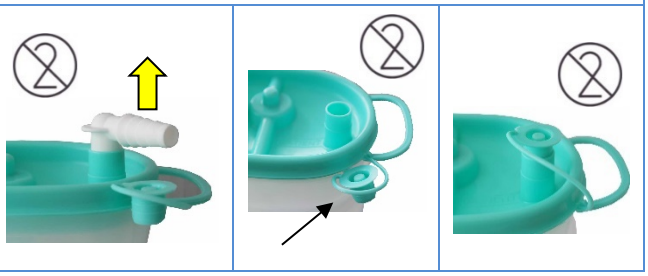
8.4. Replacing the antimicrobial filter

Carefully disconnect the silicone tubing from the contaminated filter. Dispose the filter in accordance with current laws and regulations. To easily remove the filter from the lid, screw and unscrew 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.

ANTIMICROBIAL FILTER	**Warning** 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.

8.5. Cleaning of OB-J collect container with SERRES® bag

The jar OB-J Liner is equipped with a specific disposable bag, approved for this type of use. Unlike the OB-J FA version, the disposable filter is located inside the liner. Each new bag contains a new filter that cannot be removed or replaced by the user

Before removing the disposable bag it is necessary to take some safety precautions. Discard the disposable Yankauer catheter complete with rigid probe. Always remember about risks of infection and contamination	
If the device is equipped with a silicone tube, fingertip and suction catheter proceed as follows: • Dispose the disposable catheter together with the Fingertip (see the picture beside) • Disconnect from the white connector on the SERRES® bag the silicone tube. Keep it because can be reused, disinfected, and/or sterilized	
Carefully remove the 90° white connector located on the SERRES bag (if not already done) and close the inlet hole (PATIENT) with the cap provided (see the black arrow in the picture beside).	

Disconnect the 90° red connection from the suction unit inlet by pulling with the hand the red connector.	
Pull the jar vertically out of the unit.	
Remove the disposable bag (previously closed) from the jar and dispose of it in compliance according to the indications of the clinics and hospital service	 REUSABLE PARTS
With the hand and using a small force, remove the silicone tube from the red 90 ° plastic connector.	 REUSABLE PARTS
Remove the plastic adapter from the collect container by pulling up the part. It is necessary to use two hands and force to separate the two parts. Be careful not to damage the plastic parts.	 REUSABLE PARTS
Unscrew the plastic elbow connector while keeping the screw pressed inside the jar. Be careful with the seal ring.	 REUSABLE PARTS  REUSABLE PARTS

Collect container LIFETIME	The collect container must be replaced after 30 sterilization cycles or 4 years of use.

DANGER	Risk of infection by spilled over secretion. Deadly disease can be transmitted. For this reason, always use suitable PPE and disinfection products as established by the competent authorities.

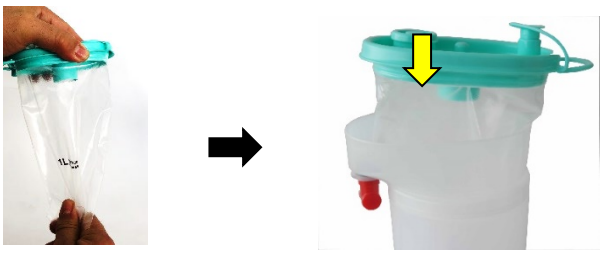
8.6. Disinfection and/or sterilisation of the reusable collect container OB-J and silicone tubing

For cleaning, disinfection and/or sterilization of the secret bottle (and silicone tube) follow the instructions in chapter § 8.2. Cleaning, disinfection and/or sterilisation of the collect container OB-J FA and silicone tubing.
Refer to the cleaning and disinfection plan on the following pages.

REUSABLE PARTS	The reusable parts indicated on page 22 can be disinfected and/or sterilized.
DISINFECTION CYCLE **WARNING**	• **Do not spray liquids on the device. Clean the device with the suction inlet closed. Put a tape or leave the jar connected to the unit.** • Do not use disinfectants based on aldehyde and/or amine to prevent discoloration. • Before proceeding with disinfection, make sure that you have the appropriate substances available and the right instruction to use them. • Use only disinfectants for the cleaning of medical devices. Before applying to the surface of the device and device collect container, verify in a small part that no damage occurs. • If substances seriously contaminated by specific infections have been aspirated, refer to the indications of the healthcare professional. • Refer to the trained personnel in the hospitals and clinics. Check for specific disinfecting and cleaning plans and/or protocols for the affected area.
STERILISATION CYCLE **WARNING**	• ***NEVER STERILIZE THE DISPOSABLE SERRES® BAG.*** • Never sterilize devices or parts that have not been cleaned before. • Do not put weight on the parts during the sterilisation cycle. • Observe the maximum limits for temperature, pressure, and duration during the autoclave cycle (temperature: 121° C, pressure: 200 kPa, time 15-20 minutes max.). • 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 to prevent loss of vacuum and carryover of fluids. • Comply with the instructions provided by the autoclave manufacturer.

8.7. Reassembling the collect container with the SERRES® disposable bag

Draw a new disposable bag from the package, stretch it out and insert it into the jar (see picture beside).
Push the new bag into the collect container firmly.



- 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.
- Make certain that the liner is completely extended in the jar. Connect the disposable patient catheter (Yankauer) to the “PATIENT” connector

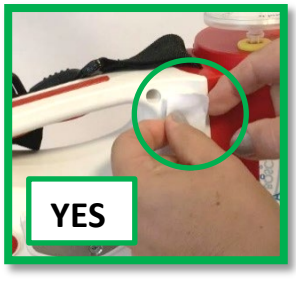
8.8. Disposal of contaminated parts

Always follow local regulations or hospital practices when dealing with contaminated materials. Never store contaminated parts with new or sterile parts. Boscarol markets specific bags identified for the contaminated parts.

8.9. Cleaning and/or disinfecting the suction unit and accessories

Disconnect the suction unit from any external power supply. To clean the device surface, use a damp cloth with dilutes specific disinfectant (same as used to clean the collect container). Be careful not to stain the membrane with the LED located on the front of the device. Sometimes the screen prints on the container may be damaged or made illegible by certain types of disinfectants. When finished, dry the surface with a dry cloth or paper towel.

DANGER **ELECTRIC SHOCK BY LIQUID IN THE DEVICE**	• ***Always disconnect the device from the energy source before cleaning.*** • To proceed for the cleaning of the device surface, always disconnect the unit from the wall bracket. • **NEVER RINSE THE DEVICE** under running water and/or immerse it into liquids. • The suction device come in a ***non-sterile condition and cannot sterilized*** • Do not immerse the suction unit in disinfectant solution. • Never use solvents that could deteriorate plastics and remove printing and labels. • Do not spray liquids on the device. The collect container inlet must always close to prevent that cleaning or disinfectants enter in the unit and damage the suction circuit.
POWER ADAPTER and WALL BRACKET **DISINFECTION PROCESS**	• Disconnect the power adapter from the mains before you start to clean it. Wait at least 1 minute after the disconnect to allows it to self-discarding the accumulated energy. • Never rinse the power supply or the wall bracket under water and never immerse in into any liquids. • Make sure that the cloth used to clean the device is slightly damp and not wet. • Never immerse the power adapter or the wall bracket in disinfectants or detergent. • To disinfect the surface of the power adapter and wall bracket please use only disinfectants for medical device and always dry the surface. The cloth must be damp and not wet. • After these operations please wait at least for one hour before use it again.
DEVICE SURFACES CLEANING	The substances that enter the suction hole are sucked by the pump and sprayed on the electronic parts. For this reason, it is always better to close the suction hole with a piece of adhesive tape or plaster. At the end of the cleaning this tape must be removed.



DISINFECTANTS AVAILABILITY	To correctly disinfect and decontaminate the suction unit, we recommend using specific, approved products. These disinfectants must be free of abrasive substances. Oscar Boscarol Srl (Ltd) can provide specific disinfectants suitable for 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 chlorine, phenols, aldehydes, and halogens.
AFTER CLEANING	**Warning** • Check after each cleaning if the device and its parts are damaged. • If necessary, send the device to the manufacturer or to an authorized centre for review and control • Always, after the reassembling process, perform a function check as described on Chapter 1.4 of these operating instructions • Prepare the device for next use

8.10. Cleaning and disinfection plan

Please print out this form and fill it in with the name of the person who carried out the process.

Operation	Cleaning	Disinfection	Sterilisation	HOW TO DO	Daily	Every 15 days	After each patient/after each suction	Operator name
OB-J FA	X	X	If required	See chapter 8	X		X	
OB-J LINER	X	X	If required, only the collect container	See chapter 8	X		X	
Overfill valve check	X	X	If required	See chapter 8.1	X		X	
Reusable Hoses	X	X	If required	See chapter 8.2	X		X	
Bacterial filter				Exchange the filter, even if blocked		X	X	
Device house	X	X	**Not allowed**	See chapter 8.9		X	X	
Power adapter	X	X	**Not allowed**	See chapter 8.9		X	X	
Wall bracket	X	X	**Not allowed**	See chapter 8.9		X	X	

9. ACCESSORIES AND OPTIONAL FOR OB3000 AND OB3000 AVIO

To be able to safely fix the device in ambulances, a wall bracket support (which provide also for the powering of the device) is available. The bracket has passed compliance tests regarding the international standard EN 1789.
The suction unit can be charged using the cable (supplied), the wall bracket (optional) or the optional power adapter (Input 100÷230 Vac). The charging cable must be connected to a 11÷30 Vdc power supply (direct current).
To be used while being charged, the suction unit must be connected to an external power supply (11÷30 Vdc) that can provide at least 80 W continuous power.

Power cable ready for use for OB3000 and OB3000 AVIO suction unit. REF code: BSU855.	

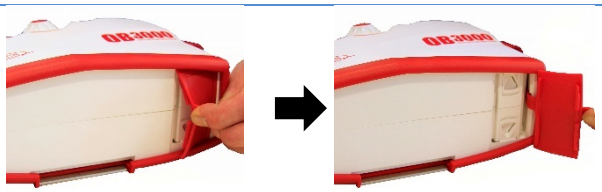
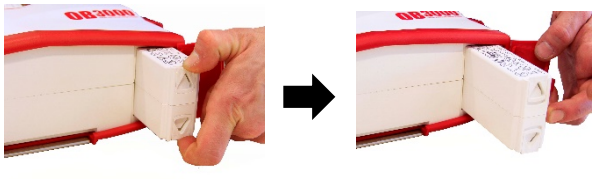
Wall bracket which can powering and recharging the suction unit. REF code: BSU810.	
Power adapter LYD with 2 pole male connector. Input voltage from 100 to 240 Vac Output voltage: 14,0 Vdc Nominal power: 60 W REF code: BSU895EU (Europe plug), BSU895UK (UK plug) – BSU895JP (Japan plug)	

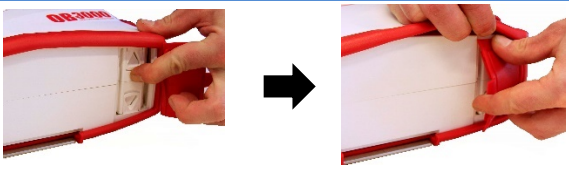
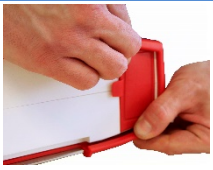
EXCLUSIVE ACCESSORIES	The adapter is an exclusive accessory, available only from the manufacturer. It is approved for such function and cannot be replaced with other brands. It can only be used indoors and on a power supply compliant with the law. The medical suction unit can only be used with this adapter.
DANGER ELECTRIC SHOCK	Never tamper with and/or open the adapter. Danger of death. The adapter contains internal electronics subject to line voltages that can be fatal.
LIFETIME	The life of the suction unit is **10 years from date of manufacture**. The device must be replaced after 10 years.

10. INTERNAL BATTERY OF OB3000 AND OB3000 AVIO

The OB3000 suction unit has an internal battery that ensures long operating life. The lithium-polymer (LiPo) battery is enclosed in an airtight, rigid plastic container that cannot be opened, and fitted with contacts. There is no need to replace the battery except for when it is damaged or after exceeding the maximum number of charging cycles (over 500 cycles). 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 free air 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. The battery is always replaced during the preventive maintenance and safety inspection. If the unit is not used for a long time, run a complete check, and fully charge the battery every 20 days.

8.11. Battery replaces

Find the red cover made of thermoplastic material (TPU) at the bottom of the device. Open it pulling the appropriate wing.	
Push two wings of the battery box with two fingers. Extract completely the battery.	

Push the battery completely to the back of the compartment. Then close the cover	
Accurately close the red cover. Check that the cover perfectly adheres to the surface.	
Check on the front part of the unit if the autonomy led went ON. If yes switch ON, the unit and perform the daily test as indicated on chapter 6.4.	

BATTERY FUNCTIONALITY TEST	• Recharge the suction unit by plugging it into an external direct current power supply rated between 11 and 25 V. 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.

BATTERY RELATED RISKS	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.	
	Check the correct closure of the cover to prevent the penetration of liquids and/or solid substances, which can damage the device.	
	After the insertion of the new battery, the LEDs on the front panel will switch on (see the picture on the right).	
Battery charge	After the replacement of the battery, plug the device to the power supply (or fix it on the wall bracket) until the yellow indicator on the front stops to flash. The device is ready for use	
Battery disposal	The old or faulty battery must be disposed of according to the regulations in force in the country where the suction unit is used.	

11. SPECIAL WORKING CONDITIONS

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 working conditions (temperature, humidity, and pressure). The technical characteristics and nominal working conditions are listed in the chapter 15.
If the suction unit needs to be used under limit conditions, check the following step on the next table.

WORKING UNDER SPECIAL CONDITIONS	• 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 15 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).

12. 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. If the device is contaminated it cannot be demolished following this directive but as expressly required by hazardous hospital waste.

Risk of infection	• Prior to dispose the suction unit always clean and disinfect it. • All the contaminated parts must be disposed according to the local laws and guidelines • Recycle the disinfected reusable parts • Never dispose the battery in domestic waste • The medical suction is fully recyclable, always refer to the country-specific laws and guidelines in force
DECONTAMINATION PROCEDURE	To clean and disinfect the unit prior the disposing, you can ask Boscarol for the decontamination procedure (mailto: info@boscarol.it)

13. ACCESSORIES, CONSUMABLES AND SPARE PARTS

Manufacturer code	Description
	Accessories
BSU810	OB WB wall bracket
BSU895EU	Power adapter LYD 100÷240 Vac - 2 poles and Euro-plug – Vout = 14 Vdc
BSU895UK	Power adapter LYD 100÷240 Vac - 2 poles and UK-plug – Vout = 14 Vdc
BSU895JP	Power adapter LYD 100÷240Vac - 2 poles and Japan/USA-plug – Vout = 14 Vdc
	User parts
SPS3500	Spare battery LI-PO 11,1 V 5 Ah
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
BSU500	Autoclavable OB-J FA jar, without filter
BSU506	OB-J LINER 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
	Spare parts
BSU855	External charging cable with cigarette lighter fitting and 2-pole plug
BSU902	Patient silicone tubing internal diameter 6 mm – 130 cm length
SPS6000	OB-J FA autoclavable collect container without lid
SPS6002	Over fill valve for OB-J FA lid – 3 pcs
SPS6004	Yellow plastic 90° connector for OB-J FA collect container
SPS6006	Lid for SPS6000 jar complete of over fill valve and 90° plastic yellow plastic connector
SPS6011	90° red connector – 3 pcs
SPS6023A	Silicone tubing 16 cm length with 90° connector for OB-J FA jar
SPS6024A	Silicone tubing 13 cm length with 90° connector for OB-J jar
SPS5092	90° red plastic connector for OB-J jar – 3 pcs
eIFU	Operating Instructions available on the link: https://www.boscarol.it/ita/eifu.php

LIST UPDATE	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).

14. TECHNICAL SERVICES

No electrical and/or mechanical part of the suction unit OB3000 and OB3000 AVIO are designed to be repaired by the dealer, customer and/or operator. The user is only authorized to replace the battery (see 10.1). 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 small operations 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 (Ltd) for a list of authorized service centres by sending an e-mail to info@boscarol.it.

14.1. Troubleshooting

Malfunction	*Possible cause(s)*	*Solution*
The suction unit does not work	• Battery low • Battery failure • Battery missing • Battery inserted incorrectly • Internal electronic circuit failure	• Charge the suction unit with the charging cable or power supply adapter • Replace the battery • Insert the battery into the box completely • Insert the battery correctly following the illustrations provided in this manual (§10.1) • Contact an authorized service centre
The suction unit does not work when connected to the wall bracket	• The wall bracket is not connected to the external power supply 11÷30 Vdc. • Power supply voltage is outside the required range • Current insufficient to power the suction unit • Suction unit contacts damaged • Wall bracket contacts damaged. • The power supply cable of the wall bracket is wrong connected • Suction unit internal circuit failure	• Connect the cable from the wall bracket to the car system • Power supply voltage must be between 11 and 30 Vdc • Increase the power of the source or fuse • Contact an authorized service centre • Contact an authorized service centre • Change the poles of the power supply cable (+ must be on the upper contact) • Contact an authorized service centre
The suction unit works ***only*** when connected to the wall bracket, power adapter, or external power cable.	• Internal battery damaged • Internal battery missing • Internal electronic circuit failure	• Replace the battery • Insert the battery in the box • 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 or • 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 • Internal battery is missing or inserted incorrectly • LED display or internal electronic circuit failure	• Disconnect the suction unit from the wall bracket or charging cable or adapter • Recharge internal battery (yellow LED flashing). Replace the battery. • Insert the battery correctly (see the page 17). • Contact an authorized service centre
Suction unit battery life is significantly reduced	• Battery has come to the end of its lifecycle • Internal charge circuit failure	• Replace battery • Contact an authorized service centre
Vacuum power on patient side is low or absent	• Vacuum regulator completely open • Protection filter clogged • Tubing connecting filter with device is clogged, bent and/or disconnected • Overflow valve for OB-J FA jar blocked • Overflow valve of disposable liner blocked • Pump damaged	• Close vacuum regulator completely and check vacuum on both instrument and patient sides (by turning the knob clockwise) • Replace the protection filter • Connect tubing to filter and/or jar; replace if clogged 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 (±20 % max inclination). • Replace disposable liner. • Contact an authorized 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 authorized service centre.
High noise, low suction, high vibration.	• Internal pump is damaged	• Contact an authorized service centre.

DANGER ELECTRIC SHOCK	Never tamper with and/or open the suction unit and/or the power adapter. Danger of death. The adapter contains internal electronics subject to line voltages that can be fatal. In the case of anomalies or malfunctions other than those indicated above, always contact only an authorized service centre or the manufacturer**.**

15. TECHNICAL DATA AND REFERENCES TO THE COMPLIANCE

Medical Device classification (according to the MDD 93/42)	**IIa**
Basic UDI number	805240088BSUGJ
Classification according to the ISO 10079-1:2019	HIGH VACUUM-HIGH FLOW
Mode of operation (short-term operation):	TEMPORARY (45 minutes “ON”, 10 minutes “OFF”)
EMC reference standard	IEC 60601-1-2:2014 - 4° EDITION
Safety compliance for electro-medical devices	IEC 60601-1:2012
Use of the device in the home environment	IEC 60601-1-11:2010 compliant
Use of the device in the emergency	IEC 60601-1-12:2014 compliant
Applied part according to IEC 60601-1	TYPE BF
Protection class against electric shocks	CLASS II
Protection against ingress of liquids and solids (IEC 529):	IP44
Device risk assessment	ISO 14971:2019
Device usability analysis	IEC 62366-1:2015
Safety and periodical maintenance:	Every 24 months
UMDNS code	15-016
GMDN code	63643
ECE R10 (automotive) type-approved	**E50 10 R - 05 0078**
Compliant with the ambulance norm	UNI EN 1789:2014
Crash test regarding the devices fixing in the ambulances	UNI EN 1789:2014
Avionics compliance regarding EMC (only for OB3000 AVIO)	RTCA DO160 - G

OB3000 – OB3000 AVIO Dimensions	
Maximum dimensions:	360 mm (l) x 244 mm (h) x 110 mm (p)
Weight of the suction unit:	Max 2,6 Kgs complete with all accessories, without wall bracket
Weight of the wall bracket:	780 gr.
Tolerance on all values:	±5 %

Technical data	
Nominal suction power	800 mbar (80 kPa, 600 mmHg) ±10 % (*)
Vacuum regulation	Linear with integrated mechanical regulator
Vacuum range regulation	30÷800 mbar (3÷80 kPa)
Nominal flow rate	33 LPM (litres per minute) at open flow ±10 %
Max running time (free air flow)	60 minutes ±10% run time
Approximate maximum noise	70 dB
Vacuum gauge precision	±2,5 %
Battery power indicator precision	±5 %
Autoclavable collect container	Type OB-J FA 1000 ml sterilizable in autoclave for max. 30 cycles
Flacone di secreti OB-J autoclavabile	Type OB-J for disposable 1000 ml SERRES® bags
Lifetime of the suction unit	10 years from the first use
(*) Note: 1bar = 100kPa = 750mmHg	

Battery charging and power supply	
Running/charging	11÷30 Vdc (Direct Current)
80% charge time	6 hours (at suggested charging temperature range)
Max charge time	10÷15 hours consecutive
Max current load	80 W
Battery type	extractable, LI-PO, 11.1 V – 5 A
Electrical safety	Internal, not accessible to operator
Type of pump	Piston type, maintenance free, 12 Vdc electric motor
Type of operation	The device can remain connected to the charging source continuously
Power adapter type 2	LYD type Model number: 601404250

Special storage and operating conditions	
Operating temperature range	-10÷45° C
Relative humidity for storage, operation, and transport	15÷95 %, not condensed
Storage and transport temperature range (packaged unit)	-20÷60° C
Charging suggested temperature range	0÷50° C
Atmospheric pressure for storage and transport and use	700÷1100 mbar (70÷110 kPa)
Operating in the rain	Protected against ingress of liquids and solids
Max. operating altitude	5000 m (above sea level)

Operating in the rain	The OB3000 suction unit is protected against ingress of liquids and solids. However, it is always preferable to protect the unit from heavy rains. 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

Consumables data	
Antibacterial filter	PTFE type, hydrophobic. Max pressure : 100 kPa
SERRES® bag/liner	Disposable type with integrated antibacterial filter
Yankauer catheter with rigid tip	Sterile, disposable. Tube length: 1,3 m. Diameter: 6 mm internal
Fingertip	Sterile, disposable
Silicone tube	Reusable and sterilizable. Internal diameter: 6 mm. Length; 1,3 m

	Other technical specifications available by the manufacturer (info@boscarol.it).

16. EMC INFORMATION FOR OB3000 AND OB3000 AVIO

16.1. RISKS OF MUTUAL INTERFERENCE WITH OTHER DEVICES

The OB3000 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 OB3000 and OB3000 AVIO 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 OB3000 suction unit is designed for use in the electromagnetic environment specified below. The customer or operator of the OB3000 suction unit should ensure that it is used in such an environment.

Emissions tests	Limit	Electromagnetic environment - guidance
Conducted emission	CISPR 11, Group 1, Class B	The OB3000 and OB3000 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.
Radiated emission	CISPR 11, Group 1, Class B	
Harmonic current emissions	IEC 61000-3-2, Class A	The OB3000 suction unit and OB3000 AVIO are directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. Only for Home healthcare environments.
Voltage fluctuations/flicker IEC 61000-3-3	IEC 61000-3-3	

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY

The OB3000 suction unit is designed for use in the electromagnetic environment specified below. The customer or operator of the OB3000 suction unit should ensure that it is used in such an environment.

IMMUNITY test	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (IEC 61000-4-2)	Contact discharge: ±8 kV contact Air discharge: ±2 kV, ±4 kV, ±8 kV, ±15 kV	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
		Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF EM filed IEC 61000-4-3	80-2700 MHz; 1kHz AM 80 %; 10 V/m	Recommended separation distance d = 1.2√P for 80 MHz to 800 MHz d = 2.3√P for 800 MHz to 2,7 GHz
		where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
	385 MHz; Pulse Modulation: 18 Hz; 27 V/m	
Proximity fields form RF wireless communications equipment (IEC 61000-4-3)	450 MHz, FM + 5 Hz deviation: 1 kHz sine; 28 V/m 710, 745, 780 MHz; Pulse Modulation: 217 Hz; 9 V/m 810, 870, 930 MHz; Pulse Modulation: 18 Hz; 28 V/m 1720, 1845, 1970 MHz; Pulse Modulation: 217 Hz; 28 V/m 2450 MHz; Pulse Modulation: 217 Hz; 28 V/m;	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance 30 cm.
	5240, 5500, 5785 MHz; Pulse Modulation: 217 Hz; 9 V/m	
Electrical fast transients / bursts (IEC 61000-4-4)	Power lines: 2 kV; 100 kHz repetition frequency Signal lines: 1 kV; 100 kHz repetition frequency	Mains power quality should be that of a typical environment.
Surges (IEC 61000-4-5)	L-N: 1kV at 0°,90°,180°,270° L-PE, N-PE: 2 kV at 0°,90°,180°,270°	Mains power quality should be that of a typical environment.
Conducted disturbances inducted by RF fields (IEC 61000-4-6)	0.15-80 MHz; 1kHz AM 80 %; 3 Vrms, 6 Vrms in ISM and amateur radio band	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** *d = 1.2√P for 150 kHz to 80MHz* where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m).
Rated power frequency magnetic fields (IEC 61000-4-8)	30 A/m, 50 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips / Voltage interruptions (IEC 61000-4-11)	0 % U_T for 0.5 cycle at 0°,45°,90°,135°,180°,225°,270°,315° 0 % U_T for 1 cycle at 0° 70 % U_T for 25/30 cycles at 0° 0 % U_T for 250/300 cycles 0°	Mains power quality should be that of a typical environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device is powered from an uninterruptible power supply or battery.

17. DCC – DECLARATION OF CONFORMITY ACCORDING TO THE MDD 93/42/EEC

We, the manufacturer: *Il produttore:*	**OSCAR BOSCAROL SRL (LTD)** 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): *Dichiariamo sotto nostra responsabilità che il dispositivo (nome):*	**MEDICAL SUCTION UNIT** **ASPIRATORE MEDICALE DI SECRETI**
Type: **Tipo:** **UMDNS code:** **GMDN code:** **Boscarol code:**	**OB3000 FA – OB3000 LINER** **15-016** **63643** **BSU3000 – BSU3001 - BSU3020 – BSU3021** **BSU3000A – BSU3001A - BSU3020A – BSU3021A**
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** **UNI EN 1789** **IEC 60601-1** **IEC 60601-1-2** **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 incaricato della valutazione 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

18. WARRANTY

Oscar Boscarol guarantees the OB3000 suction unit for a period of 5 years 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 5-years warranty period, the product is found defective, it should be sent to Oscar Boscarol Srl (Ltd) with a note describing the defect. Oscar Boscarol Srl (Ltd) 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 must be filled out and returned by mail, fax or e-mail, to the following address:

OSCAR BOSCAROL SRL (LTD) 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 (Ltd) can only be held liable if:

- all technical operations, repairs, modifications, and preventive maintenance actions are performed by Oscar Boscarol Srl (Ltd) or by an authorised service centre
- the suction unit is used correctly, strictly following the indications given in this Operating Instructions
- 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

Emergency Medical Systems
Via Enzo Ferrari 29, 39100 Bolzano IT
Tel. +39 0471932893 - Fax: +39 0257760140
info@boscarol.it
www.boscarol.it

Printed in Italy by Oscar Boscarol Srl (Ltd)
Rev. 04-2020 IFU OB3000 – OB3000 AVIO (ENGLISH)

https://www.boscarol.it/ita/eifu.php