BOSCAROL MEDICAL SUCTION UNIT

OB MINI

INSTRUCTIONS FOR USE

CE 1936

MANUFACTURED BY:

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Information on manufacturer and medical device:

- Oscar Boscarol applies a quality management system compliant with international standards ISO 13485 and ISO 9001
- The medical device OB MINI (in all its configurations) is compliant with MDR Regulation 2017/745 and bears the CE marking (CE 1936 notified body TÜV Rheinland Italia)
- The medical device meets the general safety and performance requirements described in annex I of MDR Regulation 2017/745

Information on these operating instructions:

- This document contains important information for safe, effective and compliant use of the medical device
- Use this information to train users and confirm their training
- This manual may not be modified in any way (not even partially). Only the device manufacturer can make changes when necessary.
- These instructions must always accompany the device. We recommend using the electronic version and making it available on operator PDAs, tablets and cell phones

These operating instructions apply to the following devices:

OB MINI FA
OB MINI FM
OB MINI 500
OB MINI AVIO FA
OB MINI AVIO FM
OB MINI AVIO 500

REF CODE:

BSU360EU	BSU360JP	BSU360UK	BSU360UKST	BSU364EU	BSU364EUB	BSU364JP	BSU364UK	BSU368EU
BSU368JP	BSU368UK	BSU370	BSU370JP	BSU370UK	BSU372	BSU372JP	BSU372UK	BSU374
BSU374JP	BSU374UK	BSU364JPM						

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0 MEANING OF SYMBOLS AND PICTOGRAMS

0.1 Symbols used in these operating instructions to call the reader's attention

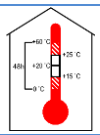
	Danger: important safety-related information covering correct use of the suction unit to prevent operator or patient injury and/or damage to unit itself
	Warnings: information requiring special attention
	Notes or information on preventing damage to the device or injury to others. Implement correct prevention measures
1.	List of actions to be performed: follow them step by step
	These operating instructions
	Electric and magnetic fields generated by radiographic or tomographic equipment, portable radio equipment, RF radios and devices bearing this symbol could have an impact on proper operation of the suction unit. In these cases, suction units OB MINI and OB MINI AVIO must not be used, or must be kept at a suitable distance from such equipment
	Suction units OB MINI and OB MINI AVIO contain electrical or electronic parts that must be recycled in accordance with WEEE/19/EU - Waste Electrical and Electronic Equipment.
	The suction unit complies with European Directive 2011/65/EU (RoHS)
	Maintenance service required (contact the manufacturer and/or its authorized service centres)

0.2 Symbols used on the device and accessories

	Class II insulation (as per IEC 60601-1)
	Class BF for part applied to the patient (as per IEC 60601-1)
	Use the suction unit only within the specified temperature range. Using the suction unit outside these limits could compromise its operation, reduce battery life and trip the internal safety devices.
	Usage range for atmospheric pressure
	Usage range for humidity
	Read these operating instructions carefully and thoroughly
	Accessories and/or consumables displaying this symbol are disposable. They cannot be reused and, after use, must be discarded and replaced with new ones. The symbol is posted on consumables
	Single patient multiple use
	Indicates that the user must consult these operating instructions for information, e.g. warnings and precautions that may not be displayed on the medical device in question
CE 1936	CE marking in accordance with MDR Regulation 2017/745 for medical devices rated higher than class I
	Manufacturer

	Date of manufacture
	Suction units OB MINI and OB MINI AVIO contain electrical and/or electronic equipment that must be recycled in compliance with European Directive 2012/19/UE - Waste Electrical and Electronic Equipment (WEEE).
	Authorized representative within the European Community if the manufacturer does not reside in Europe
	Expiry date
	Order number (device code)
	These operating instructions are available in other languages on the indicated website. Please read them.
	Do not use the device in environments where magnetic resonance imaging is performed
	Production batch
	Serial Number
	Indicates that the suction unit is a medical device
	Connection/patient suction tube (cover for collection jar and Serres® disposable liner)
INPUT	The accepted input voltage range is indicated on the external power supply inlet
OUTPUT	The output voltage is indicated on the external power supply outlet
	Internal use only
	Direct current
	Alternating current

0.3 Symbols used on battery and referred to in these operating instructions

BATTERY	The battery is integrated in the device and is not removable by the user. The battery consists of three cells and is equipped with a special electronic circuit to prevent risks and damage. The battery pack cannot be opened, modified or repaired.
LIPO	Inorganic solid lithium polymer battery, 500 charging cycles (minimum)
	Warnings, important information
	Do not short circuit the battery and its contacts
	Do not incinerate or throw into a fire
	Do not cut the battery or plastic case. Do not saw or puncture the battery (risk of explosion, fire or short circuit)
	Do not crush the battery or apply strong deforming pressures. Do not drill the battery with tools, drills or other mechanisms.
	Battery storage conditions (battery pack only): Temperature (optimal): 0 – 25° C Humidity (optimal): 60 ± 25% RH

	Do not dispose of the battery with normal household wastes. Follow national and local regulations for proper demolition and recycling. Follow the European recycling plan
	Read the operating instructions
LOT	Production batch number

1 INTENDED USE

Device name	Medical suction unit OB MINI - OB MINI AVIO BOSCAROL
Primary use	Suction unit designed to remove secretions, blood and other bodily fluids, solid pieces of food or tissue in the medical field
Other Uses	The device can also be used as a pump to empty vacuum mattresses and splints (but must be used with the jar complete of the antimicrobial filter)
Medical Purpose	Suction of the upper and lower airways
Site of application to human body	Upper airways: nose, nasal cavity, throat, mouth Lower airways: larynx, trachea, bronchial tube
Patient type	Infants, children and adults of both sexes
Length of application on a given patient	< 60 minutes - Temporary use
 **Information on usage**	• The suction unit can be used on all types of patients as long as correct medical technique is followed • Obstruction of the lower airways must be freed by medical professionals and/or health care personnel (including paramedics and emergency personnel) trained and authorized to perform such procedures • Obstruction of the upper airways must be freed by medical professionals and/or health care personnel (including paramedics and emergency personnel) trained and authorized to perform such procedures. In some countries, this information must be verified according to protocols implemented by local emergency health care services
Device application sites according to ISO 10079-1:2019	Suction units OB MINI and OB MINI AVIO can be used in many situations: in hospitals/clinics, at sites of accidents and emergency health services, for first aid in general, at home care and health care facilities, for outdoor application and during transport. The OB MINI AVIO can also be used and recharged in ambulances, helicopters and aircraft

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 what is written, please contact the manufacturer for further clarification.

 **Phone +39 0471 93 28 93**  **info@boscarol.it**

- Read these instructions carefully before using the device. Careful, correct use of the device ensures smooth operation and will protect both patients and operators.
- The suction unit is designed exclusively to remove organic fluids (secretions) during medical procedures. For this reason, it should only be used by properly trained personnel
- Never use the suction unit in the presence of flammable and/or explosive liquids, gases or anaesthetic mixtures as this could result in explosion and/or fire.
- If suction is performed without the jar and/or antibacterial filter, or if you suspect that substances may have entered the suction circuit (i.e., the OB MINI device), contact your nearest service centre or the manufacturer immediately to have the device checked.

- Do not spray substances on the device. Before cleaning the device, make certain that the suction hole on the container is closed (cover it with a piece of tape or connect the tube to the jar).
- Before cleaning the suction unit or performing any maintenance, disconnect the unit from the external power supply. Do not immerse the device in liquids since this could damage it and cause the safety devices to trip.
- Suction units OB MINI and OB MINI AVIO require no maintenance by the operator. The only authorized operations are those indicated in these instructions. For technical support, periodic service and repairs, contact the authorized service centre or the manufacturer.
- For authorized personnel — who have taken a specific technical training course — the manufacturer provides the documentation and tools needed to perform all service operations (service manual).
- To ensure patient safety, accuracy of the values displayed and correct operation, use only original spare parts. In the case of non-compliance, the operator is held responsible for any patient injury or property damage.
- Do not use any batteries other than those approved by the manufacturer. The battery is contained in the device and cannot be replaced by the user. Specific tests must be carried out when replacing the battery
- The user cannot replace the battery and must always contact the manufacturer or an authorised service centre.
- Suction units OB MINI and OB MINI AVIO do not perform any diagnostic functions on the patient.
- An excessive increase in device internal temperature may automatically cause the device to cut out, thus preventing the batteries from overheating.

 **LATEX**	Devices OB MINI and OB MINI AVIO are built and manufactured without the use of latex. However, the possibility that they may have come into contact with latex at some time during the production chain cannot be ruled out
	Do not use the device in environments where magnetic resonance imaging is performed. The device could be dangerous for users and patients
	Portable RF communications equipment (including peripherals such as antenna cables and the antennas themselves) must not be used at a distance of less than 30 cm (12 inches) from any part of the OB MINI and OB MINI AVIO, including the cables specified by the manufacturer. Failure to comply with this may reduce unit performance.
	• Caution: Never use this unit near or on top of other equipment as it could result in improper operation. If such use proves necessary, always check that this unit and other equipment function properly. • Caution: use of accessories, external power supplies, transducers, and cables other than those specified or supplied by the manufacturer of this medical device may result in increased electromagnetic emissions or decreased device electromagnetic immunity and cause the unit to function incorrectly.
 **CONTAMINATED DEVICE**	• Warning: Device contamination. If the suction unit is used following these instructions, with the original jar and antibacterial filter, the suction unit will not become contaminated. Nevertheless, if the substances sucked up have entered the device, the suction unit must be taken out of service immediately. Sending a contaminated suction unit to the manufacturer, installer or service centre is **strictly forbidden**. The risk of spreading a pandemic is high and must be avoided. • Any device received in such conditions will be rejected and the health authorities will be notified of the risk of possible contamination. In this case, the term contaminated indicates a suction unit that has not been disinfected and cleaned of the secretion aspirated from the patient. If the aspirated substances have entered the suction unit, it must be demolished. For Boscarol, the safety of its employees and authorized service centre personnel is of primary importance. If the suctions units are contaminated, they cannot be demolished according to the WEEE (Waste Electrical and Electronic Equipment) directive, as this would result in a possible risk of infection (international law regarding worker protection must be applied, where applicable). • When in doubt, before sending a device in for repair, send an e-mail to the Boscarol technical service at info@boscarol.it or call +39 0471 932893
 **REUSE OF**	• Caution: reuse of disposable parts can compromise suction unit function and be a source of contamination — whether direct or indirect — for operator and patient.

DISPOSABLE PARTS	• Sterilization and/or cleaning of disposable parts (antibacterial filters, suction tubes, Yankauer suction catheters, etc.) can cause structural damage and thus result in a loss of mechanical integrity.
 **LIPO BATTERY**	• Before using the suction unit for the first time (and/or after having received it), the internal battery must be placed under continuous charge for at least 16 hours. • The suction unit has a special test function to check the remaining battery charge. • Recharge the suction unit immediately if only one or none of the LEDs go on. • Leaving the device always connected to the vehicle power supply (11-30 Vdc) will not damage it. • The battery can be replaced by the operator. Contact Boscarol or send an e-mail to info@boscarol.it to purchase a new battery

3 INFORMATION THAT IS IMPORTANT TO KNOW BEFORE USE

The suction unit has been designed and tested according to current law and the latest regulatory standards. If the suction unit is connected to a non-compliant electrical system and/or if the connection is not made by a professional installer, both the suction unit and the electrical system may be damaged. Always consult a qualified technician who knows all the legal and regulatory aspects involved in the process.

	**If the user or the patient becomes aware of a danger of use, a side effect, an accident caused by the device or a criticality (operational and constructive) not dealt with in these instructions for use, he must immediately report it to the manufacturer to the mail address: raq@boscarol.it**
 **PERIODIC SAFETY INSPECTION**	**Preventive maintenance and periodic safety inspection:** The suction unit must be checked at least once a day (function check). The device has a special feature that alerts the operator when a maintenance/safety inspection is required, at least once every 24 months. If the suction unit is subject to intensive use, the circuit will automatically reduce this time interval, adapting it to real need. An indicator light on the front of the device signals when this is necessary. Even if no indication is present, the operator should check the purchase date and date of manufacture and have the inspection performed, by the service centre or manufacturer, 24 months after the date of manufacture (see the date of manufacture on the label).
Operator/User Responsibility	• Suction units OB MINI and OB MINI AVIO are designed for emergency medical service and must therefore be ready for use at any time and in any situation. • Always make certain that the internal battery is sufficiently charged (press the test button). • Immediately replace any damaged, altered or missing components/parts and/or those for which suction unit malfunction is suspected. Always replace these parts with original spare parts. The suction unit must be stored in a place that is out of the reach of children. • Dispose of packaging in accordance with applicable regulations and make certain it is out of the reach of children.
 **Tripping of overflow valve**	**WHAT TO DO IF THE OVERFLOW VALVE TRIPS?** • Put on protective gloves, protective eyewear and a type FFP2 or FFP3 mask. • Turn off the suction unit and disconnect the silicone tube running from the jar to the device. • Check whether the aspirated liquids have reached the maximum level in the jar. • Carefully remove the jar and store it in a safe place. • Empty the jar safely by first removing the filter (which must be discarded) and then removing the lid. Empty the jar and perform thorough cleaning and disinfection (sterilization if necessary). • Clean and disinfect the device as indicated in these operating instructions.

4 CONTRAINDICATIONS (DO NOT USE FOR)

CONTRAINDICATIONS	• Low vacuum values, e.g. drainage of chest or wounds in general • Permanent endoscopic use • Operating rooms where potential must be equalized (e.g. operating theatres for heart surgery) • Outside the medical field • Aspiration of flammable, corrosive or explosive substances • Aspiration in environments presenting risk of explosion

5 SIDE EFFECTS (POSSIBLE DURING ASPIRATION OPERATIONS)

SIDE EFFECTS	• General bleeding in the nasal pharyngeal area. Also of the throat and tongue. • Vocal cord damage • Cardiovascular instability • Side effects caused by stimulation of the vagus nerve • Stress-induced tachycardia • Suffocation, nausea, vomiting and coughing • Respiratory tract infection (typical of hospital environments) • Convulsions by patients who tend to have cramps
SIDE EFFECTS	Caution: to minimize side effects, it is important to follow the indications given in these operating instructions

6 MEDICAL SUCTION UNIT OB MINI AND OB MINI AVIO

After receiving the device, make certain that all parts are present. All Boscarol suction units come ready to use, fully assembled with everything except the antibacterial filter (in the version with reusable jar) which is not connected to the device (for transport and storage reasons).

Package contents for 500 version (500 ml reusable suction jar)

- 1 Suction unit complete and ready to use depending on the state of charge of the battery (1)
- 1 Boscarol reusable 500 ml jar complete with overflow valve in lid (2)
- 1 Antibacterial filter complete with silicone tube (3)
- 1 Yankauer catheter, sterile (not installed)
- 1 Mains power supply for charging and operating the device (6)
- 1 SELV (11-30 Vdc) voltage supply cable, ready to use (**optional – upon customer request**) (see 5)
- 1 Operating instructions in Italian or a specific language depending on the destination and technical documentation

Package contents for FA version (1000 ml reusable suction jar)

- 1 Suction unit complete with battery pack already inserted and ready to use (1)
- 1 Boscarol reusable 1000 ml jar complete with overflow valve in lid
- 1 Antibacterial filter complete with silicone tube (3)
- 1 Yankauer catheter, sterile (not installed)
- 1 Mains power supply for charging and operating the device (6)
- 1 SELV (11-30 Vdc) voltage supply cable, ready to use (**optional – upon customer request**) (see 7)
- 1 Operating instructions in Italian or a specific language depending on the destination and technical documentation

Package contents for FM version (1000 ml reusable suction jar complete with SERRES disposable bag)

- 1 Suction unit complete with battery pack already inserted and ready to use (1)
- 1 Boscarol reusable 1000 ml jar complete with overflow valve in lid
- 1 Antibacterial filter complete of a disposable bag (Serres brand) (4)
- 1 Yankauer catheter, sterile (not installed)
- 1 Mains power supply for charging and operating the device (6)
- 1 SELV (11-30 Vdc) voltage supply cable, ready to use (**optional – upon customer request**) (see 7)
- 1 Operating instructions in Italian or a specific language depending on the destination and technical documentation

6.1 Description of the suction unit

The OB MINI and OB MINI AVIO are medical suction units compliant with all reference standards.
They can be used in motor vehicles (ambulances), in the field, in hospitals, clinics and for home treatment, by doctors or trained authorized personnel (paramedics). The suction unit has an internal battery that does not contain dangerous substances; it is an inorganic, solid battery (LiPo) with an internal electronic circuit that protects against short circuits or other failures that could make the battery, and thus the suction unit, dangerous.
The battery is produced according to the standard IEC 62133 and tested according to specific standards for transport in aircraft and helicopters (UN 38.3 IATA).
The OB MINI and OB MINI AVIO secretion aspirator is available in different basic versions depending on the type of jar used.

For the 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 activate the device, press the switch (3), which is protected against infiltration of moisture, splashing of water and other cleansers. Vacuum can be adjusted by turning the knob (2) located beside the switch. Turning the control knob clockwise increases the vacuum. The vacuum produced by the internal pump can be read on the analogue vacuum gauge (1) and is expressed in millibars (mbar) and kilo-pascals (kPa) or millimetres of mercury (mmHg). The vacuum gauge is fluorescent and can be seen in the dark. Above the LEDs displaying battery charge (5) a socket is arranged to plug the unit into the mains or 11÷30 Vdc power supply (4). The charging socket is air-tight and fit with two electric poles.

1. Fluorescent analogue vacuum gauge with dual scale
2. Vacuum regulation knob
3. ON/OFF switch
4. Suction unit charging socket (11 to 30 Vdc)
5. Charge indicator panel and charge TEST button

6.3 Indicator lights

On the front are the indicator lights (LEDs) and the button with which to test the battery charge (see picture →). The light indicators serve several functions including indication of the battery charge (4 green LEDs on indicate maximum charge), charging and charging complete status (two-tone LED marked by a triangle with an exclamation mark inside) and the "TEST" button to display the residual battery charge; this button can **only** be operated when the device is off and disconnected from any external electrical power supply (power supply or the vehicle's 12 Vdc power supply). Pressing the test button displays the LEDs for about 20 seconds. During charging (which occurs automatically when the suction unit is secured to power supply or charging cable), the LED under the triangle starts flashing yellow and remains in this state until charging is complete. When the battery is fully charged, the yellow LED remains on steady, indicating that the battery is fully charged. The yellow LED remains on (confirming not only that the battery is charged but that the device is powered by an external source) until the suction unit has been disconnected from the external

power supply. In this state, the LEDs are not displayed when the TEST button is pressed or when the device is operated; this because the device is not powered by the internal battery.
After charging has been completed and the external power supply removed, if the test button is pressed, the LEDs display the current battery charge status. The table below summarizes the battery charge status based on 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 POWER VERY LOW**	The device will shut down **within two minutes** after the last green LED starts flashing because the battery is completely drained.
 **BATTERY COMPLETELY DRAINED**	Warning: a drained battery affects device operation and therefore its use. The TEST button has been added to provide indication of battery life and ensure that it can be charged when needed. It takes about 10 hours to fully charge the battery. The suction unit can always be left charging. The battery has a lifespan of 2 years and is automatically replaced during the safety inspection.
 **Electrical connections**	Always check that the charging cable plug is correctly inserted into the cigarette lighter socket: vehicle vibration can cause the plug to come loose. Therefore, always check the yellow LED on the device: it remains flashing until charging has been completed!
 **BATTERY INFORMATION**	To view the battery charge, press the TEST button: to do so, the suction unit must be disconnected from the external power supply, or charging cable. See the table above for the residual charge status.

6.4 Periodic testing of suction units OB MINI AND OB MINI AVIO

To ensure proper device operation, two types of periodic tests are envisaged:

- the first is to be performed daily to ensure device efficiency, the absence of mechanical anomalies, breakage of the external plastic casing and to ensure that the unit is functioning properly
- the second, on the other hand, is performed on a six-monthly/annual basis so as to evaluate complete device function and thus ensure its compliance. The timing of these must be reduced when the unit is subject to intensive use, operated under severe conditions and/or outside the recommended limits.

 **OB MINI AVIO**	For this variant of suction unit, given the severe operating conditions, the periodic test must be conducted every six months!

The daily test makes it possible to check (quickly) whether the device is suitable for use in the field and provides function tests that can be completed in a maximum of 5 minutes.

6.4.1 Daily periodic testing of suction units OB MINI and OB MINI AVIO

DAILY TEST	• Disconnect the device if connected to external power supply. • Place the device in an upright position on a stable surface with the front facing you. • Press the TEST button located near the battery LEDs. If all of the green LEDs are lit up, the battery is fully charged (operating time: approx. 60 minutes). If not, remember to charge the suction unit. • Using the switch on the front panel, turn on the suction unit (0 - off, 1 - on). The suction unit must operate smoothly, no fluctuations in internal pump speed must be heard. There should not be any unusual noise and/or vibrations. • Fully close the vacuum regulator (turning it clockwise) and pinch the silicone tube near the jar (before the filter for the reusable jar OB-J) or near the jar connection when using reusable jar with SERRES® bag. The noise generated by the pump should change and, in a few seconds, the reading on the vacuum gauge should reach maximum value (about 800 mbar, 80 kPa, 600 mmHg). • While keeping the tube pinched, turn the vacuum regulator counterclockwise and check the reading on the gauge to ensure that the suction drops to nearly 0 (40-50 mbar due to filter effect). • Switch off the device and connect it to the supplied power supply and check that the charging process begins (yellow LED flashing)

	• Make certain that the filter is clean and not contaminated. If the filter is soiled, it must be replaced. A soiled filter prevents the suction unit from functioning properly and reduces its performance by increasing the risk of contamination. Do not use the suction unit without a filter.

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

Test – phase	Result	Remedy
Running the autonomy 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 completely drained or faulty. Try charging the battery with the external cable or power supply or have the battery replaced by an authorised centre or by the manufacturer. During these operations, take the device out of active service
Pump function check	Noise from motor is uniform, no drop in rpm, no abnormal vibrations	Any noise that is not uniform indicates an anomaly in pump operation. A drop in rpm indicates that the current is inadequate and cannot run the motor correctly. Contact your service centre or the manufacturer.
Check for maximum suction by pinching closed the tube running from the device to the filter or disposable liner.	The maximum vacuum value that can be read on the vacuum gauge should be around 850 mbar (±10 %).	If this value is not reached, close the vacuum regulator completely by turning the knob clockwise. Check that the tube is completely plugged. If not, take the device out of service and contact your authorized service centre.
Setting the maximum vacuum value	Value between around 0 and maximum, achieved by turning the knob	If the vacuum value cannot be adjusted, contact your authorized service centre. Take the device out of service

	If problems continue after the steps indicated above have been taken, send the unit to an authorised service centre or to the manufacturer for service or repair.

6.4.2 Six-monthly/yearly test of suction units OB MINI and OB MINI AVIO

This test checks whether the device is fully compliant with the original production characteristics and therefore suitable for use in the field. The checks and controls should be performed by persons and/or companies specialized in performing such operations on medical devices and who have been instructed/authorized by the manufacturer. Following inspection, an electrical safety test must be performed in accordance with IEC 60601-1 and a test summary document must be issued and made available to the user.

SIX-MONTHLY OR ANNUAL TEST	• Replace the SERRES® disposable liner or antibacterial filter before performing these operations. • Run a complete suction unit function check: battery life, charging function, complete control of the LED functions (from maximum to minimum during battery discharge). Make certain that, during charging, the LEDs function as shown in section §6.3 Light indicators. • Check internal pump function by pressing the switch. The maximum vacuum value must fall in the 730 mbar-80 mbar range. Use a precision vacuum gauge to measure this value (tolerance ±2.5 % or less). There should be no operating anomalies — i.e. unusual noise, fluctuations in rpm, excessive vibration of the gauge needle — and the vacuum regulator knob should function smoothly and show no obstructions: when running the test, the device should be set on a stable surface to check the amount of vibrations generated. • Check the vacuum regulator which must run at full range: from minimum to maximum. Turn the knob clockwise and counterclockwise. When the regulator is fully open, a small vacuum value is normal (introduced by the antibacterial filter). • Check the minimum suction unit operating time: turn it on and let the cycle run freely for at least 20 minutes. The suction unit must operate using only the internal battery. If the test fails, the internal battery must be replaced. • Check the unit container for cracks and fissures. Penetration of liquids or solids can damage the unit and make it unsafe for operators and patients (mechanical parts running). • Check that all labels and screen-prints are present and legible. • Never open the suction unit for any reason whatsoever. For technical assistance, only contact one of the authorized service centres listed at the end of this manual. • Check that the vacuum gauge is functioning properly. When the suction unit is turned off, the needle should be at "0". • Make certain that the carrying bag is functional, intact and shows no tears. The carrying strap must be functional, intact and have no tears or deformations. • Check that the jar is intact and that there are no cracks or breaks that could compromise suction.

	• Before declaring the suction unit compliant with the manufacturer's device operating data, using a specific safety analyser, run an electrical safety test as outlined in IEC60601-1. Contact the manufacturer or an authorized service centre for information on performing this test.

DEVICE CONFORMITY	Use only consumables or replacement parts supplied by the manufacturer. Do not use components that are similar or appear identical. Component conformity can only be confirmed by the manufacturer.
	Keep on file a document certifying that all checks have been performed and, if possible, keep a photograph recording the state of the suction unit before and after these checks in addition, always keep a copy of the safety report, performed with the appropriate, duly calibrated instrument.
Special functions	In accordance with ISO 10079-1:2019, the device can only be run in an upright position and at an inclination of no more than 20 degrees. If this limit is exceeded, the overflow valve may trip, thus blocking suction.

If you have any doubts or concerns regarding how to perform the tests, we recommend always contacting the device manufacturer or an authorised service centre. If even a single test fails, contact a service centre or the manufacturer. Do not use the device if it has not passed all tests.
For any information, call +39 0471 932893 or send an e-mail to info@boscarol.it.

6.5 Special automatic functions

The OB MINI suction unit has some automatic features that are controlled by an internal microprocessor. This component does not affect suction unit operation and, even if it is blocked or fails, this does not compromise the suction produced by the unit. The microprocessor serves a particular function: it notifies the operator when it is time for the suction unit safety inspection. Normally, such inspection is required after 24 months of operation, however, the operator must check the product expiration date on the label. Not only does the suction unit's internal processor provide this information, but 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 device is used, by flashing the third LED (3 consecutive flashes alternating with a 5-second pause), the internal microprocessor tells the operator that it is time to contact the authorized service centre for periodic maintenance. If the device is not used, the LED goes on 730 days after initial use of the device. This time decreases if the unit is used frequently, thus ensuring that the device always functions properly. When the unit is subject to intense use, it is possible, and absolutely normal, for this LED to go on, for example after 700 days.

6.7 Safety information to ensure user, patient and third party safety

To prevent undesirable effects and risks, always follow the information given below:

- Make certain that all accessories are functioning properly and replace the external power supply or cables if defective. Do not take unnecessary risks: always replace defective parts so as to ensure that the device is always in good working order for use and, above all, emergencies.
- Always keep the device in a safe place and, if used in an emergency vehicle, avoid possible injury to the user and the patient due to sudden acceleration or braking of the vehicle.
- Even if the device is not used, recharge the battery at least once a week.
- We recommend keeping on hand another suction unit to stand in if this one does not work or is defective (e.g. a manual suction unit).
- Always remember what was stated in the initial warnings regarding the risks arising from the effects of magnetic fields (EMC).
- Always select the appropriate vacuum level for the patient and according to the medical guidelines.
- Do not alter or modify the medical device. Serious consequences may occur for patient and user.
- Units OB MINI and OB MINI AVIO **are not sterile devices** and cannot be sterilized, except for the jar and silicone tube.
- Keep children away from tubes and connection cables. Also keep them away from small parts.

Risk of infection

- Incorrect use of the device can lead to the transmission of infections, even fatal ones.

- Always wear disposable gloves, especially when there is the risk of coming into contact with the aspirated secretions.
- Never use components marked as disposable more than once. Disposable parts or medical devices are marked as shown in the figure to the side (a number 2 that has been crossed out).
- Never use the device without the antibacterial filter or the disposable SERRES bag.
- Always disconnect the unit from the power adapter, or SELV source before performing cleaning and disinfection.
- Only use the power supply indoors and in dry areas. Never use the power supply outdoors!
- Always use only original accessories and original spare parts.

Caution	Assembly operations, repairs and modifications to the device are strictly forbidden and may only be performed by the manufacturer or authorized personnel.

7 JARS FOR OB MINI AND OB MINI AVIO

The device is sold with three different types of jars:

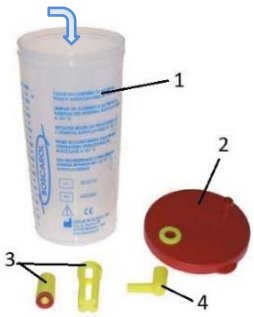
1. Suction unit with 500 ml autoclavable jar (OB MINI 500 and OB MINI AVIO 500).
2. Suction unit with 1000 ml autoclavable jar (OB MINI FA and OB MINI AVIO FA).
3. Suction unit with 1000 ml jar fit with disposable liner (OB MINI FM and OB MINI AVIO FM).

7.1 Autoclavable 500 ml collection jar

The bottle is made of transparent plastic (polycarbonate). It includes the vessel (3), the snap on lid (5), overflow valve (2) and the 90° plastic connection (1). The protective filter is inserted in series with the suction circuit between the suction jar (lid) and the device. The Yankauer catheter or silicone tubing can be connected to the plastic fitting on the lid (4). The autoclavable bottle can be sterilised conventionally in a steam autoclave at a maximum temperature of 121° C and a pressure of 2 bar (200 kPa). The bottle must be replaced if it is deformed, broken or cracked. The secretion bottle must be used vertically to prevent the anti-reflux valve from tripping. If the anti-reflux valve is triggered, switch off the device and disconnect the tube connected to the suction unit, remove the antibacterial filter to rebalance the pressure inside the bottle.

7.2 Autoclavable OB-J FA collection jar

The jar is made of transparent plastic (medical-grade polypropylene). It includes the jar (1), snap-on lid (2), overflow valve (3) and 90° plastic connection (4). The jar's lid makes it possible to directly insert the antibacterial filter (from the outside). 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 sign of deformation, breakage or fissuring. The jar must always be used in the upright position, thus preventing the overflow valve from tripping. If this protection does trip, turn off the device and disconnect the tube connected to the suction unit, remove the antibacterial filter to rebalance the pressure inside the jar.



Lifespan of jar OB-J FA	The jar must be replaced after 30 sterilization cycles or 5 years from the date of manufacture.

7.3 Antibacterial filter

To prevent fluid overflow, a special protection filter is used between the jar and the unit. The filter is produced with PTFE hydrophobic material which prevents fluids entering the pneumatic circuit. Working together with the overflow valve on the jar, the filter isolates the pneumatic suction pump from gas and fluid substances. The filter is disposable and **must be replaced after each use**. If contamination, discoloration and increased resistance to suction occurs, it must always be replaced.

Antibacterial filter	If the device is used on patients whose infectiousness is unknown, always replace the filter after use on that patient. This will prevent contamination, even serious contamination, of the environment where the device is installed and thus protect operators and patients. Instead, if the patient's infectiousness is known and/or if there is no risk of indirect contamination, we recommend replacing the filter after each shift or whenever the degree of suction decreases or the filter changes colour.
Risk of infection	• Never use the device without the antibacterial filter. Always keep at least three spare replacement filters on hand in case of emergency. • Always wear gloves and personal protective equipment when changing the antibacterial filter and emptying the jars. • Before each use, check that the filter is dry and clean (it must not be any colour other than white). Change the wet or contaminated filter with a new one. • Never reuse the antibacterial filter (disposable).

7.4 OB J LINER: jars for SERRES® disposable liner

The OB-J jar for SERRES® disposable liners is made of transparent plastic (medical grade polypropylene). It includes a container (1), an adapter for SERRES® disposable liners (2), a red 90-degree connector (3) and a SERRES® disposable liner (4). The antibacterial filter is integrated into the cover of the disposable liner and prevents aspirated fluids from entering the suction unit. 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 disposable liner should be replaced after use on a given patient or when full. When used in a home environment, the jar can be cleaned using a special detergent able to ensure medical device disinfection. Contact Boscarol for information about disinfectants.

Risk of infection	• Always keep at least three spare SERRES® liners on hand. • Always wear gloves and personal protective equipment when changing and disposing of the SERRES® liner. • Before each use, check that the SERRES® container has not already been used. • **Always** replace the contaminated disposable liner with a new one.

7.5 Connection of the suction jars with the device

The secretion jar is connected to the suction unit via a silicone tube and a reusable straight or 90° plastic connector (red or white). Insert or extract the connector into the device as shown in the adjacent image. Do not force the insertion. This applies to all types of secretion bottles accepted by the device.

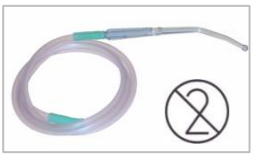
500 ml jar

OB-J LINER

OB-J FA

7.6 Sterile, disposable Yankauer catheter with suction control system

The OB MINI and OB MINI AVIO units are sold complete with a sterile Yankauer-type suction catheter and tubes for connection to the jar. The suction tip and catheter are disposable and must be replaced after each use. To facilitate proper operation, the suction tip is tilted so that it can reach all parts of the mouth and upper airways. The suction tip is spherical and has side holes to prevent damaging tissues during aspiration.



	The Yankauer suction catheter is a sterile, disposable medical device. This device must never be reused and must be disposed of after use on the patient.

Yankauer PATIENT	**Caution!** Never use sterile medical devices beyond their expiration date or if the packaging has been damaged.
	Always connect the Yankauer catheter to the "PATIENT" side of the lid of the reusable jar (FA) or to the SERRES® disposable liner using the white conical connector.

7.7 Silicone suction tube and sterile Fingertip connection (conical connector)

Upon request, the device can be fit with a silicone patient tube (length: 130 cm) and a sterile conical Fingertip connector that makes it possible to use standard sterile catheters of appropriate size. The tube can be reused.	
The sterile Fingertip connection makes it possible to control the suction value with a finger, by closing and opening the hole present. The disposable devices supplied with the suction unit are identified with labels containing all information required for proper use.	
The Fingertip connection (also called the catheter connection) makes it possible to attach standard sterile catheters (see figure to the side).	

7.8 Warnings regarding the reuse of disposable parts

Disposable devices **Risk of infection**	Caution: the suction unit is supplied with some sterile disposable accessories to facilitate patient aspiration. These devices cannot be used on more than one patient. Disposable medical devices are manufactured with materials that can withstand limited use and must not be reused. The operator must dispose of them properly and restore the medical device so that it is in good working order for the next use. Reuse of disposable devices can be dangerous to both patient and operator and can result in a drop in performance and irreparable damage to the device.
SERRES® disposable liner	The SERRES® disposable liner cannot and must not be emptied. The top cap is designed so that samples of the secretion can be taken for laboratory analysis. Every time the filter comes into contact with fluids or liquids (of any kind), it locks and the liner must be replaced!

8 REUSE, CLEANING AND DISINFECTION

After each use, disconnect the suction unit, disconnect the disposable parts and dispose of them. Check that the suction unit is intact, check the connection tube and check for structural anomalies. Clean and disinfect the suction unit as described below. Replace all disposable parts with new ones and recharge the battery. After conducting the reuse operations, perform the daily test as described in section §"6.4 Periodic Testing of OB MINI and OB MINI AVIO" covering the daily test. Decontamination is a process that must always be performed meticulously; this means that specific training is required, especially in the field of emergency medicine where the patient's medical condition and degree of contamination are for the most part unknown. For this reason, the operator must always use personal protective equipment (PPE) to protect him/herself and other people. If PPE devices are not available, contact your safety representative.

Risk of infection	Always wear gloves and personal protective equipment when changing the antibacterial filter and emptying the jars.	
DANGER	Organic secretions collected in the suction unit jar can cause serious operator infection. For this reason, always use PPE and disinfectants as indicated by industry operators and the competent authorities.	

8.1 Reuse of 500 ml jar (OB MINI 500)

The steps needed to separate the jar from the suction unit, dismantle it and re-assemble it after cleaning and disinfection are described below. Before starting, put on protective gloves that cover the forearms, and also wear mouth and eye protection.

Remove the patient tube together with the yellow 90 degree connector. The Yankauer catheter should be disposed of together with the curved tip (sterile disposable devices). Do not dispose of the yellow 90-degree connector, which can be sterilised and reused.	
Disconnect the filter from the bottle as shown in the picture.	
Pull the secretion bottle vertically out of the suction unit.	
Remove the bacterial filter after removing it from the two silicone tubes.	
Remove the lid from the bottle by pressing lightly on the bottle and levering the lid flap. Empty the contents of the bottle. Remove the overflow valve from the cover and separate it from the float.	
Lid components: • Float in transparent polypropylene • Containment cage in transparent polypropylene • Black silicone cover complete with angled connection to the suction unit and connection to the patient tube	

DANGER	Risk of infection due to the release of potentially contaminated substances when emptying secretions. Possibility of transmission of fatal infections. Always use suitable PPE and disinfectants as required by hospital regulations and the competent authorities.

	Pay attention to some disinfectants that could stain the jar and parts thereof without damaging it.

8.2 Reuse of jar OB-J FA

The steps needed to separate the jar from the suction unit, dismantle it and re-assemble it after cleaning and disinfection are described below. Before starting, put on protective gloves that cover the forearms, and also wear mouth and eye protection.

Remove the patient tube together with the yellow 90° connector. The Yankauer catheter must be disposed of together with the curved tip (sterile disposable devices). Do not dispose of the yellow 90° connector as it can be sterilized and reused.	
Remove the antibacterial filter from the cover by turning it on its seat and discard it.	
Remove the 90° connection from the suction unit and then the jar from the bag.	
Remove the cover from the jar by pressing lightly on the lid itself and prying its flap. Empty the contents of the jar in accordance with local regulations or hospital practice.	
Remove the overflow valve from the lid.	
Separate all component parts.	

Parts that make up the lid: • Yellow polypropylene cage • Yellow polypropylene float • Red silicone seal • Red polypropylene lid	
DANGER	Risk of infection due to the release of potentially contaminated substances when emptying secretions. Possibility of transmission of fatal infections. Always use suitable PPE and disinfectants as required by hospital regulations and the competent authorities.
	Pay attention to some disinfectants that could stain the jar and parts thereof without damaging it.

8.3 Cleaning, disinfection and/or sterilization of jar OB-J 500, OB-J FA and silicone tube

The jar and silicone tube can be cleaned with specific, non-abrasive substances designed for cleaning medical devices. Alcohol-based cleaning agents may be used if diluted appropriately (follow the instructions given on the disinfectant label). Do not use coloured disinfectants as they could stain the plastic of the jar and the silicone tube, reducing their transparency. After disposing of the disposable antibacterial filter and Yankauer suction catheter, complete with tubes, place the reusable parts in hot water (to prevent scalding, the temperature must not exceed 60°C) containing a diluted medical device disinfectant. Rinse thoroughly and, if necessary, use a non-abrasive brush to remove any deposits. After washing, dry all parts. Always contact the cleaning and disinfection plan on the following pages. In case of serious contamination, **always** follow the instructions given by the health care personnel and competent authorities. If necessary, sterilize the "REUSABLE PARTS" (see above) in a steam autoclave at a maximum temperature of 121° C and for a maximum of 15-20 minutes (typical cycle). Do not use autoclaves with pressures above 2 bar (200 kPa). The jar must be inserted upside down. At the end of the cycle, allow the parts to cool to room temperature and check that they are intact and show no warping.

DISINFECTION CYCLE **WARNINGS**	• **Do not spray liquids on the device. Clean the device with suction inlet closed. Apply a piece of tape or leave the jar connected to the unit.** • To prevent discoloration, do not use aldehyde- and/or amine-based disinfectants. • Use only disinfectants specific for cleaning of medical devices. Before applying the disinfect on the surface of the device and jar, check it in a corner to ensure that it does not cause damage. • Consult with the hospital and clinic specialists. Check that specific disinfection and cleaning plans and/or protocols are available for the area involved.
STERILIZATION CYCLE **WARNINGS**	• Never sterilize devices or parts that have not been previously cleaned. • Never place weights on parts during the sterilisation cycle. • Observe the maximum limits for temperature, pressure and sterilization time (temperature: 200 kPa, maximum time 15-20 minutes). • Cleaning and sterilisation should be performed only by trained personnel. • Replace the jar if it has cracks, fissures, or even partial breaks. • After reassembling the jar, always check that the lid is fitted properly so as to prevent vacuum leaks and avoid spilling aspirated liquids or fluids. • Always follow the instructions given by the autoclave manufacturer.

8.4 Assembling the jar and connecting the silicone suction tube

Place all components of the jar on a flat, stable surface. During assembly and disassembly, always check all parts for damage or deformation. The overflow valve has a float that slides on a plastic cage. Check that it moves unobstructed (by sliding it) and that the red silicone seal is intact. Assemble the jar, performing the above operations in the opposite order.

AFTER CLEANING	**Caution** • After each cleaning, check whether the device and its parts are functioning properly. • When there is any doubt, send the device to the manufacturer or an authorized service centre for service and inspection. • After assembly, always run a function test as described in section § 6.4 "Periodic Testing of OB MINI and OB MINI AVIO" of these operating instructions. • Prepare the device for subsequent use.

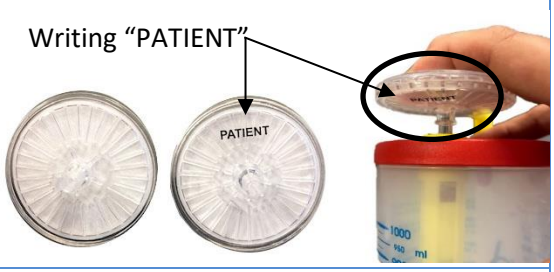
8.5 Replacing the antibacterial filter

Carefully disconnect the silicone tube from the contaminated filter. To make it easy to remove the filter from the lid, proceed by screwing it in and/or unscrewing it from its housing. This facilitates removal from the lid and prevents it from breaking inside! Dispose of the filter in accordance with local hospital waste disposal regulations.

According to our availability on stock, we can provide two different types of antibacterial filter: one has the writing “IN” one the side that must be connected to the VACUUM outlet on the lid.

The second has a side with the writing “**PATIENT**”. Connect this side to the “**VACUUM**” outlet on the lid.

Failure to do so could cause filter failure and contaminate the suction unit's suction circuit.



ANTIBACTERIAL FILTER

Caution

The filter should be inserted with the side marked "IN" or “PATIENT” facing the jar lid. Using the suction unit with the filter inserted incorrectly could result in contamination of the suction circuit itself.

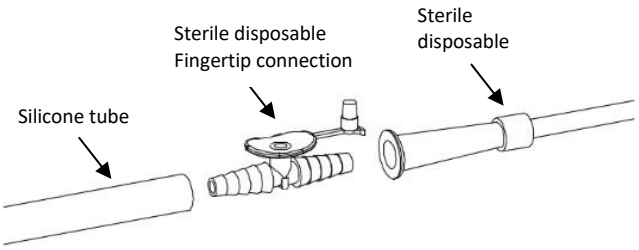
8.6 Cleaning the jar with SERRES® disposable liners

The jar OB-J LINER has a specific SERRES® brand disposable liner, approved for this type of application. Unlike the version OB-J FA, the antibacterial filter is located inside the liner and is automatically replaced after each liner change.

Before removing the disposable liner, some safety precautions must be taken. Remove the Yankauer disposable catheter, complete with suction tip. Always keep in mind the risks of infection and contamination.

If the device has a silicone tube, conical Fingertip connection and suction catheter, proceed as follows:

- Discard the disposable catheter together with the conical connection (see photo to the side)
- Disconnect the silicone tube from the white plastic connection on the SERRES® liner. Discard the liner but keep the silicone tube because it can be disinfected and/or sterilized and then reused.



Remove the white, 90° connector located on the SERRES liner (if this has not already been done) and close the inlet hole (PATIENT) with the cap (see black arrow in photo to the side).

Disconnect the red, 90° plastic connector from the suction unit by manually pulling it outwards.	
Pull the jar up vertically and out of the device.	
Remove the disposable liner (previously closed) from the jar and dispose of it in accordance with current regulations regarding the disposal of contaminated wastes.	
Manually manipulate the 90° connector on the jar and remove the silicone tube (do not discard it!).	 REUSABLE
Remove the plastic adapter from the jar by exerting some slight force. If necessary, use both hands to separate the two parts. Be careful not to damage them.	 REUSABLE
Unscrew the 90° connector by holding the screw inside the jar still with your hand. Be careful not to damage the O-ring.	 REUSABLE  REUSABLE

Lifespan of jars OB-J and OB-J FA	The jar must be replaced after 30 sterilization cycles or 5 years from the date of manufacture.

DANGER	Risk of infection due to release of substances during the cleaning process. Possibility of transmission of fatal infections. Always use suitable PPE and disinfectants as required by hospital regulations and the competent authorities.

8.7 Disinfection and/or sterilization of jar OB-J and silicone tube

For cleaning, disinfection and/or sterilization of the jar (and silicone tube), follow the instructions given in section §8.2. Cleaning, disinfection and/or sterilization of jar OB-J FA and silicone tube.
Always follows the cleaning and disinfection plan on the following pages.

REUSABLE PARTS	The reusable parts can be disinfected and/or sterilized.
DISINFECTION CYCLE **WARNINGS**	• **Do not spray liquids on the suction unit. Always clean the device with the suction inlet closed. Apply a piece of tape or leave the jar connected**. • To prevent discoloration, do not use aldehyde- and/or amine-based disinfectants. • Before proceeding with disinfection, make certain that the appropriate substances and proper instructions for their use are available. • Use only disinfectants specific for cleaning of medical devices. Before applying the disinfect on the surface of the device and jar, check it on a small area to ensure that it does not cause damage. • If substances that are severely contaminated with specific infections have been aspirated, consult the instructions given by the healthcare professional. • Consult with the qualified hospital and clinic personnel. Check that specific disinfection and cleaning plans and/or protocols are available for these devices.
STERILIZATION CYCLE **WARNINGS**	• **NEVER STERILIZE THE DISPOSABLE SERRES® LINER.** • Never sterilize devices or parts that have not been previously cleaned. • Never place weights on the parts during the sterilisation cycle. • Observe the maximum limits for temperature, pressure and sterilization time (temperature: 200 kPa, maximum time 15-20 minutes). • Cleaning and sterilisation should be performed only by trained personnel. • Replace the jar if it has cracks, fissures, or even partial breaks. • After assembling the jar, check that the lid is fitted properly so as to prevent vacuum leaks and avoid spilling liquids or fluids. • Follow the autoclave manufacturer's instructions.

8.8 Assembly of jar with SERRES® disposable liners

Withdraw a new disposable liner from its packaging, spread it out with your hands and insert it into the jar as shown in the figure to the side.
Press it all the way into the jar.

- Insert the jar into the bag of the suction unit and connect it using the red 90° connection.
- Start up the suction unit. With a finger, close the "PATIENT" connector and, at the same time, press lightly on the liner (blue lid).
- Make certain that the liner extends fully in the jar. Connect the disposable patient catheter (Yankauer) to the "PATIENT" connector.

8.9 Disposal of contaminated parts

Always follow local regulations or hospital rules when disposing of contaminated wastes. Never store contaminated parts with new or sterile parts. Boscarol markets liners that are specifically designed for disposal of contaminated hospital wastes.

8.10 Suction unit cleaning and disinfection

Disconnect the suction unit from any external power supply. To clean the surface of the device, use a damp cloth soaked in a diluted disinfectant specific for medical devices (the same type used for the jar). Be careful not to stain or scratch the membrane with the LEDs, located on the front of the device. Sometimes the screen-prints on the container can be damaged or rendered illegible by certain types of disinfectants. When finished, wipe the surface with a dry cloth or paper towel that leaves no trace.

DANGER **ELECTRIC SHOCK**	• **Always disconnect the device from the power supply before cleaning.** • DO NOT RINSE THE DEVICE under running water and/or immerse it in liquids. • The suction device is marketed as ***not sterile and cannot be sterilized.*** • Do not immerse the suction unit in any disinfectant solution. • Never use solvents that could cause deterioration of the plastic and/or remove the screen-prints and labels. • Do not spray liquids on the device. The device suction inlet must always be closed during all cleaning operations. Close the inlet hole with a piece of tape or adhesive bandage to prevent liquids from entering the unit and damaging the suction circuit.
EXTERNAL POWER SUPPLY **DISINFECTION PROCESS**	• Disconnect the power supply from the mains before starting to clean it. Wait at least 1 minute after disconnection to allow any stored internal energy to automatically drain off. • Never rinse the power supply under water and never immerse them in liquids. • Make certain that the cloth used to clean the device is only slightly damp. • Never immerse the power supply in disinfectant or detergent. • To disinfect the surface of the power supply use only disinfectant rated for medical devices and always wipe the surface dry. The cloth must be damp and not soaked. • After these operations, wait at least 30 minutes before using it again.
CLEANING DEVICE SURFACES	Substances entering the suction hole are sucked in by the pump and sprayed onto the electronic parts. For this reason, the suction hole must be closed with a piece of adhesive tape or an adhesive bandage. After cleaning, this tape or adhesive bandage must be removed.  
Availability of disinfectants	To properly disinfect and decontaminate the suction unit, we recommend using specific, approved products. These disinfectants must be alcohol-free and contain no abrasive substances. Oscar Boscarol Srl (Ltd) can provide specific disinfectants suitable for medical equipment, including our suction units. These disinfectants, available in different formats (pre-soaked wipes, sprays and concentrated liquids), have been laboratory tested and are guaranteed to deactivate viruses, bacteria and microorganisms. When used periodically, they destroy and prevent the formation of dangerous bio-films (superficial layers that easily host bacteria, moulds, viruses and microorganisms). The disinfectants we sell do not contain alcohol, chlorine, phenols, aldehydes and halogens.
After cleaning	**Caution** • After each cleaning, check whether the device and its parts for damage. • When in doubt, send the device to the manufacturer or an authorized service centre for service and inspection. • After assembly, run a function test as described in section §"6.4 Periodic Testing of OB MINI and OB MINI AVIO" of these operating instructions. Prepare the device for subsequent use

8.11 Cleaning and disinfection plan

Print this table and indicate the name of the operator who performed the process.

Operation to be performed	Cleaning	Disinfection	Sterilization	HOW TO DO IT	Daily	Every 15 days	After each patient/after each suction operation	Name of operator who performed the process
OB-J FA	X	X	If necessary	See section 8	X		X	
OB-J 500	X	X	If necessary	See section 8	X		X	
OB-J LINER	X	X	If necessary, jar only	See section 8	X		X	
Overflow valve	X	X	If necessary	See section 8.1	X		X	
Reusable tubes	X	X	If necessary	See section 8.2	X		X	
Antibacterial filter				Change filter, even if blocked		X	X	
Device surface	X	X	Not envisaged	See section 8.9		X	X	
Power supply	X	X	Not envisaged	See section 8.9		X	X	

9 ACCESSORIES AND OPTIONAL PARTS FOR OB MINI AND OB MINI AVIO

The suction unit can be charged and used through the cable or the power supply (100-230 Vac Input). The charging SELV cable must be connected to a direct current power supply with voltage ranging from 11 to 30 Vdc and power of at least 70-80 W.
In order to be used through the mains, the suction unit can only be connected to the power supply unit supplied with the device. When the suction unit is used with the power supply, usage must be limited to 20 continuous minutes, after which it must be allowed to cool down.

CAUTION	When the suction unit OB MINI is connected to the power supply, continuous usage is limited to a maximum of 20 minutes, after which the power supply and the device must be allowed to cool down for at least 10 minutes.

Power cable for suction units OB MINI and OB MINI AVIO (optional). REF code: BSU855.	
LYD mains power supply with 2-pin connector (supplied with the unit). Input voltage from 100 to 240 Vac Output voltage: 14.0 Vdc Rated power: 60 W REF code: BSU895EU (EU plug) - BSU895UK (UK plug) - BSU895JP (JP plug)	
EXCLUSIVE ACCESSORIES	The adapter is an exclusive accessory, available only from the manufacturer. It is approved for this function and cannot be replaced by other brands. It can only be used indoors and on a power supply compliant with current law. The medical suction unit can only be used with this adapter.
DANGER - Electric shock	Never tamper with and/or open the power supply. Risk of death. The adapter contains electronic parts which are connected to the mains voltage and can be fatal.
LIFESPAN	The suction unit lifespan is 10 years from the date of manufacture. The device must be replaced after 10 years.

10 INTERNAL BATTERY FOR SUCTION UNITS OB MINI AND OB MINI AVIO

Suction units OB MINI and OB MINI AVIO have an internal battery that guarantees a long operating life. The lithium polymer (LiPo) battery is placed inside the device and cannot be removed without opening the device. The battery does not need to be replaced except when damaged or after the maximum number of charging cycles (>500) has been exceeded. The maximum battery charging time (depending on residual capacity) is about 12 hours. A fully charged

battery will provide approximately 60 minutes of continuous operation (free airflow). This time may vary, even considerably, if the suction unit is used outside the manufacturer-recommended parameters (e.g. when used at very high or very low temperatures). If charged correctly, the average battery life is 24 months. After this period, we recommend replacing the battery. The battery is always replaced during preventive maintenance and safety inspections. If the unit is not used for a long period of time, run a full inspection and fully charge the battery every week.

When the device is not used	If the device is not used for a long period of time, it is preferable to charge it for at least 12 consecutive hours. This will prevent possible problems with the LiPo battery not being used or recharged.

11 SPECIAL USAGE CONDITIONS

The suction unit has no electrical and mechanical safety devices that can be accessed by the operator. Temperatures that are too high or too low can cause some of internal safety devices to trip, blocking the suction unit function. For this reason, never expose the device to extreme operating conditions (temperature, humidity and pressure). The technical characteristics and nominal operating conditions are listed in section § 15 Technical and compliance data for OB MINI and OB MINI AVIO. If the suction unit is to be used under extreme conditions, check the following information.

Use under special conditions	• Run the suction unit only for the time strictly necessary. Once used, set the suction unit in a place subject to less critical operating conditions. • If the suction unit cuts out, let it acclimatize for at least 30 minutes in an area where the temperature is between 15 and 25°C. • If humidity is high, condensation may form on the outside of the device, on the front of the suction unit. After use, remove the condensation and dry the device with a soft cloth. This condensation may also be caused by sudden changes in temperature and humidity associated with, for example, rapid changes in altitude (e.g. when used in a helicopter)

12 DEMOLITION OF THE SUCTION UNIT

The unit contains electrical and/or electronic equipment that must be recycled in accordance with EC Directive 2012/19/EU - Waste Electrical and Electronic Equipment (WEEE), in Italy implemented with decree-law 49/2014 (RAEE). If the device is contaminated, it cannot be demolished in accordance with this directive but as expressly required for hazardous hospital wastes.

Risk of infection	• Before demolishing the device, disinfect it and make certain it is clean. • All disposable and contaminated parts must be disposed of in accordance with local and national laws. • Recycle only parts that are not contaminated • Never dispose of the battery with normal household wastes • The suction unit is fully recyclable, contact the relevant specific law and all applicable guidelines
DECONTAMINATION	You can request the procedure for cleaning and decontaminating the device before it is demolished from Boscarol (info@boscarol.it).

13 ACCESSORIES, CONSUMABLES AND SPARE PARTS

Manufacturer code	Description
	Accessories
BSU895EU	Power supply LYD 100÷240 Vca - 2 pin with EU plug – Vout = 14 Vcc
BSU895UK	Power supply LYD 100÷240 Vca - 2 pin with UK plug – Vout = 14 Vcc
BSU895JP	Power supply LYD 100÷240Vac - 2 pin with JP/USA plug – Vout = 14 Vcc
	Consumables
BSU999	Antibacterial filter for FA jar - 1 piece (can also be ordered in multiples of one)
M03.1.003	Antibacterial filter for FA jar (Medutek alternative can also be ordered in multiples of one)
57157	SERRES® disposable liner – 1 piece (can also be ordered in multiples of one)
BSU504	Autoclavable jar OB-J 500 ml made of polycarbonate without antibacterial filter
BSU500	Autoclavable jar OB-J FA without antibacterial filter
BSU506	Jar OB-J LINER JAR without disposable liner
126140107191	Sterile Yankauer suction catheter
BSU750	Sterile conical Fingertip suction connector - 1 piece (can also be ordered in multiples of one)

Request codes directly from OSCAR BOSCAROL SRL info@boscarol.it	Sterile suction catheter - Ch. 10 black
	Sterile suction catheter - Ch. 12 white
	Sterile suction catheter - Ch. 14 green
	Sterile suction catheter - Ch. 16 orange
	Sterile suction catheter - Ch. 18 red
	Sterile suction catheter - Ch. 20 yellow
Spare Parts	
BSU855	Charging cable with cigar lighter plug and 2-pin connector
BSU902	Silicone patient tube - internal diameter 6 mm - length 130 cm
SPS6000	Jar OB-J FA without lid
SPS6002	Set of overflow valves for OB-J FA lid - 3 pcs
SPS6004	Set of yellow plastic 90° connections for OB-J FA - 3 pcs
SPS6006	Lid for jar SPS6000 complete with overflow valve and yellow 90° connector
SPS6011	Red plastic right-angle connector for suction unit
SPS6023A	Silicone tube with right-angle connector for OB-J FA - length 16 cm
SPS6024A	Silicone tube with right-angle connector for jar OB-J (SERRES® liner) - length 13 cm
SPS5092	Set of 90° connections for jar OB-J (SERRES® liner) - 3 pcs
SPS5093	Set of O-Rings for 90° connection for jar OB-J - 10 pcs
eIFU	Operating Instructions available at: https://www.boscarol.it/ita/eifu.php
Code update	To make technical improvements, the manufacturer can change the parts listed without prior notice. Contact the manufacturer for further information (info@boscarol.it).

14 TECHNICAL SERVICE

Suction units OB MINI and OB MINI AVIO have no electrical and/or mechanical parts that can be serviced by the retailer, customer and/or operator. Never open the suction unit and never tamper with any electrical and/or mechanical parts. Always contact your service centre or the manufacturer. Performing even minor operations on the suction unit will void the warranty. Unauthorized intervention on the suction unit can compromise its compliance with applicable laws and regulations and reduce its operating safety for operators and patients. Send an e-mail to Boscarol Srl at info@boscarol.it for a list of authorized service centres.

Malfunction	*Possible cause(s)*	*Solution*
The suction unit does not turn on	• Battery completely drained	• Charge the suction unit using the power adapter or the charging cable
	• Battery damaged	• Contact an authorised service centre or the manufacturer for battery replacement
	• Internal electronic circuit failure	• Contact an authorised service centre or the manufacturer for battery replacement
The suction unit ***only*** works if it is connected to the power adapter or fitted with the external cable.	• Internal battery damaged	• Contact an authorised service centre or the manufacturer for battery replacement
	• Internal electronic circuit failure	• Contact an authorised service centre or the manufacturer for internal electronic circuit replacement
The suction unit does not charge when connected to the mains power supply and/or does not function	• Power supply failure	• Replace the power supply adapter • Contact authorised service centre or the manufacturer
Battery autonomy indicator does not work when TEST button is pressed	• Device is charging	• Disconnect the device from charging cable or power adapter and check again
	• Internal battery is very low or damaged	• Recharge the internal battery (yellow LED flashing). Replace the battery if nothing changes
	• LED display or internal electronic circuit failure	• Contact an authorised service centre or the manufacturer
Suction unit autonomy has dropped significantly	• The battery has finished its life cycle	• Contact an authorised service centre or the manufacturer for battery replacement
	• Internal charging circuit failure	• Contact an authorised service centre or the manufacturer for internal charging circuit replacement
Patient side vacuum power very low or absent.	• Vacuum regulator completely open	• Close the regulator all the way and check the vacuum reading on the gauge and on the patient side (turn the knob clockwise).
	• Protection filter blocked	• Replace the protection filter
	• Tubes for connection to filter and device plugged, kinked or disconnected	• Replace or reconnect the tubes, check the jar connections.
	• Overflow valve on jar OB-J FA blocked	• Disconnect the tubing going to the device, empty the jar and check the regular movement of the

	• Pump damaged	valve (the silicone seal must face upward). The jar can only be used in the upright position (±20% max. inclination). • Contact authorised service centre.
The third green front LED flashes periodically	• The device must undergo scheduled safety maintenance	• Contact authorised service centre.
High noise, low suction, high vibration.	• Internal pump damaged	• Contact authorised service centre.

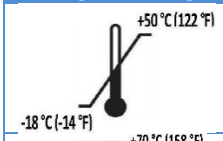
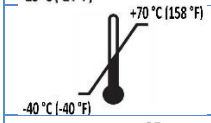
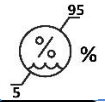
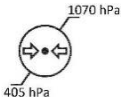
DANGER - ELECTRIC SHOCK	Never tamper with and/or open the suction unit and/or mains power supply. Risk of death. The power supply contains an electronic circuit running on the mains voltage. Contact with this voltage can be fatal. In case of failure, always contact only an authorized service centre or the manufacturer

15 TECHNICAL AND COMPLIANCE DATA FOR OB MINI AND OB MINI AVIO

Medical device classification (as per MDR Regulation 2017/745)		**IIa**
Basic UDI number (in conformity with MDR 2017/745)		805240088OBMINI9B
Suction level classification as per ISO 10079-1:2019		HIGH VACUUM-HIGH FLOW
Operating mode (short term):		TEMPORARY (45 minutes "ON", 10 minutes "OFF")
Power supply		SELV (11÷30 Vdc)
Reference standard		ISO 10079-1:2019
EMC compliance testing		IEC 60601-1-2 4th edition
Medical electrical equipment safety compliance		IEC 60601-1 last edition
Home care equipment compliance		IEC 60601-1-11:2015/AMD1 2020
Pre-hospital sector (EMS) compliance		IEC 60601-1-12:2014/AMD1 2020
	Part applied in compliance with IEC 60601-1	TYPE BF
	Protection class vs. electric shock	CLASS II
Degree of protection against ingress of liquids and solids (IEC 529):		IP43
Risk assessment (technical documentation)		ISO 14971:2019
Usability application		IEC 62366-1:2015
Mandatory periodic safety inspection		Every 24 months
UMDNS code:		15-016
GMDN code:		63643
Approval and conformity as per ECE R10 (automotive)		E50 10 R - 05 0078
Compliance with European standard for ambulances		UNI EN 1789:2021
EMC conformity for avionics sector (**only for OB MINI AVIO**)		RTCA DO160 - G

Dimensions OB MINI - OB MINI AVIO	
Maximum device dimensions	290 mm (w) x 95 mm (d) x 240 mm (h)
Weight of device	1.8 Kg max., complete with all accessories
Tolerance for all values	±5 %
Technical data	
Rated vacuum power:	850 mbar (85 kPa, 638 mmHg) ±10 %
Vacuum Regulation	Linear with built-in mechanical regulator
Vacuum regulation range	30–850 mbar (3–85 kPa)
Nominal flow	26 LPM (litres per minute) with free air ±10 %
Maximum operating time (free cycle)	Approximately 60 minutes ±10%
Maximum operating noise	70 dBA
Vacuum indicator accuracy (full scale)	±2.5 %
Battery power indicator accuracy	±5 %
Reusable, autoclavable jar (1° option)	Type OB-J FA 1000 ml, can be autoclave sterilized for max. 30 cycles
Reusable, autoclavable jar (2° option)	Type OB-J 500 ml, can be autoclave sterilized for max. 30 cycles
Autoclavable jar OB-J	Type OB-J for 1000 ml with SERRES® disposable liners
Lifespan of the device	10 years from date of manufacture
Lifespan of the jars	30 cycles of sterilization or 5 years from the manufacturing date
(*) Notes: 1bar = 100kPa = 750mmHg	
Battery charge and device power supply	
Operation/Charging	11-30 Vdc (direct current)
Time to recharge to 80%	6-8 hours (at recommended charging temperature)
Maximum charge time	10–15 hours straight
Max current load	70 W ±10 %

Battery type	Removable, LiPo, 11.1 V - 5 A
Electrical safety	Internal, not accessible to operator
Pump type	Piston, maintenance free, 12 Vdc electric motor
Type of operation	The device can remain connected to the power source continuously
Type of power supply	LYD - Model number: 601404250

Storage and usage conditions		
	Operating temperature range	-18 to 50° C (-0,4 a 122 °F)
	Temperature range for storage and transport of packaged device	-40 to 70° C (-40 a 158 °F)
	Humidity use and operating range	5÷95%, not condensed
	Temperature range recommended for charging	5 to 30° C
	Atmospheric pressure range for storage, transport	405÷1070 mbar (40,5÷107 kPa)
	Maximum operating altitude	5000 m (above sea level)

Use under rain (please read blow the note)	Degree of protection against ingress of liquids (IEC529): IP44
 **Use under rain**	Suction units OB MINI and OB MINI AVIO are protected against the ingress of liquids and solids. However, it is always preferable to protect the unit from heavy rain. 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 it.

Data on consumables	
Antibacterial filter	PTFE type, hydrophobic. Maximum pressure : 100 kPa
SERRES® disposable liner	1000 ml, disposable with integrated protection filter
Yankauer catheter with suction tip	Sterile, disposable. tube length: 1.3 m. Internal diameter: 6 mm
Conical Fingertip suction connection	Sterile, disposable
Silicone tube	Reusable and sterilisable. Internal diameter: 6 mm. Length 1.3 m
	For further technical information, contact the manufacturer (info@boscarol.it).
 **Serres Devices**	SERRES® products are factory-sterilised and must be stored in warm indoor locations. Protect the package from humidity, dirt and dust. Disposable products can be used over a period of 5 years after the date shown on the label. The sole except to this is the liners pre-filled with solidifying agent, which can be used for a period of 2 years after the date shown on the label.

16 INFORMATION ON ELECTROMAGNETIC COMPATIBILITY EMC (OB MINI – OB MINI AVIO)

Suction unit OB MINI does not interfere with any other medical devices that may be performing tests and clinical treatments in the same area. The unit does not require connection to other equipment for its operation and has an internal power supply.

16.1 RISKS OF MUTUAL INTERFERENCE WITH OTHER DEVICES

Medical electrical equipment requires special precautions regarding electromagnetic compatibility. For this reason, they must be installed and/or used in accordance with the information specified in the accompanying documents (in our case the tables below). Portable and mobile radio communication devices may affect operation of the medical device.
Medical electrical equipment and systems must not be used in proximity with, adjacent to, or on top of other electrical or radio communication equipment. If such use is necessary and unavoidable, special precautions must be taken to ensure that the electrical medical device functions properly in its envisaged configuration (e.g., with constant visual checks to ensure the absence of anomalies or failures). The tables below provide information on electromagnetic compatibility (EMC) relevant to this electrical medical device. For the purposes of electromagnetic immunity, the full functionality of this unit is considered an "essential service". Suction units OB MINI and OB MINI AVIO are electrical medical devices rated CISPR 11 Group 1 and meet Class B requirements.

 **Use with the power adapter**	Suction units OB MINI and OB MINI AVIO can be used with the approved power supply unit supplied by the manufacturer (accessory). The maximum continuous operating time is 20 consecutive minutes, after which the power supply unit must be allowed to cool for at least 15 minutes.

16.2 METHODS TO PREVENT ELECTROMAGNETIC INTERFERENCE

When there could be interference between this medical device and other electrical equipment in the vicinity, try changing the operating position or removing the sources of interference (cell phones, radio transceivers, mobile antennas). Try moving to another location (if possible) or turning off all nearby, non-essential equipment (including electrical equipment) and following the instructions below.

16.3 MANUFACTURER GUIDELINES AND DECLARATION – ELECTROMAGNETIC EMISSIONS

Suction unit OB MINI is designed for use in the electromagnetic environment specified below. The customer or user of suction unit OB MINI must make certain that it is used in such an environment.

Emission test	Limit	Guideline - electromagnetic environment
Conducted emissions	CISPR 11, Group 1, Class B	Suction units OB MINI and OB MINI AVIO use RF energy only for its internal function. Therefore, its RF emissions are very low and are unlikely to cause any interference in nearby electronic equipment.
Radiated emissions	CISPR 11, Group 1, Class B	
Harmonic current emissions	IEC 61000-3-2, Class A	Suction units OB MINI and OB MINI AVIO are connected directly to the public low-voltage power mains supplying buildings used for domestic purposes. For domestic healthcare environments only.
Voltage fluctuations/flicker emissions IEC 61000-3-3	IEC 61000-3-3	

16.4 MANUFACTURER GUIDELINES AND DECLARATION – ELECTROMAGNETIC IMMUNITY

Suction unit OB MINI is designed for use in the electromagnetic environment specified below. The customer or user of suction unit OB MINI must make certain that it is used in such an environment.

IMMUNITY test	Compliance level	Guideline - electromagnetic environment
Electrostatic discharges (IEC 61000-4-2)	Discharge contact: ±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 must be at least 30%.
		Portable and mobile RF communications equipment must not be used near any part of the device, including the cables; they must be at the recommended separation distance, calculated using the equation applicable for transmitter frequency.
Radiated radio frequencies. RF EM field IEC 61000-4-3	80-2700 MHz; 1kHz AM 80%; 10 V/m	Recommended separation distance $d = 1.2\sqrt{P}$ for 80 MHz to 800 MHz, $d = 2.3\sqrt{P}$ for 800 MHz to 2.7 Ghz
		where P is the maximum transmitter power output in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
Immunity from electromagnetic fields generated and radiated by RF communication equipment. (IEC 61000-4-3)	385 MHz; Pulse modulation: 18 Hz; 27 V/m 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; 5240, 5500, 5785 MHz; Pulse modulation: 217 Hz; 9 V/m	Portable and mobile RF communications equipment must not be used at a point that is closer to any part of the device, including the cables, than the recommended separation distance, calculated to be 30 cm.
Fast transients/bursts	Electric lines: 2 kV; 100 kHz repetition frequency	The quality of the mains power supply

(IEC 61000-4-4)	Signal lines: 1 kV; 100 kHz repetition frequency	should be that of a typical environment.
Fluctuations (IEC 61000-4-5)	L-N: 1kV at 0°,90°,180°,270° L-PE, N-PE: 2 kV at 0°,90°,180°,270°	The quality of the mains power supply should be that of a typical environment.
Conducted disturbances induced by RF electromagnetic 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 must not be used near any part of the device, including the cables; they must be at the recommended separation distance, calculated using the equation applicable for transmitter frequency. Recommended separation distance $d = 1.2\sqrt{P}$ for 150 kHz at 80MHz where P is the maximum transmitter power output in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
Power frequency magnetic field immunity (IEC 61000-4-8)	30 A/m, 50 Hz	The magnetic fields generated at the 50 and 60 Hz supply frequencies should be those expected in a typical commercial or hospital environment.
Voltage drop/Power failure (IEC 61000-4-11)	0 % UT for 0.5 cycle at 0°,45°,90°,135°,180°,225°,270°,315° 0 % UT for 1 cycle at 0° 70 % UT for 25/30 cycles at 0°, 0 % UT for 250/300 cycles at 0°	The quality of the mains power supply should be that of a typical environment. If the user of the device requires continuous operation during power outages, we recommend powering the device from a UPS or battery.

17 WARRANTY

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

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

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

Warranty conditions:

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

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

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

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

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

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

1. all technical operations, repairs, modifications, safety inspections and preventive maintenance have been carried out by Oscar Boscarol Srl (Ltd) or an authorised service centre
2. the suction unit has been and is being used correctly, strictly following the instructions given in these operating instructions
3. the electrical installation to which the suction unit is connected has been constructed in accordance with the relevant national and European regulations and standards
4. all accessories and consumables are original and have been purchased from the manufacturer or from an authorised service centre

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.

SPACE FOR USER NOTES

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