BOSCAROL MEDICAL SUCTION UNIT

OB1000 2P

OPERATING INSTRUCTIONS

CE 1936

MANUFACTURED BY:

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Information on the manufacturer and the medical device:

- Oscar Boscarol applies a quality management system in accordance with international standards ISO 13485 and ISO 9001.
- The OB1000 medical device (in all its configurations) complies with MDR Regulation 2017/745 and bears the CE mark (CE 1936 notify body TÜV Rheinland Italia).
- The medical devices meet 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 the safe, effective and compliant use of the medical device.
- Use the information reported to train users and confirm their training
- This manual may not be altered (even in part). Only the manufacturer of the device may make changes where necessary.
- These instructions should always accompany the device. We recommend using the electronic version and making it available on operators' PDAs, tablets and mobile phones.

These operating instructions apply to the following devices:

OB 1000 FA
OB 1000 FM
OB 1000 AVIO FA
OB 1000 AVIO FM

REFERENCE CODES:

BSU210	BSU210PJ	BSU210ST	BSU212	BSU216	BSU216UK	BSU220	BSU220ST	BSU226
BSU226UK	BSU228	BSU228ST	XAS0106	XAS0110	XAS0504	BSU230	BSU232	

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0. MEANING OF SYMBOLS AND PICTOGRAMS

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

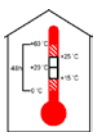
	Danger: Important safety information on the correct use of the suction unit to prevent injury to the operator or patient and/or damage to the suction unit.
	Warnings: information requiring special attention
	Notes or information to prevent damage to the device or others. Activate the correct prevention 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 may affect the operation of the suction unit. In such cases, the suction unit should not be used, or should be kept at an appropriate distance from such equipment.
	The OB1000 and OB1000 AVIO suction units contain electrical or electronic parts that must be recycled according to the WEEE Directive/19/EU - Waste Electrical and Electronic Equipment.
	The suction unit complies with the European Directive 2011/65/EU (RoHS).
	Required maintenance service (contact the manufacturer and/or its authorised service centres)

0.2. Symbols used on the device and accessories

	Insulation class II (according to IEC 60601-1)
	Patient Applied Part Grade BF (according to IEC 60601-1)
	Use the suction unit only within the specified temperature range. Using the suction unit outside this range may impair its operation, shorten battery life and cause the internal safety devices to activate.
	Limits of use referring to atmospheric pressure
	Limits of use in relation to humidity
	Read these operating instructions carefully and completely
	Accessories and/or consumables bearing this symbol are disposable. They cannot be reused and must be discarded after use and replaced with new ones. The symbol is placed on consumables
	Symbol indicating that the device is multiple-use but single-patient (in practice it can only be used more than once on the same patient)
	Indicates the need for the user to consult these operating instructions for information such as warnings and precautions that cannot be displayed on the medical device in question
CE 1936	CE mark in accordance with MDR Regulation 2017/745 for medical devices in class above I
	Manufacturer

	Production date
	OB1000 and OB1000 AVIO suction units contain electrical and/or electronic equipment that must be recycled in accordance with European Directive 2012/19/EU - Waste Electrical and Electronic Equipment (WEEE).
	Authorised representative in the European Community if the producer is not resident in Europe
	Expiry date
	Order number (device code)
	Please read the operating instructions in other languages available on the indicated website
	Do not use the device in environments where MRI investigations are conducted
	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 external mains power supply indicates the accepted input voltage range
OUTPUT	On the external mains power supply it indicates the output voltage value
	Indoor use only
	Continuous current
	Alternating current

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

BATTERY	The battery is sealed and installed in the device. The battery cannot be opened, disassembled or repaired.
SLA	Sealed lead-acid battery
	Warnings, important information
	Do not short-circuit the battery and its contacts
	Do not incinerate or throw into fire
	Do not cut the battery or the plastic case. Do not saw or puncture the battery (risk of explosion, fire or short circuit).
	Do not crush the battery or apply strong deformation pressure. Do not pierce the battery with tools, drills or other mechanisms.
	Storage and preservation conditions for the battery (battery pack only): Temperature (optimal): 0 ÷ 25° C Humidity (optimum): 60 ± 25 % RH

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

1. INTENDED USE

Device name	Medical suction units OB1000 and OB1000 AVIO BOSCAROL
Primary use	Suction unit designed to remove secretions, blood and other body fluids, solid pieces of food or tissue in the medical field
Other uses	The device can also be used as a pump to evacuate mattresses and vacuum splints (but must be used with the filter and secretion jar)
Medical purpose	Upper and lower airway suction
Part of application in the human body	Upper airways: nose, nasal cavity, throat, mouth Lower airways: larynx, trachea, bronchi
Type of patients	Babies, children and adults of both sexes
Time of application on the same patient	< 60 minutes - Temporary use
 **Information on use**	• The suction unit can be used on all types of patients following the correct medical technique • Lower respiratory tract release must be performed by medical professionals and/or healthcare personnel (including paramedics and rescuers) trained and authorised for such actions • Upper respiratory tract release should be performed by medical professionals and/or healthcare personnel (including paramedics and rescuers) trained and authorised for such actions. In some countries, this information should be verified according to the protocols implemented by local emergency health services.
Device application sites in accordance with the standard ISO 10079-1:2019	OB1000 and OB1000 AVIO suction units can be used in hospitals/clinics, accident and emergency departments, general emergency rooms, home care and nursing facilities, as well as for outdoor application and during transport.

2. WARNINGS, PRECAUTIONS AND IMPORTANT INFORMATION

Read carefully

These operating instructions have been prepared using simple, easy-to-understand language. If you have difficulty in interpreting what is written, contact the manufacturer for further clarification.

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

- Read these instructions carefully before using the device. Careful and correct use of the device will ensure smooth operation and 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 trained personnel.
- Never use the suction unit in the presence of flammable and/or explosive liquids, gases and anaesthetic mixtures as this may lead to explosions and/or fires.
- If aspiration is performed without the secretion jar and/or without the antibacterial filter, or if you suspect that substances may have entered the aspiration circuit (i.e. in the OB1000 and OB1000 AVIO devices), contact your nearest service centre or the manufacturer immediately to have the device checked.
- Do not spray substances on the device. Before cleaning, make sure that the suction hole on the device container is closed (apply a piece of tape or connect the tube of the secretion jar).

- Disconnect the suction unit from the external power supply or support bracket before cleaning or performing any maintenance. Do not immerse the device in liquids as this may damage it and cause safety devices to trip.
- The OB1000 and OB1000 AVIO suction units require no maintenance by the operator. The only authorised operations are those listed in these instructions. For technical assistance, periodic inspection and repairs, please contact the authorised service centre or the manufacturer.
- The manufacturer provides authorised personnel, who have followed a specific technical training course, with the documentation and tools required to carry out service operations (service manual).
- To ensure patient safety, the accuracy of the displayed values and correct functionality, use only original spare parts. The operator assumes responsibility for any injury to the patient or damage to property if this is not observed.
- Do not use batteries other than those approved by the manufacturer.
- Do not modify the mechanical or electrical parts of the wall bracket. Replacing parts of the wall bracket and/or altering it can seriously affect the safety anchorage of the device.
- OB1000 and OB1000 AVIO suction units do not perform diagnostic functions on the patient.

 **LATEX**	OB1000 and OB1000 AVIO devices are designed and manufactured without the use of latex. However, it cannot be excluded that during the entire production chain latex may have come into contact with
	Do not use the device in an MRI environment. The device may be dangerous to users and patients.
	Portable RF communications equipment (including peripherals such as antenna cables and the antennas themselves) should not be used closer than 30 cm (12 inches) to any part of the OB1000 and OB1000 AVIO, including cables specified by the manufacturer. Failure to do so may result in reduced performance of this equipment.
	• Warning: The use of this equipment adjacent to or stacked on other equipment should be avoided because it may cause improper operation. If such use is necessary, it should be verified that this equipment and other equipment are operating normally. • 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 electromagnetic immunity of this device and cause improper operation.
 **DEVICE CONTAMINATE**	• Warning: Device contamination. If you use the suction unit according to these instructions, with the original collection container and the bacterial filter, the circuit of the suction unit will not be contaminated. However, if aspirated substances have entered the device, the suction unit must be immediately removed from service. Sending a contaminated suction unit to the manufacturer, installer or service centre is **strictly prohibited**. The risk of spreading pandemics is high and must be avoided. • Any device received in this condition will be rejected and the health authorities will be alerted to the risk of possible contamination. In this case, the term contaminated indicates a suction unit that has not been cleaned and disinfected by the secretions aspirated by the patient. If aspirated substances have entered the suction unit, it must be demolished. For Boscarol, the safety of its employees and the staff of the authorised service centre is of paramount importance. If the suction units are contaminated, they may not be dismantled according to the WEEE (Waste Electrical and Electronic Equipment) directive, leading to a possible risk of infection (application of international worker protection law, where applicable). • If you have any doubts before sending a device for repair, please contact Boscarol's technical service department by sending an email to info@boscarol.it or by calling +39 0471 932893
 **REUSE OF DISPOSABLE PARTS**	• Caution: Reuse of disposable parts may impair the functionality of the suction unit and be a direct or indirect source of contamination of the operator and patient. • Sterilisation and/or cleaning of disposable parts (anti-bacterial filters, suction tubes, Yankauer suction catheters, etc.) can cause structural damage such that they lose their mechanical integrity.

 **SLA BATTERY**	• Before using the suction unit for the first time (and/or after receiving it), charge the internal battery for at least 16 consecutive hours. • The suction unit has a special test function that shows the remaining battery charge. • Recharge the suction unit immediately if only one or no LEDs light up. • Leaving the device permanently connected to the vehicle power supply (12÷15 VDC) will not damage it. • The battery cannot be replaced by the operator.

3. IMPORTANT INFORMATION TO KNOW BEFORE USE

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

	**If the user or patient becomes aware of a danger in use, a side effect, an accident caused by the device or a critical issue (operational and design) not covered in these instructions for use, he must immediately report this to the manufacturer at the following e-mail address: raq@boscarol.it**
 **PERIODIC SAFETY INSPECTION**	**Preventive maintenance and periodic safety inspection:** The suction unit should be checked at least once a day (function check). The device should be checked at least once every 12 months by the authorised service centre. On the other hand, a safety inspection and technical maintenance must be carried out every 24 months from the date of manufacture of the device as indicated on the label. Please refer to the manufacturer or to the authorised technical assistance centres for the scheduling of the safety inspection. The periodic safety inspection is not part of the device's warranty.
Responsibility of operators/users	• The OB1000 and OB1000 AVIO suction units are designed for emergency medical service and must therefore be ready for use at any time and in any situation. • Always ensure that the internal battery is sufficiently charged (press the test button). • Immediately replace any components/parts that are damaged, altered or missing and/or are suspected of malfunctioning of the suction unit. Always replace these parts with original spare parts. The suction unit must be stored in a place inaccessible to children. • Dispose of packaging in accordance with local regulations and ensure that it is out of the reach of children.
 **Intervention of the overflow valve**	**WHAT TO DO IF THE OVERFLOW VALVE TRIPS?** • Wear protective gloves, splash goggles and an FFP2 or FFP3 type mask. • Switch off the suction unit and disconnect the silicone tube from the secretion container to the device. • Check whether the level of aspirated liquids has reached the maximum level in the secretion container. • Carefully remove the secretion container and store it in a safe place. • Empty the secretion container safely by first removing the filter (which must be discarded), then the lid. Empty the secretion container and carry out thorough cleaning and disinfection (sterilisation if necessary). • Clean and disinfect the device according to these operating instructions

4. CONTRAINDICATIONS (DO NOT USE FOR)

 **CONTRAINDICATIONS**	• Low vacuum values, e.g. chest drainage or wound drainage in general • Permanent endoscopic use • Surgical rooms where potential equalisation is required (e.g. operating theatres for heart surgery) • Outside the medical field • Extraction of flammable, corrosive or explosive substances • Suction in explosive environments

5. SIDE EFFECTS (POSSIBLE DURING SUCTION OPERATIONS)

EFFECTS COLLATERAL	• Bleeding in general in the nasal pharyngeal area. Also throat and tongue. • Damage 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 of hospitals) • Convulsions by patients who tend to have cramps
SIDE EFFECTS	Attention: To minimise side effects, it is important to observe what is indicated in these operating instructions

6. MEDICAL SUCTION UNITS OB1000 AND OB1000 AVIO

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

Package contents for FA version

01 Complete suction unit
01 Reusable 1000 ml jar of Boscarol secretions complete with overflow valve in the lid
01 Antibacterial filter complete with silicone tube
01 Sterile Yankauer catheter (unassembled)
01 Ready-made power cable for SELV voltage (12÷15 Vdc)
01 Operating instructions in Italian or specific language depending on the destination and technical documentation

Package contents for FM version

01 Complete suction unit
01 Reusable collection container complete with SERRES disposable liner already inserted in the jar of secretions
01 Sterile Yankauer catheter (unassembled)
01 Ready-made power cable for SELV voltage (12÷15 Vdc)
01 Operating instructions in Italian or specific language depending on the destination and technical documentation

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

01 External mains power supply for supplying and charging the suction unit
01 Support bracket and 01 power supply complete with cable for connection to SELV voltage (12÷15 Vdc)

6.1. Description of the suction unit

OB1000 and OB1000 AVIO are medical suction units that comply with all relevant standards.
They can be used in motor vehicles (ambulances), in the field, in hospitals, clinics and for home treatment by trained and/or medical personnel.
The suction unit units have an internal battery of the SLA type (Hermetic Lead Battery) which contains hazardous substances; it is a battery consisting of lead and a sulphuric acid solution, so it cannot be opened, disassembled, cut or recharged.
The OB1000 and OB1000 AVIO suction units are available in two basic versions: with a reusable jar or with a disposable jar.

OB1000 FA and OB1000 AVIO FA models with reusable jar:

1. Suction unit
2. Autoclavable jar OB-J FA
3. Antibacterial filter
4. Angle connection (90°)
5. Silicone tube for filter connection.

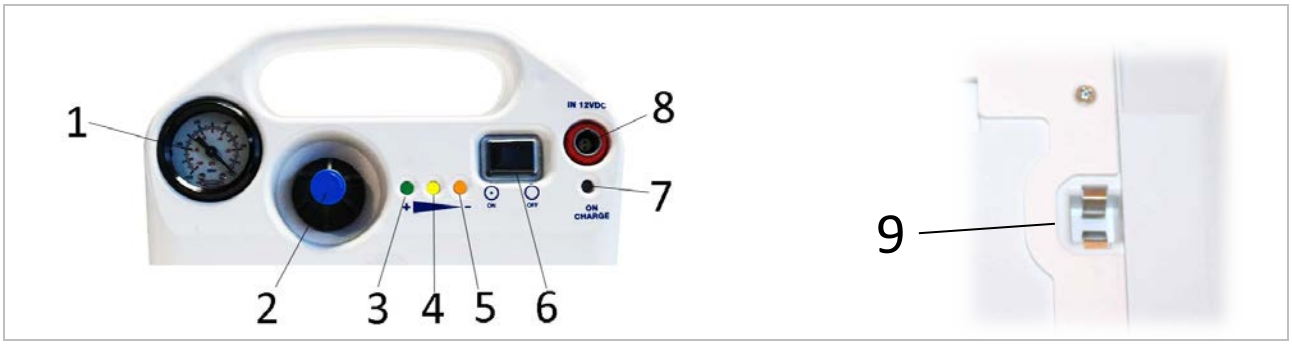
OB1000 FM and OB1000 AVIO FM models with disposable jar

1. Suction unit
2. Autoclavable jar OB-J
3. SERRES disposable bag
4. Connecting pipe with red angle fitting

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

6.2. Controls, operation and control panel

All the controls for operating the device are located on the front panel to facilitate its use even when it is anchored to the support bracket. To activate the device, simply press the switch (6), which is protected against the entry of liquids and solids, splashing water and cleaning substances. The vacuum can be adjusted by turning the knob (2). By turning the knob clockwise, the vacuum increases up to the maximum value that can be read on the analogue instrument (1) expressed in millibars (mbar) or kilo-pascals (kPa) or, on request, also in millimetres of mercury (mmHg). The instrument is fluorescent and is also visible in the dark. On the back of the device there are two contacts (9) which allow charging and operation when fixed on the support bracket. The external charging cable can also be used to charge the device by connecting it to the socket on the front of the device (8). The connector is sealed and has two electrical poles.



6.3. Indicator lights

On the front are the indicator lights (LEDs) that show the operation of the device (see figure above): the battery life (3-4-5) and the charging phase in progress (7). All the indicator lights are located on the front panel and are easily visible even with direct light on the device. The table below summarises the battery charge status based on the number of LEDs lit:

SIGNAL	AUTONOMY FOR EFFICIENT BATTERY
Green LED on (3)	>70% maximum autonomy
Yellow LED on (4)	40-50% average autonomy
Orange LED on (5)	**10-20% low autonomy (low battery, recharge immediately)**

The charging indicator < ON/CHG> (7) on the figure above has two different colours: **yellow indicates that charging is in progress; green indicates that charging is complete**. The indicator lights up whenever the device is connected for charging. If the LED does not light up, it may indicate a malfunction of the internal charging circuit, lack of power supply (12 VDC) or failure to connect the external cable to a 12 VDC power source.

VERY LOW BATTERY	The device will switch off immediately after the orange LED goes out, because the battery is completely discharged.
FLAT BATTERY	Caution: a discharged battery will impair the operation of the device and therefore its use. It takes approx. 15 hours to fully charge the battery. The suction unit can be left charging at all times. **The battery has a life of 2 years** and is automatically replaced during the safety inspection.

Electrical connections	Always check that the plug of the charging cable is correctly inserted into the cigarette lighter socket: vehicle vibrations may cause the plug to come loose. Therefore, always check the charging LED on the device: it remains yellow during charging and changes to green when charging is complete.

6.4. Periodic testing of OB1000 and OB1000 AVIO suction units

In order to ensure proper functioning of the device, two types of periodic tests are foreseen:

- the first should be on a daily basis to ensure the efficiency of the device, the absence of mechanical anomalies, breakage of the external plastic casing and correct functioning
- and the second half-yearly/annually to enable the full functionality of the device to be assessed and therefore its compliance. These times should be reduced in case of heavy use, use in severe conditions and/or outside the recommended limits.

The daily test allows you to check (quickly) whether the device is suitable for use in the field and includes functional checks that can be completed in a maximum of 5 minutes.

6.4.1. Daily periodic testing of OB1000 and OB1000 AVIO suction units

DAILY TEST	• Disconnect the device from the bracket or external charging cable. • Place the device on a stable surface in an upright position so that the front is facing you. • Press the ON-OFF button located next to the vacuum adjustment knob. If all the LEDs are lit, the battery is charged (operating time: approx. 45÷60 minutes). If not, remember to charge the suction unit. • By pressing the switch located on the front panel, switch on the suction unit (OFF - off, ON - on). The suction unit should operate smoothly and no change in the speed of the internal pump should be heard. You should not hear any unusual noise and/or abnormal vibrations. • Close the vacuum regulator completely (by turning it clockwise) and squeeze the silicone tubing towards the secretion jar (before the filter for the reusable OB-J jar) or before the connection to the jar if SERRES® disposable bags are used. The noise generated by the pump should change and the reading on the vacuum gauge should reach the maximum value (approximately 800 mbar, 80 kPa, 600 mmHg) in a few seconds. • While holding the tube, turn the vacuum regulator anti-clockwise and check the reading on the instrument to ensure that the suction falls to almost 0 (40÷50 mbar due to the filter). • Switch off the suction unit and turn it 180 degrees to check the electrical contacts on the back of the suction unit (they must be clean and free of stains, oxidation and/or burns). • Attach the device to the bracket. If the battery is discharged, charging will begin (charging indicator <ON/CHG> yellow if charging in progress, green if charging is not necessary). If the device is not equipped with a wall bracket and the battery is discharged, connect the external power cable to the cigarette lighter or to the optional power supply and check that the charging process starts (yellow LED lit = charging in progress; green LED lit = charging finished). • Check that the filter is clean and not contaminated. If the filter is not white, it must be replaced. A dirty filter prevents the suction unit from working properly and reduces its performance by increasing the risk of contamination. Do not use the suction unit without a filter.

At the end of the test operations compare them with the values in the table below:

Test phase	Test result	Recommended action with negative outcome
Operating the autonomy test	The LEDs on the front of the device light up depending on the battery charge.	If the LEDs do not light up, the battery is either completely flat or faulty. Try recharging the battery with the external cable or power supply or refer to the authorized service centre. During these operations, exclude the device from its active service.
Checking pump operation	Uniform engine noise, no rpm drops, no abnormal vibration	Uneven noise indicates a fault in the pump operation. A drop in speed indicates insufficient current to operate the motor correctly. Contact the authorised service centre or the manufacturer.
Check for maximum suction by occluding the tubing from the filter or disposable bag to the device with your fingers	The maximum vacuum value that can be read on the vacuum gauge should be around 800 mbar ±10 % (70 kPa to 80 kPa; 525 to 600 mmHg).	If this value is not reached, close the vacuum regulator completely by turning the knob clockwise. Check that the occlusion exerted on the tube is complete. If this is not the case, do not use the device and contact the authorised service centre.
Setting the maximum vacuum value	Value between approximately 0 and maximum by turning the knob	If the vacuum value cannot be adjusted, contact the authorised service centre. Remove the device from use

Checking the rear charging contacts	The contacts must be clean and free of oxidation. There must be no burn marks on the metal.	Clean the contacts with a cloth soaked in ethyl alcohol. If they are badly burnt, they must be replaced. In this case, contact the authorised service centre

	If you fail one or more of the tests, even after performing the recommended actions, send the device to the service department or the manufacturer for a complete check or overhaul.

6.4.2. Six-monthly/annual periodic testing of OB1000 and OB1000 AVIO suction units

This test is used to verify whether the device is fully compliant with the original manufacturing characteristics and therefore suitable for use in the field. The checks and controls should be carried out by persons and/or companies specialised in this type of operation on medical devices and must have been instructed/authorised by the manufacturer. Following the inspection, an electrical safety test in accordance with IEC 60601-1 should be performed and a test summary document made available to the user.

SIX-MONTHLY OR ANNUAL TEST	• Replace the SERRES® disposable bag or antibacterial filter before performing these operations. • **Mechanical operation of the wall bracket**: check that it is correctly fixed (to the wall of the vehicle), that it works, and that the upper red plastic button slides (without any obstruction). After pressing the upper red part, release it and check that the locking hook returns to its initial position. Check the charging contacts, which must not be altered, burnt or oxidised. • Check the connection of the electrical cables to the bracket (they must be fixed). • Carry out a complete check of the functionality of the suction unit: battery life, recharging function, complete check of the LED functions (from maximum to minimum during battery discharge). Check that the LEDs function as shown in chapter § 6.3 Indicator lights during charging. • Check the operation of the internal pump by pressing the switch. The maximum vacuum value must be between a minimum of 730 mbar and 880 mbar. Use a precision vacuum gauge to measure this value (tolerance ±2.5 % or less). There should be no operational anomalies such as unusual noise, rpm fluctuations, excessive gauge hand vibration and the operation of the vacuum regulator knob should be linear and unimpeded: during operation, the device should be placed on a stable surface to check the amount of vibration generated. • Check the vacuum regulator which should operate from minimum to maximum. Turn the knob clockwise and anticlockwise. When the regulator is fully open, it is normal to measure a small vacuum value (introduced by the antibacterial filter). • Check the minimum operating time of the suction unit: switch it on and allow it to run in free-cycle for at least 20 minutes. The suction unit should 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 (running mechanical parts). • Check that all labels and screen prints are present and legible. • Never open the suction unit for any reason. For technical assistance, contact only one of the authorised service centres listed at the end of this manual. • Check the function of the vacuum gauge. When the vacuum unit is switched off, the needle should be at "0". • Ensure that the carrying strap is functional, undamaged and not torn. The nylon hook of the strap must be closed. • Check that the secretion jar is intact and that there are no cracks or breaks that could impair aspiration. • Check the screws of the two steel plates fixed to the rear side of the device in order to be able to securely attach it to the support bracket. • Before declaring the suction unit compliant with the manufacturer's data plate, carry out an electrical safety test according to IEC60601-1 with a specific safety analyser. Contact the manufacturer or the authorised service centre for information on how to carry out this test.

 **DEVICE COMPLIANCE**	Only use consumable or spare parts supplied by the manufacturer. Do not use similar or apparently identical components. The conformity of the component can only be confirmed by the manufacturer.
	Keep a document confirming that all checks have been carried out and, if possible, a photographic report on the condition of the device before and after the check. Always also keep a copy of the safety report carried out with the appropriate calibrated instrument.

OPERATION	In accordance with ISO 10079-1:2019, the device can only be operated in a vertical position and at an angle of inclination not exceeding 20 degrees. If this limit is exceeded, the overflow valve may intervene and block the suction.

If you have any doubts or concerns regarding the conduct of the tests, please always contact the manufacturer of the device or its authorised service centre. If you fail even a single test, please contact a service centre or the manufacturer. Do not use the device if you have not passed all tests.
For further information please call 0471 932893 or send an e-mail to info@boscarol.it.

6.5. Periodic safety maintenance

Depending on the use of the device, the OB1000 and OB1000 AVIO suction units should be checked at least every 24 months, even if not in use. Some parts inside the unit, e.g. the battery and the filter, may be adversely affected by a long period of inactivity. Periodic maintenance includes specific maintenance, overhaul and updating of the unit. If periodic maintenance is not performed, the life of the device will be reduced.

6.6. Safety information for the safety of users, patients and third parties

To avoid unwanted effects and risks, always follow the information below:

- Ensure that all accessories are in working order and replace any defective external power supply or cables. Do not take unnecessary risks: always replace defective parts to ensure that the device is always efficient in use and especially in emergencies.
- Always keep the device secured to the support bracket (in emergency vehicles) during transport to avoid injury to the user and the patient.
- Even if you do not use the device, recharge the battery at least once a month.
- We recommend another suction unit in case this one does not work or is defective (e.g. manual suction unit).
- Always remember what is stated in the initial warnings regarding the risks of magnetic field (EMC) effects.
- Always select the appropriate level of vacuum according to the patient and medical guidelines.
- Do not alter or modify the medical device. Serious consequences for the patient and the user may occur.
- OB1000 and OB1000 AVIO suction units **are not sterile devices** and cannot be sterilised with the exception of the secretion jar and silicone tubing.
- Keep children away from hoses and connecting cables. Also keep them away from small parts.

Risk of infection

- Improper use of the device can lead to transmission of infections, even fatal ones.
- Always wear disposable gloves, especially if there is a risk of coming into contact with aspirated secretions.
- Never use components marked as disposable more than once. Disposable parts or medical devices are marked as in the figure opposite (number 2 crossed out).

- Never use the device without the bacterial filter.
- Always disconnect the unit from the power supply, bracket or SELV source before performing cleaning and disinfection processes.
- Only use the power supply unit indoors and in a dry environment. Do not use the power supply outdoors!
- Always use only original accessories and original spare parts.

Attention	Assembly, repairs and modifications to the device are prohibited and may only be carried out by the manufacturer or authorised personnel.

7. SECRETION JARS FOR OB1000 AND OB1000 AVIO

The device is marketed with two different types of jars with a capacity of 1000 ml:

- Suction unit with autoclavable secretion jar (OB1000 and OB1000 AVIO FA).
- Suction unit with secretion jar equipped with disposable bag (OB1000 and OB1000 AVIO FM)

7.1. Autoclavable secretion collection jar OB-J FA

The jar is made of transparent plastic (medical-grade polypropylene). It includes the jar (1), the snap-on lid (2), the anti-reflux valve (3) and the 90° plastic connection (4). The jar lid allows direct insertion of the antibacterial filter (from the outside). The autoclavable jar can be sterilised conventionally in a steam autoclave at a maximum temperature of 121° C and a pressure of 2 bar (200 kPa). The jar must be replaced if it is deformed, broken or cracked. The secretion jar 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 jar.

Service life of OB-J FA secretion jar	The jar of secretions must be replaced after 30 sterilisation cycles or 5 years from the date of manufacture.

7.2. Antibacterial filter

The protective filter protects the suction circuit from any contaminants sucked in during use. The filter is manufactured from hydrophobic PTFE material which prevents fluids from entering the pneumatic circuit. Working in conjunction with the overflow valve on the jar, the filter isolates the pneumatic suction pump from gases and fluids. **The filter is disposable and must be replaced after each use**. In the event of contamination, discolouration and increased suction resistance, it must always be replaced. The filter is not produced by the Boscarol company.

Antibacterial filter	If the device is used on patients where the infection status is unknown, **always replace the filter** after use on the same patient. This will prevent even serious contamination of the environment in which the device is placed and therefore of operators and patients. If, on the other hand, it is known and/or there is no risk of indirect contamination, it is advisable to replace the filter after each work shift or in any case when the suction level decreases or the filter changes colour.
Risk of infection	• Never use the device without the antibacterial filter. Please always keep at least three spare filters in case of emergency. • Always wear gloves and personal protective equipment when changing the antibacterial filter and emptying the secretion jars. • Before each use, check that the filter is dry and clean (it must not be any colour other than white). Replace the wet or contaminated filter with a new one. • Never reuse the antibacterial filter (disposable).

7.3. OB-J LINER: jar of secretions for SERRES® disposable bags

The OB-J secretion jar for SERRES® disposable bags is made of transparent plastic (medical grade polypropylene). It comprises a container (1), a SERRES® disposable bag adapter (2), a red 90 degree connector (3) and a SERRES® disposable bag (4). The antibacterial filter is integrated in the lid of the disposable bag and prevents aspirated fluids from entering the suction unit. The secretion jar can be sterilised in a conventional steam autoclave at a maximum temperature of 121° C and a pressure of 2 bar (200 kPa). The disposable bag must be replaced after use on the same patient or if it is full.

When used in a domestic environment, the jar of secretions can be cleaned using a special detergent to ensure disinfection of medical devices. Contact Boscarol for information on disinfectants.

Risk of infection	• Please always keep at least three ® SERRES bags in reserve. • Always wear gloves and personal protective equipment when changing the SERRES® bag and for disposal. • Before each use, check that the SERRES® container has not already been used. • **Always** replace the contaminated disposable bag with a new one.

7.4. Secrets jar connection

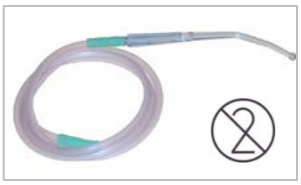
The secretion jar is connected to the aspiration unit via a silicone tube and a plastic connector (white for the FA version (Fig.1); red and 90° for the FM version (Fig.2)). Insert the connector into the device as shown in the adjacent image. Do not force the insertion. This operation is valid for both types of secretion jar.

Fig.1

Fig. 2

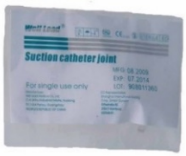
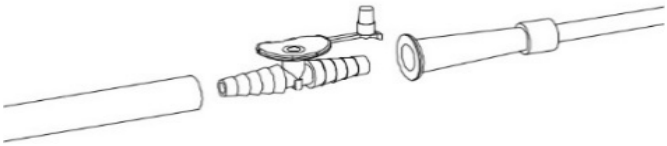
7.5. Sterile disposable Yankauer catheter with suction control system

The OB1000 and OB1000 AVIO suction units are sold complete with a sterile Yankauer-type suction catheter and tubing for connection to the jar. The suction probe and catheter are disposable and must be changed after each use. To facilitate correct functioning, the tip of the rigid suction probe is angled so that it can reach all parts of the mouth and upper airway. The rigid suction tip is spherical and equipped with lateral holes to avoid damage to tissue during suction.



Yankauer PATIENT	The Yankauer suction catheter is a sterile, single-use medical device. Never reuse this device. It must be disposed of after use on the patient.
	Caution! Never use sterile medical devices beyond their expiry date or if the packaging is damaged.
	Always connect the Yankauer catheter to the "PATIENT" side on the lid of the reusable jar (FA) or SERRES® disposable bag via the white conical fitting.

7.6. Silicone suction tube and sterile Fingertip (conical fitting)

On request, the device can be equipped with a silicone patient tube (length: 130 cm) and a sterile conical Fingertip fitting that allows the use of standard sterile catheters of an appropriate size. The tube is reusable.	
The sterile Fingertip connection allows fingertip control of the suction value by closing and opening the prepared hole. The disposable devices supplied with the suction unit are identified with labels that provide all the necessary information for correct use.	
The Fingertip (also called catheter connector) allows you to attach standard sterile catheters (see figure opposite).	

7.7. Warnings concerning the re-use of single-use parts

Disposable medical devices **Risk of infection**	Caution: The suction unit is supplied with a number of sterile disposable accessories to facilitate patient aspiration. These devices may not be used on more than one patient. Disposable medical devices are made of materials to withstand limited use and must not be reused. The operator must dispose of them properly and restore the medical device to make it efficient for the next use. Re-use of single use devices can be dangerous for both patient and operator and can cause loss of performance by damaging the device irreparably.

SERRES® disposable bag	The SERRES® disposable bag cannot and should not be emptied. The top cap is designed to allow the extraction of secretion samples for laboratory analysis. Whenever the filter comes into contact with fluids or liquids (of any kind), it is blocked and the bag must be replaced!

8. REUSE, CLEANING AND DISINFECTION

After each use, disconnect the suction unit, disconnect the disposable parts and dispose of them. Check the integrity of the suction unit, the connection tube and check that there are no 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 chapter §"6.4 Periodic test OB1000 and OB1000 AVIO" for the daily test. The decontamination process is always a process to be followed meticulously, which implies specific training, especially in medical emergencies where the medical condition of the patient and the degree of contamination are mostly unknown. For this reason, the operator must always wear personal protective equipment (PPE) to protect themselves and others. If PPE is not available, please contact your safety representative.

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

8.1. Re-use of OB-J FA secretion jar

The steps required to separate the jar of secretions from the suction unit, disassemble it and assemble it after cleaning and disinfection are described below. Before starting, wear protective gloves, also covering your forearms, mouth and protecting your eyes.

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 conical fitting from the suction unit.	
Open the strap on the side of the bag	
Pull the secretion jar vertically out of the suction unit.	

Remove the antibacterial filter from the cover by turning it on its seat and discard it.	
Remove the lid from the jar by pressing lightly on the jar and levering the lid flap. Empty the contents of the jar.	
Remove the overflow valve from the lid.	
Separate all the parts.	
Parts making up the lid: • Polypropylene cage yellow • Polypropylene float, yellow • Red silicone gasket • Red polypropylene lid	
DANGER	Risk of infection due to leakage of potentially contaminated substances during emptying of secretions. Possible transmission of life threatening infections. Always use suitable PPE and disinfectants as stipulated by hospital regulations and the relevant authorities.
	Beware of certain disinfectants that may stain the jar of secretions and its parts even without damaging it.

8.2. Cleaning, disinfection and/or sterilisation of OB-J FA secretion jar and silicone tube

The secretion jar and the silicone tube can be cleaned with specific non-abrasive substances for cleaning medical devices. Alcohol-based cleaning agents can be used if diluted appropriately (follow the instructions for use on the label of the disinfectants). Avoid using coloured disinfectants as they may stain the plastic of the jar and the silicone tube, reducing its transparency. After disposing of the disposable antibacterial filter and Yankauer suction catheter, complete with tubing, place the reusable parts in warm water (temperature not exceeding 60°C to avoid scalding) 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. In the event of serious contamination, **always refer to the** instructions of health care personnel and the competent authorities. If necessary, sterilize "REUSABLE PARTS" (see above) with steam autoclaves at a maximum temperature of 121°C for a maximum of 15-20 minutes (typical cycle). Do not use autoclaves with pressures above 2 bar (200 kPa). The jar should be placed upright and inverted. At the end of the cycle, allow the parts to cool to room temperature and check that they are undamaged and not deformed.

CYCLE OF DISINFECTION **WARNINGS**	• **Do not spray liquids onto the device. Clean the device with the suction inlet closed. Place a piece of tape or leave the secretion jar connected to the unit.** • Do not use aldehyde and/or amine-based disinfectants to prevent discolouration. • Use only disinfectants for cleaning medical devices. Before applying them to the surface of the device and the secretion jar, check at an angle for damage. • Consult specialised personnel in hospitals and clinics. Check for specific disinfection and cleaning plans and/or protocols for the area concerned.

STERILISATION CYCLE **WARNINGS**	• Never sterilise devices or parts that have not been previously cleaned. • Do not place any weight on the parts or devices during the sterilisation cycle. • Observe the maximum limits for temperature, pressure and sterilisation time (temperature: 121° C, pressure: 200 kPa, maximum time 15-20 minutes). • Cleaning and/or sterilisation should only be carried out by qualified personnel. • Replace the jar of secretion if it is cracked, fissured or even partially broken. • After reassembling the jar, always check that the lid is fitted correctly to avoid loss of vacuum and spillage of liquids or aspirated fluids. • Always follow the instructions provided by the autoclave manufacturer.

8.3. Jar assembly and connection of the silicone suction tube

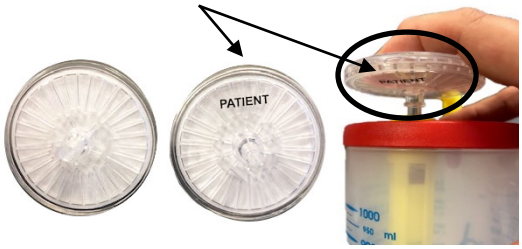
Place all jar components on a flat, stable surface. During assembly and disassembly, always check all parts for damage or deformation. The overfill valve has a float that slides on a plastic cage. Ensure that it moves inside unhindered (by sliding it) and that the red silicone gasket is intact. Assemble the jar by proceeding in the opposite direction to that seen above.

AFTER CLEANING	**Warning** • Check after each cleaning if the device and its parts are functional. • If in doubt, send the device to the manufacturer or an authorised centre for review and inspection. • After the assembly process, always perform a function check as described in chapter § 6.4 Periodic test OB1000 and OB1000 AVIO of these operating instructions. • Prepare the device for the next use.

8.4. Replacing the antibacterial filter

Carefully disconnect the silicone tube from the contaminated filter. To easily remove the filter from the lid, proceed by screwing 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 regulations for the disposal of hospital waste.
Depending on our stock availability, we can supply two different types of anti-bacterial filter: one has the inscription "IN" on the side which must be connected to the vacuum socket on the lid.
The second one has a side with the inscription "PATIENT". Connect this side to the "VACUUM" socket on the lid.

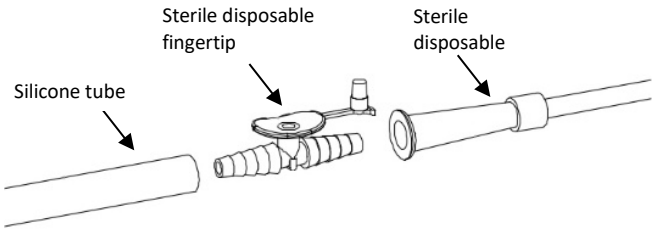
Failure to observe this detail may result in filter failure and contamination of the suction unit's suction circuit.



ANTIBACTERIAL FILTER	**Attention** The filter must be inserted with the side marked "IN" or "PATIENT" facing the jar lid. Using the suction unit with the filter inserted incorrectly may lead to contamination of the suction circuit.

8.5. Cleaning the secretion jar with SERRES® disposable bags

The OB-J Liner jar of secretions is equipped with a specific SERRES® disposable bag, which is certified for this type of use. Unlike the OB-J FA version, the antibacterial filter is located inside the bag and is automatically replaced after each bag change.

A number of safety precautions should be taken before removing the disposable bag. Remove the Yankauer disposable catheter complete with rigid probe. Always remember the risks of infection and contamination	
If the device is equipped with silicone tubing, Fingertip conical fitting and suction catheter proceed as follows: • Remove the disposable catheter together with the conical connection (see adjacent photo). • Disconnect the silicone tubing from the white plastic fitting on the SERRES® bag. Discard the bag but keep the silicone tubing as it can be reused, disinfected and/or sterilised.	
Remove the white 90-degree connector located on the SERRES bag (if not already done) and close the inlet hole (PATIENT) with the cap (see black arrow in the picture opposite).	
Disconnect the red 90-degree plastic connection from the suction unit by pulling it outwards with your hand.	
Detach the silicone tube from the jar	
Pull the entire jar vertically out of the suction unit.	
Remove the disposable bag (previously closed) from the jar and dispose of it in accordance with official instructions for disposal of contaminated waste.	

Use your hand to operate the 90° connector on the jar and remove the silicone tube (do not remove it!).	 REUSABLE
Remove the plastic adapter from the secretion jar by exerting a small amount of force. If necessary, use both hands to separate the two parts. Take care not to damage them.	 REUSABLE
Unscrew the connector by 90° while holding the screw inside the jar with your hand. Take care that the O-ring is not damaged.	 REUSABLE  REUSABLE

Service life of OB-J and OB-J FA jars	The jar of secretions must be discarded after 30 sterilisation cycles or 5 years of use from the date of first use.
DANGER	Risk of infection due to spillage during cleaning process. Possible transmission of life threatening infections. Always use suitable PPE and disinfectants as stipulated by hospital regulations and the relevant authorities.

8.6. Disinfection and/or sterilisation of the OB-J secretion jar and silicone tube

For cleaning, disinfection and/or sterilisation of the secretion jar (and silicone tubing) follow the instructions in chapter § 8.2. Cleaning, disinfection and/or sterilisation of the OB-J FA secretion jar and silicone tubing.
Please refer to the cleaning and disinfection plan on the following pages.

REUSABLE PARTS	Reusable parts can be disinfected and/or sterilised.
DISINFECTION CYCLE **WARNINGS**	• **Do not spray liquids onto the suction unit. Always clean the device with the suction inlet closed. Put on a tape or leave the jar connected**. • Do not use aldehyde and/or amine-based disinfectants to prevent discolouration. • Before proceeding with disinfection, make sure you have the appropriate substances and the right instructions for using them. • Use only disinfectants for cleaning medical devices. Before applying to the surface of the device and the container collection device, check in a small area for damage. • If substances have been aspirated that are seriously contaminated with specific infections, refer to the instructions of the healthcare professional. • Consult qualified personnel in hospitals and clinics. Check for specific disinfection and cleaning plans and/or protocols for these devices.

STERILISATION CYCLE **WARNINGS**	• **NEVER STERILISE THE SERRES® DISPOSABLE BAG.** • Never sterilise devices or parts that have not been previously cleaned. • Do not place any weight on the parts during the sterilisation cycle. • Always observe the maximum limits for temperature, pressure and duration during the autoclave cycle (temperature: 121° C, pressure: 200 kPa, maximum time 15-20 minutes). • Cleaning and/or sterilisation should only be carried out by qualified personnel. • Replace the jar of secretion if it is cracked, fissured or even partially broken. • After assembling the secretion jar, check that the lid is fitted correctly to prevent vacuum leakage and spillage of liquids and fluids. • Follow the instructions provided by the autoclave manufacturer.

8.7. Assembling the secretion jar with the SERRES® disposable bag

Remove a new disposable bag from the packaging, extend it by hand and insert it into the secretion jar as shown in the figure opposite.
Press it all the way into the jar.

- Insert the jar into the suction unit and connect it via the red 90° fitting.
- Activate the suction unit. With one finger, close the "PATIENT" connector and, at the same time, press lightly on the sides of the bag (blue lid).
- Ensure that the bag is fully extended in the jar. Connect the disposable patient catheter (Yankauer) to the "PATIENT" connector.

8.8. Disposal of contaminated single-use parts

Always follow local regulations or hospital practices when disposing of contaminated waste. Never store contaminated parts with new or sterile parts. Boscarol markets specific identified bags for the disposal of contaminated hospital waste.

8.9. Cleaning and disinfection of the suction unit

Disconnect the suction unit from any external power supply. To clean the surface of the device, use a damp cloth soaked in diluted medical device disinfectant (same as used for the secretion jar). Sometimes the screen print on the container can be damaged or made illegible by some types of disinfectants. When finished, wipe the surface with a dry cloth or paper towel that does not leave any traces.

DANGER **ELECTRIC SHOCK**	• **Always disconnect the device from the power source before cleaning.** • When cleaning the surface of the device, always disconnect the unit from the support bracket. • DO NOT RINSE THE DEVICE under running water and/or immerse it in liquids. • The suction device is marketed ***non-sterile and cannot be sterilised.*** • Do not immerse the suction unit in disinfectant solution. • Never use solvents that can deteriorate plastic and/or remove screen prints and labels. • Do not spray liquids onto the device. The suction inlet of the device must always be closed during all cleaning operations. Close the inlet hole with a piece of tape or plaster to prevent liquids from entering the unit and damaging the suction circuit.
EXTERNAL POWER SUPPLY	• Disconnect the power supply from the mains before starting to clean it. Wait at least 1 minute after unplugging to self-discharge the accumulated internal energy. • Never rinse the power supply or the bracket under water and never immerse them in liquids. • Ensure that the cloth used to clean the device is slightly damp. • Never immerse the power supply or support bracket in disinfectants or detergents.

and SUPPORT BRACKET **DISINFECTION**	• To disinfect the surface of the power supply and support bracket, use only medical device disinfectants and always dry the surface. The cloth should be damp and not wet. • After these operations, wait at least 30 minutes before using it again.

CLEANING DEL DEVICE	Substances entering the suction hole are sucked in by the pump and sprayed onto the electronic parts. For this reason, it is mandatory to close the suction hole with a piece of tape or plaster. At the end of cleaning this tape or plaster must be removed.	 
Availability of disinfectants	In order to disinfect and decontaminate the suction unit correctly, it is advisable to use specific, approved products. These disinfectants must be free of abrasive substances. Oscar Boscarol S.r.l (Ltd) can supply specific disinfectants suitable for medical equipment, including our suction units. These disinfectants, available in different formats (soaked wipes, sprays and concentrated liquids), have been tested and guaranteed in the laboratory to inactivate viruses, bacteria and microorganisms. When used periodically, they destroy and prevent the formation of dangerous biofilms (surface layers that easily harbour bacteria, moulds, viruses and micro-organisms). Our disinfectants are free of chlorine, phenols, aldehydes and halogens.	

After cleaning	**Warning** • After each cleaning process, check the device and its parts for damage. • If necessary, send the device to the manufacturer or to an authorised centre for overhaul and inspection. • After the assembly process, perform a function check as described in chapter §"6.4 Periodic test OB1000 and OB1000 AVIO" of these operating instructions. • Prepare the device for the next use

8.10. Cleaning and disinfection plan

Please print this table and indicate the name of the operator who carried out the process.

Operation to be performed	Cleaning	Disinfection	Sterilisation	HOW TO DO IT	Days.	Every 15 days	After each patient/after each aspiration	Name of the operator who carried out the process
OB-J FA	X	X	If necessary	See chapter 8	X		X	
OB-J LINER	X	X	If necessary, only the jar	See chapter 8	X		X	
Overflow valve	X	X	If necessary	See chapter 8.1	X		X	
Reusable hoses	X	X	If necessary	See chapter 8.2	X		X	
Antibacterial filter				Change the filter, even if it is blocked		X	X	
Device surface	X	X	Not foreseen	See chapter 8.9		X	X	
Power supply	X	X	Not foreseen	See chapter 8.9		X	X	
Support bracket	X	X	Not foreseen	See chapter 8.9		X	X	

9. ACCESSORIES AND OPTIONS FOR OB1000 AND OB1000 AVIO

In order to safely install the device in emergency vehicles, a support bracket (which also provides power to the device) is available. The bracket has passed conformity tests according to the international standard EN 1789.
The vacuum unit can be charged and operated using the cable (supplied), the bracket (optional) or the optional power supply unit (Input 100-230 Vac). The charging cable must be connected to 12 to 15 VDC (direct current) with a power of at least 70-80 W.
In order to be used with a mains power supply, the suction unit must be connected to an approved power supply available from the manufacturer. Use of the suction unit with the mains adapter must be limited to 20 minutes continuously, after which it must be allowed to cool down.

Power cable for OB1000 and OB1000 AVIO suction unit. REF Code: BSU855.	
Support bracket that can power and charge the device. REF Code: BSU810.	
LYD mains voltage power supply with 2-pin connector. Input voltage 100 to 240 Vac Output voltage: 14.0 VDC Rated power: 60 W REF Code: BSU895EU (EU plug) - BSU895UK (UK plug) - BSU895JP (JP plug)	

ACCESSORIES EXCLUSIVE	The power supply is an exclusive accessory, available only from the manufacturer. It is approved for this function and cannot be replaced by other brands. May only be used indoors and on legally compliant network installations.
DANGER **Electric shock**	Never tamper with and/or open the mains adapter. Danger of death! The power supply unit contains electronic parts connected to the mains voltage which can be fatal.
LIFETIME	The life of the suction unit is **ten** years from the date of manufacture. The unit must be replaced after ten years.

10. OB1000 AND OB1000 AVIO SUCTION UNITS INTERNAL BATTERY

The OB1000 and OB1000 AVIO suction units have an internal battery that ensures a long service life. The hermetic lead acid (SLA) battery is sealed and cannot be opened or repaired. If the battery is exhausted or defective it must be replaced by a new one. The battery is installed in the unit and is not accessible by the user.
The maximum battery charging time (depending on the remaining charge) is approximately 15 hours. A fully charged battery will provide approximately 60 minutes of continuous operation (at free air flow). This time may vary, even considerably, if the suction unit is used outside the manufacturer's recommended parameters (e.g. when used in very high or very low temperatures). When properly charged, the 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 period of time, perform a complete check and fully charge the battery every 15-20 days.

Failure to use the device	Recharge the unit at least once a month. This will prevent any problems related to non-use and non-recharging of the SLA battery.

 **Battery disposal**	The spent battery must be disposed of in accordance with the regulations in force in the country in which the vacuum unit is used.

11. SPECIAL CONDITIONS OF USE

The suction unit does not have electrical and mechanical safety devices accessible to the operator. Temperatures that are too high or too low may cause some of the internal safety devices to trip, stopping the operation of the suction unit. For this reason, never expose the device to extreme working conditions (temperature, humidity and pressure). The technical characteristics and nominal working conditions are listed in chapter § 15 Technical data and compliance data for OB1000 and OB1000 AVIO.
If the suction unit is to be used in borderline conditions, check the following information.

 **Use in special conditions**	• Operate the suction unit for the time strictly necessary. Once used, put the suction unit in a place with less critical operating conditions. • If the suction unit stops working, let it acclimatise for at least 30 minutes in an area where the temperature is between 15 and 25° C. • In high humidity, condensation may form on the outside of the device on the front of the suction unit. After use, wipe off the condensation and dry the unit with a soft cloth. Such condensation may also be caused by sudden changes in temperature and humidity associated with, for example, rapid changes in altitude (e.g. helicopter use).

12. DEMOLITION OF 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) converted into Italy by Decree-Law 49/2014 (WEEE). If the device is contaminated it cannot be scrapped according to this directive but according to what is expressly required for hazardous hospital waste.

 **Risk of infection**	• Before dismantling the device, disinfect it and make sure it is clean. • All disposable and contaminated parts must be disposed of in accordance with local and national laws. • Recycle only non-contaminated parts • Never throw the battery in the household waste • The suction unit is fully recyclable, please refer to the relevant legislation and all applicable guidelines.
 **DECONTAMINATION**	To clean and decontaminate the device prior to dismantling, the procedure for this process can be obtained from Boscarol (info@boscarol.it).

13. ACCESSORIES, CONSUMABLES AND SPARE PARTS

Manufacturer code	Description
	Accessories
BSU810	Support bracket OB WB
BSU895EU	LYD power supply 100÷240 Vac - 2 poles with EU plug - Vout = 14 Vdc
BSU895UK	LYD power supply 100÷240 Vac - 2 poles with UK plug - Vout = 14 Vdc
BSU895JP	LYD power supply 100÷240Vac - 2 poles with JP/USA plug - Vout = 14 Vdc
	Consumables
BSU999	Antibacterial filter for FA secretion jar (can also be ordered in multiples of one)
M03.1.003	Antibacterial filter for FA secretion jar (Medutek alternative can also be ordered in multiples of one)
57157	SERRES® disposable bag 1 piece (can also be ordered in multiples of one)
BSU500	Autoclavable secretion jar OB-J FA without antibacterial filter
BSU506	Jar of OB-J LINER secretions without disposable bag
126140107191	Sterile Yankauer suction catheter
126140108001	Fingertip sterile suction cone connector - 1 piece (can also be ordered in multiples of one)
	Sterile suction catheter Ch 10 black
	Sterile suction catheter Ch 12 white

Request codes directly from OSCAR BOSCAROL SRL **info@boscarol.it**	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 complete with cigarette lighter plug and 2-pin flying connector
BSU902	Silicone patient tube inner diameter 6 mm - length 130 cm
SPS6000	Secretion collection vessel OB-J FA without lid
SPS6002	3-piece overflow valve set for cover OB-J FA
SPS6004	3-piece plastic connector set yellow 90° OB-J FA
SPS6006	Lid for SPS6000 secretion collection tank complete with overflow valve and 90° connection yellow
SPS6011	Plastic corner connector red suction unit
SPS6023A	Silicone tubing 16 cm long with angle connector for OB-J FA jar
SPS6024A	Silicone tube 13 cm long with angle connector for OB-J jar (SERRES® bag)
SPS5092	3-piece 90° connection set for OB-J jar (SERRES® bag)
SPS5093	10-piece O-ring set for 90° connection for OB-J jars
eIFU	Operating Instructions available on the link: https://www.boscarol.it/ita/eifu.php

Updating codes	In order to make technical improvements, the parts listed may be changed by the manufacturer without notice. Contact the manufacturer for further information (info@boscarol.it).

14. TECHNICAL SERVICE

No electrical and/or mechanical parts of the OB1000 and OB1000 AVIO suction unit are designed to be repaired by the dealer, customer and/or operator. The user is not authorised to replace the battery. Do not open the vacuum unit or tamper with the electrical and/or mechanical parts. Always contact the authorised service centre or the manufacturer. Carrying out even minor operations on the suction unit voids the warranty. Unauthorised intervention on the suction unit may compromise its compliance with relevant laws and regulations and reduce the safety of use for operators and patients. Contact Boscarol Srl for a list of authorised service centres by sending an e-mail to info@boscarol.it.

14.1. Solving common problems

Malfunctioning	*Possible causes*	*Solution*
The suction unit does not switch on	• Low battery	• Charging the suction unit with the charging cable or mains adapter
	• Battery damaged	• Contact the authorised service centre to replace the battery
	• Faulty internal electronic circuit	• Contact the authorised service centre
Suction unit does not work when connected to support bracket	• Bracket not connected to external 12 to 15 VDC source.	• Connect the cable of the support bracket to the external power source
	• Supply voltage outside the expected range	• The supply voltage must be between 12 and 15 VDC.
	• Not enough current to power the device	• The rated current must be at least 8 A
	• Damaged device contacts	• Contact the authorised service centre
	• Damaged bracket contacts.	• Contact the authorised service centre
	• Bracket connection cable reversed	• Reverse the poles of the power cable (+ on top contact)
	• Faulty internal device circuit	• Contact the authorised service centre
The suction unit ***only*** works when connected to the support bracket, the mains adapter or the external cable.	• Internal battery damaged	• Contact the authorised service centre to replace the battery
	• No internal battery	• Contact the authorised service centre to insert the battery
	• Faulty electronic internal circuit	• Contact the authorised service department
The suction unit does not charge when connected to the mains power supply and/or does not operate	• Faulty power supply unit	• Replace the power supply unit or • Contact the authorised service department
The suction unit works, but the autonomy indicator is off.	• Range indicator damaged.	• Check whether the autonomy indicator works when the suction unit is connected to the support bracket or the external cable. If it does, recharge the device for at least 24 hours, otherwise contact the authorised service centre.
	• Very low battery.	• Recharge the suction unit for at least 24 hours.
The autonomy of the suction unit is considerably reduced	• Battery has reached the end of its life cycle	• Replace the battery at an authorised service centre or contact the manufacturer
	• Faulty internal charging circuit	• Contact the authorised service department.

Little or no vacuum power on the patient side	• Vacuum regulator fully open	• Close the regulator completely and check the vacuum power on the instrument and patient side (turn the knob clockwise).
	• Blocked protection filter	• Change the protective filter
	• Clogged, kinked and/or disconnected filter and device connection pipes	• Connect connecting hoses to the filter and/or jar, replace if blocked, remove any kinks
	• OB-J FA jar overflow valve blocked	• Disconnect the tube going to the device, empty the jar and check the smooth movement of the valve (the silicone seal must be upwards). The jar can only be used in a vertical position (±20 % maximum inclination).
	• Pump damaged	• Contact the authorised service department.
It is not possible to adjust the vacuum power, which is always maximum, even if the jar is completely removed.	• Fault in the internal suction circuit.	• Contact the authorised service department.
Increased noise, poor suction, increased vibration.	• Damaged internal pump	• Contact the authorised service department.

DANGER	**ELECTRIC SHOCK** - Never tamper with and/or open the suction unit and/or the mains power supply. Risk of death. The power supply contains an electronic circuit which is subjected to mains voltage and can be fatal if touched. In the event of a fault, always contact only an authorised service centre or the manufacturer**.**

15. TECHNICAL DATA AND COMPLIANCE DATAFOR OB1000 AND OB1000 AVIO

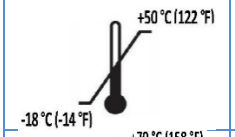
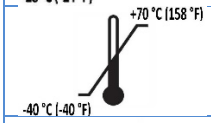
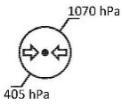
Classification of the medical device (in accordance with MDR Regulation 2017/745	**IIa**
Basic UDI number (in conformity with MDR 2017/745)	805240088OB1000TC
Suction level classification according to ISO 10079-1:2019	HIGH VACUUM-HIGH FLOW
Operating mode (short term):	TEMPORARY (50 minutes 'ON', 10 minutes 'OFF')
Supply voltage:	SELV (12÷15 Vdc)
Reference standard	ISO 10079-1:2019
EMC compliance testing	IEC 60601-1-2 4th edition
Medical device safety compliance	IEC 60601-1 latest edition
Compliance for use in the home sector	IEC 60601-1-11:2015/AMD1 2020
Compliance for use in the pre-hospital sector (EMS)	IEC 60601-1-12:2014/AMD1 2020
 Part applied according to IEC 60601-1	TYPE BF
 Protection class against electric shock	CLASS II
Degree of protection against ingress of liquids and solids (IEC 529):	IP34d
Risk assessment (technical documentation)	ISO 14971:2019
Application of usability	IEC 62366-1:2015
Compulsory periodic safety inspection	Every 24 months
UMDNS code	15-016
Code GMDN	63643
Approval and conformity according to ECE R10 (automotive)	E50 10 R - 05 0078
Compliance with European ambulance standard	UNI EN 1789:2021
Crash test of ambulance support systems	UNI EN 1789:2021
Avionics EMC compliance (**OB1000 AVIO only**)	RTCA DO - 160F

Dimensions OB1000 and OB1000 AVIO	
Maximum device size	320 mm (width) x 100 mm (depth) x 250 mm (height) 12.60 in (width) x 3.94 in (depth) x 9.84 in (height)
Device weight	3.5 kg complete with all accessories
Weight of the support bracket	780 g
Tolerance on all values	±5 %

Technical Data	
Nominal suction power	850mbar (85kPa, 638mmHg) ±10 %.
Vacuum regulation	Linear with integrated mechanical controller
Vacuum setting range	30÷850 mbar (3÷85 kPa)
Nominal flow	> 25 LPM (litres per minute) at free air speed ±10 %.
Maximum operating time (free-cycle)	60 minutes ±10%.
Maximum noise	65 dB
Accuracy of vacuum gauge (full scale)	±5 %

Accuracy of range indicator	±5 %
Autoclavable jar of secretions	Type OB-J FA 1000 ml autoclavable for 30 cycles max.
Autoclavable jar of OB-J secretions	Type OB-J for disposable bags 1000 ml SERRES®
Service life of the device	10 years from the date of manufacture
(*) Notes: 1bar = 100kPa = 750mmHg	

Battery charging and device power supply	
Operation/Charge	12÷15 Vdc (direct current)
Recharge time for 80	Ten hours (at the suggested charging temperature)
Maximum charging time	10÷15 consecutive hours
Max. current load	70 W
Battery type	Internal, SLA 12 V - 4 Ah
Electrical safety	Internal, not accessible to the operator
Pump type	Piston, maintenance-free, 12 VDC electric motor
Type of operation	The device can remain connected to the power source continuously
Power supply type	LYD - Model number: 601404250 or GLOBTEK

Conditions of storage and use		
	Operating temperature range	-18 to 50° C (-0.4 to 122 °F)
	Temperature range for storage and transport	-40 to 70° C (-40 to 158 °F)
	Relative humidity for storage, transport and use	5÷95 %, non-condensing
	Suggested temperature range for charging	5 to 30°C (41 to 86°F)
	Atmospheric pressure range for storage, transport	405÷1070 mbar (40.5÷107 kPa)
	Maximum working altitude	5000 m (above sea level)
Use in rain (see note below)		Protected against the ingress of liquids and solids (IEC 529): IP34d

 **Use in the rain**	The OB1000 and OB1000 AVIO suction unit units are protected against the ingress of liquids and solids. However, it is always preferable to protect the unit from heavy rain. If the vacuum unit is completely wet, move it to a dry area, dry the outside and wait at least 30 minutes before attempting to restart it.

Consumables data	
Antibacterial filter	PTFE type, hydrophobic. Maximum pressure: 100 kPa
SERRES® disposable bag	1000 ml disposable type with integrated protection filter
Yankauer catheter with rigid suction probe	Sterile, single-use. Tube length: 1.3 m. Internal diameter: 6 mm
Conical suction connection Fingertip	Sterile, single-use
Silicone tube	Reusable and sterilisable. Internal diameter: 6 mm. Length: 1.3 m

	For further technical information, please contact the manufacturer (info@boscarol.it).
Serres devices	SERRES® products are disinfected at the factory and should be stored indoors and protected from the cold. Protect packaging from moisture, dirt and dust. Disposable products can be used for a period of 5 years after the date on the label, with the exception of collection bags pre-filled with solidifying agent, which can be used for a period of 2 years after the date on the label.

16. INFORMATION CONCERNING ELECTROMAGNETIC COMPATIBILITYEMC (OB1000 - OB1000 AVIO)

The OB1000 and OB1000 AVIO suction units do not create interference for other medical devices performing clinical tests and treatments in the same area. The units do not need to be connected to other equipment in order to operate and have an internal power supply.

16.1. RISKS OF MUTUAL INTERFERENCE WITH OTHER DEVICES

Medical electrical equipment requires special precautions with regard to electromagnetic compatibility. For this reason, they must be installed and/or operated in accordance with the information specified in the accompanying documents (in this case in the tables below).
Portable and mobile radio communication devices may affect the operation of the medical device. Medical electrical equipment and systems should not be used in close proximity to, 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 medical electrical device operates correctly in its intended configuration (e.g. by constantly and visually checking for faults or failures). The following tables provide electromagnetic compatibility (EMC) information relevant to this medical electrical unit. Full functionality of the unit is considered an "essential service" for the purposes of electromagnetic immunity. The OB1000 and OB1000 AVIO suction units are CISPR 11 Group 1 electromedical units and comply with Class B requirements.

Use with power supply	The OB1000 and OB1000 AVIO suction units can be used with the approved power supply unit supplied by the manufacturer (accessory).

16.2. METHODS TO PREVENT ELECTROMAGNETIC INTERFERENCE

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

16.3. GUIDELINES AND MANUFACTURER'S DECLARATIONS - ELECTROMAGNETIC EMISSIONS

The OB1000 and OB1000 AVIO vacuum units are intended for use in the electromagnetic environment specified below. The customer or the operator of the OB1000 and OB1000 AVIO vacuum units must ensure that they are used in such an environment.

Emission test	Limit	Guide - electromagnetic environment
Conducted emissions	CISPR 11, Group 1, Class B	The OB1000 and OB1000 AVIO secretarial suction units 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 emission	IEC 61000-3-2, Class A	OB1000 and OB1000 AVIO suction unit units are connected directly to the public low-voltage power supply network that supplies buildings used for domestic purposes. For domestic sanitary environments only.
Voltage fluctuations/flicker emission IEC 61000-3-3	IEC 61000-3-3	

16.4. GUIDELINES AND MANUFACTURER'S DECLARATIONS - ELECTROMAGNETIC IMMUNITY

The OB1000 and OB1000 AVIO vacuum units are intended for use in the electromagnetic environment specified below. The customer or the operator of the OB1000 and OB1000 AVIO suction unit units must ensure that they are used in such an environment.

IMMUNITY Tests	Compliance level	Guide - 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 made of wood, concrete or ceramic tiles. If floors are covered with synthetic material, the relative humidity must be at least 30%.
		Portable and mobile RF communications equipment should not be used near any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated radiofrequency RF EM field IEC 61000-4-3	80-2700 MHz; 1kHz AM 80 %; 10 V/m	Recommended separation distance d = 1.2√P for 80 MHz at 800 MHz d = 2.3√P for 800 MHz at 2.7 GHz
		where P is the maximum output power of the transmitter in watts (W) according to the transmitter manufacturer and d is the

		recommended separation distance in metres (m).
Immunity to 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 should not be used closer to any part of the device, including cables, than the recommended separation distance of 30 cm.
Fast transients/bursts (IEC 61000-4-4)	Power lines: 2 kV; 100 kHz repetition frequency Signal lines: 1 kV; 100 kHz repetition frequency	The quality of the mains power supply should be that of a typical environment.
Overhangs (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 should not be used near 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 $d = 1.2\sqrt{P}$ for 150 kHz at 80MHz where P is the maximum output power of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).
Rated power frequency magnetic fields (IEC 61000-4-8)	30 A/m, 50 Hz	The magnetic fields of the power frequency must 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°	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 mains interruptions, it is recommended that the device be powered from a UPS or battery.

17. WARRANTY

Oscar Boscarol guarantees the OB1000 and OB1000 AVIO suction unit for a period of 2 years from the date of purchase from the original distributor. The company guarantees that the suction unit is free from defective materials and/or defects due to manufacturing processes.

The warranty does not cover: the jar of secretions, the electrical power cord, the battery, normal wear and tear on the unit, discolouration and any other cosmetic irregularities that do not affect the operation of the unit.

If, during the entire warranty period of 2 years, the product is found to be defective, it must be sent to Oscar Boscarol Srl (Ltd) with a note describing the defect. Oscar Boscarol Ltd. (Ltd) will repair or replace at its discretion the defective parts and/or the whole unit. All shipping costs shall be borne by the customer.

Warranty conditions:

To benefit from the guarantee, the registration form in the product documentation must be completed and returned by post, 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 guaranteed process, the customer must provide evidence of the following documentation:

1. copy of the invoice and/or purchase receipt containing the serial number of the device and the date of purchase
2. confirmation by the manufacturer or a person representing the manufacturer that it is indeed a fault due to the production process or defective components since their procurement
3. absence of tampering, modifications and/or anything not conforming to the original product

In terms of safety, reliability and function of the suction unit, Oscar Boscarol S.r.l. can only be held responsible if:

1. all technical operations, repairs, modifications and safety and preventive maintenance inspections have been carried out by Oscar BOSCAROL S.r.l. (Ltd) or by 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 system to which the suction unit is connected has been constructed in accordance with the relevant national and European standards and regulations
4. if all accessories and consumables are original and have been purchased from the manufacturer or from an authorised service centre

With reference to what is described in these warranty conditions, Oscar Boscarol S.r.l. cannot be held responsible for accidental direct or indirect damages, if modifications, repairs, unauthorized technical interventions have been made on the device or any of its parts have been damaged due to accident and improper use. There are no other warranties, expressed or implied, of merchantability, fitness, or any other kind with respect to the suction unit other than those described in this user manual.

SPACE DEDICATED TO USER NOTES

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