BOSCAROL MEDICAL SUCTION UNIT

OB500
FA / FM / LINER

INSTRUCTIONS FOR USE

OB500 FA type A

OB500 FM type WE

OB500 LINER type IR

OB500 FA type ARI

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 OB500 medical device (in all its configurations) complies with MDR Regulation 2017/745 and bears the CE marking (CE 1936 notify body TÜV Rheinland Italia).
- The medical device fulfils the general safety and performance requirements described in Annex I of MDR Regulation 2017/745.

Information on these instructions for use:

- 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 instructions for use apply to all reference codes belonging to the following OB500 device models:

OB500 FA
OB500 LINER
OB500 FM

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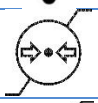
0. MEANING OF SYMBOLS AND PICTOGRAMS

0.1. Symbols used in these instructions for use 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 instructions for use
	Electric and magnetic fields generated by radiographic or tomographic equipment, portable radio equipment, RF radio and devices bearing this symbol may affect the operation of the suction unit. In such cases the OB500 suction unit must not be used or must be kept at a suitable distance from such equipment.
	OB500 suction units contain electrical or electronic parts that have to 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 components

	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 and cause the internal safety devices to activate.
	Limits of use referring to atmospheric pressure
	Limits of use in relation to humidity
	Read these instructions for use carefully and completely
	Components 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 instructions for use 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
	The OB500 suction unit contains electrical and/or electronic equipment that must be recycled in accordance with European Directive 2012/19/EU - Waste Electrical and Electronic Equipment (WEEE).
EC REP	Authorised representative in the European Community if the producer is not resident in Europe
	Expiry date
REF	Device code
	Please read the instructions for use in other languages available on the indicated website
	Do not use the device in environments where MRI investigations are conducted
LOT	Production batch
SN	Serial number
MD	Indicates that the suction unit is a medical device
PATIENT	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

1. INTENDED USE

Device name	Medical suction unit OB500 BOSCAROL
Primary use	Suction unit designed to remove secretions, blood, bodily fluids and foreign matter, including solid food or tissue residues, from the patient's upper and lower airways, in order to maintain or restore airway patency in emergency or urgent situations.
Other uses – not medical	The device can also be used as a pump to evacuate mattresses and vacuum splints (but must be used with the filter and suction 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	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 should 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 protocols implemented by local emergency health services.
Device application sites in accordance with the standard EN ISO 10079-1:2022	The OB500 suction unit can be used as a stationary device in medical emergency vehicles. As it has no internal power source it cannot be used in the field or outdoors.

2. WARNINGS, PRECAUTIONS AND IMPORTANT INFORMATION

Read carefully

These instructions for use 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 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 suction jar and/or without the antibacterial filter, or if it is suspected that substances may have entered in the aspiration circuit (i.e. the OB500), contact the nearest service centre or the manufacturer immediately to have the device checked.
- Do not spray substances onto the device. Before cleaning, make sure that the suction hole to the device is closed (apply a piece of tape or connect the tube of the suction jar).
- The OB500 suction unit does not require any maintenance by the operator. The only authorised operations are those listed in these instructions for use. For technical assistance, periodic inspection and repairs, 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.
- The OB500 suction unit in all its variants does not perform diagnostic functions on the patient.
- An excessive increase in the internal temperature of the device can automatically interrupt the operation of the device to prevent damage to the suction pump.

LATEX	The OB500 device is designed and manufactured without the use of latex. However, it cannot be ruled out that latex may have come into contact with it during the production chain.
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 from 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, please contact Boscarol's technical service before sending a device in for repair by sending an e-mail to info@boscarol.it or 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.

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 installation work is not carried out by specialised personnel, 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 must be checked at least once a day (functional check). The operator must check the date of purchase and manufacture and arrange for a safety inspection to be carried out by the service centre or manufacturer 24 months after the date of manufacture (see date of manufacture on the label).
Responsibility operators/users	• The OB500 suction unit is designed for emergency medical service and must therefore be ready for use at any time and in any situation. • Immediately replace any components/parts that are damaged, altered or missing and/or suspected of malfunctioning of the suction unit. Always replace such parts with original spare parts. • 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 instructions for use

4. CONTRAINDICATIONS (DO NOT USE FOR)

CONTRAINDICATIONS	• Chest drains or wound drains requiring constant, controlled vacuum • Permanent or continuous endoscopic use

5. SAFETY WARNINGS

	• Do not use the device in operating theatres or environments where potential equalisation is required (e.g. operating theatres for cardiac surgery).

SAFETY WARNINGS	• Do not use the device in type 'C' ambulances where potential equalisation is required. • Do not aspirate flammable, corrosive or explosive substances. • Do not use the device in environments with a potentially explosive atmosphere.

6. 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 instructions for use

7. OB500 MEDICAL SUCTION UNIT

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

1 OB500 suction unit complete with power cable
1 Vacuum control and regulation unit and connection to reusable jar
1 Reusable 1000 ml jar of Boscarol secretions complete with overflow valve in the lid
1 Antibacterial filter complete with silicone tube
1 Sterile Yankauer catheter (unassembled)
1 Ready-made power cable for SELV voltage (12÷15 Vdc)
1 Instructions for use in Italian or specific language depending on the destination and technical documentation

Package contents for LINER (SERRES®) version

1 OB500 suction unit complete with power cable
1 Vacuum control and regulating unit and jar connection with Serres® disposable bag
1 Serres® jar of secretions complete with Serres® disposable bag already inserted in the jar of secretions
1 Sterile Yankauer catheter (unassembled)
1 Ready-made power cable for SELV voltage (12÷15 Vdc)
1 Instructions for use in Italian or specific language depending on the destination and technical documentation

Package contents for FM version with SERRES® disposable bag

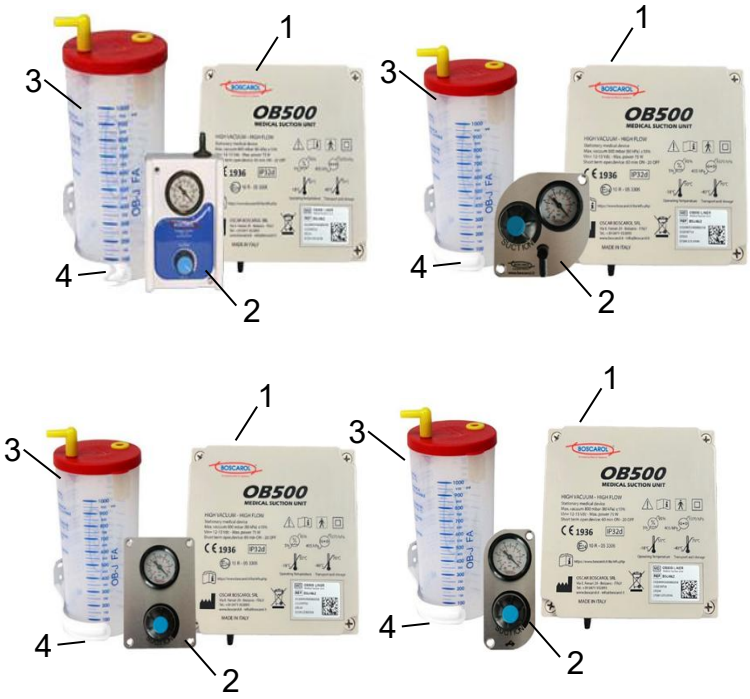
1 OB500 suction unit complete with power cable
1 Vacuum control and regulating unit and jar connection with Serres® disposable bag
1 reusable 1000 ml jar of Boscarol complete with Serres® disposable bag already inserted in the jar of secretions
1 Sterile Yankauer catheter (unassembled)
1 Ready-made power cable for SELV voltage (12÷15 Vdc)
1 Instructions for use in Italian or specific language depending on the destination and technical documentation

7.1. Description of OB500 suction unit

Model OB500 FA:

1. Suction unit
2. Vacuum regulation unit
3. Autoclavable jar OB-J FA
4. Jar holder

The versions alongside differ only in the vacuum control module. The version with ABS box is the only one that must be installed above the ambulance wall. All other versions are flush-mounted.
The vacuum control module consists of a metal plate that can have different dimensions depending on the type of ambulance.
In the version with the plastic module, all connection pipes are visible. In the other models they are concealed under the wall of the vehicle.
All these versions are equipped with the reusable (autoclavable) OB-J FA 1000 ml jar.
The jar is equipped with an overflow valve and an antibacterial filter on the lid (not visible in the picture opposite).



Model OB500 LINER:

1. Suction unit
2. Vacuum regulation unit
3. SERRES® jar
4. SERRES® disposable bag

The versions alongside differ only in the vacuum control module. The version with ABS box is the only one that must be installed above the ambulance wall.
All other versions are flush-mounted. The vacuum control module consists of a metal plate which can have different dimensions depending on the type of ambulance.
In the version with the plastic module, all connection pipes are visible. In the other models they are concealed under the wall of the vehicle.
All these versions use the reusable (autoclavable) 1000 ml jar of the SERRES® brand. They are equipped with a disposable bag of the same brand. The antibacterial filter is located in the lid of the disposable bag.

Model OB500 FM:

1. Suction unit
2. Vacuum regulation unit
3. Jar OB-J
4. SERRES® disposable bag

The versions alongside differ only in the vacuum control module. The version with ABS box is the only one that must be installed above the ambulance wall.
All other versions are flush-mounted. The vacuum control module consists of a metal plate which can have different dimensions depending on the type of ambulance.

In the version with the plastic module, all connection pipes are visible. In the other models they are concealed under the wall of the vehicle.
All these versions are equipped with the reusable 1000 ml OB-J jar and the SERRES® disposable bag. The antibacterial filter is located in the lid of the disposable bag.

PRELIMINARY INSPECTION	Upon receipt of the device, inspect all parts contained in the packaging and check their integrity. Do not use the device if any parts are missing or damaged

The OB500 suction unit is an active medical device that complies with all relevant standards.
It is used in rescue vehicles in general to clear the airways. Manufactured and marketed in kit form, its flexibility makes it easy to install. The suction unit can be installed in inaccessible spaces (e.g. under a seat or cabinet), while the adjustment block (together with the jar holder bracket) can be installed in the immediate vicinity of the patient stretcher. The suction unit is electrically secured and must be connected to the vehicle's power supply circuit (12 VDC). The device complies with the general standard ISO 10079-1 and is not transportable. OB500 is not equipped with an internal battery.
The OB500 is available in a number of variants that allow it to be fitted separately in various types of ambulances, while maintaining performance and compliance.

With the exception of consumables and spare parts, the OB500 has no other components. Please consult the manufacturer in case of further clarifications by sending an email to info@boscarol.it.

7.2. Controls, operation and control panel

All the controls for operating the device (except the operating switch, which is the responsibility of the installer) are located on the front side of the control block. The device can be operated by means of an external switch provided in the ambulance. The suction block has no controls or vacuum measuring instruments and is normally located in a remote position from the control module and the jar.

The regulating block for external wall mounting is supplied ready to use and consists of a plastic container (white ABS), a vacuum gauge and a vacuum regulator. The plastic material is self-extinguishing and UL V0 grade.
The enclosure has two holes that allow it to be fixed to the wall with specific screws.
Vacuum adjustment is possible by means of a knob. By turning it clockwise, the maximum vacuum value is reached (as indicated by the silk screen). The vacuum value achieved can be measured using the analogue instrument and is expressed in millibar (mbar) and in kilo-pascals (kPa).
In the adjacent drawing, the word "IN" indicates the connection to the pump-motor block, which can be fixed in another position.

The flush-mounted version with metal plate has the same controls: the vacuum gauge, the vacuum regulator operated by the knob and the outlet to the suction jar. The connection to the pump-motor block is possible by connecting the hose on the rear side (see figure opposite). This also applies to the version with a rectangular cover.	 Towards the pump-motor	 Towards the bottle of

Indicator lights on the device	The device does not have indicator lights because the power switch is normally located in an ambulance control unit or set of controls. Depending on the ambulance model and the type of control, the indicator light may be directly installed in the switch or in the central display showing the activation of the various devices.
Installing the module	Before attaching the module to the wall, check whether there are any electrical cables or pneumatic tubes under the wall! After installing the control module, connect the pipe coming from the suction unit to the top connector (version with external module) or rear connector (in the case of a flush-mounted version).

7.3. Motor block unit (suction pump)

The suction unit consists of a shock-proof and fire-resistant ABS plastic housing (UL-V0 grade) and a suction pump. It is equipped with a detachable power cable and a plastic connection for connecting the pneumatic tube to the control module. The installation in the vehicle can be made on the floor or on the wall, by means of angle brackets fixed appropriately (not included in the kit). Do not pierce the container of the suction unit, without first making sure not to damage the internal parts. If necessary, unscrew the four screws that block the cover and identify the free spaces for fixing. Do not use adhesives or mastics to fix the suction unit to the floor. Always check that the vent holes are not obstructed. When removing the cover, make sure that the gasket is not damaged when closing it. Never install the unit near sources of excessive heat, and/or near electric ventilation heaters. Do not install the unit in inaccessible parts of the vehicle or where ventilation could be impaired. The unit should be easily removable for safety inspections and in case of failure.

Installation of the suction pump	The picture opposite shows the suction unit and the areas (green) where metal brackets can be fixed for installation in specific areas of the rescue vehicle. Avoid the connection area, as this can damage the connectors and the electrical connection.		
Installation easy	The suction unit is identical for all OB500 variants. Remember that since the unit must be subjected to periodic inspections, it must be installed in such a way that it can be easily inspected, checked and, if necessary, removed.		

7.4. Electrical connections of the engine block unit (suction pump)

The suction unit is designed and built to be connected to the electrical system of the rescue vehicle. Normally such vehicles have special connection and protection systems in accordance with the law. Remember to connect the device to a suitable source of available current. Protection of the device by means of electrical safety devices is always mandatory. A non-compliant cable section would produce a voltage drop that would not allow the suction unit to work effectively and in compliance.

	Refer to international and local standards for vehicle installations. The power supply connections for the device are shown in the figure on the next page. The cross-section of the power source wires must

	not be less than 1 mm² per wire. Do not connect the negative to the vehicle's housing, but to a common point provided by the vehicle's electrical system.	
Electrical safety	Interpose a fuse on the positive side of the intake unit power cable. If connected to a protected control unit, use at least one 15 A fuse to prevent tripping during engine start-up.	
Electrical connections	Use the supplied cable for the electrical wiring of the suction unit. The cable has two electrical wires which are coloured brown and blue. The brown wire is connected to the 12 V positive (+).	

7.5. Periodic test of OB500 suction unit (all variants)

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

- the first on a daily basis to ensure the device is working properly, that there are no mechanical faults or cracks in the outer plastic casing, and that it is functioning correctly
- 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.

7.5.1. Daily periodic test of the OB500 suction unit (valid for all variants)

DAILY TEST	• Stand in front of the suction control unit. • Switch on the suction unit with the switch provided (depending on the type of installation on the rescue vehicle). The suction unit should run smoothly, and you should not hear any changes in the speed of the external pump. You should not hear any unusual noise and/or abnormal vibrations (however, this depends on where the suction unit is installed, which may dampen the noise generated). • Close the vacuum regulator completely (by turning it clockwise) and squeeze the silicone tubing towards the suction jar (before the reusable OB-J jar filter) 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 check that all parts are intact (knob, pressure gauge, fittings, etc.). • 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. • Check that all disposable parts have been replaced and that the jar is clean.

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
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.
Check for maximum suction by occluding the tubing from the filter or disposable bag to the device with your fingers	The maximum vacuum value readable on the vacuum gauge should be around 800 mbar (±10 %).	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

⚠	If one or more tests fail, even after carrying out the recommended actions, request the intervention of an authorised technician or contact the manufacturer for a full field check.

7.5.2. Periodic six-monthly/annual test of OB500 suction unit (valid for all variants)

This test is used to check whether the device conforms to the original manufacturing characteristics and is therefore suitable for use in the field. Inspections and checks must be carried out by individuals and/or companies specialising in this type of work on medical devices, and who have been trained and authorised by the manufacturer. Following the inspection, an electrical safety test must be carried out in accordance with standard IEC 60601-1, and a test summary report must be issued and made available to the user.

SIX-MONTHLY OR ANNUAL TEST	• Replace the SERRES® disposable bag or antibacterial filter before performing these operations. • Check the connection of the electrical cables to the motor block. • Check the operation of the internal pump by operating the vacuum. 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 movement, and operation of the vacuum regulator knob should be linear and unobstructed. • 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 control and suction unit for structural damage (ask the installer for the location of access to this unit or consult the technical documentation of the vehicle). All plastic containers must be intact and not deformed. • 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 available by the manufacturer. • Check the function of the vacuum gauge. When the vacuum unit is switched off, the needle should be at "0". • Check that the suction jar is intact and that there are no cracks or breaks that could impair suction. Penetration of liquids or solids may damage the unit and make it unsafe for operators and patients (running mechanical parts). • Check that the jar holder is fixed to the wall and in a vertical position. If the jar is tilted more than 20° from the vertical, the overflow valve may be triggered. • 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.

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 +39 0471 932893 or send an e-mail to info@boscarol.it.

7.6. Regular safety maintenance (every two years)

Regardless of how the device is used, OB500 extractors must be inspected at least every 24 months from the date of manufacture. Failure to comply with the prescribed maintenance schedule, including the omission of even a single periodic safety inspection carried out at intervals of no more than 24 months, will result in the manufacturer being relieved of all liability in relation to the device. In such circumstances, the device can no longer be considered compliant

with the established structural, safety and performance requirements, nor for the purposes of CE marking. This schedule has been established because certain parts within the unit may be adversely affected by a long period of inactivity. Periodic maintenance includes specific maintenance, servicing and updating of the device.

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

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

- Do not take unnecessary risks: always replace defective parts to ensure that the device is always efficient in case of use and emergency.
- We recommend another suction unit in case this one does not work or is defective (e.g. manual suction unit).
- Always bear in mind what is stated in the initial warnings regarding the risks arising from the effects of magnetic fields (EMC).
- 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.
- OB500 (all variants) is **not a sterile device** and cannot be sterilised with the exception of the suction 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 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 use only original components 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.

8. *SUCTION JARS FOR OB500 (all variants)*

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

- Suction unit with autoclavable suction jar (OB500 FA).
- Suction unit with suction jar equipped with disposable bag (OB500 FM and OB500 LINER)

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

8.2. 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 suction 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).

8.3. OB-J FM: jar of secretions for SERRES® disposable bags

The OB-J suction 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 suction 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.

8.4. SERRES® jar for OB500 LINER

The SERRES® suction jar is suitable for disposable bags from the same manufacturer (as for the OB-J FM version) and is made of transparent plastic (polycarbonate). It comprises a container (1), a grey movable connector for connection to the suction control module (2) and a SERRES® disposable bag (3) complete with disposable connector (white in the picture). The antibacterial filter is integrated in the green lid of the disposable bag and prevents aspirated fluids from entering the suction unit. The jar of secretions (not the disposable bag) 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.

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.

8.5. Secrets jar connection

The suction jar must be connected to the control unit module (which can be recessed or fixed externally to the wall).
Depending on the version of the control module (external or flush-mounted), the suction jar must be connected to the control unit via the silicone tube from the jar. In the adjacent photos you can see the OB-J FA suction jar connected to the external wall-mounted module (photo A) and the pipe connection point in the built-in version (photo B).

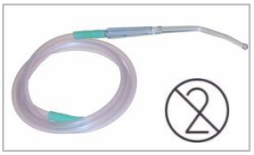
A

B

From the suction jar

8.6. Sterile disposable Yankauer catheter with suction control system

OB500 is sold complete with a sterile Yankauer type suction catheter and two tubes for connection from the jar to the regulating unit and from the regulating unit to the suction unit respectively. The suction probe and catheter are disposable and must be changed after each use. To facilitate correct operation, 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.



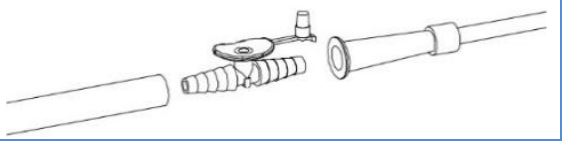
Yankauer PATIENT	The Yankauer suction catheter is a sterile, single-use medical device. Never reuse this device. It must be disposed of after use on the patient.
	Caution! Never use sterile medical devices beyond their expiry date or if the packaging is damaged.
	Always connect the Yankauer catheter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

8.7. 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 specific 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).



8.8. 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 devices 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. Reuse of single-use devices can be dangerous for both patient and operator and may result in loss of performance and irreparable damage to the device.
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!

8.9. Support bracket for suction jar (wall mounting)

The OB500 FA and FM devices include a special metal bracket, which is required for wall mounting of the suction jar. The bracket must be installed in such a way that the jar is kept in a vertical position (maximum inclination ±20°).
The bracket is made of painted metal and has two holes for vertical and horizontal adjustment. The ideal position, both for use and for cleaning and sterilisation, is under the adjustment module. The silicone tube, supplied with the device, can be shortened appropriately, depending on the distance of the bracket from the module itself.

The OB500 Liner suction unit includes a special original bracket produced by the manufacturer SERRES® to fix the suction jar on the wall. The bracket must be installed in such a way that the jar is kept in a vertical position (**maximum inclination ±20°**).	

9. REUSE, CLEANING AND DISINFECTION

After each use, disconnect all disposable parts and dispose of them. Check the integrity of the jar, the connection tube and check the state of cleanliness and contamination of the control unit. Clean and disinfect the suction unit as described below. Replace all disposable parts and restore the functionality of the device. After conducting the reuse operations, carry out the daily test as described in chapter § 7.5 Periodic test of the OB500 suction unit (all variants) 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 suction jars.	
DANGER	Organic secretions collected in the suction jar can cause serious infections to the operator. For this reason, always use PPE and disinfectants as recommended by the industry and competent authorities.	

9.1. Re-use of OB-J FA suction 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 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 that make 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.

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

The suction 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 medical 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 vertically upside down. 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 suction 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 suction 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.

9.3. 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, whether 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 carry out a function check as described in chapter § 7.5 Periodic test of the OB500 suction unit (all variants) of these instructions for use. • Prepare the device for the next use.

9.4. Replacing the antibacterial filter

Carefully disconnect the silicone tube from the contaminated filter. To easily remove the filter from the cover, screw it in and/or unscrew it from its housing. This makes it easier to remove from the cover and prevents it from breaking inside! Dispose of the filter in accordance with local regulations on the disposal of hospital waste.
The new filter must be inserted with the word 'IN' on the side that is to be connected to the vacuum socket on the cover.

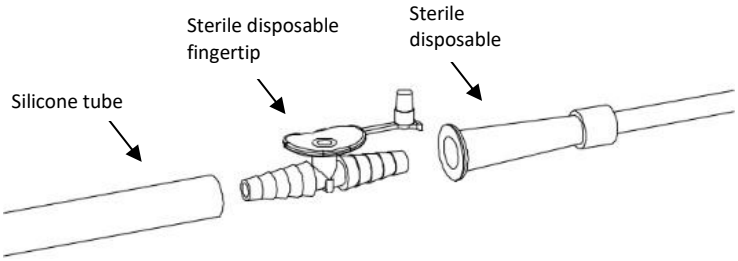
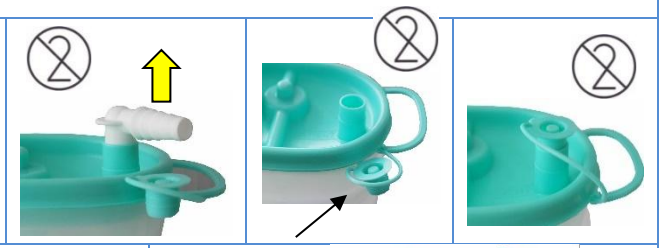
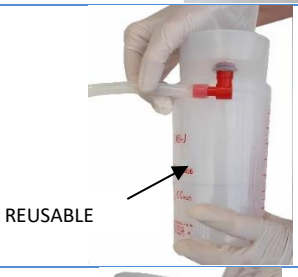
Failure to observe this detail may cause filter failure and contaminate the suction circuit of the suction unit.

Written 'IN'

ANTIBACTERIAL FILTER	**Warning** The filter must be inserted with the side marked 'IN' facing the bottle cap. Using the aspirator with the filter inserted incorrectly could lead to contamination of the aspiration circuit.

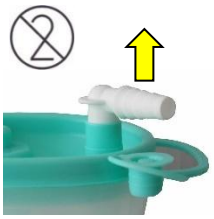
9.5. Cleaning the suction jar (OB-J or SERRES®) with SERRES® disposable bags

The OB-J Liner or SERRES® version of the suction jar is equipped with a specific SERRES® brand 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).	
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!).	
Remove the plastic adapter from the suction jar by exerting a small amount of force. If necessary, use both hands to separate the two parts. Take care not to damage them.	

Unscrew the connector by 90° while holding the screw inside the jar. Take care not to damage the O-ring.	 REUSABLE	 REUSABLE

In the following illustrations the procedures for the SERRES® brand jar

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).			
Although seemingly trivial, these operations can be dangerous due to their possible contamination of users.			
Use your hand to operate the 90° connector on the jar and remove the silicone tube (do not remove it!).			
Remove the disposable bag (previously closed) from the jar and dispose of it in accordance with official instructions for disposal of contaminated waste.		 REUSABLE	

Lifespan of suction jars	The jar of secretions must be discarded after 30 sterilisation cycles or **5 years** from the date of manufacture.
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.

9.6. Disinfection and/or sterilisation of the OB-J suction jar and silicone tube

For cleaning, disinfection and/or sterilisation of the suction jar (and silicone tubing) follow the instructions in chapter § 9.2. Cleaning, disinfection and/or sterilisation of the OB-J FA suction 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.
	• **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.

DISINFECTION CYCLE **WARNINGS**	• 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 them 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 suction 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.

9.7. Assembling the suction jar with the SERRES® disposable bag

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

- Insert the jar (either OB-J or SERRES® version) into the jar holder, connect the silicone tube to the suction unit and the jar itself.
- Activate the suction unit. With one finger, close the "PATIENT" connector on the jar and press lightly on the centre 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.

9.8. 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.

9.9. Cleaning and disinfection of the suction unit

To clean the surface of the device, use a damp cloth soaked in diluted medical device disinfectant (same as used for the suction jar). Sometimes the serigraphs on the container can be damaged or made illegible by some types of disinfectant. Prioritise a small corner of the device before proceeding. When finished, dry the surface with a dry cloth or a paper towel that does not leave any traces.

⚠ **CLEANING OF THE SURFACE 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.	 From the jar of secretions	 From the jar of secretions

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 Srl (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 whether the device and its parts are damaged. • If necessary, send the device to the manufacturer or to an authorised centre for overhaul and inspection. • After the assembly process, carry out a function check as described in chapter §"7.5 Periodic test OB500 suction unit (all variants)" of these instructions for use • Prepare the device for the next use

9.10. 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 9	X		X	
OB-J LINER	X	X	If necessary, only the jar	See chapter 9	X		X	
SERRES® jar	X	X	If necessary, only the jar	See chapter 9	X		X	
Overflow valve	X	X	If necessary	See chapter 9.1	X		X	
Reusable hoses	X	X	If necessary	See chapter 9.2	X		X	
Antibacterial filter				Change the filter, even if it is blocked		X	X	
Device surface	X	X	Not foreseen	See chapter 9.9		X	X	

10. SUCTION UNIT POWER SUPPLY

The device must only be powered by an external 12 Vdc source, suitably protected by a fuse placed in series with the power supply positive (minimum 15 A fuse). Ensure that the ambulance builder has written instructions on the position of the suction unit and the connection to the ambulance control unit.

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 conformity data for OB500 (all variants). If the suction unit is to be used under extreme 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.

12. DEMOLITION OF 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) 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 • 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).
LIFESPAN	The service life of the suction unit is set at 10 (ten) years from the date of manufacture. This service life is subject to the performance of the prescribed periodic safety maintenance, to be carried out every two years from the date of manufacture of the device. The device must be taken out of service and replaced upon reaching the aforementioned service life. Failure to comply with this requirement will result in the manufacturer being relieved of all liability in relation to the device. A device that has exceeded the 10-year service life cannot be considered compliant with the structural, safety and performance requirements established by the manufacturer, nor for the purposes of CE marking. Any accidents or adverse events associated with the use of a device beyond its declared service life are to be considered the sole responsibility of the owner/user, excluding any liability on the part of the manufacturer.

13. CONSUMABLES AND SPARE PARTS

Code	Description
Consumables	
BSU999	Antibacterial filter for FA suction jar (can also be ordered in multiples of one)
57157	SERRES® disposable bag 1 piece (can also be ordered in multiples of one)
BSU500	Autoclavable jar OB-J FA complete, without filter
BSU506	Autoclavable OB-J jar without disposable bag
57308	SERRES jar without disposable bag
Request codes directly from OSCAR BOSCAROL SRL **info@boscarol.it**	Yankauer sterile suction catheter - 1 piece (can also be ordered in multiples of one)
	Fingertip sterile suction cone connector - 1 piece (can also be ordered in multiples of one)
	Suction probe Finger Ch 10 black
	Finger suction probe Ch 12 white
	Finger suction probe Ch 14 green
	Suction probe Finger Ch 16 orange
	Suction probe Finger Ch 18 red
	Suction probe Finger Ch 20 yellow
Spare parts	
57820	Support bracket for SERRES® jar
BSU902	Silicone tubing (patient circuit) 130 cm long
SPS4005	Complete OB500 engine block
SPS4000	Ready-to-use type A control module (external module)
SPS4006	Ready to use type WE control module (flush-mounted)
SPS4009	Ready-to-use IR control module (flush-mounted)
SPS4015	12 Vdc 2P power cable from motor block
SPS4050	Spare silicone hose set (1 hose of 120 cm length, 1 hose of 150 cm length, 1 conical connector and fixing screws)
SPS6000	OB-J FA vessel without lid
SPS6002	Overfill valve - 3 pcs
SPS6004	Plastic fitting 90° for OB-J FA jar - 3 pcs.
SPS6006	Lid for OB-J FA jar complete with check valve and 90° connection, without filter

SPS6014	Conical connector - 5 pcs
SPS5092	L" connector for OB-J jar - 3 pcs.
eIFU	Instruction for use - available at www.boscarol.it

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 OB500 suction unit are designed to be repaired by the dealer, customer and/or operator. Do not open the vacuum unit and do not tamper with the electrical and/or mechanical parts. Always contact an authorised service centre or the manufacturer. Carrying out even minor work on the suction unit will invalidate its compliance, the manufacturer's warranty and the manufacturer's liability for damage to property or injury to persons. Unauthorised tampering with the suction unit may compromise its compliance with relevant laws and standards and reduce safety for both operators and patients. Please visit the "Support" section of the website www.boscarol.it or contact Boscarol Srl by emailing info@boscarol.it to obtain a list of authorised service centres.

14.1. Troubleshooting

Malfunctioning	*Possible cause*	*Solution*
Increased noise and poor suction of the unit even at maximum regulator.	• Damaged pump or obstructions in the internal suction circuit.	• Request assistance from the authorised service centre or send the complete device to the service department.
The unit turns on, but there is no suction.	• Pump damaged.	• Send to service or manufacturer.
The unit works but there is no suction.	• Totally open vacuum regulator. • Detached and/or poorly connected connection pipes, faulty connection pipes. • Jar not upright, full or overflow valve defective. • Disposable jar bag filled with liquids, protective filter intervention. • Possible blockage of the hydraulic circuit inside the unit.	• Check the position of the vacuum regulator. • Check the connections and integrity of the pipes. • Place the jar upright, check the overflow valve (blocked) and/or replace the jar. • Replace the disposable bag. • Contact the authorised service department.
It is not possible to adjust the suction value, which is always maximum.	• Damage to the internal hydraulic circuit or blockage of the hoses connecting to the suction unit.	• Contact the authorised service centre or the manufacturer.
Protection is always triggered when the device is activated.	• Possibly damaged or short-circuited pump.	• Contact the authorised service centre or the manufacturer

NOTE	In the event of anomalies and/or malfunctions other than those listed in the table above, always contact the authorised service centres and/or the manufacturer of the device.

15. TECHNICAL DATA AND CONFORMITY DATA FOR OB500 (ALL VARIANTS)

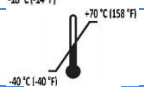
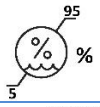
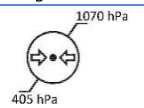
Classification of the medical device (in accordance with MDR Regulation 2017/745)		**IIa**
Basic UDI number (in conformity with MDR Regulation 2017/745)		805240088OB500YY
Suction level classification according to EN ISO 10079-1:2022		HIGH VACUUM-HIGH FLOW
Operating mode (short term)		TEMPORARY (60 minutes 'ON', 20 minutes 'OFF')
Supply voltage:		SELV (12÷15 Vdc)
Reference standard		EN ISO 10079-1:2022
EMC compliance testing		IEC 60601-1-2:2015/AMD1:2020
Medical device safety compliance		EN 60601-1:2006/A13:2024
Compliance for use in the pre-hospital sector (EMS)		IEC 60601-1-12:2014/AMD1 2020
	TYPE BF	TYPE BF
	CLASS II	CLASS II
Degree of protection against ingress of liquids and solids (IEC 529):		IP32d
Risk assessment (technical documentation)		EN ISO 14971:2019+A11:2021

Application of usability	IEC 62366-1:2015/AMD1:2020
Compulsory periodic safety inspection	Every 24 months
UMDNS code	15-016
Code GMDN	63643
Approval and conformity according to ECE R10 (automotive)	E24 10R - 05 3306

Dimensions OB500	
Maximum dimensions of suction unit	175 mm (w) x 175 mm (h) x 100 mm (d)
Maximum dimensions of ABS module control unit	90 mm (w) x 130 mm (h) x 85 mm (d)
Maximum dimensions standard built-in control unit	53 mm (w) x 110 mm (h) x 70 mm (d)
Maximum dimensions of AR built-in control unit	80 mm (w) x 110 mm (h) x 70 mm (d)
Maximum dimensions of IR built-in control unit	90 mm (w) x 90 mm (h) x 60 mm (d)
Device weight:	Max. 2 kg complete with mounting components
Tolerance on all values:	±5 %

Technical Data	
Nominal suction power	800 mbar (80 kPa, 600 mmHg) ±10 % (*)
Vacuum regulation	Linear with integrated mechanical controller
Vacuum setting range	30÷800 mbar (3÷80 kPa)
Nominal flow	30 LPM (litres per minute) at free air speed ±10 %.
Maximum operating time (free-cycle)	60 minutes ±10%.
Maximum noise	70 dB
Accuracy of vacuum gauge (full scale)	±2,5 %
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®
Alternative suction jar	Type SERRES® for disposable bags 1000 ml SERRES®
Service life of the device	10 years from the date of manufacture
(*) Notes: 1bar = 100kPa = 750mmHg	

Device power supply	
Operation	12÷15 Vdc (direct current)
Max. current load	80 W
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

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
	Atmospheric pressure range for storage, transport	405÷1070 mbar (40.5÷107 kPa)
	Maximum working altitude	5000 m (above sea level)
Degree of protection according to IEC 529		IP32d

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 ON EMC ELECTROMAGNETIC COMPATIBILITY

The OB500 suction unit does not create interference for other medical devices performing clinical tests and treatments in the same area. The unit does not need to be connected 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 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. Electromedical 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 OB500 suction unit is a CISPR 11 Group 1 electromedical unit and complies with Class B requirements.

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 OB500 vacuum unit is intended for use in the electromagnetic environment specified below. The customer or the operator of the OB500 suction unit must ensure that it is used in such an environment.

Emission test	Limit	Guide - electromagnetic environment
Conducted emissions	CISPR 11, Group 1, Class B	OB500 secretarial suction units (all variants) 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	OB500 suction units (all variants) 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 OB500 vacuum unit is intended for use in the electromagnetic environment specified below. The customer or the operator of the OB500 suction unit must ensure that it is 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 $d = 1.2\sqrt{P}$ for 80 MHz at 800MHz $d = 2.3\sqrt{P}$ 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).
Proximity fields form RF wireless 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√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 % 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 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 mains interruptions, it is recommended that the device be powered from a UPS or battery.

17. WARRANTY

Oscar Boscarol guarantees the OB500 suction unit (in all its variants) 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, normal wear and tear on the unit, discolouration and any other cosmetic irregularities that do not affect the operation of the unit.

If, at any time during the 2-year warranty period, the product is found to be faulty, you must notify Oscar Boscarol S.r.l. by emailing info@boscarol.it and providing detailed information regarding the fault found. Only after authorisation for the return has been granted may the device, complete with all its accessories, be sent to Oscar Boscarol S.r.l. Oscar Boscarol S.r.l. (Ltd) will, at its discretion, repair or replace the defective parts and/or the entire unit. All shipping costs are to 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 04711880333 - 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 Srl can only be held responsible if:

1. all technical operations, repairs, modifications and safety and preventive maintenance inspections were 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 instructions for use
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 the present warranty conditions, Oscar Boscarol srl cannot be held responsible for direct or indirect accidental 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 express or limited warranties 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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