MEDICAL SUCTION UNIT

OB2012 2P

OPERATING INSTRUCTIONS

CE 0123

MANUFACTURED BY:

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Information on manufacturer and medical device:

- Oscar Boscarol applies a quality management system compliant with international standards ISO 13485 and ISO 9001
- The medical device OB2012 (in all its configurations) is compliant with MDD 93/42/EEC (as subsequently amended) and bears the CE marking (CE 0123 notified body TÜV SÜD PRODUCT SERVICE GmbH)
- The medical device meets the essential requirements described in annex I of MDD 93/42/EEC

Information on these operating instructions:

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

These operating instructions apply to the following devices:

OB 2012 FA
OB 2012 LINER

BSU100	BSU104	BSU108	BSU150	BSU154	BSU158	XAS0200	XAS0210	XAS0220
XAS0230	XAS0240	XAS0250	XAS0260	XAS0300	XAS0302	XAS0304	XAS0356	XAS0400
XAS0402	XAS0222							

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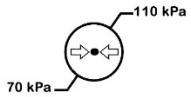
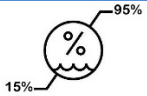
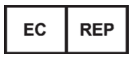
0. MEANING OF SYMBOLS AND PICTOGRAMS

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

	Danger: important safety-related information covering correct use of the suction unit to prevent operator or patient injury and/or damage to unit itself
	Warnings: information requiring special attention
	Notes or information on preventing damage to the device or injury to others. Implement correct prevention measures
1.	List of actions to be performed: follow them step by step
	These operating instructions
	Electric and magnetic fields generated by radiographic or tomographic equipment, portable radio equipment, RF radios and devices bearing this symbol could have an impact on proper operation of the suction unit. In these cases, suction units must not be used, or must be kept at a suitable distance from such equipment
	Suction units OB 2012 contain electrical or electronic parts that must be recycled in accordance with WEEE/19/EU - Waste Electrical and Electronic Equipment.
	The suction unit complies with European Directive 2011/65/EU (RoHS)
	Maintenance service required (contact the manufacturer and/or its authorized service centres)

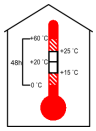
0.2. Symbols used on the device and accessories

	Class II insulation (as per IEC 60601-1)
	Class BF for part applied to the patient (as per IEC 60601-1)
	Use the suction unit only within the specified temperature range. Using the suction unit outside these limits could compromise its operation, reduce battery life and trip the internal safety devices.
	Usage range for atmospheric pressure (from 70 kPa to 110 kPa)
	Usage range for humidity (from 15% to 95%)
	Read these operating instructions carefully and thoroughly
	Accessories and/or consumables displaying this symbol are disposable. They cannot be reused and, after use, must be discarded and replaced with new ones. The symbol is posted on consumables

	Indicates that the user must consult these operating instructions for information, e.g. warnings and precautions that may not be displayed on the medical device in question
	CE marking in accordance with MDD 93/42/EEC for medical devices rated higher than class I
	Manufacturer
	Date of manufacture
	Suction units OB 2012 contain electrical and/or electronic equipment that must be recycled in compliance with European Directive 2012/19/UE - Waste Electrical and Electronic Equipment (WEEE).
	Authorized representative within the European Community if the manufacturer does not reside in Europe
	Expiry date
	Order number (device code)
	These operating instructions are available in other languages on the indicated website. Please read them.
	Do not use the device in environments where magnetic resonance imaging is performed
	Production batch
	Serial Number
	Indicates that the suction unit is a medical device
	Follow the operating instructions
	Connection/patient suction tube (cover for collection jar and Serres® disposable liner)
INPUT	The accepted input voltage range is indicated on the external power supply inlet
OUTPUT	The output voltage is indicated on the external power supply outlet
	Internal use only
	Direct current
	Alternating current

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

BATTERY	The battery is enclosed in a stiff plastic case and has a special internal electronic circuit to prevent damage. 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 a fire
	Do not cut the battery or plastic case. Do not saw or puncture the battery (risk of explosion, fire or short circuit)
	Do not crush the battery or apply strong deforming pressures. Do not drill the battery with tools, drills or other mechanisms.
	Battery storage conditions (battery pack only): Temperature (optimal): 0 ÷ 25° C Humidity (optimal): 60 ± 25% RH
	Do not dispose of the battery with normal household wastes. Follow national and local regulations for proper demolition and recycling. Follow the European recycling plan
	Read the operating instructions
LOT	Production batch number

1. INTENDED USE

Device name	Medical suction unit OB 2012 BOSCAROL
Primary use	Suction unit designed to remove secretions, blood and other bodily fluids, solid pieces of food or tissue in the medical field
Other Uses	The device can also be used as a pump to empty vacuum mattresses and splints (but must be used with the jar complete of the antimicrobial filter)
Medical Purpose	Suction of the upper and lower airways
Site of application to human body	Upper airways: nose, nasal cavity, throat, mouth Lower airways: larynx, trachea, bronchial tube
Patient type	Infants, children and adults of both sexes
Length of application on a given patient	< 60 minutes - Temporary use
 **Information on usage**	• The suction unit can be used on all types of patients as long as correct medical technique is followed • Obstruction of the lower airways must be freed by medical professionals and/or health care personnel (including paramedics and emergency personnel) trained and authorized to perform such procedures • Obstruction of the upper airways must be freed by medical professionals and/or health care personnel (including paramedics and emergency personnel) trained and authorized to perform such procedures. In some countries, this information must be verified according to protocols implemented by local emergency health care services

Device application sites according to ISO 10079-1:2019	Suction units OB 2012 can be used in many situations: in hospitals/clinics, at sites of accidents and emergency health services, for first aid in general, at home care and health care facilities, for outdoor application and during transport.

2. WARNINGS, PRECAUTIONS AND IMPORTANT INFORMTION

Read carefully

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

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- Read these instructions carefully before using the device. Careful, correct use of the device ensures smooth operation and will protect both patients and operators.
- The suction unit is designed exclusively to remove organic fluids (secretions) during medical procedures. For this reason, it should only be used by properly trained personnel
- Never use the suction unit in the presence of flammable and/or explosive liquids, gases or anaesthetic mixtures as this could result in explosion and/or fire.
- If suction is performed without the jar and/or antibacterial filter, or if you suspect that substances may have entered the suction circuit (i.e., the OB 2012 device), contact your nearest service centre or the manufacturer immediately to have the device checked.
- Do not spray substances on the device. Before cleaning the device, make certain that the suction hole on the container is closed (cover it with a piece of tape or connect the tube to the jar).
- Before cleaning the suction unit or performing any maintenance, disconnect the unit from the external power supply or from the wall bracket. Do not immerse the device in liquids since this could damage it and cause the safety devices to trip.
- Suction unit OB 2012 requires no maintenance by the operator. The only authorized operations are those indicated in these instructions. For technical support, periodic service and repairs, contact the authorized service centre or the manufacturer.
- For authorized personnel — who have taken a specific technical training course — the manufacturer provides the documentation and tools needed to perform all service operations (service manual).
- To ensure patient safety, accuracy of the values displayed and correct operation, use only original spare parts. In the case of non-compliance, the operator is held responsible for any patient injury or property damage.
- Do not use any batteries other than those approved by the manufacturer.
- Do not modify the mechanical or electrical parts of the support bracket. Replacing any parts of the wall bracket and/or modifying the bracket itself can seriously affect safe anchoring of the device.
- Suction units OB 2012 do not perform any diagnostic functions on the patient.

 **LATEX**	Devices OB 2012 are built and manufactured without the use of latex. However, the possibility that they may have come into contact with latex at some time during the production chain cannot be ruled out
	Do not use the device in environments where magnetic resonance imaging is performed. The device could be dangerous for users and patients

	Portable RF communications equipment (including peripherals such as antenna cables and the antennas themselves) must not be used at a distance of less than 30 cm (12 inches) from any part of the OB 2012, including the cables specified by the manufacturer. Failure to comply with this may reduce unit performance.
	• Caution: Never use this unit near or on top of other equipment as it could result in improper operation. If such use proves necessary, always check that this unit and other equipment function properly. • Caution: use of accessories, external power supplies, transducers, and cables other than those specified or supplied by the manufacturer of this medical device may result in increased electromagnetic emissions or decreased device electromagnetic immunity and cause the unit to function incorrectly.
 **CONTAMINATED DEVICE**	• Warning: Device contamination. If the suction unit is used following these instructions, with the original jar and antibacterial filter, the suction unit will not become contaminated. Nevertheless, if the substances sucked up have entered the device, the suction unit must be taken out of service immediately. Sending a contaminated suction unit to the manufacturer, installer or service centre is **strictly forbidden**. The risk of spreading a pandemic is high and must be avoided. • Any device received in such conditions will be rejected and the health authorities will be notified of the risk of possible contamination. In this case, the term contaminated indicates a suction unit that has not been disinfected and cleaned of the secretion aspirated from the patient. If the aspirated substances have entered the suction unit, it must be demolished. For Boscarol, the safety of its employees and authorized service centre personnel is of primary importance. If the suctions units are contaminated, they cannot be demolished according to the WEEE (Waste Electrical and Electronic Equipment) directive, as this would result in a possible risk of infection (international law regarding worker protection must be applied, where applicable). • When in doubt, before sending a device in for repair, send an e-mail to the Boscarol technical service at info@boscarol.it or call +39 0471 932893
 **REUSE OF DISPOSABLE PARTS**	• Caution: reuse of disposable parts can compromise suction unit function and be a source of contamination — whether direct or indirect — for operator and patient. • Sterilization and/or cleaning of disposable parts (antibacterial filters, suction tubes, Yankauer suction catheters, etc.) can cause structural damage and thus result in a loss of mechanical integrity.
SLA BATTERY	• Before using the suction unit for the first time (and/or after having received it), the internal battery must be placed under continuous charge for at least 16 hours. • Recharge the suction unit immediately if only one or none of the LEDs go on. • Leaving the device always connected to the vehicle power supply (12÷15 Vdc) will not damage it. • The battery cannot be replaced by the operator.

3. INFORMATION THAT IS IMPORTANT TO KNOW BEFORE USE

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

 **PERIODIC SAFETY INSPECTION**	**Preventive maintenance and periodic safety inspection:** The device must be checked at least once a day (functionality check). The device should be checked at least once every 12 months by the authorized service centre. On the other hand, starting from the date of manufacture (see the date of manufacture on the label) an inspection of safety and technical maintenance is required every 24 months. Refer to the manufacturer itself or to the authorized service centers for planning of inspection. The periodic safety inspection of the device does not fall under warranty.
Operator/User Responsibility	• Suction units OB 2012 are designed for emergency medical service and must therefore be ready for use at any time and in any situation. • Always make certain that the internal battery is sufficiently charged (press the test button). • Immediately replace any damaged, altered or missing components/parts and/or those for which suction unit malfunction is suspected. Always replace these parts with original spare parts. The suction unit must be stored in a place that is out of the reach of children. • Dispose of packaging in accordance with applicable regulations and make certain it is out of the reach of children.

 **Tripping of overflow valve**	**WHAT TO DO IF THE OVERFLOW VALVE TRIPS?** • Put on protective gloves, protective eyewear and a type FFP2 or FFP3 mask. • Turn off the suction unit and disconnect the silicone tube running from the jar to the device. • Check whether the aspirated liquids have reached the maximum level in the jar. • Carefully remove the jar and store it in a safe place. • Empty the jar safely by first removing the filter (which must be discarded) and then removing the lid. Empty the jar and perform thorough cleaning and disinfection (sterilization if necessary). • Clean and disinfect the device as indicated in these operating instructions.

4. CONTRAINDICATIONS (DO NOT USE FOR)

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

5. SIDE EFFECTS (POSSIBLE DURING ASPIRATION OPERATIONS)

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

6. MEDICAL SUCTION UNITS OB 2012

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

Package contents for FA version

01 Complete suction unit
01 Boscarol reusable 1000 ml jar complete with overflow valve in lid
01 Antibacterial filter complete with silicone tube
01 Yankauer catheter, sterile (not installed)
01 SELV (12÷15 Vdc) voltage supply cable, ready to use
01 Operating instructions in Italian or a specific language depending on the destination and technical documentation

Package contents for LINER version

01 Complete suction unit
01 Reusable jar complete with SERRES disposable liner already inserted in jar
01 Yankauer catheter, sterile (not installed)
01 SELV (12÷15 Vdc) voltage supply cable, ready to use
01 Operating instructions in Italian or a specific language depending on the destination and technical documentation

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

01 External power supply from the mains to power and recharge the suction unit
02 Wall bracket and power supply, complete with SELV voltage cable (12÷15 Vdc)

6.1. Description of the suction unit

The OB2012 is a medical suction unit compliant with all reference standards.

It can be used in motor vehicles (ambulances), in the field, in hospitals, clinics and for home treatment by doctors or trained authorized personnel (paramedics).

The suction unit has an internal SLA battery (sealed lead acid battery) that contains dangerous substances (lead and a solution of sulfuric acid) and cannot be open, disassembled, cut or topped up.

The suction units OB2012 come in two basic versions: with reusable and disposable jar.

Model OB2012 with reusable jar:

1. Suction unit
2. OB-J FA jar
3. Protection filter
4. 90° plastic joint
5. Silicone tube with conical connector for filter connection

Model OB2012 with disposable jar:

1. Suction unit
2. OB-J jar
3. 90° plastic joint
4. Disposable bag SERRES
5. 90° connector

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

6.2. Controls, operations and control panel

All device operating controls are located on the front to facilitate its use, even when anchored to the wall bracket. To activate the device, press switch (4), which is protected against ingress of liquids and solids, splashes of water and cleansers. The vacuum can be adjusted by turning knob (5) located over the switch. Turning the knob clockwise increases the vacuum to maximum — the value can be read on the analogue instrument (1), expressed in millibar (mbar) or kilo-pascal (kPa) or, upon request, even in millimetres of mercury (mmHg). The instrument is fluorescent and can be seen in the dark. On the back are two contacts (7) that allow the device to be charged and operated when fitted on the wall bracket. The device can also be charged using the external charging cable, plugging it into the outlet on the back of the device. The connector is sealed air-tight and has two electrical poles (6).

6.3. Indicator lights

All lights are placed on the front and display the operation of the device (see figure above): the autonomy of the battery (3) and the recharge state (2). The table below indicates the condition of the LEDs and the relative power of the battery:

SIGNALLING	BATTERY POWER LEVEL
4 LEDS on	>80% of the maximum power
3 LEDS on	50÷79% of the maximum power
2 LEDS on	20÷49% of the maximum power
1 LED on	**<20% battery low - the device will shut down shortly**

The indicator for charging <ON/CHG> (2) on the previous figure, has two different colors: y***ellow indicates that charging is taking place***; ***green indicates that charging is complete.*** The indicator lights up whenever the device is connected for recharging. If the LED does not light up, there could be a malfunction of internal recharge circuit, lack of power (12 Vdc) or lack of connection of external cable to a power source for 12 Vdc.

 **BATTERY POWER VERY LOW**	The device will shut down soon after the last LED is switching off, because the battery is completely drained.
 **BATTERY COMPLETELY DRAINED**	Warning: a drained battery affects device operation and therefore its use. It takes about 15 hours to charge a fully discharged battery. The suction unit can always be left charging. **The battery has a lifespan of 2 years** and is automatically replaced during the safety inspection.
 **Electrical connections**	Always check that the charging cable plug is correctly inserted into the cigarette lighter socket: vehicle vibration can cause the plug to come loose. Therefore, always check the charging LED on the device: it remains yellow during charging and switch green until charging has been completed

6.4. Periodic testing of suction units OB2012

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

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

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

6.4.1. Daily periodic testing of suction units OB2012

DAILY TEST	• Disconnect the unit from the bracket or from the external charging cable • Place the device in an upright position on a stable surface with the front facing you. Do not withdraw the unit from its carrying/storage bag • Press the ON-OFF button located near vacuum regulator. If all of the yellow LEDs are lit up, the battery is fully charged (operating time: approx. 60 minutes). If not, remember to charge the suction unit as soon as possible.

	• Using the switch on the front panel, turn on the suction unit (0 - off, 1 - on). The suction unit must operate smoothly, no fluctuations in internal pump speed must be heard. There should not be any unusual noise and/or vibrations. • Fully close the vacuum regulator (turning it clockwise) and pinch the silicone tube near the jar (before the filter for the reusable jar OB-J) or near the jar connection when using SERRES® disposable liners. The noise generated by the pump should change and, in a few seconds, the reading on the vacuum gauge should reach maximum value (about 800 mbar, 80 kPa, 600 mmHg). • While keeping the tube pinched, turn the vacuum regulator counter-clockwise and check the reading on the gauge to ensure that the suction drops to nearly 0 (40÷50 mbar due to filter effect). • Turn off the suction unit and turn it 180 degrees to check the electrical contacts on the back of the unit (they must be clean and free of any signs of stains, oxidation and/or burning). • Connect the device to the powered support bracket. If the battery is drained, it will start charging (yellow LED flashing or on steady if charging is not necessary). If the device does not have a wall bracket and the battery is low, connect the external power cord to the cigarette lighter or optional power supply and check that the charging process starts (yellow LED on). • Make certain that the filter is clean and not contaminated. If the filter is soiled, it must be replaced. A soiled filter prevents the suction unit from functioning properly and reduces its performance by increasing the risk of contamination. Do not use the suction unit without a filter.

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

Test – phase	Result	Remedy
Running the autonomy test	The yellow LEDs go on according to the battery charge (1 to 4 LEDs).	If the LEDs do not go on, the battery is completely drained or faulty. Try charging the battery with the external cable or power supply. During these operations, take the device out of active service
Pump function check	Noise from motor is uniform, no drop in rpm, no abnormal vibrations	Any noise that is not uniform indicates an anomaly in pump operation. A drop in rpm indicates that the current is inadequate and cannot run the motor correctly. Contact your service centre or the manufacturer.
Check for maximum suction by pinching closed the tube running from the device to the filter or disposable liner.	The maximum vacuum value that can be read on the vacuum gauge should be around 800 mbar ±10 % (70 kPa ÷ 80 kPa; 525 ÷ 600 mmHg)	If this value is not reached, close the vacuum regulator completely by turning the knob clockwise. Check that the tube is completely plugged. If not, take the device out of service and contact your authorized service centre.
Setting the maximum vacuum value	Value between around 0 and maximum, achieved by turning the knob	If the vacuum value cannot be adjusted, contact your authorized service centre. Take the device out of service
Rear charging contacts check	The contacts must be clean and free of oxidation. The metal must show no burn marks.	Clean the contacts with a cloth soaked in ethyl alcohol. If strong burns are seen, they must be replaced. In this case, contact your authorized service centre

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

6.4.2. Six-monthly/yearly test of suction units OB2012

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

SIX-MONTHLY OR ANNUAL TEST	• Replace the SERRES® disposable liner or antibacterial filter before performing these operations. • **Mechanical wall bracket function**: check that it is secured properly (to the wall of the vehicle), that it functions properly and that the upper red plastic button slides correctly (not hindered in any way). 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 show any signs of alteration, burning or oxidation. • Check connection of electrical cables to the bracket (they must be fixed). • Run a complete suction unit function check: battery life, charging function, complete control of the LED functions (from maximum to minimum during battery discharge). Make certain that, during charging, the LEDs function as shown in section §6.3 Light indicators. • Check internal pump function by pressing the switch. The maximum vacuum value must fall in the 730 mbar÷80 mbar range. Use a precision vacuum gauge to measure this value (tolerance ±2.5 % or less). There should be no operating anomalies — i.e. unusual noise, fluctuations in rpm, excessive vibration of the gauge needle — and the vacuum regulator knob should function smoothly and show no obstructions: when running the test, the device should be set on a stable surface to check the amount of vibrations generated. • Check the vacuum regulator which must run at full range: from minimum to maximum. Turn the knob clockwise and counter-clockwise. When the regulator is fully open, a small vacuum value is normal (introduced by the antibacterial filter). • Check the minimum suction unit operating time: turn it on and let the cycle run freely for at least 20 minutes. The suction unit must operate using only the internal battery. If the test fails, the internal battery must be replaced. • Check the unit container for cracks and fissures. Penetration of liquids or solids can damage the unit and make it unsafe for operators and patients (mechanical parts running). • Check that all labels and screen-prints are present and legible. • Never open the suction unit for any reason whatsoever. For technical assistance, only contact one of the authorized service centres listed at the end of this manual. • Check that the vacuum gauge is functioning properly. When the suction unit is turned off, the needle should be close to "0". • Make certain that the carrying bag is functional, intact and shows no tears. The nylon strap must be intact. No damages shall be reported. • Check that the jar is intact and that there are no cracks or breaks that could compromise suction. • Check the screws on the steel plate at the back of the device, ensuring that it can be securely attached to the support bracket. • Before declaring the suction unit compliant with the manufacturer's data plate, using a specific safety analyser, run an electrical safety test as outlined in IEC60601-1. Contact the manufacturer or an authorized service centre for information on performing this test.

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

If you have any doubts or concerns regarding how to perform the tests, we recommend always contacting the device manufacturer or an authorised service centre. If even a single test fails, contact a service centre or the manufacturer. Do not use the device if it has not passed all tests.

For any information, call 0471 932893 or send an e-mail to info@boscarol.it.

6.5. Periodic safety maintenance

Depending on how the device is used, the OB2012 should be checked at least every 24 months even if not used. Some parts inside of the unit, i.e. the battery and the filter may be affected by a long period of inactivity of problems. Periodic maintenance includes specific maintenance, revision and updating of the device. If periodic maintenance is not performed, the life span of the device decreases.

6.6. Safety information to ensure user, patient and third part safety

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

- Make certain that all accessories are functioning properly and replace the external power supply or cables if defective. Do not take unnecessary risks: always replace defective parts so as to ensure that the device is always in good working order for use and emergencies.
- Always keep the device attached to the support bracket (in emergency vehicles) during transport as this will prevent damage to user and patient.
- Even if the device is not used, recharge the battery at least once a month.
- We recommend keeping on hand another suction unit to stand in if this one does not work or is defective (e.g. a manual suction unit).
- Always remember what was stated in the initial warnings regarding the risks arising from the effects of magnetic fields (EMC).
- Always select the appropriate vacuum level for the patient and according to the medical guidelines.
- Do not alter or modify the medical device. Serious consequences may occur for patient and user.
- Units OB2012 **are not sterile devices** and cannot be sterilized, except for the jar and silicone tube.
- Keep children away from tubes and connection cables. Also keep them away from small parts.

Risk of infection

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

- Never use the device without the antibacterial filter.
- Always disconnect the unit from the power supply, bracket, or SELV source before performing cleaning and disinfection.
- Only use the power supply indoors and in dry areas. Never use the power supply outdoors!
- Always use only original accessories and original spare parts.

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

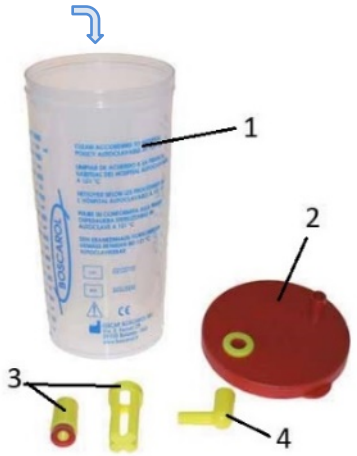
7. JARS FOR OB2012

The device is sold with two different types of 1000 ml jar:

- Suction unit with autoclavable jar (OB2012 FA).
- Suction unit with jar fit with disposable liner (OB2012 LINER)

7.1. Autoclavable jar OB-J FA

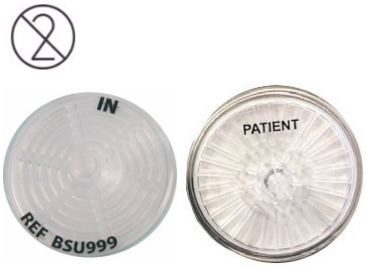
The jar is made of transparent plastic (medical-grade polypropylene). It includes the jar (1), snap-on lid (2), overflow valve (3) and 90° plastic connection (4). The jar's lid makes it possible to directly insert the antibacterial filter (from the outside). The jar can be sterilized in a conventional steam autoclave at a maximum temperature of 121°C and pressure of 2 bar (200 kPa). The jar must be replaced if it shows any sign of deformation, breakage or fissuring. The jar must always be used in the upright position, thus preventing the overflow valve from tripping. If this protection does trip, turn off the device and disconnect the tube connected to the suction unit, remove the antibacterial filter to rebalance the pressure inside the jar.



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

7.2. Antibacterial filter

To prevent fluid overflow, a special protection filter is used between the jar and the unit. The filter is produced with PTFE hydrophobic material which prevents fluids entering the pneumatic circuit. Working together with the overflow valve on the jar, the filter isolates the pneumatic suction pump from gas and fluid substances. The filter is disposable and **must be replaced after each use**. If contamination, discoloration and increased resistance to suction occurs, it must always be replaced. The filter isn't manufactured by the Boscarol company.



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

7.3. OB-J LINER: jars for SERRES® disposable liners

The OB-J jar for SERRES® disposable liners is made of transparent plastic (medical grade polypropylene). It includes a container (1), an adapter for SERRES® disposable liners (2), a red 90 degree connector (3) and a SERRES® disposable liner (4). The antibacterial filter is integrated into the cover of the disposable liner and prevents aspirated fluids from entering the suction unit. The jar can be sterilized in a conventional steam autoclave at a maximum temperature of 121°C and pressure of 2 bar (200 kPa). The disposable liner should be replaced after use on a given patient or when full.

When used in a home environment, the jar can be cleaned using a special detergent able to ensure medical device disinfection. Contact Boscarol for information about disinfectants.

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

7.4. Connecting the jar

The jar is connected to the suction unit through a silicone tube and a plastic connector (white for FA suction unit version (Fig.1); red and at 90-degree for LINER suction unit version (Fig.2)).

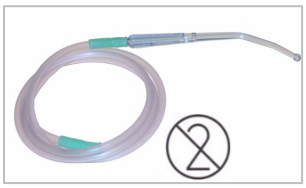
Insert the connector into the device as shown in the photo to the side. Do not force insertion. This applies to both types of jars.

Fig.1

Fig.2

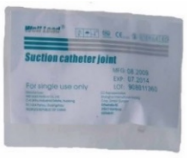
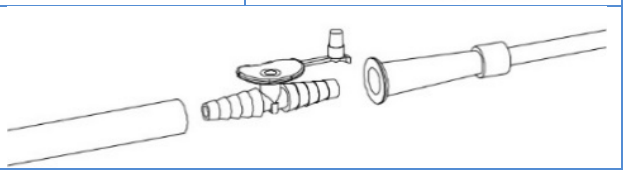
7.5. Sterile, disposable Yankauer catheter with suction control system

The OB2012 units are sold complete with a sterile Yankauer-type suction catheter and tubes for connection to the jar. The suction tip and catheter are disposable and must be replaced after each use. To facilitate proper operation, the suction tip is tilted so that it can reach all parts of the mouth and upper airways. The suction tip is spherical and has side holes to prevent damaging tissues during aspiration.



Yankauer PATIENT	The Yankauer suction catheter is a sterile, disposable medical device. This device must never be reused and must be disposed of after use on the patient.
	Caution! Never use sterile medical devices beyond their expiration date or if the packaging has been damaged.
	Always connect the Yankauer catheter to the "PATIENT" side of the lid of the reusable jar (FA) or to the SERRES® disposable liner using the white conical connector.

7.6. Silicone suction tube and sterile Fingertip connection (conical connector)

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

7.7. Warnings regarding the reuse of disposable parts

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

8. REUSE, CLEANING AND DISINFECTION

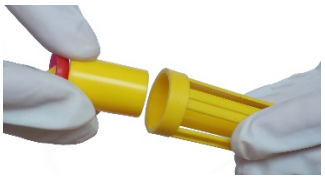
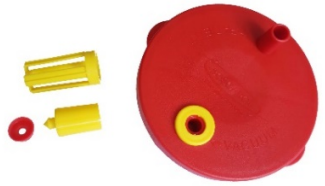
After each use, disconnect the suction unit, disconnect the disposable parts and dispose of them. Check that the suction unit is intact, check the connection tube and check for structural anomalies. Clean and disinfect the suction unit as described below. Replace all disposable parts with new ones and recharge the battery. After conducting the reuse operations, perform the daily test as described in section §"6.4 Periodic Testing of OB2012" covering the daily test. Decontamination is a process that must always be performed meticulously; this means that specific training is required, especially in the field of emergency medicine where the patient's medical condition and degree of contamination are for the most part unknown. For this reason, the operator must always use personal protective equipment (PPE) to protect him/herself and other people. If PPE devices are not available, contact your safety representative.

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

8.1. Reuse of jar OB-J FA

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

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

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

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

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

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

8.3. Assembling the jar and connecting the silicone suction tube

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

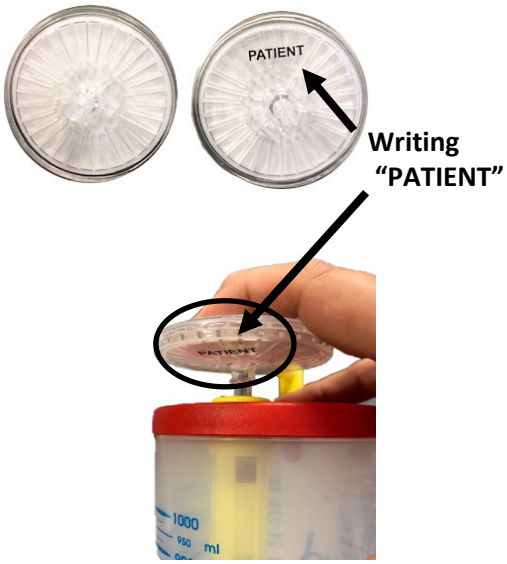
AFTER CLEANING	**Caution** • After each cleaning, check whether the device and its parts are functioning properly. • When there is any doubt, send the device to the manufacturer or an authorized service centre for service and inspection. • After assembly, always run a function test as described in section § 6.4 “Periodic Testing of OB2012" of these operating instructions. • Prepare the device for subsequent use.

8.4. Replacing the antibacterial filter

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

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

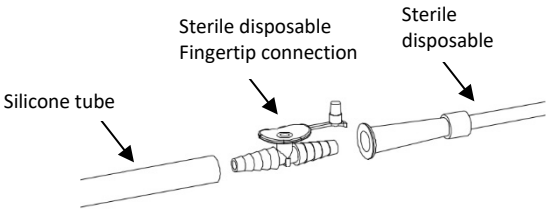
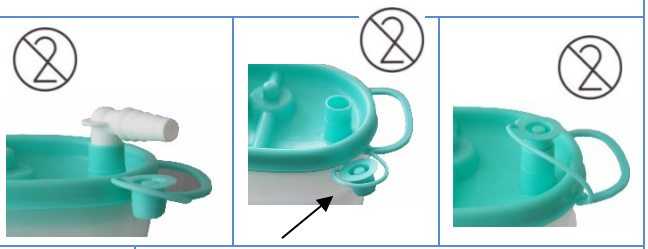
Failure to do so could cause filter failure and contaminate the suction unit suction circuit.



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

8.5. Cleaning the jar with SERRES® disposable liners

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

Before removing the disposable liner, some safety precautions must be taken. Remove the Yankauer disposable catheter, complete with suction tip. Always keep in mind the risks of infection and contamination.	
If the device has a silicone tube, conical Fingertip connection and suction catheter, proceed as follows: • Discard the disposable catheter together with the conical connection (see photo to the side) • Disconnect the silicone tube from the white plastic connection on the SERRES® liner. Discard the liner but keep the silicone tube because it can be disinfected and/or sterilized and then reused.	
Remove the white, 90° connector located on the SERRES liner (if this has not already been done) and close the inlet hole (PATIENT) with the cap (see black arrow in photo to the side).	
Disconnect the red, 90° plastic connector from the suction unit by manually pulling it outwards. Pull the jar up vertically and out of the device.	
Remove the disposable liner (previously closed) from the jar and dispose of it in accordance with current regulations regarding the disposal of contaminated wastes.	
Manually manipulate the 90° connector on the jar and remove the silicone tube (do not discard it!).	
Remove the plastic adapter from the jar by exerting some slight force. If necessary, use both hands to separate the two parts. Be careful not to damage them.	

Unscrew the 90° connector by holding the screw inside the jar still with your hand. Be careful not to damage the O-ring.	REUSABLE 	REUSABLE 

Lifespan of jars OB-J and OB-J FA	The jar must be replaced after 30 sterilization cycles or 5 years from the date of first use.
DANGER	Risk of infection due to release of substances during the cleaning process. Possibility of transmission of fatal infections. Always use suitable PPE and disinfectants as required by hospital regulations and the competent authorities.

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

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

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

8.7. Assembly of jar with SERRES® disposable liners

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

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

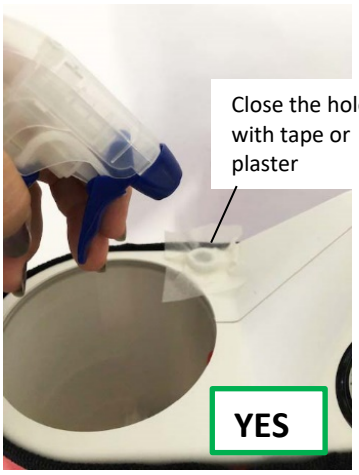
8.8. Disposal of contaminated parts

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

8.9. Suction unit cleaning and disinfection

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

DANGER **ELECTRIC SHOCK**	• **Always disconnect the device from the power supply before cleaning.** • To clean the surface of the device, always disconnect the unit from the wall bracket. • DO NOT RINSE THE DEVICE under running water and/or immerse it in liquids. • The suction device is marketed as ***not sterile and cannot be sterilized.*** • Do not immerse the suction unit in any disinfectant solution. • Never use solvents that could cause deterioration of the plastic and/or remove the screen-prints and labels. • Do not spray liquids on the device. The device suction inlet must always be closed during all cleaning operations. Close the inlet hole with a piece of tape or adhesive bandage to prevent liquids from entering the unit and damaging the suction circuit.
EXTERNAL POWER SUPPLY and WALL BRACKET **DISINFECTION PROCESS**	• Disconnect the power supply from the mains before starting to clean it. Wait at least 1 minute after disconnection to allow any stored internal energy to automatically drain off. • Never rinse the power supply or bracket under water and never immerse them in liquids. • Make certain that the cloth used to clean the device is only slightly damp. • Never immerse the power supply or wall bracket in disinfectant or detergent. • To disinfect the surface of the power supply and wall bracket, use only disinfectant rated for medical devices and always wipe the surface dry. The cloth must be damp and not soaked. • After these operations, wait at least 30 minutes before using it again.

CLEANING DEVICE SURFACES	Substances entering the suction hole are sucked in by the pump and sprayed onto the electronic parts. For this reason, the suction hole must be closed with a piece of adhesive tape or an adhesive bandage. After cleaning, this tape or adhesive bandage must be removed.	 
Availability of disinfectants	To properly disinfect and decontaminate the suction unit, we recommend using specific, approved products. These disinfectants must be alcohol-free and contain no abrasive substances. Oscar Boscarol Srl (Ltd) can provide specific disinfectants suitable for medical equipment, including our suction units. These disinfectants, available in different formats (pre-soaked wipes, sprays and concentrated liquids), have been laboratory tested and are guaranteed to deactivate viruses, bacteria and microorganisms. When used periodically, they destroy and prevent the formation of dangerous bio-films (superficial layers that easily host bacteria, moulds, viruses and microorganisms). The disinfectants we sell do not contain alcohol, chlorine, phenols, aldehydes and halogens.	
After cleaning	**Caution** • After each cleaning, check whether the device and its parts for damage. • When in doubt, send the device to the manufacturer or an authorized service centre for service and inspection. • After assembly, run a function test as described in section §"6.4 Periodic Testing of OB2012" of these operating instructions. • Prepare the device for subsequent use	

8.10. Cleaning and disinfection plan

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

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

9. ACCESSORIES AND OPTIONAL PARTS FOR OB2012

To safely secure the device in rescue vehicles, a wall bracket (which also powers the device) is available. The bracket has passed conformity tests performed in accordance with international standard EN 1789.
The suction unit can be charged and used through the cable (supplied), the bracket (optional) or the optional power supply (100-230 Vac Input). The charging cable must be connected to a direct current power supply with voltage ranging from 11 to 30 Vdc and power of at least 70-80 W.
If it is to be used through a mains power supply, the suction unit must be connected to an approved power supply available from the manufacturer. When the suction unit is used with the power supply, usage must be limited to 20 continuous minutes, after which it must be allowed to cool down.

CAUTION	When the suction unit OB2012 is connected to the power supply, continuous usage is limited to a maximum of 20 minutes, after which the power supply and the device must be allowed to cool down for at least 10 minutes.

Power cable for suction units OB2012. REF code: BSU855.	
Wall bracket that can power and charge the device. REF code: BSU810.	
LYD mains power supply with 2-pin male connector Input voltage from 100 to 240 Vac (standard plug type C7) Output voltage: 14.0 Vdc Rated power: 60 W REF code: BSU895EU (EU plug) – BSU895UK (UK plug) – BSU895JP (JP plug)	
EXCLUSIVE ACCESSORIES	The adapter is an exclusive accessory, available only from the manufacturer. It is approved for this function and cannot be replaced by other brands. It can only be used indoors and on a power supply compliant with current law. The medical suction unit can only be used with this adapter.

DANGER **Electric shock**	Never tamper with and/or open the power supply. Risk of death. The adapter contains electronic parts which are connected to the mains voltage and can be fatal.
LIFESPAN	The suction unit lifespan is **10 years** from the date of manufacture. The device **must be replaced after 10 years.**

10. INTERNAL BATTERY FOR SUCTION UNITS FOR OB2012

Suction units OB2012 have an internal battery that guarantees a long operating life. The SLA (sealed lead acid) battery is sealed and cannot be opened or serviced. If the battery is exhausted or defected 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 residual capacity) is about 15 hours. A fully charged battery will provide approximately 60 minutes of continuous operation (free airflow). This time may vary, even considerably, if the suction unit is used outside the manufacturer-recommended parameters (e.g. when used at very high or very low temperatures). If charged correctly, the average battery life is 24 months. After this period, we recommend replacing the battery. The battery is always replaced during preventive maintenance and safety inspections. If the unit is not used for a long period of time, run a full inspection and fully charge the battery every 15-20 days.

When the device is not used	Recharge the unit at least every month. This prevents problems related to non-use and non-charging of the SLA battery.
Disposal of the battery	The spent battery must be disposed of according to the regulations in force in the country where the suction unit is used.

11. SPECIAL USAGE CONDITIONS

The suction unit has no electrical and mechanical safety devices that can be accessed by the operator. Temperatures that are too high or too low can cause some of internal safety devices to trip, blocking the suction unit function. For this reason, never expose the device to extreme operating conditions (temperature, humidity and pressure). The technical characteristics and nominal operating conditions are listed in section § 15 Technical and compliance data for OB2012.
If the suction unit is to be used under extreme conditions, check the following information.

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

12. DEMOLITION OF THE SUCTION UNIT

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

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

13. ACCESSORIES, CONSUMABLES AND SPARE PARTS

Manufacturer code	Description
	Accessories
BSU810	Wall bracket OB WB
BSU895EU	Battery charger 100/240 Vca 50/60 Hz Globtek - LYD 14V - 2 poles and Euro-plug
BSU895UK	Battery charger 100/240 Vca 50/60 Hz LYD 14V - 2 poles and UK-plug
BSU895JP	Battery charger 100/240 Vca 50/60 Hz LYD 14V - 2 poles and Japan / USA-plug
	Consumables
BSU730	Protection filter for OB-J FA jar – 5 pcs
BSU732	Protection filter for OB-J FA jar – 15 pcs
BSU734	Protection filter for OB-J FA jar – 40 pcs
BSU705	Disposable bag SERRES – 6 pcs
BSU706	Disposable bag SERRES – 12 pcs
BSU707	Disposable bag SERRES – 36 pcs
BSU500	Autoclavable OB-J FA jar, without protection filter
BSU506	OB-J jar, without disposable bag
126140107191	Yankauer suction tube
BSU750	End-piece sterile disposable Finger-typ – 5 pcs
BSU752	End-piece sterile disposable Finger-typ – 15 pcs
BSU754	End-piece sterile disposable Finger-typ – 50 pcs
11214101003	Sterile suction catheter Ch.10 black
11214101104	Sterile suction catheter Ch.12 white
11214101005	Sterile suction catheter Ch.14 green
11214101006	Sterile suction catheter Ch.16 orange
11214101007	Sterile suction catheter Ch.18 red
11214101008	Sterile suction catheter Ch.20 yellow
	Spare parts
BSU854	External charging cable with cigar lighter fitting and 3 poles plug
BSU902	Silicone patient tube - length 130cm / 51,2inch (int.diam.6mm/ext.12mm)
SPS6000	Bottle OB-J FA without lid
SPS6002	Shut-off valve – 3 pcs
SPS6004	90° plastic joint for OB-J FA jar – 3 pcs
SPS6006	Lid for OB-J FA complete with shut-off valve and 90° plastic joint
SPS6014	Conical connector – 5 pcs
SPS6023	Silicone tube 16 cm with conical connector for OB-J FA
SPS6011	Red angular connector – 3 pcs
SPS6023A	Silicone tube 16 cm with red angular connector for OB-J
SPS5092	"L" joint for OB-J jar – 3 pcs
eIFU	Operating Instructions available at: https://www.boscarol.it/ita/eifu.php

Code update	To make technical improvements, the manufacturer can change the parts listed without prior notice. Contact the manufacturer for further information (info@boscarol.it).

14. TECHNICAL SERVICE

Suction units OB2012 have no electrical and/or mechanical parts that can be serviced by the retailer, customer and/or operator. The user is not authorized to replace the battery. Never open the suction unit and never tamper with any electrical and/or mechanical parts. Always contact your service centre or the manufacturer. Performing even minor operations on the suction unit will void the warranty. Unauthorized intervention on the suction unit can compromise its compliance with applicable laws and regulations and reduce its operating safety for operators and patients. Send an e-mail to Boscarol Srl at info@boscarol.it for a list of authorized service centres.

14.1. Troubleshooting

Malfunction	*Possible cause(s)*	*Solution*
The suction unit does not turn on	• Battery completely drained • Battery damaged • Internal electronic circuit failure	• Charge the suction unit using the charging cable or mains power supply • Contact authorised service centre • Contact an authorised service centre
The suction unit does not function when connected to the wall bracket	• Bracket not connected to the external 12÷15 Vdc source. • Supply voltage out of envisaged range • Current insufficient to power the device • Device contacts damaged • Bracket contacts damaged • Bracket connection cable inverted • Internal device circuit failure	• Connect the wall bracket cable to the external power source • The power supply voltage must be between 11 and 15 Vdc • The rated current must be at least 8 A • Contact an authorised service centre • Contact an authorised service centre • Reverse the power cable poles (+ on upper contact) • Contact an authorised service centre
The suction unit ***only*** works if it is mounted on the wall bracket, mains power supply or fitted with the external cable.	• Internal battery damaged • Internal electronic circuit failure	• Contact authorised service centre • Contact authorised service centre
The suction unit does not charge when connected to the mains power supply and/or does not function	• Power supply failure	• Replace the mains power supply or contact an authorised service centre
The suction unit works, but the battery power indicator lights are off	• LED display or internal electronic circuit failure • Very low battery power	• Check that the LED display work if connected to the wall-bracket or to the external charger cable. If works, immediately charge the battery for at least 24 hours. If does not works, contact an authorized service centre. • Charge the battery for at least 24 hours.
Suction unit charge has dropped significantly	• The battery has finished its life cycle • Internal charging circuit failure	• Contact authorised service centre • Contact authorised service centre.
Patient side vacuum power very low or absent	• Vacuum regulator completely open • Protection filter blocked • Tubes for connection to filter and device plugged, kinked or disconnected • Overflow valve on jar OB-J FA blocked • Pump damaged	• Close the regulator all the way and check the vacuum reading on the gauge and on the patient side (turn the knob clockwise). • Replace the protection filter • Replace or reconnect the tubes, check the jar connections. • Disconnect the tubing going to the device, empty the jar and check the regular movement of the valve (the silicone seal must face upward). • The jar can only be used in the upright position (±20% max. inclination). • Contact authorised service centre.
Vacuum is always at maximum level even if the jar is removed.	• Fault on the internal pneumatic circuit.	• Contact an authorised service centre
High noise, low suction, high vibration.	• Internal pump damaged	• Contact authorised service centre.

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

15. TECHNICAL AND COMPLIANCE DATA FOR OB2012

Medical device classification (as per MDD93/42/EEC)	**IIa**
Basic UDI number (in conformity with MDR 2017/745)	805240088BSUGJ
Suction level classification as per ISO 10079-1:2019	HIGH VACUUM-HIGH FLOW
Operating mode (short term):	TEMPORARY (50 minutes "ON", 10 minutes "OFF")
Reference standard	ISO 10079-1:2016 + AMD 2018
EMC compliance testing	IEC 60601-1-2 4th edition
Medical electrical equipment safety compliance	IEC 60601-1
Pre-hospital sector (EMS) compliance	IEC 60601-1-12:2014
Part applied in compliance with IEC 60601-1	TYPE BF
Protection class vs. electric shock	CLASS II
Degree of protection against ingress of liquids and solids (IEC 529):	IP34d
Risk assessment (technical documentation)	ISO 14971:2019
Usability application	IEC 62366-1:2015
Mandatory periodic safety inspection	Every 24 months
UMDNS code:	15-016
GMDN code:	63643
Approval and conformity as per ECE R10 (automotive)	E11 10 R - 049484
Compliance with European standard for ambulances	UNI EN 1789:2014
Crash test for ambulance support systems	UNI EN 1789:2014

Dimensions OB2012	
Maximum device dimensions	350 mm (width) x 120 mm (depth) x 240 mm (height) 13.77 in (width) x 4.72 in (depth) x 9.44 in (height)
Weight of device	4.6Kg max. complete with all accessories
Weight of wall bracket	780 gr
Tolerance for all values	±5 %

Technical data	
Rated vacuum power:	800 mbar (80 kPa, 600 mmHg) ±10 %
Vacuum Regulation	Linear with built-in mechanical regulator
Vacuum regulation range	30÷800 mbar (3÷80 kPa)
Nominal flow	30 LPM (litres per minute) with free air ±10 %
Maximum operating time (free cycle)	Approximately 60 minutes ±10%
Maximum noise	70 dBA
Vacuum indicator accuracy (full scale)	±2.5 %
Battery power indicator accuracy	±5 %
Reusable, autoclavable jar	Type OB-J FA 1000 ml, can be autoclave sterilized for max. 30 cycles
Autoclavable jar OB-J	Type OB-J for 1000 ml SERRES® disposable liners
Lifespan	10 years from first use if regularly serviced
(*) Notes: 1bar = 100kPa = 750mmHg	

Battery charge and device power supply	
Operation/Charging	12÷15 Vdc (direct current)
Time to recharge to 80%	10 hours (at recommended charging temperature)
Maximum charge time	10–15 hours straight
Max current load	70 W
Battery type	Internally, SLA 12 V - 4 Ah
Electrical safety	Internal, not accessible to operator

Pump type	Piston, maintenance free, 12 Vdc electric motor
Type of operation	The device can remain connected to the power source continuously
Type of power supply	LYD - Model number: 601404250 or GLOBTEK

Storage and usage conditions	
Operating temperature range	-10 to 50° C
Relative humidity for storage, transport and use	15÷95%, not condensed
Temperature range for storage and transport of packaged device	-20 to 60° C
Temperature range recommended for charging	0 to 50° C
Atmospheric pressure range for storage, transport	700–1100 mbar (70–110 kPa)
Operation in rain	Degree of protection against ingress of liquids (IEC529): IP34d
Maximum operating altitude	5000 m (above sea level)

Use under rain	Suction units OB2012 are protected against the ingress of liquids and solids. However, it is always preferable to protect the unit from heavy rain. If the suction unit is completely wet, move it to a dry area, dry the outside and wait at least 30 minutes before attempting to restart it.

Data on consumables	
Antibacterial filter	PTFE type, hydrophobic. Maximum pressure: 100 kPa
SERRES® disposable liner	1000 ml, disposable with integrated protection filter
Yankauer catheter with suction tip	Sterile, disposable. tube length: 1.3 m. Internal diameter: 6 mm
Conical Fingertip suction connection	Sterile, disposable
Silicone tube	Reusable and sterilisable. Internal diameter: 6 mm. Length 1.3 m

	For further technical information, contact the manufacturer (info@boscarol.it).

Serres Devices	SERRES® products are factory-sterilised and must be stored in warm indoor locations. Protect the package from humidity, dirt and dust. Disposable products can be used over a period of 5 years after the date shown on the label. The sole except to this is the liners pre-filled with solidifying agent, which can be used for a period of 2 years after the date shown on the label.

16. INFORMATION ON ELECTROMAGNETIC COMPATIBILITY EMC FOR SUCTION UNITS OB2012

Suction unit OB2012 does not interfere with any other medical devices that may be performing tests and clinical treatments in the same area. The unit does not require connection to other equipment for its operation and has an internal power supply.

16.1. RISKS OF MUTUAL INTERFERENCE WITH OTHER DEVICES

Medical electrical equipment requires special precautions regarding electromagnetic compatibility. For this reason, they must be installed and/or used in accordance with the information specified in the accompanying documents (in our case the tables below).

Portable and mobile radio communication devices may affect operation of the medical device.

Medical electrical equipment and systems must not be used in proximity with, adjacent to, or on top of other electrical or radio communication equipment. If such use is necessary and unavoidable, special precautions must be taken to ensure that the electrical medical device functions properly in its envisaged configuration (e.g., with constant visual checks to ensure the absence of anomalies or failures). The tables below provide information on electromagnetic compatibility (EMC) relevant to this electrical medical device. For the purposes of electromagnetic immunity, the full functionality of this unit is considered an "essential service". Suction units OB2012 are electrical medical devices rated CISPR 11 Group 1 and meet Class B requirements.

Use with the power supply unit	Suction units OB2012 can be used with the approved power supply unit supplied by the manufacturer (accessory)

16.2. METHODS TO PREVENT ELECTROMAGNETIC INTERFERENCE

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

16.3. MANUFACTURER GUIDELINES AND DECLARATION – ELECTROMAGNETIC EMISSIONS

Suction unit OB2012 is designed for use in the electromagnetic environment specified below. The customer or user of suction unit OB2012 must make certain that it is used in such an environment.

Emission test	Limit	Guideline - electromagnetic environment
Conducted emissions	CISPR 11, Group 1, Class B	Suction units OB2012 use RF energy only for its internal function. Therefore, its RF emissions are very low and are unlikely to cause any interference in nearby electronic equipment.
Radiated emissions	CISPR 11, Group 1, Class B	
Harmonic current emissions	IEC 61000-3-2, Class A	Suction units OB2012 are connected directly to the public low-voltage power mains supplying buildings used for domestic purposes. For domestic healthcare environments only.
Voltage fluctuations/flicker emissions IEC 61000-3-3	IEC 61000-3-3	

16.4. MANUFACTURER GUIDELINES AND DECLARATION – ELECTROMAGNETIC IMMUNITY

Suction unit OB2012 is designed for use in the electromagnetic environment specified below. The customer or user of suction unit OB2012 must make certain that it is used in such an environment.

IMMUNITY test	Compliance level	Guideline - electromagnetic environment
Electrostatic discharges (IEC 61000-4-2)	Discharge contact: ±8 kV contact Air discharge: ±2 kV, ±4 kV, ±8 kV, ±15 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity must be at least 30%.
		Portable and mobile RF communications equipment must not be used near any part of the device, including the cables; they must be at the recommended separation distance, calculated using the equation applicable for transmitter frequency.
Radiated radio frequencies RF EM filed IEC 61000-4-3	80-2700 MHz; 1kHz AM 80%; 10 V/m	Recommended separation distance $d = 1.2\sqrt{P}$ for 80 MHz to 800 MHz, $d = 2.3\sqrt{P}$ for 800 MHz to 2.7 GHz
		where P is the maximum transmitter power output in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).

Proximity fields form wireless RF communication equipment (IEC 61000-4-3)	385 MHz; Pulse modulation: 18 Hz; 27 V/m 450 MHz, FM + 5 Hz deviation: 1 kHz sine; 28 V/m 710, 745, 780 MHz; Pulse modulation: 217 Hz; 9 V/m 810, 870, 930 MHz; Pulse modulation: 18 Hz; 28 V/m 1720, 1845, 1970 MHz; Pulse modulation: 217 Hz; 28 V/m 2450 MHz; Pulse modulation: 217 Hz; 28 V/m 5240, 5500, 5785 MHz; Pulse modulation: 217 Hz; 9 V/m	Portable and mobile RF communications equipment must not be used at a point that is closer to any part of the device, including the cables, than the recommended separation distance, calculated to be 30 cm.
Fast transients/bursts (IEC 61000-4-4)	Electric 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.
Fluctuations (IEC 61000-4-5)	L-N: 1kV at 0°,90°,180°,270° L-PE, N-PE: 2 kV at 0°,90°,180°,270°	The quality of the mains power supply should be that of a typical environment.
Conducted disturbances induced by RF electromagnetic fields (IEC 61000-4-6)	0.15-80 MHz; 1kHz AM 80%; 3 Vrms, 6 Vrms in ISM and amateur radio band	Portable and mobile RF communications equipment must not be used near any part of the device, including the cables; they must be at the recommended separation distance, calculated using the equation applicable for transmitter frequency. Recommended separation distance d = 1.2√P for 150 kHz at 80MHz where P is the maximum transmitter power output in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
Magnetic fields of nominal power frequency (IEC 61000-4-8)	30 A/m, 50 Hz	The level of the magnetic fields produced by the power frequency must be that characteristic of a typical location in a typical commercial or hospital environment.
Voltage drop/Power failure (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 at 0°	The quality of the mains power supply should be that of a typical environment. If the user of the device requires continuous operation during power outages, we recommend powering the device from a UPS or battery.

17. DECLARATION OF CONFORMITY

We, the manufacturer: *The manufacturer:*	**OSCAR BOSCAROL SRL (LTD)** Via E. Ferrari, 29 – 39100 BOLZANO – ITALY Tel. +39 0471 932893 – Fax. +39 0257760140 Web: www.boscarol.it - Email: info@boscarol.it Certifies EN ISO 13485:2016 Certificate No. Q5 042208 0031 Certifies UNI EN ISO 9001:2015 Emission: TÜV–SÜD Product service (CE0123) EC Certificate No. G1 042208 0032 rev.00
We declare under our sole responsibility that the device (name): *Dichiariamo sotto nostra responsabilità che il dispositivo (nome):*	**MEDICAL SUCTION UNIT** **ASPIRATORE MEDICALE DI SECRETI**
Type: **Tipo:**	**OB2012 FA – OB2012 LINER**
UMDNS code:	**15-016**
GMDN code:	**63643**
Boscarol code:	**BSU100 - BSU104 - BSU108** **BSU150 - BSU154 - BSU158** **XAS0200 - XAS0210 - XAS0220 - XAS0222** **XAS0230 - XAS0240 - XAS0250 - XAS0260** **XAS0300 - XAS0302 - XAS0304 - XAS0356** **XAS0400 – XAS0402**
Devices classification (MDD 93/42/EEC – Annex IX): *Classificazione dispositivo (MDD93/42/CEE – Allegato IX):*	**Class IIa**
Meets all provisions of directive MDD 93/42/EEC and subsequent amendments which apply to it. *Soddisfa tutte le disposizioni della direttiva MDD 93/42/CEE e successivi emendamenti che lo riguardano.*	
Applied harmonised standards, national standards, or other normative documents: *Norme armonizzate o nazionali applicate, altri documenti normative applicate:*	**ISO 10079-1** **UNI EN 1789** **IEC 60601-1** **IEC60601-1-2** **IEC 60601-1-12** **ECE-R10**
Conformity assessment procedure: *Procedimento di valutazione della conformità:*	**MDD93/42/EEC, Annex II (Allegato II)**
Notified body: *Organismo di notifica incaricato della valutazione della conformità:*	**TÜV SÜD PRODUCT SERVICE GmbH** **CE 0123** **Ridlerstrasse 65 – 80339 München – Germany**

Bolzano, 25/08/2020

DIR/QM – Quality Manager
Dr. MARCHETTI BENEDETTA

DIR/CEO
BRAZZO DANIELE

18. WARRANTY

Oscar Boscarol guarantees the suction units OB2012 for a period of 3 years from the date of purchase from the original distributor. The company guarantees that the suction unit is free of material and/or manufacturing defects.

The warranty does not cover: the jar, power cord, normal wear, discoloration and any other cosmetic irregularities that do not affect unit operation.

If, at any time during the entire 3-year warranty period, the product is found to be defective, it must be sent to Oscar Boscarol Srl (Ltd) with a note describing the defect. Oscar Boscarol Srl (Ltd) will repair or replace the defective parts and/or the whole unit at its own discretion. All shipping costs are charged to the customer.

Warranty conditions:

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

OSCAR BOSCAROL SRL V. E. Ferrari, 29 – 39100 BOLZANO, ITALY
Fax: +39 0257760142 – E-mail: production.manager@boscarol.it

To validate the warranty process, the customer must provide evidence of the following documentation:

1. copy of the invoice and/or receipt of purchase containing the device serial number and date of purchase
2. confirmation from the manufacturer or its representative that it really does involve a fault stemming from the manufacturing process or components deemed defective from the time of their supply
3. absence of any tampering, changes and/or anything that does not conform with the original product.

In terms of suction unit safety, reliability and function, Oscar Boscarol Srl may be held responsible only if:

1. all technical operations, repairs, modifications and safety and preventive maintenance inspections have been performed by Oscar Boscarol Srl (Ltd) or by an authorized service centre
2. the suction unit has been and is used correctly, strictly following the instructions given in these operating instructions
3. the electrical system to which the suction unit is connected has been built according to national and European reference standards and regulations
4. all accessories and consumables are original and have been purchased from the manufacturer or from an authorized service centre

With reference to what has been described in these warranty conditions, Oscar Boscarol srl cannot be held responsible for any accidental damage, whether direct or indirect, that may occur on devices subject to modification, repair, unauthorised technical interventions or if any of its parts are damaged due to accident or incorrect use. On the suction unit are no other warranties expressed or limited, of merchantability, fitness or other outside those described in this manual.

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