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**MEDICAL SUCTION UNIT BOSCAROL**

**OB 2012 FA  
OB 2012 LINER**

**USER MANUAL**



**OB2012FA with autoclavabile jar**



**OB2012FM with disposable jar**

**MANUFACTURED BY:**



**Emergency Systems**

Tel. ++39/0471/932893 • Fax ++39/0471/932331

E-mail: [boscarol@supernet.it](mailto:boscarol@supernet.it)

[www.boscarol.it](http://www.boscarol.it)

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<b>1. Caution notice.</b>
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**PLEASE READ BEFORE THE USE!**

- Before the use of the OB2012 Suction Unit, please read this instruction manual carefully.
- The OB2012 Suction Unit is an independent active medical device. Laws in force restricts this device to sale, distribution, and use by-or on the order of a physician, emergency medical technician, or other medical practitioner
- Do not use the suction unit in presence of flammable agents or anesthetics.
- Due to the nature of the unit's use, all precautions must be taken to ensure the unit's reliability (cleaning, storage, environmental conditions, etc.).
- In case of suction without the jar and/or the protection filter, or in the case of a suspicion that any substances are penetrated in the unit, send immediately the suction unit to the service center for the control and the decontamination (see the 6. chapter).
- Before cleaning the unit and/or to proceed to the maintenance of the device, disconnect the unit from the wall-bracket or from the recharging cable. Do not put the unit in water or fluid substances to avoid the damage of the device.
- Do not suction substances for disinfecting or cleaning fluid in the unit, without the protection filter and/or the jar. These substances can damages the internal parts of the unit.
- There are no serviceable components in the unit, refer always to trained service people.
- Use only original and authorized spare parts furnished from the manufacturer (Boscarol Emergency Systems), to have always the maximum security and efficiency of the device.
- Do not alter the mechanical and/or electrical parts on the wall-bracket unit. The change and/or the alteration of parts on this unit can be very dangerous for the security retention. Never change, release and/or modify the spring on the wall-bracket. This part is very important for the security in the case of very high negative acceleration force (up 10g negative force).

**Internal battery:**

- Reconnect the suction unit for charging after every use. The charging switch on automatically, when the unit is put on the wall bracket, when it is connected with the external cable to a 12VDC source or with the optional battery charger (from the main supply). On receipt of the suction unit from the manufacturer, recharge the unit at least for 24 hours.
- The correct use and recharging of the internal battery guarantees a typical lifetime of 2-3years. After this time it is better to change the internal battery.
- If it is impossible to recharge the battery (in case of not use for long time, for example) verify every month the good operation of the unit and recharge the internal battery for not less of 24 hours.
- Never forget to store the suction unit after the use, without to have recharged the battery. When sealed acid battery voltage fail following a "deep discharge", have to be replaced.
- The replace of the internal battery is not possible from the user and/or customer. Refer always to the service authorized.
- During the recharging time verify the light on the front side. On the charging phase the colour of the light is red, and switch on green colour when the battery is completely recharged.

**Security inspection:**

The device have to be checked form the service authorized people, at less every **24 mounth** from the receipt date of the suction unit.

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<b>2. Introduction.</b>
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**2.1 Package contents**

OB2012 FA Medical suction unit:

- N.1 Suction unit OB 2012 ready to use.
- n.1 1000cc reusable collect container with integrated overfill valve.
- N.1 protection filter (type AIR SAFETY 60mm).
- N.1 external recharging cable 4 poles.
- N.1 sterile Jankauer suction catheter complete with suction tube.
- N.1 red carrying bag.
- N.2 spare fuse of T15A.
- N.1 user manual.

OB2012 LINER Medical suction unit:

- N.1 Suction unit OB 2012 ready to use.
- N.1 1000cc reusable collect container with disposable liner complete with integrated filter.
- N.1 external recharging cable 4 poles.
- N.1 sterile Jankauer suction catheter complete with suction tube.
- N.1 red carrying bag.
- N.2 spare fuse of 15AT.
- N.1 user manual.

Optional (only if needed by customers):

- Battery charger from the main supply (100÷230Vac 50-60Hz).
- Set patient silicon tube with end piece Finger-typ.
- Wall bracket with electrical connections for the recharging in the vehicle (12Vdc).
- Blue colour carrying bag.

**2.2 General description.**

The OB 2012 FA/LINER is a portable, battery operated medical suction unit used to clear the upper airway and restore breathing either spontaneously or forced. The unit is suitable for use in paramedic services, in a doctor's office or for home medical care. The OB2012 is powered by sealed acid battery capable of driving the unit at full power for about 40 minutes ( $\pm 10\%$ ). The internal battery (12V) is recharged with a special inside electronic circuit (DC-DC converter) which is activated by the connection to the vehicle electrical system (12Vdc). Upon request the unit can be fitted with a special charging/retention shelf (wall-bracket OB20WB).

**2.3 Contra-indication use.**

Do not use the suction unit OB2012 for the thorax drainage.

**2.4 Technical features of the device.**

The OB2012 Suction unit is manufactured in accordance with the laws in force, and is engineered for a very easy use during the emergency situations. The most benefits are these:

- Very strong ABS antishock chassis, with special design, easy to clean and protected against the penetration of fluid substances and water.
- Easy way to replace the disposable and/or maintenance parts.
- Dual mode battery charger: with the external cable (with cigarette lighter socket) or with the optional wall-bracket.
- It is possible to recharge the battery from a main supply with an optional battery charger (230VAC or 100VAC).
- When the unit is put on the wall bracket or at the external cable, the unit doesn't use the energy from the internal battery.
- Easy switch on of the device with a protected switch accessible also with glove.
- Realtime value of depression on the double range analogic gauge (mbar/kPa).
- Vacuum regulation from minimum to maximum without step (linear). It is possible to set any value from a minimum of -800mbar (-80kPa).
- Very high powerful pump motor (about 30LPM).
- High affidable system with double piston pump.
- Realtime indication of battery autonomy with light indicator (4 steps).
- Realtime indication of recharging with green colour led.
- All controls are on the front side of the unit, to be used also when the unit is fixed on the wall-bracket.

## 2.5 Special storage and operating instructions.

### 2.5.1 Storage and transport conditions.

The unit must be stored in a dry room and protected against high value of temperatures. When not utilized for a long time period, the unit must be checked every month and recharge the battery for not less of 24 consecutive hours. The temperature range for the right storage is between -25°C and +60°C (degrees C), and the humidity range is from 10% to maximum 80% (relative value, not condensed) in order to prevent sudden discharge of the internal batteries. The storage is possible only with the original package, which avoid damage and discharge of the internal batteries. When disassembled for cleaning operation, see this manual for the right operation. Atmospheric pressure range: 700/1060hPa (700/1060mbar).

### 2.5.2 Operating instructions.

While in operation, the unit should not be exposed to extreme temperature fluctuations. Normal operations should only take place between -10°C and +50°C. The acceptable humidity range is between 20% and 90%UR. If the unit is operating correctly outside the displayed values, these values in relation to suction, pressure and charging could be distorted. Never operate the unit in temperatures above +60°C. Be aware that if the unit is operating at altitude over 2,500 meters above NN, the pressure value can slightly decrease. This is caused by the decrease in the atmospheric pressure. We suggest recharging the unit with temperature range between 15 and 30°C. Atmospheric pressure range: 700/1060hPa (700/1060mbar).

### 2.5.3 Operating in the rain.

The OB2012 FA/LINER is protected against the rain penetration. Otherwise the unit should never be operated by very heavy rain. Whether during operation or storage the unit must always stand upright. In the event that water gets into the side compartments suction unit clear and then dry throughly.

## 2.6 Guarantee.

The Boscarol Emergency Systems offers for the OB2012 FA e OB2012 LINER a 36 months guarantee from the date of the first purchase. Boscarol Emergency Systems, guarants that each new OB2012FA and OB2012 FM products is free of defects in material and workmanship. From this guarantee are excluded: ***the collect container and/or the liner, the external cable for the recharging, the internal battery, the normally wear and tear of the unit, discoloration, colour alteration and all the other aesthetical irregularity which not produced degradations the operations of the unit.*** If returned to Boscarol Emergency Systems, the factory will arrange for repairs or replacement within the terms of this guarantee. The defective device should be decontaminated and returned properly packaged, with included writing note about the defect of the unit. All costs for the shipment (postal and/or courier) are to sender expense.

The guarantee shall not apply to any Boscarol product which has been repaired by otherone other than authorized Boscarol emergency Systems representative, or altered in any way so as, in Boscarol's judgment, to affect its safety or efficacy, nor which has had the serial number altered, effaced or removed. Neither shall this guarantee apply to any Boscarol product which has been connected or charged otherwise than in accordance with the instructions furnished by Boscarol.

### **Conditions for the validity of the guarantee**

For the validity of the guarantee, the customer shall produce this documentation:

- Copy of the invoice and/or the purchase declaration with the serial number of the unit and the date of the purchasing.

For all legal purposes, Boscarol Emergency Systems is responsible for the security, operation and affidability only if:

- All technical operations, repairs, modify and mainenance actions are executed from the Boscarol Emergency Systems and/or from the authorized service center.
- The device is right used, as indicated in this user manual.
- The electrical systems where the suction unit is connected, is performed on the international norms and national law in force.

Refer to above descripted, Boscarol Emergency Systems is not responsible for accidental or indirectal damage resulted by not authorized modify, not authorized repair, not authorized technical intervents, or when any parts of the unit are damaged in case of incident, accident, bad use and/or misuse. On the OB2012 suction unit doesn't is it other guarantee (limited, etc.) and/or other ability not descripted on the present user manual. Jurisdiction for legal department is Bolzano - Italy.

**3. Description of the device.**

**3.1 Controls, indications and check panel.**

All the controls of the suction unit are on the front side of the unit. The control of the unit is possible also when the unit is fitted on the wall-bracket and/or with the carrying bag.

**3.1.1 Mechanical controls.**

On the front side the switch (4) is protected against the penetration of humidity, water and fluid substances. Adjustment of the negative pressure can be accomplished with the knob (5) also found on the front side. Turning the knob clockwise achieves maximum depressure. The double range analogic gauge (1) shows in realtime the value of the negative pressure on the patient side. The range of the gauge is in millibar (mbar) and kilo-Pascal (kPa). On the back side of the unit the two contacts (7) are located for the connection of the unit in the wall-bracket. The contacts are maintenance free. The recharging is possible also with the external cable to put on the socket (6) near the switch. Do not force the insertion of the connector into the socket (refer to the figure 1 and 2).

**3.1.2 Lighting indications.**

On the front side of the unit the lighting indicators allow the control of the switch condition, the battery autonomy (3) and the recharging phasis (2) (see fig.1). All lighting indicators are easy to see in presence of strong sun light. The autonomy of the internal battery is displayed by four red leds. The table below indicates the condition of the leds and the relative value of the autonomy:

LED'S STATUS	AUTONOMY VALUE
4 LED on	>80% maximum autonomy
3 LED on	50-75% of the maximum autonomy
2 LED on	20-40% of the maximum autonomy
1 LED on	<20% <b>low battery voltage - recharging immediately</b>

The use of the unit with low battery voltage **damages the internal battery and reduces his lifetime**. It is very important to reconnect the unit to charge after each use.

The replaced of the internal battery is always excluded from the guarantee.

At side of the autonomy indicator is the control light for the charging phase (2). This indicator is a red/green coloured led: **red indicates rechargement, green indicates rechargement terminated**. The not lighting of this led indicates a bad work condition of the internal electronic circuit, and/or absence of external power source, and/or bad connection of the external cable, and/or bad connection of the wall-bracket. Verify always the insertion of the unit on the wall bracket and/or the cigar lighter plug in the power source. It is possible that the noise and vibration of the vehicles disconnect the cigar lighter plug from the socket. The continuous recharging of the unit doesn't make damage on the internal battery. Otherwise this condition offers the maximum autonomy of the battery.

CHG/ON LED STATUS	AUTONOMY VALUE
red colour on	charging phase
green colour on	charging terminated



**Mechanical controls and lighting indicators (fig.1 and 2).**

- |   |   |
|---|---|
| 1. Double range analogical gauge                              | 2. Charging phase indicator                 |
| 3. Battery autonomy indicator                                 | 4. Switch (ON-OFF)                          |
| 5. Depressure regulator (increase the value clockwise)        | 6. Socket for the external recharging cable |
| 7. Electrical contacts for the connection on the wall bracket |   |

**3.1.3 Testing of the unit.**

This operation agrees the user to verify the right operation of the unit. Establish a daily check-list to assure good performance of the equipment.

**Daily operations list:**

- disconnect the unit from the wall bracket or from the external recharging cable
- place the unit stabil in an upright position (ex. on a table)
- switch on the unit
- control the light indicator for the autonomy on the front side (with fully charged battery all red light have to be on)
- turning the knob of the regulator depressure clockwise for the maximum value
- close with a finger the patient tube (on the collect container)
- verify the maximum value of the depressure (-800mbar +/-10%) on the analogical gauge
- turning the knob of the regulator counter-clockwise and verify the decrease of the depressure on the gauge

At finish compare the results of this test with the value on the table below:

Test - phase	Result	Action to be taken with negative result
Switch on of the unit.	The indication lights for the autonomy and the pump motor switch in on condition (noise from the motor).	Pump failure and/or battery completely discharged. Recharging the battery and verify the depended light (green).
Verify of the autonomy indicator.	With battery fully charged all red lights have to be on.	Recharging immediately the unit.
Verify of the maximum vacuum.	Value range between 750 and 800 mbar (75kPa and 80kPa).	Check to be sure that the lid on the collect container is tight and vacuum connections are sure. Change the disposable liner.
Check of the regulation the vacuum.	Value range between minimum and maximum.	Check the vacuum connections and/or the regulator (counter-clockwise for minimum vacuum).



**Note: in case of negative results after the action above described send the unit to the authorized service center (chapter 6).**

**3.2 Collect container.**

The OB2012 suction unit is sold with a reusable 1000cc jar (code OB2012FA) or with reusable jar and disposable 1000cc liner (code OB2012 LINER). The OB2012 FA includes an external protection filter which prevents the contamination of the pneumatic circuit.

**3.2.1 Reusable autoclavable collect container.**

The OB2012FA includes a 1000cc reusable jar with integrated a mechanical shut-off valve. The jar is produced with a plastic material (polypropilene) and it is transparent with a graduated external printed range. The cover of the jar, allow inserting the protection filter on the VACUUM side. The filter is hydrofobic (PTFE), which doesn't allows the flowing back from the fluid and wet gas substances. The jar can be sterilized in an autoclave (max. pressure 2bar and maximum temperature 121°C) for maximum 15 minutes. T he maximum number of sterilization procedures is 30. When this limit is achieved the jar has to be replaced. During the jar's use must always be used in an upright position. If the vacuum during the use shuts down, empty contents immediately or replace the jar with a new one. To release the shut-off valve, switch off the unit; disconnect the patien tube (VACUUM writing over the lid). Do not use the suction unit without the jar and/or the protection filter. The next pictures show the parts of the jar, the tubing and the right connections.

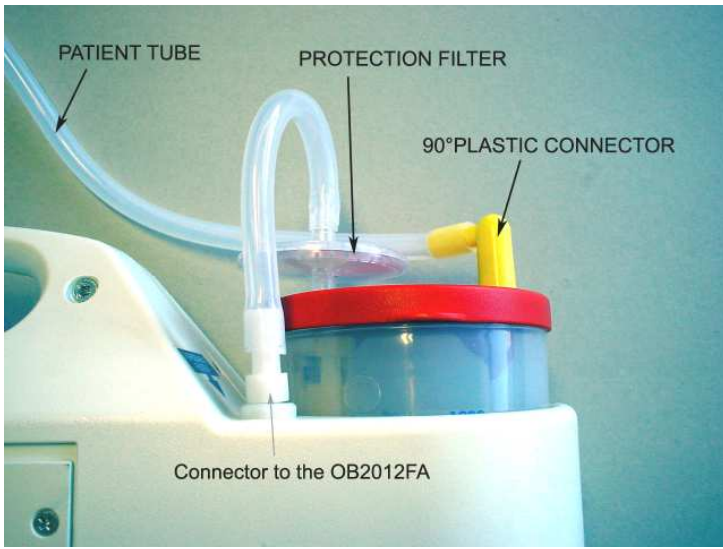


Fig. 3 – OB-J FA inserted in the OB2012 FA suction unit

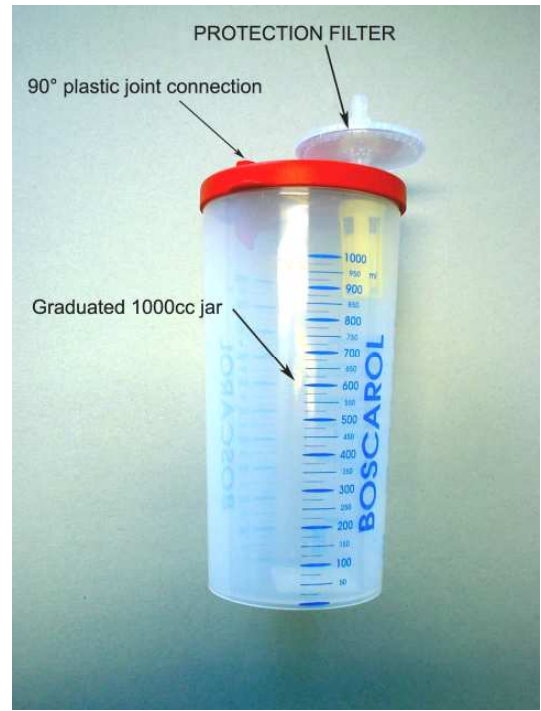
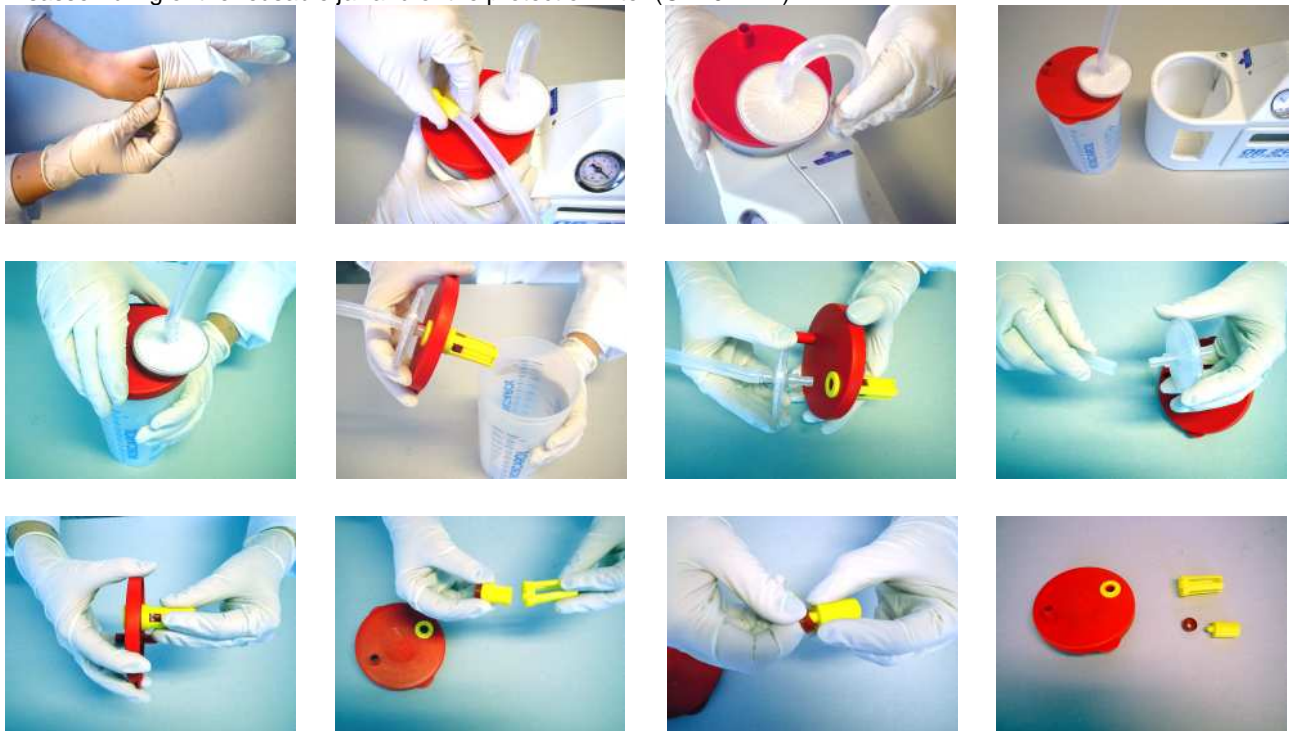


Fig. 4 OB-I FA Jar →

### 3.2.2 Protection filters.

To prevent fluid overflow on the unit, a special protection filter is used between the jar and the unit. The filter is produced with PTFE hydrofobic material, which blocks the way of fluid substances into the pneumatic circuit. Working together with the shut-off valve on the jar, the filter isolates the pneumatic suction pump from gas and fluid contaminated substances. When the filter is wet, it is not possible to suction and have to be changed immediately. The protection filter can not be sterilized or decontaminated. In the case of possible contamination, and/or colour change, change the filter immediately. Do not forget to connect the side with the green point on the jar side. Otherwise the filter doesn't function in the right operation, and doesn't protect the pneumatic circuit. **Do not use the suction unit without the protection filter!** On the next drawing, the sequence of the disassembling of the protection filter and of the jar.

Disassembling of the reusable jar and of the protection filter (OB2012FA):



Place all components on a stable and safety table. During the assembly phases, verify always the absence of damage on the components. The shut-off valve includes one special floating, which run on the plastic yellow rail. Verify



always the easy running of this floating. To extract the protection filter from the cover of the jar, operate to screw/unscrew the filter. This operation allows extracting of the filter without any damage!

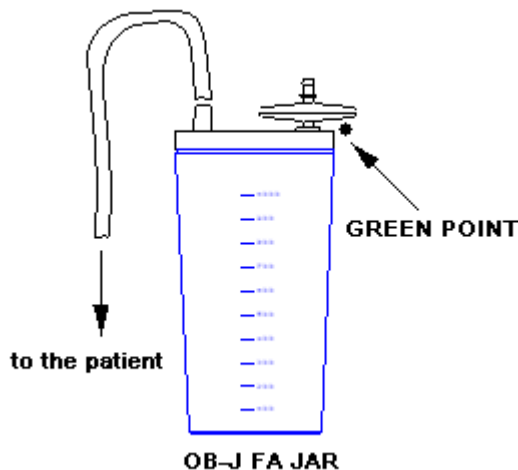


### 3.2.2.1 Use's caution of the protection filter.

If the suction unit is used on patient and/or in emergency situation, where is not possible to know the real risk of a possible contamination, **change always the filter after every use**. Otherwise when the clinic pathology of the patient is known, and/or doesn't exist the danger of a direct possible contamination, we recommende to change the filter after every duty, or at most every month even if the unit is not used.



**Note:** Control that the insertion of the protection filter is as illustrated on the draw 6. The wrong insertions break the filter, with the right possibility of a unit contamination.



*The side with the green point have to be connected on the jar side (writing VACUUM).*

fig.6

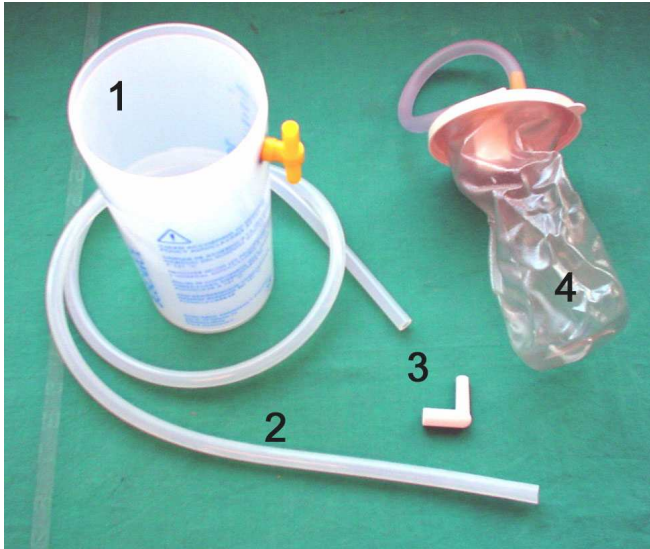
### 3.2.3 Reusable collect container with disposable liner (LINER).

The OB2012 LINER is sold with a transparent graduated 1000cc reusable jar and with a disposable liner. In the liner is integrated a special protection filter with double function: protection against the fluid overflow and shut off valve. In case of fluid substances go in contact with this filter, the suction is blocked, and the user has to change immediately the liner. The clean operation and the disinfection of the tubes are described on the 4 Chapter.



**Note:** Always verify before the use, the right insertion of the jar into the unit. The joint of the jar (yellow part) have to go in the special hole on the suction unit. Insert completely the liner in the jar and verify the good close of the lid. Otherwise the maximum depressure can not be reached.

The next pictures illustrates the composition of the reusable jar, with the disposable liner and the related connections.



1. Reusable 1000cc OB-J FM jar.
2. Silicone patient tube (length 130cm – 51,2in).
3. Disposable plastic connector to the patient tube. Tube (and to fix on the liner).
4. Disposable 1000cc ABBOTT liner with connection tube and protection filter integrated.



1. Disconnect the patient tube from the liner.
2. On the upright position extract the jar from the unit.
3. On the lid of the jar close the patient side with the disconnected tube.
4. Extract and dispose the liner form the jar, after replace with a new one.

For the reassembling proceed with the operation in the opposite direction.

### 3.3 Jankauer suction tube and Finger-tyt end-piece.

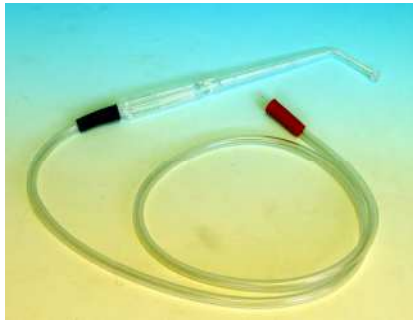
The device is soled with a special sterile suction probe, type Jankauer, connect to one plastic suction tube. The probe and the tube are disposable and must be changed after every suction. To facilitate the suction operation's, the probe is bended and allow the entrance on the mouth and on the respiratory way. Under customer request it is possible to order one suction set, which include one silicone tube (length 130cm – 51,1in) and one special sterile joint, called Finger-tyt. This joint allows the user to control the vacuum with a finger. When the hole is completely open, the vacuum reach the minimum value. Otherwise with hole completely closed the vacuum can reach the right value set on the unit. Refer to the chapter 4 for the change and replace operations.

### 3.4 Power supply and recharging of the unit.

The internal battery of the OB2012 suction unit can be recharged with the external cable or when the unit is fixed on the wall-bracket. The range of the external power source has to be from 12VDC to 15VDC (direct current). The right operation during the charging is confirmed by the front bicolour light (see fig.1). The connection with an external power source allows sparing the internal energy from the battery and at the same time recharges the battery at the maximum efficiency. The power of the external source have to be minimum 6A (working current). If needed by customer, it is possible to recharge the unit with a special adapter (optional) from the main supply (230VAC or 100VAC). Boscarol Emergency Systems has a large family of this adapter with the right plug every type of market (UK, Japan, USA, Europe, etc.). Refer to page 13 for the right codes.



**Do not use the suction unit on the patient during the recharging phase with the adapter connected to the main supply!**



Sterile Jankauer probe



Silicone patient tube and Finger-tyt



**Note: Do not connect the suction unit direct to the main supply! You have to be sure, of the value and type of the external power source. The external power source have to be protected with a security fuse for a minimum 10AT (delayed type). Never open the battery charger! It will work with main supply (100VAC or 230VAC) and it is very dangerous for the people (DANGER!)**

The maximum time for the recharging of the internal battery is about 15 hours. For reduce this time reconnect the suction unit to charging source after each use. The permanent connection of the unit on the vehicle electrical system doesn't damage the battery and/or the unit. A special electronic circuit controls the battery voltage and optimizes the efficiency of the battery. The contacts on the back side of the unit are performed for the connection on the wall-bracket. The contacts are maintenance free. Do not alterate these contacts. Do not introduce any parts in or between the contacts. In the case of alteration, break or misuse the contact can be changed only by the authorized people of the service centre.

#### 4. Maintenance and reuse.

##### 4.1 After use.

After the use switch off the device, disconnect the disposable parts (finger-tyt, catheters, liner, and etc.) and dispose it. Verify always the integrity of the device, the connection tubes and the controls on the front side. Control the chassis and verify the possible anomalies (chassis broken or alterate, knob and vacuum regulator, etc.). Proceed to the cleaning and disinfection of the unit as descript on the chapter 4.5, replace the disposable parts and recharge the device with the external cable or on the wall-bracket. Establish a daily checklist as descript on the 3.1.3 chapter.

##### 4.2 Reusable collect container.

Operations list for the clean and disinfection of the reusable jar:

- Put gloves and protection (if needed protective glasses and/or protection mask).
- Disconnect the jar from the unit.
- Disconnect all tubes from the jar and from the protection filter.
- Empty the jar and dispose the content, if necessary the filter, the disposable Finger-tyt, the suction catheter (refer to the local law in force for the dispose of this material).
- Disassemble the parts of the jar (lid, shut-off valve, ribbon, etc.).

Follow the indication on the draw of page 8 for the disassembling and reassembling of all parts. After the dispose of the disposable parts, put the other parts in cold water and good rinse. After this operation rinse the parts in hot water (temperature not higher of 60°C) with a soft not alco holic detergent. Good wash the parts and if necessary use soft brushes. At finish rinse the parts with hot water (30-40°C max.) and after dry the parts with a not abrasive to wel. Before the reassembling, control that all parts are cleaned, dry and not broken.

##### 4.2.1 Decontamination of the jar.

The jar can be disinfected with appropriate chemical substances not aggressive and not abrasive. Do not use any type of substances which contains alcohol and solvents. Do not use coloured disinfection substances, which may reduced the transparency of the jar. Never use pure disinfectant substances (only solution). The jar is on special material and it offers a good protection against the water and the humidity, but longer time immersion on the water may produce a lower chemical decomposition, which with the time reduce the resistance of mechanical and pressure crash. For the sterilization use only steam autoclaves, at the maximum temperature of 121°C (max. pressure 2bar) for a max. ti me of 15 minutes. The jar has to be inserted in the autoclave upside-down. At the finish of the sterile cycle, put the parts on a table and leave to cool at the ambient temperature. Before the reassembling, verify the integrity off all parts.



**CAUTION:**

- Do not put weight on the parts during the sterilization cycle.
- Observe the maximum limits for temperature, pressure e timing on the autoclave.
- Never exceed the value of 60°C during the wash and cleaning operations.
- All the cleaning, disinfection and sterilization operations have to be making from qualify people.
- Every 30 sterilization cycles, replace the jar with a new one. All tubes, joint and plastic connectors have to be replacing with the jar.
- At the finish of the reassembling of the jar, verify the good closing of the lid on the jar.

**4.2.2 Replacing of the protection filter.**

Disconnect the tube from the contemned filter, extract them from the cover and dispose it (refer to the local laws in force). Replace the new filter and reconnect the tube. Verify that the green point side on the filter have to be connected to the jar (writing VACUUM on the lid of the jar). The opposite connection causes the immediately break of the filter (draw 6).

**4.3 Reusable collect container with disposable Abbott® liner.**

After the use, extract the complete jar (with the liner) from the unit and put it security on a table. Put for the operation mask, glasses and gloves. Leave the liner from the jar in the upright position and disconnect the tube to the jar. Close with this tube the entrance with the writing VACUUM and dispose the liner. Replace the liner with a new one and reassembling the jar proceeding in the opposite direction of the disassembling.

**4.4 Disposing of the disposable contemned parts.**

Refer always to the local law and norms in force for the disposing of the contemned parts. Never store the used parts near the new and sterile parts.

**4.5 Cleaning of the device (chassis).**

To clean the chassis of the suction unit, use soft towel and/or a moist sponge (if need, use a soft not alcoholic detergent). To finish the cleaning operations, rinse the chassis only with a moist sponge and dry it with a soft dry towel.



**CAUTION:**

- Before to proceed on the cleaning operations, put out the suction unit from the wall-bracket or disconnect the external recharging cable.
- Never dip or immerse the suction unit into fluid substances and/or water.
- Do not use abrasive substances, alcohol, and/or solvents that can damage the plastic chassis of the unit and destroy the label.

**4.6 Recharging of the internal battery.**

The recharging of the internal battery is possible with the external charger cable, or if the unit is fixed on the wall-bracket (see chapter 3.4). An optional battery charger (only if needed by customers) permits the recharge of the battery from the main supply (see code on page 13). This unit can be used only indoor and can not be connected when the unit is used on the patient. The internal battery can not be changed from the user. Refer always to the authorized people from the service centre. The normal lifetime of the battery, if good recharged, is about 24/30 months. We suggest replacing battery every 30 months. The maximum time for the recharging (with a completely discharged battery) is about 15 following hours.

***Never use different battery charger as indicated on page 13!***

**4.7 Test on the battery capacity.**

For testing and verify the real capacity of the battery, and/or if presumed the bad quality of the battery, proceed with this operations list:

- Recharging the suction unit for at least 15 following hours.
- Set the maximum value of the vacuum.
- Running the suction unit on a free air cycle for at least 20 minutes.
- If the suction unit stops the running before this time period, the battery is damaged and need to be replaced. Send the unit to the service people (chapter 6).

**4.8 Security on the device.**

The OB2012 is performed with special electrical security for the fault conditions. Any of these securities are placed inside the unit and are not accessible from the user. Only the fuse for the protection of the battery circuit is accessible from the user. To replace this fuse, please remove with a planar screw-driver the head of the fuse holder on the back side of the unit. The value of this fuse is T15A (delayed function). The customers become from the Boscarol Emergency Systems 2 spare fuses pro each suction unit. Do not use other type of fuse. Replace the fuse and verify the good closed of the head on the home-fuse. If after the replacing of the fuse goes again broken, refer to the service people.

**4.9 Demolition and out of order.**

The OB2012 suction unit contains electrical parts and one sealed acid battery. In case of demolition and/or for out of service, do not put the unit in fire or water. Refer to the local law in force.

**5. Accessories and spare parts.**

**5.1 Accessoires liste and identification code.**

<b>Index Code</b>	<b>Description</b>
BSU100	Medical suction unit OB2012 LINER (white) with reusable jar and disposable 1000cc Abbott liner
BSU102	Medical suction unit OB2012 LINER (yellow) with reusable jar and disposable 1000cc Abbott liner
BSU150	Medical suction unit OB2012 FA (white) with reusable 1000cc jar
BSU152	Medical suction unit OB2012 FA (yellow) with reusable 1000cc jar
<b>User parts</b>	
ASP 72000	Protection filter type AIR SAFETY 60mm for the OB2012 FA (1 piece)
BSU730	Protection filter type AIR SAFETY 60mm for the OB2012 FA (set 5 pieces)
BSU732	Protection filter type AIR SAFETY 60mm for the OB2012 FA (set 15 pieces)
BSU734	Protection filter type AIR SAFETY 60mm for the OB2012 FA (set 40 pieces)
BSU700	Disposable 1000cc ABBOTT liner with tube and connector (set 10 pieces)
BSU702	Disposable 1000cc ABBOTT liner with tube and connector (set 30 pieces)
BSU704	Disposable 1000cc ABBOTT liner with tube and connector (set 50 pieces)
BSU502	Reusable 1000cc OB-J FM jar without disposable liner
BSU500	Reusable 1000cc OB-J FA autoclavable jar with connectors and protection filter
BSU770	Sterile rigid probe type Jankauer complete with plastic connections tube
BSU750	End-piece sterile disposable Finger-typ (set 5 pieces)
BSU752	End-piece sterile disposable Finger-typ (set 15 pieces)
BSU754	End-piece sterile disposable Finger-typ (set 50 pieces)
BSU780	Sterile suction catheter Ch.10 black
BSU782	Sterile suction catheter Ch.12 white
BSU784	Sterile suction catheter Ch.14 green
BSU786	Sterile suction catheter Ch.16 orange
BSU788	Sterile suction catheter Ch.18 red
BSU790	Sterile suction catheter Ch.20 yellow
<b>Spare parts</b>	
ZC42000/UK	Multilanguage user manual in English language
BSU902	Silicone patient tube length 130cm / 51,2inch (int.diam.6mm/ext.12mm)
BSU906	Connection tube between the protection filter and the suction unit with plastic joint
SPS66000	90° yellow plastic connector for the OB -J FA jar (on the cover) (5pieces)
SPS65000	Complete kit shut-off valve for the OB-J FA jar (3 pieces)
SPS67000	Complete "T" connector for the OB-J FM jar (3 pieces)
BSU852	External recharging cable with cigar lighter plug
<b>Accessories and optionals</b>	
BSU834	Carrying bag (with safety belt) red colour
BSU830	Carrying bag (with safety belt) blue colour
BSU800	Charging/Retention shelf mounting (Wall-bracket) OB20WB with recharging cable for the 12Vdc
BSU862	Battery charger 100/240VCA 50/60Hz Euro-plug
BSU866	Battery charger 100/240VCA 50/60Hz UK-plug
BSU868	Battery charger 100/240VCA 50/60Hz Japan-plug

**Note: the list above can be modified from the manufacturer without notice to the customers!**

**6. Service.**

There are no serviceable components within, refer to trained service people for service. Do not open the suction unit, do not modify any parts and/or the electronic circuit. Refer always to the manufacturer for the update spare list. Each intervent, even if not important for the right operations on the unit, declines immediately the guarantee and doesn't guarantee the technical requirements scheduled on the MDD 93/42/EEC and refer to the norm ISO 10079-1:1999.

**7. Trouble shooting.**

<b>Malfunction</b>	<b>Possible cause</b>	<b>Corrective action</b>
The suction unit doesn't work with the internal energy from the battery.	<ul style="list-style-type: none"> <li>Completely discharged battery.</li> <li>Battery damaged.</li> </ul>	<ul style="list-style-type: none"> <li>Charge the unit at least 24 following hours.</li> <li>Refer to the service people.</li> </ul>
The suction unit doesn't work if fixed on the wall bracket or with the external charger cable.	<ul style="list-style-type: none"> <li>Cable damaged.</li> <li>Damaged wall bracket and/or contacts on the suction unit.</li> <li>External power source failure (12/15VDC - min.6A).</li> </ul>	<ul style="list-style-type: none"> <li>Replace the cable.</li> <li>Replace the wall-bracket.</li> <li>Verify the external power source and the value of the voltage.</li> </ul>

The suction unit works only if fixed on the wall-bracket or with the external cable	<ul style="list-style-type: none"> <li>Battery fuses protection broken.</li> <li>Damaged battery.</li> </ul>	<ul style="list-style-type: none"> <li>Replace the fuse under the front cover (T15A).</li> <li>Refer to the service people.</li> </ul>
The battery charger doesn't work property.	<ul style="list-style-type: none"> <li>Battery charger damaged.</li> </ul>	<ul style="list-style-type: none"> <li>Verify the front light indicator. If it is on, but the battery not charged, refer please to the service people.</li> <li>Replace the battery charger.</li> </ul>
The suction unit works, but the indicator of the autonomy is off.	<ul style="list-style-type: none"> <li>Damaged internal circuit.</li> <li>Very low battery voltage.</li> </ul>	<ul style="list-style-type: none"> <li>Verify the indicator work if connected to the wall-bracket or to the external charger cable. If works recharging immediately the unit at least 24 following hours o refer to the service people.</li> <li>Recharge the suction unit at least 24 following hours.</li> </ul>
The autonomy of the suction unit is very short.	<ul style="list-style-type: none"> <li>Damaged battery.</li> <li>Internal recharging circuit failure.</li> </ul>	<ul style="list-style-type: none"> <li>Make the test descript on the chapter 4.7 of this manual and/or refer to the service people.</li> <li>Refer to the service people.</li> </ul>
The vacuum power on the patient side is very low and/or absent.	<ul style="list-style-type: none"> <li>Regulator vacuum completely open.</li> <li>Protection filter blocked and/or damaged.</li> <li>Connection tubes closed and/or folding and/or disconnected.</li> <li>Disposable liner not good inserted.</li> <li>Shut off valve blocked or damaged.</li> <li>Disposable liner full of fluid substances, protection filter blocked.</li> <li>Pump motor damaged.</li> </ul>	<ul style="list-style-type: none"> <li>Turning clockwise the regulator and verify the value of the vacuum on the gauge.</li> <li>Replace the filter.</li> <li>Replace and/or reconnect the tubes, verify the jar connections.</li> <li>Insert the liner on the jar.</li> <li>Replace the reusable jar.</li> <li>Empty the jar, and/or disconnect the tube from the jar for unblock the shut-off valve. The unit can work only on the upright position.</li> <li>Replace the disposable liner.</li> <li>Refer to the service people.</li> </ul>
It is impossible the regulation of the vacuum, which is always max., even if the jar is extracted.	<ul style="list-style-type: none"> <li>Fault on the internal pneumatic circuit.</li> </ul>	<ul style="list-style-type: none"> <li>Refer to the service people.</li> </ul>
High noise, low suction, high vibration.	<ul style="list-style-type: none"> <li>Internal pump damaged.</li> </ul>	<ul style="list-style-type: none"> <li>Refer to the service people.</li> </ul>

**Note: For others type of anomalies, and not indicated on the table above, refer always to the authorized service centre and/or to the manufacturer.**

## 8. Technical data and conformity to the international law.

### 8.1 Classification on the MDD 93/42/EEC.

ACTIVE MEDICAL SUCTION UNIT for the field use, transportable use and performed on the norm ISO10079:1-1999.

Classification for medical device:

**IIb**

Type of suction:

HIGH VACUUM-HIGH FLOW

Destination of use:

TEMPORARELY (max. continue use 60 minutes)

Type of power supply:

SELV (12/15VDC) - type BF - class II - performed on the IEC601-1:1988

Protection against the water (IEC529:1989)

IPX32d (Protected against the penetration of a solid matter with diameter over 2.5mm, protected against the water splash and against the penetration of metallic wiring)



***Do not use the suction unit in the presence of flammable and/or explosive substances!***



***Do not use the suction unit on the patient during the recharging phase (with the adapter connected to the main supply!)***

**8.2 Size and dimensions.**

Max dimensions: 350mm (width) x 120mm (depth) x 240mm (height).  
 13,77inch (width) x 4,72inch (depth) x 9,44inch (height).  
 Weight: 4,6Kg max. complete with all accessories.  
 Tolerance max on all measures: ±5%.

**8.3 Technical features of the device.**

Max vacuum power: 800mbar, 80kPa, 610mmHg ±10% on the range.  
 Vacuum Regulation: linear.  
 Regulation range of the vacuum: 30÷800mbar (0-80kPa).  
 Max flow rate: 30 LPM (litre pro minute) on free air ±10%.  
 Max autonomy with the maximum current-load: about 40 minutes ±10%.  
 Approximate max. noise : 70dB.  
 Precision of the analogical gauge: ±5%.  
 Precision of the battery voltage monitor: ±5%.

**8.4 Power supply.**

Working/recharging: 12÷15Vdc (Direct Current).  
 Max current load: 70W (max. current 6A).  
 Battery: internal, hermetically, sealed acid, rechargeable with 4Ah capacity.  
 Max time for recharging: 15 following hours.  
 External Fuse: T15A.  
 Internal Fuse: 1x F2,5A + 2x 7A RAY + 1x F0,5A (not accessible from the user).



Note: the external power source must supply at least 6ADC for the working and the recharging of the internal battery. With the battery charger from the main supply, the unit during the work uses the internal battery energy.

**8.5 Environmental and transport conditions.**

Working/recharging temperatures: 0° ÷ 50°C.  
 Suggested temperature for charging: 15° ÷ 30°C.  
 Storage temperatures: -25° ÷ 55°C (with original package).  
 Humidity /UR% for the work and the storage: 20 ÷ 80%, non condensed.  
 Range of atmospheric pressure: 700 ÷ 1060hPa (700/1060mbar).

**8.6 Technical data of the protection filter.**

Type AIR SAFETY 60mm, with PTFE filter and polypropylene hermetical chassis  
 Max pressure applicable: 1bar (100kPa)  
 Retention capacity:  
 • for water solution: up to 0,9bar (90kPa)  
 • nebulized parts: 0,1um 99,99%

**8.7 Simbology.**

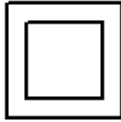
VCA = Voltage (alternate current)  
 VDC = Voltage (direct current)  
 °C degrees °C  
 bar unit for pressure and vacuum  
 kPa unit for pressure and vacuum  
 mmHg unit for pressure  
 Conversion formula: 1bar = 100kPa = 750mmHg



**DISPOSABLE PART**



**APPLIED PART  
TYPE BF**



**CLASS II**



**REFER TO THE  
USER MANUAL**



**0000**

**DEVICE PERFORMED ON THE MDD 93/42/EEC  
FOR DEVICE CLASSIFIED IIa AND IIb**



**023555**

Device conforms to the requirements of Directive  
72/245/EEC.



8.8 Declaration of conformity

## EEC Letter of Conformity on Medical Product



*We, the manufacturer:*

**BOSCAROL EMERGENCY SYSTEMS**  
V. G. Di Vittorio, 33 - 39100 BOLZANO – ITALY  
Tel. +39 0471 932893 – Fax. +39 0471 932331  
[www.boscarol.it](http://www.boscarol.it) - Email : [info@boscarol.it](mailto:info@boscarol.it)  
Certifies UNI EN ISO 9001 :2000  
Certificate N°9120.BOS1  
Certifies UNI EN ISO 13485 :1996  
Certificate N°9124.BOS2  
Emission: IMQ –ITALY – Notify body: 0051  
Annex II for Medical Suction Unit N°666/Med

*declare in sole responsibility the product (name):*

**MEDICAL SUCTION UNIT (UMDMS Code: 15016)**

*Type:*

**OB 2012 FA – OB 2012 LINER (SELV)**

*Code:*

**BSU 100 – BSU 102 – BSU 104 – BSU 106  
BSU 108 – BSU 110 – BSU 150 – BSU 152  
BSU 154 – BSU 156 – BSU 158 – BSU 160**

*being, in conformity with the Council Directive:  
and performed on the essential requirements:*

**93/42/EEC for Medical Devices  
Annex I – 93/42/EEC**

*Devices classification (MDD 93/42/EEC):*

**CLASS IIb**

*The device is also performed on the following  
Guidelines and/or norms:*

**MDD 93/42/EEC  
IEC 60601-1:1988 + Annexes  
EN ISO 10079-1:1999**

Bolzano, 30.09.2003

**Oscar Boscarol**  
President of the company

**Brazzo Daniele**  
Chief Engineering Department  
Quality Management Control

**8.9 Traceability of the product (MDD 93/42/CEE)**

DEVICE:	SERIAL NUMBER:
Date of purchasing:	from:
Actual property:	
Address:	
Post N°:	City/Town:
Phone:	Fax:
Date :	Signature:

***MONITORING OF THE BACK-INFORMATION THE PRODUCT***

Your observations, critics, suggestions, help the Boscarol Emergency Systems to get better the production activities, the products, the service office and the business way. Thank You!

Please fill in the form and send by fax to the number: +39 0471 932331 or by E-mail to the address: [production@boscarol.it](mailto:production@boscarol.it)

All data are only used to perform the request of the MDD 93/42/EEC and norm UNI CEI EN 46001 – ISO13485:1996.

**Italy:** BOSCAROL EMERGENCY SYSTEMS SRL  
V. G. Di Vittorio 33, 39100 BOLZANO  
Tel. +39 0471 932893  
Fax. +39 0471 932331

**Austria:** CHEMOMEDICA GMBH  
Wiipplingerstrasse 19  
Postfach 80, WIEN  
Tel. +43 1 53326660  
Fax. +43 1 535330658

**Belgio:** M.E.D.I.Q. EMERGENCY SYSTEMS  
Alexander Farneselaan 15  
B-9120 MELSELE  
Tel. +32 3 3142569  
Fax. +32 3 3149687

**Czech Republik:** DARTIN SPOOL S.R.O.  
Budejovicka 47/615  
14000 PRAHA  
Tel. +420241470361  
Fax. +420261216076  
Email : info@dartin.cz

**China:** MEDTEC INT'L Co, (HK) LTD  
Rm. 202,2/F, At Tower 180 Electric Rd  
North Point- HONG KONG  
Tel. +852 28875432  
Fax. +852 28070908

**France:** DIRECT MEDICAL  
84, Bis Route De Behobie - BP 424  
F-64700 HENDAYE  
Tel. +33 5 59480557  
Fax. +33 5 59480263

**Germany:** MEDITEACH GBR  
Frau Nauses 46  
D-64823 GROSS-UMSTADT  
Tel. +49 6078 75208  
Fax. +49 6078 75208

**Indonesia:** PT.DYTANDO ALDA ABADI  
JL.MERUYA ILIRRAYA  
11650 JAKARTA BARAT - INDONESIA  
Tel. +62 021 5863569 70  
Fax. +62 21 58491102

**Netherland:** KP MEDICAL BV  
Rumpsterweg 16A  
3981 AK BUNNIK  
The Netherlands  
Tel. +31 (0)30 2439114  
Fax. +31 (0)30 6668073

**Polonia:** PARAMEDICA POLSKA  
02-815 WARSZAWA, UL.ZOLNY 11  
Tel. +4822 6435920, 6433581  
Fax. +4822 6449359

**Japan:** NORMECA ASIA Co, LTD Tokyo  
Daito Shiko Blvd. 17/27  
1-3-11 KURAMAE, TAITO-KU  
Tel. +81 3 56873899  
Fax. +81 3 56873911

**Slovakia:** DARTIN S.R.O.  
Masarikova 16  
08001 PRESOV  
Tel. +421517734403  
Fax. +421517734403

**Spain:** EMERGENCIA 2000  
Velencia De D. Juan, 23  
E-28940 FUENLABRADA (MADRID)  
Tel. +34 91 6420009  
Fax. +34 91 6420359

**United Kingdom and Ireland:** MERLIN MEDICAL  
The Whitbread Centre  
RHYMNEY GWENT  
NP22 5XD UK  
Tel. +44 (0)1685 843676  
Fax. +44 (0)1685 843860

**New Zealand:** Frontier Medical  
North Shore Mail Centre P.O. Box 101-715  
AUCKLANDGWENT  
NP22 5XD UK  
Tel. +649 4145640  
Fax. +649 4145642



[www.boscarol.it](http://www.boscarol.it)