BOSCAROL IMMOBILISATION DEVICES

VACUUM MATTRESSES

OPERATING INSTRUCTIONS

Class I medical device compliant with European Medical Device Regulation 745/2017

CE

PRODUCED BY:

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Information on the manufacturer and the medical device:

- Oscar Boscarol applies a quality management system in accordance with international standards ISO 13485 and ISO 9001.
- Medical devices in the "Immobilization" category (in all their configurations) comply with European Regulation MDR 2017/745 and bear the CE marking in accordance with risk class I (see Annex VIII of the Regulation).
- The medical device meets the safety and performance requirements (GSPR) described in Annex I of European Regulation 2017/745

Information on these operating instructions:

- This document contains important information for the safe, effective and compliant use of the medical device.
- Use the information reported to train users and confirm their training
- This manual may not be modified (even partially). Only the manufacturer of the device may make changes
- These instructions should always accompany the device. We recommend using the electronic version and making it available on operators' PDAs, tablets and mobile phones.

These operating instructions apply to the following devices:

IMM120012	IMM120129	IMM120150	XIMM120131	XIM0425	XIMM120132	IMM120060	XIMM120014	XIMM120130
IMM120132	XIM0429							

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0. MEANING OF SYMBOLS AND PICTOGRAMS

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

	Danger: important safety information on the correct use of the vacuum mattress to prevent injury to the operator or patient and/or damage to the device itself
	Warnings: information requiring special attention
	Notes or information for proper use and to prevent damage to the device or others. Activate the correct prevention measures
1.	List of actions to be performed: follow them step by step
	These operating instructions
	Required maintenance service (contact the manufacturer and/or its authorised service centres)

0.2. Symbols used on the device and its accessories

	Only use the vacuum mattress within the specified temperature range. Using the vacuum mattress outside this range may reduce its functional performance and damage it.
	Limits of use in relation to humidity
	Read these operating instructions carefully and completely
	Indicates the need for the user to consult these operating instructions for information such as warnings and precautions that cannot be displayed on the medical device in question
CE	CE mark in accordance with European Regulation MDR 2017/745 for medical devices in class I
	Manufacturer
REF	Order number (device code)
	Please read the operating instructions in other languages available on the indicated website
MD	Indicates that the vacuum mattress is a medical device
	Example of medical device UDI-DI and UDI-PI code: (01) Identification of manufacturer and associated device (11) Date of production (20) Product variant (10) Lot number

1. INTENDED USE

Device name	Boscarol vacuum mattress
Primary use	A medical device intended for the immobilisation and transport of polytraumatised patients or patients with different kinds of injuries.
Other uses	It can also be used for patient's evacuations in cases of emergency or public calamity. Boscarol vacuum mattresses can also be used in the veterinary sector.
Medical purpose	Immobilization and stabilisation of the patient before transport

Part of application in the human body	Entire human body (external surface of the body)
Type of patients	Children and adults of both sexes from 20 kg Baby vacuum mattress: maximum load capacity 18 kg
Time of application on the same patient	Short-term use (maximum 30 days of consecutive use)
Information on use	• The vacuum mattress can be used on all types of patients (except those weighing less than 5 kg) following the appropriate medical immobilisation technique. • It can be used in conjunction with other lifting and transport systems such as scoop stretchers or other suitable systems. • The immobilisation and transport of polytraumatised patients or those suspected of being polytraumatised should always be carried out by professional rescuers who are trained and familiar with specific patient lifting and transport technologies.
Compliance with EN 1865-1	All Boscarol vacuum mattresses (except some models in extra-large sizes or for paediatric use) comply with the European standard EN 1865-1. Devices that are not fully compliant with the standard do not bear references to the standard on the label and accompanying documents

2. WARNINGS, PRECAUTIONS AND IMPORTANT INFORMATION

Read carefully

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

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

LATEX	Boscarol vacuum mattresses are designed and manufactured without the use of latex. The materials used are latex-free, however, it cannot be excluded that latex or traces of it may have come into contact during the entire production chain
DEVICE CONTAMINATE	Warning about device contamination: Immobilization of the patient on the vacuum mattress may be a source of contamination. Therefore, the device must be cleaned and disinfected after each use to eliminate any residual risk. Follow the instructions in this user manual. If you have any doubts before sending a device for repair, please contact Boscarol's technical service department by sending an email to info@boscarol.it or by calling +39 0471 932893

3. IMPORTANT INFORMATION TO KNOW BEFORE USE

The vacuum mattress has been designed and tested to comply with the requirements imposed by the Medical Device Regulation 745/2017. The carrying sheet is a medical device of risk class I according to Annex VIII of the Regulation.

	If the user or patient becomes aware of a danger in use, a side effect, an accident caused by the device or a critical issue (operational and design) not covered in these instructions for use, he must immediately report this to the manufacturer at the following e-mail address: raq@boscarol.it
PERIODIC SAFETY INSPECTION	**Preventive maintenance and periodic safety inspection:** The vacuum mattress should be checked periodically (a full functional check at least once a week is recommended). There is no periodic safety inspection on the device In the event of a fault, please contact the manufacturer

LIFETIME	Boscarol vacuum devices all have a lifetime of **8 years** from the date of manufacture if stored and used according to these instructions for use
Responsibility of operators/users	• **Take precautions if the device comes into direct contact with the patient's body and always place a sterile sheet over it (biocompatibility).** • The Boscarol vacuum mattress is designed for emergency medical service and must therefore be ready for use at any time and in any situation. • Immediately replace any damaged, altered or missing components/parts and/or for which a vacuum mattress malfunction is suspected. Always replace such parts with original spare parts. The vacuum mattress should be stored in a place that is inaccessible to children. • Dispose of packaging in accordance with current regulations and ensure that it is out of the reach of children. • Tampering with, altering or modifying the device is not permitted without the manufacturer's consent. • Operators must be trained and aware of the legal regulations and provisions regarding safety at work.
Attention	• The device cannot be considered as floating and, although it can be used in water, auxiliary measures must be taken to avoid sinking. • The device cannot be winched without the aid of specific devices approved for the purpose • The device is suitable for mounting on stretchers and inside ambulances • Every 30 minutes check the vacuum in the mattress and restore it if necessary. • During transport, the patient must always be secured to the mattress and in turn to the stretcher or device attached in the vehicle.

4. CONTRAINDICATIONS (DO NOT USE FOR)

CONTRAINDICATIONS	• Direct contact of the patient's skin (injured or intact) with the device (**always place a sterile sheet in between**) • Infants weighing less than 5 kg • Patients suffering from disorders such as claustrophobia or the like • Very large or very small patients who, due to their size, cannot be correctly and completely immobilised

5. SIDE EFFECTS (POSSIBLE DURING USE)

SIDE EFFECTS	• Skin irritation and reactivity phenomena due to direct contact with PVC • Tachycardia caused by stress • Suffocation (due to immobilisation) • Phenomena related to claustrophobia and similar disorders

6. BOSCAROL PROFI AND SDM VACUUM MATTRESSES

After receiving the device, make sure that all parts are present (in case of sets). The vacuum mattress can be equipped with a manual suction pump (sets are available on request). The pump is not to be considered as a "medical device".

Available vacuum mattress types according to EN 1865-1

IMM120012 SDM vacuum mattress
IMM120129 PROFI EVOLUTION Vacuum mattress
IMM120150 PROFI Vacuum mattress

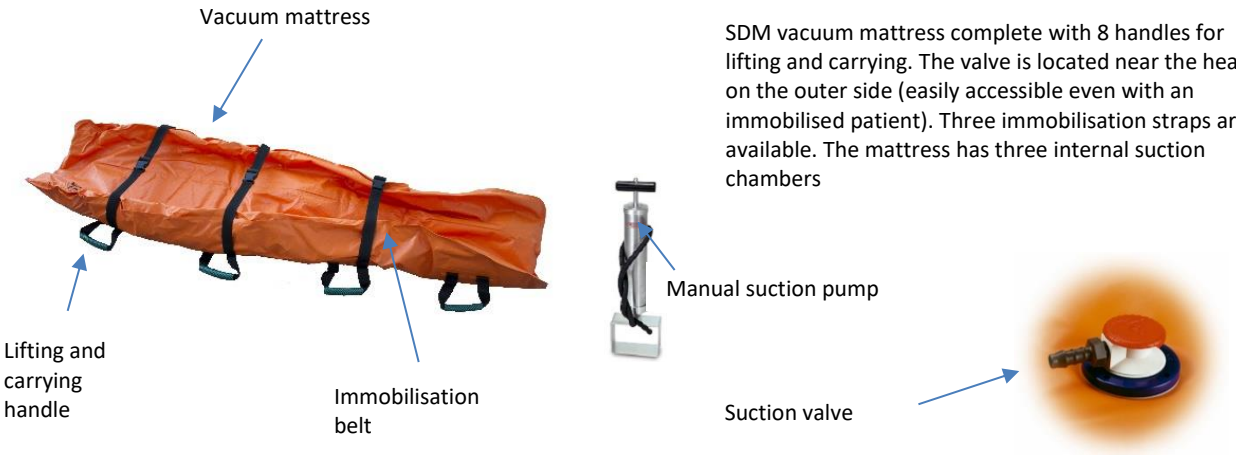
Depending on the chosen configuration, the device can be equipped with the following accessories:

- Manual suction pump (complying with the requirements of EN 1865-1)
- Storage and transport bag

7. COMPOSITION OF DEVICES

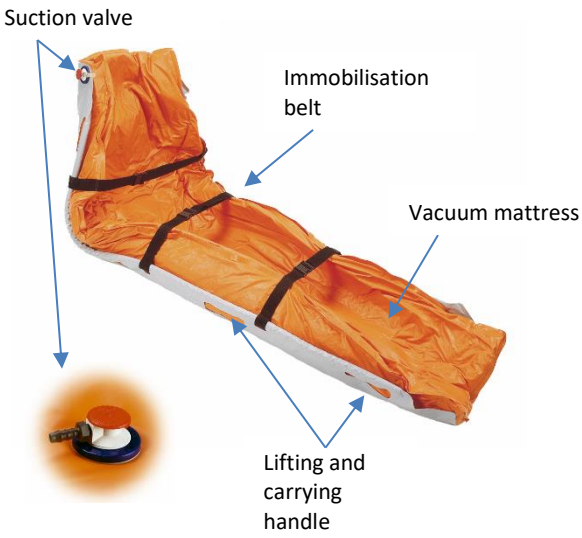
PROFI, PROFI EVOLUTION and SDM vacuum mattresses are made from two or more sheets of PVC, cut to size and welded together using a high-frequency process that guarantees stability and safety over time.
The mattress consists of three internal chambers (obtained by a specific process) to better distribute the polystyrene microspheres which, through suction, make it possible to shape it to the patient's anatomical form.
A plastic (ABS) valve with no metal elements (which would compromise the radio transparency and translucency of the device) allows the air contained in the mattress to be sucked in and closes the inlet when the required vacuum level is reached.

SDM VACUUM MATTRESS



SDM vacuum mattress complete with 8 handles for lifting and carrying. The valve is located near the head on the outer side (easily accessible even with an immobilised patient). Three immobilisation straps are available. The mattress has three internal suction chambers

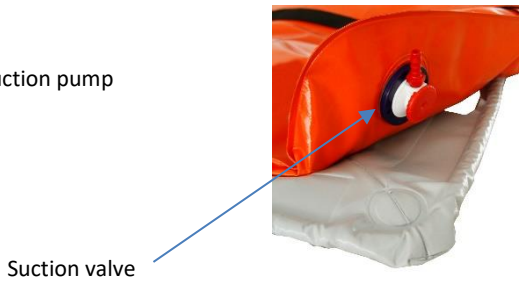
PROFI VACUUM MATTRESS



Vacuum mattress PROFI complete with 8 handles for lifting and carrying. The valve is located close to the head on the outer side (easily accessible even with an immobilized patient). 3 immobilisation straps are available.
The mattress incorporates a semi-rigid support in which the 8 handles are located. The mattress has three internal suction chambers

PROFI EVOLUTION VACUUM MATTRESS

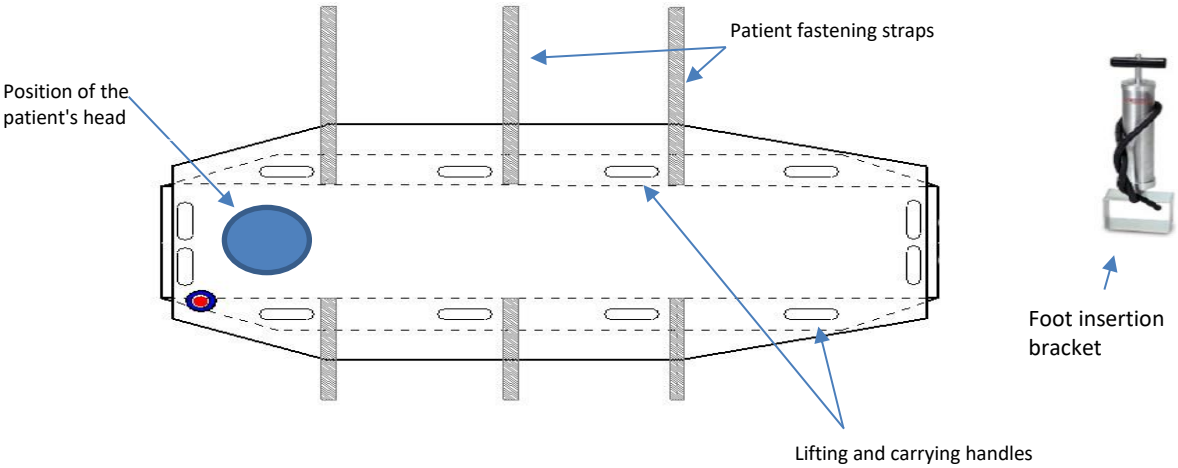
Vacuum mattress PROFI complete with 8 handles for lifting and carrying. The valve is located close to the head on the outer side (easily accessible even with an immobilized patient). 3 immobilisation straps are available.
The mattress incorporates a semi-rigid support in which the 8 handles are located. The mattress has three internal suction chambers. Two specific holes are provided for attaching the mattress to a metal stretcher used in air rescue.



How to use the device

Carefully follow the instructions below. Remember to use all known techniques to achieve correct immobilisation and to facilitate transport. The user manual must be read and attached to the device at all times. For this reason, it should be kept (also in digital format on your smartphone) near or with the device. The device should be checked for functional integrity before use.

1. Place the mattress on a flat, stable surface at least as large as the mattress.
2. Evenly distribute the microspheres contained in the three chambers by hand.
3. Open the suction valve by turning it counterclockwise by 90°.
4. Connect the pump suction pipe to the valve connection
5. Place the patient on the mattress after placing a sterile sheet in between. The head must be on the side where the valve is located.

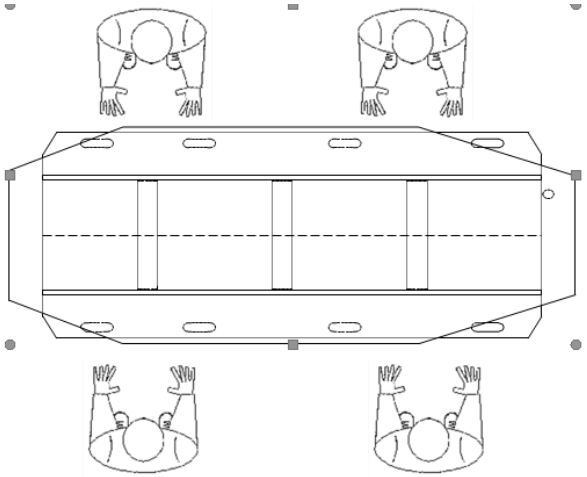


6. Slide the rescuer's foot into the pump bracket provided for this purpose.
7. Start sucking air from the mattress
8. Conforming the mattress to the patient's body by wrapping it around during suction operations
9. When the correct suction level has been reached, close the valve in the opposite direction before disconnecting the pump.
10. Close the fastening straps and make sure the mattress is completely rigid
11. Always check the patient's vital condition

12. Proper restraint of the patient on the mattress prevents it from flexing during lifting. The mattress should remain rigid

Lifting and carrying a patient requires care and attention. Never overestimate your own strength and, if necessary, always ask for help from other rescuers. The illustration below shows the correct way to lift a patient safely.

The PROFI EVOLUTION mattress also has two handles on the upper short side and two on the lower short side. The two holes in this mattress allow for a more secure attachment to the stretchers used in air rescue helicopters.



8. REUSE OF BOSCAROL VACUUM MATTRESSES

The medical device must be cleaned and disinfected after each use. This is even more important if the patient's pathological condition is unknown and direct contamination may be present.

The user must always take protective measures and means to protect his own safety.

The vacuum mattress can be washed with water jets that must not exceed 40°C.

Attention	Always close the suction valve before cleaning and disinfecting
Pressure washers	Do not use high-pressure washing machines as they may damage the surface layers of the PVC fabric.
Attention	Never under-inflate the mattress! It may be irreparably damaged

After removing all substances from the mattress with water, use a non-abrasive sponge to remove any encrustations. Remove any traces of blood and/or organic matter left by the patient before disinfecting. Disinfect the mattress (the entire surface) with products suitable for this purpose (test on one side of the device to ensure no damage). Do not use bleach and iron brushes, steel wool or blades of any kind to remove scale. Coloured disinfectants may permanently stain the surfaces of the device itself.

Before storing the device, make sure it is completely dry to prevent mould from forming on the PVC.

9. STORAGE OF THE DEVICE

Boscarol vacuum mattresses can be used and stored in the temperature range -30 to +70 °C. At very low or too high values the material in contact with the patient may become extremely cold or hot, leading to complications for the patient (hypothermia and hyperthermia).

Take all necessary measures to contain these effects and limit them as much as possible.

The mattress must be stored clean and dry. It should be inspected periodically to avoid mould, damage due to folding and leakage at welds. If the mattress is stored in a very humid environment, it should be checked every month by stretching and airing it in order to avoid the formation of mould or other substances that could degrade the device.

10. DEMOLITION OF THE VACUUM MATTRESS

The device can be dismantled according to national and local regulations for the disposal of PVC-based substances, ABS (the intake valve) and polystyrene (internal microspheres). All materials are REACH compliant and contain no hazardous substances.

11. TECHNICAL SERVICE AND SPARE PARTS

In the event of a functional failure or if you need additional information regarding reuse and/or storage and transport, please contact the manufacturer by phone at +39 0471 932893 or by sending an email to info@boscarol.it.

11.1. Solving common problems

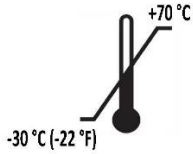
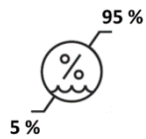
Malfunctioning	Possible cause	Solution
The mattress does not compress	• ON-OFF valve closed • Pump damaged • Damaged mattress	• Open the valve by turning 90° anticlockwise (follow the embossed instructions on the valve) • The pump must be able to suck by operating it. If not, replace it. The pump must be a suction pump • Contact the manufacturer
The suction ON-OFF valve is blocked	• Damaged valve • Damaged valve seat	• Contact the manufacturer • Replacing the mattress
Boscarol suction pump does not work	• Damage to the plunger • Damaged internal gasket	• Contact the manufacturer • Contact the manufacturer

12. TECHNICAL DATA AND CONFORMITYFOR BOSCAROL VACUUM MATTRESSES

Classification of the medical device (in accordance with MDR 2017/745)	I
Basic UDI number (in conformity with MDR 2017/745)	805240088IMMGK
Technical specifications	3 independent interior rooms
Degree of protection against ingress of liquids and solids (IEC 529):	IP67 (with closed valve)
Risk assessment (technical documentation)	ISO 14971:2019
Application of usability	IEC 62366-1:2015
Service life	8 years from date of manufacture
Maximum load on the PROFI, SDM and PROFI EVOLUTION device	150 kg
Maximum load on PROFI XL	200 kg
Maximum load on BABY device	18 Kg

Vacuum mattress dimensions		
PROFI vacuum mattress	205x95x8h cm	Device weight: 10 kg
SDM vacuum mattress	200x80x6h cm	Device weight: 7 kg
PROFI EVOLUTION vacuum mattress	205x95x10h cm	Device weight: 8.2 kg
BABY vacuum mattress	87x65x4h cm	Device weight: 1.6 kg
PROFI XL vacuum mattress	210x100x10h cm	Device weight: 14 kg
Manual suction pump with bracket	6x13x55h cm	Device loss: 1.4 kg

Compliance with EN 1865-1	
PROFI vacuum mattress	The device complies with the standard requirements
SDM vacuum mattress	The device complies with the standard requirements
PROFI EVOLUTION vacuum mattress	The device complies with the standard requirements
BABY vacuum mattress	Does not comply with the standard
PROFI XL vacuum mattress	Does not comply with the standard
Manual suction pump with bracket	The pump complies with the standard requirements

Conditions of storage and use		
	Temperature range for transport, use and storage	-30 to 70° C (-22 to 158 °F)
	Humidity range for transport, use and storage	5-95 % R.H. n.c.

	For further technical information or information on the use and storage of the device, please contact the manufacturer (info@boscarol.it).
Declaration of conformity	
	The declaration of conformity is kept by the manufacturer together with all traceability data applicable to the materials and production processes. You can request a copy from the manufacturer by sending an email to info@boscarol.it.

13. WARRANTY

Oscar Boscarol guarantees the vacuum mattress (all models) for a period of 1 year from the date of purchase from the original distributor or manufacturer. The company guarantees that the device is free from defective materials and/or defects due to manufacturing processes.

The guarantee does not cover: normal wear and tear of the device or the suction pump, discolouration and any other cosmetic irregularities that do not affect the operation of the unit.

If, during the entire warranty period of 1 year, the product is found to be defective it must be sent to Oscar Boscarol S.r.l. (Ltd) with a note describing the defect. Oscar Boscarol S.r.l. (Ltd) will repair or replace at its discretion the defective parts and/or the whole unit. All shipping costs are the responsibility of the customer.

Warranty conditions:

To benefit from the guarantee, the registration form in the product documentation must be completed and returned by post, fax or e-mail to the following address:

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

Fax: +39 0257760142 - E-mail: info@boscarol.it

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

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

In terms of safety, reliability and functionality of the vacuum mattress, Oscar Boscarol S.r.l. can only be held liable if:

1. all technical operations, repairs, modifications and inspections were carried out by Oscar Boscarol S.r.l. or an authorised service centre
2. the device has been and is being used correctly, strictly following the instructions given in these operating instructions

With reference to what is described in these warranty conditions, Oscar Boscarol S.r.l. cannot be held responsible for accidental direct or indirect damages, if modifications, repairs, unauthorised technical interventions have been carried out on the device or any of its parts have been damaged by accident or improper use. There is no express or limited guarantee of merchantability, suitability or any other kind on the carrying sheet other than those described in this user manual.

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