



PRS

REF VMOP1004X03

Brand name / Basic UDI-DI	MedVac / 9010710MedVac7J
UDI-DI/GTIN	9010710100809



Issue 03 / 04-10-2021 MG



KOHLBRAT & BUNZ Ltd.
Loretostrasse 4-8
A-5550 Radstadt
Tel: +43-6452-7193-0
office@kohlbrat-bunz.com
www.redvac.com - www.kohlbrat-bunz.com



Medical Device

We are glad that you have chosen our product.

MedVac = Optimal solutions for storage in the OR area.

The MedVac series from Kohlbrat&Bunz stands for highest quality and latest technology. Surgeries and invasive examination procedures require precise patient positioning to provide the surgeon with optimal access to the surgical area. Through the additional use of pressure-relieving materials, position-related damage can be avoided.

Our MEDVAC products have been designed together with experts and are constantly being further developed. MedVac products are made of biocompatible TPU material and are therefore designed for easy and quick cleaning / disinfection.

To take full advantage of the product's performance and to ensure that you get many years of enjoyment from your patient restraint system (hereinafter referred to as PRS), please read these operating instructions carefully before use and operate the PRS according to the instructions.

The operational safety and the function of the PRS can only be guaranteed if both the general safety and accident prevention regulations of the legislator and the safety instructions in the operating manual are observed.

We accept no liability for damage caused by improper use or incorrect operation.

Please ensure that all persons who operate or use the PRS have read and understood the operating instructions.

Keep the operating instructions in a safe place so that you can refer to them at any time if necessary.

The PRS (Patient Restraint System) is a medical device that may only be used by trained medical personnel who have received regular training on the product.


The type of application is based on the current, generally accepted medical guidelines and recommendations of the relevant professional societies.

Table of contents

1. scope of delivery	4
2. features	6
3. purpose.....	6
4. safety	7
4.1 Operating instructions.....	7
4.2 Accessories	7
4.3 Combination with other products.....	7
4.4 Safety instructions.....	7
4.5 Liability for function and damage.....	7
5. areas of application	7
5.1 Unpacking / transport.	7
5.2 Installation / storage.	8
6 Commissioning	8
6.1 Vacuum valve variants.....	8
6.2 Suction by external device	9
6.3 Setting up / preparing the PRS system.....	10
7.0 Operation	12
8. cleaning	15
9. warranty	15
10. spare parts and accessories	15
11. repairs.....	15
12. EG/MDR - DECLARATION OF CONFORMITY	16

1.Scope of delivery



No	Image	Art. No.
2		9300X03 2 piece
3		9300X19 2 piece
4		9300X02 4 piece
5		9300X08 2 piece
6		9047X21 2 piece
7		VMOP KLOBE Hooks x 2 pieces Left x 1 piece Right x 1 piece
8		OPK01X02 1 piece
9		OPK03X01 2 piece

2.Features

The **PRS** patient restraint system offers you the highest quality and sophisticated technology. Great attention

has been paid to the user-friendliness and precise manufacturing of the product.

The **PRS** consists of a multi-chamber system made of latex-free materials.

A 3D knitted fabric in the shoulder area ensures additional pressure relief in extreme head low positions.

The two shoulder fixations provide redundant fixation/securing of the patient in the PRS system in the event of unexpected damage to the main chamber and the resulting loss of vacuum.

The **PRS** is used for fixation / positioning of patients in the intraoperative setting.

Positioning aids used to date (shoulder supports, side supports, wedge pads, etc.) are limited in their use in extremely head-down positioning (Trendelenburg positioning) due to their punctual support.

The whole system is designed to be ready for immediate operation without prefabrication of the filling material. No complex preparation is required with this product.

The **PRS** is designed for a patient weight from **50kg to MAXIMUM 120kg!**



3. purpose

The **PRS** is used for fixation / positioning of patients in the intraoperative setting.

Detail Definition:

Vacuum mattress for positioning in the areas such as. e.g. general and visceral surgery, gynecological, urological surgery), which are performed

in minimally invasive techniques (laparoscopy, single incision surgery).


4. security

4.1 Operating instructions

Observe the operating instructions. Any commissioning and handling of the system requires precise knowledge of and compliance with these operating instructions.

The PRS is intended only for the use described.

In these operating instructions, particularly important remarks are highlighted as follows:

	<p>Warning. This is a warning that indicates risk situations and dangers. Disregarding this warning can sometimes lead to life-threatening situations. It is essential to heed these warnings.</p>
-----------------------------------------------------------------------------------	-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

4.2 Accessories

The accessories approved by the manufacturer are included in the scope of delivery of the **PRS**. A detailed overview can be found at the beginning of the operating instructions.

4.3 Combination with other products

You must also follow the manufacturer's instructions for use for the absorbent, pressure-relieving insert to be inserted and keep it available accordingly.


4.4 Safety instructions

The **PRS** is designed to ensure the greatest possible safety for the patient when handled correctly and used properly.

4.5 Liability for function and damage

The liability for the function of the **PRS** is in any case transferred to the owner or operator, as far as the product is improperly maintained, repaired or changed by persons who do not belong to an authorized specialist company, or if a handling or use takes place which does not correspond to the intended use.

The **PRS** must be used in accordance with these operating instructions. Kohlbrat & Bunz is not liable for any damage caused by non-observance of the above instructions. Warranty and liability conditions of the sales and delivery conditions of Kohlbrat & Bunz are not extended by the above instructions.

	<p>Ensure that the operating instructions are accessible at all times and that they are read and understood.</p>
-------------------------------------------------------------------------------------	-------------------------------------------------------------------------------------------------------------------------

5. areas of application

The PRS is a mattress, vacuum / vacuum stabilized cushion within the definition of a medical device.

It is a multi-chamber product for patient fixation in extreme head - low positioning in the medical field.

Only use the **PRS** in the defined intraoperative application area.

5.1 Unpacking / transport.

Remove the **PRS** from the supplied bag and place the product on a firm and level surface. Check that the scope of delivery is complete.

5.2 Installation / Storage.

The **PRS** can be used on any commercially available operating table. To ensure maximum compatibility, the PRS is supplied with various "clamps" (mounting elements) for attaching the **PRS** via the "system rail". Always use the **PRS** in such a way that the working area and the ability to operate are not restricted.

Do not bend the **PRS** when not in use for a long time and protect it from moisture and dust.

6. commissioning

Before starting up the **PRS**, check that the system is tight by aspirating the air. After this test is positive (**PRS** remains hard), open the valve briefly and close it again.

To do this, observe the following procedure for the vacuum valve:

The vacuum valve is turned clockwise - closed (turn to the right)

To open the **PRS** system

Basic position - turn valve counterclockwise (turn to the left)

6.1 Vacuum valve variants

Valve variant 1:



Valve variant 2:



6.2 Suction by external device

An external suction device is required to extract the air or to create the vacuum in the **PRS** system. Suction devices that can generate a vacuum of at least 0.8 bar are suitable for this purpose, e.g. OP suction devices.

If you do not have such a device at your disposal, you will need a manual suction pump, which is available from us separately as an accessory.



Fig. of an exemplary OP suction cup

To establish the connection between the suction device and the **PRS** system, you need the commercially available connection hoses. Depending on the type, these can either be connected directly to the valve or via an adapter, which is also available as an accessory.



Hose directly connected



Hose connected via adapter

6.3 Setting up / preparing the PRS system



Place the **PRS** on the operating table with the outside (gray side) facing down.
 Position the **PRS** so that the recesses of the **PRS** and those of the table are aligned.
 The anti-slip strips attached to the underside minimize slippage of the **PRS**.
 The strips applied to the top prevent the warming system from slipping away.

Straps 1 to 4 prevent the **PRS** from slipping off and are hooked onto the standard rails or fixed in place using Klobe. (see accessories)

<p>Directly connected with table</p>	<p>Connected by means of a clamp hook</p>
<p>By means of system rail and Klobe</p>	

The straps are tensioned diagonally, this ensures that the **PRS** remains centered in position.
 The head shell is placed on the gray tab with the anti-slip strips (marking field for weight) and adjusted in height to the patient by means of segment padding.

Optionally, it is recommended to use the back pad with the designation OPK1 (component 8 in the overview) for cachectic patients.



7.0 Operation

Now place a pressure-relieving pad on the **PRS**.

Use the current list to find the supports that have been approved by us or tested for the **PRS**.



**Only use an approved support according to the accessories list.
Please consult us if anything is unclear.**

The patient can now be placed on the **PRS**, which is fixed to the operating table and provided with an absorbent, pressure-relieving pad. It is important to ensure that the parts in the shoulder area are fold-free.

For details on the exact handling of the carpet pad, please refer to the corresponding instructions.



Application example

The patient belts are pushed onto the mushroom holders of the **PRS** on one side and locked in place.



These are subsequently used to adapt the **PRS** to the patient and save personnel.

When the patient is released by the anesthesia team, all access lines and cables are routed caudally and passed between the inserted pad and the **PRS** cranially to the shoulder elements.

The patient straps are now placed over the patient, who is covered with a sheet, on the opposite side of the **PRS**, where they are also hooked onto the mushroom holders and locked in place.

The patient straps are taken at the free ends and tightened! If necessary, the left and right side panels are now folded outward and secured with the patient straps. The valve in the right shoulder section must be closed! Insert the appropriate hose into the valve (attachment optional), from the head end press the shoulder elements firmly with both hands along the neck in the direction of the head and at the same time suck the air out of the **PRS with** a suitable device.



**Now bring the PRS system to negative pressure / vacuum
min. 800 mmHg is recommended!**

When this value is reached, remove the hose from the valve and tighten the belts again!



**Belts 2 and 3 belong to the securing system, which secure the patient for a short time in the event of a loss of vacuum. Check the positioning of all belts, adjust if necessary and tighten!
Patient belts must now be removed!**

Shoulder fixation in shape:

Shape the pillow, close the straps and suck the air out of the pillow as described above. Repeat the step for the left and right sides respectively.

These two fixations additionally secure the patient in case of possible damage to the system (loss of vacuum).



Before the planned intervention, or before sterile draping, the patient must be brought into the final position in order to be able to carry out any positional changes.

After the end of the operation, the patient belts are loosely passed over the patient to the other side and hooked onto the mushroom heads, after which the valve can be opened. It is recommended to allow only enough air into the **PRS** so that it remains dimensionally stable but not hard.

8. cleaning

Approved surface disinfectants as of 12.2016.

Please observe the current list of approved disinfectants. The use of non-approved agents may lead to discoloration or even damage to the TPU material.

Possible antiseptics for purification:

Descogen liquid,
Incidin Pro,
Incidin Active ,
TPH protect,
Microzide AF liquid,
Acrylic Des
Perform.

Only lint-free cloths may be used to clean the anti-slip strips!

9. warranty

The warranty period of our products is 12 months. If a defect occurs in your product within this warranty period, contact our service staff directly. The **PRS** may only be operated in a technically perfect condition. In the event of defects that could endanger employees or third parties, the **PRS may** only be used again after it has been repaired. Damage caused by improper use, external mechanical influences, transport damage or unauthorized intervention by unauthorized persons is not covered by this warranty.

10. spare parts and accessories

On the basis of the list of the scope of delivery under point 1, you will find all articles / components which can be obtained from us as spare parts.

11. repairs

Repair kits including instructions are available for repairing minor damage (pinholes, etc.). After the repair has been carried out, the **PRS** must be checked for leaks again; if this is the case, the **PRS** may be used again.

If more extensive repairs are required, these may only be carried out by the manufacturer or a person authorized by him.

12. EG/MDR - DECLARATION OF CONFORMITY