

Instructions for use

2023-03-21

Standard mattresses

PRIMA BM

PRIMA 6

Optimal M3

Optimal BOB

Optimal Junior

Instructions for use item number: 95-001102-EN0000



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WARNINGS AND SAFETY PRECAUTIONS

Read all instructions before use or repair

WARNING! To minimize the risk of fire, personal injury and equipment/property damage, adhere to the following instructions:

- 1 The product must only be used for its intended purpose as described in this manual. The product may not be combined, assembled or repaired with other parts, accessories or spare parts other than those described in this manual or other documentation from Care of Sweden.
- 2 DO NOT USE in the vicinity of or in contact with fire sources/hot surfaces, such as fire, burning cigarettes or hot lamps. Although the product has undergone fire testing, it could become damaged if it comes into contact with fire sources.
- 3 Position and use the product in a manner that prevents it from becoming trapped or damaged. NOTE: Be particularly aware of trapping damage when using bed rails.
- 4 Always make sure the mattress has the right size.
- 5 The mattresses are protected with a hygiene cover. Avoid using multiple hygiene covers as this can affect the vapor permeability of the mattress.
- 6 The hygiene cover does not allow liquid or air to penetrate but is vapor permeable. Make sure that the patient is positioned correctly to avoid the risk of suffocation. Monitor a patient with special needs continuously.
- 7 Prevent damage to the hygiene cover from sharp objects.
- 8 Mattresses cover is supplied with handles on the long sides, these handles are only to be used lifting and moving the mattress itself. All other use will be at your own responsibility and is not covered by the product warranty.
- 9 Do not put the product in direct sunlight.

1 Introduction



Always read the instructions for use prior to use.

1.1 General information

The product is a medical device with CE marking in accordance with MDR (EU) 2017/745. According to this regulation the manufacturer is required to report all accidents or incidents involving the products. All information involving accidents or incidents relating to our products, shall be reported immediately to Care of Sweden.

1.2 Intended purpose

The mattress is intended to be used for prevention and as an aid in alleviation of pressure ulcers and pressure injuries (PU/PI).

1.3 Intended user

The mattresses are intended to be used by all kind of patients, including lay persons.

1.4 Intended use environment

The mattresses are intended to be used in all kinds of healthcare environments, including home care.

1.5 Indications

Suitable for patients with increased risk for pressure ulcers/injuries (PU/PI).

1.6 Contraindications

There are no known contraindications.

1.7 Clinical benefit

The clinical benefit for the mattresses included in this instruction for use are:

- Safety
- Comfort
- Easy to handle

2 Assembly and installation

When unpacking, check that no parts are damaged. If any damage is found, contact Care of Sweden or your local distributor before using the product.

- 1 Unpack the product carefully, do not use any sharp objects.
- 2 Correct the cover. Mattresses that are delivered with the divisible Evac-cover are packed with the top part folded inside the mattress. Lay out the top part and close the zipper.
- 3 The mattress should lay unpacked on a flat surface for about 2 hours before it is used. If necessary, the mattress can be used immediately.

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▪ **Note:**

- It is recommended to use a bedsheet on the mattress.
 - It can take up to a week before the mattress has resumed to its full size after the compression.
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3 Operation

When the steps in section 2 have been performed, the mattress is ready to use.

3.1 Operation Evac cover

This section will only explain how to use the evac cover. Refer to your local evacuation routines to perform the whole evacuation safely.

Evac cover is a mattress cover with a built-in function for evacuation of bed-bound patients. The Evac cover is equipped with three handles on the head and foot end. On the sides, there are handles with velcro straps. These straps are to be used to fixate the patient to the mattress before commencing the evacuation. The straps are folded in the protective pockets on the side of the mattress with the ends sticking out to ensure that they are easy to pull out.

Operation

1. Pull out and fasten the Velcro straps so that the mattress forms a tube around the patient.
2. Use the outer handles at the foot end of the mattress and turn the mattress out from the bed.
3. Slowly pull the patient down on the floor.
4. Pull on the outer handles at the foot end of the mattress.
5. The patient may now be moved, refer to local evacuation routines.



Note:

- If the velcro straps are not used, there is a risk of the patient sliding/rolling down from the mattress.
- Pulling at the foot end reduces the strain on the puller, meaning faster and safer evacuation is possible.
- The arms of the patient shall be inside of the velcro straps. This reduces the risk of the patient grabbing hold to something out of fear.

4 Product description

The system has been tested and approved according to following standards where applicable demands are fulfilled: SS 876 00 01, SS 876 00 02, SS 876 00 04, SS 876 00 11, SS 876 00 20, SS-EN ISO 20342, SS-EN ISO 14971, SS-EN ISO 10993-1, EN 597-1, EN 597-2.

4.1 PRIMA BM

PRIMA BM is a reversible overlay mattress that offers comfort and easy handling.

Core: HR foam 35 kg/m³ (High Resilience)

Height: 6 cm

Cover: Marin and Quilt

Patient weight: 0-130 kg*

*Please note that the underlying mattress affects the overall function including the recommended patient weight.

4.2 PRIMA 6

PRIMA 6 is a reversible mattress distance/elevation pad for placement under an overlay mattress.

Core: HR foam 35 kg/m³ (High Resilience)

Height: 6 cm

Cover: Marin and Quilt

Patient weight: 0-130 kg (to not disclose when it is used with another mattress)

4.3 Optimal M3

Optimal M3 is a standard replacement mattress for all types of healthcare environments.

Core: HR foam 50 kg/m³ (High Resilience)

Height: 12 cm

Cover: Marin, Marin/Evac

Patient weight: 0-130 kg

4.4 Optimal Junior

Optimal Junior is a reversible standard replacement mattress.

Core: HR foam 30 kg/m³ (High Resilience)

Height: 5 cm

Cover: Marin

Patient weight: 0-20 kg

4.5 Optimal BOB

A mattress for emergency healthcare, operating and stretcher trolleys. The mattress is equipped with our patented sit function DuoCore®.

Core: HR foam 50 kg/m³

Height: 9 cm

Cover: BOB

Patient weight: 0-130 kg



5 Reuse and cleaning

The product is reusable. Before using the product again for a new patient, it is recommended to clean the product. Follow the instructions below for cleaning and reconditioning. Consult your hygiene manager or Care of Sweden for help and instructions if you are unsure.

5.1 Mattress cover hygiene

Wipe off



Primarily use solvent-free soap with a neutral pH value. For a daily basis cleaning, a disinfectant and/or cleaning agent can be used such as: alcohol with/without surfactants or oxidizing solutions such as: chlorine and/or hydrogen peroxide, concentration 1000ppm/0,1%. In exceptional cases, a concentration of a maximum of 10,000ppm/1% can be used, then consider that high concentrations can shorten the life of the coating.

Mechanical cleaning



Multi-layer covers should be divided before washing. Wash with similar colours.

5.2 Mattress cover quilt

The cover can be machine washed and tumble dried.



5.3 Mattress core



Clean the affected area with a mild detergent (such as washing-up liquid) and water or with an alcohol-based disinfectant cleaner intended for this purpose. Gently squeeze out any water.

Note:

- Check the product every time it is being cleaned. If damaged, it must be replaced or repaired. If the product is equipped with an Evac cover, handles and straps also need to be checked regularly.

6 Storage

Store the mattress on a flat surface or carefully rolled/folded with the zipper closed. Store at room temperature in a dry area. Make sure the mattress is stored where it will not be exposed to thrusts, hits or other damages. Avoid direct exposure to sunlight. If the mattress is to be stored more than 3 months, it is recommended to store it on a flat surface (not folded or rolled up).

7 Maintenance




























The product needs no other service or maintenance than cleaning as described in section 5.

8 Marking and symbol key

8.1 Marking

The product is labelled with product name, production date, item number, size, care and wash instructions, EAN-bar code as well as space for own labelling. It is also marked with indications on which side to place upwards.

8.2 Symbol key

Symbols to convey medical device information			
	CE-marked in accordance with Medical Device Regulation (EU) 2017/745		Manufacturer
	Medical Device		Distributor
	UDI		
Symbols for traceability and product information			
	Item number		
Symbols for user information			
	Recommended patient weight	XXXX-XX-XX	Year-month-day
	Directly on bed base		Place on top of existing mattress
	Can be rotated		Can be turned
	Place underneath		Counteract shear force
	Read the instructions for use		Place on top
	Read the instructions for use		
Symbols for cleaning and recycling			
	Machine wash at 95 °C		Machine wash at 70 °C
	Do not wash		Chlorine
	Wipe clean		Tumble dry
	Do not dry clean		Do not tumble dry
	Drip dry		Do not iron
	Recycling		

9 Other information

9.1 Recommended lifetime of the product

The estimated lifetime of PRIMA BM, PRIMA 6 and Optimal BOB is 3 years.

The estimated lifetime of Optimal Junior and Optimal M3 is 5 years.

9.2 Disassembly and recycling

The product is fully recyclable and should be sorted as combustible waste. No dismantling is needed.

9.3 Returns

Contact Care of Sweden or your local distributor before returning the product.



Manufactured by



care of sweden

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