

Instructions for use

2021-06-08

Standard mattresses

For the following products:

PRIMA BM

PRIMA 6

Optimal M3

Optimal BOB

Optimal Junior

Instructions for use item number: 95-001102



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WARNINGS AND SAFETY PRECAUTIONS

Read all instructions prior to use

WARNING!

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 user is positioned correctly to avoid the risk of suffocation.
7. Prevent damage to the hygiene cover from sharp objects.
8. If the cover are 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.

1 Introduction



Always read the instructions for use prior to use.

1.1 General information

These systems are medical devices with CE-marking in accordance to MDR (EU) 2017/745. According to statutory regulations made by the authorities regarding medical devices, the manufacturer the manufacturer is required to report all accidents incidents involving their products. We would be very grateful for all information involving accidents or incidents relating to our products, by reporting them immediately to us here at Care of Sweden. The systems has been tested and approved according to the following standards: 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.

1.2 Intended use

Optimal standard mattresses are intended to be used for prevention and as an aid in alleviation of pressure ulcers and pressure injuries (PU/PI).

1.3 Indications

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

1.4 Contraindications

There are no known contraindications.

1.5 Intended user

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

1.6 Intended use environment

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

1.7 Other information

Action plan Pressure ulcers/pressure injuries

For the best possible results when using these products, we recommend a structured and planned approach. Examples that can be applied to the use of our products can be found in the 'Action plan for pressure ulcers' guidelines.

Mattress guide

This guide provides guidance to personnel and prescribers when choosing a mattress from Care of Sweden. Optimal mattresses are mattresses in function group A.

This information can be obtained from our website, www.careofsweden.com, or ordered from Customer Services (see contact information on the final page).

1.8 Evac instructions

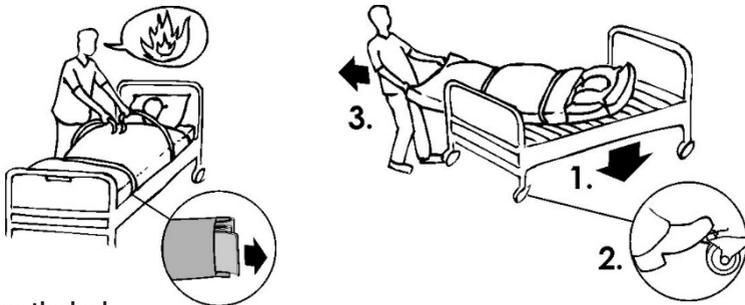
Evac is a mattress cover with a built-in function for evacuation of bed-bound users. In case of fire or other emergency, there is no time to think about what to do next. Therefore, it is very important that the safety equipment, as well as the evacuation procedures, is well planned and known in advance.

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 user 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.

WARNING!

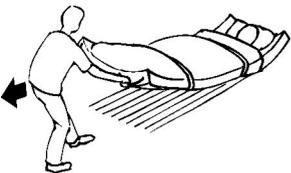
Person to perform an evacuation needs to have the necessary training. Always check the equipment, cover and mattress before commencing, to make sure an evacuation can be carried out safely.

Evacuation instructions



Down from the bed

- Inform the user about what will happen.
- Lower and lock the bed in position.
- Pull out and fasten the velcro straps so that the mattress forms a tube around the user.
- Use the outer handles at the foot end of the mattress and turn the mattress out from the bed.
- Slowly pull the user down onto the floor.

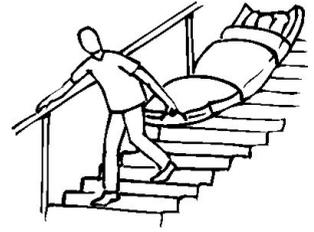


On an even surface

- Pull on the outer handles at the foot end of the mattress.
- Working position should be a little bit leaning back.

Down the stairs

- Walk backwards until the main part of the mattress has slid past the top stair.
- Turn the back to the user and look in the moving direction.
- Hold one hand on the stair handle and pull with the other hand on the middle handle of the mattress.
- Walk down the stairs. It is important to maintain speed, without running.



Training/practise

To bear in mind when training.

Pulling down from the bed:

- The user in the bed should not be at the very top of the mattress. There could be a risk of hitting the head in the bed when pulling down.

Pulling in the stairs:

- Start with pulling an empty mattress down the stairs, in order to practice the technique.
- When training with a person on the mattress, a string or rope can be fastened to the handles at the head end. Another person can then walk behind the mattress and help out if problems should occur.
- It is advisable to practice in the same stairs where an evacuation can be necessary.

General:

- The main purpose of the training is not to reach high speed, but to learn the correct technique.

Training covers

- Because of the heavy strain on the equipment when evacuating, always check the seams and handles at the end of training. We recommend that equipment used for training is marked with “Training equipment” and is only used for this purpose.

Explanations

- If the velcro straps are not used, there is a risk of the user sliding/rolling down from the mattress.
- Pulling at the foot end reduces the strain on the puller, which means that a faster and safer evacuation is possible.
- Pulling in the stairs is the most difficult part of the evacuation and should be practiced extra carefully.
- The arms of the user shall be inside of the velcro straps. This way reduces the risk of the user grabbing hold to something out of fear.

Note!

When using wider mattresses, make sure that the evacuation routes are clear (size of doors etc.). Responsible personnel have to ensure that the evacuation can be performed safely. To ensure proper function of the Evac cover, it is important to regularly check the quality of the mattress. Check for damages that could cause problems when evacuating.

2 Product description and performance

The Optimal mattresses are available in the following sizes (WxL):
80/85/90/105/120 x 200/205/210 cm.

For more information contact Care of Sweden or your local distributor.

2.1 Introduction covers

All covers are hygienic cover. They are easy to handle and operate and manage the highest standards of cleanliness and hygiene. The covers are vapour permeable, which reduces the risk of skin maceration.

Cover Marin - This cover is available in different designs. It is removable by zipper on one or three sides. Also available with handles on one long side, for the transport of mattress. Colour blue.

Bottom part Evac – Cover with protected zipper on all sides, divisible (top and bottom part). Functional handles for evacuation, moving and transport. Colour black.

Other covers

Cover Quilt - Quilted cover with zipper on three sides. The cover is only available for certain products and is available in a limited number of sizes. For more info see section 6, Accessories.

2.2 Product description

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

User weight: 0-130 kg*

Warranty: 2 years

This product's expected lifetime is estimated to be 3 years.

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

PRIMA 6

PRIMA 6 is a reversible mattress distance/elevation pad for placement under an overlay mattress, type a CuroCell® Nova (air mattress).

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

Height: 6 cm

Cover: Marin and Quilt

User weight: - (to not disclose when it is used with another mattress)

Warranty: 2 years

This product's expected lifetime is estimated to be 3 years.

Optimal M3

Optimal M3 is a standard replacement mattress for all types of healthcare environments. A two-part foam core made of HR-foam with a high weight per unit volume.

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

Height: 12 cm

Cover: Marin, Marin/Evac

User weight: 0-130 kg

Warranty: 3 years

This product's expected lifetime is estimated to be 5 years.

Optimal Junior (40x65x5 cm)

Optimal Junior (40x65x5 cm) is a reversible standard replacement mattress.

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

Height: 5 cm

Cover: Marin

User weight: 0-20 kg

Warranty: 2 years

This product's expected lifetime is estimated to be 5 years.

Optimal BOB

A mattress specially developed to increase the comfort of healthcare emergency, operating and stretcher trolleys. The mattress' foam core is made of HR-foam with a high volume weight and is equipped with our unique seating function.

Core: HR foam 50 kg/m³

Height: 9 cm

Cover: BOB

User weight: 0-130 kg

Warranty: 2 years

This product's expected lifetime is estimated to be 3 years.

Optimal Junior (70x160x9 cm)

Optimal Junior (70x160x9 cm) is a reversible standard replacement mattress.

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

Height: 9 cm

Cover: Marin

User weight: 0-70 kg

Warranty: 2 years

This product's expected lifetime is estimated to be 5 years.



3 Unpacking the mattress

Our mattresses are delivered compressed and packed in recyclable plastic. They are compressed to make them easier to handle for our customers and by minimizing the transported volume; we reduce our effect on the environment.

1. Start with making sure that the package is undamaged. Remove the plastic bag and any protective material. Avoid using a knife when opening the package, since this could damage the hygiene cover.
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. However if needed, the mattress can be used immediately. It can take up to a week before the mattress has resumed its full width/length/height after the compression.

4 Reuse, cleaning and reconditioning

The product is reusable. When reusing, it is important to follow the instructions below for cleaning and reconditioning. Before using the product again for a new user, it is recommended to clean the mattress in accordance with the instructions below. Consult your hygiene manager or Care of Sweden for help and instructions if you are unsure. Cleaning and reconditioning should otherwise be performed as required.

4.1 MATTRESS COVER HYGIENE



Covers can be wiped off with a mild cleaning solution for this purpose such as: alcohol with or without tensides, Isopropanol 70 %, oxidating solutions or chlorine max 1 %.

Excrements and blood spots must be removed immediately with cold water. Carefully follow local instructions and usage instructions for the cleaner.



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



Chlorine and phenol-based cleaners could have a negative impact on the PU surface and should be avoided. If chlorine is used, we recommend a mixture of max. 1%.

MATTRESS COVER QUILT

The cover can be machine washed and tumble dried.



4.2 MATTRESS CORE



Clean the affected area with a mild cleaning solution for this purpose such as: alcohol with or without tensides, Isopropanol 70 %, oxidating solutions or chlorine max 1 %.

Press out the water carefully. Let the foam core dry in a warm, ventilated area, without direct exposure of sunlight. The foam core needs to be completely dry before it is used again.

NOTE!

Check the hygiene cover every time the product 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. Follow the local instructions and the cleaning agents' instructions carefully.

5 Miscellaneous

5.1 Storage

Store the mattress on a flat surface or carefully rolled/folded with the zipper closed. Always 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 things that can damage it. Avoid direct exposure of sunlight. If the mattress is to be stored more than 3 months, we recommend it is stored on a flat surface (not folded or rolled up).

5.2 Labelling

The mattress is labelled with product name, production date, item number, size, care and wash instructions, EAN-bar code, as well as space for own labelling.

5.3 Warranty

See section 2.2 for detailed information regarding warranty for each mattress. The warranty is valid for production errors. It is not valid for normal wear or deterioration of the product or damages that occur because of careless handling or care of the product.

5.4 Service and maintenance

The mattress needs no other service or maintenance than cleaning as described in this instruction for use.

5.5 Repairs

For instructions, contact the supplier.

5.6 Recycling

All bed products are fully recyclable and should be recycled as “combustible waste”. No dismantling needed.

5.7 Returns and complaints

Complaints are to be reported to the supplier. Return of a product shall follow the supplier’s instructions and can only be done after the complaint has been reported. Damages due to the transport should be reported to the transportation agent.

5.8 Symbol key



Item number



Manufacturer

XXXX-XX-XX

Year-Month-Day



Read the instructions for use



Group of function



CE-marked in accordance with
Medical Device Regulation
(EU) 2017/745



Recycling



Recommended user weight



Directly on bed base



Place on top of
existing mattress



Can be rotated



Can be turned



Counteract shear force



Place on top



Place underneath



Do not wash



Machine wash at 70 °C



Machine wash at 95 °C



<1%
Chlorine



Tumble dry



Do not tumble dry



Drip dry



Do not iron



Do not dry clean



Wipe off



Distributed by



UDI



Medical Device

6 Accessories

For these mattresses, there is a number of accessories. These are shown in the list below.

Top part Marin, 4 cm (Optimal M3)	421-xxxxxx*
Bottom part Evac, 11 cm (Optimal M3)	461-xxxxxx*
Cover Marin, 6 cm, zipper on one short side (PRIMA BM, PRIMA 6)	22-xxxxxx*
Cover Marin, 11 cm, zipper on one short side (Optimal M3)	23-xxxxxx*
Cover Marin, 12 cm, zipper on three sides (Optimal M3)	234-xxxxxx*
Cover Quilt, 7 cm (PRIMA 6, BM) only available in sizes 80/90/105/120 x 200 cm	820-xxxxxx*
Bag for mattress 80-90 cm wide, sturdy polyester	58-900902
Bag for mattress 105-120 cm wide, sturdy polyester	58-900905

*-xxxxxx in the item numbers signifies the size of the product. For example, 461-090200 signifies a bottom part Evac in the size 90x200.

6.1 Other accessories

Optimal Extension

The Extension is an accessory used to fill out the space that a short mattress leaves in a long bed. The extension part is available in many different sizes, depending on width and height of the mattress. Extending a mattress with Optimal Extension is only a temporary solution and doesn't replace a mattress in the preferred size. In the need of an extension during a longer period of time, we recommend that a mattress in the preferred size is used.

Optimal Hygiene Pillow

The Optimal Hygiene Pillow is developed for caring environments, is comfortable and very easy to clean. Delivered with a removable hygiene cover. The pillow is available in the following sizes: 35x45, 50x60 and 50x70 cm.

Optimal Sens

An anatomically shaped pillow that gives neck and head support. Produced in visco-elastic foam and delivered with a removable hygiene cover.

Curera® Support Wedge

An aid for positioning and position changes. The support wedge is easy to use and has a removable liquid resistant and vapour permeable hygiene cover.

Molly Heel Protection

Molly provides comfort for relief of heel. The user can move the leg and make position changes. Comes with a removable liquid resistant and vapour permeable hygiene cover. Molly is available in sizes Small, Medium and Large.

Curera® Positioning Pillows

Curera® is a range of pillows used for positioning, relief and support in all kinds of care facilities. When bedbound individuals don't move enough, it increases the risk of pressure ulcers/pressure injuries. With regular position changes, this risk can be reduced and the comfort level increased.

Please contact Care of Sweden or your local distributor for accessories or more information on our products.



Manufactured by

 care of sweden

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