

Instructions for use

2021-06-08

Optimal preventative mattresses

Instructions for use item number: 95-001101







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WARNINGS AND SAFETY PRECAUTIONS

Read all instructions prior to use

WARNING!

- 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.
- 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.
- The hygiene cover does not allow liquid or air to penetrate, but is vapour permeable.Make sure that the user is positioned correctly to avoid the risk of suffocation.
- 6. The mattresses are protected by a hygiene cover; avoid using multiple hygiene covers as this can affect the vapor permeability of the mattress.
- 7. Prevent damage to the hygiene cover from sharp objects.
- 8. Mattresses with the Evac cover have handles and velcro straps for evacuation. If the cover has handles, they are intended for lifting the empty mattress. All other use is at your own risk and is not covered in the product guarantee.

1 Introduction



Always read the instructions for use prior to use.

1.1 General information

This product is a medical device and is CE-marked according to MDR (EU) 2017/745. According to statutory regulations made by the authorities regarding medical devices, the manufacturer is required to report all accidents or 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. It also fulfills the applicable standards according to the medical directives: 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.

Unprevented/untreated pressure ulcers/pressure injuries can very quickly deteriorate resulting in higher risk of complications, pain and suffering for the user.

1.2 Intended use

The preventative support surface/-s can be used as aid for prevention and in the treatment of pressure ulcers/pressure injuries (PU/PI).

1.3 Indications

Suitable for a wide range of persons with increased risk for pressure ulcers/injuries, including those with superficial ulcers, up to category 1-2 (in association with an individualised plan of care)¹. The Optimal 5zon®, Optimal 5zon® Plus, Optimal Care, Optimal Cool, Optimal Cura, Optimal Mono, Optimal Solett, Optimal Maxx and Prima 12 mattresses are replacement mattresses to be placed directly on the base of the bed. Optimal 5zon® BM and Optimal Solett BM are overlay mattresses to be placed on top of an existing mattress.

1.4 Contraindications

There are no known contraindications.

1.5 Intended user

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

1.6 Intended use environment

The mattresses can be used in all kinds of health care environments, including home care.

(1) European Pressure Ulcer Advisory Panel, National Pressure Injury Advisory Panel and Pan Pacific Pressure Injury Alliance. Prevention and Treatment of Pressure Ulcers/Injuries: Clinical Practice Guideline. The International Guideline. Emily Haesler (Ed). EPUAP/NPIAP/PPPIA: 2019

1.7 Other information

Action plan Pressure ulcers/pressure injuries

For the best possible results when using this product, 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 Preventative mattresses are mattresses in function group B.

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

1.7 Evacuation 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, are well planned and known in advance.

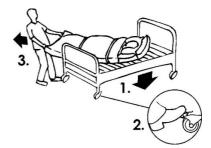
The Evac cover is equipped with three handles on the head and foot end. On the sides, there are handles with velcro straps. These straps are to be used to fixate the user to the mattress before commencing the evacuation. The straps are folded in the protective pockets on the side of the mattress with 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 on to 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 slided pass 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.



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 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 preventative mattresses are available in following sizes: In the width 80/85/90/105/120 cm and in the length 200/205/210 cm. If other sizes are needed, contact Care of Sweden or your local distributor.

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

2.1 Introduction covers

All covers are hygienic covers. They are easy to handle and operate. The covers are vapour permeable, which reduces the risk of skin maceration.

Cover Olivia – Cover with protected zipper on three sides. Several different heights are available. Colour: grey.

Cover Olivia H – Same as Olivia cover but with handles for transport and moving.

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

Cover Olivia/5zon® Plus – Same as the Olivia/Evac cover but without handles for evacuation. Functional handles on four sides for transportation of mattress. Colour: grey/black.

Cover Nordic – Cover with welded seams and a protected zipper on three sides. Handles on one long side, for transportation of the mattress. Colour: blue.

Cover Steel/Evac – Cover with welded seams and a protected zipper on all sides, divisible (top and bottom part). Functional handles for evacuation, moving and transport. Colour: blue/black.

Cover Stone – Crib 5 cover with welded seams and a protected zipper on three sides. Colour: grey.

Cover Stone/Evac – Crib 5 cover with welded seams and a protected zipper on all sides, divisible (top and bottom part). Functional handles for evacuation, moving and transport. Colour: grey/black.

Other covers

Cover Quilt – Quilted cover with zipper on three sides. This cover is only available for some products and only in a limited number of sizes.

Cover Tricot - Thin knitted cover.

Top part LF (Low Friction) – With increased sliding function, can be used for heavy immobile users.

Inner cover Optimal 5zon - Inner cover to be placed on the underlying foam part with the orange sliding surface upwards. Provides an improved comfort during position changes and contributes to reduce the risk of shearing forces. Suitable for Optimal 5zon.

2.2 Product description

Optimal 5zon®

A replacement mattress that offers good pressure redistribution and is equipped with our patented sit function.

Function: For prevention and as an aid in treatment of

pressure ulcers/pressure injuries up to and including category 2.

Core: HR-foam 65 + 50 kg/m³

Height: 14 cm

Cover: Olivia/Evac, Olivia, Olivia H, Nordic, Steel/Evac, Stone, Stone/Evac, LF/Evac, Quilt and

Tricot

User weight: 0-180 kg Warranty: 3 years

This product's expected life time is estimated to be 5 years

Optimal 5zon® BM

A soft and flexible overlay mattress that is placed on top of an existing mattress. The design of the mattress ensures good pressure redistribution properties.

Function: For prevention and as an aid in treatment of pressure ulcers/pressure injuries up to

and including category 2. Core: HR-foam 65 kg/m³

Height: 6 cm

Cover: Olivia and Quilt User weight: 0-150 kg* Warranty: 2 years

This product's expected life time is estimated to be 5 years

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

Optimal 5zon® Plus

A mattress replacement system especially designed for heavy people and is equipped with our patented sit function.



Function: For prevention and as an aid in treatment of pressure ulcers/pressure injuries up to and including

category 2.

Core: HR-foam 65 kg/m3 + 50 kg/m3

Height: 15 cm

Cover: Olivia/5zon® Plus

User weight: 0-300 kg (Optimal 5zon® is recommended for user weights up to 180kg)

Warranty: 2 years

This product's expected life time is estimated to be 5 years

Optimal Care

A replacement mattress with a profiled surface.

Function: For prevention and treatment of pressure ulcers/pressure injuries up to and

including category 2. Core: HR-foam 50 kg/m³

Height: 14 cm

Cover: Olivia/Evac, Olivia, Olivia H, Nordic, Steel/Evac, LF/Evac, Quilt and Tricot

User weight: 0-160 kg Warranty: 3 years

This product's expected life time is estimated to be 5 years

Optimal Cool

A mattress replacement system with a profiled surface.

Function: For prevention and treatment of pressure ulcers/pressure injuries up to and

including category 1. Core: HR-foam 35 kg/m³

Height: 13 cm

Cover: Olivia and Nordic User weight: 0-110 kg Warranty: 2 years

This product's expected life time is estimated to be 3 years

Optimal Cura

A mattress replacement system in two layers, HR-foam and visco elastic foam.

Function: For prevention and treatment of pressure ulcers/pressure injuries up to and

including category 1.

Core: HR-foam + visco-elastic foam 50 kg/m³

Height: 13 cm

Cover: Olivia, Olivia/Evac, Olivia H, Nordic, Steel/Evac and Tricot.

User weight: 0-130 kg Warranty: 3 years

This product's expected life time is estimated to be 5 years

Optimal Mono

A replacement mattress with a profiled surface.

Function: For prevention and treatment of pressure ulcers/pressure injuries up to and

including category 2. Core: HR-foam 45 kg/m³

Height: 14 cm

Cover: Olivia/Evac, Olivia, Nordic, Steel/Evac, Quilt and Tricot

User weight: 0-160kg Warranty: 3 years

This product's expected life time is estimated to be 5 years

Optimal Solett

A mattress replacement system, especially designed for light and sensitive persons.

Function: For prevention and as an aid in treatment of pressure ulcers/pressure injuries up to

and including category 1.

Core: HR-foam 35 kg/m³ + visco-elastic foam 50 kg/m³

Height: 12 cm

Cover: Olivia/Evac, Olivia, Nordic, Steel/Evac and Tricot

User weight: 0-60 kg Warranty: 2 years

This product's expected life time is estimated to be 5 years

Optimal Solett BM

A soft mattress overlay, especially designed for light and sensitive persons.

Function: For prevention and as an aid in treatment of pressure ulcers/pressure injuries up to

and including category 1.

Core: HR-foam 35 kg/m³ + visco-elastic foam 50 kg/m³

Height: 6 cm

Cover: Olivia, Quilt and Tricot

User weight: 0-60 kg* Warranty: 2 years

This product's expected life time is estimated to be 5 years

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

Optimal Maxx

A standard replacement mattress specially made for higher user weights.. The foam core is made of cold foam with high density and is equipped with our patented sit function.

Function: For prevention and as an aid in treatment of pressure ulcers/pressure injuries up to and including category 1.

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

Height: 15 cm

Cover: Marin/Evac and Quilt User weight: 0-180 kg Warranty: 3 years

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

PRIMA 12

PRIMA 12 is a reversible replacement mattress. PRIMA is a simple and functional line of basic mattresses that offer good comfort and durability.

Function: For prevention and as an aid in treatment of pressure ulcers/pressure injuries up to

and including category 1.

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

Height: 13 cm

Cover: Marin, Marin/Evac, Quilt and Tricot

User weight: 0-130 kg



Warranty: 3 years

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

3 Unpacking the mattress

Our mattresses are delivered compressed in recyclable plastic. The reason for the compression is to make the handling of the mattress easier.

- 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.
- Always check that the mattress is correctly placed inside the cover, see label.
- 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.
- 4. 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 one 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 Hygiene cover including inner cover

MATTRESS COVER HYGIENE

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

Excrement and blood spots must be removed immediately with cold water. Carefully follow local instructions and usage instruction for the cleaning solutions.



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 TRICOT

The cover can be machine washed and tumble dried.



MATTRESS COVER OUILT

The cover can be machine washed and tumble dried.



4.2 Mattress core



The hygiene cover protects the foam core completely, which means cleaning seldom is necessary. If, for any reason, the core needs to be cleaned, use a mild cleaning solution and water (for example spray on). 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. When needed, use a mild cleaning solution or disinfect with solutions for this purpose such as: alcohol with or without tensides, Isopropanol 70 %, oxidating solutions or Chlorine max 1 %.

Carefully follow local instructions and usage instruction for the cleaning solutions.

Note!

Check the hygiene cover every time it is being cleaned. If the cover is damaged, it is to be replaced or repaired. If the product is equipped with an Evac-cover, handles and straps also need to be check regularly. Follow the local instructions and the cleaning agents' instructions carefully.

5 Other information

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 mattresses are 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 instructions 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 Definitions



Item number



Manufacturer



Year-Month-Day



Read the instructions for use



Group of function



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





Recommended user weight



User information - category



Directly on bed base



Place on top of existing mattress



Can be rotated



Can be turned



Counteract shear force



Place on top





Do not wash



Machine wash at 70 °C



Machine wash at 95 °C





Tumble dry



Do not tumble dry



Drip dry





Do not dry clean



Wipe off



Distributed by



Medical Device



6 Accessories

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

| Description and size Inner cover Optimal 5zon (Optimal 5zon) | Item number 400-xxxxxx* |
|---|-------------------------------------|
| Top part Olivia, 4 cm (Optimal 5zon®, Optimal 5zon® Plus, Optimal Care, Optimal Cura, Optimal Mono, Optimal Solett) | 431-xxxxxx* |
| Top part Marin, 4 cm (PRMA 12, Optimal Maxx) | 421-xxxxxx* |
| Top part Steel, 4 cm (Optimal 5zon®, Optimal Care, Optimal Cura, Optimal Mono Optimal Solett) | , 451-xxxxxx* |
| Top part Stone, 4 cm (Optimal 5zon®) | 452-xxxxxx* |
| Top part LF (Low Friction), 4 cm (Optimal 5zon®, Optimal Care) | 441-xxxxxx* |
| Bottom part Evac, 11 cm (Optimal 5zon®, Optimal Care, Optimal Cura, Optimal Mono, Optimal Solett, PRIMA 12) | 461-xxxxxx* |
| Bottom part Evac, 15 cm (Optimal Maxx) | 471-xxxxxx* |
| Bottom part 5zon® Plus (Optimal 5zon® Plus) | 481-xxxxxx* |
| Cover Olivia, 7 cm (Optimal 5zon® BM, Optimal Solett BM) | 29-xxxxxx* |
| Cover Olivia, 13 cm (Optimal 5zon®, Optimal Care, Optimal Cool, Optimal Cura, Optimal Mono, Optimal Solett) | 292-xxxxxx* |
| Cover Olivia H, 13 cm (Optimal 5zon®, Optimal Care, Optimal Cura) | 297-xxxxxx* |
| Cover Marin, 12 cm, zipper on one short side (PRIMA 12) | 23-xxxxxx* |
| Cover Marin, 12 cm, zipper on three sides (PRMA 12) | 234-xxxxxx* |
| Cover Marin, 12 cm, zipper on three sides, handles on the long side (PRIMA 12) | 236-xxxxxx* |
| Cover Nordic, 13 cm (Optimal 5zon®, Optimal Care, Optimal Cool, Optimal Cura, Optimal Mono, Optimal Solett) | 287-xxxxxx* |
| Cover Quilt, 7 cm (Optimal 5zon® BM, Optimal Solett BM) - only available in sizes: 80/90/105/120 x 200 cm | 820-xxxxxx* |
| Cover Quilt, 15 cm (Optimal 5zon®, Optimal 5zon® Plus, Optimal Care, Optimal Mono, Optimal Maxx) – only available in size: 90 x 200 | 821-xxxxxx* |
| Cover Tricot (PRIMA 12) | 91-xxxxxx* |
| Bag to mattress overlay, 80-90 cm width Bag to mattress replacement, 80-90 cm width, polyester Bag to mattress replacement, 105-120 cm width, polyester | 58-900904 58-900902 58-900905 |

^{*-}xxxxxx in the item numbers signifies the size of the product. For example, 29-<u>090200</u> signifies a cover Olivia in the size 90x200 cm.

6.1 Other accessories

Optimal Extension

The extension part is an accessory used to fill out the space that a short mattress leaves in a long bed. The extension 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 maximum neck 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 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 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.

| 7. Own notes | | | | | |
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| Own notes | | |
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