

## Instructions for use

2023-03-17

### Optimal preventative mattresses

Optimal 5zon®

Optimal 5zon® BM

Optimal 5zon® Plus

Optimal Care

Optimal Cura

Optimal Mono

Optimal Solett

Optimal Solett BM

Optimal Maxx

Prima 12

Instructions for use item number: 95-001101



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## WARNINGS AND SAFETY PRECAUTIONS

Read all instructions prior to use

**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 hygiene cover does not allow liquid or air to penetrate but is vapour permeable. Make sure that the patient is positioned correctly to avoid the risk of suffocation. Make sure to continuously monitor patients that need special supervision.
6. The mattresses are protected by a hygiene cover; avoid using multiple hygiene covers as this can affect the vapor permeability of the mattress. It is also recommended to use a bedsheet on 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

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 use

The mattress is intended to be used for prevention and as an aid in the treatment of pressure ulcers/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 a wide range of patients with increased risk for pressure ulcers/injuries, including those with superficial ulcers, category 1-2 (in association with an individualized plan of care).

The Optimal 5zon®, Optimal 5zon® Plus, Optimal Care, 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.

## 1.6 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
- Pressure redistribution
- 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.

The following instructions apply to all the mattresses included in these instructions for use.

1. Remove the plastic bag and any protective material. Avoid using a knife when opening the package, since this could damage the hygiene cover.
2. Always check that the mattress is correctly placed inside the cover, see label on foam.
3. Adjust 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. Check that the mattress is the correct size for the bed.
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.
5. The mattress is ready for use.



## 3 Operation

### 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

### 4.1 Optimal 5zon®

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

**Core:** HR-foam 65 + 50 kg/m<sup>3</sup>

**Height:** 14 cm

**Cover:** Olivia/Evac, Olivia, Olivia H, Quilt, LF/Evac, Stone, Stone/Evac

**Patient weight:** up to 180 kg



### 4.2 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.

**Core:** HR-foam 65 kg/m<sup>3</sup>

**Height:** 6 cm

**Cover:** Olivia and Quilt

**Patient weight:** Up to 150 kg\*

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

### 4.3 Optimal 5zon® Plus

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

**Core:** HR-foam 65 kg/m<sup>3</sup> + 50 kg/m<sup>3</sup>

**Height:** 15 cm

**Cover:** Olivia/5zon® Plus and Stone/5zon Plus

**Patient weight:** Up to 300 kg (Optimal 5zon® is recommended for patient weights up to 180kg)



### 4.4 Optimal Care

A replacement mattress with a profiled surface.

**Core:** HR-foam 50 kg/m<sup>3</sup>

**Height:** 14 cm

**Cover:** Olivia/Evac, Olivia, Olivia H, Quilt and LF/Evac

**Patient weight:** Up to 160 kg

### 4.5 Optimal Cura

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

**Core:** HR-foam + visco-elastic foam 50 kg/m<sup>3</sup>

**Height:** 13 cm

**Cover:** Olivia/Evac, Olivia and Olivia H

**Patient weight:** Up to 130 kg

## 4.6 Optimal Mono

A replacement mattress with a profiled surface.

**Core:** HR-foam 45 kg/m<sup>3</sup>

**Height:** 14 cm

**Cover:** Olivia/Evac, Olivia and Quilt

**Patient weight:** Up to 160kg

## 4.7 Optimal Solett

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

**Core:** HR-foam 35 kg/m<sup>3</sup> + visco-elastic foam 50 kg/m<sup>3</sup>

**Height:** 12 cm

**Cover:** Olivia/Evac and Olivia

**Patient weight:** Up to 60 kg

## 4.8 Optimal Solett BM

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

**Core:** HR-foam 35 kg/m<sup>3</sup> + visco-elastic foam 50 kg/m<sup>3</sup>

**Height:** 6 cm

**Cover:** Olivia and Quilt

**Patient weight:** Up to 60 kg\*

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

## 4.9 Optimal Maxx

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

**Core:** HR foam 50 kg/m<sup>3</sup>

**Height:** 15 cm

**Cover:** Marin/Evac and Quilt

**Patient weight:** Up to 180 kg



## 4.10 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.

**Core:** HR foam 35 kg/m<sup>3</sup> (High Resilience)

**Height:** 13 cm

**Cover:** Marin, Marin/Evac, Quilt and Tricot

**Patient weight:** Up to 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

#### 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



Covers consisting of several parts must be separated before washing.

### 5.2 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. 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).

Carefully follow local instructions and usage instructions 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.



## **6 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).

## **7 Maintenance**

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






## **8 Marking and symbol key**

### **8.1 Marking**


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.

## 8.2 Symbol key












### Symbols to convey medical device information

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












### Symbols for traceability and product information

	Item number		
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### Symbols for user information

	Recommended patient weight	XXXX-XX-XX	Year-month-day
	User information - category		Place on top of existing mattress
	Directly on bed base		Can be turned
	Can be rotated		Place on top
	Counteract shear force		Place underneath
	Read the instructions for use		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 this product is 5 years.

### **9.2 Disassembly and recycling**

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

### **9.3 Returns**

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

 Manufactured by

 care of sweden

**Contact:**                    **SUPPORTING LIFE**

Phone:    + 46 771 106 600

Fax:        + 46 325 12840

Email:     [export@careofsweden.se](mailto:export@careofsweden.se)

Internet: [www.careofsweden.com](http://www.careofsweden.com)

**Address:**

Care of Sweden AB  
P.O. Box 146  
SE-514 23 Tranemo  
SWEDEN

**Visit address:**

Fabriksgatan 5A  
SE-514 33 Tranemo  
SWEDEN

**Cargo address:**

Byns väg 4A  
SE-514 33 Tranemo  
SWEDEN

**Distributed by:**