

**Instructions for use**

2025-11-07

**Optimal preventative mattresses**

Optimal 5zon®

Optimal 5zon® BM

Optimal 5zon® Plus

Optimal Care

Optimal Cura

Prima 12

Instructions for use item number: 95-001101



7 331345 015484



Read the instructions carefully before use.

All user instructions and safety instructions must be followed.

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











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# 1 Symbol key

<b>Symbols to convey medical device information</b>			
	CE-marked in accordance with Medical Device Regulation (EU) 2017/745		Manufacturer
	Medical device		Distributor
	Unique device identifier		Date of manufacture
	Warning		Caution
	Catalogue number		Batch code
	Serial number		Read the instructions for use
	Consult instructions for use		
<b>Symbols for product information - Mattress</b>			
XXXX-XX-XX	Year-Month-Day		Recommended patient weight
	Patient information – pressure ulcer category		Counteracts shear
	Can be turned		Can be rotated
	Place on top of existing mattress		Place on top of the bed
	Place on top		Place underneath
	Size of mattress		

***Symbols for cleaning, reconditioning and recycling***

	Machine wash at 95 °C		Machine wash at 70 °C
	Do not wash		Drip dry
	Tumble dry		Do not tumble dry
	Wipe clean		Do not iron
	Chlorine		Do not dry clean
	Recycling		Do not dispose of with household waste

## 2 Warnings- and safety precautions



**The following points contain important information about using the product.**

- The instructions in this document shall always be followed.
- The instructions for use shall always be kept together with the product.
- It is recommended to always use the original packaging to store and transport the product.
- 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.
- Always make sure the mattress has the right size.



**Adhere to the following points to minimize risk for fire, personal injury, equipment- or property damage.**

- 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.
- 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.
- 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. Make sure to continuously monitor patients that need special supervision.
- 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.
- Prevent damage to the hygiene cover from sharp objects.
- 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.

## 3 Introduction

This instructions for use contain information about six different products. Read the label of your products carefully to understand which products you are using.



For safety reasons you shall carefully read the recommendations and instructions in these instructions for use before installing and using the product.

### 3.1 General information

The system 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.

### 3.2 Intended purpose

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

### 3.3 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).

Optimal 5zon®, Optimal 5zon® Plus, Optimal Care, Optimal Cura and Prima 12 mattresses are replacement mattresses to be placed directly on the base of the bed. Optimal 5zon® BM is an overlay mattress to be placed on top of an existing mattress.

### 3.4 Intended user

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

### 3.5 User qualification

Training is not mandatory to use the mattress included in this instructions for use.

### 3.6 Intended use environment

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

#### 3.6.1 Optimum environmental conditions

The mattress is intended to be used indoors at room temperature.

### **3.7 Contraindications**

There are no known contraindications.

### **3.8 Clinical benefit**

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

- Safety
- Comfort
- Pressure redistribution
- Easy to handle

## 4 Assembly and installation

When the product is unpacked, check that no parts are damaged. If damage is found, contact Care of Sweden or your local distributor before using the product. Do not use sharp objects when unpacking as it might damage the product. The operator should follow and check the below information before use.

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.



It can take up to a week before the mattress has resumed to its full size after the compression.

## 5 Operation Optimal preventative mattresses

When the steps in section 4 have been performed, the mattress is ready to use.

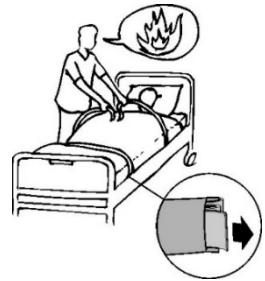
## 6 Operation Evac cover

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.

How to use the Evac cover:

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.



If the Velcro straps are not used, there is a risk of the patient sliding/rolling down from the mattress.



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.



Pulling at the foot end reduces the strain on the puller, meaning faster and safer evacuation is possible.

## 7 Product description

Read the label of your products carefully to understand which products you are using.

### 7.1 Product combinations

The table below shows which mattress covers that may be used with the mattresses.

Mattress	Mattress cover
Optimal 5zon®	Olivia/Evac Olivia Olivia H Quilt LF/Evac Stone Stone/Evac
Optimal 5zon® BM	Olivia Quilt
Optimal 5zon® Plus	Olivia/5zon® Plus Stone/5zon® Plus
Optimal Care	Olivia/Evac Olivia Olivia H Quilt LF/Evac
Optimal Cura	Olivia/Evac Olivia Olivia H
PRIMA 12	Marin Marin/Evac Quilt Tricot

## 7.2 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

Patient weight: up to 180 kg

## 7.3 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

Patient weight: up to 150 kg



The underlying mattress affects the overall function including the recommended patient weight.

## 7.4 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

Patient weight: up to 300 kg (for patients up to 180 kg, Optimal 5zon® is recommended)

## 7.5 Optimal Care

A replacement mattress with a profiled surface.

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

Height: 14 cm

Patient weight: Up to 160 kg

## 7.6 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

Patient weight: Up to 130 kg

## 7.7 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

Patient weight: Up to 130 kg

## 8 Reuse and cleaning

The product is reusable. Before reusing, it is important to follow the instructions below for cleaning, disinfection, and reconditioning. Disinfection is recommended between patients according to the instructions below.



Always follow local instructions and the instructions for use of the cleaning and disinfecting agent. Consult your hygiene manager or Care of Sweden for help and instructions in case of uncertainty.



Check the hygiene cover each time the product is cleaned. If the product is equipped with an Evac cover, handles and straps also need to be checked regularly. Damaged parts must be repaired or replaced.

### 8.1 Cleaning and disinfection

#### MATTRESS COVER

Information on detergent	
Primarily	Solvent-free soap with a neutral pH-value.
If necessary	Disinfectant, such as alcohol with or without surfactants or oxidizing solutions. For example, chlorine or hydrogen peroxide. Concentration: 1000 ppm (0,1%).
Exceptional cases	Disinfectant, such as alcohol with or without surfactants or oxidizing solutions. For example, chlorine or hydrogen peroxide. Concentration: 10 000 ppm (1%). Consider that high concentrations can shorten the life of the coating.

Mechanical cleaning:



#### 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:

1. Use a mild cleaning solution and water (for example spray on).
2. Press out the water carefully.
3. Let the foam core dry in a warm, ventilated area, without direct exposure of sunlight.
4. 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.

## 9 Maintenance

The mattress needs no other service or maintenance than cleaning as described in section 8.

## 10 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).

## 11 Other information

### 11.1 Technical lifetime

The technical lifetime of the products included in this instructions for use is 5 years when used under normal conditions.

### 11.2 Warranty

The product warranty covers manufacturing defects and is valid from the date the product is shipped with intent of usage, either directly from Care of Sweden or through one of Care of Sweden's designated distributors. The product warranty does not cover normal wear and tear, issues resulting from improper use, or damage caused by non-compliance with usage instructions. Any intentional damage, such as modifications, disassembly, or unauthorized repairs, voids the warranty. Contact Care of Sweden or your distributor for more information.

### 11.3 Disassembly and recycling

All bed products should be recycled as combustible waste. No dismantling needed.



The products shall not be disposed of with household waste.



If the product is, or could be, contaminated the product must be handled according to the healthcare provider's or local authority's procedures for contaminated waste.

### 11.4 Return

Contact Care of Sweden or your distributor before the product is returned.

### 11.5 Customer responsibilities

The safety of the unit and of the operator cannot be guaranteed if the following conditions are not satisfied:

- Always use mattress cover, never keep sharp objects nearby mattress.
- Operators should be familiar with the procedures, prohibitions and warning described in this manual, in addition with safety regulations applicable.

Manufactured by



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