

Instructions for use

2025-11-12

PRIMA 6

Instructions for use item number: 95-001102-EN0000
























Read the instructions carefully before use.
All user instructions and safety instructions must be followed.












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1 Symbol key

Symbols to convey medical device information			
	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		
Symbols for product information - Mattress			
XXXX-XX-XX	Year-Month-Day		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
	Recommended patient weight		

Symbols for cleaning, reconditioning 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		

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 mattresses are protected with a hygiene cover. Avoid using multiple hygiene covers as this can affect the vapor permeability of the mattress.
- 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.
- 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.
- Do not put the product in direct sunlight.

3 Introduction



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 mattress 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 for prevention and as an aid in alleviation of pressure ulcers and pressure injuries (PU/PI).

3.3 Indications

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

3.4 Intended user

The mattress is 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 mattress is 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 benefits for the mattress in this instruction for use are:

- Safety
- Comfort
- 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.

- 1 Unpack the product carefully.
- 2 Correct the cover.
- 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.



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

5 Operation Standard mattresses

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

6 Product description

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

Height: 6 cm

Patient weight: 0-130 kg. To not disclose when it is used with another mattress.

Materials the user comes in contact with:

- HR foam, 35 kg/³ (High Resilience)

PRIMA 6 may be used together with mattress cover Marin or mattress cover Quilt.

7 Reuse and cleaning

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



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. Damaged parts must be repaired or replaced.

7.1 Cleaning and disinfection

MATTRESS COVER MARIN

Information on detergent <i>If other agents are used, choose one that does not harm the exterior of the control unit.</i>	
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:



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

MATTRESS COVER QUILT

The cover can be machine washed and tumble dried.



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.

8 Maintenance

The product needs no other service or maintenance than cleaning.

9 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).

10 Standards

The system is tested and approved according to the following European standards, where applicable requirements are met.

SS 876 00 01	SS-EN ISO 20342	SS-EN ISO 14971	EN 597-1
SS 876 00 02		SS-EN ISO 10993-1	EN 597-2
SS 876 00 04			
SS 876 00 11			
SS 876 00 20			

11 Other information

11.1 Technical lifetime

The technical lifetime of the products is 3 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

The product should be sorted as combustible waste. No dismantling is 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.

Own notes

Manufactured by



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