

Instructions for Use and Technical Description

Passive Mattresses

EffectaCare 20

EffectaCare 20 B

EffectaCare 20 P

PrimaCare 10

CliniCare 10 P



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Passive Mattresses

EffectaCare 20
EffectaCare 20 B
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PrimaCare 10
CliniCare 10 P

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Related links: www.linet.com

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Table of Contents

1 Symbols and Definitions	4
1.1 Warning Notices	4
1.1.1 Types of Warning Notices	4
1.1.2 Structure of Warning Notices	4
1.2 Instructions	4
1.3 Lists	4
1.4 Symbols on the Package	4
1.5 Symbols and Labels on mattress	5
1.5.1 Mattress Wash Label	8
1.5.2 Fire Resistance Label	8
1.6 Serial Labels	9
1.6.1 Mattress Serial Label	9
1.7 Abbreviations	10
1.8 Definitions	10
2 Safety Instructions	11
2.1 Safety Instructions	12
3 Intended use	13
3.1 User population	13
3.2 Contraindications	13
3.3 Operator	13
4 Re-use	13
5 Description of Mattresses	14
5.1 Correct Mattress Orientation	15
6 Technical Specification	16
7 Use and Storage Conditions	17
8 Scope of Delivery and Product Variants	18
8.1 Delivery	18
8.2 Scope of Delivery	18
8.3 Variants	18
9 Using the Mattress	19
9.1 Preparing the mattress for use	19
9.2 Rotating the mattress	19
10 Accessories and Replacement Components	20
11 Cleaning and Maintenance	21
11.1 General Cleaning	21
11.2 Mattress Inspection	21
12 Disposal	22
12.1 Environment Protection	22
12.2 Disposal	22
12.2.1 Within Europe	22
12.2.2 Outside Europe	22
13 Warranty	23
14 Standards and Regulations	23

1 Symbols and Definitions

1.1 Warning Notices

1.1.1 Types of Warning Notices

Warning notices are differentiated by the type of danger using the following signal words:

- ▶ **CAUTION** warns about the risk of material damage.
- ▶ **WARNING** warns about the risk of physical injury.
- ▶ **DANGER** warns about the risk of fatal injury.

1.1.2 Structure of Warning Notices



SIGNAL WORDS!
Type and source of danger!
▶ Measures to avoid the danger, if necessary.

1.2 Instructions

Structure of instructions:




- ▶ Perform this step.
Results, if necessary.

1.3 Lists


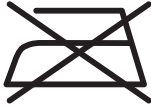

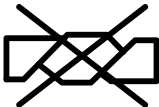



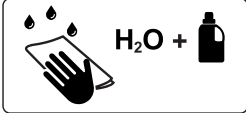


Structure of bulleted lists:




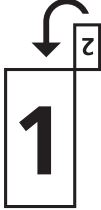






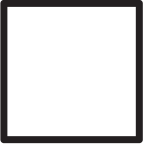
- List level 1
 - List level 2
 - List level 3






1.4 Symbols on the Package

	KEEP DRY (PROTECT FROM HUMIDITY)
	LOW DENSITY POLYETHYLENE RECYCLING SYMBOL
	RECYCLING SYMBOL

1.5 Symbols and Labels on mattress

	<p>READ INSTRUCTIONS FOR USE</p>
	<p>DO NOT IRON</p>
	<p>DO NOT USE A CLEANER CONTAINING PHENOL</p>
	<p>DO NOT WRING!</p>
	<p>REGULARLY INSPECT THE INSIDE OF THE COVER FOR CONTAMINATION</p>
	<p>MACHINE WASH AT 71°C WITH DETERGENT</p>
	<p>TUMBLE DRY ON LOW HEAT SETTING (MAX. 60°C)</p>
	<p>RINSE WITH WARM WATER AND NEUTRAL DETERGENT (INITIAL TEMPERATURE OF HOT WATER SHOULD NOT EXCEED 50°C)</p>
	<p>DISINFECT USING SOLUTION NO GREATER THAN 1,000PPM OF CHLORINE (SEE CHAPTER 'CLEANING AND MAINTENANCE')</p>
	<p>RINSE WITH WARM WATER</p>

 <p>BS 7175 MEDIUM HAZARD</p>  <p>BS 7175 RESISTANT</p>	<p>MATTRESS CONFORMS TO BS7177:2008 FOR MEDIUM HAZARD</p>
	<p>CE MARK OF CONFORMITY WITH EU REGULATION</p>
	<p>SYMBOL FOR TURNING AND ROTATING THE MATTRESS (SEE CHAPTER 'USING THE MATTRESS')</p>
	<p>DO NOT BLEACH</p>
	<p>PROFESSIONAL CHEMICAL CLEANING (MODERATE PROCEDURE)</p>
	<p>MANUFACTURER</p>
	<p>MEDICAL DEVICE (compatible with Medical Device Regulation)</p>
	<p>GENERAL WARNING SIGN </p>
	<p>NATURAL DRYING</p>

	<p>RINSE WITH WARM WATER AND NEUTRAL DETERGENT (INITIAL TEMPERATURE OF HOT WATER SHOULD NOT EXCEED 50°C)</p>
 <p>NaClO 1,000 ppm max</p>	<p>DISINFECT USING SOLUTION NO GREATER THAN 1,000PPM OF CHLORINE (SEE CHAPTER 'CLEANING AND MAINTENANCE')</p>
	<p>RINSE WITH WARM WATER</p>
	<p>REFERENCE NUMBER (PRODUCT TYPE DEPENDING ON CONFIGURATION)</p>
	<p>MANUFACTURING DATE</p>

1.5.1 Mattress Wash Label

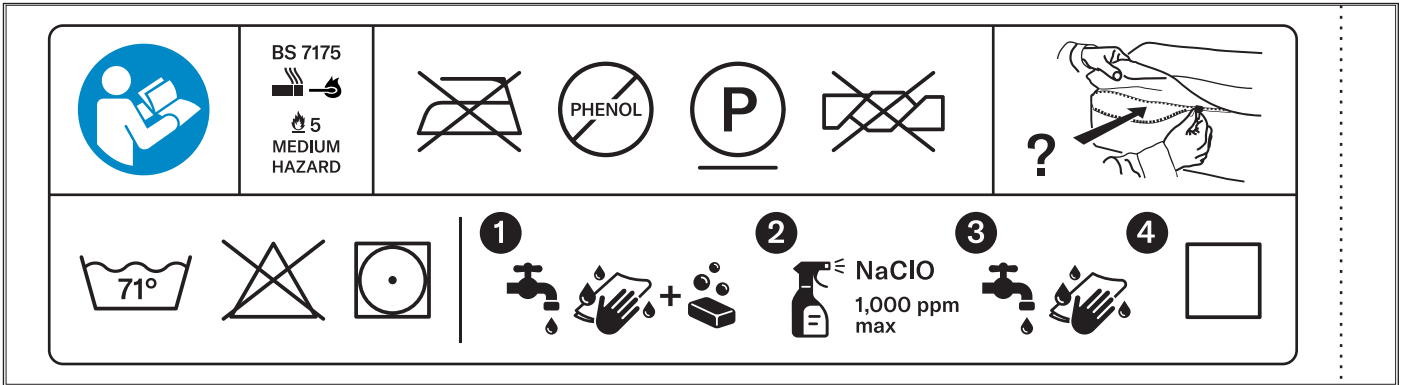


Fig. Mattress Wash Label for EffectaCare 20, EffectaCare 20 B, EffectaCare 20 P, PrimaCare 10 and CliniCare 10 P

1.5.2 Fire Resistance Label



Fig. Fire Resistance Label for EffectaCare 20, EffectaCare 20 B, EffectaCare 20 P, PrimaCare 10 and CliniCare 10 P

1.6 Serial Labels

Picture of serial label below serves just for explanation of the signs and fields on the serial labels.

1.6.1 Mattress Serial Label

1	Mattress name (one name for different configurations)
2	Reference number depending on configuration
3	Mattress dimensions depending on configuration
4	Maximum Load

Fig. Description of Mattress Serial Label

1.7 Abbreviations

B	Bariatric (mattress)
CE	European Conformity
CMHR	Combustion Modified High Resilience
CPR	Cardiopulmonary Resuscitation
ICU	Intensive Care Unit
IP	Ingress Protection
IV	Intravenous
MD	Medical Device
ME	Medical Electrical (Equipment)
P	Paediatric (mattress)
PCM	Phase Change Material
ppm	parts per million, millionth (1000 ppm = 0,1%)
REF	Reference Number (product type depending on configuration)
SN	Serial Number
SWL	Safe Working Load
PU	Polyurethane
LDPE	Low Density Polyethylene

1.8 Definitions

Maximum Patient Weight on the bed with mattress	Maximum Patient Weight depends on the application environment according to IEC 60601-2-52. For application environment 1 (intensive/critical care) and 2 (acute care) reduce Safe working Load by 65 kg. For application environment 3 (long-term care) and 5 (ambulatory care) reduce Safe working Load by 35 kg.
Maximum Load	The highest allowable load on the mattress.
Adult	Patient having a physical size equal to or more than 146 cm, a mass equal to or more than 40 kg and a body mass index (BMI) equal to or more than 17 (according to IEC 60601-2-52).
Child	Patient having a physical size equal to or less than 155 cm and a mass equal to or less than 70 kg.

2 Safety Instructions



WARNING!

These instructions for use **MUST** be given to the user of the product **BEFORE** using this product. Please read these instructions for use and save for future reference.



WARNING!

Do not use these products or any additional equipment without reading and understanding these instructions for use and any other instruction provided!



WARNING!

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established!



WARNING!

This medical device is not intended for oxygen enriched environment!



WARNING!

This medical device is not intended for use with flammable substances!



WARNING!

This medical device is not portable medical electrical equipment!



WARNING!

Limited patient handling leads to development of pressure injury!



WARNING!

Before placing a patient on mattress, always have a suitably clinically qualified person perform a risk assessment to ensure that the support provided is appropriate and fulfils the local stipulations!



WARNING!

Support surface selection should be based on documented clinical reasoning, taking into consideration factors of the individual patient, e.g. mobility, heat, moisture, comfort etc.



WARNING!

High specification support surfaces are designed to complement, rather than replace, best practice in nursing care, e.g. regular patient turning.



WARNING!

Only nursing personnel trained according to the instructions for use is authorised to perform the installation of the mattresses on a compatible mattress support platform.

2.1 Safety Instructions

- ▶ It is necessary to read the instructions for use before using the mattress and perform maintenance according to the instructions for use.
- ▶ Follow the instructions carefully.
- ▶ Do not use a damaged mattress.
- ▶ If possible, check the mattress daily or between changing patients.
- ▶ Before positioning the patient the user must verify the condition of the mattress.
- ▶ Single sided mattresses are only to be used with the screen printing uppermost, and, if necessary, to check the mattress core has the profiling uppermost.
- ▶ The mattress must not be used if failures have been found that can do harm to the patient or mattress.
- ▶ The selection of the correct mattress type and application of the mattress must always be consulted with qualified clinical professional, especially in the case of an injury of the head, spinal cord or backbone.
- ▶ A patient with the indication of a higher risk of pressure ulcers than the mattress is designed for must not be placed on the mattress.
- ▶ It is necessary to monitor the condition of the patient and his/hers skin continuously and to change his/hers position on the mattress to prevent stressing risk and affected parts of his/hers body.
- ▶ The mattress must not be laid on the mattress platform if there is a danger the mattress could be disturbed or the cover torn with sharp parts of the bed or other sharp objects.
- ▶ During using of the mattress it is necessary to monitor the condition of the mattress core to ensure that it is not permanently compressed which will reduce the anti-decubitus properties of the product.
- ▶ Prolonged exposure of light can change the color tone of the mattress core. This change has no effect on physical properties of the mattress core. Polyurethane foams can have different colours. This has no effect on physical properties of the mattress core.
- ▶ The mattress cover may shrink slightly or its colour may fade. The mattress is still suitable for use provided the cover does not become a very tight fit (i.e can still bend under gentle pressure) and shows no signs of damage to the top coating.
- ▶ The mattress is equipped with PU cover and must not be covered with an additional waterproof sheet as this will stop its moisture vapour permeability function of mattress cover.
- ▶ Do not put the bed into Trendelenburg or Anti-Trendelenburg position, when the head board and/or foot board are removed unless the bed frame is fitted with a retaining method to prevent the mattress from sliding up/down the bed when it is at such angles.
- ▶ The mattress must be placed on suitable type of mattress support platform according to the size of gaps between parts of mattress platform, which should not exceed 4 cm.
- ▶ The mattress must respect safety siderail height of a compatible medical bed.
- ▶ If the mattress platform has not features to provide ventilation to the base of the mattress, then the mattress should be regularly lifted and the base allowed to dry/breathe before further use. This will prevent moisture damage to the base cover and extend the life of the mattress.
- ▶ Continually loaded mattress has shorter lifetime period.

3 Intended use

The intended use of the EffectaCare 20, EffectaCare 20 B, EffectaCare 20 P, PrimaCare 10 and CliniCare 10 P mattresses is to assist in the prevention of pressure ulcers.

3.1 User population

- ▶ (Standard - **no code**) - Adult patients (weight \geq 40 kg, height \geq 146 cm, BMI \geq 17)
- ▶ (Paediatric - **code P**) - Paediatric patients from age of 3 years (10 kg \leq patient weight \leq 75kg)
- ▶ (Bariatric - **code B**) - Bariatric patients (patient weight \leq 250kg)
- ▶ Caregivers (nurses, doctors, technical personnel, transport personnel, cleaning personnel)

3.2 Contraindications

Patient with higher risk of pressure ulcers than the mattress is designed for:

- ▶ patients with higher weight than mattress weight limit
- ▶ patient's showing signs of pressure related tissue damage should be transferred onto an alternative support surface based on risk assessment, clinical reasoning and best clinical practice (EPUAP, NPUAP guidelines)
- ▶ Limited patient handling leads to development of pressure injury!

3.3 Operator

- ▶ Caregiver

4 Re-use

This product is suitable for repeated use. Before repeated use, ensure that the product is cleaned as per the cleaning and care instructions in these instructions for use.

5 Description of Mattresses

These mattresses are designed to be used in conjunction with a suitably sized mattress support platform, and as part of a pressure ulcer prevention care programme. These mattresses are not designed for any other use and any such use would void the manufacturer's warranty. These mattresses have been designed to deliver effective pressure re-distribution when used in accordance with the instructions in the instructions for use.

Mattress Feature	Mattress Type				
	EffectaCare 20	EffectaCare 20 B (Bariatric)	EffectaCare 20 P (Paediatric)	PrimaCare 10	CliniCare 10 P (Paediatric)
High resilience foam base	✓	✓	✓	✓	✓
Supporting side walls					
High resilient foam topper					
Visco-elastic (memory foam) topper					✓
PCM top layer					
Machine-hinged profiling	✓	✓	✓	✓	✓
Single sided	✓	✓	✓	✓	✓
Rotate only design	✓	✓	✓	✓	✓
Welded cover seams	✓	✓	✓	✓	✓
180° degree zip	✓	✓	✓	✓	✓
Maximum Load	150kg	300kg	72kg	200kg	72kg

5.1 Correct Mattress Orientation

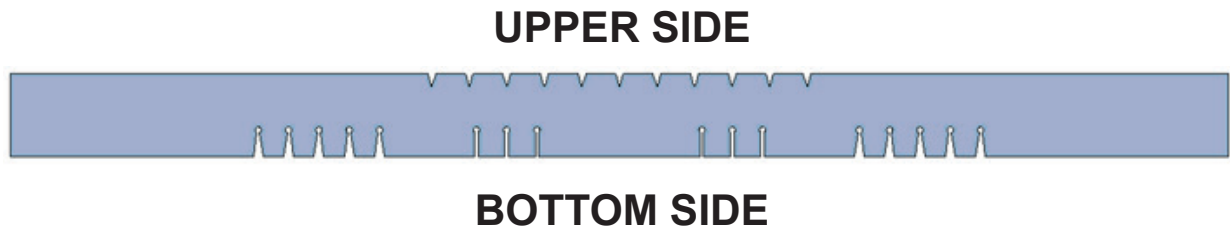


Fig. EffectaCare 20 (side view)

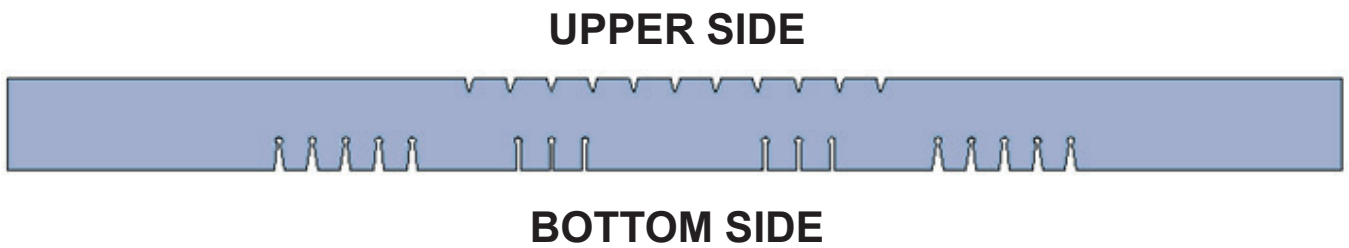


Fig. EffectaCare 20 B (side view)

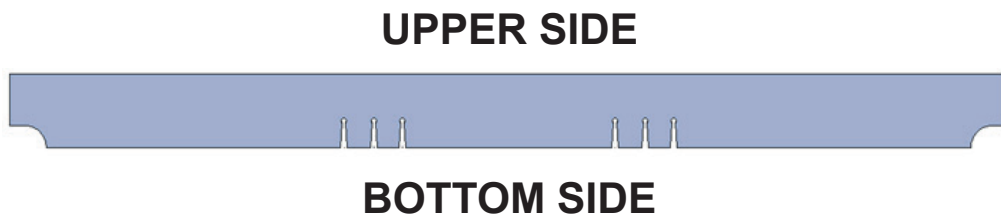


Fig. EffectaCare 20 P (side view)

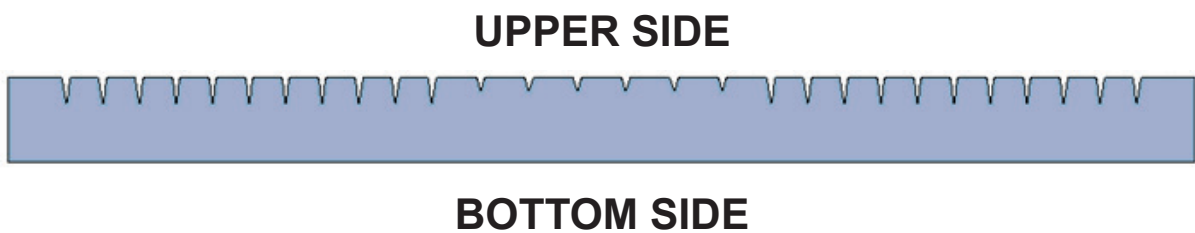


Fig. PrimaCare 10 (side view)

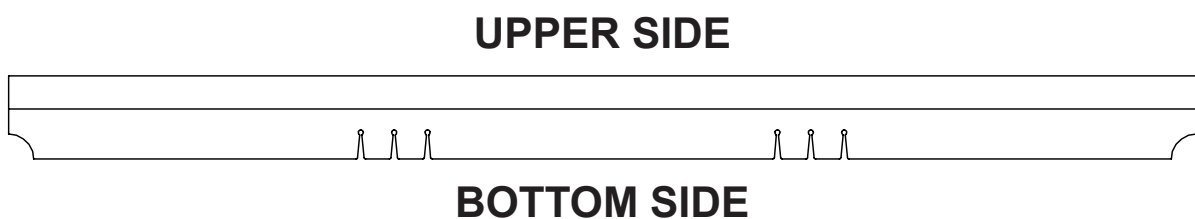


Fig. CliniCare 10 P (side view)

6 Technical Specification



WARNING!

If these mattresses are used with any compatible medical bed, respect values of mechanical specifications which can harm neither mattress nor medical bed!

	EffectaCare Range		
	EffectaCare 20	EffectaCare 20 B (Bariatric)	EffectaCare 20 P (Paediatric)
Mattress type	Preventive anti-decubitus	Preventive anti-decubitus	Preventive anti-decubitus
Material of foam	Polyurethane foam	Polyurethane foam	Polyurethane foam
Material of cover Backing Coating	100% polyester 100% polyurethane		
Cover	Water resistant and vapour permeable See Cleaning and Maintenance for additional information		
Weight of mattress	8kg	15kg	3,5kg
Height of mattress	14cm	16cm	10cm
Stacking limit	15 pieces	15 pieces	25 pieces

	PrimaCare Range
	PrimaCare 10
Mattress type	Preventive anti-decubitus
Material of foam	Polyurethane foam
Material of cover Backing Coating	100% polyester 100% polyurethane
Cover	Water resistant and vapour permeable See Cleaning and Maintenance for additional information
Weight of mattress	10kg
Height of mattress	14cm
Stacking limit	15 pieces

	CliniCare Range
	CliniCare 10 P (Paediatric)
Mattress type	Preventive anti-decubitus
Material of foam	Polyurethane foam, visco-elastic foam
Material of cover Backing Coating	100% polyester 100% polyurethane
Cover	Water resistant and vapour permeable See Cleaning and Maintenance for additional information
Weight of mattress	6kg
Height of mattress	10cm
Stacking limit	25 pieces

7 Use and Storage Conditions

Respect values of the parameters connected with environment conditions in the chapter Technical Specification during use and storage of the product.

EffectaCare 20, EffectaCare 20 B, EffectaCare 20 P, PrimaCare 10 and CliniCare 10 P mattresses are not suitable for indoor environments containing flammable gases (except oxygen cylinders).

EffectaCare 20, EffectaCare 20 B, EffectaCare 20 P, PrimaCare 10 and CliniCare 10 P mattresses are suitable for continuous operation.

When mattress is not in use:

- ▶ Store the mattress flat.
- ▶ Do not fold the mattress.
- ▶ Do not place heavy objects on the mattress surface when not in use.
- ▶ Do not allow sharp objects to penetrate the cover coating.
- ▶ Keep the mattress clean.
- ▶ Regularly inspect the exterior of the mattress.
- ▶ Do not store in damp conditions.
- ▶ When removing packaging use great care to ensure the cover is not damaged.

8 Scope of Delivery and Product Variants

8.1 Delivery

- ▶ Upon receipt, check that the shipment is complete as specified on the delivery note.
- ▶ Notify the carrier and supplier of any deficiencies or damages immediately as well as in writing or make a note on the delivery note.

8.2 Scope of Delivery

- Mattress
- Instructions for use

8.3 Variants

- EffectaCare 20
- EffectaCare 20 B
- EffectaCare 20 P
- PrimaCare 10
- CliniCare 10 P

9 Using the Mattress



DANGER!

Risk of suffocation due to air-impermeable mattress cover!

- ▶ Use mattress cover correctly.
- ▶ The nursing staff are responsible for the safety of the patient on the mattress cover!



WARNING!

Always consider shape and dimensions of the mattress platform for which the mattress will be used.



WARNING!

Ensure that the surface of the bed is clear from debris before placing the mattress – debris can damage the coating of the fabric.



WARNING!

Always ensure where is the upper side and bottom side of the mattress before putting the mattress cover back on the mattress foam core!



WARNING!

Never manipulate with mattress by grabbing it by its seams. This may cause damaging the mattress cover and risk of fluids penetrating into the mattress core!



CAUTION!

Material damage due to dampness or contamination!

- ▶ Make sure mattress cover has been cleaned and is completely dry.

9.1 Preparing the mattress for use

- ▶ Ensure that all packaging is removed from the mattress before use
- ▶ Lay the mattress flat on to the frame of the bed
- ▶ For a rolled mattress, lay the mattress flat and allow at least an hour for the mattress to restore to its original shape.
- ▶ Ensure the mattress is dry before use

9.2 Rotating the mattress

The LINET EffectaCare mattresses, PrimaCare mattress and CliniCare mattress detailed in these Instructions for Use are single-sided. Single-sided mattresses have numbers **1** and **2** on the top surface and can only be rotated, not turned (refer to the picture below for demonstration).

When replacing the mattress cover on a single-sided mattress, make sure that the protective flap on the cover zip is correctly positioned to prevent fluid ingress.

Frequent rotation is strongly recommended for non-turn mattresses as all foam grades fatigue during use and rotating will ensure loading is evenly spread across both ends of the mattress. Recommended interval of rotating/turning is once a month. When rotating a mattress, always grab the mattress from bottom side. Never manipulate with mattress by grabbing it by its seams. This may damage the cover and increase the risk of fluid ingress entering via the zip.

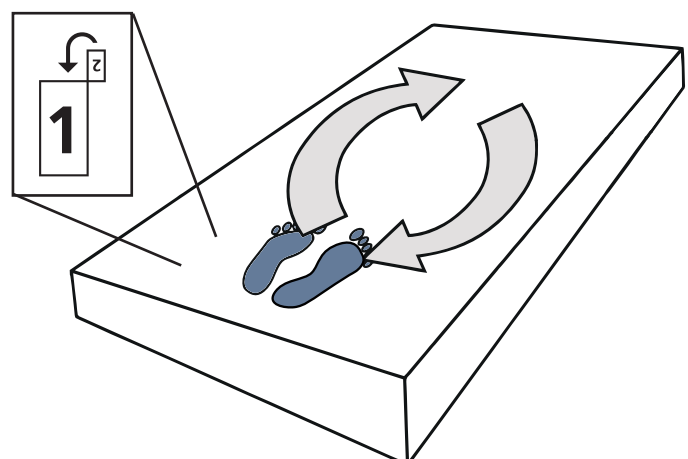
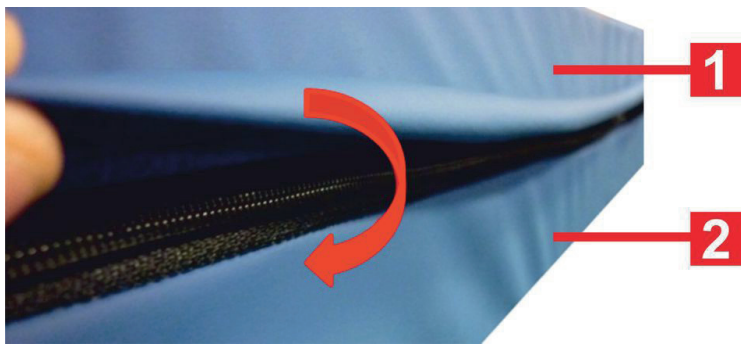


Fig. Rotation of mattress and screen print symbol



- 1. Top cover
- 2. Base cover

Fig. Correct placement of the top cover flap

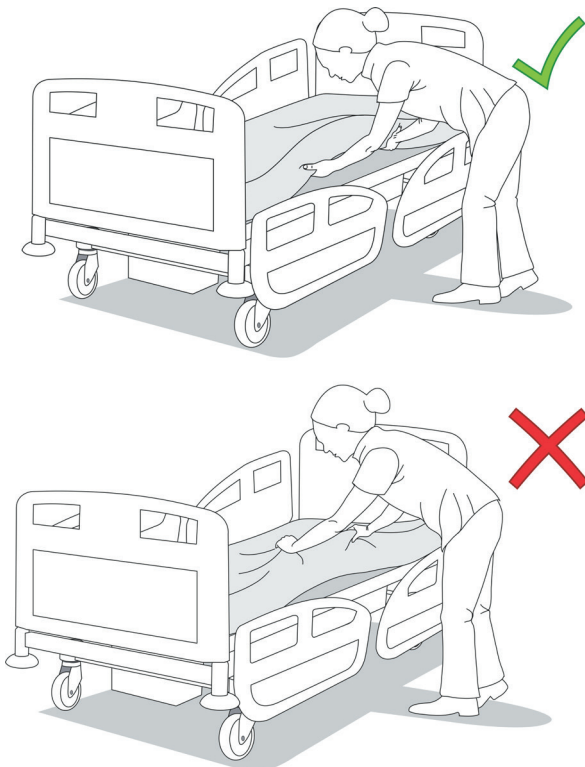


Fig. Manipulation with mattress

10 Accessories and Replacement Components

Extensions, Foams and Covers

There is a selection of mattress extensions available where necessary. Suitability of extension will be dependent on application and mattress type. Three styles of extension are available:

- Standard (CMHR foam layers)
- Comfort (CMHR base with a visco layer top)
- Bariatric (High durability CMHR foam layers)

Replacement foam and covers are available where necessary. For more information on the following items please contact your local LINET distributor.

11 Cleaning and Maintenance

**WARNING!**

The cover fabric is treated with biocide against bacteria and fungi. This antibacterial agent reduces effectively the development of bacteria. The active biocide substance is zinc pyrithione.

**WARNING!**

The following instructions apply to the cleaning and maintenance of the cover only. The foam construction must not be disinfected or laundered as this will affect the integrity of the mattress.

**WARNING!**

It is recommended to clean this product with water and soap only. Cleaning products containing alcohol, solvent, bleach or abrasive products can damage this product.

11.1 General Cleaning

For general cleaning and superficial dirt, use a disposable wipe with a solution of warm water and neutral detergent. Do not use abrasive or phenolic-based cleaners. Cleaning by neutral water and soap, followed by rinsing with water, is sufficient to clean this product. Solvent containing alcohol, bleaching or abrasive products can be harmful. On request, the manufacturer will provide list of cleaning agents and disinfectants tested with the mattresses.

To disinfect in situ, use a 0.1% sodium hypochlorite solution (1,000ppm chlorine). If required, a 1% chlorine solution (10,000ppm) and cold water may be applied for no more than 2 minutes. Thoroughly rinse the cover with clean water and allow drying before re-use or storage.

Removable, contaminated covers should be laundered at 71°C for no more than 10 minutes or at 95°C for no more than 3 minutes. Spin and tumble dry at no more than 60°C. Do not mangle or iron.

11.2 Mattress Inspection

1. Check the mattress for signs of tearing and/or punctures.
2. Check the seams for any signs of splitting.
3. Check the zip(s) if applicable for any signs of damage.
4. Check for any signs of permanent staining.

12 Disposal

12.1 Environment Protection

The company LINET® is aware of the importance of environmental protection for future generations. Within this company the environmental management system is applied in accordance with the internationally agreed standard ISO 14001. The compliance with this standard is annually tested by the external audit executed by an authorised company. Materials used in this product are not environmentally hazardous. LINET® products meet valid requirements of national and European legislation in the areas of **RoHS** and **REACH**, so they do not contain any prohibited substances in excess quantities. None of the wooden parts is made of tropical wood (such as mahogany, rosewood, ebony, teak etc.) or made of timber from the Amazon region or from similar rainforests. Used packaging materials are in accordance with requirements of the Packaging Act (**Zákon o obalech**). For disposal of packaging materials after installation of products contact your sales representative or manufacturer's customer service about the possibility of a free take-back of packaging through an authorized company (more details on www.linnet.cz).

12.2 Disposal

12.2.1 Within Europe

To dispose of the mattress:

- ▶ Ensure that the mattress is fully decontaminated prior to disposal.
- ▶ The equipment must not be disposed of as household waste.
- ▶ Dispose of this equipment at designated collection points or take-back points.

LINET® participates in a collective system with take-back company REMA System (see www.remasystem.cz/sberna-mista/). By bringing electric and electronic equipment to a take-back point, you participate in recycling and you save primary raw material resources while protecting your environment from effects of unprofessional disposal.

12.2.2 Outside Europe

To dispose of the mattress:

- ▶ Ensure that the mattress is fully decontaminated prior to disposal.
- ▶ Dispose of the product or its components in accordance with local laws and regulations!
- ▶ Hire an approved waste disposal company for disposal!

13 Warranty

The EffectaCare mattresses, PrimaCare mattress and CliniCare mattress are covered against faulty manufacture and materials as replacement goods. The length of warranty for each type of mattress is stated in chapter Technical Specification.

Normal wear and tear expected would not be included.

All warranties subject to LINET terms and conditions of trading.

In order to claim under warranty refer to the batch number printed on the product label. Never remove the label.

If a defect or fault is discovered, the LINET representative from whom the product was obtained must be notified immediately. For potentially serious and/or life-threatening situations, your local Competent Authority must be informed.

14 Standards and Regulations

Applied norms are stated on Declaration of Conformity.

The manufacturer adheres to a certified quality management system in compliance with the following standards:

- ISO 9001
- ISO 14001
- ISO 13485
- MDSAP (Medical Device Single Audit Program)

All LINET EffectaCare mattresses, PrimaCare mattress and CliniCare mattress are considered as medical devices, and therefore feature the CE mark, in accordance with EU Medical Device Regulation 2017/745.

Manufacturer is committed to advancing responsible care, continuously improving environmental, health and safety knowledge and the performance of used technologies, processes and products over their lifecycles. As a result, only REACH compliant materials and components are used.

The foam and cover used to manufacture the LINET EffectaCare mattresses, PrimaCare mattress and CliniCare mattress are independently tested and are certified in accordance with EN597-1 and EN597-2 (Assessment of the ignitability of mattresses and upholstered bed bases – ignition source: smouldering cigarette (1) and match flame equivalent (2)).

Each product is individually tested as a composite in accordance with BS7177 ignition sources 0,1 and crib 5.

For further information on standards and regulations, please contact your LINET representative.