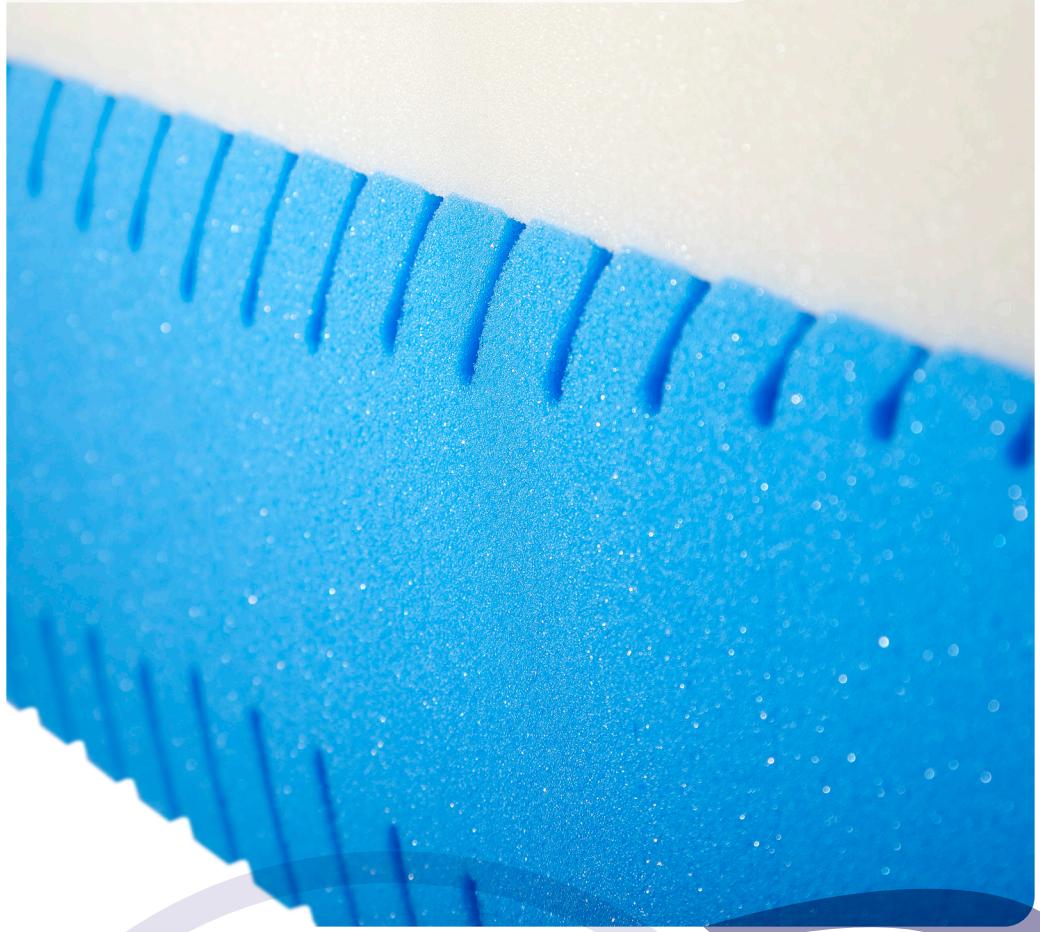




User manual Presstige Mattresses



Presstige Mattresses

Instructions for Use

Read this user manual carefully before installation and use!

English

Other languages are available upon request.

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Revision History

Rev.	Description	Who
2.0.0	Concept	Sven Vermaas, QM
2.1.0	Final	Sven Vermaas, QM



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Medical Device
Class I
(EU) MDR 2017/745

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1. Introduction

This manual applies to the complete Presstige mattress line.

Thank you for purchasing a Presstige mattress.

This manual provides information on maintenance and use, including important tips and relevant safety instructions.

Before commissioning the Presstige mattress, it is important to read the entire manual.

Deron BV is the manufacturer of the Presstige mattresses.

For more information, please visit: www.deron.nl

Team Deron

2. General Instructions

The Presstige mattresses from Deron BV are manufactured in accordance with international standards and regulations.

The Presstige mattresses comply with the applicable requirements regarding safety and functionality and are therefore CE-marked in accordance with the essential safety requirements for medical devices, according to (EU) MDR 2017/745.

Intended Use:

The intended use of the Presstige mattresses is a non-active anti-decubitus mattress.

Medical device	Yes
Risk classification	I
Risk rule	1
Intended use	Non-active anti-decubitus mattress
Applicable legislation	(EU) MDR 2017/745
On the European market	Yes
EMDN	V080702 NON ACTIVE ANTI-DECUBITUS MEDICAL MATTRESSES

The Presstige mattresses have been tested in the factory for safety and functionality. Before commissioning these mattresses, it is important to physically check the mattress for any damage.

3. Warranty and Liability

The warranty conditions for the Presstige mattress range can be found in our general terms and conditions.

The Bossy® Smart Mattress from Connect Foam Care BV has a ten-year factory warranty on material and manufacturing defects, excluding wear resulting from normal use and aging. "Normal" use is defined as 8 hours per 24 hours.

The electronic components and sensors of the Bossy® Smart Mattress carry a two-year factory warranty covering material and manufacturing defects. The warranties are included in the rental agreement.

All forms of warranty become void if a defect arises from or results from improper use of the Bossy® Smart Mattress, or if third parties have made or attempted to make alterations to the Bossy® Smart Mattress. This naturally also applies to the module.

No claims for compensation can be made, regardless of the legal basis on which such claims are made.

Connect Foam Care BV is not responsible for damage or functional failures caused by operating errors or by not following these instructions for use.

Connect Foam Care BV can never be held liable for claims resulting from force majeure, such as failure/outage of the communication network or power outages.

4. General Safety Regulations

 Before using the Presstige mattress for the first time, this user manual must be read thoroughly.
Ensure that every caregiver is informed about this user manual.

4.1 Explanation of Symbols



Operating instructions



Read the information marked with this symbol carefully. It describes safety-relevant information.



Conformity marking according to the Medical Device Regulation.



Medical device



Manufacturer



Symbol for maximum patient weight



Safe working load symbol



This product must be stored dry.



LOT number

REF

Reference (GTIN)



Do not use if the packaging is opened or damaged.

SN

Serial number

UDI

Unique Device Identification (GS1 Data Matrix barcode)

4.2 Intended Use

The Presstige mattresses are intended for lying on.

The Presstige mattresses are suitable for adult patients with a height of 146 cm or more, and a body weight between 55 and 140 kilograms.



4.3 Safety Instructions



Guidelines for the use of Presstige mattresses:

Some variants of the Presstige mattresses must not be turned over. These mattresses have a distinct top and bottom side. Symbols on the incontinence cover indicate how the mattress should be placed on the bed. "This side up" marks the top side of the mattress. This marking is always located at the head end of the mattress.

- Always ensure that the mattress zipper is fully closed.
- Protect fingers when opening and closing the zipper.
- Contamination of the foam core by food, feces, blood, fungi, or excessive moisture is harmful to the user. Replace the smart mattress if such contamination is detected.
- This mattress is, and should be, temperature-sensitive.
- The core of the mattress is sensitive to UV exposure; discoloration does not affect quality.
- Presstige mattresses may be used with an electric bed base and an electric blanket.
- It is recommended to inspect the mattress for defects, functionality, and quality after three years of use. Replace the product if defects are found.
- Always use these mattresses (foam core and incontinence cover) together with:
 - The original IC mattress cover from Deron.
 - The original mattress core from Deron.
 - The original tricot from Deron.
 - A well-ventilated bed base.
 - Always with a bed.

4.4 Environment

The Presstige mattresses can be used in an environment between 10 and 38 °C with a relative humidity of 0% to 85% without condensation.

4.5 Incident Reporting and Competent Authority

Any serious incident related to the device must be reported to the manufacturer and to the competent authority of the member state where the user and/or patient is located

5. Commissioning

5.1 First Use

Read the user manual carefully to prevent damage and hazards caused by incorrect use.

- Check whether the Presstige mattress has been received in good condition.
- When changing the patient on the mattress, the incontinence cover must be thoroughly cleaned.
- Any defects must be reported to the distributor immediately.

5.2 Checklist

The Presstige mattresses are carefully inspected at delivery using the checklist below. This checklist is provided digitally. If the mattress is put back into use after temporary storage, this checklist serves as a mandatory inspection.

Performed by:

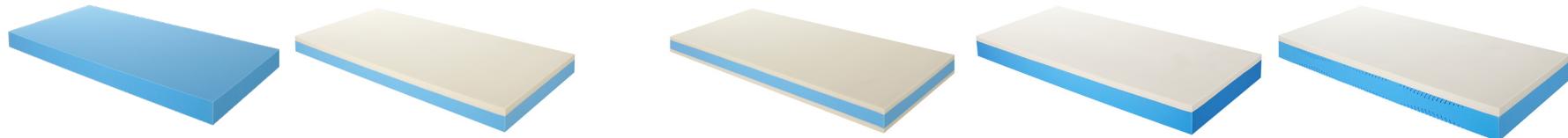
Date:

Mattress for department:

Serial number:

Component	Check for	OK	Not OK	Not Present	Damaged
Mattress	Position. See instructions on IC cover				
Mattress core	Damage and contamination				
Cover	Damage				
Zipper	Damage				

6. Product Overview



Swivity matras

Presstige Cold Foam

15 cm HRC cold foam

1 firmness

50 kg/m³

-

3,5 kPa

-

80,0 kPa

-

120%

-

BS EN 1021-1
BS EN 1021-2

Incontinence cover complies with the standard:

BS 7115

Composition Mattress core

Presstige Memory Foam

10 cm HRC cold foam + 5 cm
Traagschuim

1 firmness

50 kg/m³

55 kg/m³

3,5 kPa

2,8 kPa

80,0 kPa
150,0 kPa

120%
220%

BS EN 1021-1
BS EN 1021-2

BS 7115

Firmness

Presstige Memory Foam Twin

9 cm HRC cold foam + 2x 3
cm memory foam

1 firmness

50 kg/m³

55 kg/m³

3,5 kPa

2,8 kPa

80,0 kPa
150,0 kPa

120%
220%

BS EN 1021-1
BS EN 1021-2

BS 7115

Density

Top layer

Secondary layer(s)

Presstige Memory Foam Deluxe

14 cm HRC cold foam + 5 cm
memory foam

soft, medium and firm

50 kg/m³

55 kg/m³

3,5 kPa

2,8 kPa

80,0 kPa
150,0 kPa

120%
220%

BS EN 1021-1
BS EN 1021-2

BS 7115

Stiffness

Top layer

Secondary layer(s)

Presstige Memory Foam Profiled

14 cm HRC cold foam + 5 cm
memory foam

soft and medium

50 kg/m³

55 kg/m³

3,5 kPa

2,8 kPa

80,0 kPa
150,0 kPa

120%
220%

BS EN 1021-1
BS EN 1021-2

BS 7115

Tensile Strength

Top layer

Secondary layer(s)

Elongation at Break

Top layer

Secondary layer(s)

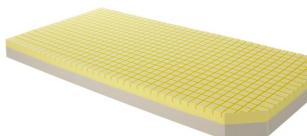
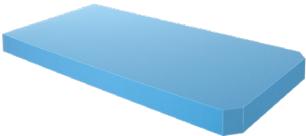
Fire Safety

Foam complies with the
standards:

Incontinence cover complies with the standard:

3D cover complies with:

Product Overview



Swivity mats

Flexobed Memory Foam

15 cm HRC cold foam

1 firmness

50 kg/m³

-

3,5 kPa

-

80,0 kPa

-

120%

-

BS EN 1021-1
BS EN 1021-2

BS 7115

Secure the straps around the sleeping surface of the bed to prevent shifting.

Flexobed Memory Foam Combi Care

10 cm HRC cold foam + 5 cm Traagschuim

1 firmness

50 kg/m³

55 kg/m³

3,5 kPa

2,8 kPa

80,0 kPa
150,0 kPa

120%
220%

BS EN 1021-1
BS EN 1021-2

BS 7115

Secure the straps around the sleeping surface of the bed to prevent shifting.

Flexobed Memory Foam Firm

9 cm HRC cold foam + 7 cm memory foam

1 firmness

50 kg/m³

60 kg/m³

4,8 kPa

3,7 kPa

110,0 kPa
200,0 kPa

160%
200%

BS EN 1021-1
BS EN 1021-2

BS 7115

Secure the straps around the sleeping surface of the bed to prevent shifting.

Composition Mattress core

Firmness

Density

Top layer

Secondary layer(s)

Stiffness

Top layer

Secondary layer(s)

Tensile Strength

Top layer

Secondary layer(s)

Elongation at Break

Top layer

Secondary layer(s)

Fire Safety

Foam complies with the standards:

Incontinence cover complies with the standard:

3D cover complies with:

Straps



7. Cleaning and Disinfection

7.1 Initial Cleaning of a Presstige Mattress

Before using the mattress, we recommend wiping the incontinence cover with a lightly damp cloth and a neutral cleaning agent, and then neutralizing it with a damp cloth without cleaning agent.

Note: observe the safety precautions mentioned in section 7.2.

7.2 Safety Measures For Cleaning

When cleaning the mattress, always follow the safety measures below:

- Be careful when using liquids that are aggressive or acidic.
- If a disinfectant is used, always check whether the product is included in the list below. If not, contact the distributor so the cleaning agent can be verified. Never exceed the recommended dosage of the cleaning agent.
- Do not use iodine tincture.
- Ensure that after cleaning the mattress cover is neutralized with a damp cloth without cleaning agent.

List of Disinfectants

Product name	Concentration/Amount
Incidin Plus (Ecolab)	2%
Kodan Tinktur Forte (Schulke)	Pure
Mikrobac Forte (Hartmann)	4%
Sodiumhypochlorite (Standard)	1000 ppm
Octenispert (spray) (Schulke)	Pure
P3-topax 66 (Ecolab)	5%
Sagrotan (spray) (Reckitt Benckiser)	Pure
Sanit P20 (Iberian Cleaning Expert	Pure
Spring (kalle Original)	Pure
Sprint 200 (Diversey)	2%
Suma Bac D10 (Johnson Diversey)	1%
SurfaSafe (Anios Laboratories)	Pure
Topmax 421 (Ecolab)	5%
Virkon (Du Pont)	10 g/l
Volvone (Oyar)	40%
Actichlor Plus (Ecolab)	1000 ppm
Anios DDHS (Anios Laboratories)	Pure
B45 (Orochemie)	Pure
Bacillol 30 Foam (Hartmann)	Pure
Clinell Sporicidal Wipes(Garna Healthcare)	Pure
Chlor-Clean tablets(Guest Medical)	1000 ppm
Dettol (Reckitt Benckiser)	5%
Dismozon Pur (Hartmann)	4%
Formaldehyde (Pharmacy)	30%
Germatol (kiarah Chem)	5%
Hansamed (spray) (beiersdorf AG)	Pure
Haz-Tabs (Guest Medical)	1000 ppm
Hibicet (Molnlycke Health Care)	Pure
Incidin Extra N (Ecolab)	2%
Volvone (Oyar)	40%

7.3 Purpose of Cleaning

- Prevent the client from contamination.
- Prevent the caregiver from contamination.
- Keep the incontinence cover in optimal condition.

7.4 Cleaning

To ensure the longevity of the mattress with incontinence cover, it is important to follow this cleaning protocol.

- The incontinence cover is made of biocompatible material. This hypoallergenic product is easy to clean.
- The mattress and incontinence cover do not serve as a breeding ground for microorganisms and therefore do not need to be treated as such.
- The mattress is standard delivered with an incontinence cover. If cleaning in a laundry facility is desired, the mattress should be protected with an incontinence cover with diver zipper. This can be ordered from the distributor.
- Alcohol-based disinfectants can be used on the mattress without affecting its quality.

7.4.1 Daily Cleaning

- Check for surface dirt or other unwanted substances. If detected, clean the surface with a slightly damp cloth that has been washed above 80 °C.
- Do not use abrasive cleaners, caustic agents, or solvents with high acetone content.
- Use disinfectants if necessary. See section 7.2.

7.4.2 Cleaning after Client Change on the Smart Mattress

- Check for surface dirt or other unwanted substances. If detected, clean the surface with a slightly damp cloth that has been washed above 80 °C.
- Do not use abrasive cleaners, caustic agents, or solvents with high acetone content.
- Use disinfectants if necessary. See section 7.2.

7.4.3 Periodic Cleaning

- Ventilate the smart mattress core (without incontinence cover) at least twice a year.
- Wash the incontinence cover at least once a year. This can be done in a washing machine set at 95 °C. Tumble dry: low temperature.

8. Technical Specifications

- To follow (image to be added)

9. Maintenance

Check the mattress at least once a month. Evaluate after 6 years whether the mattress needs to be replaced. Optionally, perform an interim evaluation after three years.

9.1 Storage



Before storing the mattress, it must be cleaned and disinfected. The mattress can be packed in a plastic cover. Storage should be in a dry room, without any exposure to sunlight. Stack a maximum of 15 mattresses on top of each other.

10. Transport

The smart mattress must always be well protected in plastic during transport.



Do not use sharp objects.

11. Helpdesk and Service

For problems or questions regarding your mattress, please contact your dealer.