

INSTRUCTIONS FOR USE

AtmosAir 9000X

Hybrid mattress





WARNING

To avoid injury, always read this Instructions for use and accompanied documents before using the product.



Mandatory to read the Instructions for use.

Design Policy and Copyright

® and ™ are trademarks belonging to the Arjo group of companies.

© Arjo 2021.

As our policy is one of continuous improvement, we reserve the right to modify designs without prior notice. The content of this publication may not be copied either whole or in part without the consent of Arjo.

Contents

Foreword	5
Intended use	6
Safety instructions	8
Preparation	9
Parts designation	10
Product description	11
Covers	11
Handles	11
Non-slip base	11
Assemble the hybrid mattress	12
Assemble the 9000X mattresses	12
Reactive therapy	13
Patient position	13
Homecare use	14
Cleaning and disinfection	15
Clean and disinfect	17
Care and preventive maintenance	18
Technical specifications	19
Labels	21

Intentionally left blank

Foreword

Thank you for purchasing the AtmosAir® 9000X hybrid mattress.

Customer contact information

For questions regarding this product, supplies, maintenance, or other Arjo products and services, contact Arjo, an Arjo authorised representative or visit www.arjo.com.

Read and fully understand this IFU before using the product

The information in this Instructions For Use (IFU) is necessary for the proper operation and maintenance of your device. It will help to protect your product and make sure that it performs to your satisfaction. The information in this IFU is important for your safety. You must read and understand the IFU to help prevent possible injury. Unauthorised modifications on any Arjo device can affect its safety and performance. Arjo cannot be held responsible for any accidents or incidents resulting from such modifications to its products.

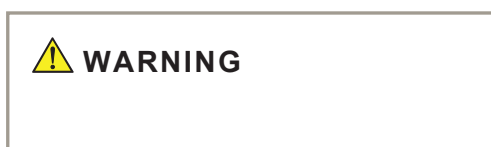
Service and support

Routine maintenance before every use or every week (in long-term care) is necessary to maintain the safety and reliability of the product. See the Care and preventive maintenance section for more information. If you require further information or spare parts, see Customer contact information.

Serious incident

If a serious incident occurs in relation to this medical device, affecting the user, or the patient, then the user or patient should report the serious incident to the medical device manufacturer or the distributor. In the European Union, the user should also report the serious incident to the Competent Authority in the member state where they are located.

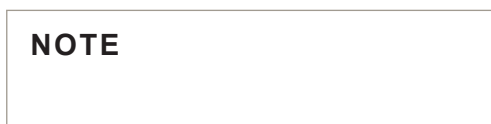
Definitions in this IFU



Warning means: Safety warning. Failure to understand and obey this warning may result in injury to you or others.



Caution means: Failure to follow these instructions may cause damage to all or parts of the system or device.



Note means: This is important information for the correct use of this system or device.

Intended use

The AtmosAir 9000X hybrid mattress (Reactive only) is intended for use by caregivers¹ in acute care, long-term care and home care facilities, including private homes.

The hybrid mattress is indicated for the prevention and management of pressure injuries. It should be used as part of an individualised, comprehensive pressure injury protocol. This typically includes: repositioning, nutritional support and skin care. The hybrid mattress should be selected based on full assessment of the patient needs.

The hybrid mattress represents one aspect of a pressure injury management protocol. All other aspects of care should be considered by the healthcare professional. If existing wounds do not improve, or the patient's condition changes the overall therapy regimen should be reviewed by the healthcare professional.

As guidance the hybrid mattress is indicated for patients that are deemed to be 'At Risk' of a pressure injury.²

The above are guidelines only and should not replace clinical judgement.

The hybrid mattress is for patients within the weight range of 40 kg (90 lbs) to 250 kg (550 lbs).

The hybrid mattresses should only be used for the purpose specified in this Instructions for Use. Any other use is prohibited.

1 Caregiver may be a healthcare professional or lay person who operates this medical device.

2 European Pressure Ulcer Advisory Panel, National Pressure Injury Advisory Panel and Pan Pacific Pressure Injury Alliance. *Prevention and Treatment of Pressure Ulcers/Injuries: Clinical Practice Guideline. The International Guideline.* Emily Haesler (Ed). EPUAP/NPIAP/PPPIA: 2019, Chapter 4 Risk Factors and Risk Assessment

Contraindications

None

Patient assessment

Ongoing assessment by a healthcare professional and continuous monitoring of the patient is advised for patients with unstable cervical, thoracic and/or lumbar fracture, cervical traction, and skeletal traction when used in conjunction with the hybrid mattress.

Facilities should establish regular assessment routines. Caregivers should assess each patient before using the product. The patient weight must not exceed:

250 kg (550 lbs) for the hybrid mattresses

If the patient does not meet these criteria an alternative medical device/system shall be used.

Expected service life

The expected service life of the AtkomsAir 9000X hybrid mattress element is:

- Mattress – 5 Years

The expected service life of this equipment is subject to preventive maintenance being carried out in accordance with the instructions for care and maintenance found in the Instructions for Use.

Safety instructions



WARNING

To avoid pressure injury, make sure that the hybrid mattress is assembled correctly.



WARNING

To avoid bodily injury, do not use the mattress as a patient movement device.



WARNING

To avoid injury and/or unsafe product, do not use unapproved accessories or attempt to modify, disassemble or otherwise misuse the hybrid mattress.



WARNING

To avoid pressure injury the patient must not wear clothing that may cause areas of localized high pressure due to creases, seams, etc. Objects in pockets must be avoided for the same reason.



WARNING

To avoid reduced benefits from the mattress, do not place extra layers between the patient and the mattress.

CAUTION

To avoid damage to the device, do not use sharp objects or electrical heat under the blankets on or under the hybrid mattress.

CAUTION

To avoid damage, do not expose the device to naked flames, such as cigarettes.

Preparation

Bed frame recommendation

The mattress range is designed to be used on Arjo bed frames. See Technical specifications on page 19 of this IFU.

The mattress range may also be used with other bed frames (non-Arjo). The clinician or caregiver should assess the needs and determine which mattress and bed frame to use. See the bed frame IFU for compatible mattress sizes. Find the dimensions of all mattresses in section Measurements and compatibility on page 19.

Actions before first use

1. Visually check the package for damage. If the package is damaged, contact the transport agency. Do NOT use the product.
2. Read this IFU.
3. Check that all parts of the product are supplied: Compare to section Parts designation on page 10. If any part is missing or damaged – do NOT use the product.
4. Recycle the packaging according to local regulations.
5. Choose a designated area where this Instructions for Use should be kept and is easily accessible at all times.

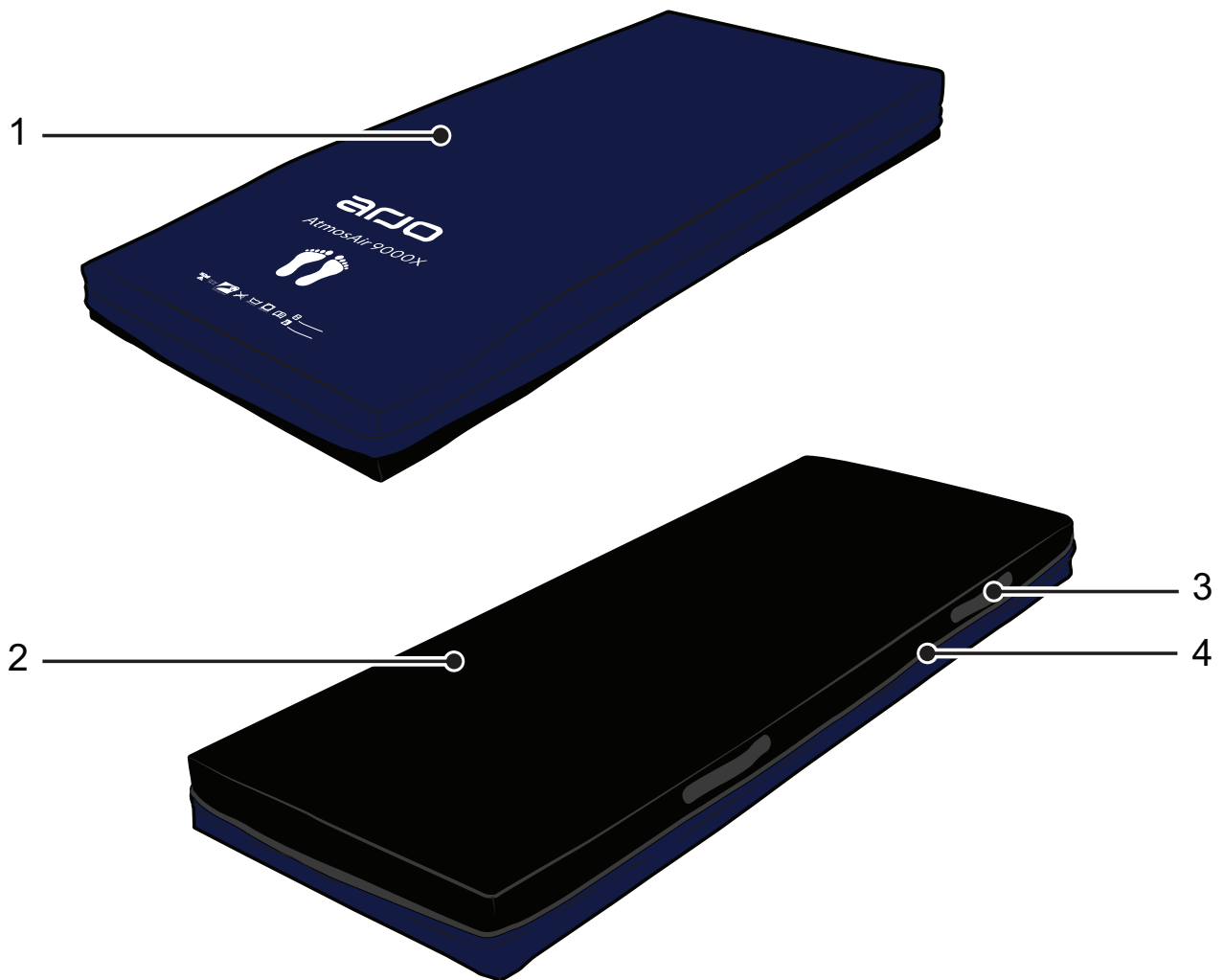
Actions before every use

Inspect the hybrid mattress according to section Care and preventive maintenance on page 18. If any item is damaged - do NOT use the product.

Action after each patient

Clean and disinfect the product after each patient according to section Cleaning and disinfection on page 15.

Parts designation



1. Detachable top cover

2. Detachable non-skid bottom cover

3. Handles

4. Cover attachment zip with zip flap

Product description

Covers

The mattress top and bottom welded covers are co-joined by a zip.

Handles

See Figure 1



WARNING

To avoid bodily injury, never use the mattress as a patient movement device.

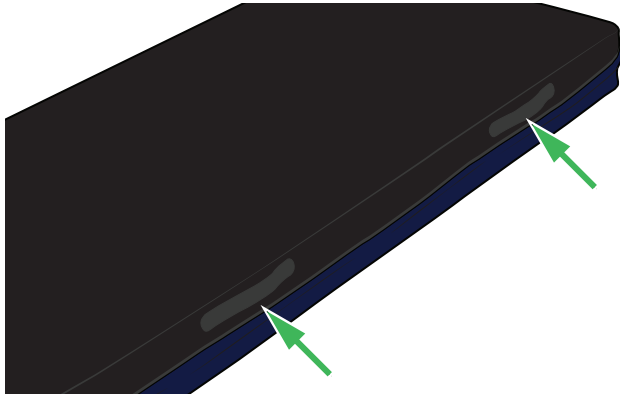


Figure 1

To move the mattress use the four handles on the bottom mattress cover.

Detachable non-skid bottom cover

See Figure 2

Base cover made from non-slip material to prevent the mattress from slipping on the bed frame



Figure 2

Assemble the hybrid mattress

1. Remove any existing mattress from the bed frame.
2. Check that there are no protruding sharp objects on the frame surface.

3.



WARNING

To avoid death or serious injury by entrapment, always select the correct mattress size for the bed.

Select the correct mattress size for the bed frame. Make sure that there are no gaps to trap the patient's head or body.

For mattress sizes see section Measurements and compatibility on page 19

4. Position the mattress on the bed frame. Make sure that the mattress is orientated correctly. See Figure 3.

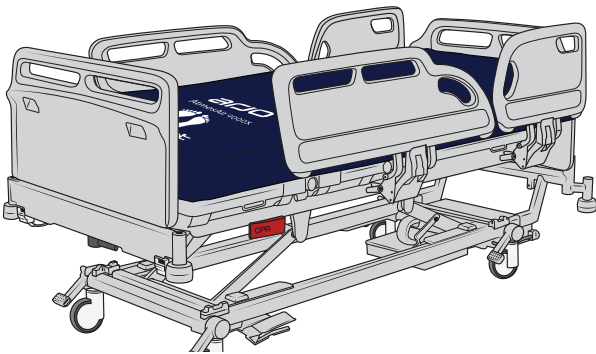


Figure 3

Reactive therapy

The AtmosAir 9000X reactive therapy is controlled by the Air Redistribution Module (Velaris ARM™) that allows pressure to be distributed between the air cells across the mattress surface. It adjusts itself by slowly, letting air in and out of the mattress, to maintain an optimum pressure level inside the air cells.

Make sure that the mattress is correctly installed on the bed frame before delivery of reactive therapy. See Assemble the hybrid mattress on page 12.

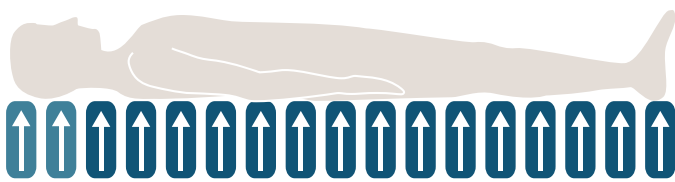


Figure 4

Patient position

Place the patient on the mattress. Make sure that the patient's head is placed on the head end of the mattress. See Figure 4.

Homecare use

WARNING

To avoid injury to the patient when operating the hybrid mattress as a caregiver and as a lay person:

- Make sure that the device is operating according to section Reactive therapy on page 13.
- If the device is not operating correctly, or if you have concerns, contact the patient's doctor or nursing staff for advice.

WARNING

To avoid risk of entanglement, never leave children or vulnerable persons unattended with the device

WARNING

To avoid injury to the patient, keep children and pets away from the device.

WARNING

To avoid suffocation, keep the bags supplied with this device away from babies and small children.

WARNING

To avoid choking, never leave children unattended near the device. The device includes small parts that may present a choking hazard to small children, vulnerable persons and pets if inhaled or swallowed.

CAUTION

To avoid damage to the device, pets and children must be supervised in the vicinity of the hybrid mattress.

Before using the AtmosAir 9000X hybrid mattress in a home environment, make sure that all caregivers, including relatives, have read and understood the instructions in this IFU.

When the hybrid mattress is in use, make sure that:

- It is kept away from sources of heat and moisture, and protected from dust, lint and dirt.

When the hybrid mattress is not in use, make sure that:

- No children can access it.
- No pets can come into contact with it.
- The storage environment meets the requirements. See section Transport and storage on page 19

Cleaning and disinfection

The hybrid mattress should be cleaned and disinfected at regular intervals and between patients. Follow your local practices for all reusable medical devices.

Contact Arjo Customer Service for any questions regarding the cleaning and disinfection of the device. Make sure that the Safety Data Sheet (SDS) is available for the disinfectant used.

WARNING

To avoid eye and skin damage, always use protective glasses and protective gloves. If contact occurs, rinse with plenty of water. If eyes or skin become irritated, contact a physician.

Always read the material safety data sheet of the disinfectant.

WARNING

To prevent cross-contamination, always follow the disinfection instructions in this IFU.

WARNING

To avoid eye or skin irritation, never disinfect in the presence of a patient.

CAUTION

To avoid equipment damage:

- Do not use Phenol-based solutions or abrasive compounds or pads during the disinfection process as these damage the surface coating.
- Do not autoclave or boil any part of the hybrid mattress.

Allowed disinfectants

DISINFECTANT	TOP COVER	BOTTOM COVER	RECOMMENDATIONS FOR USE
Alcohol solution ≤ 70%	●	●	Coating may swell when wet hence care must be taken to avoid accidental scratches and fold only when dry before storage.
Chlorine solution ≤ 1% (10,000 ppm) ¹	●	●	Acceptable use at pH 7-9. Must be towel dried (avoid harsh abrasion) after rinsing with clean water.
Quaternary ammonium solution 1920ppm	●	●	Acceptable for use at pH 7-10 only. Always check the label first. DO NOT USE WIPES containing Sodium Hydroxide (NaOH). Fully rinse with clean water to remove residual chemicals
Quaternary ammonium solution, 3-15%	●	●	Acceptable for use at pH 7-10 only. Always check the label first. DO NOT USE WIPES containing Sodium Hydroxide (NaOH). Fully rinse with clean water to remove residual chemicals.
Hydrogen peroxide solution, 3-10%.	●		Acceptable for use at pH 5-9 only. Low and high pH's will DAMAGE the coating. Fully rinse with water to remove any acid or alkali.
¹ Chlorine concentrations may vary from 250 ppm to 10,000 ppm depending on local policy and contamination status.			
<p>NOTE</p> <p>Rinse and dry thoroughly with clean water to remove residual chemicals after disinfecting with each chemical before storage</p>			

Accessories needed for cleaning/ disinfection

- Protective glasses
- Protective gloves
- Spray bottle with cleaning solution
- Spray bottle with disinfectant solution
- Spray bottle with water
- Cloths



Clean and disinfect

(13 steps)

Always follow these steps for proper cleaning and disinfection after each patient.

Clean the mattress covers

NOTE

The top cover should be assessed for the level of soiling. If this soiling is deemed excessive, the top cover should be washed. The bottom cover should always be cleaned and disinfected by wiping.

1. Spray all external areas of the mattress top and bottom covers with the cleaning solution. Wipe off any dirt with a clean cloth.
2. Clean areas with residual dirt (e.g. handles) with the cleaning solution as needed.
3. Use a new cloth soaked in water to wipe off all traces of cleaning solution
4. Use a dry cloth to remove any excess moisture.

Disinfect the mattress covers

5. Spray disinfectant solution on a clean cloth and wipe all external areas and handles of the mattress top and bottom covers.
6. Allow time for disinfection according to the instructions provided by the disinfectant manufacturer.
7. Use a new cloth soaked in water to wipe off all traces of disinfectant solution from the mattress.
8. Use a dry cloth to remove any excess moisture.
9. Allow the mattress top and bottom covers to air dry.

Wash the mattress top cover

10. Unzip and remove the top cover from the mattress.
11. Launder the top cover at a maximum temperature of 80°C (176°F) with detergent.
12. After washing, allow the top cover to air dry (preferred) or tumble dry at 40°C (104°F) or up to 80°C (176°F) maximum.
13. Once dry refit the top cover to the mattress.

Care and preventive maintenance

Under normal use the hybrid mattress is subject to wear and tear. the hybrid mattress does not require routine maintenance other than cleaning and disinfection as detailed above or routine inspection as detailed below.

CAREGIVER OBLIGATION	BEFORE EVERY USE OR EVERY WEEK	AFTER EACH PATIENT
Visually check the top and bottom covers	●	
Clean and disinfect		●
Visually check all labels		●
Visually check all zips		●

Caregiver obligations - before every use or every week

Visually check the top and bottom covers

- Remove the top cover and check for signs of wear, tears or strike-through (stained firesock).
- Inspect the bottom cover for signs of wear and tears

Caregiver obligations - after each patient

Clean and disinfect

The hybrid mattress has to be cleaned and disinfected. For further instructions see section Cleaning and disinfection on page 15.

Visually check all labels

Check that all labels are attached on the hybrid mattress according to section Labels on page 21. If any label is missing, contact Arjo Customer Service.

Visually check all zips

- Check that all zips are undamaged and not loose.
- Check that the zip puller is not missing.

Technical specifications

MEASUREMENTS AND COMPATIBILITY

Standard mattress

Part no	Size mm (in)	Top cover material	Weight kg (lb)	Arjo bed frames
633032	860 x 1980 x 180 (34 X 78 X 7)	Reliant	14.5 (32)	Contoura 460/480, Minuet 2, Prioma
633037		Premium		
633033	880 x 2020 x 180 (35 X 80 X 7)	Reliant	15.5 (34)	Contoura C880, Enterprise 5000X, 8000X, 9000X (Standard), Citadel (Standard)
633038		Premium		
633034	880 x 2140 x 180 (35 x 84 x 7)	Reliant	15,5 (34)	Enterprise 5000X, 8000X, 9000X (Extended), Citadel (Extended)
633039		Premium		
633035	900 x 2000 x 180 (35 x 79 x 7)	Reliant	15,5 (34)	Evenda
633040		Premium		
633036	1070 x 2000 x 180 (42 x 79 x 7)	Reliant	17 (37)	Evenda Wide
633041		Premium		

OPERATING CONDITIONS

Temperature (Ambient):	5 °C to 40 °C (41 °F to 104 °F)
Relative humidity range:	15 % to 90 % (non-condensing)
Atmospheric pressure:	700 hPa to 1060 hPa

TRANSPORT AND STORAGE

Short term (Up to 30 days):	
Temperature (Ambient)	-20 °C to 60 °C (-4 °F to 140 °F)
Relative humidity range	0 % to 95 %
Long term (> 30 days):	
Temperature (Ambient)	0 °C to 40 °C (32 °F to 104 °F)
Relative humidity range	0 % to 95 % (non-condensing)

CAUTION

To avoid damage to the hybrid mattress:

- Do not store in direct sunlight.
- Clean and disinfect the mattress before storage.

END OF LIFE DISPOSAL

Package	Corrugated cardboard, recyclable.
Product	<ul style="list-style-type: none"> • Fabric material used on the mattresses or any other textiles, polymers or plastic materials etc. should be sorted as combustible waste. • Mattresses at the end of life should be disposed of as waste according to the national or local requirements, which may be landfill or combustion.

TOP COVER SPECIFICATION		
Feature	Reliant cover	Premium cover
Removable Cover	Yes	Yes
Moisture Vapour Permeable MVTR - Index method BS3424-34	10%	4%
Polyurethane coating includes an antimicrobial agent to control microbial deterioration of fabric	Yes	Yes
Fire Retardant ¹	BS 7175: 0, 1 & 5	BS 7175: 0, 1 & 5
Material stretch properties	4-way	4-way
Recommended wash Temperatures	80°C (176°F) 15 minutes	80°C (176°F) 15 minutes
Recommended Drying Temperatures	40°C (105°F) or air dry	40°C (105°F) or air dry
Maximum Drying Temperatures	Max 80°C (176°F)	Max 80 °C (176 °F)
Wipe-down Chemicals ²	<ul style="list-style-type: none"> Chlorine at strength of ≤1% (10,000 ppm) at pH 7-9 Quaternary Ammonium Chloride at 1920ppm at pH 7-10 Alcohol at 70% concentration. Phenolic solutions are NOT recommended/suitable. <p>Always rinse thoroughly with clean water after disinfection and dry before storage. Alcohol does not require rinsing with water.</p> <p>Further following disinfecting agents are also considered to be acceptable by the TOP COVER material manufacturer</p> <ul style="list-style-type: none"> Quaternary Ammonium solution 3-15% at pH range 7-10 see Allowed disinfectants on page 16 for recommendations. Hydrogen Peroxide solution 3-10% at pH 5-9 see Allowed disinfectants on page 16 for recommendations.. <p>Always allow time for disinfection according to the instructions provided by the disinfectant manufacturer.</p>	
Lifetime Expectancy	Standard	Increased by x2.5 times longer when tested with accelerated aging (ISO 1419:1995)
Abrasion resistance	130 000 cycles	260 000 cycles (minimum)

¹ For additional flammability testing standards, refer to individual product law tags, if applicable.

² Chlorine concentrations may vary from 250 ppm to 10,000 ppm depending on local policy and contamination status. If an alternative disinfectant is selected from the wide variety available, Arjo recommend that suitability for use be confirmed with the chemical supplier prior to use

Labels

Labels on the surfaces









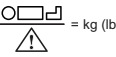
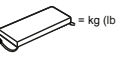






LABEL EXPLANATION	
Top cover label	States the top cover identification and maximum patient weight
Surface ID Label	States the product identification and product weight
Law tag	States certification of flammability test

Example of mattress



- 1. Silkscreens
- 2. Top cover label (inside the top cover)
- 3. Surface ID label (inside the bottom cover)
- 4. US law tag (inside the bottom cover)
- 5. Canadian law tag (inside the bottom cover)

SYMBOL EXPLANATION

	Read the Instructions for use before use.
	CE marking indicating conformity with European Community harmonized legislation.
	Indicates the product is a Medical Device according to EU Medical Device Regulation 2017/745.
	Lot number
	Serial number
	Reference number
	Name and address of the manufacturer
	Manufacturing date
	Safe working load defines the maximum total load of the patient kg (lb) (mattresses)
	Product weight (surface)
	Recommended wash temperature: 15 min at 80 °C (176 °F)
	Tumble dry at 80 °C (176 °F)
	Do not iron
	Wipe surfaces with cleaning solution, then wipe with a cloth moistened with water and dry
	Identifies the facility and ward where the surface is used
	The date when the surface was fitted to current bed frame.

At Arjo, we are committed to improving the everyday lives of people affected by reduced mobility and age-related health challenges. With products and solutions that ensure ergonomic patient handling, personal hygiene, disinfection, diagnostics, and the effective prevention of pressure ulcers and venous thromboembolism, we help professionals across care environments to continually raise the standard of safe and dignified care. Everything we do, we do with people in mind.