

Norfolk Bari Static Mattresses

INSTRUCTIONS FOR USE

This manual **MUST** be read **BEFORE** using this product



Norfolk Bari Static Mattresses

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1. Introduction

This document outlines important information and instructions for use (IFU) about the safe and effective use of the product. Read all instructions carefully before using the product. Store the IFU in a designated area, where it is always easily accessible. If unsure, consult a medical professional regarding the correct use of the product. For further product-related information, contact Winncare PAC Ltd directly; see the “Contact Information” section of this document.

2. Symbols

Symbols and advisory notices are used in this document to help safe and optimal operation of the product. See information below for definitions of the symbols.

 WARNING	<p>Warning: Safety warning. Failure to obey and understand could lead to injury to yourself or others, and in some circumstances death.</p>
 CAUTION	<p>Caution to highlight potential hazards that, if failed to follow, could lead to damage or failure in parts or all of the system and equipment.</p>
<div style="border: 1px solid black; padding: 5px; display: inline-block;"> NOTE </div>	<p>Note: Important information users should be aware of for correct use of the equipment.</p>










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3. Product Labelling







The labels shown are for illustrative purposes only – some symbols on your product may differ from the examples shown.

	UK marking indicating conformity with UK Medical Device Regulations 2002 (SI 2002 No 8, as amended)		CE marking indicating conformity with European Community harmonized legislation. Figures indicate Notified Body supervision.
	Name and address of the manufacturer		Authorized Representative in the European Community
	Unique device identifier		Temperature limitation to indicate the temperature limitation for the product during usage
	Product Reference Number		Indicates the product is a Medical Device according to EU Medical Device Regulation 2017/745.
	Lot number		Serial Number
	Instructions for Use Read the Instructions for use before use		Date of manufacture
	Recycling		Resistant to ignition
	Foot end of mattress		Safe Working load (SWL) is the maximum combined weight of the patient and any equipment that the mattress can safely support.
	Max Patient weight defines the maximum total load of the patient kg		Do not use sharp objects

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	Do not fold. Roll pack the system		Do not use when damp, ensure surface is dry before use
	Do not place heavy objects on surface of cover other than the patient		Ensure system is dry before storing, use and reuse.
	Do not iron		Do not use harsh abrasives or Phenol cleaners
	Tumble dry on a low setting		Machine wash up to 95°C.
	Disinfect by wiping the surface using a hypochlorite solution diluted 1000 ppm.		

4. Warnings and Precautions for Use

 WARNING Ensure the device is assembled and operated as intended. RISK OF PRESSURE INJURY.	 WARNING Do not expose any parts of the device to a naked flame. Do not smoke. RISK OF FIRE AND PROPERTY DAMAGE.
 WARNING Ensure the patient is manually repositioned at frequent intervals. RISK OF PRESSURE INJURY.	 CAUTION Perform a risk assessment when pairing devices with medical beds and accessories.
 CAUTION Do not use if device does not fit bed frame. Device performance may be affected.	 CAUTION Device performance may be affected when in use with incontinence products. Complete a risk assessment prior to use.

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5. Product Overview

NOTE

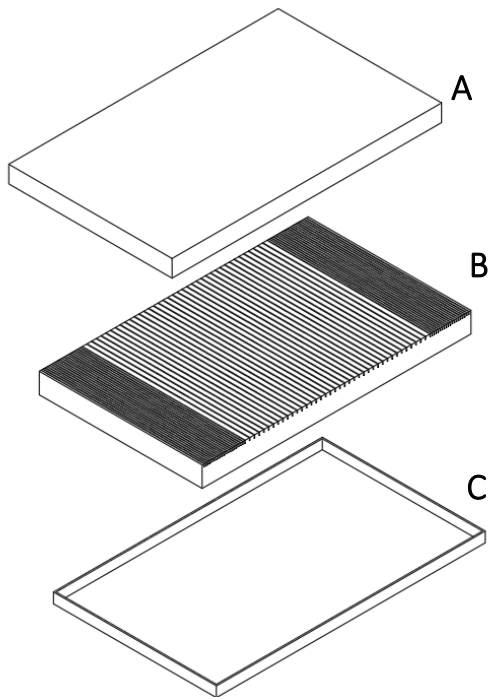
This IFU is only applicable to the variants of the Norfolk mattresses listed in Technical specification Section of this document. Please ensure this IFU is applicable to your product, otherwise consult a different IFU.

Intended Use	To provide pressure redistribution when used in conjunction with an appropriately sized bed frame and as part of an overall package of care for pressure injury prevention.
Intended Users	Plus size patients, with restricted to limited mobility, undergoing some medical supervision and monitoring in hospital, long-term care or care home settings.
Indications	Suitable for users identified as being at risk to high risk of developing pressure injuries.
Contraindications	Patients below the minimum or above the maximum user weight stated for the associated device.
Users	Caregivers, laypersons and/or medical professionals.
Warranty	2 years subject to regular maintenance and care.
Reusable	Devices are re-usable and must be cleaned between each patient use.
Maintenance or calibration	Perform regular mattress audits to check for foam functionality, fluid ingress and strike-through on the mattress top cover.
Accessories	Devices are not sold with accessories.
Risk Assessment	<p>It is the responsibility of the end user/care provider to carry out the necessary risk assessment to ensure patient safety. This should be carried out before using the mattress. A risk assessment should include, but not be limited to:</p> <ul style="list-style-type: none"> • Product combinations (bed frame, mattress, side rails etc.) • Extent of tissue damage (if any) • Entrapment • Patient falls • Small adults (and children) • Patients with learning difficulties • Patients with atypical anatomy • Unauthorised people with access to the controls • Use with other medical accessories e.g. incontinence products

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6. Product Description

Norfolk is a range of high-specification full-replacement static foam mattresses, developed using the very latest combustion modified ether (CME) foam technology. Castellations to the foam surface (B) help the foam conform to the patient’s body and increase the surface area in contact with the mattress, through immersion and envelopment. Vulnerable areas are protected via smaller castellations at the head and foot of the patient, and larger castellations at the torso to support larger bony prominences.



A	Multi-stretch waterproof, antimicrobial, vapour permeable cover
B	Castellated foam insert
C	Polyurethane base cover

7. Product Installation & Use

7.1 Preparing the Mattress for Use

Rolled mattresses must be allowed to recover before use.

1. Take the mattress to the room it is intended for and remove from packaging. Do this using scissors rather than a knife, taking care not to damage your rolled up mattress while removing the packaging.
DO NOT USE a blade or Stanley knife as this can easily damage the cover, and the mattress will not be suitable for use.
2. The room should be warm, approx. 20°C. **DO NOT USE** a hair dryer or leave it too close to portable heaters, as this can cause damage.
3. To provide full support, leave the mattress for **at least 24 hours** before use.

Mattresses that are delivered flat-wrapped can be used immediately.

7.2 Installation

1. Remove all packaging before use.

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NOTE

Ensure the printed side of the mattress cover always faces upwards.

- Place the mattress directly on the bed frame with the "foot" symbol at the foot end of the bed.

NOTE

Do not grip the mattress by the top cover or the zip flaps when lifting. WinnCare recommends performing the lifting step with 2 people wherever possible

- Ensure the mattress is positioned centrally on the bed frame. If there is excessive movement of the mattress on the bed frame, this could indicate a size incompatibility between the bed frame and the mattress. Do not use.
- Ensure there are no gaps between the mattress and bed frame/side rails. Perform the necessary risk assessments to mitigate entrapment risk.

NOTE

Ensure the mattress is only used with compatible equipment/accessories.

NOTE

Do not use if mattress is sliding in the bed frame. Reconsider mattress size.

NOTE

Do not use if mattress is tight fitting in the bed frame. Reconsider mattress size

NOTE

Do not drag the mattress, always carry it.



WARNING






Do not remove the mattress from the bed frame if the occupant is still on the mattress. RISK OF FALL.

8. Cleaning & Disinfection

Cleaning and disinfection of the device is mandatory. As a minimum, cleaning and disinfection should be performed before use, between each patient, at regular intervals whilst in use and before being returned to storage. Consult local practice guidelines for more details on cleaning and disinfection of reusable medical devices.

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Follow the instructions below to achieve a minimum level of cleaning and disinfection for safe use of the device.

 <p>WARNING</p> <p>Wear appropriate personal protective equipment (PPE) when cleaning the mattress or control unit. RISK OF SKIN IRRITATION</p>	 <p>CAUTION</p> <p>Do not use phenol-based cleaning solutions, solvents, neat bleach or abrasive products to clean the casing as this may cause damage.</p>
 <p>CAUTION</p> <p>Do not use top cover if strike-through or damage is suspected.</p>	 <p>CAUTION</p> <p>Do not use Phenol-based solutions or abrasive compounds.</p>
 <p>CAUTION</p> <p>Do not autoclave.</p>	

8.1 Cleaning & Disinfection Protocol: Mattress

1. Unzip the cover on all sides.
2. Inspect the underside of the cover and the foam mattress for any signs of strikethrough or contamination. If damaged, use a new cover or mattress. Dispose of damaged items as per local protocols.
3. For general cleaning; (if using an existing cover)
 - a. Wipe down with a soft, clean, non-abrasive cloth moistened with a mild detergent and diluted in warm water (40°C).
 - b. Rinse with cold, clean water and a fresh, soft, non-abrasive cloth and allow to fully dry before use.
4. For disinfection
 - a. **Light Soiling:** Unzip the top cover from the mattress. The top cover can be machine washed up to 95°C and tumble dried on a cool setting.
 - b. **Heavy Soiling:** Carefully clean with (1,000 ppm) prepared solution of sodium hypochlorite and allow to dry completely. In extreme circumstances 10,000 ppm can be used; wipe with cold water to finish (Frequent cleaning with a high concentration disinfectant solution i.e. 10,000 ppm available chlorine, may reduce the life-span of the device).
5. Reassemble the mattress.
6. Ensure the mattress is completely dry before storage or reuse.

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NOTE	Frequent or prolonged exposure to higher concentration disinfectant solutions may prematurely age the fabric cover of the mattress.
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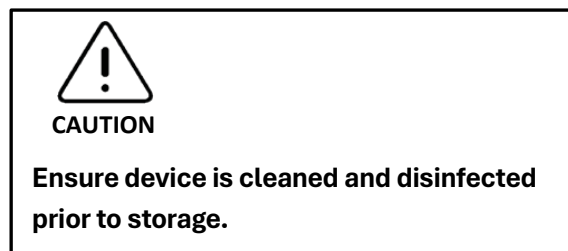
NOTE	In the event of contamination, contact your infection prevention and control department. Remove contaminated foams from use.
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8.2 Replacing the cover

1. Unzip the cover from the mattress and remove it carefully from the foam inner.
2. Place a new cover onto the foam inner
3. Ensure the foam inner is positioned correctly, with the corners of the foam sitting in the corners of the cover.
4. The castellated foam surface should be facing upwards when inserted into the cover.
5. Close the zip.

9. Storage

Follow the instructions below to prepare the product for storage.



1. Lay the mattress out flat.
2. Store in a dry environment, sealed in a polythene bag to protect from dirt, debris, fluids etc., with a suitable identification tag.
3. Never store items on top of a device.

NOTE	Do not store near radiators or other sources of heat.
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NOTE	Protect the device from direct sunlight.
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4. If taking a device out of storage, allow it to acclimatise to the operating conditions.

10. Care and Preventative Maintenance

The expected service life of this product is five years when used daily and maintained according to the manufacturer’s instructions.

Check mattresses (foam and cover) for strike-through (due to fluid ingress, stains, rips or damage) after each patient, after use or every month (depending on which occurs first) by a suitably qualified and competent person.

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The effective service life can vary according to the frequency and intensity of use. Winncare PAC Ltd. recommends an annual audit of all foam surfaces. Contact Winncare PAC Ltd to arrange your annual audit. For optimal performance, more frequent visual and operational inspections are encouraged wherever possible.

NOTE

No modification of this equipment is allowed. Use original parts only.

11. Warranty

This product is covered by a two year manufacturer's warranty as part of the General Terms and Conditions of Business.

Any warranty claims during the warranty period must be investigated by Winncare PAC Ltd, where return of the original product may be required. A warranty claim is successful if the product is faulty due to a manufacturing defect. This warranty does not cover any other damage, including but not limited to: misuse, natural wear and tear, lack of maintenance, accidental damage and unauthorised modifications.

12. Disposal

It is recommended the mattress should be disinfected prior to decommissioning. Adhere to local laws and regulations for the safe disposal of medical devices and accessories. If in doubt, contact Winncare PAC Ltd for guidance or to arrange for collection and disposal.

**WARNING**

Do not dispose in general waste. RISK OF ENVIRONMENTAL CONTAMINATION.

Norfolk Bari Static Mattresses

13. Technical Specifications

Product Code	NOR-114
Product Description	Norfolk 1980x1200x150 Mattress
Dimensions	198 x 120 x 15 cm
Top Cover Material	Purple Polyurethane-coated Polyester fabric
Base Cover Material	Navy non-slip Polyurethane-coated Polyester fabric
Foam Components	Combustion-modified ether (CME) polyurethane foam mattress
Cover Style	Book style (welded + sewn)
Weight (kg)	18

Product Code	NOR-114-BREATHE
Product Description	Norfolk Breathe Bariatric
Dimensions	198 x 120 x 15 cm
Top Cover Material	Purple Polyurethane-coated Polyester fabric
Base Cover Material	Navy non-slip Polyurethane-coated Polyester fabric
Foam Components	Combustion-modified ether (CME) polyurethane foam mattress
Cover Style	Book style (welded + sewn)
Weight (kg)	18

Product Code	NOR-114-V
Product Description	Norfolk Visco 1980 x 1200 x 150
Dimensions	198 x 120 x 15 cm
Top Cover Material	Purple Polyurethane-coated Polyester fabric
Base Cover Material	Navy non-slip Polyurethane-coated Polyester fabric
Foam Components	Combustion-modified ether (CME) polyurethane foam mattress with high-grade viscoelastic memory foam top
Cover Style	Book style (welded + sewn)
Weight (kg)	18

Product Code	NOR-114-V10
Product Description	Norfolk Mattress 2000x1000x150
Dimensions	200 x 100 x 15 cm

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Top Cover Material	Purple Polyurethane-coated Polyester fabric
Base Cover Material	Navy non-slip Polyurethane-coated Polyester fabric
Foam Components	Combustion-modified ether (CME) polyurethane foam mattress
Cover Style	Book style (welded + sewn)
Weight (kg)	18

Product Code	NOR-114-V12
Product Description	Fully Welded Norfolk 1920x1220x160
Dimensions	192 x 122 x 16 cm
Top Cover Material	Purple Polyurethane-coated Polyester fabric
Base Cover Material	Navy non-slip Polyurethane-coated Polyester fabric
Foam Components	Combustion-modified ether (CME) polyurethane foam mattress
Cover Style	Fully Welded (welded only)
Weight (kg)	18

Product Code	NOR-114-V13
Product Description	Norfolk Bari Mattress 2180x1200x150mm
Dimensions	218 x 120 x 15 cm
Top Cover Material	Purple Polyurethane-coated Polyester fabric
Base Cover Material	Navy non-slip Polyurethane-coated Polyester fabric
Foam Components	Combustion-modified ether (CME) polyurethane foam mattress
Cover Style	Book style (welded + sewn)
Weight (kg)	18

Product Code	NOR-114-V14
Product Description	Norfolk Mattress 2030x1200x150
Dimensions	203 x 120 x 15 cm
Top Cover Material	Purple Polyurethane-coated Polyester fabric
Base Cover Material	Navy non-slip Polyurethane-coated Polyester fabric
Foam Components	Combustion-modified ether (CME) polyurethane foam mattress
Cover Style	Book style (welded + sewn)
Weight (kg)	18

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Product Code	NOR-114-V15
Product Description	Norfolk Mattress 1900x1200x150
Dimensions	190 x 120 x 15 cm
Top Cover Material	Purple Polyurethane-coated Polyester fabric
Base Cover Material	Navy non-slip Polyurethane-coated Polyester fabric
Foam Components	Combustion-modified ether (CME) polyurethane foam mattress
Cover Style	Book style (welded + sewn)
Weight (kg)	18

Product Code	NOR-114-V16
Product Description	Norfolk 1930x1220x165 Mattress
Dimensions	193 x 122 x 16.5 cm
Top Cover Material	Purple Polyurethane-coated Polyester fabric
Base Cover Material	Navy non-slip Polyurethane-coated Polyester fabric
Foam Components	Combustion-modified ether (CME) polyurethane foam mattress
Cover Style	Book style (welded + sewn)
Weight (kg)	18

Product Code	NOR-114-V2
Product Description	Norfolk Bari 2000 x 1170 x 150
Dimensions	200 x 117 x 15 cm
Top Cover Material	Purple Polyurethane-coated Polyester fabric
Base Cover Material	Navy non-slip Polyurethane-coated Polyester fabric
Foam Components	Combustion-modified ether (CME) polyurethane foam mattress
Cover Style	Book style (welded + sewn)
Weight (kg)	18

Product Code	NOR-114-V4
Product Description	Norfolk 1980x1200x185 Mattress
Dimensions	198 x 120 x 18.5 cm
Top Cover Material	Purple Polyurethane-coated Polyester fabric
Base Cover Material	Navy non-slip Polyurethane-coated Polyester fabric

Norfolk Bari Static Mattresses

Foam Components	Combustion-modified ether (CME) polyurethane foam mattress
Cover Style	Book style (welded + sewn)
Weight (kg)	18

Product Code	NOR-114-V5
Product Description	Norfolk Mattress 2000x900x150
Dimensions	200 x 90 x 15 cm
Top Cover Material	Purple Polyurethane-coated Polyester fabric
Base Cover Material	Navy non-slip Polyurethane-coated Polyester fabric
Foam Components	Combustion-modified ether (CME) polyurethane foam mattress
Cover Style	Book style (welded + sewn)
Weight (kg)	18

Product Code	NOR-114-V7-FW
Product Description	Norfolk Bariatric Mattress 2000x1350x150 Fully Welded
Dimensions	200 x 135 x 15 cm
Top Cover Material	Purple Polyurethane-coated Polyester fabric
Base Cover Material	Navy non-slip Polyurethane-coated Polyester fabric
Foam Components	Combustion-modified ether (CME) polyurethane foam mattress
Cover Style	Book style (welded + sewn)
Weight (kg)	18

Product Code	NOR-114-V9
Product Description	Norfolk Bariatric Mattress 1980x1200x200
Dimensions	198 x 120 x 20 cm
Top Cover Material	Purple Polyurethane-coated Polyester fabric
Base Cover Material	Navy non-slip Polyurethane-coated Polyester fabric
Foam Components	Combustion-modified ether (CME) polyurethane foam mattress
Cover Style	Book style (welded + sewn)
Weight (kg)	18

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14. Transport & Operating Conditions

Transport and storage conditions	Store in a cool dry place.
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15. Compliance

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.
UK MDR 2002: The Medical Devices Regulations 2002 (SI 2002/618), as amended by SI 2019/791 and subsequent legislation.
ISO 13485:2016 – Medical devices – Quality management systems – Requirements for regulatory purposes
ISO 14971:2019 – Medical devices – Application of risk management to medical devices
ISO 15223-1:2021 – Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements
BS7175:1989 – The Ignitability of Bedcovers and Pillows by Smouldering and Flaming Ignition Sources
BS 597 parts 1&2 – Furniture – Assessment of the Ignitability of Mattresses and Upholstered Bed Bases
BS7177:2008 + A1:2011 Table 1: Medium Hazard Use

16. Complaints

Users of the devices referenced in this document are encouraged to report any complaints related to product quality, identity, durability, reliability, safety, effectiveness, or performance. Complaints should be directed to either the local distributor or Winnicare PAC Ltd, using the contact details provided in the following section.

When submitting a complaint, please include as much relevant information as possible, such as:

- Device name and product code
- Lot number(s)
- Your name and address
- A detailed description of the issue

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17. Contact Information



WINNCARE PAC Ltd.
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NOTE

Inform the competent authority if you believe or have reason to believe that the device presents a serious risk or that it has been tampered with.
All serious incidents which are related to the device must be notified to the manufacturer and the competent authority of the member state in which the user and/or patient resides.