

OPERA® SERENE
PROFILING MATTRESS

User Guide and Technical Specifications



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1. Explanations of Symbols



Read information with this symbol carefully and urgently follow instructions. This information is safety-relevant.



This symbol indicates general hazards. There is danger to life and health.



Conformity mark in accordance with the European Medical Device Directives 93/42 EEC amended by 2007/47/EC.



Conformity mark in accordance with the UK Conformity Assessed.



= Maximum patient weight.



Indoor use only.



This product must be disposed of in a separate refuse collection in the European Union. Do not dispose of as normal domestic waste.



Read instructions.



Manufacturer.



Date of Manufacture.

2. User Instructions

2.1 Intended Uses

The Opera Serene Profiling Mattress is a medical device intended to be used with care beds in residential homes, nursing homes and the domestic environment as a pressure redistribution mattress. The mattress is intended to be used by occupants* weighing up to 29st 11lb/185kg.

The mattress is designed to be used to prevent the development of pressure ulcers in occupants in the high risk** category, but it may also be used for lower risk categories. The mattress may also be used as a mattress to sleep, rest on and to receive care from.

The mattress can be used in conjunction with profiling care beds, including the Opera Classic Profiling Beds, the Signature Profiling Beds and the Solo Profiling Bed collections. Before using the mattress with a care bed, confirm that the mattress specifications meet the requirements of the care bed.

If the mattress used does not meet the care bed requirements, entrapment and injury may occur. The mattress may also be used with mattress underlays and fall prevention systems, always conduct a risk assessment when using the mattress with other products. Using the mattress with the wrong bed may void the warranty terms and conditions.

*The mattress may be used by adults, the elderly and children, subject to a clinician's guidance. The mattress is not intended to be used by young children or as a cot mattress.

**Indication of use based upon interference pressure readings, this is not a prescriptive criteria. Always defer to a clinician's judgement, and advice.

2.2 Non Intended Uses

A non-intended use is a use that deviates from the intended purpose and is not outlined in the Instruction Manual.

Non-intended uses include, but are not limited to the following:

- Loading the mattress beyond the maximum user weight (29st 11lb/185kg).

- Using the mattress with any devices that will compromise the general safety and performance requirements of the mattresses.
- Modifying the mattress or mattress cover.
- Using the mattress with a different mattress cover or vice versa.
- Using the mattress as an underlay or overlay.
- Using the mattress without it's cover.
- Using the mattress when the cover or foam is compromised.

Using the mattresses for any of the above uses or a use that is not outlined in this instruction manual will be regarded as a non-intended use, this may void the warranty terms and conditions.

2.3 Using the Mattress



The mattress arrives compact rolled. Carefully remove the plastic packaging and unroll. The mattress should be unrolled within 21 days of receipt. The mattress can be used one hour after unrolling, however it may take longer before the mattress is fully restored to its original shape.



Before using the mattress for the first time, ensure upon arrival that there is no damage to the mattress and cover, this includes cuts, tears and frayed edging. Make sure that once unrolled that the cover seams sit correctly to the edges of the mattress and that the three zips are fully closed.



If the mattress cover is compromised do not use it as this may result in infection. Take the mattress out of service and inform the person responsible for the mattress.



Always clean the mattress cover before using it for the first time, and in between patients. See section 3 on how to maintain and clean the mattress and cover.



Ensure that the surface of the bed is clear from debris before placing the mattress onto the bed mattress platform. Not checking this may result in

damaging/puncturing the cover, allowing fluid ingress to contaminate the foam core.

After ensuring that the bed platform is clear from debris, place the mattress onto the bed, the audit box should be at the foot end of the bed.



Place a clean light cotton or linen type bed sheet over the mattress.



Do not use heavy duvets or tightly “tucked in” blankets which may force additional pressure on the toes leading to damage on the bony prominences of the heels. The usage of additional waterproof mattress covers, electric blankets, or other similar items, may reduce the effectiveness of the pressure reducing properties of the mattress. These may also lead to an additional increase of body temperature which may result in skin maceration. Please seek clinical advice should you wish to use any covering other than cotton or linen bed sheets.



Regular turning is recommended for 4-way turning mattresses such as the Opera Serene Profiling Mattress, to prevent foam fatigue. Regular turning ensures that weight is distributed evenly across both sides and ends of the mattress, prolonging its service life.



The cover may be removed for cleaning, please see chapter 3 for further instructions on how to clean the cover. To remove the cover unzip it and remove from the mattress, when replacing, ensure that the outer cover is on the outside and not the inside. Non-compliance may result in compromising the functions of the cover, this includes the antimicrobial, water resistant, white substrate and chlorine resistance properties. Non-compliance may result in serious infection.

The label on this mattress has a unique serial number which should be used in the event of a warranty claim. Never remove the label.

2.4 Confirm Compliance



When used with a care bed, make sure that the mattress meets the requirements of the care bed, failure to do this may result in entrapment hazards and injury.



The side rail height from the top of the mattress in an uncompressed condition and the top upper edge of the side rail must be a minimum of 220mm. Failure to comply may result in creating entrapment and fall hazards which could result in serious injury.

3. Maintenance and Inspections

3.1 Inspections and Audits

It is recommended that audits occur every 6 months to inspect for signs of damage. In a community setting audits should also be conducted in between each change of patient. Mattresses should be cleaned as and when required.



Inspect the inner and outer surfaces of the mattress covers and inspect the zips and seams for any signs of damage. Failing to check this may compromise the features of the mattress cover.



If the cover has been stained, soiled or compromised, the inner mattress must be examined. The white audit substrate on the inside of the cover helps to identify any strike through from heavy soiling/fluids. If the cover is compromised the mattress should be withdrawn from use immediately. Failure to withdraw the mattress and cover from use poses a significant risk of infection to the patient and any carers.

3.1.1 Mount Vernon Test

The Mount Vernon Test should be performed during an audit, patient change or when there are doubts about the foam condition. The test ensures that the foam continues to deliver support.

Follow the below steps to perform the Mount Vernon Test on the mattress and cover:

- Adjust the bed platform height so that the top of the mattress is level with the testers hip.
-  Standing at the side of the bed, link both hands to form a fist. Keep the elbows straight and lean forward, push your fists into the mattress at the points in **Figure 1**. If the bed base can be felt at any point, the mattress has 'bottomed out', and should be withdrawn from service immediately. Failing to observe this instruction may pose a significant risk of pressure damage to the user.

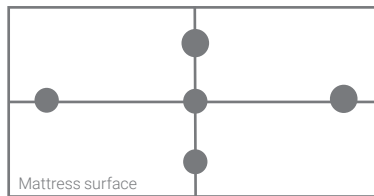


Figure 1: Mount Vernon Test points

For further information on how to inspect and audit the mattress, please refer to the following: Mattresses: Prevention of Cross Infection MDA SN 1999 (31), Medical Device Alert: All types of bed mattresses MDA/2010/002 and the BHTA guidance on the care, cleaning and inspection of healthcare mattresses (BHTA Protect, Rinse and Dry). Always follow your local regulations and guidelines.

3.2 Cleaning and Disinfection

Clean the mattress regularly, and as and when required.

For general cleaning and superficial dirt, use a disposable wipe with a solution of warm water with neutral detergent. Do not use abrasive or phenologic-based cleaners.

To disinfect in situ, use a 0.1% sodium hypochloride solution (1000 ppm chlorine). Do not use biological or phenolic-based cleaners. Removable, contaminated covers should be laundered at 65°C for no less than 10 minutes or at 95°C for no less than 3 minutes.

Thoroughly rinse and dry the cover before re-use or storage. Store in a cool, dry area.

Do not mangle or iron.

Spin and tumble-dry at no more than 60°C.

3.3 Storage and Care

- Store the mattress flat – do not fold.
- Do not place heavy objects on the mattress surface when not in use.
- Do not allow sharp objects to penetrate the cover or damage its coating.
- Keep the mattress clean.
- Regularly inspect the interior and exterior of the mattress.
- Do not store in damp conditions.
- Store out of direct sunlight.
-  • Store away from sources of ignition and sources of heat, such as, radiators, open fires, heaters and electric heaters.

To aid storage and handling, store the mattress in a protective covering. When removing packaging be careful to not damage or catch the mattress cover. Always clean the mattress before putting back into service and inspect/audit the mattress and cover. Not observing this instruction may result in creating hazardous situations and posing risks such as infection.

3.4 Flammability

The Opera Serene meets the requirements of BS7177:2008 for medium hazard. The mattress meets the requirements of The Furniture & Furnishings (Fire Safety) Regulations 1988.

4. Safety Instructions

4.1 General Safety Instructions



During the briefing, specific attention must be drawn to any potential dangers for the first time, the instruction manual must be read conscientiously and in detail by the user / care personnel.

Any incidents or issues must be reported to Opera at, support@operabeds.com.



When the mattress is used with a care bed make sure that the mattress meets the requirements of the care bed, failure to do this may result in causing entrapment hazards and injury.



When using the mattress with side rails, the side rail height from the top of the mattress in an uncompressed condition and the top edge of the side rail must be a minimum of 220mm, failure to comply may result in injury caused by entrapment or falls.



If the cover is compromised the mattress should be withdrawn from use immediately, if the foam and cover are compromised the mattress and cover should be withdrawn from use immediately and replaced. Failure to withdraw the mattress and cover from use poses a significant risk of infection to the patient and any carers.



Do not pierce or compromise the mattress cover, this will compromise the foam and poses a significant risk of infection to the user and any carers.



Do not use the mattress without the mattress cover, failing to observe this warning will compromise the infection and control properties of the mattress, this may result in the development of infections, sores, and other alignments.



Do not store the mattress near heating devices such as electrical fires, radiators, or sources of heat, this may result in fire leading to serious injury, property damage and death.



Avoid contact with sharp objects and abrasive surfaces etc. Do not drag mattresses, failure to observe this may result in compromising the cover and foam mattress.



The mattress is not designed for use in a mental health facility, or by those at risk of vandalising the mattress, using the mattress in this environment may result in vandalism and the creation of hazardous situations which may lead to injury, property damage and death.



Do not smoke around or on the mattress, this is a common cause of fires. Failure to observe this warning may result in severe injury, property damage and death.



Keep the cover away from young children when not in use, openings can result in asphyxiation and death.



If the bed base can be felt, the mattress has 'bottomed out' and should be withdrawn from use immediately. Failing to observe this warning may pose a risk of pressure damage to the user.



When used with a profiling bed, ensure that the mattress is fitted into the mattress retainers. Failure to do this may result in the mattress moving, this may result in shear and friction to the users skin which can pose a risk of pressure ulcer development.

4.2 Service Life and Disposal



The service life of the mattress and cover is dependent upon the manner of use. The service life may be exceeded if the product is carefully used and maintained. It may also be significantly reduced by incorrect and/or significant use. When the service life ends do not dispose as normal domestic waste, please contact your local waste recycling facility for further guidance on safe disposal.

To put the mattress back into service conduct an audit on the mattress and mattress cover as advised in section 3.

It is advised that a cleaning and service record is kept. Always clean the mattress in between patients and as and when required in accordance with local guidelines and this instruction manual.

5. Technical Specifications

5.1 Technical Data

Specifications for the Serene Profiling Mattress			
Specifications	3ft	3ft 6'	4ft
Maximum User Weight	29st 1lb/185kg		
Depth	150mm/6"		
Length	2000mm/78.7"		
Width	900mm/35.4"	1050mm/41.3"	1200mm/47.2"
Weight of foam	8.5kg	10.5kg	12kg
Foam Type	Castellated SB33/160 CMHR		
Turn Cycles	4		
Warranty	1 year		
	Mattress Cover		
Multi stretch cover with white substrate	Yes		
Antimicrobial cover	Yes* *Tested in a group test against Aspergillus niger & Staphylococcus aureus		
Moisture Vapour Permeable	Yes		
Cover Material	PU coated polyester		
Chlorine resistance	0.1% (1000ppm)		
Zips	3 Zips		
Seam type	Sewn		
Machine washable	<95°C		
Water resistance	Yes		
Weight of cover (Approx.)	0.96kg	1.1kg	1.23kg
Warranty	1 year		

5.2 Classification



Medical Device Class (Medical Device Directive 93/42 EEC)	Class I
CRIB Rating	BS7177:2008 – Crib 5 (Ignition source 5)
Treatment/Prevention Risk Category	High Risk

5.3 Storage and Transport

Storage and Transport Conditions
Store the mattress in a dry, dark, clean environment, do not store near heating appliances such as radiators, open fires or electrical fires. Do not drag the mattress when transporting.

6. Guarantee

As stated in the Warranty Terms and Conditions, below, Opera provides a manufacturer’s warranty of 1 year from the date of purchase for the mattress and mattress cover.

7. Opera Warranty Terms and Conditions

7.1 Warranty Terms

7.1.1 Subject to the terms and conditions set out below, Opera agrees to repair or replace the product within the United Kingdom at its own cost, and any Opera accessory supplied with it, purchased by you from Opera. In circumstances where the product does not perform in accordance with Opera’s specifications during the warranty period commencing on the date of delivery (or deemed delivery) of the product.

7.1.2 This contractual product warranty does not operate to limit rights under the statutory warranties referred to in clause 7.3.1 below.

7.2 Warranty Conditions

7.2.1 Proof of purchase (invoice) must be provided when requesting service under warranty.

7.2.2 Opera requires any customer requesting service under the warranty to comply with directions from Opera staff in relation to troubleshooting any issue and facilitating any repair or replacement under these Warranty Terms and Conditions.

7.2.3 The customer is responsible for inspecting all goods received from Opera upon arrival. In instances where goods have been damaged in transit, the customer must report this to Opera within 3 working days of receipt of the product. Failure to report physical damage on arrival within 3 working days of receipt may result in denial of warranty for physical damage.

7.2.4 Opera reserves the right to replace the product or relevant part with the same or equivalent product or part, rather than repair it. Where a replacement is provided, Opera will determine, in its discretion, the closest product within the current range of products offered by Opera with which to replace the faulty or damaged product. The replacement product may differ with the replaced product in size and specifications, at the reasonable election of Opera. Opera may replace parts with refurbished parts. Replacement of the product or a part under the warranty does not extend or restart the warranty period.

7.2.5 If Opera is unable to repair or replace the product, the customer will be provided with credit for Opera products or may be refunded the price of the product (at Operas election). This credit or refund will be for the amount of the purchase price of the product, excluding the associated delivery cost.

7.2.6 In the event that a replacement, refund, or store credit is provided as per section 7.2.5, the faulty item will become the property of Opera.

7.2.7 Opera may seek reimbursement of any costs incurred by you where the product is found to be in good working order.

7.2.8 Opera reserves reasonable discretion to determine whether any product is or is not performing in accordance with Opera specifications, subject to applicable law.

7.3 General

7.3.1 Legislation may imply warranties, conditions or imposes obligations on Opera, which cannot be excluded, restricted or modified in relation to consumer goods.

7.3.2 To the full extent permitted by law, but subject always to clause 7.3.1, the warranty will not apply in respect of a product:

- (a) If the product has not been installed, operated, maintained or used in accordance with the Opera instructions or specifications provided with the product;
- b) If the factory-applied serial number has been altered or removed from the product;
- (c) To damage, malfunction or failure resulting from alterations, accident, misuse, abuse, fire, liquid spillage, mis-adjustment of customer controls, use on an incorrect voltage, power surges and dips, thunderstorm activity, force majeure, voltage supply problems, tampering or unauthorised repairs by any persons, use of defective or incompatible accessories, exposure to abnormally corrosive conditions or entry by any insect, vermin or foreign object in the product.
- (d) To damage arising during transportation, installation or while moving the product or to any transportation costs of the product or any parts thereof to and from the customer, unless otherwise specified in these warranty terms and conditions;
- (e) To any third-party software or hardware not contained in the product as originally configured by Opera.
- (f) To any failure, to the extent that the failure is not a failure of the product to perform in accordance with its specifications.
- (g) To service of any product whilst it is outside the United Kingdom.

7.3.3 To the full extent permitted by law, but subject always to clause 7.3.1:

(a) Opera will not be liable for any loss, damage or alterations to third party products, no matter how occurring; or for any loss or damage arising from loss of use, loss of profits or revenue, or for any resulting indirect or consequential loss of damage.

(b) Opera's aggregate liability in respect of all claims under the warranty shall not exceed the original purchase price of the product or, at Opera's option, the replacement of the product with a like or similar product.

(c) Opera excludes all other warranties, conditions, terms, representations and undertakings whether express or implied.

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