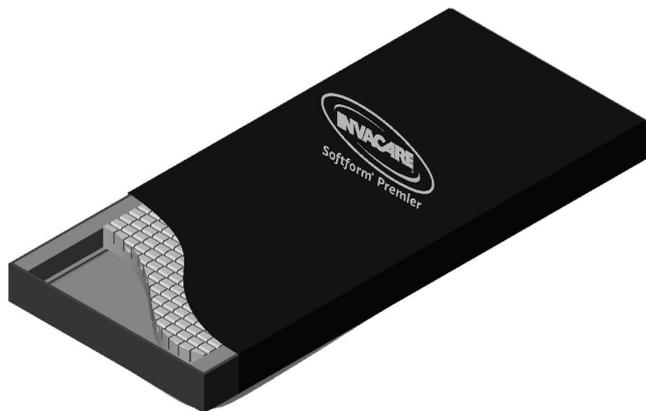


Invacare® Softform®

en **Fully sealed mattress**
User Manual



This manual **MUST** be given to the user of the product.
BEFORE using this product, read this manual and save for future reference.



Yes, you can.®

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I General

I.1 General information

Essential nursing care is pivotal in pressure ulcer prevention. These mattresses will positively contribute to the outcome of a pressure ulcer prevention care plan.

Education, clinical judgement and action based planning based on vulnerability are fundamental factors in the prevention of pressure ulcers.

A range of assessment scales can be used as a formal method of assessing risk from pressure ulcer development, and should be used in conjunction with an informal assessment (informed nursing judgement). Informal assessment is considered to be of greater importance and clinical value.

This user manual contains important information about the handling of the product. In order to ensure safety when using the product, read the user manual carefully and follow the safety instructions.

For further information contact Invacare® in your country (addresses see back page of this user manual).

To access valuable information and useful links for Pressure Area Care training and education, refer to www.thinkpressurecare.co.uk.

I.2 Symbols in this user manual

In this User Manual warnings are indicated by symbols. The warning symbols are accompanied by a heading that indicates the severity of the danger.



WARNING

Indicates a potentially hazardous situation which if not avoided could result in death or serious injury.



CAUTION

Indicates a potentially hazardous situation which if not avoided could result in product damage, minor injury or both.



IMPORTANT

Indicates a hazardous situation which if not avoided could result in damage to the product.



Gives useful tips, recommendations and information for efficient, trouble-free use.



This product complies with the directive 93/42/EEC for medical products. The launch date for this product is specified in the CE declaration of conformity.



Manufacturer

I.3 Warranty

We provide a manufacturer's warranty for the product in accordance with our General Terms and Conditions of Business in the respective countries. Guarantee claims can only be made through the provider from whom the appliance was obtained.

Standard Invacare® Terms

This is to certify that your Invacare® Softform® Mattress is warranted by Invacare Ltd for a period stated in the Table "Technical Data" of this user guide.

The Warranty of your Invacare® Softform® product is valid from time of shipping.

If a defect or fault is discovered the Invacare® customer or Local Business Development Manager from whom the appliance was obtained must be notified immediately. The manufacturer will not accept responsibility for damage caused by misuse or non-observance of the instructions set out in this user guide.

During the period of the warranty, any products that have become defective due to faulty workmanship or materials will be renewed without charge. The warranty will be forfeited should any unauthorized alteration be made to the equipment. Both warranty and fire retardancy Certification will become null and void if non-Invacare® spares are used on any Invacare® Mattress products. The purchaser's statutory rights under the Consumer Protection Act are not affected.

1.4 Standards and regulations

Quality is fundamental to the company's operation, working within the disciplines of ISO 9001 and ISO 13485.

All Invacare® Softform® Mattress products feature the CE mark, in compliance with the Medical Device Directive 93/42/EEC Class I.

Invacare® is continuously working towards ensuring that the company's impact on the environment, locally and globally, is reduced to a minimum. We only use REACH compliant materials and components.

The foam and cover used to manufacture the Invacare® Softform® range of mattresses are independently tested and certified in accordance with EN 597-1 and EN 597-2 (Assessment of the ignitability of mattresses and upholstered bed bases - ignition source: smouldering cigarette (1) and match flame equivalent (2)).

All products in the range are individually tested as a composite in accordance with BS 7177 ignition sources 0, 1 and crib 5. The fully sealed mattress option for high hazard has been tested to crib 7 (refer to 8.1 General Data, page 12), both top and bottom tests comply.

For further information please contact Invacare® in your country (addresses see back page of this manual).

1.5 Intended use

This pressure redistribution mattress is intended to be used in conjunction with an appropriately sized bed frame, as part of an overall pressure ulcer prevention program of care.

Any other use is prohibited.

This product has been designed to deliver effective pressure redistribution to users, when the product is in normal use which is defined by Invacare as when the support surface is covered with a cotton, cotton combination or linen bed sheet, and any one of these would be the only item deployed between the support surface and the user.

1.6 Service life

We estimate a life expectancy of up to 3 years for these products, provided they are used in strict accordance with the intended use as set out in this document and all maintenance and service requirements are met. The estimated life expectancy can be exceeded if the product is carefully used and properly maintained, and provided technical and scientific advances do not result in technical limitations. The life expectancy can also be considerably reduced by extreme or incorrect usage.

The fact that we estimate a life expectancy for these products does not constitute an additional warranty.

2 Safety

2.1 Safety information



WARNING!

– Do not use this product or any available optional equipment without first completely reading and understanding these instructions and any additional instructional material such as user manuals, service manuals or instruction sheets supplied with this product or optional equipment. Invacare® product manuals are available on your local Invacare web site or at your local dealer.



WARNING!

Risk of developing pressure ulcers

Bed sheets must be loosely fitted, with creases smoothed out. Care must always be taken to ensure that the support surface in contact with the user is kept free from crumbs and other food debris, and that drip cables, stents, and other foreign objects do not become entrapped between the user and the pressure reducing surface of the mattress, as this may result in the development of pressure ulcers.



WARNING!

Risk of fire or explosion!

A cigarette can burn a hole in the bed surface and cause damage to the mattress. Also, patient clothing, bed sheets, etc. may be combustible and cause a fire. Failure to observe this warning can result in a severe fire, property damage and cause physical injury or death. Do not use in oxygen rich environments (A small electrical spark inside pump may cause explosion).
 – Do not smoke.

2.2 Symbols on the product

	Do not pierce or cut		Wash by hand
	Do not dry clean		CE conform
	User weight limit*		Do not iron
	Do not put near flame		Do not bleach
	Date of manufacture		Refer to user manual

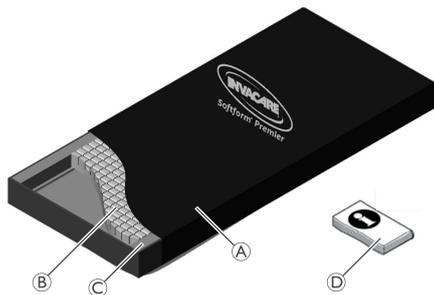
* Maximum user weight as per section 8 Technical data, page 12.

3 Components

3.1 Components and description

The following components are included within the scope of delivery:

Softform® Premier mattress (fully sealed)



A	Multi-stretch waterproof polyurethane cover (no zip, non-removable)
B	Castellated foam insert
C	Single piece foam “U” core
D	User Manual

The Invacare® Softform® mattress offers exceptional pressure reducing qualities, specific to the individuals needs. By promoting even weight distribution, they reduce tissue pressure at potentially vulnerable areas. The water-resistant cover provides a vapour-permeable, multi stretch surface, to promote patient comfort and to maximize the effectiveness of the foam core.

4 Usage

4.1 Safety information



WARNING!

It is very important for the patient to reposition themselves, or to be repositioned, on a regular basis. This must be based on the clinical judgement of a qualified health care professional. This relieves pressure which helps prevent both tissue compression and potential ulcer formation.

- Always consult a qualified health care professional before using the product.
- Monitor the patient frequently.



CAUTION!

- Make sure that the printed side of the mattress cover always faces upwards.
- Make sure that the distance between the surface of the mattress and the top of the side rail is at least 220 mm.



IMPORTANT!

If holes are present in the mattress cover, there is a danger that liquids may ingress and contamination may occur.

- Medical equipment including infusion pumps and monitors should be attached to appropriate bed accessories.
- For home use common causes of damage include cigarette burns and the claws of pets that puncture sheets, allowing fluid ingress and staining.



IMPORTANT!

Risk of damage to the mattress cover

- To prevent accidental damage, do not place hypodermic needles, venflons, scalpels or other similarly sharp objects onto the mattress.
- Ensure that all venflons are taped down correctly with no sharp edges exposed.
- When using patient transfer aids, care should be taken not to damage the mattress. All transfer aids should be checked for any sharp edges or burrs before use as these can damage the mattress.
- Make sure that the mattresses are not jammed or damaged by sharp edges when used on beds with an adjustable frame.
- When using the mattress on a profiling bed ensure that the knee break is used before the backrest.

4.2 Preparing the mattress for use

1. Remove all packaging before use.
2. Place the mattress directly on the frame of the bed.

The mattress is designed for beds with adjustable lying surface.

5 Transport

5.1 Safety information

**IMPORTANT!**

- Take care when handling mattresses to ensure no damage to the cover. It is recommended that two people lift/carry mattresses.
- Avoid contact with jewellery, nails, abrasive surfaces etc.
- Do not drag mattresses.
- Avoid contact with wall, door frames, door catches or locks etc.
- Do not transport in roll cages unless completely protected from the sharp edges of the cage.

1. Refer to the storage and shipping conditions in section 8.3 Environmental Parameters, page 12.

6 Maintenance

6.1 Inspection

It is recommended that the mattresses is checked for any damage, punctures or ribs after the release of each patient, after ending of the period of use or on a minimum monthly basis (depending on which occurs first) by a suitably qualified and competent person.

6.2 Cleaning and care



IMPORTANT!

All cleaning agents and disinfectants used must be effective, compatible with one another and must protect the materials they are used to clean.

- For further information on decontamination in health care environments, please refer to 'The National Institute for Clinical Excellence' guidelines on Infection Control www.nice.org.uk/CGI39 and your local infection control policy.

Cleaning covers

(Removal of contaminants such as dust and organic matter)

1. Clean the mattress cover with a solution of neutral detergent and warm water with a single use non-abrasive cloth.
2. Rinse the cover with clean water using a single use non-abrasive cloth and dry thoroughly.

Disinfecting covers

(Reducing the number of microorganisms)

Please contact your hygiene specialist in the event of contamination.



IMPORTANT!

- Ensure that any residual detergent has been removed prior to disinfection.

1. Wipe down the cover with a 0.1% Chlorine Solution (1,000 ppm).
2. Rinse the cover with clean water using a single use nonabrasive cloth and dry thoroughly.



IMPORTANT!

- Do not use phenols, alcohols, bleaches, or other abrasive materials.



IMPORTANT!

Polyurethane coated fabrics can absorb liquids for short periods causing a temporary change to the polyurethane characteristics. The mattress cover swells temporarily and is more vulnerable to physical damage for a period after it is completely surface dried, by which time it will revert to its previous state.



CAUTION!

- Keep clear of open heat sources.

7 After Use

7.1 Storage

**IMPORTANT!**

- Store mattresses in a dry environment.
- Store mattresses within a protective cover.
- Store items on clean, dry, off-flooring free from sharp edges to avoid any possible damage.
- Never store other items on top of a mattress.
- Do not store mattresses next to radiators or other heating devices.
- Protect mattresses from direct sunlight.

1. Refer to the storage and shipping conditions in section 8.3 Environmental Parameters, page 12.

7.2 Re-Use

A cleaning record must be kept as part of cleaning the system.

The product is suitable for repeated use. The number of times it can be used depends on how often and in which way the product is used.

1. Before reuse, clean the product thoroughly,
® 6.2 Cleaning and care, page 10.

7.3 Disposal

The disposal and recycling of used devices and packaging must comply with the applicable local legal regulations.

1. Ensure that the mattress is cleaned prior to disposal to avoid any risk of contamination.

8 Technical data

8.1 General Data

Product	Warranty ¹⁾	Firetesting	Grade ref & Colour	Nominal density range [kg/m ³]	Nominal hardness range [N]	Maximum user weight [kg]	Weight of product [kg] ²⁾
PREMIER Fully sealed	Cover: 2 years Foam: 5 years	EN 597-1, 2 BS 7177: Crib 5 BS 7177: Crib 7	RX 39/120 Pink RX 39/200 Blue	38 – 40 38 – 40	105 – 135 180 – 200	247.6	14

¹⁾ Warranty is against manufacturing defects.

²⁾ Based on the weight of a standard size mattress. This can change if different sizes are ordered.

8.2 Materials

Invacare® Softform® Premier	
Foam	Polyurethane Combustion Modified High Resilience Foam
Cover	Polyurethane transfer coating on weft knitted fabric

All mattress components are Latex-free.

8.3 Environmental Parameters

Operating conditions	
Ambient temperature	10 - 35 °C
Relative humidity	30% - 75% Non-Condensing
Atmospheric pressure	70 - 106 kPa
Storage and shipping conditions	
Ambient temperature	-40 - 70 °C
Relative humidity	10% - 100%
Atmospheric pressure	50 - 106 kPa

Notes

Notes

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