

Invacare® Softform® Premier Active 2 and Active Care

en **Mattresses**
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.

*Softform Premier Active 2 Mattress: a novel step-up/step-down approach, British Journal of Nursing, 2006, Vol 15, No 11.

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 comply with the current environmental legislation (e.g. WEEE and RoHS directives).
- 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, EN 597-2 and BS 7177 Crib 5.

The control unit is tested to EC Directive 2004/108/EEC and EN 55011. Manufactured to comply with EN 60601-1.

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

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1.5 Intended use

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

It can be used safely in static mode (deflated) for static pressure redistribution, or in dynamic mode (inflated) should an alternating pressure support surface be required. *

Any other use is prohibited.

This product has been designed to deliver effective pressure reduction to users, when the product is in normal use which is defined by Invacare Ltd 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.

* Operator action is required to change settings only.

1.6 Service life

We estimate a life expectancy of five 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 the user manual supplied. Invacare® product manuals are available at www.invacare.co.uk or your local dealer. If you are unable to understand the warnings, cautions or instructions please contact a health care professional, dealer or technical personnel before attempting to use this equipment – otherwise, injury or damage may occur.



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!

Invacare® products are specifically designed and manufactured for use in conjunction with Invacare® accessories. Accessories designed by other manufacturers have not been tested by Invacare® and are not recommended for use with Invacare® products. The introduction of certain third party products between the cushion surface and the user may reduce or impede the clinical effectiveness of this product. 'Third party products' may include, but are not limited to items including under blankets, plastic sheets and sheepskins, etc. Heated over blankets must only be used in consultation with a suitably qualified health care professional, as an increase in temperature can increase the risk of developing 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.



IMPORTANT!

The information contained in this document is subject to change without notice.













- Check all parts for shipping damage and test before using.
- In case of damage, do not use.
- Contact Invacare® / Carrier for further instructions.

	Type BF applied part		Date of manufacture
	WEEE conform		Keep dry

2.2 EMC information

There is no known risk of adverse effects on the Active 2 / Active Care control unit caused by other electromagnetic devices, present at the time of treatment. Similarly there is no known risk of the Active 2 / Active Care control unit causing adverse effects on other electromagnetic devices.

2.3 Symbols on the product

	Do not pierce or cut		Line dry
	Do not dry clean		CE conform
	User weight limit 247.6 kg		Recommended 80 °C
	Do not put near flame		Do not iron
	Do not bleach		Tumble dry low heat
	Class II medical equipment		Refer to user manual

3 Components

3.1 Product description

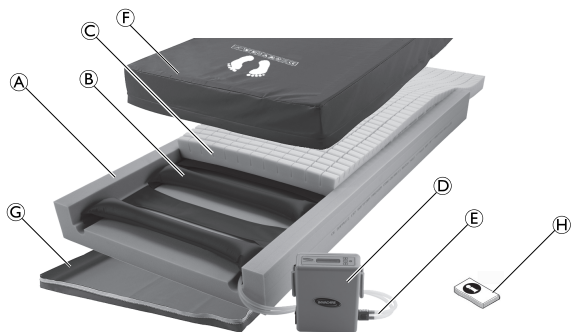
The Softform® Premier Active 2 / Active Care mattress system acts as a static pressure reducing support/mattress for patients at high risk that can, by facilitating the air pump, introduce effective alternating pressure if the patients condition requires alternating pressure therapy.

The water-resistant cover provides a vapor-permeable, multi stretch surface, to promote patient comfort and to maximise the effectiveness of the foam core.

The mattress is the only part intended to come into physical contact with the patient (the only applied part with temperature of maximum 41.1 °C)

3.2 Components

The following components are included within the scope of delivery:



(A)	U-shape, non-castellated base layer
(B)	Alternating air cell insert
(C)	Castellated insert
(D)	Micro-processor controlled control unit
(E)	Twin air connector hose
(F)	Multi-stretch vapour-permeable cover
(G)	Toughed PU coated base
(H)	User Manual

* Power lead supplied not shown.

4 Setup

4.1 Safety information

**WARNING!****Electrical shock hazard!**

- Do not remove control unit cover.
- Refer to qualified service personnel.
- Before performing any maintenance to the control unit, disconnect the power lead from the wall outlet.
- Do not insert items into any openings of the control unit. Doing so may cause fire or electric shock by shorting the internal components.
- The control unit must be kept away from all heat sources and radiators during operation.
- Connect the equipment to a two or three prong wall outlet using the five meter power lead provided with the product.
- Position the device ensuring that access to the connections on the device are not obscured and has ease of access.

**WARNING!**

If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment.

- Do not modify this equipment without authorization of the manufacturer.

**WARNING!****Risk of entrapment!**

Patient entrapment with the bed side rails may cause injury or death. A thorough patient assessment should be completed and monitored and the equipment should be used as specified and maintained to reduce the risk of entrapment. Variations in bed rail dimensions, and mattress thickness, size and density could increase the risk of entrapment.

- Mattress must fit bed frame and side rails to prevent patient entrapment. Follow the bed manufacturer's instructions.
- After any adjustments, repair or service and before use, make sure all attaching hardware is tightened securely. Rails with dimensions different from the original equipment supplied or specified by the bed manufacturer may not be interchangeable and may result in entrapment or other injury.



WARNING!

This mattress is recommended to be installed on medical bed frames with bed sides or assist rails. It is preferred that the rails to be in the raised position whenever the patient is on the bed. Health care professionals assigned to each case should make the final decision as to whether side assist rails are warranted after assessing patient risk of entrapment.

Controls on the footboard may be obstructed by the control unit on a few bed frames. It may be necessary to relocate the control unit.

- Before placing the patient on the bed, check that air hoses and power cord are clear of moving bed components.
- Operate all bed frame motorized functions through their full range of motion to be certain that there is no pulling, interference or pinching.
- Take care when positioning hoses and cables to eliminate the risk of tripping hazards or strangulation.

4.2 Installing the system

	<p>1. Place the pump unit at the end of the bed using the built in pump hooks. Placing the pump on the floor will not affect the performance, but may expose it to accidental damage.</p>
	<p>2. Detach the Softform® Premier Active 2 / Active Care twin hose from the end of the mattress. 3. Connect it to the control unit. (An automatic click will signify a secure connection).</p>
	<p>4. Connect the mains power lead to the control unit and a suitable power supply.</p>
	<p>5. Switch on mains power. 6. Switch on control unit switch. System will pressurize (see chart 5.3 Control unit Software Schematic, page 13) shown by a green light and three audible beeps. Correct pressure shown by a green light and two audible beeps.</p>



Refer to section 5.4 Control unit Menu Display, page 14 for shutdown procedure.

5 Usage

5.1 Safety information

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.



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.

5.2 CPR procedure

The Softform® Premier Active 2 / Active Care mattress has been fully tested to comply with the current CPR standard of 4 – 5 cm compression depth. This was achieved at all stages of inflation/deflation.

A report on these findings conducted by the Resuscitation Unit at the University Hospital of Wales, Cardiff is available upon request.

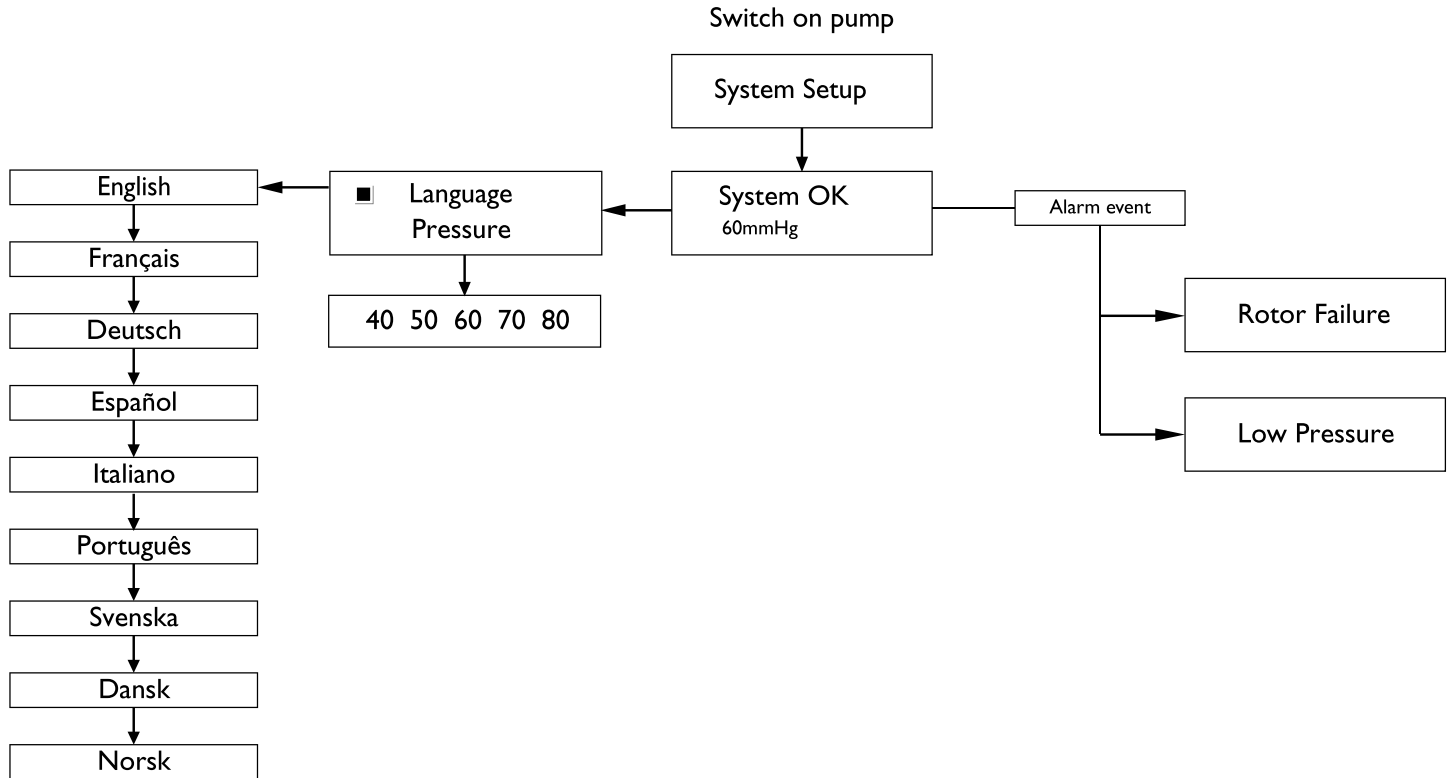
1. Hold down Red CPR button.
2. Pull hose connector firmly away from the control unit.
3. Switch off the control unit.



Mattress will start to deflate. The deflation time is 20 seconds.

4. When CPR is complete reactivate the system following section 4.2 Installing the system, page 10.

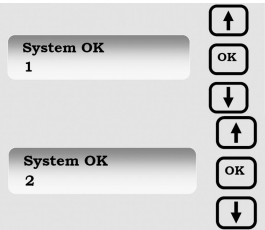


5.3 Control unit Software Schematic



5.4 Control unit Menu Display

	<p>(A) LCD display screen</p>
	<p>(B) Up arrow button</p>
	<p>(C) OK button / Silence alarm</p>
	<p>(D) Down arrow button</p>
	<p>(E) Green LED light</p>

Task	Action	Display
<p>1. Power up</p>	<p>Push main switch of control unit.</p>	<p>3 audible beeps. LCD (A) illuminates. (see figure above) Green light (E) illuminates. (see figure above) “System set up” displayed on LCD display. After 10 minutes “System OK” displayed on LCD display.</p>
<p>2. Menu option</p>	<p>Cannot enter menu.</p>	<p>The menu can only be served after the system has gone through full cycle set up and “System OK” is displayed on the LCD display. Wait until set up is complete “System OK”. System OK can take up to 15 minutes to complete cycle.</p>
<p>3. Power down</p>	<ol style="list-style-type: none"> 1. Move control unit switch to off position (See figure above). 2. Disconnect from power source. 	<p>The LCD display and the green LED go out.</p>

Task	Action	Display
<p>3. How to enter menu</p> 	<p>Press arrow Up. then Press arrow Down. then Press OK. (3 second time limit between each function).</p>	<p>“System OK” with “1” underneath on LCD display. “System OK” with “2” underneath on LCD display. “Pressure” displayed on LCD display. Pump display will revert back to “System OK” if no selection made within 15 seconds.</p>
<p>4. Pressure adjustment</p> 	<p>Press OK button to select Pressure. Arrow Up to selected pressure. Arrow Down to selected pressure. Press OK button.</p>	<p>Default set at 60mmHg. There is a pressure transducer in the pump which limits the pressure. 60 - 70 - 80 60 - 50 - 40 Desired pressure on LCD display is taken over and displayed under “System OK”.</p>
<p>5. Language adjustment</p> 	<p>Press arrow Up. Press arrow Down. Press OK. Press arrow up or down. Press OK. Navigate to desired language using - or - buttons. Press OK.</p>	<p>“System OK” with “1” underneath on LCD display. “System OK” with “2” underneath on LCD display. “Pressure” displayed. “Language” displayed. “Language” selected. Languages (in local language) are displayed individually. “English” is default language. For available languages, see section 5.3 Control unit Software Schematic, page 13. Selected language on display is taken over for the whole menu display.</p>

6 Transport

6.1 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 10.4 Environmental Parameters, page 24.

6.2 Transport Mode

If it is necessary to move the bed or mattress simply:

1. Turn off power supply.
2. Disconnect control unit power lead (if necessary the air hose).
3. When system is ready to reactivate following section 4.2 Installing the system, page 10.

Air supply hose should be stored by attaching to the fastener at foot of the mattress.

For Active Care mattress, the air hose is located inside the mattress. To access the hose Unzip the mattress take out hose and connect to the pump, ensure that zip is closed once connection is made.

7 Maintenance

7.1 Inspection (multiple use)

It is recommended that the mattress is checked (foam, air insert and cover) for strike-through (this may include fluid ingress, stains, rips or damage) 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.

Check mattress (multiple use)

1. Unzip the cover completely.
2. Check for any staining on the white underside of the cover.
3. Check for any staining on the interior foam.
4. Replace any stained items and dispose of as per local authority procedure.
5. Remove mains power and check audible sounder operates.
6. Visually inspect mains cord for signs of damage or wear.

7.2 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/CG139 and your local infection control policy.

Cleaning Handle

1. The exterior of the Handle can be periodically wiped using a cloth dampened with disinfectant.

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Cleaning control unit



WARNING!

Electrical shock hazard!

- Ensure the control unit is disconnected from the mains electricity supply before cleaning.
- Do not spray disinfectant directly on to the control unit, or immerse the control unit in any type of liquid. This could result in a severe electrical hazard as this equipment has no protection against ingress of water.
- This equipment is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

1. Wipe all controls, pump casing and hose fittings with a quaternary disinfectant solution.
2. Using a nylon brush, gently clean all crevices as they can harbor microorganisms.
3. Air dry all treated surfaces.

Cleaning covers

(Removal of contaminants such as dust and organic matter)

1. Remove all covers for laundering.
2. Launder the covers with the recommended temperature at 80 °C using a diluted detergent solution (Instructions on label).



IMPORTANT!

Washing at higher temperatures will cause shrinkage.

Drying covers

1. Hang mattress covers from a line or bar and drip dry in a clean indoor environment.
or
Tumble dry on a low heat setting.

! IMPORTANT!

- Tumble dry setting must not exceed 40 °C.
- Do not tumble dry for longer than 10 minutes.
- Dry thoroughly before re-fitting to the foam.

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.

Light soilage

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.
3. Dry the cover thoroughly.

Heavy soilage

Where the mattress is badly soiled, we recommend cleaning with a dilute cleaning solution at 80 °C in the washing machine.



Large spillages of blood should be absorbed and removed with paper towels first, followed by as above.

1. Clean up all spillages of bodily fluids i.e. blood, urine, faeces, sputum, wound exudate and all other bodily secretions as soon as possible using a 1% Chlorine Solution (10,000 ppm).
2. Rinse with clean water using a single use nonabrasive cloth.
3. Dry the cover thoroughly.

! 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.

! IMPORTANT!

1% Chlorine Solution used on a regular basis can diminish the life of the cover if not rinsed and dried properly.
– Do not use granules.



WARNING!

– Remove contaminated foams from use.



CAUTION!

– Keep clear of open heat sources.

**IMPORTANT!**

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

Replacing covers

1. Unzip the cover and remove it carefully from the foam core.
2. Place new cover onto the foam core.
3. Then close the zipper.

**IMPORTANT!**

- Ensure that the corners of the foam core are positioned correctly into the corners of the cover.
- Ensure that the profiled side of the foam is facing uppermost when packed into its cover.

8 After Use

8.1 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 10.4 Environmental Parameters, page 24.

8.2 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,
 © 7.2 Cleaning and care, page 17.

8.3 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.

9 Troubleshooting

9.1 Identifying and repairing defects

There are audio and visual alarms present on the control unit.

Problem / Alarm	Cause	Solution
Mattress not inflating (not alternating properly).	Mattress CPR hose disconnected.	Connect CPR hose connector, lock it in place.
	Has power and fuse is good, control unit does not come on.	Send control unit back to Invacare for repair.
	Major leak in air cell.	Replace leaking air cell.
	CPR hose or tube connectors kinked or split.	Unkink or replace split CPR hose or tube connectors.
	Not alternating, rotor failure.	Send control unit back to Invacare for repair.
	No air (control unit failure).	Send control unit back to Invacare for repair.
No power.	Control unit off.	Check power source, turn unit on.
	Power cord disconnected.	Connect power cord and ensure the power source is on.
	No power in the power source.	Check the power source has power and turn it on.
	Power outage.	Wait till the power source has power.
	Fuse blown.	Change fuse on power inlet connector with spare fuse or identical replacement only (consult a trained engineer if you are unsure how to change a fuse).
Cannot enter menu.	System set up not complete.	Wait until set up is complete and "System OK" displayed.
Low pressure alarm* "Low Pressure" displayed with audible beeps.	Disconnection of CPR (connection hose).	Connect hose properly.
	Disconnection of connector tubes to air cells in air insert.	Check individual air cells in insert are correctly connected to connector tubes.

* Low pressure alarm will only function after the system has gone through full cycle set up and “System OK” displayed.



In the event of an alarm, the audible sound can be muted by pressing the „OK“ button ©. The LCD display Ⓐ and Green light Ⓔ will flash to indicate the alarm is still evident. (See figure 5.4 Control unit Menu Display, page 14) Once muted, the system will automatically go into set up mode, to check the diagnostics of the system. If the fault reoccurs after the system has been through set up, the pump alarm will sound again, to notify the user of the fault.



In case of issues with troubleshooting, please contact Invacare for further assistance (contact details on the back page of this User Manual).

10 Technical data

10.1 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⁾
SOFTFORM® PREMIER ACTIVE 2 / ACTIVE CARE	Cover: 4 years Foam: 8 years Pump: 2 years	EN 597-1 EN 597-2 BS 7177: Crib 5	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.

Warranty on air cell insert	2 years
Air cell height	75 mm

10.2 Control unit

Main Supply	220 – 240 V~, 50 Hz
Rated Input Current	1 A
Supply Fuse	1 A
Noise Level	< 32 dB
Classification	Class II Type BF
Cycle Time	10 min, A/B +/- 1 min
Size	237 mm x 205 mm x 80 mm
Weight	1.75 kg
Air Flow	4 l/min
Operating Pressure	60 mmHg (8 kPa)
Power	23 VA
Control unit fuse	T1 AL 250 V

10.3 Materials

Foam	Polyurethane Combustion Modified High Resilience Foam
Cover	Polyurethane transfer coating on weft knitted fabric
Air Cells	Polyurethane coated nylon
Glide Membrane	Polyurethane Film

Control unit and mattress components are Latex-free.

10.4 Environmental Parameters

Operating conditions	
Ambient temperature	5 - 40 °C
Relative humidity	15% - 93%, non-condensing
Atmospheric pressure	70 - 106 kPa
Storage and shipping conditions	
Ambient temperature	-25 - 70 °C
Relative humidity	10% - 100%, non-condensing
Atmospheric pressure	50 - 106 kPa

10.5 Spare parts



For spare parts/components list, please contact your nearest Invacare dealer in your country specified on back of this user manual.

Notes

Notes

Invacare® distributors

United Kingdom:

Invacare Limited
Pencoed Technology Park, Pencoed
Bridgend CF35 5AQ
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Making Life's Experiences Possible™



Yes, you can.®