Invacare® Softform Active® 2 Rx

en 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.

Contents

1 General

1.1 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.

A range of peer reviewed published articles are available to support the use of the Softform Active hybrid mattress concept. Please refer to www.thinkpressurecare.co.uk for details.

1.2 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

1.3 Compliance

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

All Invacare® Softform® Mattress products feature the CE mark, in compliance with the Medical Device Directive 93/42/EEC Class 1.

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 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).

1.4 Warranty information

We provide a manufacturer's warranty for the product in accordance with our General Terms and Conditions of Business in the respective countries.

Warranty claims can only be made through the provider from whom the product was obtained.

1.5 Limitation of liability

Invacare accepts no liability for damage arising from:

- Non-compliance with the user manual
- Incorrect use
- Natural wear and tear
- Incorrect assembly or set-up by the purchaser or a third party
- Technical modifications
- Unauthorized modifications and/or use of unsuitable spare parts

1.6 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.

A healthcare professional or carer is the intended operator.

1.7 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 on your local Invacare website or at 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 mattress 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.
– 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 for further guidance/information.

2.2 EMC information

This product needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided, and this unit can be affected by portable and mobile RF communications equipment.

CAUTION!
– Do not use a mobile phone or other devices that emit electromagnetic fields, near the unit. This may result in incorrect operation of the unit.
– This device should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, this device should be observed to verify normal operation in the configuration in which it will be used.

2.3 Labels and symbols on the product

	Do not pierce or cut		Line dry
	Do not dry clean		CE conform
	User weight limit		Recommended 80 °C
	Do not put near flame		Do not iron
	Do not bleach		Tumble dry low heat
	Double Insulated		Refer to user manual
	Type BF applied part		Date of manufacture
	WEEE conform		Warning symbol

	CPR label

3 Components

3.1 Product description

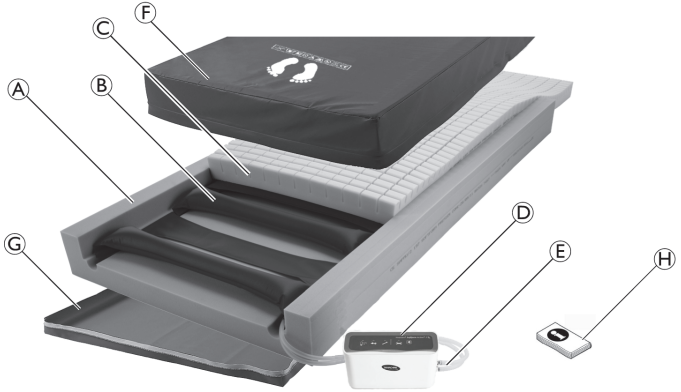
The Invacare® Softform Active® 2 Rx mattress system acts as a static pressure reducing support/mattress for patients at High/Very High risk that can, by facilitating the air pump, introduce effective alternating pressure if the patients condition requires alternating pressure therapy.

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:



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

* Power lead supplied not shown.

4 Setup

4.1 Safety information

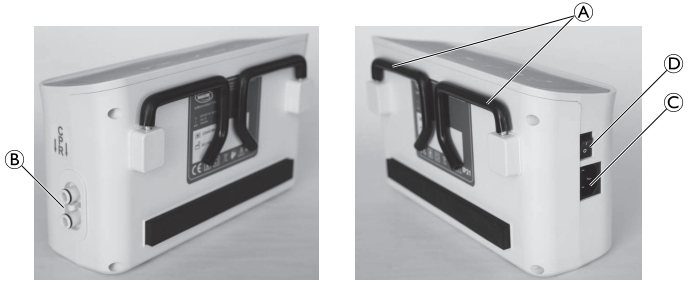
WARNING!
Electrical shock hazard!
- Do not remove control unit cover.
- Refer to qualified service personnel.
- Before performing any maintenance to the control unit, disconnect the power lead from the wall outlet.
- Do not insert items into any openings of the control unit. Doing so may cause fire or 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 in such a way that ensures access to the power switch and CPR Connector at all times.

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.

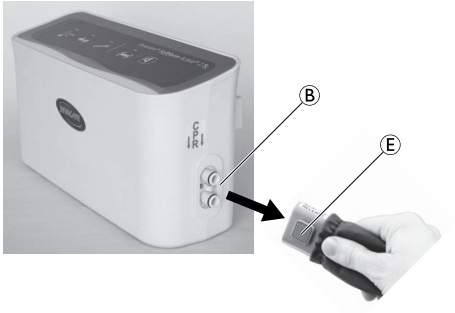
WARNING!
Risk of entrapment!
Patient entrapment with the bed side rails may cause injury or death. A thorough patient assessment should be completed and monitored and the equipment should be used as specified and maintained to reduce the risk of entrapment. Variations in bed rail dimensions, and mattress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



1. Hang the control unit by means of the 2 built in hangers Ⓐ at the end of the bed or place it on a horizontal surface. (Placing the control unit on the floor will not affect the performance, but may expose it to accidental damage.)



2. Connect the CPR hose Ⓔ to air outlets on the mattress and control unit Ⓑ, ensuring that the hose is not kinked or twisted. Allow space for bed rails to drop freely.
3. Connect the mains power cable to the power supply socket Ⓒ of the control unit and a suitable outlet.

4. Switch on mains power of the outlet if present.
5. Move the mechanical switch Ⓓ on the left side of the Control unit to the On position. A faint single beep sounds and the system in cycle light flashes while the system powers up.

Refer to *9 Troubleshooting, page 22* if the indicator is not flashing.

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.

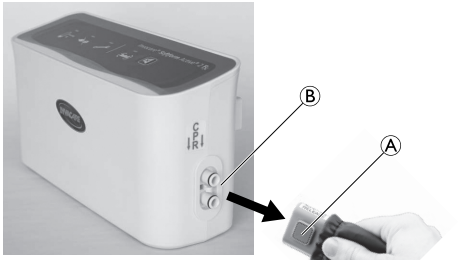
CAUTION!
– Make sure that the printed side of the mattress cover always faces upwards.
– Ensure that the distance between the surface of the mattress and the top of the side rail is at least 220 mm. If this is not achievable a risk assessment must be carried out.

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 Invacare® Softform Active® 2 Rx mattress has been fully tested to comply with the current CPR standard of 5-6 cm compression depth. This was achieved at all stages of inflation/deflation.



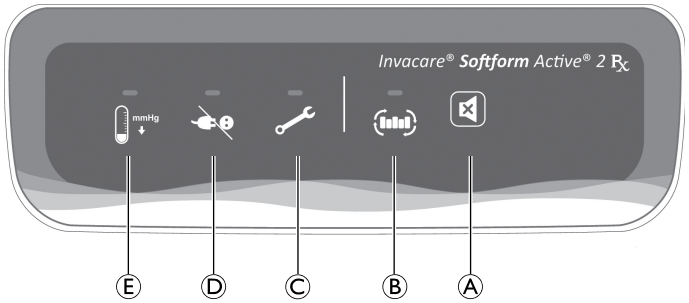
1. Hold down Red CPR button Ⓐ.
2. Pull hose connector firmly away from the control unit Ⓑ.
3. Switch off the control unit.

> 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 11*.

5.3 Control unit menu display

Overview



Pos.	Description	Function
Ⓐ	Mute button	The relevant audible / visible indicator turns on when low pressure, power failure or alternate failure is recognised. To mute the audible signal, press the Mute button. The visible indicator will flash until the problem is solved. If the problem indicated has not been solved within 10 minutes, the indicator will sound again. Press the Mute button to mute the audible indication, the indicator will not sound again. Refer to chapter *9 Troubleshooting, page 22*.
Ⓑ	System in cycle / Setup indicator (Operative LED)	Green LED indicator flashes whilst system is setting up – Solid green LED indicates normal operational.
Ⓒ	Alternating system / Timing failure indicator	Red LED indicator flashes and audible buzzer sounds if the system recognises a cycle time problem.

Pos.	Description	Function
Ⓓ	Power failure indicator	Red LED indicator flashes and audible buzzer sounds if the system has no power connected. This could be in the event of a power failure, for example caused by power cord unplugged or power off when control unit is working. When power is restored, control unit will automatically start working.
Ⓔ	Pressure failure / Low pressure indicator	Red LED indicator flashes and audible buzzer sounds if the system recognises a low pressure failure.

Operation

1. The power indicator will flash and control unit will enter static mode initially until pressure reaches 15mmHg. Then control unit will enter alternate mode and power indicator will remain on. The cycle time is set at 10 min, and the pressure is set at 60±3mmHg.

The first inflation of new mattress: the indicator function (visible and audible indicators) will activate if the mattress does not inflate completely within 15 minutes.

Operation failures

- During control unit operation, low pressure indicator will activate within 1 minutes if air hoses are disconnected or air cells are broken.
- In the case of abnormal alternate or no alternate, the audible signal will be activated and alternate failure indicator will flash.

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 25*.

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 11*.

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 control unit, ensure that zip is closed once connection is made.

7 Maintenance

7.1 Inspection (multiple use)

It is recommended that the mattress (foam, air insert, cover and CPR hose) is checked for damage by a suitably qualified and competent person. The checks must be performed after the release of each patient, after the end of the period of use or on a minimum monthly basis (depending on which occurs first).

WARNING!
Electrical shock hazard!
– Maintenance and servicing of the product must only be carried out by a qualified technician.
– Never maintain/service the equipment while it is in use.
– Disconnect the electrical equipment from the mains power during maintenance/servicing.

Check mattress (multiple use)

1. Unzip the cover completely.
2. Check for any staining or damage on the white underside of the cover.
3. Check for any staining or damage on the interior foam (fluid ingress into the interior foam, stains, rips or damage).
4. Replace any stained or damaged items and dispose of as per local authority procedure.
5. Remove cable from the wall or socket and check audible sounder operates.
6. Visually inspect mains cable for signs of damage or wear.

WARNING!
Electrical shock hazard!
– If damage is found to the mains cable do not use the device and refer to qualified service personal.

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 Healthcare-associated infections: prevention and control in primary and community care www.nice.org.uk/CG139 and your local country infection control policy.

Cleaning hangers

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

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.
- 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 the control unit 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.
4. Re-connect the control unit to the power outlet and turn it back on. Refer to *4.2 Installing the system, page 11*.

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 with clean water 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 exudater 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 castillated 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 25*.

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 18*.

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). Alternating system / Timing failure indication	Mattress CPR hose disconnected.	Connect CPR hose connector, lock it in place.
	Power cable and fuse has been checked, control unit does not operate.	Send control unit back to Invacare for repair.
	Major leak in air cell or complete air insert.	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 / Power failure indication	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 outlet.	Switch on the power outlet (if pole switch available). Have the power outlet repaired by an electrician.

Problem / Alarm	Cause	Solution
	Power outage.	Wait until 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).
Pressure failure / Low pressure indication	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.
	Kinked connection hose	Make sure that there are no kinks or bends in the hose.

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	Firetesting	Grade ref & Colour	Nominal density range [kg/m3]	Nominal hardness range [N]	Maximum user weight [kg]	Weight of product [kg][1)]
Invacare® Softform Active® 2 Rx	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)]Based on the weight of a standard size mattress. This can change if different sizes are ordered.

Air cell height	75 mm

10.2 Control unit

Main Supply	220 – 240 V~, 50/60 Hz
Rated Input Current	1 A
Supply Fuse	1 A
Noise Level	≤ 24 dB
Classification	Class II Type BF
Cycle Time	10 min, A/B +/- 1 min
Size	275 mm X 155 mm X 105 mm
Weight	1.75 kg
Air Flow	4 l/min
Operating Pressure	60 mm Hg (8 kPa)
Power	23 VA
Control unit fuse	T1 AL 250 V
Ingress protection	IP21 *
* Protected from touch by fingers and objects greater than 12 millimeters. Protected against vertically falling drops of water or condensation.	

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 do not contain natural rubber latex.

10.4 Environmental Parameters

Operating conditions	
Ambient temperature	10 °C to 35 °C
Relative humidity	20% - 80%, non-condensing
Atmospheric pressure	70 - 106 kPa
Storage and shipping conditions	
Ambient temperature	-15 °C to 50 °C
Relative humidity	10% - 90%, non-condensing
Atmospheric pressure	50 - 106 kPa

10.5 Spare parts / circuit diagrams

Upon request, manufacturer will provide circuit diagrams.

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

10.6 Guidance and manufacturer's declaration

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

Electromagnetic emissions

Emission test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Electromagnetic immunity

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for Input/output lines	±2 kV for power supply lines ±1 kV for interconnecting cable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line to line ± 2 kV line to earth	±1 kV line to line	Mains power quality should be that of a typical commercial or hospital environment.
Interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the CT515, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
			Recommended separation distance:
Conducted RF IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz	3 V_{rms} 150 kHz to 80 MHz	*$d = [3.5/V_1] \times \sqrt{P}$*
	6 V_{rms} in ISM bands	6 V_{rms} in ISM bands	

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m 80 MHz to 2.7 GHz	*d = 1.12 x √P 80 MHz to 800 MHz* *d = 2.3 x √P 800 MHz to 2.5 GHz*
	385MHz - 5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014)	**385MHz - 5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014)**	Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a)], should be less than the compliance level in each frequency range[b)]. Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the device

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = 1.12\sqrt{P}$	80 MHz to 800 MHz $d = 1.12\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Invacare distributors:

United Kingdom:
Invacare Limited
Pencoed Technology Park, Pencoed
Bridgend CF35 5AQ
Tel: (44) (0) 1656 776 222
Fax: (44) (0) 1656 776 220
uk@invacare.com
www.invacare.co.uk

Australia:
Invacare Australia PTY. Ltd.
1 Lenton Place, North Rocks NSW 2151
Australia
Phone: 1800 460 460
Fax: 1800 814 367
orders@invacare.com.au
www.invacare.com.au

Ireland:
Invacare Ireland Ltd,
Unit 5 Seatown Business Campus
Seatown Road, Swords, County Dublin
Tel : (353) 1 810 7084
Fax: (353) 1 810 7085
ireland@invacare.com
www.invacare.ie

Invacare UK Operations Limited
Pencoed Technology Park, Pencoed
Bridgend CF35 5AQ
UK

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