



# Invacare® Softform Premier Active 2 with RX pump

en Hybrid mattress  
User Manual

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



**Yes, you can.®**

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# 1 General

## 1.1 Introduction

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

Note that there may be sections in this document, which are not relevant to your product, since this document applies to all available models (on the date of printing). If not otherwise stated, each section in this document refers to all models of the product.

The models and configurations available in your country can be found in the country-specific sales documents.

Invacare reserves the right to alter product specifications without further notice.

Before reading this document, make sure you have the latest version. You find the latest version as a PDF on the Invacare website.

If you find that the font size in the printed document is difficult to read, you can download the PDF version from the website. The PDF can then be scaled on screen to a font size that is more comfortable for you.

For more information about the product, for example product safety notices and product recalls, contact your Invacare distributor. See addresses at the end of this document.

In case of a serious incident with the product, you should inform the manufacturer and the competent authority in your country.

## 1.2 Symbols in this Document

Symbols and signal words are used in this document and apply to hazards or unsafe practices which could result in personal injury or property damage. See the information below for definitions of the signal words.



### WARNING

Indicates a hazardous situation that could result in serious injury or death if it is not avoided.



### CAUTION

Indicates a hazardous situation that could result in minor or slight injury if it is not avoided.



### IMPORTANT

Indicates a hazardous situation that could result in damage to property if it is not avoided.



### Tips and Recommendations

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

## 1.3 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.

## 1.4 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
- Unauthorised modifications and/or use of unsuitable spare parts

## 1.5 Service Life

The expected service life of this product is five years when used daily and in accordance with the safety instructions, maintenance intervals and correct use, stated in this manual. The effective service life can vary according to frequency and intensity of use.

## 2 Safety

### 2.1 Safety Information

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

A range of assessment scales can be used as a formal method of assessing risk from pressure injury 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.



#### **WARNING!**

##### **Risk of Serious Injury or Damage**

Improper use of this product may cause injury or damage.

- If you are unable to understand the warnings, cautions or instructions, contact a health care professional or provider before attempting to use this equipment.
- 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 manual, service manual or instruction sheet supplied with this product or optional equipment.



#### **WARNING!**

##### **Risk of Developing Pressure Injuries**

The mattress delivers effective pressure reduction, when the support surface is covered with a cotton, cotton combination or linen bed sheet, and any one of these is the only item deployed between the support surface and the user.

- Bed sheets must be loosely fitted, with creases smoothed out.
- 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 support surface and the user.
- Heated over blankets must only be used in consultation with a qualified healthcare professional, as an increase in temperature can increase the risk of developing pressure injuries.



#### **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.

- Take special care in oxygen rich environments.
- Do not smoke.

**CAUTION!****Risk of Injury**

Non-original or wrong parts may affect the function and safety of the product.

- Only use original parts for the product in use.
- Due to regional differences, refer to your local Invacare catalog or website for available options or contact your Invacare distributor. See addresses at the end of this document.

- 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.

## 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 Safety Information for Transport

- 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.

## 3 Product Overview

### 3.1 Product Description

The 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 106 °F).

### 3.2 Intended Use

This pressure redistribution mattress and control unit are intended to be used in conjunction with an appropriately sized bed frame.

The mattress can be used safely in static mode for static pressure redistribution, or in dynamic mode should an alternating pressure support surface be required.

This product delivers effective pressure redistribution to users, when the support surface is covered with a cotton, cotton combination or linen bed sheet, and any one of these is the only item deployed between the support surface and the user.

### 3.2.1 Indications

Suitable for supporting the management of all categories of pressure injuries when combined with an individual and comprehensive pressure injury protocol.

Suitable for use in home care, residential, nursing and acute care settings.

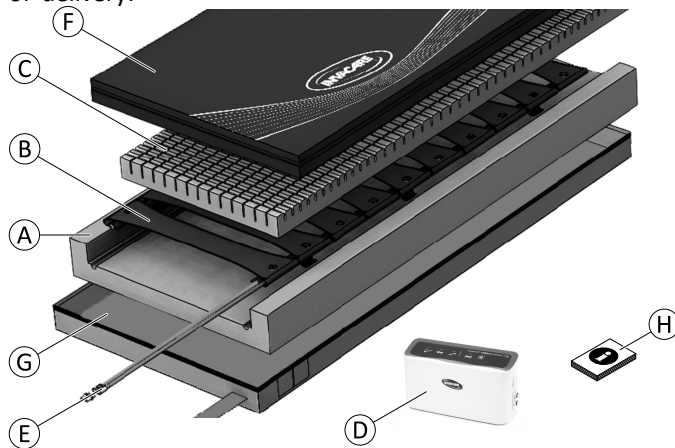
### 3.2.2 Contraindications

Not suitable for users with unstable spinal cord fractures and/or cervical traction.

Always consult a physician prior to using this device.

## 3.3 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)	CPR connector
(F)	Multi-stretch vapour-permeable cover
(G)	Toughened PU coated base
(H)	User Manual

\* Power lead supplied not shown.

### 3.4 Labels on the Product

The shown label serves as examples only. The labels on your product might differ from these examples.

#### Control Unit



Fig. 3-1













(A)	Product name and Model version
(B)	Input Voltage, Frequency range and Input Current
(C)	Serial number
(D)	Date of manufacture
(E)	Country of origin








#### Mattress / Cover

Since the identification labels on the mattress and cover may change depending on used model and date of manufacture,

the labels for these components are not shown here. For explanations of the symbols which are printed on the mattress and the cover, see section 3.5 *Symbols on the Product*, page 10 in this document.

### 3.5 Symbols on the Product

	Read user manual		Medical Device
	Manufacturer		Date of manufacture
	Serial number		LOT number
	Type BF applied part		Caution
	WEEE conform		User weight limit. See 9 <i>Technical Data</i> , page 24.
	Do not pierce or cut		Do not put near flame

	Machine wash temperature. Max. temperature is shown in symbol.		Do not iron
	Do not dry clean		Do not bleach
	Tumble dry low temperature		CPR label
	UL Certification number Exxxxxxx		

## 4 Setup

### 4.1 Safety information



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

- Do not remove control unit shroud.
- 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!**

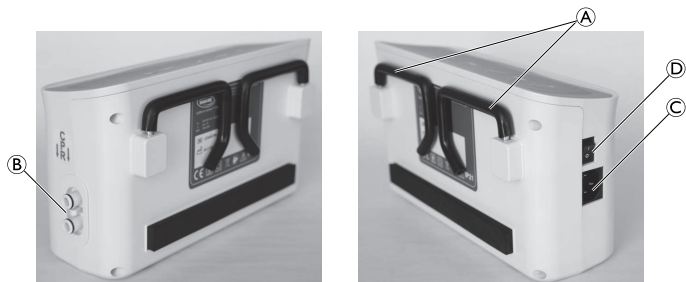
- Patient entrapment with bed side rails may cause injury or death.
- Mattress **MUST** fit bed frame and side rails snugly to prevent patient entrapment.
  - Follow the manufacturer's instructions.
  - Monitor patient frequently.



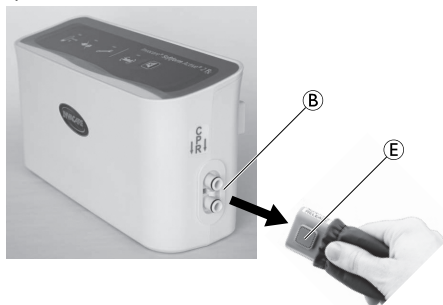
**WARNING!**

- This mattress is recommended to be installed on medical bed frames with bed side rails 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 **A** 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 **E** to air outlets on the mattress and control unit **B**, 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 **C** of the control unit and a suitable outlet.

4. Switch on mains power of the outlet if present.
5. Move the mechanical switch **D** 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 *8 Troubleshooting, page 22* if the indicator is not flashing.

## 5 Usage

### 5.1 Safety Information

**WARNING!**

Insufficient repositioning of the patient can lead to tissue compression and potential injury formation.

To relieve pressure, it is very important for the patients to reposition themselves, or to be repositioned, on a regular basis.

- Before using the product, always consult a qualified healthcare professional for clinical judgement.
- 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 8.7 inches.

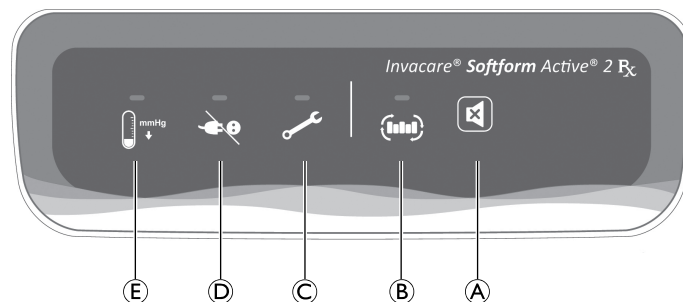
**CAUTION!****Risk of damage to the mattress**

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

- Ensure that the mattress is not jammed or damaged by sharp edges.
- Do not place hypodermic needles, venflons, scalpels or other similarly sharp objects on or under the mattress.
- Do not use electrically heated blankets directly on or under the mattress.
- Ensure that all venflons are taped down correctly with no sharp edges exposed.
- When using bridging boards or other patient transfer aids, check for any sharp edges or burrs before use.
- When using the mattress on a profiling bed ensure that the knee break is used before the backrest.
- Attach medical equipment including infusion pumps and monitors to appropriate bed accessories.
- Avoid cigarette burns and pet claws puncturing the mattress cover.

## 5.2 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 8 <i>Troubleshooting</i> , 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

- 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  $60 \pm 3$ mmHg.



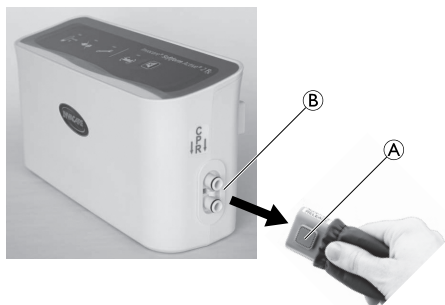
The first inflation of new mattress: the indicator function (visible and audible indicators) will activate if the mattress does not inflate completely within 15 minutes.

## 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.

## 5.3 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 (A).
2. Pull hose connector firmly away from the control unit (B).
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 12*.

## 5.4 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 12*.

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



## 6 Maintenance

### 6.1 Inspection

It is recommended to check mattresses (air cells and cover) for strike-through (this may include fluid ingress, stains, rips or damage) after the release of each patient or after each period of use by a suitably qualified and competent person.

#### Check mattresses

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 air cells.
4. Replace any stained items and dispose of as per local authority procedure.

### 6.2 Cleaning and Disinfection

#### 6.2.1 General Safety Information



#### CAUTION!

##### Risk of Contamination

- Take precautions for yourself and use appropriate protective equipment.



#### CAUTION!

##### Risk of electric shock and product damage

- Switch off the device and disconnect from mains, if applicable.
- When cleaning electronic components consider their protection class regarding water ingress.
- Make sure that no water splashes to the plug or the wall outlet.
- Do not touch the power socket with wet hands.



#### IMPORTANT!

Wrong fluids or methods can harm or damage the product.

- All cleaning agents and disinfectants used must be effective, compatible with one another and must protect the materials they are used to clean.
- Never use corrosive fluids (alkalines, acid etc.), abrasive cleaning agents or solvents (cellulose thinner, acetone etc.). We recommend a mild detergent.
- Always make sure that the product is completely dried before taking it into use again.



For cleaning and disinfection in clinical or long-term care environments, follow your in-house procedures.

## 6.2.2 Cleaning Intervals

- ! **IMPORTANT!**  
Regular cleaning and disinfection enhances smooth operation, increases the service life and prevents contamination.  
Clean and disinfect the product
  - regularly while it is in use,
  - before and after any service procedure,
  - when it has been in contact with any body fluids,
  - before using it for a new user.

- ! **IMPORTANT!**
  - Keep a cleaning record as part of cleaning the system.

## 6.2.3 Cleaning Instructions

- ! **IMPORTANT!**
  - The product does not tolerate cleaning in automatic washing plants, with high-pressure cleaning equipment or steam.



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

### Cleaning control unit

1. Wipe down the control unit casing and hose fittings with a damp cloth and suitable detergent.
2. Using a nylon brush, gently clean all crevices as they can harbor microorganisms.

3. Wipe off the control unit casing and hose fittings with a damp cloth to remove all detergent.
4. Air dry all treated surfaces.

### Cleaning hangers

1. Wipe down the exterior of the hangers periodically, using a damp cloth and suitable detergent.

### Cleaning covers

(Removal of contaminants such as dust and organic matter)

1. Remove all covers for laundering.
2. Launder the covers with maximum temperature as stated on product label, using a diluted detergent solution (Instructions on label).

- ! **IMPORTANT!**
  - Washing at higher temperatures will cause shrinkage.

### Drying covers

1. Hang 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 104 °F.
  - Do not tumble dry for longer than 10 minutes.
  - Dry thoroughly before use.

## 6.2.4 Disinfection Instructions



### IMPORTANT!

- Only use disinfectants and methods approved by your local infection control institution and follow your local infection control policy.
- Follow your local decontamination protocols.

### Disinfecting covers

(Reducing the number of microorganisms)



### IMPORTANT!

- Failure in disinfection process may result in the accumulation of reagent that could damage the polyurethane coating, react with the bed frame, or negate the biocompatibility results.
- Ensure that all cleaning agents, and disinfectants, are thoroughly rinsed off.
  - Dry thoroughly before use.

1. Wipe down the cover with a suitable detergent.
2. Rinse the cover thoroughly 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 maximum temperature in the washing machine (see product label).
- 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 suitable detergent.
  - Large spillages of blood should be absorbed and removed with paper towels first.



### WARNING!

- In event of contamination, contact your hygiene specialist.
- Remove contaminated foams from use.

### Autoclaving covers

Autoclave the cover at 230 °F.



### IMPORTANT!

- Make sure the cover is outstretched (not folded).
- Do not place covers on top of each other.

## 6.3 Replacing Cover

1. Unzip cover and remove it carefully from foam insert.
2. Place new cover onto foam insert.
3. Close zipper.



**IMPORTANT!**

- Ensure that the corners of the foam insert are positioned correctly into the corners of the cover.
- Ensure that the castellated foam is facing upwards when inserted into its cover.



**WARNING!**

- In event of contamination, contact your hygiene specialist.
- Remove contaminated foams from use.

## 7 After Use

### 7.1 Storage

- !** **IMPORTANT!**
- Store mattresses in a dry environment.
  - Store mattresses within a protective cover.
  - Ensure mattress is carefully rolled and stored in protective bag provided 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.

For environmental conditions for storage, see chapter 9 *Technical Data*, page 24.

### 7.2 Reconditioning

This product is suitable for reuse. To recondition the product for a new user, carry out the following actions:

- Inspection
- Cleaning and disinfection

For detailed information, see *6 Maintenance*, page 17.

Make sure that the user manual is handed over with the product.

If any damage or malfunction is detected, do not reuse the product.

### 7.3 Disposal

Be environmentally responsible and recycle this product through your recycling facility at its end of life.

Disassemble the product and its components, so the different materials can be separated and recycled individually.

The disposal and recycling of used products and packaging must comply with the laws and regulations for waste handling in each country. Contact your local waste management company for information.

## 8 Troubleshooting

### 8.1 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).

## 9 Technical Data

### 9.1 Mattress Specifications

Product	Dimensions [inch]			Air cell height [inch]	Maximum user weight [lbs]	Weight of product [lbs] <sup>1</sup>
	Length	Width	Height			
Softform Active 2 Rx	80	36	6	3	500	35
	80, 84	39, 42, 48			650	

### 9.2 Control Unit Specifications

Supply Voltage	120 V, 60 Hz
Rated Input Current	1 A
Fuse Rating	1 A
Noise Level	below 24 dB
Classification	Class II Type BF
Cycle Time	10 min, A/B +/- 1 min
Dimensions (Length x Width x Height)	10.8 in x 6.1 in x 4.1 in
Weight	3.9 lbs
Air Flow	8 lpm
Operating Pressure	60 mm Hg (8 kPa)

1. Weight can vary depending on mattress size. Average weight used as an indication.



Power rating	23 VA
Control unit fuse	T1 AL 250 V

### 9.3 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.

### 9.4 Environmental Conditions

	Operation	Storage and Transport
Ambient temperature	50 °F – 95 °F	5 °F – 122 °F
Relative humidity	20 % – 80 %, non-condensing	10 % – 90 %, non-condensing
Atmospheric pressure	70 – 106 kPa	50 – 106 kPa

## 9.5 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**

<b>Immunity test</b>	<b>IEC 60601 test level</b>	<b>Compliance level</b>	<b>Electromagnetic environment – guidance</b>
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 <sub>T</sub> (>95% dip in U <sub>T</sub> ) for 0.5 cycle 40% U <sub>T</sub> (60% dip in U <sub>T</sub> ) for 5 cycles 70% U <sub>T</sub> (30% dip in U <sub>T</sub> ) for 25 cycles <5% U <sub>T</sub> (>95% dip in U <sub>T</sub> ) for 5 sec	<5% U <sub>T</sub> (>95% dip in U <sub>T</sub> ) for 0.5 cycle 40% U <sub>T</sub> (60% dip in U <sub>T</sub> ) for 5 cycles 70% U <sub>T</sub> (30% dip in U <sub>T</sub> ) for 25 cycles <5% U <sub>T</sub> (>95% dip in U <sub>T</sub> ) 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.
			<b>Recommended separation distance:</b>
Conducted RF IEC 61000-4-6	3 $V_{rms}$ 150 kHz to 80 MHz 6 $V_{rms}$ in ISM bands	3 $V_{rms}$ 150 kHz to 80 MHz 6 $V_{rms}$ in ISM bands	$d = [3.5/V_1] \times \sqrt{P}$

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	$d = 1.12 \times \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \times \sqrt{P}$ 800 MHz to 2.5 GHz
	<b>385MHz - 5785MHz            Test specifications            for ENCLOSURE            PORT IMMUNITY            to RF wireless            communication            equipment (Refer            to table 9 of IEC            60601-1-2:2014)</b>	<b>385MHz - 5785MHz            Test specifications            for ENCLOSURE            PORT IMMUNITY            to RF wireless            communication            equipment (Refer            to table 9 of IEC            60601-1-2:2014)</b>	<p>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).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey<sup>a</sup>), should be less than the compliance level in each frequency range<sup>b</sup>).</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 

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.

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