Invacare® SoftAIR® Super / SoftAIR® Excellence

CE

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

INVACARE

Yes, you can.

Contents

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1 General

1.1 General information

Essential nursing care is pivotal in pressure ulcer prevention. The SoftAIR® 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 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.

Please heed all the notes, particularly the safety information, and act accordingly.

For more information about the product, contact your local Invacare representative. For address and website see back page of this manual.

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 Intended use

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

It 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 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.

Indications

The SoftAIR® mattresses are suitable for the prevention and treatment of pressure ulcers in the 'Very High Risk' patient. It is suitable for use in all home care, residential, nursing and acute care settings and is appropriate for the treatment of pressure ulcers up to grade 4 as well as severe pressure ulcers.

1.4 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 SoftAIR® mattress is warranted by Invacare Ltd for a period stated in the Table "Technical Data" of this user guide. This is subject to the individual country's Sales Agreements.

Please contact your local Invacare Sales Office for further information.

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

If a defect or fault is discovered please contact and notify the provider from whom the appliance was obtained 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 SoftAIR® Mattress products.

The purchaser's statutory rights under the Consumer Protection Act are not affected.

Quality and Flame Retardancy

Quality is fundamental to the company's operation, working within the disciplines of ISO 9001 (Quality management systems - Requirements) and ISO 13485 (Medical devices - Quality management systems - Requirements for regulatory purposes).

The Invacare SoftAIR® mattresses 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 according to 3rd version safety standard IEC/EN60601-1 (Medical electrical equipment - Part 1: General requirements for basic safety and essential performance) & EMC standard IEC/EN60601-1-2 (Collateral standard: Electromagnetic compatibility - Requirements and tests).

The SoftAIR® mattress is fire safety tested and certified in accordance with EN 597–1 & –2.

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

1.5 Service Life

We estimate a life expectancy of five years (5 yrs) for these products, provided they are used in strict accordance with the intended use as set out in this document and all maintenance and service requirements are met. The estimated life expectancy can be exceeded if the product is carefully used and properly maintained, and provided technical and scientific advances do not result in technical

limitations. The life expectancy can also be considerably reduced by extreme or incorrect usage.

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

2 Safety

2.1 Safety information

WARNING!
– Do not use this product or any available optional equipment without first completely reading and understanding these instructions and any additional instructional material such as user manuals, service manuals or instruction sheets supplied with this product or optional equipment. Invacare product manuals are available at your local dealer or Invacare in your country, addresses are on the back page of this manual. If you are unable to understand the warnings, cautions or instructions, please contact a healthcare professional, dealer or technical personnel before attempting to use this equipment – otherwise, injury or damage may occur.

WARNING!
There are siginificant risks of reciprocal interference posed by the presence of the system during specific investigations or treatments.
– In the event of electromagnetic or other interference between the system and other devices, move the equipment away from the sensitive devices or contact the manufacturer.

WARNING!
– Unplug the control unit from the mains power supply to disconnect the power.

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.

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

WARNING!
Risk of fire or explosion!
A cigarette can burn a hole in the bed surface and cause damage to the mattress. Also, patient clothing, bed sheets, etc, may be combustible and cause a fire. Failure to observe this warning can result in a severe fire, property damage and cause physical injury or death. There is an explosion risk if used with flammable anesthetics.
There is a possible fire hazard when used with oxygen administering equipment other than nasal mask or half bed tent type.
– Do not smoke while using this device.
– An oxygen tent may not extend below mattress support level.

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.

2.2 Symbols on the product

	Do not pierce or cut		Line dry
	Do not dry clean	CE	Declaration of conformity

	Do not put near flame	95°	Maximum 95 °C
xxx kg	User weight limit*		Do not iron
	Do not bleach		Tumble dry low heat
	Refer to user manual		Manufacturer
	Type B applied part		Class II medical equipment
	WEEE conform	EC REP	Authorised Representative in the European Community
SN	Serial number		Power
	Date of manufacture		

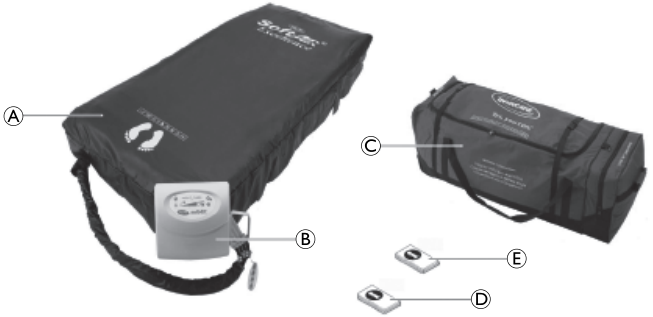
* Minimum / Maximum user weight as per section 10 Technical data, page 26.

3 Components

3.1 Overview

The following components are included within the scope of delivery:

SoftAIR® Excellence / SoftAIR® Super



Ⓐ	SoftAIR® Mattress System including Mattress Base, CPR Tag, Air Hoses, Handle with Transport Cap attached, Top cover with quick release zip. Two inflatable side formers (only SoftAIR® Excellence)
Ⓑ	Digital Control Unit
Ⓒ	Carry Bag
Ⓓ	Quick Setup Guide
Ⓔ	User Manual
	Medical Grade Power Cord (not shown)

3.2 Description

SoftAIR® Alternating Mattress Systems

The SoftAIR® Excellence and SoftAIR® Super are alternating Mattress Systems that provide alternating pressure to patients who are vulnerable to, or suffer from, pressure ulcers. They are designed to replace your existing mattress and can be used on both standard and profiling bed frames.

Digital Control Unit

The Control Unit provides the air supply to the Mattress.

- It is controlled via a touch panel. There is a visual and audible alarm when pressure fails or power is interrupted. Alarm Mute silences the alarm for a maximum of 20 minutes – the alarm resumes if cause of failure is not resolved. The Alarm will sound for up to two hours following an interruption to power. As soon as power is restored, the battery memory back up will restore the previous pressure/user setting.
- The Control Unit includes a battery for digital memory back up. This battery is continuously re-charged and will last the life time of the product.
- Buttons on the control panel adjust the eight alternating pressure settings.
- The system will automatically revert to Alternation Mode up to 20 minutes after static mode has been selected. See 5.2 Using the control unit panel, page 14 for further instruction.

The visible and audible alarm function has a number of indications depending on the cause of the failure. See chapter 5.5 Alarm Functions, page 17.

On the side of the control unit are four male air connectors for connecting the Handle.

The rapid release Handle includes an attached transport cap which can be inserted into the opening to seal air in the system for up to 72 hours as a transport feature.

The mains supply to the Control Unit can be easily disconnected and is designed to detach if tugged too firmly - protecting the internal wiring of the unit.

Should this occur, the alternation sequence is suspended and the Mattress cells remain inflated and/or deflated based on the current cycle. The Power failure indicator will sound.

SoftAIR® Super

The SoftAIR® Super Mattress comprises 21 high density cells which all feature a permanently inflated internal cell to prevent the patient "bottoming out" in the event of low pressure due to incorrect settings, electrical or cell failure.

This system includes three static head cells to provide static "pillow" support for optimum user comfort, while air pressure in the other 18 cells is alternated over a 10~12 minute cycle. This provides regular periods of pressure reduction to aid blood and lymphatic flow to vulnerable tissue.

SoftAIR® Excellence

The SoftAIR® Excellence Mattress comprises 19 high density cells which all feature a permanently inflated internal cell to prevent the patient "bottoming out" in the event of low pressure due to incorrect settings, electrical or cell failure.

This system includes three static head cells to provide static "pillow" support for optimum user comfort, while air pressure in the other 16 cells is alternated over a 10~12 minute cycle. This provides regular periods of pressure reduction to aid blood and lymphatic flow to vulnerable tissue.

The SoftAIR® Excellence has a hinged back to allow the mattress to conform to the profile of the bed when articulated. The SoftAIR® Excellence also includes an independent heel zone of five micro cells for individualized therapy to this sensitive area.

In addition, two permanently inflated side formers assist in lateral support for the user and carer, while increasing the effectiveness of the one in three alternation cycle. The hinged mattress base conforms to profiling bed movement.

4 Setup

4.1 Safety information

WARNING!
Electrical shock hazard!
- Only plug into a grounded power outlet and use the power cord supplied with the system.
- Do not expose the electronic control unit to any liquid while it is plugged in.
- Always use fuses of the same rating as specified in the Technical section. Using fuses with higher ratings could result in damage and/or injury.
- The electronic control unit is a precision electronic product. Handle and transport with care. Dropping or other sudden impacts may result in damage to the unit.
- Do not open the control unit.
- Do not attempt to repair or service the control unit without being authorized to do so.
- Do not place any objects or items such as blankets on or over the control unit.
- The power cord to the Control Unit must be positioned to avoid a trip hazard and/or damage to the cord. Careful consideration is required when routing the power cable. Invacare Ltd recommends placing the cord under the bed frame and attaching it to an electrical outlet at the head of the bed.
- Do not insert items into any openings of the control unit. Doing so may cause fire or electric shock by shorting the internal components.
- Keep the control unit away from all heat sources and radiators during operation.

WARNING!
- Do not modify this equipment without authorization of the manufacturer.
- If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment.

4.2 Installing the mattress system

It is recommended that all packing materials and instructions be kept in the carry bag provided in the event the product has to be shipped to an approved Invacare Service Center. The mattress is treated as the applied part. Carefully remove the Control Unit, Mattress and accessories from the shipping cartons. Inspect all items for any damage that may have occurred during shipping. Any damaged or missing parts must be reported to an Invacare Service Center immediately.

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

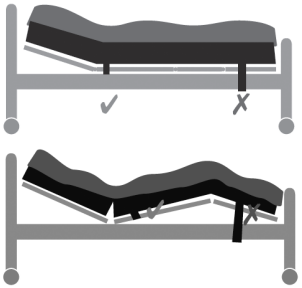
   The mattress is designed for beds with adjustable lying surface.

1. Remove all covers, sheets and mattress from the bed.

CAUTION!
Risk of injury or damage
- Prior to attaching the control unit to the foot board of the bed, check that the bed end is robust enough or that the unit is placed on an even enough surface to support the control unit safely without risk to the carer or patient or damage to the product itself.

IMPORTANT
– Prior to activation ensure the CPR valve (4 plugs) located near the head end of the mattress is fully engaged and that the rapid release handle is firmly connected to the control unit.

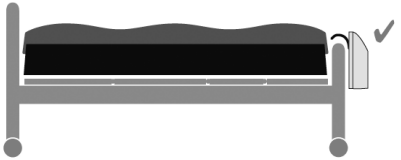
2. On a standard bed, position the Mattress on top of bed frame, top cover facing upwards and air hoses at foot of bed for control unit positioning.
3. Attach to the bed by securing the two (2) adjustable straps under each end of the bed. Ensure buckles are securely fastened and straps are pulled tight.
   Or on a profiling bed:
4. Secure the adjustable straps around the moveable sections of the bed frame.



IMPORTANT!
Risk of damage to the mattress
– Ensure there are no sharp objects which may come into contact with the mattress system.
– Check that the attachment of the Mattress does not interfere with the movement or operation of the bed.
– Do not secure straps to bed side rails as straps will tear.
– Ensure that the positioning of the system does not interfere with the ability to disconnect the electrical power.

4.3 Activating the control unit

1. Position the control unit by hanging the hooks over the foot board of the bed or side rails, ensuring that they are robust enough to hold the control unit.



CAUTION!
– Ensure the air hose does not kink between the bed frame and control unit.

IMPORTANT!
– Prior to pump activation ensure the CPR valve (4 plugs) located near the head end of the mattress is fully engaged.
– Also ensure that the rapid release handle is firmly connected to the control unit.

2. Connect the handle to the control unit.
3. Insert the power cord into the control unit then plug into a grounded 220V 50Hz electrical outlet.

IMPORTANT
– Prior to activation ensure the CPR valve (4 plugs) located near the head end of the mattress is fully engaged and that the rapid release handle is firmly connected to the control unit.

4. Press the power button for at least two (2) seconds to activate the control unit.

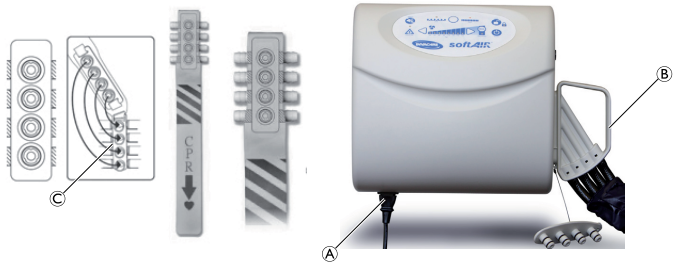
The pressure LEDs will flash indicating the system has activated.

5. Allow 40 – 50 minutes for the mattress to fully inflate. Once ready, you should see the fourth pressure LED plus alternating mode LED illuminate to indicate that the system is ready for use (system automatically defaults to Alternating Mode after start-up).
6. Once the Mattress is fully inflated the bedding can be placed. Fit sheets loosely enough to allow for free movement of the mattress air cells.
7. Ensure each sheet corner is placed through retaining buckle.

4.4 Removing the mattress system

1. Switch off the control unit and disconnect from mains supply Ⓐ.
2. Remove the rapid release handle Ⓑ from the control unit and disconnect the CPR tag Ⓒ.
3. Place control unit and power cord on top of the mattress and detach mattress from the bed frame.
4. Once air has been released from all cells, roll up the mattress and return all items to the carry bag for safe keeping.

IMPORTANT!
– Prior to restarting the system, ensure the CPR tag is replaced and all four sealing connectors are firmly attached; and that the rapid release handle is replaced and firmly connected to the control unit.
– Use target design to line up each plug with its corresponding socket.



5 Usage

5.1 Safety information

Operating conditions, see 10.1 General Data, page 26.

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 healthcare professional. This relieves pressure which helps prevent both tissue compression and potential ulcer formation.
– Always consult a qualified healthcare professional before using the SoftAIR® mattress.
– 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.

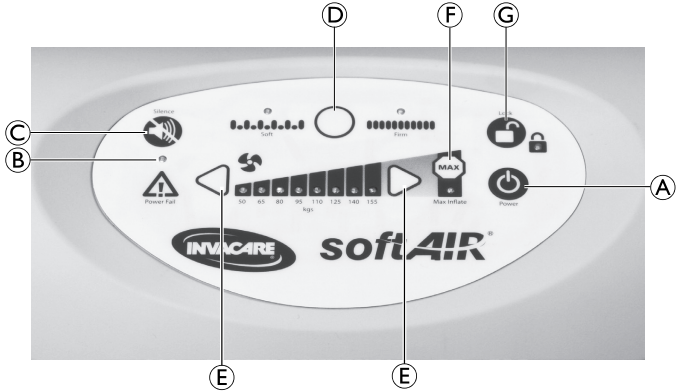
IMPORTANT!
Strikethrough can occur in mattress covers.
– Medical equipment including infusion pumps and monitors should be attached to appropriate bed accessories.
– For home use common causes of damage include cigarette burns and the claws of pets that puncture covers, allowing fluid ingress and staining.

IMPORTANT!
Risk of damage to the mattress cover
– To prevent accidental cover 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 bridging boards or other patient transfer aids, care should be taken not to damage the mattress cover. All transfer aids should be checked for any sharp edges or burrs before use as these can damage the mattress cover.
– Make sure that the mattresses are not jammed or damaged by sharp edges when used on beds with an adjustable frame.
– When using the SoftAIR® mattress on a profiling bed ensure that the knee break is used before the backrest.

5.2 Using the control unit panel

WARNING!
– Ensure this manual is read and understood fully before operating the control unit panel.

WARNING!
This equipment is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.



Ⓐ	**Power Button** Turns system power on and off. Press for two (2) seconds
Ⓑ	**Alarm LED** This red light flashes, and an audible alarm sounds, to alert when control unit or Mattress pressure fails. The alarm has five different signals to indicate the cause of the failure. The audible alarm also sounds when power is switched off – press Alarm Mute to silence. Refer to 9.1 Identifying and repairing faults, page 24.
Ⓒ	**Alarm Mute Button** Silences the audible alarm (on / off). Audible alarm will resume after 20 minutes if cause of failure is not resolved.
Ⓓ	**Mode Button** Press to select either Alternation Mode (alternative cells cyclically inflating and deflating) or Static Mode (all cells fully inflated with no dynamic alternation). Static Mode will automatically revert back to Alternation Mode after up to 20 minutes.
Ⓔ	**Pressure Arrow Buttons** Press arrows to increase or decrease pressure setting. Eight available pressure settings from soft to hard (18 mmHg to 60 mmHg; 6 mmHg per step). The green LEDs illuminate to indicate which of the eight settings is operational.
Ⓕ	**Max Firm Button** Press to facilitate rapid inflation to maximum pressure setting (60 mmHg). After £ 30 minutes, the system automatically reverts back to the previous pressure setting for patient safety.
Ⓖ	**Control unit Lock / Unlock Button** Press for at least five (5) seconds to lock the control unit settings – a beep sounds and the amber LED illuminates to indicate system is locked. When locked, only the Alarm Mute and Lock / Unlock buttons remain operational. Press again for at least two (2) seconds to unlock (beep sounds and amber LED turns off).

The control unit will automatically unlock in the event of a power failure.

5.3 Using the mattress system

Establishing Pressure (supine / face up position)

1. When mattress is fully inflated place the user onto the mattress.
2. Press Pressure button to select the best setting for effective pressure relief and support, based on patient weight and comfort requirements.
3. Assess whether the patient is comfortable and the system is functioning correctly by performing a 'bottoming out' test.

Bottoming Out Test

When altering the pressure setting, ensure the patient is not 'bottoming out' (insufficiently supported by the air cells and therefore coming in contact with bed base).

1. Ensure system is in alternation mode but is not undergoing an alternation.
2. With the patient lying in a supine position, unzip top cover just past sacral (bottom) region.
3. Slide your hand along a deflated cell under the patients sacral area (bottom). The inner static cell will remain inflated but your hand should slide easily between patient and base.
4. If hand can pass under patient then patient is adequately suspended and pressure can be lowered.
5. Repeat Bottoming Out test after pressure has been lowered.

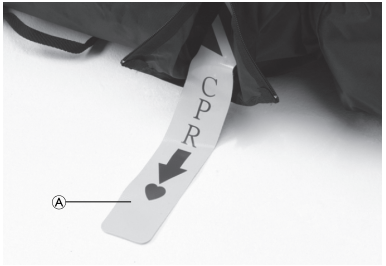
In the event of a system malfunction, the alarm will activate and pressure LEDs will flash.

Establishing Pressure (inclined position)

When moving the patient to a more upright position, pressure may need to be increased (by approximately 20%) to provide added support and to avoid 'bottoming out'.

IMPORTANT!
- Return to the original pressure setting when the patient returns to the supine position, and perform a Bottoming Out test.
- Wait a minimum of 10~12 minutes between pressure adjustment and patient assessment, as it may take a full cycle for the system to adjust to any new setting.

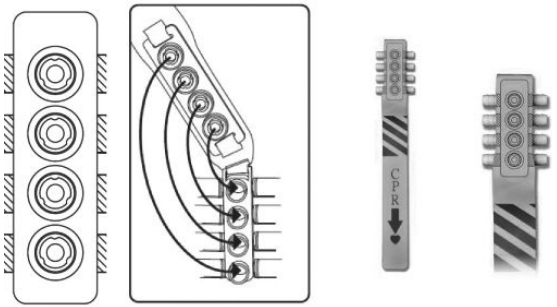
5.4 CPR Procedure



1. Firmly pull the yellow rapid release CPR tag Ⓐ from the side of the mattress to deflate the whole system.
2. Switch off the control unit.

Mattress will start to deflate.

3.



When CPR is complete replace the yellow CPR Tag ensuring the four sealing connectors are firmly attached and restart the control unit following chapter 4.3 Activating the control unit, page 12. Using the target design to line up each plug with it's corresponding socket.

IMPORTANT!
– Wait for the mattress system to gain optimal pressure.
– Perform a Bottoming Out test after inflating the mattress following rapid deflation.

5.5 Alarm Functions

The red Alarm LED flashes, and an audible alert sounds, to indicate the control unit or mattress pressure has failed. The LED will remain illuminated until appropriate pressure is restored. The audible alarm can be silenced by pressing the Alarm Mute button.

The system has five different alarm signals, identified by five different Pressure Setting illumination sequences. The signals and corresponding Pressure Setting LED displays are illustrated below.

Display	Alarm Signal	Description
	Initial Failure	Mattress has failed to reach minimum operational pressure within 50 minutes
	Low Pressure	Pressure has fallen 5mmHg or more below the setting minimum
	High Pressure	Pressure has exceeded the setting maximum by 10mmHg or more
	Alternat-ing Mode failure	Mattress has failed to commence alternation
	AC power failure	No pressure output due to mains power failure

If alarm activates and the system fails to inflate or loses pressure, refer to 9.1 Identifying and repairing faults, page 24.

5.6 Transporting a patient on the mattress

1. Switch modes from alternating to static and wait up to 10–15 minutes for cells to inflate to maximum pressure (Button Ⓓ on control unit).

   If a quicker response is required (up to 5-10 minutes) then the Max inflate button can be used.

2. Turn off control unit and then remove the rapid release handle from the control unit.
3. Allow air to escape for a couple of seconds before sealing with the attached transport cap. This will soften the Mattress surface for pressure relief and comfort. If patient is responsive, question their comfort level based on current pressure and adjust accordingly.

When in transportation mode (e.g. sealed with the transportation cap) the mattress will stay inflated for a minimum of 72 hours.

CAUTION!
Air pressure is released from all internal static cells as well as alternating sections.
– Regularly perform a 'Bottoming Out' test to ensure the patient is appropriately supported.

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.

7 Maintenance

7.1 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.

7.2 Cleaning and Care

Infection Control and routine cleaning must be carried out in accordance with your local Infection Control Policy. It is suggested that all disinfection be done with a commonly high grade disinfectant or a solution of Sodium Hypochlorite or similar (up to 10,000 ppm available chlorine).

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 Healthcare Environments, contact you hygiene specialist or local infection control policy.

The top cover seams are sealed to prevent moisture ingress and bacterial growth in the seam stitching.

IMPORTANT!
– Do not use high temperature autoclave for cleaning.

IMPORTANT!
It is recommended the system is cleaned between patients and approximately every two weeks if in constant use.

Please contact your hygiene specialist in the event of contamination.

Cleaning mattress top cover

Remove all covers for laundering.

Heavy soilage

IMPORTANT!
– To establish the amount of disinfectant to use, determine the amount of water in the washer and then follow the manufacturers' instructions for dilution.
– Use only approved disinfectants.

1. If present, 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 commonly used disinfectant or 1% Chlorine Solution (10,000 ppm). This is dependent on infection control protocols and local market requirements.

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

2. Launder the covers with a maximum temperature of 95 °C using a diluted detergent solution (Instructions on label).
3. Soak the top cover in the disinfectant during the wash cycle.
4. After laundering rinse the cover well in clean water and dry thoroughly before use.

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!
– May be tumbled dried on a low heat setting, however the cycle should be disrupted to ensure that no water is trapped.

5. Hang mattress covers from a line or bar and drip dry in a clean indoor environment.

IMPORTANT!
1% Chlorine Solution used on a regular basis can diminish the life of the cover if not rinsed and dried properly.

Light soilage

If there are visible signs of body fluids and or substances on the top cover, the top cover should be sanitized.

1. Apply an intermediate level of commonly used disinfectant (or a solution of Sodium Hypochlorite or similar up to 10,000 ppm available chlorine) to the top cover upper surface either by spraying or by hand application. This is dependent on infection control protocols and local market requirements.

IMPORTANT!
– Ensure the surface is completely covered with the disinfectant and remains in contact with the surface according to manufacturer's instructions.

2. Remove disinfectant and rinse thoroughly.
3. Allow to air dry before use.

Cleaning mattress base

IMPORTANT!
– Do not machine wash or dry the Mattress base.

1. Wipe down the outside shell with a commonly used disinfectant solution (or a solution of Sodium Hypochlorite or similar up to 10,000 ppm available chlorine). This is dependent on infection control protocols and local market requirements.

IMPORTANT!
– Ensure that all surfaces come in contact with the disinfectant.

2. Rinse off well with a clean damp cloth and air dry.

Disinfecting the air cells

IMPORTANT!
– Do not disassemble the Mattress unless cleaning is required.
– Do not disconnect the pipes from individual air cells.
– Do not machine wash or dry the air cells.

1. Disconnect air cells from the base by unfastening the press studs at each end.
2. Disconnect air pipes from main air hoses.
3. Slide each cell out from the cell straps.

4. Swab with a cloth damped with warm water containing detergent or a solution of Sodium Hypochlorite or similar (up to 10,000 ppm available chlorine). This is dependent on infection control protocols and local market requirements.
5. Dry thoroughly with a soft cloth before refastening.

Cleaning the handle

1. The exterior handle can be periodically wiped using a cloth dampened with disinfectant.

Cleaning the control unit

WARNING!
Electrical shock hazard!
The control unit has no protection against ingress of water.
– 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.

1. Wipe down control unit and hose fittings using a cloth dampened with warm water containing detergent (or with a solution of Sodium Hypochlorite or similar). This is dependent on infection control protocols and local market requirements.
2. Dry thoroughly before use.

Preventive inspections and calibration of the control unit are not required.

The manufacturer will provide circuit diagrams, component part lists, and descriptions to assist service personnel in repairing the equipment.

7.3 Replacing the air filter

IMPORTANT!
Good filter maintenance is critical to maintain your SoftAIR system in optimal operating condition. Failure to keep the filters clean will result in system downtime and increase repair costs. It is recommended that the air filter be replaced annually. Replacement air filters are available from an Invacare Service Centre.

1. Switch off the power supply to the control unit.
2. Disconnect the power cord and air hoses.
3. Place the control unit on a flat surface with its back panel uppermost (place soft cloth under unit to prevent scratches).
4. Carefully remove the air filter cover. Remove and discard the filter and fit with new filter.
5. Refit the air filter cover to the control unit.

The control unit is now ready for re-connection.

7.4 Replacing fuse (1 amp slow blow fuse)

CAUTION!
– Ensure the replacement of fuses is carried out in accordance with local legislation.

1. Switch off the power supply to the control unit.
2. Remove the power cord from the electrical socket on the side of the control unit.
3. Insert a small Flat Head screwdriver into the groove and turn anti-clockwise (1/4 turn).
4. Remove the “blown” fuse from the fuse holder clip and discard.
5. Insert a new fuse into the plug. Push against the force of the spring and turn clockwise with the screwdriver (1/4 turn).

8 After Use

8.1 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.

Environmental conditions for storage, see 10.1 General Data, page 26.

8.2 Re-use

A cleaning record should 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, see chapter 7.2 Cleaning and Care, page 20.

8.3 Disposal

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

9 Troubleshooting

9.1 Identifying and repairing faults

This section provides basic troubleshooting support for the SoftAIR® Mattress Systems.

WARNING!
Electric shock hazard!
Opening the control unit could cause personal injury or equipment damage.
– Do not try to open the control unit. Ensure the replacement of fuses is carried out in accordance with local legislation.

Alarm/Fault	Cause	Solution
Control unit does not operate; no display lights illuminate	The Control Unit may not be attached to a power source A fuse may need replacing in the control unit	1. Check the Control Unit is connected to mains power outlet with the correct voltage. 2. Check the Control Unit is switched on. 3. Check the mains plug fuse (3 AMP) then check both control unit fuses (1 amp slow blow fuse) – fuses can be released using a screwdriver to push and turn.
Alarm LED  + audible alarm	Initial failure	1. Reset the alarm – turn off Power and press the Alarm Mute button. 2. Check the Handle is intact, ensuring all four sealing connectors are firmly fitted to Control Unit and the air hoses. Check the CPR Tag is attached and all four sealing connectors are firmly secure. 3. Check all air hoses along the inside of the mattress – each should be firmly connected. Check each air cell is securely attached to its connecting air pipe. 4. Check all cells, pipes and hoses for any air leakage. 5. Switch on Power.

Alarm/Fault	Cause	Solution
Alarm LED  + audible alarm	Pressure too low	1. Reset the alarm – turn off Power and press the Alarm Mute button. 2. Check the Handle is intact, ensuring all four sealing connectors are firmly fitted to Control Unit and the air hoses. Check the CPR Tag is attached and all four sealing connectors are firmly secure. 3. Check all air hoses along the inside of the mattress – each should be firmly connected. Check each air cell is securely attached to its connecting air pipe. 4. Check all cells, pipes and hoses for any air leakage. 5. Check that the air filter cover is correctly secured and the air filter is clean. 6. Switch on Power.
Alarm LED  + audible alarm	Pressure too high	1. Reset the alarm – turn off Power and press the Alarm Mute button. 2. Disconnect the air hoses to reduce pressure – reconnect when pressure has decreased. 3. Check for twists in the air hoses between Mattress and Control Unit. 4. Switch on Power.
Alarm LED  + audible alarm	Alternating Mode Failure (no alternation)	1. Reset the alarm – turn off Power and press the Alarm Mute button. 2. Disconnect the air hoses to reduce pressure – reconnect when pressure has decreased.
Alarm LED  + audible alarm	AC power failure	1. Press the Alarm Mute button to silence the audible alarm. 2. Check the power cable is firmly plugged into the mains outlet and the Control Unit; and check the mains power is switched on. 3. Check the Control Unit fuse (1 amp slow blow fuse) – fuse can be released using a screwdriver to push and turn.
Patient is sinking or "bottoming out" whilst lying flat on the Mattress	The pressure may be set too low for the patient's weight	1. Increase the pressure setting by pressing up the Pressure arrow. 2. To check effective system performance, conduct a "Bottoming Out" test, ® 5.3 Using the mattress system, page 16.
If the problem is not resolved, please contact an authorised Invacare Ltd Service Centre.		

10 Technical data

10.1 General Data

	SoftAIR® Super	SoftAIR® Excellence
Cycle Control	Purpose designed distributor valve supplying operating air to the inflatable cells	
Cycle Time	10–12 minutes	
Supply Voltage	220 - 240 V, 50/60 Hz, 0.2 A for control unit	
Fuse Rating	1 A (x1) Slow Blow Fuse	
Battery Source	VARTA, V80H, 1.2 V DC, 70 mAh	
Power Rating	12 VA	
Number of Cells	21 (cell in cell) including 3 static head cells	19 (cell in cell) including 3 static head cells and 5 micro cells plus 2 side bolsters
Cell Height	200 mm	230 mm
Minimum/maximum User Weight	£ 30 – 200 kg	
Mattress Dimensions:		
Length	2000 mm	2000 mm
Width	830 mm / 880 mm	830 mm / 880 mm
Height	200 mm	250 mm (including side formers)
Mattress weight	9.2 kg / 10.5 kg	9.5 kg / 10.8 kg
Control Unit Dimensions:		
Length	290 mm	
Width	170 mm	
Height	270 mm	

	SoftAIR® Super	SoftAIR® Excellence
Control unit weight	3.2 kg	
Cell Material	0.15 mm TPU film laminated on 210 denier nylon fabric	
Base Material	Nylon fabric 420 denier with a 0.1 mm TPU coating	
Cover Material	100% Polyurethane surface, 100% Polyester inside	
Hose Connection	Push on connection handle	
Emergency	CPR Tag	
Mode of Operation	Non-continuous	
Operating Environment		
Air humidity	30% to 70%	
Ambient temperature	10 °C to 40 °C	
Altitude	£ 2000m	
Storage/Transportation Environment		
Air humidity	10% to 70%	
Ambient temperature	-10 °C to 60 °C	
Warranty		
Control unit	2 years	
Mattress	2 years	

All product specifications are subject to change without notice.

10.2 Guidance and manufacturer's declaration

The SoftAIR® Super & Excellence are intended for use in the electromagnetic environment specified below. The customer or the user of the SoftAIR® Super or Excellence should ensure that it is used in such an environment.

Electromagnetic emissions

Emission test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The SoftAIR® Super & Excellence use RF energy only for their internal functions. 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 SoftAIR® Super & Excellence are 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	±6 kV contact ±8 kV air	±6 kV contact ±8 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	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.

Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Surge IEC 61000-4-5	± 1 kV line(s) to line(s)	±1 kV differential mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short 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 SoftAIR® Super or Excellence requires continued operation during power mains interruptions, it is recommended that the SoftAIR® Super or Excellence be powered from an uninterruptible power supply or a battery.
Power frequency (50 Hz) magnetic field IEC 61000-4-8	3 A/m	3 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
Conducted RF IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz	3 V_{rms}	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: d = 1.167ÖP d = 1.167ÖP 80 MHz to 800 MHz d = 2.333ÖP 800 MHz to 2.5 GHz 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: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

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 SoftAIR® Super or Excellence is used exceeds the applicable RF compliance level above, the SoftAIR® Super or Excellence should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the SoftAIR® Super or Excellence.

[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 SoftAIR® Super & Excellence Alternating Control Unit

The SoftAIR® Super & Excellence are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the SoftAIR® Super or Excellence can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SoftAIR® Super or Excellence 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 = 1.167ÖP	80 MHz to 800 MHz d = 1.167ÖP	800 MHz to 2.5 GHz d = 2.333ÖP
0.01	0.117	0.117	0.233
0.1	0.369	0.369	0.738
1	1.167	1.167	2.333
10	3.689	3.689	7.379
100	11.667	11.667	23.333

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.