

Flexi Crossover Hybrid Mattress System (SM017P)

INSTRUCTIONS FOR USE

This manual **MUST** be read **BEFORE** using this product



Flexi Crossover Hybrid Mattress System (SM017P)

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1. Introduction

This document outlines important information and instructions for use (IFU) on the safe and effective use of the product. Read all instructions carefully before using the product. Store the IFU in a designated area, where it is always easily accessible. If unsure, consult a medical professional regarding the correct use of the product. For further product-related information, contact Winncare PAC Ltd; see the “Contact Information” section of this document.

2. Symbols










Symbols and advisory notices are used in this document to help safe and optimal operation of the product. See information below for definitions of the symbols.

 WARNING	<p>Warning: Safety warning. Failure to obey and understand could lead to injury to yourself or others, and in some circumstances death.</p>
 CAUTION	<p>Caution to highlight potential hazards that, if not followed, could lead to damage or failure in parts or all of the system and equipment.</p>
<div style="border: 1px solid black; padding: 5px; display: inline-block;"> NOTE </div>	<p>Note: Important information users should be aware of for the correct use of the equipment.</p>




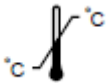









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3. Product Labelling




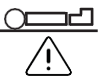




The labels shown are for illustrative purposes only – some symbols on your product may differ from the examples shown.

	<p>Instructions for Use Read the Instructions for use before use</p>
	<p>Type BF Applied Part Applied Part: The parts of the device that come into physical contact with the user/occupant for it to carry out its intended function. Type BF: Applied parts which are electrically isolated from earth and other parts of the medical equipment - Complying with specific requirements for protection against electric shock to IEC 60601-1.</p>
	<p>W.E.E.E Label Waste Electrical and Electronic Equipment.</p>
	<p>Class II electrical device The user/occupant is protected by at least two layers of insulation between the current carrying parts (e.g. mains cable). If damage is noticed to the control unit or mains cable assembly, turn off at the mains supply and contact your provider or Winnicare UK Ltd. immediately.</p>
<p>IP21</p>	<p>Protected from touch by fingers and objects greater than 12mm. Protected from condensation.</p>
	<p>CE marking indicates conformity with European Community harmonized legislation. Figures indicate Notified Body supervision.</p>
	<p>UK marking indicating conformity with UK Medical Device Regulations 2002 (SI 2002 No 8, as amended).</p>
	<p>Indicates the product is a Medical Device according to EU Medical Device Regulation 2017/745.</p>
	<p>Serial number</p>
	<p>Reference number</p>

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	Batch code
	Name and address of the manufacturer
	Date of manufacture
	Temperature limitation indicates the temperature limitation for the product during usage
	Unique device identifier
	Authorized Representative in the European Community
	Disinfect by wiping the surface using a hypochlorite solution diluted 1000 ppm.
	Machine wash up to 95°C.
	Tumble dry on a low setting
	Do not use harsh abrasives or Phenol cleaners
	Do not iron
	Ensure the system is dry before storing, use and reuse.
	Do not place heavy objects on the surface of the cover other than the patient

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	<p>Do not use when damp, ensure surface is dry before use</p>
	<p>Do not fold. Roll pack the system</p>
	<p>Do not use sharp objects</p>
	<p>Max Patient weight defines the maximum total load of the patient in kg (lb)</p>
	<p>Safe Working Load (SWL) is the maximum combined weight of the patient and any equipment that the mattress can safely support.</p>
	<p>Foot end</p>
	<p>Resistant to ignition</p>
	<p>Recycling</p>

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4. Warnings and Precautions for Use


WARNING


Do not use device control unit in oxygen rich environment or near flammable gases. **RISK OF FIRE AND BURN INJURY.**


WARNING


CPR connector must be accessible at all times. **RISK OF SERIOUS INJURY.**


WARNING


Do not use device with a damaged power cable. **RISK OF ELECTROCUTION AND FIRE.**


WARNING


Ensure the device is assembled and operated as intended. **RISK OF PRESSURE INJURY.**


WARNING


Ensure appropriate cable management. Avoid operating the device with loose or severely taught cables. **RISK OF TRIP AND FALL INJURY.**


WARNING


Do not cover the control unit with blankets and other items. **RISK OF FIRE.**


WARNING

Do not spray liquid on the control unit whilst it is connected to mains power. **RISK OF ELECTRICAL BURNS.**


WARNING


Do not open or repair the control unit whilst it is in use or connected to mains power supply. **RISK OF ELECTRIC SHOCK.**


WARNING

Do not expose any parts of the device to a naked flame. Do not smoke. **RISK OF FIRE AND PROPERTY DAMAGE.**


WARNING

Do not use the device as a repositioning tool. **RISK OF PRESSURE INJURY.**


WARNING

Ensure the patient is manually repositioned at frequent intervals. **RISK OF PRESSURE INJURY.**

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CAUTION

Complete a risk assessment if any accessory is used with the device.



CAUTION

Ensure there are no additional layers between the surface of the mattress and the patient. Device performance may be affected. Complete a risk assessment if in doubt.



CAUTION

Ensure the device is suitable for the patient. Complete a risk assessment if in doubt. Consult a medical professional if in doubt.



CAUTION

To ensure optimal function of the device, use suitably trained personnel for servicing and repair. Use original parts only.



CAUTION

Ensure the mains cable does not become compressed, trapped or damaged by the bed frame or other equipment.



CAUTION

Ensure the device is plugged into mains power supply for optimal function.



CAUTION

Ensure the mains cable does not become compressed, trapped or damaged by the bed frame or other equipment.



CAUTION

Do not use device alongside hot water bottles or electric blankets. Device performance may be affected.



CAUTION

Complete a risk assessment when using device with incontinence products.

NOTE

Use a CE marked extension cable if device power cable cannot reach wall socket. If in use, do not overload.

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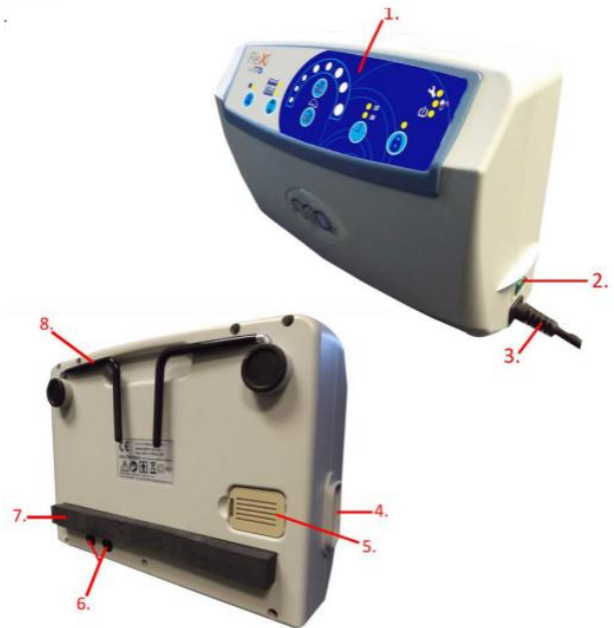
5. Product Overview

This product is made of the following components:

SM017P: Flexi Crossover Hybrid Mattress System	
Control Unit	SM017Q20
Mattress Unit Only	SM017M
Top Cover	SM017TC

Control Unit

1. Control Panel
2. On/Off switch
3. Mains Power Cable
4. Female Air Connector Port
5. Air Filter
6. Fuse Holders
7. Anti vibration cushion bar
8. Hooks



Mattress

1. Removable top cover
2. Air cells incorporating visco elastic & combustion modified ether foam
3. Base foam incorporating firm wall edges
4. Cable management tabs
5. Removable base cover
6. Male air connector & CPR



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6. Product Features

SM017P: Flexi Crossover Hybrid Mattress System	
Size (mm) L/W/H	1950 x 860 x 150
Maximum Patient Weight	< 222 kg (35 stone)
Safe working load	222 kg (35 stone)
Other Features	<ul style="list-style-type: none"> • One in two cell-cycle design providing optimum therapy • 13 fully alternating air cells • Durable PU air cell construction • Visco elastic & combustion modified ether foams • Welded, multi-stretch waterproof and vapour permeable cover • Machine washable cover up to 95°C (15 mins) • CPR connector for rapid deflation • Comfort adjustment for optimal support • External easy replacement pump filters • Visual low pressure alert • Audible low pressure alert • Semi-auto pressure adjustment • Constant low pressure (CLP) • Cycle fault audible alert • Alert mute • Control panel lock

7. Product Description

Intended Use	To provide pressure relief and aid in the prevention and management of pressure related injuries as part of a standard package of care.
Target Population	Typical adults with limited mobility, undergoing some medical supervision and monitoring. Individuals assessed as “at risk” and up to “very high risk” of pressure damage and/or with existing tissue damage as determined by a combination of clinical judgment and validated assessment tools.
Contraindications	Patients below the minimum or maximum user weight listed for the associated device. Cervical or skeletal traction. Unstable skeletal fractures. Unstable spinal injury.
Users	Caregivers, laypersons and/or medical professionals.
Warranty	3 years subject to regular maintenance and servicing.
Reusable	Devices are re-usable but must be cleaned in between each patient use.
Maintenance or calibration	Perform regular mattress audits to check for fluid ingress and strike-through on mattress top cover. The system should be serviced once a year, as a minimum.
Accessories	Devices are not sold with accessories.

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Risk Assessment	<p>It is the responsibility of the end user/care provider to carry out the necessary risk assessment to ensure the patient’s safety. This should be carried out before using the mattress system. A risk assessment should include, but is not limited to:</p> <ul style="list-style-type: none"> • Product combinations (bed frame, mattress, side rails etc.) • Extent of tissue damage (if any) • Entrapment • Patient falls • Small adults (and children) • Patients with learning difficulties • Patients with atypical anatomy • Unauthorized people with access to the controls • Use with other medical accessories e.g. incontinence products
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8. Installation

1. Carefully open the packaging.
2. Check the device for any signs of damage. Do not use if damaged and contact your provider or Winnicare PAC Ltd.
3. Place the mattress on top of the bed frame with the top cover facing upwards and the feet print at the foot end of the bed.
4. If the mattress is to be used in alternating mode then continue following the instructions.
5. Using the hooks on the back of the control unit, hang the unit over the frame/board at the foot end of the bed. If there is no foot frame/board lay the unit on the floor, under the bed with the front control panel facing upwards.

NOTE

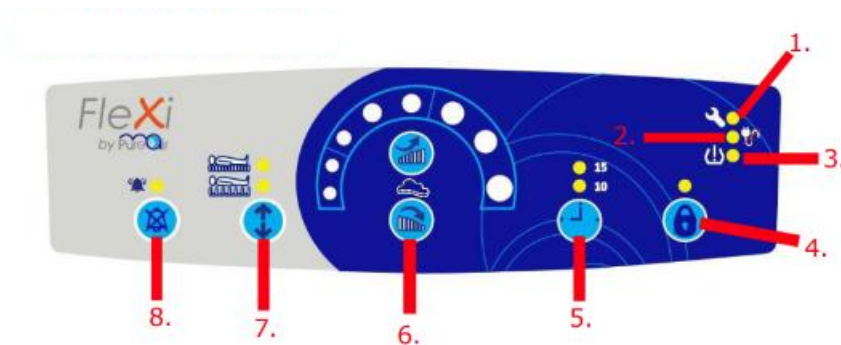
If you are placing the control unit on the floor it is advisable to place the unit on a firm surface.

6. Attach the air tube set using the male air connector on the mattress to the female air connector port on the control unit/pump, ensuring the air hose is not kinked or trapped between parts of the bed frame/other equipment.
7. Plug the mains cable into a suitable mains supply and switch on the control unit.
8. The mattress will start to inflate and will be completely inflated within 20 minutes.
9. Cover the mattress loosely with a sheet, ensuring it does not interfere with cell alternation.

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9. Product Operation

9.1 Control Panel







9.2 Control Unit Operation




	<p>1. Cycle Fault An amber indicator flashes and an audible signal sounds if alternation failure occurs.</p>
	<p>2. Power Failure An amber indicator flashes and an audible alert will sound if a power failure occurs.</p>
	<p>3. Low Pressure An amber indicator illuminates when setting the pressure initially. An amber indicator flashes and an audible signal sounds if the pressure becomes unacceptably low during operation.</p>
	<p>4. Function Lock The control unit will automatically lock out all functionality 2 minutes after a function change. To unlock the control unit press the 'lock' button for 2 seconds. To re-engage the lock, the button can either be pressed again for 2 seconds or the user can wait for the automatic lock to re-engage. When the system is locked an amber indicator will illuminate.</p>

CAUTION


Ensure there is no accidental deactivation of the system. Function lock does not lock the on/off switch.

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	<p>5. Cycle Time Press the button to change between cycle times. The green indicator next to the '10' or '15' will be illuminated to show which one is selected.</p>
	<p>6. Comfort Adjustment Press  to increase the pressure.</p> <p>Press  to decrease the pressure.</p> <p>For ALP there are 3 available pressure settings. The green lights illuminate to indicate which of the 3 settings is operational; 2 lights = 11mmHg, 5 lights = 14mmHg, 8 lights = 17mmHg.</p> <p>For CLP there is just 1 pressure setting. 1 green light illuminated indicates CLP operational at 12mmHg.</p>

	<p>7. CLP/ALP</p> <p>Use the 'Up & Down' arrow to select  alternating low pressure (ALP) mode which inflates and deflates the cells in sequence over the cycle time selected – green light illuminated.</p> <p>Use the 'Up & Down' arrow to select  constant low pressure (CLP) mode which fully inflates all cells and provides a reactive surface – amber light illuminated.</p>
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NOTE	In CLP mode pressure remains at a constant 12mmHg
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	<p>8. Alert Mute To mute an audible alert press the button. The amber indicator will illuminate. Press the button again to reset the alert.</p>
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NOTE	If the 'power failure' indicator activates the mute button will not silence the audible signal. To silence, the system must be turned off by pressing the power button.
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NOTE	The mute setting will automatically cancel after 15 minutes. The audible signal will re-sound.
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9.3 Mattress operation

1. Turn on the power on the control unit. The control unit starts to inflate the whole mattress with the CLP LED illuminated (the control unit inflates at 14mmHg).
2. The amber low pressure indicator will illuminate as inflation commences.
3. Green indicators will illuminate to show which cycle time, pressure range and mode are selected. Once initial inflation process has completed, default settings are ALP, 10 minute cycle time and a 14mmHG (5 green lights) pressure setting.

Default mode:	
Operation Mode:	Alternating
Alternating Cycle Time:	10 minutes
Pressure Setting:	14mmHg
Complete settings:	
Operation Mode	Alternating or CLP
Alternating Cycle Time:	10 or 15 minutes
Pressure Setting:	11 / 14 / 17mmHg (Alternating) 12mmHg (CLP)

4. Within 2 minutes the amber function lock indicator will be illuminated.
5. Once optimum pressure is reached (within 20 minutes) the red low pressure indicator will switch off. The system will produce an audible alert to indicate the system is now ready for use. The control unit will revert automatically to ALP.
6. For the first 72 hours monitor your patient to ensure the system is suited to their needs. If possible, have regular dialogue with the patient. Always use clinical judgement.

NOTE

The mattress can be used with backrest in an upright position, however the comfort setting may need to be increased. Use clinical judgement to ensure patient comfort and effective support is maintained.

Semi-Automatic Pressure Adjustment

The control unit monitors the mattress pressure and maintains it at the set level. If the pressure falls below this level the control unit will automatically speed up the inflation of the mattress until the correct pressure is achieved. If the control unit is unable to maintain the set pressure an audible signal will sound and the low pressure indicator light will flash. If this occurs refer to the section on 'Troubleshooting'.

CPR Function

In an emergency rapid deflation of the mattress may be required. Disconnect the male connector from the control unit. To re-inflate reconnect the male connector to the control unit.

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NOTE	Carers/care providers should always familiarise themselves with the position of the CPR.
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CLP (Continuous Low Pressure) Mode

When CLP mode is selected, all air cells inflate to deliver continuous low pressure increasing the area of support, with the aim of reducing peak pressure at the interface via immersion and envelopment.

NOTE	For optimum performance in CLP mode, it is recommended that the surface be utilised in a recumbent position.
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Static Mode

Flexi Crossover can be used without the control unit, creating a reactive surface meeting the step-up, step-down need of the patient.

Transporting the Mattress

If the mattress is disconnected from the power supply so it can be moved, or in the event of a mains power failure, carry out the following procedure to maintain mattress inflation:

1. Disconnect the air tube set with male connector from the control unit by squeezing the two tabs (A) and pulling away from the control unit (B).



2. Seal using the cap marked "Transport" which is attached to the male connector.
3. Switch off the control unit.
4. Disconnect from the power supply.
5. The mattress can now be moved.

NOTE	In the event of a power fail, the mattress will remain inflated for up to 24 hours. The mattress should be returned to the mains supply as soon as possible. If not plugged into the mains device performance will be affected.
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NOTE	Do not drag the mattress, always carry it.
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NOTE	Complete instructions above quickly to minimize air loss
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WARNING

Do not remove the mattress from the bed frame if the occupant is still on the mattress. RISK OF FALL.



WARNING

When not connected to mains power supply, alternating mode will not be available. RISK OF LIMITED PRESSURE RELIEF.

9. Cleaning and Disinfection

Cleaning and disinfection of the device is mandatory. As a minimum, cleaning and disinfection should be performed as soon as the device is taken out of storage, between each patient, at regular intervals whilst in use and before being returned to storage. Consult local practice guidelines for more details on cleaning and disinfection of reusable medical devices. Follow the instructions below to achieve a minimum level of cleaning and disinfection for safe use of the device.



WARNING

Wear appropriate personal protective equipment (PPE) when cleaning the mattress or control unit. RISK OF SKIN IRRITATION



CAUTION

Do not immerse or soak the control unit. Do not spray any cleaning solution onto the control unit.



CAUTION

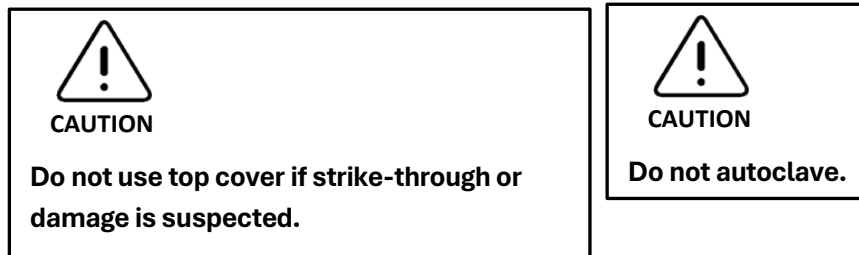
Do not attempt to clean the device whilst its connected to mains power.



CAUTION

Do not use phenol-based cleaning solutions, solvents, neat bleach or abrasive products to clean the casing as this may cause damage.

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10.1 Cleaning and Disinfection Protocol: Control Unit

1. Visually check the control unit for external damage – do not use if damage is found.
2. Place the control unit on a work surface and using a soft, clean, non-abrasive cloth, wipe the outside of the case with a prepared sodium hypochlorite solution (recommended 1,000 ppm).
3. The control unit should be cleaned by starting with the cleanest areas and systematically moving to the dirtiest areas. Extra care should be taken in areas where excess dirt or dust may gather.
4. Change the cloth if it becomes dirty.
5. Once clean, wipe down with a fresh, clean, soft, non-abrasive cloth moistened with clean water to remove detergent residue.
6. Dry off with a paper towel. Always allow the surfaces to dry thoroughly before reuse.

10.2 Cleaning and Disinfection Protocol: Mattress

NOTE

Before attempting to clean the mattress, the top cover should be checked for physical signs of damage that may lead to strike-through (ingress of fluid through cover). Staining to the underside of the top cover is a sign of strike-through.

1. The mattress should be regularly checked for damage or tears. Replace if damaged.
2. Wipe down with a soft, clean, non-abrasive cloth moistened with a mild detergent and diluted in warm water (40°C).
3. Rinse with cold, clean water and a clean, soft, non-abrasive cloth and allow to fully dry before use.

Disinfection

1. Unzip the top cover from the mattress.
2. The top cover can be machine washed up to 95°C and tumble dried on a cool setting.
3. Unsnap the air cells from the mattress base on both sides.
4. Carefully clean with (1,000 ppm) prepared solution of sodium hypochlorite and allow to dry completely. In extreme circumstances 10,000 ppm can be used, wipe with cold water to finish (Frequent cleaning with a high concentration disinfectant solution (i.e. 10,000 ppm available chlorine) may reduce the life span of the system).

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5. Make sure to disconnect all the air cells and spray the cleaning solution on all sides, including the connecting tubes and hoses.
6. Re-assemble the mattress.
7. Ensure the mattress is completely dry before either storing or reuse.

NOTE

Frequent or prolonged exposure to higher concentration disinfectant solutions may prematurely age the fabric cover of the mattress.

10. Storage

Follow the instructions below to prepare the product for storage.


 CAUTION Ensure device is cleaned and disinfected prior to storage.	 CAUTION Do not fold, crease or stack mattress.
 CAUTION Do not stack the control units when in storage.	 CAUTION Do not store whilst inflated.
 CAUTION Do not stack control units with other medical equipment.	

1. Detach the control unit from the mattress.
2. Lay the mattress out flat.
3. Store in a sealed polythene bag to protect from dirt, debris, fluids etc. with a suitable identification tag.
4. Store the control unit in a sealed polythene bag to protect from dirt, debris, fluids etc. with a suitable identification tag.
5. If taking a device out of storage, allow product to acclimatise to the operating conditions.

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11. Troubleshooting

Table below provides a guide to the product’s alarms.



WARNING

Do not open or repair the control unit whilst it is in use or connected to mains power supply. RISK OF ELECTRIC SHOCK.

NOTE	If mains cable or plug is visibly damaged turn off power supply at the mains and contact your approved services engineer.
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Problem	Actions		
Power Failure	<ol style="list-style-type: none"> 1. Turn off the control unit to silence the alarm and unplug from the mains supply <div style="border: 1px solid black; padding: 5px; margin: 10px 0;"> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 15%; border: 1px solid black; text-align: center; vertical-align: middle;">NOTE</td> <td style="padding-left: 10px;">If the ‘power failure’ indicator activates the mute button will not silence the audible signal. To silence, the system must be turned off by pressing the power button.</td> </tr> </table> </div> <ol style="list-style-type: none"> 2. Check the mains socket is working - plug in a device that is known to work. 3. Plug the control unit back into the wall socket. 4. Turn on the control unit. If the control unit still fails to operate: 5. Turn off the control unit at the wall & replace plug fuse. 6. Turn on the control unit. If the control unit still fails to operate: 7. Replace control unit fuses. For fuse types see ‘Technical Specifications’ section. 8. Turn on the control unit. If control unit still fails to operate, turn off at the mains and contact your approved service provider. 	NOTE	If the ‘power failure’ indicator activates the mute button will not silence the audible signal. To silence, the system must be turned off by pressing the power button.
NOTE	If the ‘power failure’ indicator activates the mute button will not silence the audible signal. To silence, the system must be turned off by pressing the power button.		
Incomplete inflation/low pressure	<ol style="list-style-type: none"> 1. Ensure the mattress air connector is properly connected to the control unit, is not constricted in any way and has no kinks. 2. Turn the unit off and then on again to clear the indicator. If the ‘low pressure’ indicator continues to illuminate: 3. Remove the top cover and ensure there is no air leakage within the mattress – cells, tubing and connectors. 		

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	<p>4. Turn the unit off and then on again to clear the indicator. If a low-pressure indicator is still evident turn off at the mains and contact your approved service provider</p>
Alternating mode failure	<p>1. Turn off the control unit. 2. Disconnect the male air connector to reduce cell pressure. 3. Reconnect air connector. 4. Turn on the control unit. 5. If alternating mode is still inoperable, turn off at the mains and contact your approved service provider</p>
Patient is bottoming out	<p>1. Ensure the patient is suited to the rating of the mattress. 2. Ensure the patient is centrally positioned on the mattress. 3. Increase the pressure setting – refer to ‘Mattress Operation’ section. 4. If the patient is still bottoming out refer to ‘incomplete inflation’ above</p>

12. Care and Preventative Maintenance

The expected service life of this device is 6 years, subject to appropriate servicing and use in accordance with these instructions. Winnicare PAC Ltd. recommends annual servicing of this product as a minimum. For optimal performance of the device, more frequent visual and operational inspections are encouraged wherever possible. Contact Winnicare PAC Ltd to arrange your annual service. Failure to do so may invalidate product warranty.

NOTE	Always disconnect the control unit from the mains power supply prior to performing any maintenance procedures (when viable).
NOTE	No modification of this equipment is allowed. Use original parts only.
NOTE	The mattress system should be vacated by the patient before any maintenance or inspection takes place. If this is not possible due to the patient’s mobility, care should be taken for the service engineer not to make contact with the patient when working on electrical items.

13. Warranty

This device is covered by a manufacturer’s warranty as part of the General Terms and Conditions of Business. Some warranty periods may differ – refer to the product features section of this document for the exact warranty period pertaining to your product.

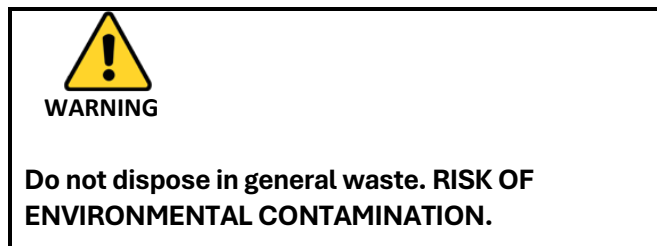
Any warranty claims during the warranty period must be investigated by Winnicare PAC Ltd, where return of the original product may be required. A warranty claim is successful if the product is faulty

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due to a manufacturing defect. This warranty does not cover any other damage including but not limited to: misuse, natural wear and tear, lack of maintenance, accidental damage and unauthorised modifications.

14. Disposal

Should the device reach the end of its use and may no longer be repaired, ensure that it is disposed of following local W.E.E.E. (Waste Electrical and Electronic Equipment) policies. Alternatively, contact WinnCare PAC Ltd to arrange for collection. The metal and plastic components used in both the mattress and control unit should be separated, and recycled – consult local recycling practices for further information.



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15. Technical Specifications

16.1 Control Unit

Control Unit: SM017Q20	
Dimensions (mm) H x W x D	206 x 280 x 104
Weight (kg)	2.6
Cycle time (min)	10 & 15 (AB)
Air Output (L/min)	6.5
Power cord length (m)	4.5
Noise Level	<40dB(A)
Supply Rating	230V, 50Hz, 12W
Fuse Rating	Mains Plug – 5A Control Unit - T1A, 250VAC
Mains Plug	Type G/BS1363/A
Electrical classification	Electrical shock protection: Class II, Type BF Applied Part: Mattress Liquid ingress protection: IP21 Not AP or APG equipment*
<i>*Not suitable for use in the presence of flammable aesthetic mixtures with air, oxygen or nitrous oxide.</i>	

16.2 Mattress and Top Cover

Mattress Unit Only: SM017M and Top Cover: SM017TC	
Number of cells	13 Cells (8 Torso cells, 5 Heel cells)
Cell Material	TPU
Cell depth (inches)	4" (Inflated)
Base Material	Polyurethane & Polyester Mix
Weight (kg)	15
Emergency	CPR Connector
Top Cover Material	Polyurethane & Polyester Mix

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16.3 Transport and Operating Conditions

Transport and storage conditions	Temperature: -25°C to +70°C Humidity: < 93% max, non-condensing
Operational conditions	Temperature: +5°C to +40°C Humidity: 15% - 93%, non-condensing Atmospheric Pressure: 700hPa to 1060hPa Operating Altitude: ≤ 2000m Pollution: Degree 2 UV: Intended for indoor use only

16.4 Safety Standards

BS EN 60601-1:2006+A13:2024
IEC 60601-1-11
IEC 60601-1-2
BS EN 61000
IEC 61000-3-3
IEC 61000-3-2
IEC 61000-4-2
IEC 61000-4-4
IEC 61000-4-5
IEC 61000-4-11
IEC 61000-4-8
IEC 61000-4-6
IEC 61000-4-3

16.5 Electromagnetic Compatibility

The control unit has been designed to meet the EMC requirements of BS EN 61000. This standard defines the levels of immunity to electromagnetic interference as well as maximum levels of electromagnetic emissions for medical devices. They are in place to provide reasonable protection against dangerous interference in a medical or residential environment.

Immunity to electromagnetic interference - this refers to the levels of electromagnetic interference that the control unit can withstand from nearby sources radiating radio frequency (RF) energy (e.g. from mobile phones, network devices etc).

Electromagnetic emissions - this refers to the levels of RF energy the control unit emits.

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The immunity levels are set out in the following manufacturer’s guidance. If these levels are exceeded, then the system may not operate correctly or stop operating. It is important, therefore, to try to ascertain the source of the interference by turning nearby equipment off. There are simple measures that can be taken to correct the problem:

- Remove or relocate the interfering equipment,
- Increase the separation distance between the control unit and the interfering equipment.

The RF emissions are set out in the following manufacturer’s guidance. The control unit generates very low RF energy, however, interference to sensitive equipment is still possible. If interference to radio/tv reception and/or other equipment is suspected, turning the control unit off and on can determine if this is the case. There are simple measures that can be taken to correct the problem:

- Relocate the receiving antenna,
- Increase the separation distance between the control unit and affected equipment.

Due to the increasing number of wireless devices, such as laptops and mobile phones, it is important that the system is installed following the manufacturer’s guidance to ensure continued and reliable operation.

Requirements according to BS EN 61000 and BS EN 60601-1:2006+A13:2024: Guidance and manufacturer’s declaration – electromagnetic emissions		
Emission test	Compliance	Electromagnetic environment – guidance
RF emission CISPR 11	Group 1	The control unit 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 emission CISPR 11	Class B	Hybrid Mattress System 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	

Requirements according to BS EN 61000 and BS EN 60601-1:2006+A13:2024: Guidance and manufacturer’s declaration – 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

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			relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
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% UT† (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60Hz) 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.
<i>†UT is the a.c. mains voltage prior to application of the test level.</i>			
Conducted RF IEC 61000- 4-6 Radiated RF IEC 61000- 4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the control unit, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance. d = 1.2VP

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			<p>$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz</p> <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). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey*, should be less than the compliance level in each frequency range**.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> <div style="text-align: center;">  </div>
<p>* Field strengths from fixed transmitters 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 Hybrid mattress system is used exceeds the applicable RF compliance level above, Hybrid mattress system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the system.</p> <p>** Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

NOTE	<p>At 80 MHz and 800 MHz, the higher frequency range applies. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>
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Hybrid mattress system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer/user can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Hybrid mattress system as recommended below, according to the maximum output power of the communications equipment.

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Recommended separation distances between portable and mobile RF communications equipment and the control unit			
Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m) Electromagnetic environment – guidance		
	150 KHZ TO 80 MHZ D = 1.2VP	80 MHZ TO 800 MHZ D = 1.2VP	800 MHZ TO 2.5 GHZ D = 2.3VP
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

At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. 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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16. Contact Information



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NOTE

Inform the competent authority if you believe or have reason to believe that the device presents a serious risk or that it has been tampered with.
All serious incidents which are related to the device must be notified to the manufacturer and the competent authority of the member state in which the user and/or patient resides.