harvesthealthcare®

General User/ Safety Guide

SUPREME 2 OVERLAY SYSTEM

ACTIVE MATTRESSES

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CONTENTS

WARNINGS & CAUTIONS

READ THIS INSTRUCTION MANUAL AND OBSERVE SAFETY INSTRUCTIONS.

WARNING

- This system must be properly installed and operated as directed by this user manual.
- The system should be checked regularly to ensure correct operation. Loss of function will remove all pressure relieving properties that this system provides.
- This system is intended for use as part of a pressure ulcer prevention program; do not rely solely on this device to achieve the result. The medical professional is responsible for applying best medical judgment when using this system.
- Select the correct setting for the occupant's weight and therapy required (see **pages 20-22**). Care should be taken not to accidently change pressures once set as the effectiveness of the therapy may be reduced.
- In order for alternating air pressure range to be effective, avoid placing objects on the surface that may obstruct the movement of air between the cells. For the same reason, discourage people from sitting on the edge or on the end of the mattress whilst it is in use.
- All hoses must be free of kinks, twists and must be properly connected and positioned so as not to cause any obstruction.
- Do not position the system in a way that prevents access to the disconnection device (mains power plug).
- Ensure the mains lead or pump cannot become trapped or crushed, e.g. by raising or lowering of bed or bed rails or any other moving object.
- Check the mains lead is damage free and positioned so as not to cause an obstruction, or injury, e.g. Strangulation or trip hazard.
- Ensure that the electricity supply is of the type stated on the SMPS and the pump unit.
- Protect your system from open flames. Ensure that the system is not used in the presence of flammable anaesthetics.
- Do not place device on or near a heat source or cover pump with bedding.
- Harvest Healthcare advise against smoking whilst the system is in use, to prevent the accidental ignition of associated items which may be flammable, such as bed linen.

WARNINGS & CAUTIONS

- Do no expose the pump to liquids.
- Do not use with hot water bottles or electric blankets.
- Wireless equipment such as mobile phones should be kept at least 10ft / 3m away from the system.
- Do not allow sharp objects to puncture the mattress material.
- The mattress and pump should be cleaned between patient uses.
- Do not use bleach, chlorine releasing agents in concentrations over 1000 ppm, solvents or alcohol-based cleansers, e.g. Phenicol, Hibiscrub, Clearsol, Stericol, Hycoline as these will destroy the mattress material. Full cleaning instructions can be found on **page 23-24**.
- Suitable for continuous use.
- Do not modify the mattress or pump unit in any way.
- Do not connect to any other medical device or equipment.
- Not for use in an oxygen enriched environment.
- Not for use in an outdoor environment.
- Store the system in a clean and dry environment, out of direct sunlight.

Electrical equipment can be hazardous. Only authorised technical personnel should remove the rear pump case for maintenance. Removal of the case by unqualified personnel will invalidate the warranty.

Before cleaning the unit ensure that the electrical supply to the pump has been disconnected by removing the plug from the power supply.

Do not use this system for lifting the patient. This will damage the system and could put the patient at risk.

This product is fire rated. The mattress cover material on the mattress is tested to BS7175:1989 Crib 5. The internal cells are tested to BS EN 597-1:1995. Use of this product should be subject to a risk assessment in which all hazards are considered.

GENERAL INFORMATION

BEFORE USING THIS SYSTEM FOR THE FIRST TIME:

- **Read through this instruction manual conscientiously from start to finish.**
- **Please note that the various safety instructions must be observed.**

Harvest Healthcare products bear the CE mark and meet all safety and functionality requirements.
These safety requirements can only be met if the user is satisfied with the proper condition of the product (including accessories) before use.

GENERAL INFORMATION

The **Supreme 2 Overlay System** is an alternating pressure relieving mattress system used in the prevention and treatment of pressure ulcers, and is recommended for use by a patient who is at risk from developing pressure sores. The mattress is fitted with a vapour permeable two way stretch cover.

By using the established principles of alternating therapy, the **Supreme 2 Overlay System** offers the patient comfortable and relaxing support that can both prevent tissue breakdown and enhance healing.

The **Supreme 2 Pump** unit is lightweight and compact; its features include an audible and visual low-pressure warning, optional 10 hour battery backup and a manual pressure / comfort control function.

The **Supreme 2 Mattress** is made up of 17 alternating air cells. split into 2 sections - odd cells e.g. 1,3,5 etc and even cells e.g. 2,4,6 etc. These two sections will alternate through a 10 minute cycle in which time both sets of air cells will have inflated and deflated sequentially. All air cells are individually replaceable should any damage occur.
The quick release 3 pipe connector complete with transport cap enables easy patient transport arrangements. For rapid deflation of the system simply twist open the CPR.

1 DEFINITION OF THE GROUPS MENTIONED

OPERATOR

An operator is any natural or legal person who uses the equipment or on whose instruction it is used (e.g. nursing homes, specialised retailers, health insurance companies, medical suppliers).

GENERAL INFORMATION

USER / CARE PERSONNEL

Users are persons who as a result of their vocational training, experience or briefing are authorised to operate the equipment.
Furthermore, the user/ care personnel can recognise and avoid potential dangers and assess the clinical condition of the service user.

PATIENT / OCCUPANT / SERVICE USER

The person in need of care, handicapped or infirm.

QUALIFIED PERSONNEL

Qualified personnel are employees of the operator who as a result of their vocational training or briefing are entitled to deliver, assemble, disassemble and transport the product.

2 NON-COMPLIANT USE

All uses deviating from the intended purpose, which may also be hazardous as a result.
This includes for example:

- Incorrect installation.
- Operation by persons who have not been instructed in its use.
- Using the system with non-approved parts/accessories.
- Using the system if any of the components are damaged or faulty.

3 SAFETY INSTRUCTIONS

3.1 GENERAL SAFETY INSTRUCTIONS

During the briefing, specific attention must be drawn to any potential dangers which can occur despite correct operation. Before putting the product into service for the first time, the Instruction Manual must be read conscientiously and in detail by the user / care personnel.

Programming of the system should be carried out by competent trained personnel.

Use only spares and accessories supplied or approved by Harvest Healthcare.

Only suitably trained personnel are allowed to operate the system.

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The mains cable must be free and not be allowed to be caught up in the bed's moving mechanisms. The mains cable may be torn out of its strain relief and damaged or it may be pulled out of its socket and electric leads exposed as a result.

This system is supplied with 3 adhesive clips. It is suggested that these clips are used to attach the power cable to the bed frame. Full installation instructions can be found on **page 15**

If the mains cable or the mains plug are damaged, the relevant part must be replaced. This work should be carried out by the manufacturer or authorised service agents.

When connecting the mains plug do not use multiple sockets since liquids may penetrate into these (fire hazard and electric shock).

3.2 SAFETY INFORMATION FOR THE OPERATOR

With the help of this Instruction Manual, instruct each user in the safe operation of this system before it is put into service for the first time.

Advise the user of any hazards which may occur if not handled correctly.

Only persons who have been properly instructed may operate this system. This also applies for persons who only operate the system on a temporary basis.

3.3 SAFETY INFORMATION FOR THE USER

Ensure that the operator instructs you in the safe operation of this system.

In addition, pay particular attention to the Warnings and Cautions (**page 4-5**) and the general safety information as described in **3.1**.

If there is a suspected fault or damage, unplug the mains plug from the socket. Clearly mark "Out of Order" and take out of service immediately, and inform the person in charge without delay.

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GENERAL INFORMATION

3.4 SYMBOLS USED

Conformity mark in accordance with the Medical Device Directive (93/42 EEC).

The symbol for Protection Class II device, double insulated.

The symbol for type B device according to EN 60601-1.

Handle with care

This way up

Keep dry

Recycling symbol. Refers to packaging that can be recycled (cardboard)

Fragile, handle with care

This product must be disposed of in a designated refuse bin for waste electronic devices (WEEE) in the European Union. Do not dispose of as normal domestic waste.

Symbol for direct current.

Accredited by TUV Rheinland of North America is a Nationally Recognized Testing Laboratory.

This symbol indicates general hazards. There is a danger to life and health.

This product may only be used indoors.

The symbol for Safely Isolating Transformer.

The symbol to indicate correct connection from the power supply cable to the pump

IPX1

IP: Ingress protection (protection from vertically dripping water)

IPX6

IP: Liquid ingress protection (protection from heavy water spray).

Read instructions / consult manufacturers guide

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GENERAL INFORMATION

3.5 CLEANING & DISINFECTION

Do not immerse electrical components in water but wipe with a damp cloth only. The electrical components must not be cleaned with a high-pressure cleaner or water jet. Disinfection by wiping only is allowed.

Full cleaning and disinfection instructions can be found on **pages 23-24**.

3.6 SERVICING & MAINTENANCE

Servicing must only be carried out by qualified personnel.

A technical check and/or safety inspection must be conducted at least once a year and after a lengthy break in use.

Any defects, damage or signs of wear must be rectified without delay. Only original spare parts from Harvest Healthcare may be used, otherwise all guarantees or warranties will be excluded.

See **pages 25-27** for Routine Maintenance and Servicing.

3.7 SERVICE LIFE & DISPOSAL

The system must not be disposed of as normal domestic waste after its service life, but must be disposed of in a designated refuse bin for waste electronic devices (WEEE) in the European Union. Do not dispose of as normal domestic waste.

Our Full Terms & Conditions including product warranties are available by request or can be found on our website **www.harvesthealthcare.co.uk.**

PARTS AND DATA MAY UNDERGO FURTHER DEVELOPMENT AND THEREFORE DEVIATE FROM THE DETAILS GIVEN.

TECHNICAL SPECIFICATION

SUPREME 2 TECHNICAL SPECIFICATION

Product Code	HS300.02
Pump Model No.	NS2015/1
Pressure Sore Risk Level	High Risk
Minimum Patient Weight	5 Stone / 32 kg
Maximum Patient Weight	24 Stone / 152 kg
Inflated Mattress Dimensions	2000 x 900 x 130 mm
Mattress Weight	6 kg
Pump Dimensions	240 x 370 x 120 mm
Pump Weight	3.4 kg
Operating Cycle	10 minutes
Fire Retardancy (Cover)	BS7175 Crib 5

PUMP POWER REQUIREMENTS

Power Rating	0.7 A
Voltage	100-240V / 50/60Hz
Noise Level	NC30
Fuse	T 1AH 250V
Medical Classification	Type B Applied Part
IP Rating	IPX1
Safety Standards	EN 60601-1. EN 60601-1-2
Electric Shock Protection	Class II ME equipment externally powered/ internally powered.

OVERVIEW

SYSTEM OVERVIEW

CPR Valve
The mattress can be rapidly deflated through the use of the CPR valve, allowing emergency personnel to begin resuscitation.

Supreme Cells
The Supreme 2 has 17 independent cells which can be individually removed and replaced to allow for cost effective repair and in-depth cleaning.

Mattress Cover
The cover comprises of a two-way vapour permeable and fully welded stretch PU top with a durable base fabric.

Supreme 2 Pump
The Supreme 2 pump has a moulded ABS case with non-slip feet on the base and integrated bed hooks.

Feed Tubes
The Feed tubes are flexible, durable and have excellent anti-kink properties.

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OVERVIEW

PUMP OVERVIEW

A	Air Filter	E	Location of Fuses
B	Feed Tube Connection	F	Power Switch
C	Control Panel	G	Power Cable
D	SMPS - Switch Mode Power Supply	H	Bed Hooks

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INSTALLATION

INSTALLING THE SUPREME 2 SYSTEM

The Supreme 2 is an alternating overlay system to be used in conjunction with a foam underlay. This mattress should NOT be used as a replacement system.

1 Remove the mattress from its packaging and lay the parts out on the floor. You should have the following items:

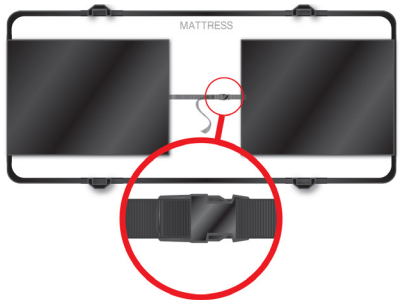
- Carry bag (holdall)
- Mattress with feed tubes attached
- Pump
- 3 adhesive clips
- Instruction booklet

If you intend to keep this mattress system in storage at some point please retain the packaging. This will lengthen the life of the mattress.

Prior to installing the mattress, check that there are no protruding/ sharp objects which may puncture the cover or air cells.

2 Carefully unroll the mattress over the foam underlay. Ensure that the pipes at both the head and foot ends are kink free and straight to prevent restriction of air flow. Ensure that the air tubing to the pump is at the foot of the bed.

3 Tuck the end flaps under the existing underlay on the bed and secure using the straps as per the image here.



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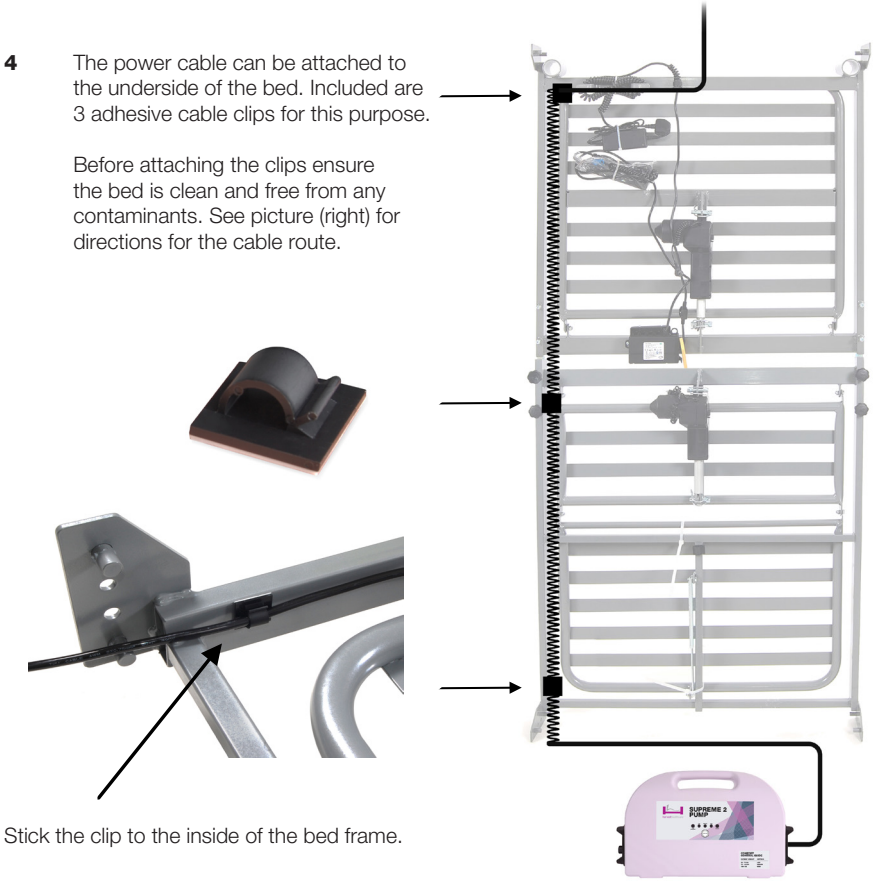
INSTALLATION

4 The power cable can be attached to the underside of the bed. Included are 3 adhesive cable clips for this purpose.

Before attaching the clips ensure the bed is clean and free from any contaminants. See picture (right) for directions for the cable route.



Stick the clip to the inside of the bed frame.

Please make sure that the cable is not connected to any moving part of the bed or routed where it can become trapped or damaged.

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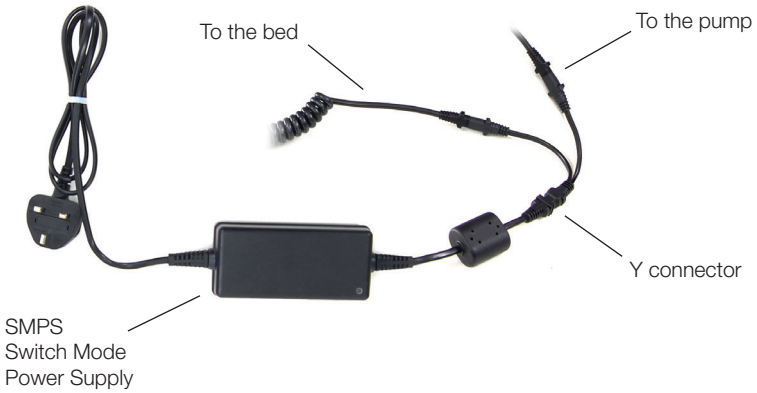
INSTALLATION

5 The Supreme 2 pump can be powered from a Harvest Healthcare Woburn/ Low/ Community/Ultimate or Haddon bed (if fitted with the Limoss low voltage system).

A Y connector is used to split the power from the SMPS to the bed and the pump. (See the diagram below).



6 The pump has integral bed hooks for hanging the pump on the foot end of the bed.

The pump and feed tubes should be at the foot end of the bed.

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INSTALLATION

7 Check that the CPR valve is set to the **CLOSED** setting as indicated below.

The mattress will not inflate if the CPR valve is open.

8 Connect the feed pipes to the pump using the quick release coupling and ensure the connection has securely clicked into place.

9 When the mattress is ready to be inflated, insert the mains plug into the wall socket and turn on the power.

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OPTIONAL BATTERY PACK

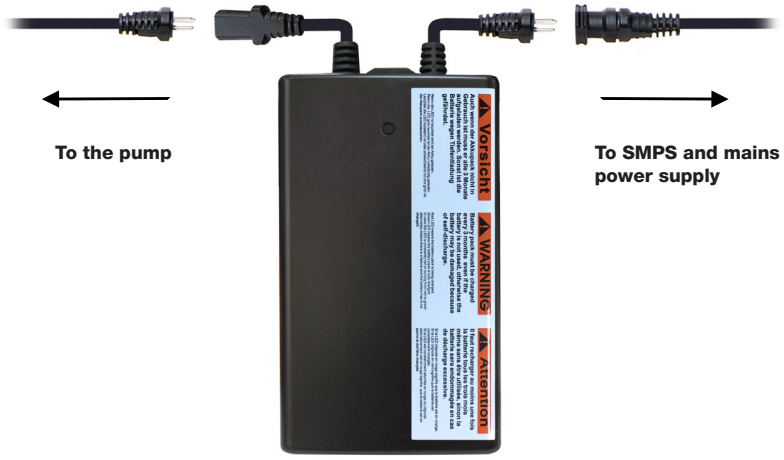
CONNECTING THE OPTIONAL MC160 BATTERY PACK

1 Unplug the equipment from the mains power supply.

2 Remove the screw from the connector (on the output side of the SMPS).

3 Remove the cable clip and seperate the connector.

4 Connect the Battery Pack as shown below between the 2 connectors, reattach the cable and refit the screws.



OPTIONAL BATTERY PACK

5 Plug in and check for the green power light on the SMPS.

6 Check for a flashing amber light on the battery backup.

7 The LED on the battery flashes while charging and turns green when fully charged.

8 If the power supply is interupted, the power will automatically switch to the battery pack. The pump should operate for up to 10 hours if the battery is in good condition and fully charged.

9 When the battery is discharged to around 20% a buzzer will sound. Please charge the battery immediatey.

Take care to observe the safety warnings on the battery.

MC160 - BATTERY PACK SPECIFICATIONS

Dimensions:	90mm x 150mm
Cell:	18650, 25.2V, 1800mAH
IP Rating:	IP66

Temperature and Humidity:
Working: 0-40, 20%-85%
Storage: 0-40, 20%-85%

OPERATION

INFLATING THE MATTRESS

1 Switch on: the alarm will sound. Press the **Function** button to silence the alarm. The pump will automatically select Medium and start a 30 minute mattress inflation mode (with the orange light illuminated) until the correct pressure is reached.

2 During this stage **select a weight setting** to suit the service user - Low, Medium or High. The weight setting is selected by pressing the **Function** button.

Set the pump to run at the correct pressure to suit the weight of the service user. Refer to the Comfort Control Guide located in this manual (page 19) or on the front of the pump.

IN THE EVENT OF A POWER FAILURE

1 Should the supply to the pump be cut, the alarm will sound for 60 seconds.

2 If the power is restored, the pump will automatically restart and continue on the previous selected setting.

3 If the **Function** button is pressed to silence the alarm (when the power has been restored) the pump will return to the Medium setting and will begin a 30 minute inflation cycle. The correct weight setting will then need to be selected.

DEFLATING THE MATTRESS / CPR VALVE

If rapid deflation is required, simply twist the CPR to the OPEN position.

To deflate the mattress, simply open the CPR valve and disconnect the pump from the mattress using the quick release connector.

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OPERATION

SWITCHING OFF THE SYSTEM

Set the switch on the inlet panel to **OFF** position and disconnect the plug from the mains supply. The pump's alarm will sound to indicate a power failure, press the **Function** button once to cancel this.

TRANSPORT MODE

A transport cap is provided to hold the air in the mattress if the pump is disconnected temporarily for any reason.

To prevent deflation please ensure that the transport cap (attached to the air tubes) is fitted to the 3 pipe connector on the mattress (see picture)

The alternating action stops in this mode.

COMFORT CONTROL GUIDE

	WEIGHT KG	WEIGHT LB	WEIGHT STONES LB
LOW	32 - 75 kg	70.5 - 167 lb	5 - 11 stone 11 lb
MEDIUM	76 - 100 kg	166 - 220 lb	12 - 15 stone 10 lb
HIGH	100 - 254 kg	220 - 560 lb	15 stone 10 lb - 40 stone

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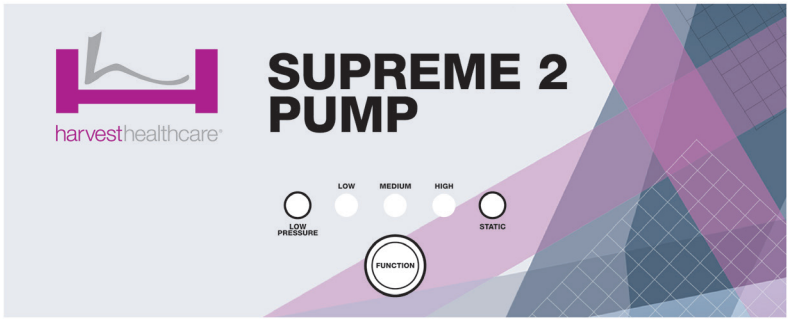
OPERATION

OPERATION OF THE SYSTEM



ORANGE LOW PRESSURE WARNING LIGHT

When the pump starts inflating the mattress the low pressure light will glow orange until the required pressure is reached when the light will extinguish. If the required pressure is not reached within 20 minutes the light will turn red and an alarm will sound. Please check that the CPR is closed and ensure that all pipes are correctly connected.

If the light still does not go out, contact your supplier for assistance.

RED LOW PRESSURE WARNING LIGHT

The low pressure light will glow red when a fault is detected. Check that the CPR is closed and ensure that all pipes are connected to the mattress.

If the warning light does not go out, contact your supplier for assistance.

ADJUSTING THE COMFORT SETTING

Adjust the comfort setting by pressing the function button to cycle the pump through the different settings i.e. Medium (default setting turning the system on) Static, Low, Medium and then High.

STATIC FUNCTION

This is used during patient care and inflates all 17 cells for 20 minutes; after this the pump will return to its previous setting.

CLEANING & CARE

⚠ WARNING

Ensure that the mains power supply to the pump is disconnected before cleaning

Eye protection, gloves and protective clothing should be worn when carrying out cleaning and disinfection procedures

When disinfecting the system, Harvest Healthcare recommends the following guidelines which have been developed to comply with recognised infection control procedures. These procedures are also to be used to prevent cross infection when transferring the system between patients.

MATTRESS

During general use the mattress and internal tubes can be cleaned by wiping with a mild detergent solution.

Where necessary the mattress cover can be removed for laundering or sterilisation. Where there is staining or body fluids on the mattress, cells or tubing, wash thoroughly with soap and water, then wipe with a sodium hypochlorite solution diluted to 1000ppm before laundering.

Mattress covers may be laundered as follows:

1 Pre-wash Cold 10 minutes
2 Main Wash 80°C 10 minutes
3 Followed by cold rinses and extraction.

⚠ Do not use abrasive cleaners, phenol disinfectants, solvents or alcohol-based cleansers, e.g. Dettol, Phenicol, Hibiscrub, Clearsol, Stericol, Hycoline, as these will damage the cover materials.

⚠ Do not iron.

⚠ Ensure that the mattress/cushion is thoroughly dried before remaking the bed or placing in storage.

⚠ **HYPERCARBONATE AND PHENOL-BASED SOLUTIONS SHOULD NOT BE USED AS THESE WILL DAMAGE THE MATTRESS COVER**

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CLEANING & CARE

PUMPS

For general cleaning wipe with a soft cloth dampened with a mild detergent and water solution. This may be followed by either wiping with a sodium hypochlorite solution to a dilution of 1000ppm (parts per million) or by using alcohol wipes.

DO NOT USE HYPERCARBONATE, PHENOL-BASED CLEANING SOLUTIONS, ABRASIVE COMPOUNDS OR CLEANING PADS.

NOTES

- Following the use of a detergent and or disinfectant solution rinse the mattress cover with clean water using a clean cloth and allow to dry.
- Frequent or prolonged exposure to high concentrations of disinfectant solutions will reduce the useful life of the mattress cover.
- Where high concentration disinfectants e.g. > 10,000ppm chlorine releasing agent (e.g. Haztab or bleach) or combined cleaning/chlorine releasing agent (e.g. Chlorcleam, Actichlor) and detergent solutions are used to remove blood or other body fluids, mattresses should be thoroughly rinsed with clean water to remove any residues. This will help prevent any long term compatibility issues associated with disinfectant residues.
- Alternatively, disinfection may be achieved by laundering at temperatures not exceeding 80°C for 10 minutes which may include a chlorine rinse.

TRANSPORT & STORAGE

Storage conditions as follows:
–15 °C without relative humidity control; and +40 °C at a relative humidity up to 93%, non-condensing. An atmospheric pressure range of 700 hPa to 1 060 hPa. Suitable for all standard modes of transport when in the correct packaging.

Operation Conditions:
A temperature range of +5 °C to +35 °C; A relative humidity range of 15% to 93%, non-condensing; and Operational Atmospheric Pressure: 700 hPa to 1060 hPa. Suitable for pollution degree 2. Operational altitude ≤ 2 000 m.

Transportation of the mattress system:
The mattress should be loosely rolled lengthwise with the cover innermost, taking care not to strain the feed pipes. It can then be stored / transported in the carry bag with the pump, mains cable and this booklet. Do not stack bagged mattresses more than two high.

ROUTINE MAINTENANCE

These checks should be carried out at each decontamination process, i.e. between patients or patient occupancy and weekly for longer term patients.

MATTRESS

The mattress cover, which is made from waterproof and vapour permeable material, should be kept clean. Take care to avoid puncturing cover with sharp objects whilst performing the maintenance checks:

1 Remove cover and inspect for damage, tears or staining, which could lead to contamination of the internal parts.
2 Check that the zips are sound and in good working order.
3 Check that all connectors are fitted properly to prevent leaking of air.
4 Check that all cells are attached to the base sheet by the pop fittings provided.
5 Check the stitching on the straps and the seams to ensure no tearing or fraying has occurred.

PUMP

1 Check the pump casing for cracks or other damage that could be dangerous.
2 Check the power cord (ensure there are no bare wires).

If any faults are detected report to your distributor for replacements to facilitate repairs.

COMPONENTS

- Check air cells and mattress interior for signs of damage or contamination, e.g. staining or fluid ingress at each decontamination process, i.e. between patients or patient occupancy (or weekly for longer term patients).
- The individual cells can be wiped clean with a mild antiseptic solution.
- All cells are replaceable and can be sourced from Harvest Healthcare.

POWER UNIT

Disconnect the power unit from the electricity supply before carrying out maintenance, repairs or cleaning.

Check all electrical connections and power lead for signs of wear and damage.
The power unit can be wiped down with detergent, disinfectant solution or wipe*. Do not use solvents. Unsuitable for sterilisation.

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ROUTINE MAINTENANCE

- * In line with the MHRA Medical Device Alert (MDA/2013/019), Harvest Healthcare advises customers to use pH neutral, high-level disinfectant cleaning products to sanitise reusable medical devices to prevent damage to materials and the degradation of plastic surfaces after prolonged use.
- The use of inappropriate cleaning and detergent materials on medical equipment could damage surfaces and may compromise the ability to decontaminate medical devices adequately or may interfere with device function

At end of use dispose of the pump / mattress in accordance with the local regulations including WEEE requirements, which apply to the pump and SMPS only.

SERVICING YOUR SYSTEM

Failure to follow the Supreme 2 service schedule may invalidate future warranty claims. The Supreme 2 should be serviced every **18 months** by Harvest Healthcare approved personnel using genuine Harvest Healthcare spare parts.

The following checks should be made:

- Inspect pump case filter, clean and refit.
- Ensure all hoses both inside the pump and on the mattress are free from kinks and splits.
- Check power cables and SMPS for damage.
- Replace the Shuttle assembly in the Compressor, the rubber mountings and internal air filter (**service kit *NP163**).
- Check pump case for damage.
- After service check pressure level (at the pump case outlet)
- Check low pressure 30mm hg + – 10%
- Check medium pressure 50mm hg + – 10%
- Check high pressure 70mm hg + or – 10%
- Check air flow rate (at pump outlet): should be a minimum of 8 litres per minute.
- Read and record the number of days in service from the pump memory (remember that every digit = 10 days).

When carrying out the scheduled service, you must complete all sections in the service record in the user manual. You will need the Type 2804 Calibration Tool to carry out calibration of the Supreme 2 Pump.

SERVICING SCHEDULE

Serial No:

PROCEDURE	SERVICE 1	SERVICE 2	SERVICE 3	SERVICE 4
Date carried out				
Inspect pump case filter, clean and refit				
Replace internal air filter (Part no. NP158)				
Replace compressor shuttle assembly (Part no. NP114)				
Check pump case for damage (replace as required)				
Check power cable and SMPS (replace as required)				
Check compressor mounting rubbers and replace if necessary (Part no. NP105)				
Record low pressure setting 30mm hg + or - 10%				
Record medium pressure setting 50mm hg + or - 10%				
Record high pressure setting 70mm hg + or - 10%				
Check the record air flow rate (litres per minute)				
Number of days in service				
Name of authorised distributor				
Signature of authorised technician				

To take advantage of the warranty, the pump MUST be serviced (without exception) every 18 months by a Harvest Healthcare Ltd approved technician using only Harvest Healthcare Ltd original spare parts. The above service record MUST be completed.
Failure to carry out the above will invalidate your 5 year warranty.

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TROUBLE SHOOTING

FAULT	CHECK THAT	STAGE 2 CHECK	IF PROBLEM PERSISTS
Pump shows no indication that it is powered up	1. Mains plug is plugged in and power switched on. 2. The power switch on the pump is switched on. 3. The light on the SMPS is illuminated. 4. The fuse in the mains plug is not blown. 5. The wall socket that the pump is connected to is working correctly	1. Connect the pump to the nearest (working) mains outlet. 2. Switch the power supply on the pump off and then back on. 3. Disconnect the SMPS from the power outlet, separate the connection in the pump power cable (just after the SMPS) reconnect the SMPS to the electrical outlet and turn on, check for a green power light. 4. Replace the Fuses with the correct T1A fuses. 5. Try a different device in the mains outlet	Contact Harvest Healthcare technical support. **Before calling:** Please ensure you have the serial number and model of equipment. Please record details of the results of the recommended tests. (Notes pages are provided at the back of this user manual).

FAULT	CHECK THAT	STAGE 2 CHECK	IF PROBLEM PERSISTS
The Pump appears to be running but the mattress is not inflating correctly and or the low pressure light is illuminated.	**PLEASE NOTE the low pressure light will glow orange when the system is first put into service until the mattress has reached the desired pressure (this can take up to 20 minutes)** 1. The hoses are routed correctly (not kinked) and connected to the pump correctly. 2. The CPR valve is not trapped and is in the closed position.	1. Disconnect and then re-connect the hoses to the outlet on the side of the pump. 2. Open then reclose the CPR valve, make sure the valve is not trapped in the bed mechanism	Contact Harvest Healthcare technical support. **Before calling:** Please ensure you have the serial number and model of equipment. Please record details of the results of the recommended tests. (Notes pages are provided at the back of this user manual).
	1. There are no leaks in the mattress. 2. The tubes in the mattress are not disconnected or kinked.	1. Replace any damaged or leaking mattress parts with the correct genuine Harvest 2. Healthcare spare parts. Straighten out any kinked pipes and reconnect any disconnected joints.	

TROUBLE SHOOTING

FAULT	CHECK THAT	STAGE 2 CHECK	IF PROBLEM PERSISTS
Some of the cells appear to be deflated.	This is normal for alternating pressure therapy. The mattress is made up of 17 air cells. The alternating section is split up into 2 sections consisting of odd cells e.g. 1,3,5 etc and even cells e.g. 2,4,6 etc. These two sections will alternate through a 10 minute cycle in which time both sets of alternating air cells will have inflated and deflated sequentially.		
The system does not appear to be alternating.	1. Carefully mark one of the inflated cells with a pen. 2. Ensure that there are no kinks in the pipework down the side of the mattress 3. Ensure that the static function on the pump has not been activated.	1. Monitor the cell for 7 minutes to see if it deflates. 2. Straighten out any kinked pipes. 3. Press the function button until the static light goes out and set the pressure control to the appropriate setting for the person on the mattress.	Contact Harvest Healthcare technical support. **Before calling:** Please ensure you have the serial number and model of equipment. Please record details of the results of the recommended tests. (Notes pages are provided at the back of this user manual).

FAULT	CHECK THAT	STAGE 2 CHECK	IF PROBLEM PERSISTS
The pump is vibrating or making excessive noise.	The pump is fitted to the bed correctly	Reposition the pump unit.	Contact Harvest Healthcare technical support. **Before calling:** Please ensure you have the serial number and model of equipment. Please record details of the results of the recommended tests. (Notes pages are provided at the back of this user manual).
The mattress is uncomfortable.	Check the comfort setting on the pump.	Set the pump to the correct setting using the guide on the front of the pump case.	

A comprehensive service manual for this system is available upon request.

PARTS LIST

APPLIED PARTS

HS302	Supreme 2 Mattress (only)
NS2015/1	Supreme 2 Pump (only)
HS309	Supreme 2 Top Cover and Base
HP574/2	CPR Valve
HH33	Seat Cushion (Optional)

REPLACEMENT PARTS

HS308T/90	Cell
HS306RAW	Supreme Innerl
HP468_1	3 Pipe Connector (only)
HP611	10mm T Connector
HP589	10mm Elbow
HLDW300	Pump Hangers
HP-470	Transport Cap with Tag
HS305B	Supreme 2 Bag/ Holdall
HLDW106BB	Battery Back Up

EMC STATEMENT

USE OF PORTABLE TELEPHONES OR OTHER RADIO FREQUENCY (RF) EMITTING EQUIPMENT NEAR THE SYSTEM MAY CAUSE UNEXPECTED OR ADVERSE OPERATION

The Supreme has been tested to EN60601-1-2:2007, regarding its ability to operate in an environment containing other electrical/electronic equipment (including other medical devices).

The purpose of this testing is to ensure that the Supreme is not likely to adversely affect the normal operation of other such equipment and that other such equipment is not likely to adversely affect the normal operation of the Supreme

Despite the testing of the Supreme that has been undertaken, normal operation of the Supreme can be affected by other electrical/electronic equipment and portable and mobile RF communications equipment.

As the Supreme is medical equipment, special precautions are needed regarding EMC (electromagnetic compatibility).

It is important that the Supreme is configured and installed/put into service, in accordance with the instructions/guidance provided herein and is used only in the configuration as supplied.

Changes or modifications to the Supreme may result in increased emissions or decreased immunity of the harvest supreme in relation to EMC performance.

The Supreme should not be used adjacent to or stacked with other equipment. If adjacent or stacked use with other equipment is necessary, the Supreme and the other equipment should be observed / monitored, to verify normal operation in the configuration in which it will be used.

For the purposes of EN60601-1-2 the Supreme has an essential performance (the Supreme must maintain required pressure within a tolerance of +/-10%).

1 The use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of the equipment or system as replacements for internal components, may result in increased emissions or decreased immunity of the equipment or system.

2 The use of the accessory, transducer or cable with equipment and systems other than the Supreme may result in increased emissions or decreased immunity of the equipment or system.

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EMC STATEMENT

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS

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

EMISSION TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
RF emissions CISPR 11	Group 1	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	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 IEC61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC61000-3-3	Complies	

EMC STATEMENT

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY

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

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
Electrostatic discharge (ESD) IEC61000-4-2	± 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 IEC61000-4-4	± 2 kV for power supply lines ± 1 kV for input / output lines	± 2 kV for power supply lines ± 1 kV for input / output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	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 IEC61000-4-11	<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 s	<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 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the harvest supreme requires continued operation during power mains interruptions, it is recommended that the harvest supreme be powered from an uninterruptable power supply or a battery.
Power frequency (50/60Hz) Magnetic field IEC61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristics 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.

EMC STATEMENT

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY

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

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
Conducted RF IEC61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Supreme including any cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance (d)** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 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 metres (m). Fields 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 this symbol: 
Radiated RF IEC61000-4-3	3 V/m 80 MHz to 2.5 GHz	3V/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 harvest supreme is used exceeds the applicable RF compliance level above, the harvest supreme should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orientating or relocating the harvest supreme

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

EMC STATEMENT

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY

The Supreme is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Supreme can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the harvest supreme 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 $D = 1.2\sqrt{P}$	80 MHZ TO 800 MHZ $D = 1.2\sqrt{P}$	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	23.3

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (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.

GUARANTEES & WARRANTIES

MATTRESS (COVER AND INTERIOR COMPONENTS)

All Harvest Healthcare Ltd Mattress are covered by warranty for a period of 12 months from date of purchase. Damage through incorrect use and penetration by sharp instruments will invalidate this warranty.

PUMP

The Supreme 2 Pump is covered by warranty for a period of 5 years from the date of purchase. This excludes all serviceable parts such as the bellows and filters which are recommended to be changed every 18 months in line with the service schedule.

To take advantage of the 5 year warranty, the pump must be serviced (without exception) every 18 months by a Harvest Healthcare Ltd approved technician using only Harvest Healthcare Ltd original spare parts. The service record must be completed on **page 27**.

Failure to carry out the above will invalidate your 5 year warranty.

A service manual for this system is available upon request.

GUARANTEES & WARRANTIES

GUARANTEE

Harvest Healthcare Ltd guarantees to repair or replace all goods supplied to its customers which are found to be defective whilst still in their applicable warranty period. All warranties are subject to the following conditions:

a Warranty/ guarantee is subject to all guidelines being adhered to.

b That the equipment has been used for the purpose for which it was intended.

c That the usage has been on a fair wear and tear basis. This does not include user damage.

d That Harvest Healthcare Ltd's cleaning/ disinfecting guidelines have been followed.

e Harvest Healthcare Ltd's maintenance guidelines have been followed (Please refer to the product manual).

f That ALL maintenance has been carried out by a suitably qualified and competent person.

g That all parts used are OEM (Original Equipment Manufacturer) parts and were supplied by Harvest Healthcare Ltd either directly or through a distributor.

h All warranties begin from the time the product leaves the premises of Harvest Healthcare Ltd.

i All repairs and replacements will be at the sole discretion of Harvest Healthcare Ltd.

Our standard terms and conditions of sale can be found on our website or by request to Harvest Healthcare Ltd

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DECLARARTION OF CONFORMITY

Declaration of Conformity
Annex VII
EU Directive 93/42/EEC

We, as company: **Harvest Healthcare Limited**
Sheaf House
Bradmarsh Way
Bradmarsh Business Park
Rotherham, S60 1BW

Confirm on our own behalf that the medical product: **SUPREME 2 ACTIVE MATTRESS SYSTEM**

Complies with all applicable requirements in Appendix I of the EU directive 93/42/EEC.

The following compliance evaluation process was applied: **Annex VII**

In the event of modification of this product without consultation with the manufacturer, this declaration of conformity will lose its validity.

Rotherham, **01.12.2015**

Director

NOTES

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Serial No:

RENCE: HS300.02/MANUAL01 - Jan 2016

e 2 pump supplied by Harvest Healthcare Ltd.
to the standard EN 60601-1.