harvesthealthcare®

General User/ Safety Guide

ROYAL/ ROYAL EXTRA REPLACEMENT MATTRESS

ACTIVE MATTRESSES

www.harvesthealthcare.co.uk

CONTENTS

WARNINGS & CAUTIONS

READ THIS INSTRUCTION MANUAL AND OBSERVE SAFETY INSTRUCTIONS.

WARNING

- This mattress must be properly installed and operated as directed by this user manual.
- The mattress should be checked regularly to ensure correct operation. Loss of function will remove all pressure relieving properties that this system provides.
- This mattress 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 18-19?**). 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 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.

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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 21-22**.
- 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. 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 **Royal 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 **Royal System** offers the patient comfortable and relaxing support that can both prevent tissue breakdown and enhance healing.

The **Royal Mattress** is made up of 17 individual cells. 14 alternating air cells and 3 static cells at the head end. The alternating cells are 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.

The **Royal Extra Mattress** is based on the Royal Replacement Mattress System with an additional foam surround, suitable for wider beds The mattress has 14 alternating air cells and 2 static cells at the head end. Available in 1200mm and 1370mm width, the mattresses have an increased maximum weight limit of 50 stones / 317 kg. The surround is visco topped for comfort and can be used on a profiling bed.

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GENERAL INFORMATION

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).

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.

GENERAL INFORMATION

3.5 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.

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TECHNICAL SPECIFICATION

ROYAL SPECIFICATION

Product Code	**HR402**
Pressure Sore Risk Level	Very High Risk
Minimum Patient Weight	5 Stone / 31.7 kg
Maximum Patient Weight	39 Stone / 247 kg
Inflated Mattress Dimensions	1940 x 920 x 205 mm
Mattress Weight	9 kg
Fire Retardancy (Cover)	BS7175 Crib 5

ROYAL EXTRA SPECIFICATION

Product Code	**1200- HR434**
Pressure Sore Risk Level	Very High Risk
Minimum Patient Weight	5 Stone / 31.7 kg
Maximum Patient Weight	50 Stone / 317 kg
Inflated Mattress Dimensions	1940 x 1200 / 1370 x 240 mm
Fire Retardancy (Cover)	BS7175 Crib 5

OVERVIEW

ROYAL OVERVIEW

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

Royal Cells
The Royal 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.

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

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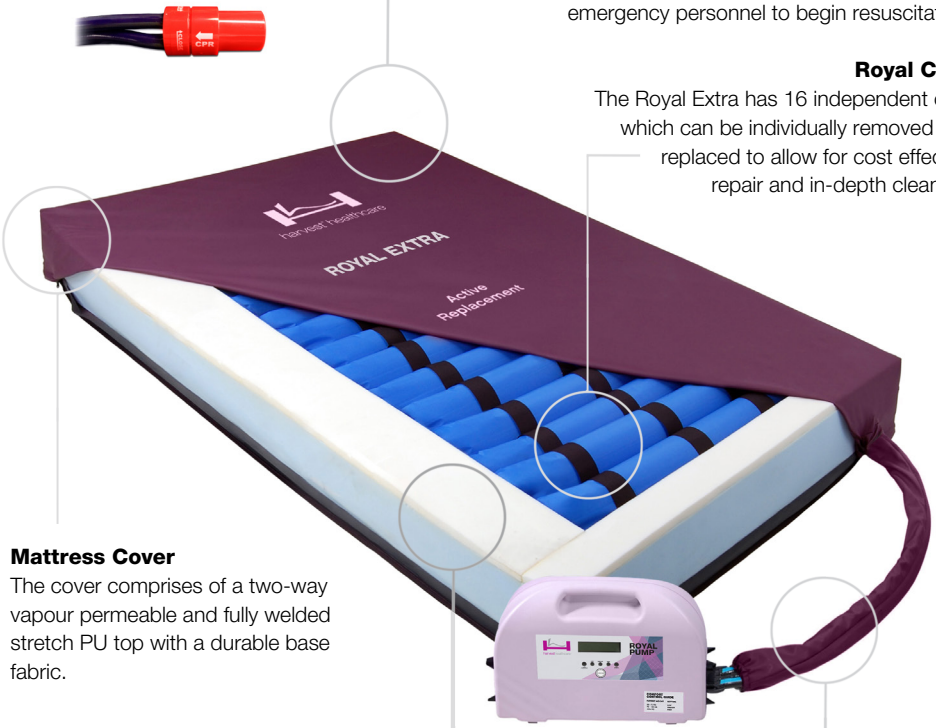
OVERVIEW

ROYAL EXTRA OVERVIEW

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

Royal Cells
The Royal Extra has 16 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.

Foam Surround
The Royal Extra is surrounded by a foam wall. This makes the Royal Extra suitable for wider beds and a higher maximum weight.

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

INSTALLATION

INSTALLING THE ROYAL MATTRESS

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
- Instruction booklet

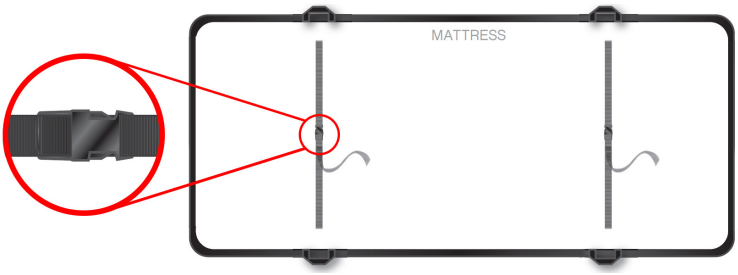
If you intend to keep this mattress system in storage at some point please retain the packaging. This will lengthen the life of the mattress.

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 on to the mattress platform. 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 The straps on the under side of the mattress are used to secure the mattress to the bed. Secure the straps using the plastic clips around the bed frame and tighten. **Note: Secure the straps to the moving parts of the platform only.**

Care must be taken when fixing the mattress to the bed frame.



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INSTALLATION

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.

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.

INSTALLATION

INSTALLING THE ROYAL EXTRA SYSTEM (ADDITIONAL INFORMATION)

Please refer to the previous installation instructions (**pages 15-16**). However, please be aware of the following additional guidelines when installing the Royal Extra systems:

- Your Royal Extra system will be delivered to you in a box. This prevents the foam surround from damage during trasportation. In addition, any attempt to roll or fold the mattress may result in damage to the foam surround
- The Royal Extra mattress does not include securing straps. Please ensure that the mattress is correctly sized for the bed and that the mattress is positioned onto the mattress base using the mattress guides.
- After switching the system on, It is advised that the system is left to fully inflate before putting into use.

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.

Ensure that the Royal Extra Mattress is fully inflated before being put into use.

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OPERATION

INFLATING THE MATTRESS

1 Switch on: The pump will automatically begin to inflate and start a 30 minute mattress inflation mode until the correct pressure is reached. Manually set the comfort setting for the Service User.

2 When the mattress has fully inflated. The Service User can now be layed on the mattress.

Set the pump to run at the correct pressure to suit the weight of the service user. Refer to the Comfort Control Guide on the front of the pump.

IN THE EVENT OF A POWER FAILURE

1 Should the power supply to the pump be cut, the system will alarm.

2 If the power is restored, the pump will continue on the selected setting.

3 When the power is restored, check the setting for the Service User.

DEFLATING THE MATTRESS / CPR VALVE

If rapid deflation is required, simply twist the CPR to the <u>OPEN</u> position.

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

OPERATION

SWITCHING OFF THE SYSTEM

1 Turn off and unplug from the mains supply.

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.

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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

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

The Royal system should be serviced every **12 months** by Harvest Healthcare approved personnel using genuine Harvest Healthcare spare parts.

Failure to follow the Royal service schedule may invalidate future warranty claims (Gurantees & Warranties can be found on page 35).

PARTS LIST

APPLIED PARTS

HR402	Royal Mattress (only)
HR423	Royal Top Cover and Base
HR433C	Royal Extra 1200 Top Cover and Base
HR433D	Royal Extra 1370 Top Cover and Base
HR432C	Royal Extra 1200 Foam Surround
HR432D	Royal Extra 1370 Foam Surround
HS384	Royal Inner (Complete)
HP574/3	CPR Valve

REPLACEMENT PARTS

HS382	Royal Cell (Static)
HS383	Royal Cell (Alternating)
HS381	Inner Base Sheet
HP468_1	3 Pipe Connector (only)
HP611	10mm T Connector
HP589	10mm Elbow
HLDW300	Pump Hangers
HP468	Transport Cap with Tag
HR405B	Royal Bag/ Holdall

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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 fuse in the mains plug is not blown. 4. The wall socket that the pump is connected to is working correctly	1. Connect the pump to the nearest (working) mains outlet. 2. Replace the Fuses with the correct T1A fuses. 3. 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).

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 individual 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 tatic 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 appears to be running but the mattress is not inflating correctly and or the low pressure light is illuminated.	**PLEASE NOTE** **Inflation can take up to 30 minutes.** **If the Low Pressure Alarm sounds, press the mute button and check the CPR is closed.** 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.	

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.	

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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 Pump is covered by warranty for a period of 3 years from the date of purchase. This excludes all serviceable parts such as the bellows and filters which are recommended to be changed every 12 months in line with the service schedule.

A service manual for this system is available upon request.

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

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

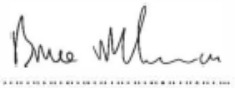
Confirm on our own behalf that the medical product: **ROYAL ACTIVE MATTRESS SYSTEM**

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

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Annex VII
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