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ACTIVE MATTRESSES

General User/Safety Guide

BALMORAL II/ BALMORAL PLUS ACTIVE REPLACEMENT

www.harvesthealthcare.co.uk

CE

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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. 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 not expose the pump to liquids.
- Do not use with hot water bottles or electric blankets.
- Do not allow sharp objects to puncture the mattress material.
- The mattress and pump should be cleaned between patient uses.
- Wipe up any fluid or debris before wiping down with clean, cold water. Use a 0.1% chlorine solution (1,000 ppm) in cold water. In case of blood or other bodily fluids, it is recommended to use a 1% chlorine solution (10,000 ppm). Full cleaning instructions can be found on **pages 14-15**.
- 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.
- Do not use a fitted sheet as this could reduce pressure relief.
- Replace contaminated cells if they can not be decontaminated.

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.

INTENDED PURPOSE

The **Balmoral II/ Balmoral Plus Replacement 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 of developing pressure sores. The mattress is fitted with a vapour permeable four way stretch cover.

By using the established principles of alternating therapy, the **Balmoral II / Balmoral Plus Replacement System** offers the patient comfortable and relaxing support that can both prevent tissue breakdown and enhance healing.

The **mattress** is made up of 27 individual cells. 23 alternating air cells and 4 static pillow section cells. 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 connector has transport cap to maintain the air pressure within the mattress, for easy patient transport arrangements. When using the transport cap, the mattress will stay inflated for approximately 24 hours. For rapid deflation of the system simply pull open the CPR and disconnect the pump.

In the event of a power outage, both systems have been designed to protect the end-user. The Balmoral II has foam fitted underneath the alternating cells. The Balmoral Plus has been designed with a three-part static air cell mat that can be deflated in the event of cardiac arrest by opening the CPR valve.

INTENDED USER / CARER

1 DEFINITION OF INTENDED USERS /CARERS

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).

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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.

GENERAL INFORMATION

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.

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 and follow the power down procedure (**page 16**). 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


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


Conformity mark in accordance with the Medical Device Regulation 2017/745/EU.


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)


Operation and storage temperture.

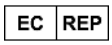

This product must be disposed of in a designated refuse bin for waste electronic devices (WEEE) in the European Union. Do not dispose of as normal domestic waste.


No smoking. No naked flames.


Read instructions / consult manufacturers guide


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

The product is a ‘Medical Device’.



EU Representative.

UK Representative.

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 14-15**.

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 16-17** 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.

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TECHNICAL SPECIFICATION

BALMORAL II TECHNICAL SPECIFICATION

Product Code	HAMBALM003
Pressure Sore Risk Level	Very High Risk
Maximum Patient Weight:	
Harvest Pump 2	29 Stone / 184 kg
Harvest Pump 250	31 Stone / 200 kg
Harvest Pump 3	40 Stone / 254 kg
Inflated Mattress Dimensions	2000 x 900 x 150 mm
Mattress Weight	14 kg

BALMORAL PLUS TECHNICAL SPECIFICATION

Product Code	HAMBALM004
Pressure Sore Risk Level	Very High Risk
Maximum Patient Weight:	
Harvest Pump 2	29 Stone / 184 kg
Harvest Pump 250	31 Stone / 200 kg
Harvest Pump 3	40 Stone / 254 kg
Inflated Mattress Dimensions	2000 x 900 x 150 mm
Mattress Weight	10 kg

The Balmoral II / Balmoral Plus systems have been designed with no minimum weight limit. However, it is recommended that end users below 32kg are reviewed on a more regular basis to ensure the suitability of the mattress surface for their individual needs. The manufacturer cannot guarantee the clinical benefits and it is down to the clinical judgment of a medical professional.

Please Note: Maximum patient weight is dependent on which pump is attached to the mattress.

OVERVIEW

SYSTEM OVERVIEW

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

Mattress Cover
The mattress cover comprises a four-way vapor-permeable PU top cover and a durable base fabric.

Balmoral II / Balmoral Plus Cells
The Balmoral II / Balmoral Plus has 27 independent cells which can be individually removed and replaced to allow for cost effective repair and in-depth cleaning.

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INSTALLATION

INSTALLING THE BALMORAL II / BALMORAL PLUS SYSTEM

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

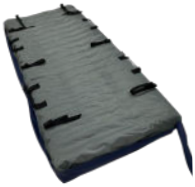
- System Packaging
- Mattress with feed tubes attached
- Instruction booklet

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. 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 Fit the mattress to the bed. Straps should be fitted loosely only fitted to the moving section of the bed platform.



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

The pump and tube set connector should be at the foot end of the bed.

5 Check that the CPR is in the Closed Position.

The mattress will not inflate if the CPR has not been closed.

6 Connect the tube set to the pump using the quick release coupling and ensure the connection has securely clicked into place.

7 When the mattress is ready to be inflated, insert the mains plug into the wall socket and turn on the power to the pump. Refer to the pump user guide.
Once the mattress is fully inflated and the pump has been set up correctly for the end user, the active mattress system should be ready to be used.

8 When the mattress needs to be stored, disconnect the pump unit, open the CPR valve, and allow all the air to escape. If the mattress is clean and dry, it can then be rolled up, starting from the foot-end. Use the two top fixing straps; these can be used to keep the mattress compact by clipping them into the middle fixing straps.

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.

Cover, Cells and Internal tubing

General Cleaning

Wipe down with a clean cloth moistened with a mild detergent and dilute with warm water.
Rinse by wiping with a cloth with clean water to remove detergent residue.
Ensure it is dry before use.

Decontamination - Covers

Wipe up any fluid or debris before wiping down with clean cold water.
Wipe using a 0.1% Chlorine solution (1,000ppm) in cold water. In case of blood or other bodily fluids, it is recommended to use a 1% Chlorine solution (10,000ppm).
Rinse by wiping with cold clean water and a clean cloth.
Ensure it is dry before use.

Alternatively, disinfection may be achieved by laundering at temperatures not exceeding 85°C for 10 minutes, as follows:

1 Pre-wash Cold 10 minutes
2 Main Wash 85°C 10 minutes
3 Followed by cold rinses and extraction.
4 Tumble dry the top cover on a low heat until it is dry.

Frequent or prolonged exposure to high concentrations of disinfectant solutions will reduce the useful life of the mattress cover, always ensure it is thoroughly wiped with clean water and dried before use.

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CLEANING & CARE

PUMPS

Wipe down with a clean cloth moistened with a mild detergent and dilute with warm water. Rinse by wiping with a cloth with clean water to remove detergent residue.

If there are blood spillages or bodily fluids present wipe surfaces down with 0.1% Chlorine solution (1,000 ppm) and wipe down with a clean cloth with clean water.

Ensure the cleaned surfaces are allowed to fully dry before putting back into use.

PLEASE NOTE

Do not use bleach, solvents or alcohol-based cleansers, e.g. Phenicol, Hibiscrub, Clearsol, Stericol, Hycoline as these will destroy the mattress material.
Always check for damage before cleaning.

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

TRANSPORT & STORAGE

Storage conditions as follows:
-15 ^{0}C without relative humidity control; and +40 ^{0}C at a relative humidity up to 80%, non-condensing.

Operation Conditions:
A temperature range of +5 ^{0}C to +35 ^{0}C; a relative humidity range of 20% to 80%, non-condensing.

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 water-resistant and vapor-permeable material, should be kept clean. Take care to avoid puncturing the 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.

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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 Balmoral II / Balmoral Plus system should be serviced every **12 months** by Harvest Healthcare approved personnel using genuine Harvest Healthcare spare parts.

Failure to follow the Balmoral II / Balmoral Plus service schedule may invalidate future warranty claims (Gurantees & Warranties can be found on page 23).

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 plug fuse with the correct 5A fuse. 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).

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.** 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 Healthcare spare parts. 2. 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 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. **Check that the static mode is not turned on.** 2. Check the mattress is not in CLP mode. 3. Ensure that there are no kinks in the pipework down the side of the mattress.	1. Monitor the cell for 7 minutes to see if it deflates. 2. Straighten out any kinked pipes.	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. Check the pump has not been left in the seated mode if the end-user is laying down.	Set the pump to the correct setting using the guide on the front of the pump case.	

PARTS LIST

APPLIED PARTS (BALMORAL II)

HAMBALM003.P2 **HAMBALM003.P250** **HAMBALM003.P3**	Balmoral II Mattress (only)
HAMBALM003C	Balmoral II Cover
AMUNI010	One Way Valve

REPLACEMENT PARTS

AMBALM005	Top Cover for Balmoral II
AMBALM006	Base Cover for Balmoral II
AMBALM007	Base Sheet for Balmoral II
AMBALM008	Quick Connector for Balmoral II
AMUNI013	Air Cell for Balmoral II
AMUNI012	Turning CPR for Balmoral II
AMUNI014	Air Cell, Double Connector (1st Cell) for Balmoral II
HAR387HS	Balmoral Foam (50mm)

APPLIED PARTS (BALMORAL PLUS)

HAMBALM004.P2 **HAMBALM004.P250** **HAMBALM004.P3**	Balmoral Plus Mattress (only)
HAMBALM004C	Balmoral Plus Cover
AMUNI010	One Way Valve for Balmoral Plus

REPLACEMENT PARTS

AMBALM009	Static Air Base Section for Balmoral Plus
HAMBALM004BC	Base Cover for Balmoral Plus
HAMBALM004BS	Base Sheet for Balmoral Plus
AMUNI011	Quick Connector for Balmoral Plus
AMUNI013	Air Cell for Balmoral Plus
AMUNI012	Turning CPR for Balmoral Plus

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GUARANTEES & WARRANTIES

MATTRESS (COVER AND INTERIOR COMPONENTS)

All Harvest Healthcare Ltd Mattress are covered by warranty for a period of 3 years from date of purchase. Damage through incorrect use and penetration by sharp instruments will invalidate this warranty.

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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