



General User/ Safety Guide

BLenheim ACTIVE SEAT CUSHION



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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 **page 17**). Care should be taken not to accidentally 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.
- 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.

WARNINGS & CAUTIONS

- Do not 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 seat cushion material.
- The seat cushion 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 seat cushion material. Full cleaning instructions can be found on **page 18-19**.
- Suitable for continuous use.
- Do not modify the seat cushion 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.



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.

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.

GENERAL INFORMATION

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.



The mains cable must be free and not be allowed to be caught up in any moving mechanisms such as a chair and bed. 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).

GENERAL INFORMATION

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.

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 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.



No smoking. No naked flames.



Read instructions / consult manufacturers guide



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

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 18-19**.

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 20-21** 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

9 CELL SEAT SYSTEM TECHNICAL SPECIFICATION

Product Code	HACBLEN001
Pump Model No.	HPU2
Pressure Sore Risk Level	High Risk
Minimum Patient Weight	5 Stone / 30 kg
Maximum Patient Weight	20 Stone / 127 kg
Inflated Cushion Dimensions	460 x 460 x 60 mm
Cushion Weight	1 kg
Pump Dimensions	270 x 90 x 140 mm
Pump Weight	1.5 kg
Operating Cycle	10 minutes

PUMP POWER REQUIREMENTS

Power Rating	1A
Voltage	AC220-240V / 50Hz
Noise Level	NC30
Fuse	Plug Fuse 5A
Medical Classification	Type BF Applied Part
Safety Standards	EN 60601-1

OVERVIEW

SYSTEM OVERVIEW

Place the seat cushion on chair, where the patient will be seated with the cells and/or vapour permeable cover up most.



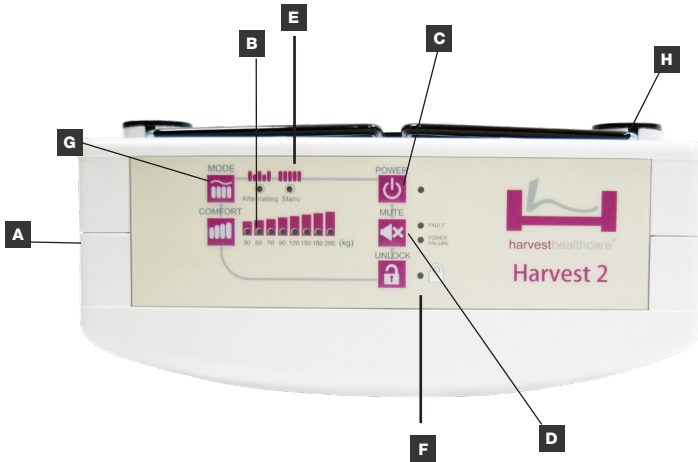
OVERVIEW

Internal view of alternating cells.



OVERVIEW

PUMP OVERVIEW



- | | | | |
|----------|---|----------|-------------------------------------|
| A | Feed Tube Connection | E | Alternating / Static Mode Indicator |
| B | Comfort Setting | F | Auto-Lock Indicator |
| C | Power Switch | G | Static Mode |
| D | Visual and Audible Low-Pressure and Power Failure Warning / Alarm with mute | H | Bed Hooks |



Power Failure: The alarm will sound until the power is reinstated. If the Mute button is pressed to silence the alarm, you must press the On/ Off switch to restart the pump. When the power is reinstated check the status of the pump and ensure it is switched on.



Static Mode is only to be used for patient care.

OVERVIEW

A Feed Tube Connector

The pipes from the mattress will connect here. It is important that pump can be disconnected in an emergency .If CPR is to be administrated.

B Comfort Setting

The pump has a scale printed on the front panel in kilograms. Press the comfort control button until the nearest desired weight setting is illuminated on the display panel. When the mattress is in use the user can adjust the comfort setting as required for the service user's needs. A slight increase of the comfort setting may be required if the service user needs more support when the bed is profiled. When the bed platform is laid flat readjust the setting as required for the service user.

C Power Switch

Press the power button on the front control panel once to start and stop the pump. If you cannot change the setting check the lock out mode is not activated. Ref to section F in this manual

D Visual and Audible Low Pressure and Power Failure Warning / Alarm

The pump is fitted with an audible and visual alarm. Press the Mute button to reset the alarm.

The alarm will active after 45 mins if the mattress has not fully inflated while in the start-up mode. When the mattress is inflated the alarm mode will reset. The alarm will now reactivate when it detects a fault on the system.

The LED next to 'fault' will illuminate red when a fault is detected with the system. The LED next to 'power failure' will illuminate red when a fault is detected with the power supply.

E Alternating / Static Mode Indicator

When the pump is switched on for the first time it will inflate all the cells. The alternating mode LED will flash to indicate that the pump is in start-up mode. Once all the cells have been inflated the LED will change a constant light and the alternating mode will activate. The cells in the mattress will then inflate and deflated to prove pressure relief for the service user.

F Auto-Lock Indicator

The auto lock out will active after 1 minute, signified by the LED green light next to the unlock symbol. This function will not allow you to alter the setting on the pump unless you press down on the unlock button. Press down on the unlock button symbol, wait for the pump will bleep once and the LED light will extinguish. Access to the different functions will now be made available.

G Static Mode

The static mode can be operated by the user to inflate all the cells for patient care. Press the static mode button, the static mode LED will illuminate when this mode is engaged. The static mode will stop working after 30 mins and the pump will revert back to the alternating mode if there is no further interaction with the pump.

H Bed Hooks

Attach the pump to the foot end of the bed. Adaptor brackets are available to fit different sizes of beds. If the pump cannot be attached to the foot end of the bed it is the user's responsibility to ensure that the pump is placed in such a position that it will not cause harm or injury to the service user. **The pump unit must be placed so that it clearly be seen and monitored at all times.**

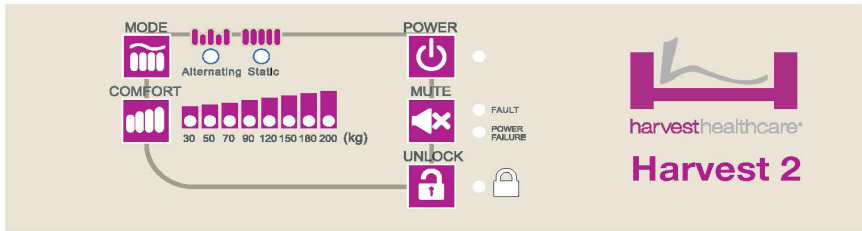
INSTALLATION

INSTALLING THE SEAT CUSHION SYSTEM

- 1** Unpack the system and place the pump unit in a safe place to avoid trip hazards.

Place the seat cushion on chair where the patient will be seated with the cells and/or vapour permeable cover upmost and the tubing at the front.
- 2** Connect the seat pump to the power supply and switch on the pump. At this stage main power will illuminate.
- 3** Refer to the comfort control setting on the pump and adjust the setting to the patient's weight.
- 4** Cover the seat cushion with a loose fitting cover if desired
- 5** When the low pressure indicator has extinguished the patient may be placed on the support surface.
- 6** We advise a risk assessment is carried out to ensure that the equipment is suitable for the patient and the environment in which it is being used.

OPERATION



SETTING PROCEDURE

It is important to follow the correct setting procedure to ensure that the patient receives sufficient support whilst achieving maximum pressure relief and comfort.

Failure to follow this procedure could result in the patient being put at risk.

COMFORT CONTROL GUIDE

Ensure that the pressure setting is set to the correct setting when the patient is using this product. Refer to the pump control panel for the weight 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 seat cushion and internal tubes can be cleaned by wiping with a mild detergent solution.

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

Seat cushion 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 seat cushion is thoroughly dried before putting back into use or placing in storage.



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

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. Chlorclean, 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.

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.

SEAT CUSHION

The seat cushion 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).
- 3** Check for the correct function of the low pressure light, disconnect the pipes from the seat cushion into transport mode, the pump should indicate low pressure within a few seconds

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

COMPONENTS

Check air cells and seat cushion 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.

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 / seat cushion in accordance with the local regulations including WEEE requirements, which apply to the pump only.

SERVICING YOUR SYSTEM

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

Compressor/ Bellows should be changed.
Filters should be changed.
Low pressure switch should be changed.



Failure to follow the service schedule may invalidate future warranty claims and could lead to faults developing with the system that could affect core/pressure relief (Guarantees & Warranties can be found on page 35).

TROUBLE SHOOTING

FAULT	CHECK THAT	STAGE 2 CHECK	IF PROBLEM PERSISTS
<p>Pump shows no indication that it is powered up</p>	<ol style="list-style-type: none"> 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. 	<ol style="list-style-type: none"> 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. 	<p>Contact Harvest Healthcare technical support.</p> <p>Before calling:</p> <p>Please ensure you have the serial number and model of equipment.</p> <p>Please record details of the results of the recommended tests. (Notes pages are provided at the back of this user manual).</p>

FAULT	CHECK THAT	STAGE 2 CHECK	IF PROBLEM PERSISTS
<p>The Pump appears to be running but the mattress is not inflating correctly and or the low pressure light is illuminated.</p>	<p>PLEASE NOTE Inflation can take up to 30 minutes.</p> <ol style="list-style-type: none"> The hoses are routed correctly (not kinked) and connected to the pump correctly. The CPR valve is not trapped and is in the closed position. 	<ol style="list-style-type: none"> Disconnect and then re-connect the hoses to the outlet on the side of the pump. Open then reclose the CPR valve, make sure the valve is not trapped in the bed mechanism. 	<p>Contact Harvest Healthcare technical support.</p> <p>Before calling:</p> <p>Please ensure you have the serial number and model of equipment.</p> <p>Please record details of the results of the recommended tests. (Notes pages are provided at the back of this user manual).</p>
	<ol style="list-style-type: none"> There are no leaks in the mattress. The tubes in the mattress are not disconnected or kinked. 	<ol style="list-style-type: none"> Replace any damaged or leaking mattress parts with the correct genuine Harvest Healthcare spare parts. Straighten out any kinked pipes and reconnect any disconnected joints. 	

TROUBLE SHOOTING

FAULT	CHECK THAT	STAGE 2 CHECK	IF PROBLEM PERSISTS
<p>Some of the cells appear to be deflated.</p>	<p>This is normal for alternating pressure therapy.</p> <p>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.</p>		
<p>The system does not appear to be alternating.</p>	<ol style="list-style-type: none"> Check that the static mode is not turned on. Carefully mark one of the inflated cells with a pen. Ensure that there are no kinks in the pipework down the side of the mattress. 	<ol style="list-style-type: none"> Monitor the cell for 7 minutes to see if it deflates. Straighten out any kinked pipes. 	<p>Contact Harvest Healthcare technical support.</p> <p>Before calling:</p> <p>Please ensure you have the serial number and model of equipment.</p> <p>Please record details of the results of the recommended tests. (Notes pages are provided at the back of this user manual).</p>

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

PARTS LIST

APPLIED PARTS

HPU2	Harvest 2 Pump (only)
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REPLACEMENT PARTS

PU200	Compressor
PU201	Power Lead 5 metres
PU202	Inlet Power Lead
PU203	Label Panel (Tactile)
PU204	Timer and Motor
PU205	Front Casing
PU206	Rear Casing
PU207	Bed Hooks
PU208	PCB
PU209	Filter
PU210	Fuse and Holder
PU211	Connectors

GUARANTEES & WARRANTIES

CUSHION (COVER AND INTERIOR COMPONENTS)

All Harvest Healthcare Ltd cushions 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

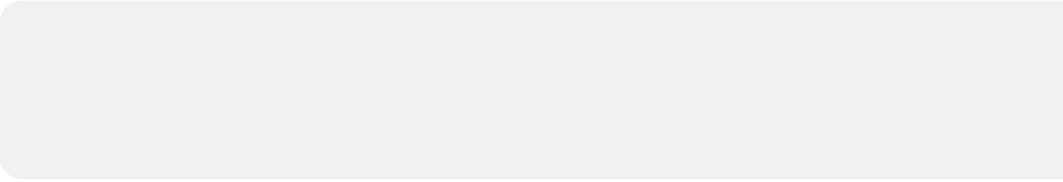
The Harvest 2 Pump is covered by warranty for a period of 3 years from the date of purchase. This excludes all serviceable parts such as the bellows and filters which are recommended to be changed every 12 months in line with the service schedule.

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





Special Products and Service

Contact Us

Units 5 and 6 Lower Vicarage
Road
Southampton
Hampshire
SO19 7RJ

T: 02380 420678

E: info@easycare systems.co.uk

www.easycare systems.co.uk