APH053/HERA

Apollo 8 System

Instructions for Use

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About This Document

IMPORTANT: The equipment must be installed and operated in the manner for which it is intended as outlined in this Instructions for use (IFU). The caregiver/patient is responsible for reading and understanding the product Instructions for use as it contains safe use of the device and installation instructions. If instructions for use are unclear, please contact Apollo Healthcare Technologies customer support (see section 21 for contact details)

Apollo Healthcare Technologies Ltd will not be responsible for any injuries resulting from failure to comply with the instructions and precautions in this IFU.

READ THE INSTRUCTIONS FOR USE CAREFULLY BEFORE USE AND RETAIN FOR FUTURE REFERENCE.

NO MODIFICATION TO THE DEVICE IS ALLOWED.

NOTE

Information in this Instructions for use is subject to change without notice and does not represent commitment on the part of Apollo Healthcare Technologies Ltd. No part of this IFU may be reproduced or transmitted in any form or by any means, electronic or mechanical, including photocopying and recording for any purpose without the written permission of Apollo Healthcare Technologies Ltd.

Table of Contents

1. Convention Used in This Instructions for Use

This Instructions for use includes information essential to the safety of the patient, personnel and equipment during normal operation of the Apollo 8 System. The safety information is displayed in this IFU by using the following conventions:

WARNING: A warning is a statement that alerts the user to the possibility of injury, death or other serious adverse reactions associated with the use or misuse of the device.

CAUTION: A caution is a statement that alerts user to the possibility of a problem with the device associated with its use or misuse.

IMPORTANT: Indicates a harmful situation that could result in damage to the product or some-thing around it.

NOTE **Indicates to explain or amplify a procedure or condition.**

2. Explanation of Label Symbols

The following symbols indicate the severity of the danger:

	Warning		Caution		Important
	Consult Safety Instructions for Use		Consult Instructions for Use		Latex Free
	Manufacturer		Date of Manufacture	NOTE	Note
REF	Catalogue Number	SN	Serial Number	IP21	Protection from Ingress of Fluids
	Safe Working Load		Class II Electrical Device (Double Insulated)		Type BF Applied Part
	Possible Electric Shock Hazard		Not Suitable for use in presence flammable anaesthetic mixture with oxygen or nitrous oxide		Use 0.1% chlorine solution diluted to 1,000ppm
	Machine Wash 95°C Max		Tumble Dry Low Heat		Do Not Dry Clean
	Do Not Iron		Do Not Bleach		Do NotUse Phenol
	Do Not Use Sharp Instruments		No Smoking		Fragile, Handle with Care
	Protect from Heat and Radioactive Sources		Storage Temperature Limitation		Operating Temperature Limitation
	Humidity Limitation		Atmospheric Pressure Limitation		Keep Dry
MD	Medical Device under EU MDR 2017/745	EU REP	Authorised Representative in the European Union		Foot End
UDI	The Unique Device Identifier		Max Patient weight defines the maximum total load of the patient kg (lb)	LOT	Batch or LOT number
	Disposal of electric and electronic equipment in compliance with WEEE regulations. This product should be handed over to an applicable collection point for the recycling of electrical and electronic equipment.				
CE 0197	Conformitè Europëenne (CE) Mark indicates conformity in accordance with EU MDR 2017/745 and MDR 2002(#618).				

3. Introduction

Thank you for choosing to use the Apollo 8 System. The product is intended to help and reduce the incidence of pressure ulcers while optimising patient comfort.

The HERA Pump (Control Unit) features include:

- Self-adjusting for all patient morphologies and positions
- Auto firm for patient transfer
- CLP continuous low pressure and alternating therapy modes over 3 preferred comfort settings
- Audio and visual alarms to differentiate between low pressure and power failure errors

The Apollo 8 Mattress features include:

- Consists of 17 'figure of 8' alternating cells plus 3 static head cells
- Dynamic therapy for alternating action for lower interface pressures and gentle capillary stimulation
- Humidity management to help prevent tissue breakdown and skin maceration
- Multi-stretch, breathable cover to enhance shear and friction protection
- Removable cells and connectors for lower cost servicing
- High frequency welded seams reduce the risk of fluid ingress, supporting infection control protocols
- Quick access CPR for emergency mattress deflation

Apollo Healthcare Technologies Ltd regularly pursues the goal of manufacturing products that are durable and of a superior quality. All required functions are tested prior to delivering products to customers. All our devices are tested before leaving our warehouse.

4. Intended use and Contraindications

Always consult a physician or health professional before using this device. The use of this system does not replace the regular repositioning, monitoring, and nursing of the patient.

4.1. Intended Use

The device is intended to help and reduce the incidence of pressure ulcers while optimizing patient comfort.

4.2. Target population

The Apollo 8 System is suitable for patients with limited mobility who are under medical supervision and monitoring, including those assessed as being 'at risk' to 'very high risk' of pressure damage, as well as individuals with existing tissue damage, based on a combination of clinical judgment and validated assessment tools.

4.3. Intended Users

This product is intended for use by trained healthcare professionals, caregivers, and laypersons (non-professional users).

4.4. Frequency of Use and Reusability

The Apollo 8 System is designed for continuous and repeated use. It may be used for extended periods (hours or days) as required by clinical need. The system can be reused across multiple patients, provided that validated cleaning and disinfection protocols are strictly followed between patients' uses.

4.5. Environment of Use

The **HERA Pump in combination with the Apollo 8 Mattress** is intended to be used in the following environments:

- Hospitals / Medical Facility
- Professional Healthcare Facilities
- Domestic Healthcare

Operation of the device does not require specialized training; however, users are expected to be familiar with standard patient care practices. It is essential that the instructions for use (IFU) provided with the device are read and understood prior to operation to ensure safe and effective use.

4.6. Contraindications

The **Apollo 8 System** is not suitable for:

- Patients who are above the maximum patient weight limit for the associated device
- Patients with cervical or skeletal traction
- Patients with unstable skeletal fractures
- Patients with unstable spinal injury

4.7. Risk assessment

The end user or care provider is responsible for conducting a comprehensive risk assessment for all support surfaces used on electric profiling beds in accordance with the latest guidance from the MHRA ref NatPSA/2023/010/MHRA

5. Warnings, Cautions and General Information

The **Apollo 8 System** is full replacement mattress system. The risk of entrapment may occur when they are used on an **inappropriate** bed frame that leaves gaps between the mattress and head panel, foot panel, and side rails. The **Apollo 8 Mattress** is NOT to be used when such gaps are present.

Where they are used on bed frames, compatibility should be assessed independently, and it is the caregiver / patient's responsibility to ensure the **Apollo 8 Mattress** fits the bed frame correctly.

NOTE **Apollo Healthcare Technologies Ltd is NOT responsible for the placement of the mattress and the head panel, foot panel, or side rail which presents a risk of harm to patients**

When using either mattress system, always ensure that the patient is positioned properly within the confines of the bed. Do not let any parts of the body stick out over the side or between the bed rails when the mattress is being used

The medical professional is responsible for applying his/her best medical judgment when using this system.

- Suitable for continuous use.
- The materials used in the manufacture of all components of the mattress comply with the required fire safety regulations.
- All components of the **Apollo 8 System** are manufactured without the use of latex. This device is suitable for use with patients who have latex sensitivities or allergies.
- Do not allow sharp objects to penetrate the mattress material.
- Do not store in damp conditions.
- Not suitable for use with oxygen or in an oxygen enriched environment.
- This device contains materials that comply with applicable fire safety standards (BS 7175:1989 Crib 5), however, do not use the device in the presence of flammable anaesthetic mixture with oxygen or nitrous oxide. Unplug the pump when using oxygen administering devices other than the nasal mask.
- Do not smoke in bed / on the mattress.
- Do not burn candles in the same room as the bed/mattress.
- Do not use matches or lighters in the vicinity of the bed/mattress.
- Do not have electrical equipment in the vicinity of the bed/mattress e.g. a TV over the bed.
- Do not use electric blankets in combination with the bed / mattress.
- Do not have fires and heaters in the vicinity of the bed / mattress.
- Do not place hot items such as hairdryers or heated appliances on the bed/ mattress.
- If you use a mobility aid keep it within reach of your bed or mattress.
- Do not use in an outdoor environment.
- No part of the medical device should be serviced while it is in use by the patient.
- Not suitable for sterilisation.
- The mattress must be properly set up as directed.
- Do not use abrasive cleaners, phenol disinfectants, solvents or alcohol-based cleansers, e.g., Dettol, Phenicol, Clearsol, Stericol, Hycoline, as these may destroy the cover materials (*see Care and Maintenance in Section 13).

To reduce the risk of electric shock, adhere to the following. Failure to do so could result in injury or equipment damage.

- Immediately after using the **HERA** pump, unplug it from its power source
- Do not place or store the **HERA** pump where it can fall or be pulled into a sink or bath
- Do not place or drop the **HERA** pump into water or other liquid
- Do not remove the back of the **HERA** pump, this could result in potential electric shock hazard.

Water or other liquids can cause corrosion and the pump may not operate as intended and possible cause potential hazards for users.

The above warnings, cautions and any safety considerations should be observed on a routine and regular basis, not only upon installation.

Despite all safety measures, residual risks such as undetected system failure may exist. Regular inspection and patient monitoring are essential.

6, 7 & 8. Installation, Transport and Clinical Procedure

6.1 Installing the HERA Pump with Apollo 8 Mattress

1. Remove the existing mattress from the bed frame and store in a safe place.

2. Place the **Apollo 8 Mattress** on to the bed frame, ensuring the foot symbol is at the foot end and uppermost.

3. Secure the **HERA** pump at the foot of the bed using the hook system on the back of the pump and connect the air hose connectors from the mattress to the pump.

4. Ensure the power cable is connected to the control unit, and fit the cable into the cable management on the side of the mattress base cover if required. Then plug the power cable into a suitable AC outlet.

5. Press the Power ON button to turn the control unit on (see section 9 for further control unit instructions).

6. Once the mattress has fully inflated the pump will sound with 2 audible beeps andthe LED display on the pump will display “ON” and stay in the CLP, at this point the patient can be placed on the mattress.

7. The mattress takes approximately 20 minutes to fully inflate. Once fully inflated and “ON” being on the LED display the mattress will calculate the desired patient’s comfort setting and self-set. This will be confirmed by 2 audible beeps.
   If no patient is placed on the mattress, the pump will self-set to the soft setting and automatically readjust every 2 hours to the patients position / comfort setting.

NOTE	**If the mattress is being used in non-powered mode, it is essential that the control unit is disconnected. If the mattress is being used in powered mode, it is essential that the control unit is connected correctly and switched on.**

6.2 Recommended Linen

Based upon the patients’ specific needs, the following may be utilised:

1. Incontinence barrier pad for patients incontinent of urine and/or stool, and patients with heavily draining wounds.
2. Top sheet, blanket and/or bedspread as needed for patient comfort, however these should not be fitted tightly or tucked into the mattress as hammocking may occur and the therapeutic benefits of the mattress may be compromised.
3. Minimal padding between the patient and the surface to provide optimum performance.

7. Transport Mode

To transport patients or for periods with no power, simply turn off the pump, disconnect the air hose connectors from the pump, and place the transport cap over the air hose connectors.

8. Clinical Procedure

8. Cardiopulmonary Resuscitation (CPR)

Should CPR be required in an emergency, pull the CPR tab located towards the head end of the mattress. The HERA pump can also be quickly and easily detached from the mattress by disconnecting the air hose connectors to further aid rapid deflation of the mattress.

9. Control Unit Functions

1. Power

Press the POWER button to turn the control unit on. When the controlled unit is on, the LED will display the words ‘inF’ (Inflating). To turn the control unit off, press the POWER button. When the control unit is off, no LEDs will display.

The mattress will inflate to a set level of 15mmhg and once fully inflated the pump unit will then bleep and the LED will display “AdJ” (Adjust), at this stage the patient can be placed on the mattress. Once the patient is placed on the mattress the pump will inflate and then calculate the patients required setting. Once completed the pump will then set the required setting and adjust to Dynamic mode.

2. Mode Button

The **HERA** pump has the option of two therapy modes: Continuous Low Pressure (CLP) and Dynamic Low Pressure (Dynamic).

3. Continuous Low Pressure (CLP)

For powered immersion where the cells maintain constant low pressure to maximise patient contact area, press the MODE button until an LED is visible under the Continuous Low Pressure (CLP) icon.

Note: when the control unit is powered on, the system will default to Constant Immersion.

4. Dynamic Low Pressure (Dynamic)

The **HERA** pump can be placed in Dynamic (Dynamic) Low Pressure. This alternates the pressure between the cells in a 1-in-2 cycle to provide periodic off-loading. For this mode, press the MODE button until an LED is visible under the Dynamic Low Pressure (Dynamic) icon.

5. Maximum Inflation

This function will rapidly inflate the cells to maximum pressure (Max Inflate) to allow for a stable surface for repositioning, nursing procedures or entry/exit from the bed. This is an untherapeutic mode, therefore as a safety feature and to avoid accidental use, Max Inflate is locked out. To use Max Inflate, **press and hold** the MODE button until an LED is visible under the Max Inflate icon.

Note: As an additional safety feature, Max Inflate will automatically switch off and default to the last used mode after 20 minutes.

6. Comfort Adjust

The softness/firmness of the mattress may be adjusted to suit individual patient preference. To make the mattress softer, press the COMFORT icon until a LED is visible under the Soft icon. To make the mattress firmer, press the COMFORT icon until a LED is visible under the Firm icon.

Note: when first switched on, the control unit will default to Medium comfort. All comfort settings are within a therapeutic window and will not alter the therapeutic benefits for the patient.

7. Lock/Unlock

The **HERA** pump will automatically lock-out after 30 seconds of inactivity. When the control unit is locked out, no functions can be altered to prevent unauthorised changes of the chosen therapy settings. When the control unit is locked, an LED will be visible adjacent to the LOCK button. To unlock the control unit, press and hold the LOCK/UNLOCK button for 3 seconds until the LED extinguishes.

8. Alarm Functions

The **HERA** pump has both a visual and an audible power failure and low pressure alarm.

If the alarm sounds and the power failure LED is illuminated, ensure the power cord is still connected and plugged in to a wall socket.

If the alarm sounds and the low pressure LED is illuminated, ensure the mattress hoses are securely connected to both the control unit and the mattress.

To silence the alarm, press the SILENCE button.

If the fault cannot be resolved, contact Apollo Healthcare Technologies Ltd or your medical Engineering Team.

9. Calibration Requirements

The **HERA** Pump is factory-calibrated during the manufacturing process. No calibration is required during first installation or during standard operation. The unit is recalibrated during any service or repair conducted by Apollo Healthcare Technologies Ltd or its authorised partners.

10, 11 & 12. Cleaning, Disinfection & Inspection

The Apollo 8 System is a reusable medical device intended for limited, indirect contact with intact skin. The only component with potential patient contact is the top cover of the mattress, which is generally used beneath a bed sheet acting as a barrier. Based on this configuration, the top cover is classified as having limited exposure (<24 hours cumulative contact time) with intact skin. To ensure patient safety, infection control, and long-term performance, the following validated cleaning, disinfection, and inspection procedures must be followed between patient uses and during routine maintenance.

10. Cleaning

In order to prevent cross-contamination, the cleaning and disinfection of the entire **Apollo 8 System** must be carried out between uses with different patients.

The contact with contaminated cleaning fluids can cause infections. Disinfectants can contain harmful substances.

Please follow these Instructions for Use of the manufacturer of the disinfectant and the hygiene of the operator during the cleaning and disinfection. Disconnect the system and wear personal protective equipment: safety glasses, protective gloves, mouth and nose protective. Work on a cleanable surface.

In compatible cleaning agents. The components of the Apollo 8 Mattress are made of thermoplastic polymers. Solvents can spoil synthetic material and coating. Strong acids or alkalis can cause damage.

10.1 General Cleaning

Mattress top covers should be cleaned regularly including between patients' uses.

- Wipe the whole surface of the mattress with a neutral detergent e.g. soap and water, rinse with clean water and dry.
- If a disinfectant wipe is applied to the mattress cover, any residue should be rinsed with clean water after the dwell time phase (normally less than 10 minutes).
- Allow time for the cover to dry (normally less than 10 minutes) or dry with clean paper towels.
- Do not use abrasive or phenolic based cleaners.

10.2 Cleaning the HERA Pump

Remove the power cord from the wall socket before cleaning the control unit. Do not spray any cleaning liquid directly on to the control unit.

- Turn off the control unit and unplug the power cord from the AC outlet (socket).
- Wet a soft cloth with water, mix it with approved or recommended disinfectant solution.
- Wipe off dirt and dust accumulations.
- Then dry the surfaces with a clean, soft cloth.

10.3 Contamination with Blood or Body Fluids

If the mattress top cover is not securely fixed onto the mattress, it could increase the risk of the inners of the mattress becoming contaminated.

- If the mattress top cover is heavily soiled or has been exposed to bodily fluids such as blood, urine or faeces it will require a more thorough cleaning and disinfection procedure.
- Large spillages of blood on the mattress top cover should first be disinfected by use of chlorine-releasing solutions instead of granules.
- Other body fluids should be removed with paper towels followed by use of chlorine-releasing solutions instead of granules.
- The mattress top cover should then be rinsed using clean water with a clean cloth.
- Wipe the cover using a single-use wipe and a 0.1% chlorine solution (1,000ppm) and cold water.
- If required a 1% chlorine solution (10,000ppm) and cold water. Residual chlorine salts should be rinsed with clean water after the chlorine activation phase (normally less than 10 minutes)
- Allow time for the cover to dry (normally less than 10 min) or dry with clean paper towels.

If the mattress cover is soiled or loses its water-resistant properties, it must be replaced. Any resulting damage of the mattress caused by a soiled cover will be not covered by the warranty. Please follow the hygiene control regulations of your local authority.

If the mattress cover is not securely fixed onto the mattress, the cells and cover movement may be unstable and may cause risk of user injury.

11. Disinfection

The operator must be notified about which measures apply to the mattress and the actual hygiene directives for disinfection. The disinfection of the **Apollo 8 Mattress** or parts of it can be performed only by trained personnel, who are familiar with the hygiene requirements of the institution.

11.1 Disinfection Procedures

Please follow the procedure required by your local health authority.

Please follow the hygiene control regulations of your local authority.

12. Inspection

The safe operating condition of the **Apollo 8 System** has to be checked at each use by the operator or during use by the patients and at least once in a year in particular with regards to the following:

- Condition of the air hoses.
- Condition of the air and foam cells.
- Condition of the cover.
- Check the main power cord and plug are not excessively worn or cut.
- Check the filter is not excessively dirty or clogged.

13. Care and Maintenance

13.1 Mattress - Exterior Components

- Inspect the cover for signs of damage or wear which could result in the contamination of the interior, e.g., tears, holes, damage to seams or zips, underside staining, etc. The frequency of these checks should be at each decontamination process, i.e., between patients or patient occupancy (or weekly for longer term patients).
- Care should be taken to avoid puncturing the cover with objects such as needles, scalpels, pat slides, acrylic nails, etc.
- Always keep the cover as clean as is practicable. The material is waterproof and vapour permeable.
- Frequent or prolonged exposure to high concentrations of aggressive disinfectant solutions will reduce the useful life of the cover.
- Where high concentration disinfectants e.g., > 1,0000ppm chlorine releasing agent (e.g., Haztab or bleach) or combined cleaning/chlorine releasing agent and detergent solutions are used to remove blood or other body fluids, covers should be thoroughly rinsed with clean water to remove any residues. This will help prevent any possible long term compatibility issues associated with disinfectant residues.
- Alternatively, disinfection may be achieved by laundering cover at temperatures not exceeding 95°C for 10 to 15 minutes.
- Do not use abrasive cleaners, phenol disinfectants, solvents or alcohol-based cleansers, e.g. Dettol, Phenicol, Clearsol, Stericol, Hycoline, as these may destroy the cover materials (see Section 10 for Cleaning details).
- Do not iron and do not bleach.
- Ensure that the cover is thoroughly dried before remaking the bed or placing in storage.

13.2 Mattress - Interior Components

- Check air cells and mattress interior for signs of damage or contamination e.g., staining or evidence of fluid ingress. The frequency of these checks should be at each decontamination process, i.e., between patients or patient occupancy (or weekly for longer term patients).
- Care should be taken to avoid puncturing air cells with objects such as needles, scalpels, pat slides, acrylic nails, etc.
- All cells are replaceable and can be obtained easily from Apollo Medical Technologies Ltd.

13.3 Control Unit

- Inspect the condition of the main power cord and plug for signs of excessive wear or tears. If cord is torn, immediately remove the plug form the AC socket and replace the power cord.
- Inspect the condition of the filter. If it is dirty if can be cleaned with soap and water. Ensure filter is fully dry before re-using. Replacement filters can be purchased and used if filter is excessively dirty or damaged.
- Inspect the condition of the outer casing including control panel for signs of damage or cracking, especially if the control unit has received rough treatment e.g., dropped onto a hard surface. If the outer casing is damaged in any way, immediately stop using the pump, unplug from AC socket and contact Apollo Healthcare Technologies Ltd or medical engineering team.

13.4 Control Unit - Air Filter

Refer to Fig. 00001, gently press air filter cover securing tab (1) and pivot air filter cover (2) away from control unit. Remove air filter (3). Inspect the condition of the air filter. If the air filter is dirty, clean it with soap and water. Ensure the air filter is completely dry before reuse. If it cannot be adequately cleaned, replace as necessary, see Spares and Accessories for additional information.

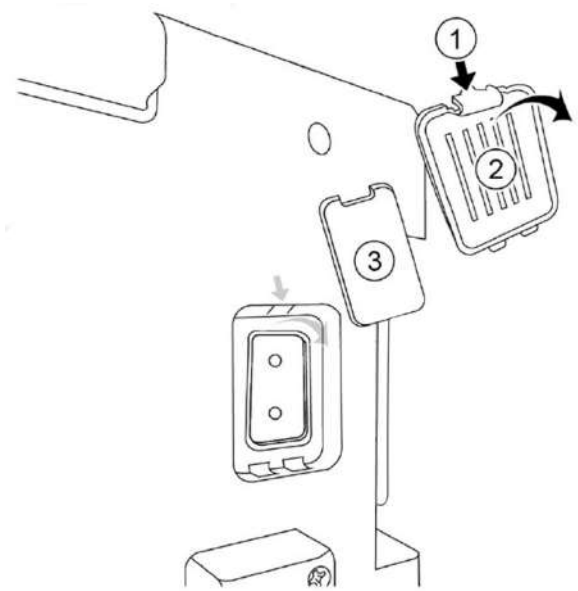

Fig. 00001

13.5 Servicing

To prevent an unacceptable risk, all information necessary for correct replacement of detachable or interchangeable parts should be available and replaced by qualified service personnel only.

Before returning any product for repair, service, warranty assessment, or investigation, the product must be fully decontaminated. A signed and completed decontamination certificate must be enclosed with the returned product. Products returned without this certificate will not be accepted for processing.

14. Storage, Transport and Disposal

14.1 Storage and Transport

Thoroughly wipe down the outside of the support surface and control unit as described in previous section and allow to air dry prior to storage.

The mattress should be deflated & rolled & stored in holdall supplied.

The control unit should be placed into the original packaging that it came with in order to fully protect it whilst in storage. If original packaging is not available, wrap in bubble wrap and place in cardboard box.

Handle with care. Please report instances of damage or impact to Apollo Healthcare Technologies Ltd Service Personnel.

Operational and Storage Conditions

- An operating temperature range of +5°C to +40°C
- A storage temperature range of -15°C to +70°C
- A relative humidity range of 10% to 90%, non-condensing;

Suitable for all standard modes of transport when in the correct packaging.

14.2 Disposal

- The **Apollo 8 Mattress** must be decontaminated before disposal.
- The **HERA** pump must be disposed of observing the proper disposal of electrical & electronic equipment WEEE regulations.

The disposal of mattress in accordance with the local regulations.

15. Troubleshooting

The HERA pump is not adjusting in powered mode:

- Ensure the hose connection from the mattress to the control unit is securely connected.
- Verify that the control unit is in the correct therapy mode you require (e.g. continuous low pressure or dynamic low pressure)
- Verify that the control unit is plugged into a suitable AC outlet.
- Ensure that the Power light is illuminated.

If the fault cannot be resolved after checking the above, contact Apollo Healthcare Technologies Ltd or your Medical Engineering Team.

16. Electromagnetic Compatibility (EMC)

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the **HERA pump**, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

The purpose of this testing is to ensure the **HERA pump** 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 **HERA pump**.

Despite the testing of the **HERA pump** that has been undertaken, normal operation of the **HERA pump** can be affected by:

Using cell phone or microwave oven, HF surgical equipment, magnetic resonance imaging or other radio radiant equipment near this product may cause malfunction or lead to loss of essential performance.

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

<table>
<tr><th colspan="3">Guidance and manufacture’s declaration – electromagnetic emission</th></tr>
<tr><td colspan="3">The HERA pump is intended for use in the electromagnetic environment specified below. The customer or the user of the HERA pump should assure that it is used in such an environment.</td></tr>
<tr><th>Emission test</th><th>Compliance</th><th>Electromagnetic environment – guidance</th></tr>
<tr><td>Conducted and Radiated RF emissions
CISPR 11</td><td>Group 1</td><td>The HERA pump 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.</td></tr>
<tr><td>Conducted RF emissions
CISPR 11</td><td>Class B</td><td rowspan="4">The HERA pump is suitable for use in all establishments, including professional/domestic and those not directly connected to the public low-voltage power supply network that supplies buildings used for professional/domestic purposes except for near active HF surgical equipment and the RF shielded room for magnetic resonance imaging.</td></tr>
<tr><td>Radiated RF emissions
CISPR 11</td><td>Class B</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations and flicker emissions
IEC 61000-3-3</td><td>Complies</td></tr>
</table>

Guidance and manufacture's declaration – electromagnetic immunity			
The **HERA pump** is intended for use in the electromagnetic environment specified below. The customer or the user of the **HERA pump** should assure that it is used in such an environment.			
Immunity test	**IEC 60601-1-2 test level**	**Compliance level**	**Electromagnetic environment-guidance**
Electrostatic discharge IEC 61000-4-2	±8kV contact; ±2kV, ±4kV, ±8kV, ±15 kV air	±8kV contact; ±2kV, ±4kV, ±8kV, ±15kV 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 transients/bursts IEC 61000-4-4	±2kV AC power supply lines; ±1kV DC power/Signal lines. 100 kHz repetition frequency	±2kV for AC power supply lines 100 kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
Surges IEC 61000-4-5	±0.5kV, ±1kV lines to lines; ±0.5kV, ±1kV, ±2kV lines to earth	±0.5kV, ±1kV lines to lines	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips IEC 61000-4-11	0% U_T, 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°; 0% U_T, 1 cycle and 70% U_T, 25/30 cycle Single phase: at 0°	0% U_T, 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°; 0% U_T, 1 cycle and 70% U_T, 25/30 cycle Single phase: at 0°	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Apollo 8 Mattress Control Unit requires continued operation during power mains interruptions, it is recommended that the Apollo 8 Mattress Control Unit be powered from an uninterruptible power supply or a battery.
Voltage interruptions IEC 61000-4-11	0% U_T, 250/300 cycle	0% U_T, 250/300 cycle	
Rated power frequency magnetic fields IEC 61000-4-8	30A/m 50Hz or 60Hz	30A/m 50Hz	Power frequency magnetic fields should be at levels characteristic 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. E.g.: 25/30 means 25 periods at 50 Hz or 30 periods at 60 Hz. 250/300 means 250 periods at 50 Hz or 300 periods at 60 Hz.			

Guidance and manufacture's declaration – electromagnetic immunity			
The **HERA pump** is intended for use in the electromagnetic environment specified below. The customer or the user of the **HERA pump** should assure that it is used in such an environment.			
Conducted disturbances induced by RF fields IEC 61000-4-6	3Vrms in 0.15MHz – 80MHz; 6Vrms in ISM bands between 0.15MHz and 80MHz (Professional healthcare facility environment), 6Vrms in ISM and amateur radio bands between 0.15MHz and 80MHz (Home healthcare environment)	3Vrms in 0.15MHz – 80MHz, 6Vrms in ISM and amateur radio bands between 0.15MHz and 80MHz (Home healthcare environment)	Portable and mobile RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer to any part of the Apollo 8 Mattress Control Unit including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
	80% AM at 1kHz	80% AM at 1kHz	
Radiated RF EM fields IEC 61000-4-3	3V/m (Professional healthcare facility environment); 10V/m (Home healthcare environment), 80MHz – 2.7GHz 80% AM at 1kHz	10V/m (Home healthcare environment) 80MHz – 2.7GHz 80% AM at 1kHz	Recommended separation distance: $d = 1,2\sqrt{P}$ $d = 1,2\sqrt{P}$ 80Hz to 800MHz $d = 1,2\sqrt{P}$ 800MHz to 2,7GHz Where *P* is the maximum output power rating of the transmitter manufacturer and *d* is the recommended separation distance in metres(m). Interference may occur in the vicinity of equipment marked with the following symbol: 
Note: The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.			

Recommended separation distance between
Portable and mobile RF communications equipment and HERA pump

The **HERA pump** is intended for use in the electromagnetic environment (for home and professional healthcare) in which radiated RF disturbances are controlled. The customer or the user of the **HERA pump** can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **HERA pump** 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		
	150kHz to 80 MHz $d = 1,2\sqrt{P}$	80MHz to 800 MHz $d = 1,2\sqrt{P}$	800MHz to 2,7 GHz $d = 1,2\sqrt{P}$
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

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE1 At 80MHz and 800Mhz, the separation distance for the higher frequency range applies.

NOTE2 These guidelines may not apply in all situations Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Guidance and manufacture's declaration – electromagnetic immunity

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

The **HERA pump** is intended for use in the electromagnetic environment specified below. The customer or the user of the **HERA pump** should assure that it is used in such an environment.

Test frequency (MHz)	**Band** [a] (MHz)	**Service** [a]	**Modulation**	**Maximum Power (W)**	**Distance (m)**	**Immunity Test Level** (V/m)	**Compliancy Level** (V/m) (for home and professional healthcare)
385	380 – 390	TETRA 400	Pulse modulation [b] 18 Hz	1,8	0,3	27	27
450	430 – 470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	2	0,3	28	28
710	704 – 787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0,2	0,3	9	9
745							
780							
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0,3	28	28
870							
930							
1 720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0,3	28	28
1 845							
1 970							
2 450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0,3	28	28
5 240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0,2	0,3	9	9
5 500							
5 785							

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

a) For some services, only the uplink frequencies are included.

b) The carrier shall be modulated using a 50 % duty cycle square wave signal.

c) As an alternative to FM modulation, the carrier may be pulse modulated using a 50 % duty cycle square wave signal at 18 Hz. while it does not represent actual modulation, it would be worst case.

17. Technical Specification

The **Apollo 8 System (APH053/HERA)** is suitable for continuous operation.

HERA Pump Specifications	
Model Reference:	APH500/3W
Control Unit Weight:	1.8kg
Control Unit Dimensions:	28cm x 17cm x 12cm
Power Supply:	AC 220-240V 50Hz, 0.09A
Fuse Rating:	T1AH 250V
Cycle Time:	10 minutes
Pressure Range:	30 – 50 mmHg
Flow Rate:	9 LPM
Expected service life:	5 years
Specified shelf life:	2 years

Apollo 8 Mattress Specifications	
Model Reference:	APH053/MATT
Mattress Weight:	9kg
Mattress Dimensions:	200cm x 90cm x 20cm
Max. Patient Weight	200kg
Cells Material:	Nylon TPU
Top Cover Material:	Polyurethane coated polyester 200gsm
Base Cover Material:	600D Nylon coated PVC
Fire Retardancy:	BS 7175:1989 Crib 5
Expected service life:	5 years
Specified shelf life:	2 years

18. Consumables and Spare Parts

Catalogue No	Description
APH053/MATT	Apollo 8 Mattress
APH053/TC	Apollo 8 Top Cover
APH053/BC	Apollo 8 Bottom Cover
APH053/CELL	Apollo 8 Replacement Cell

NOTE **USE ONLY APOLLO HEALTHCARE TECHNOLOGIES LTD. CONSUMABLES AND ACCESSORIES.**

19. Product Conformance Standards

The HERA pump and the Apollo 8 Mattress are developed in conformance with ISO 13485 Quality management system, ISO 14971 Risk Management, ISO 10993 Biocompatibility, Electrical Safety IEC 60601-1, Electro Magnetic Compatibility (EMC) 60601-1-2, UK Medical Device Regulation 2002 (#618) and Medical Device Regulation (EU MDR 2017/745).

The consumables and accessories section of this IFU are in conformance with NICE guidelines.

20. Warranty

All internal mattress components, mattress top cover, control unit, and electrical components are covered by a 24 months manufacturer's warranty. Damages arising from improper use will not be covered by this warranty. Improper use is defined as those caused by burns, chemicals, excessive loads, staining, cuts or abrasions, improper maintenance including handling and/or cleaning.

Any deviations from intended use may result in performance of the mattress and is excluded from warranty and liability.

All warranties subject to terms and conditions of trading.

> ***NOTE*** **Normal wear and tear is NOT included in the manufacturer's warranty.**

In order to claim **product** under warranty refer to the serial/batch number printed on the product label.

Summary patient care instructions are also printed on the mattress outer cover.

21. Contact Us

Apollo Healthcare Technologies Ltd. customer service is available to answer questions. Our sales team is available for pricing and order processing and order status.

Also, in the event of complaints, questions regarding the product, service support or reporting of incidents, please contact the following Apollo Healthcare Technologies Ltd.

Notify the competent authority if you suspect or have reason to believe that the device poses a serious risk or has been tampered with.
All serious incidents related to the device must be reported to the manufacturer and the competent authority in the member state where the user and/or patient resides.

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