

APH168 Apollo Pro Plus 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/user is responsible for reading and understanding the 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.

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1. Convention Used in This Instructions for Use

This Instructions of use includes information essential to the safety of the user, personnel and equipment during normal operation of the Apollo Pro Plus System. The safety information is displayed in this Instructions of use 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 something 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
	Catalogue Number		Serial Number		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 Not Use 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
	Medical Device under EU MDR 2017/745		Authorised Representative in the European Union		Foot End
	The Unique Device Identifier		Max Patient weight defines the maximum total load of the patient kg (lb)		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.				
	Conformité Européenne (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 Pro Plus System. The product benefits from a uniquely designed cell configuration in order to ensure the best possible pressure relieving qualities. The patented cell technology offers a revolutionary 'Very High Risk' dynamic mattress, ensuring optimum patient comfort and safety.

The Apollo Pro Plus System features include:

- 'Cell on Cell' replacement system with static base
- Adjustable weight settings
- Timed static switch to assist in patient transfer and for good nursing practice
- Auto-lockout function
- Manual adjustment to patient's body shape and position for optimum pressure care
- Dynamic mode for alternating action for lower interface pressures and gentle capillary stimulation
- Enhanced shear and friction protection
- Autofirm option to inflate the mattress to maximum pressure to allow safe patient transfer
- Audio and visual alarms to differentiate between low pressure and alternating failure; visual low battery warning to alert the user or carer during use
- CPR function to ensure rapid deflation of mattress
- Welded vapour permeable multi stretch PU cover to enhance shear and friction protection, and prevent fluid ingress and internal mattress contamination
- Clinically effective against bacteria / viruses with proven resistance to MRSA
- Lithium-ion battery back-up for up to 8 hours in case of power failure

Clinical benefits: Apollo Pro Plus System provides clinical benefit by reducing the risk of pressure ulcer formation, supporting the healing of existing tissue damage, and improving patient comfort. This is achieved through alternating pressure redistribution and customizable support settings tailored to the patient.

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

Standard adults with limited mobility who are under medical supervision and monitoring. This includes individuals assessed as being “at risk” to “very high risk” of pressure damage, as well as those 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 Pro Plus 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 Apollo Pro Plus System 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 Pro Plus System is not suitable for:

- Patients above the maximum patient weight listed 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 patient 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

5.1. Warnings, Cautions and General Information



The Apollo Pro Plus Mattress is a dynamic replacement mattress. The risk of entrapment may occur if the mattress is used on an **inappropriate** bed frame that leaves gaps between the mattress and head panel, foot panel, and side rails. The Apollo Pro Plus Mattress is **NOT** to be used when such gaps are present.

Where the Apollo Pro Plus Mattress is used on bed frames, compatibility should be assessed independently, and it is the caregiver / user's responsibility to ensure the Apollo Pro Plus Mattress fits the bed frame correctly.



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



When using the 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 Pro Plus 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 Atlas Pump for Pro Plus, unplug it from its power source
- Do not place or store the Atlas Pump for Pro Plus where it can fall or be pulled into a sink or bath
- Do not place or drop the Atlas Pump for Pro Plus into water or other liquid
- Do not remove the back of the Atlas Pump for Pro Plus, this could result in potential electric shock hazard.



Water or other liquids can cause corrosion and the control unit 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. Installation

6.1. Installing the Apollo Pro Plus Mattress & Control Unit

1. Remove the existing mattress from the bed frame and store in a safe place.
2. Place the Apollo Pro Plus Mattress on to the bed frame, ensuring the foot symbol is at the foot end and uppermost.
3. Place linen, if required, on the mattress. (see section 6.3 for recommended linen).
4. Secure the Atlas Pump for Pro Plus on to the footboard of the bed frame using the securing hooks. Alternatively, the control unit may be placed on a flat surface.
5. Connect the air hose connectors from the mattress to the pump, ensuring the connection is completely secured and the air hoses are not kinked or tucked under the mattress.
6. Ensure the power cable is connected to the control unit and plugged in to a suitable AC outlet.
7. Switch on the primary power switch on the side of the pump, then press the power button to turn on the control unit (see section 9 for further control unit instructions.)
8. We recommend putting the pump into Max Inflate mode at first in order to rapidly inflate all the cells.
9. Once the mattress is ready, place the patient on the Apollo Pro Plus Mattress and adjust the comfort setting to their desired level.



The pump can only be used for the mattress recommended by the Manufacturer. Do not use for any other purpose.

6.2. Disconnecting the Apollo Pro Plus Mattress & Control Unit

1. Ensure that the patient is off the mattress.
2. Turn off the control unit (see section 9 for control unit instructions).
3. Pull the CPR tab to allow the air to rapidly exit the mattress.
4. To disconnect the control unit from the mattress, locate the air hose block at the side of the pump, and squeeze the top and bottom levers simultaneously to release.
5. Unplug the control unit from the AC outlet.

6.3. 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 Apollo Pro Plus Mattress may be compromised.
3. Minimal padding between the patient and the surface to provide optimum performance.

7. Transport Mode

To transport patients, set the mattress to Static Mode Mode. Once the mode is ready, 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

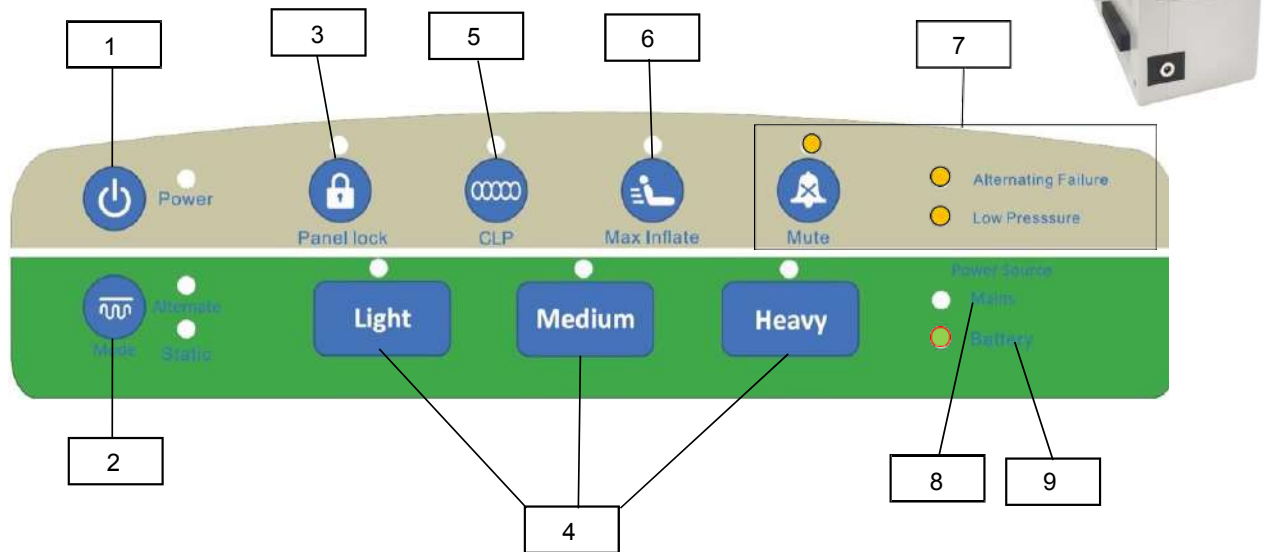
8.1. Cardiopulmonary Resuscitation (CPR)

Should CPR be required in an emergency, pull the CPR tab located towards the head end of the mattress.

Disconnect the control unit from the mattress to further aid rapid deflation of the mattress.

9. Control Unit Functions

The Atlas Pump for Pro Plus is operated by simple tactile control.



1. Power

This button is a secondary switch. After switching on the primary power switch on the side of the pump, press this button to turn the control unit on, and the indicator light will turn green. Press the button again to turn off the pump, or the light will go out in case of a power failure.

2. Mode Button

Pressing the mode button switches between 'alternate' and 'static' modes. Depending on the selected function, the corresponding light will illuminate. As a safety feature, the pump automatically switches from static to alternating after 30 minutes.

3. Panel Lock

If no buttons are pressed within 2 minutes, the panel will automatically lock. The light will illuminate to indicate the panel is locked. To unlock it, hold down the button for 2 seconds.

4. Comfort Adjust

Adjust the comfort setting by pressing the desired button. The weight settings should only be used as a comfort setting and as a guide in conjunction with a qualified Clinicians advice for each individual patient.

Level	Light	Medium	Heavy
Alternating pressure	25mmHg	40mmHg	55mmHg
Pressure at static	30mmHg	30mmHg	30mmHg
CLP pressure	15mmHg	20mmHg	25mmHg
Max Inflate	60mmHg		

NOTE Check if the pressure is suitable for the patient by sliding one hand beneath the air cells at the level of the patient's buttocks. Always leave at least 1 inch space between patient and the static cell to prevent bottoming out.

5. CLP Mode

This mode is for patients who cannot tolerate alternating therapy. In this mode, the pressure is continuously maintained at a low level and will not automatically switch to other modes. The user can activate CLP mode by pressing and holding the key for at least 3 seconds.

6. Maximum Inflation

The user can start Max Inflate mode by pressing this button. The maximum pressure in this mode is 60mmHg. As a safety feature, the pump will automatically switch off Max Inflate and return to the previously selected mode after 20 minutes.

7. Alarms Mute Function

When either the fault or power failure alarm is triggered, pressing this button will temporarily silence the alarm while the issue is being fixed.

Low pressure alarm: After normal work, if the mattress is leaking due to the quick connection and fall off, the low pressure alarm function will be triggered after 2 minutes if the pressure is too low. Press alarm mute button to temporary suspend the alarm. If the situation did not resolve in 5 minutes, the alarm will resume to notify the caregiver.

Alternating fail alarm: In the normal alternate mode, if the solenoid valve broken, causing the alternate function to fail, the alternating failure alarm function will be triggered after 2 minutes, and the indicator will light up in orange. Press alarm mute button to temporary suspend the alarm. If the situation did not resolve in 5 minutes, the alarm will resume to notify the caregiver.

8. Mains Power Source Indicator

When the pump is connected to the power supply and the primary power switch is turned on, the Mains indicator will light up green, and the battery will charge. If there is no power or the primary power switch is turned off, the Mains indicator will be off.

9. Battery Level Indicator

When the pump is using the battery, there will be double beep every 30 minutes notifying the caregiver that battery mode is being used, along with the visual LED on the panel.

The battery level indicator shows the battery charge level in different colours.

Battery Charge Level	High	Medium	Low
Colour of light	Green	Orange	Red

When the battery is low, the LED on the panel will flash constantly notifying the caregiver, and they will need to put the mattress in transport mode.

10. Calibration Requirements

The Atlas Pump for Pro Plus 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 Pro Plus 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 Pro Plus 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.



Incompatible cleaning agents. The components of the Apollo Pro Plus System 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 Control Unit



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) (for example: Haztab or Chlorclean) 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 top cover is soiled or loses its water-resistant properties, it must be replaced. Any resulting damage of the mattress caused by a soiled top 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 Apollo Pro Plus System and the actual hygiene directives for disinfection. The disinfection of the Apollo Pro Plus System 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 Pro Plus 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 cells and foam underlay.
- 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., > 10,000ppm 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 Healthcare 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 from the AC socket and replace the power cord.
- Inspect the condition of the filter. If it is dirty it 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. Pump – Parts Replacement

Fuse Replacement

- (1) Disconnect the plug from mains power when a blown fuse is suspected.
- (2) Remove the cover of the fuse holder by means of a small screwdriver.
- (3) Insert a new fuse of the correct rating(T1AH/250V, 2 pcs), and replace the cover of the fuse holder.

Air Filter Replacement

- (1) Replace the air filter located at the handle back of the pump.
- (2) The filter is reusable and can be washed gently with a mild detergent and water. Dry the filter before use.
- (3) Check and replace air filter regularly if environment is dirty.

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 +35°C
- A storage temperature range of -15°C to +50°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 Pro Plus Mattress must be decontaminated before disposal.
- The Atlas Pump for Pro Plus 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

Trouble	Possible Reasons/Solutions
Q1. Power is not on	<ul style="list-style-type: none"> • Check if the pump battery has power. • Check for a blown fuse.
Q2. Low Pressure Alarm is on	<ul style="list-style-type: none"> • Check if the Quick Connector is tightly secured. • Check if all tubing connections along mattress are secured. • Check if the air hoses broken.
Q3. Alternating Failure Alarm is on	<ul style="list-style-type: none"> • Check if the solenoid valve is broken.
Q4. Patient is bottoming out	<ul style="list-style-type: none"> • Pressure setting might be inadequate for the patient, adjust comfort range 1 to 2 levels higher and wait for a few minutes for best comfort or low pressure alarming is happening an check Q2.
Q5. Mattress form is loose	<ul style="list-style-type: none"> • Check if all the snap buttons or straps of mattress are all securely fastened. • Check if the mattress is fixed to the bed frame by straps.
Q6. No air produced from some air outlets of the air tube connector	<ul style="list-style-type: none"> • This may normal since there is alternating mode. Air outlets take turns to produce air during their cycle time. If the air outlets keep no air output always then refer Q3.

If the problems persist after checking all the possible reasons, please contact Apollo Healthcare Technologies Ltd. technical support or your medical Engineering Team.

Before calling, please ensure you have the serial number and model of equipment

16. Electromagnetic Compatibility (EMC)



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.



Use of adapter or USB cable other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.



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 Control Unit, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Guidance and manufacture's declaration – electromagnetic emission

The Atlas Pump for Pro Plus is intended for use in the electromagnetic environment specified below. The customer of the user of the Atlas Pump for Pro Plus should assure that it is used in such an environment.

Emission test	Compliance	Electromagnetic environment – guidance
Conducted and Radiated RF emissions CISPR 11	Group 1	The Atlas Pump for Pro Plus 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.
Conducted RF emissions CISPR 11	Class B	The Atlas Pump for Pro Plus 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.
Radiated RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations and flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacture's declaration – electromagnetic immunity			
The Atlas Pump for Pro Plus is intended for use in the electromagnetic environment specified below. The customer of the user of the Atlas Pump for Pro Plus 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, ±15kV 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%.
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	
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.
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) 80% AM at 1kHz	3Vrms in 0.15MHz – 80MHz, 6Vrms in ISM and amateur radio bands between 0.15MHz and 80MHz (Home healthcare environment) 80% AM at 1kHz	

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.

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.
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 Atlas Pump for Pro Plus requires continued operation during power mains interruptions, it is recommended that the Atlas Pump for Pro Plus 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 cycles	

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 Atlas Pump for Pro Plus is intended for use in the electromagnetic environment specified below. The customer of the user of the Atlas Pump for Pro Plus should assure that it is used in such an environment.

Immunity test	IEC 60601-1-2 test level	Compliance level	Electromagnetic environment-guidance
Proximity fields from RF wireless communications equipment IEC 61000-4-3	See the following table	Complies	

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications Equipment

Test frequency (MHz)	Band ^{a)} (MHz)	Service ^{a)}	Modulation ^{b)}	Maximum power (W)	Distance (m)	Immunity Test Level (V/m)
385	380 - 390	TETRA 400	Pulse modulation ^{b)} 18Hz	1,8	0,3	27
450	430 - 470	GMRS 460, FRS 460	FM ^{c)} ± 5 kHz deviation 1 kHz sine	2	0,3	28
710	704 - 787	LTE Band 13, 17	Pulse modulation ^{b)} 217 Hz	0,2	0,3	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
870						
930						
1720	1700 - 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation ^{b)} 217 Hz	2	0,3	28
1845						
1970						
2450	2400 - 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation ^{b)} 217 Hz	2	0,3	28
5240	5100 - 5800	WLAN 802.11 a/n	Pulse modulation ^{b)} 217 Hz	0,2	0,3	9
5500						
5785						

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, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

The MANUFACTURER should consider reducing the minimum separation distance, based on RISK MANAGEMENT, and using higher IMMUNITY TEST LEVELS that are appropriate for the reduced minimum separation distance. Minimum separation distances for higher IMMUNITY TEST LEVELS shall be calculated using the following equation:

$$E = \frac{6}{d} \sqrt{P}$$

Where P is the maximum power in W, d is the minimum separation distance in m, and E is the IMMUNITY TEST LEVEL in V/m.

17. Technical Specification

The Apollo Pro Plus System is suitable for continuous operation.

Apollo Pro Plus Mattress Specifications

Model Reference:	APH168M
Mattress Weight:	13.2 kg
Mattress Dimensions:	200cm x 120cm x 20cm
Max. Patient Weight:	350 kg
Cell Configuration:	4 static, 16 figure of 8 cells
Top Cover Material:	Polyurethane coated polyester
Fire Retardancy:	BS 7175:1989 Crib 5
Expected service life:	5 years
Warranty:	2 years

Atlas Pump for Pro Plus Specifications

Model Reference:	APH320/BARI
Control Unit Weight:	2.8kg
Control Unit Dimension:	36cm x 21cm x 12cm
Power Supply:	100-240Vac50/60Hz, 1.5A max
Fuse Rating:	T1AH 250V (2 pcs)
Cycle Time:	10 minutes
Pressure Range:	15 - 60mmHg
Expected service life:	5 years
Warranty:	2 years

Environment	Atmospheric Pressure	80kPa to 106kPa
	Temperature	Operation: 5°C to 35°C Storage: -15°C to 50°C Shipping: -15°C to 50°C
	Humidity	Operation: 10% to 90% non-condensing Storage: 10% to 90% non-condensing Shipping: 10% to 90% non-condensing
Classification	Class II, Type BF, IP21 Applied Part: Air Mattress Not suitable for use in the presence of a flammable anaesthetic mixture (No AP or APG protection)	

18. Consumables and Spare Parts

Part No.:	Description:
APH168/TC	Apollo Pro Plus Top Cover
APH168/BC	Apollo Pro Plus Bottom Cover
APH168/CELL	Apollo Pro Plus Body Cell
APH168/HEADCELL	Apollo Pro Plus Head Cell
APH320/BARI	Atlas Pro Plus Plus
APH320/BAT	Replacement Battery for Atlas Pump Range
APH320/CONN2W	Connector for Atlas Pro Plus Range
APH320/FILTER	Replacement Filter for Atlas Pump Range
APH320/FUSE	Replacement Fuse for Atlas Pump Range
APH320/POWERAD	Power Adapter for Atlas Pump Range
APH320/POWERJACK	Power Jack Round for Atlas Pump Range



NOTE

USE ONLY APOLLO HEALTHCARE TECHNOLOGIES LTD. CONSUMABLES AND SPARE PARTS.

19. Product Conformance Standards

The Apollo Pro Plus System is 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 spare parts section of this IFU are in conformance with NICE guidelines.

20. Warranty

All internal mattress components are covered by a 24 month manufacturer's warranty. The control unit and electrical components are covered by a 24 month 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 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 a 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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