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Domus 1 Operation Manual
Alternating Bubble System

Care for a Healthy Life

APEX

IMPORTANT SAFEGUARDS

READ ALL INSTRUCTIONS BEFORE USING

DANGER - To reduce the risk of electrocution:

1. Always unplug this product immediately after using.
2. Do not use while bathing.
3. Do not place or store this product where it can fall or be pulled into a tub or sink.
4. Do not place in or drop into water or other liquid.
5. Do not reach for a product that has fallen into water. Unplug immediately.

WARNING - To reduce the risk of burns, electrocution, fire or injury to persons:

1. Evaluate patients for entrapment risk according to protocol and monitor patients appropriately.
2. This system is not for use with patients who have a spinal cord injury.
3. Close supervision is necessary when this product is used on or near children. Electrical burns or choking accident may result from a child swallowing a small part detached from the device.
4. Use this product only for its intended use as described in this manual. Do not use other mattress not recommended by the manufacturer.
5. Never operate this product if it has a damaged cord or plug, if it is not working properly, if it has been dropped or damaged, or dropped into water. Return the product to your supplier or Apex Medical Corp. for examination and repair.
6. Keep the cord away from heated surfaces.
7. Never block any air openings of this product or place it on soft surfaces, such as a bed or couch, where openings may be blocked. Keep the air opening free of lint, hair, and other similar particles.
8. Never drop or insert any object into any opening or hose.
9. Do not modify this equipment without authorization of the manufacturer.
10. Do not directly contact mattress without top cover. Apex medical corp. provides optional covers that have passed skin sensitization and skin irritation test. However, if you suspect that you may have had or are having an allergic reaction, please consult a physician immediately.
11. Do not leave long lengths of tubing around the top of your bed. It could lead to strangulation

CAUTION –

If there is a possibility of electro-magnetic interference with mobile phones, please increase the distance (3.3m) between devices or turn off the mobile phone.

NOTE, CAUTION AND WARNING STATEMENTS:

NOTE - Indicate some tips.

CAUTION - Indicate correct operating or maintenance procedures in order to prevent damage to or destruction of the equipment or other property

WARNING - Calls attention to a potential danger that requires correct procedures or practices in order to prevent personal injury.

1. INTRODUCTION

This manual should be used for initial set up of the system and for reference purposes.

1.1 General Information

The system is a high quality and affordable mattress system suitable for treatment and prevention of pressure ulcers.

The system has been tested and successfully approved to the following standards:

CE 0197

EN 60601-1
EN 60601-1-2
EN 61000-3-2 Class A
EN 61000-3-3
CISPR 11 Group 1, Class B

EMC Warning Statement

This equipment has been tested and found to comply with the limits for medical devices to the EN 60601-1-2. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device.
- Increase the separation between the equipment.
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.
- Consult the manufacturer or field service technician for help.

Intended Use

This product is intended:

- to help and reduce the incidence of pressure ulcers while optimizing patient comfort.
- for long term home care of patients suffering from pressure ulcers.
- for pain management as prescribed by a physician.

The product can only be operated by personnel who are qualified to perform general nursing procedures and have received adequate training in knowledge of prevention and treatment of pressure ulcers.

⚠ **NOTE:** This equipment is not suitable for use in the presence of flammable anesthetic mixture with air or with pure oxygen or nitrous oxide.

1.2 Warranty-

The Company warrants the pump at the time of its original purchase and for the subsequence time of period of one year.

The company warrants the bubble pad at the time of its original purchase and for the subsequence time of period of six months.

The warranty does not cover the followings:

1. The series number label of pump or pads is turn off or cannot be recognized.
2. Damage to the pump or bubble pad resulting from misconnections with other devices.
3. Damage to the device resulting from accidents.

Manufacturer.

EC REP Authorized representative in the European community.

Attention, should read the instructions.

Class II Equipment.

"BF" symbol, indicate this product is according to the degree of protecting against electric shock for type BF equipment.

IP21 Protected against solid foreign objects of 12.5 mm and greater. Protection against vertically falling water drops (Model:9P-047580, 9P-047500)

Refer to instruction manual/ booklet/NOTE on ME EQUIPMENT "Follow instructions for use

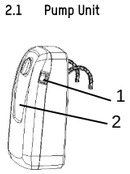
Temperature Limitation

Waste Electrical & Electronic Equipment (WEEE): This product should be handed over to an applicable collection point for the recycling of electrical and electronic equipment. For more detailed information about the recycling of this product, please contact your local city office, household waste disposal service or the retail store where you purchased this product.

SYMBOL DEFINITION

2. PRODUCT DESCRIPTION

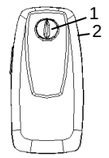
2.1 Pump Unit



Front
1. Power Switch
2. Front Panel

Rear
3. Air Hose Port
4. Hanger
5. Power Cord

2.2 Front panel

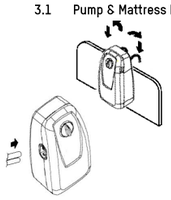


1. **Pressure Adjust Knob**
   Pressure adjust knob controls the air pressure output. Please consult the physician for a suitable setting.
2. **Main Power Switch**
   To turn the pump unit on/off.

3. INSTALLATION

Unpack the box and check the package contents for completeness. If there are any damages, please immediately contact your supplier or Apex Medical Corp

3.1 Pump & Mattress Installation



1. Place the bubble pad or mattress on top of the bed frame. Secure the mattress firmly by fixing the straps to the bed frame if available.
   ⚠NOTE: Please cover the mattress with a cotton sheet if using bubble pad to enhance comfort
   ⚠NOTE: Please cover the mattress with a top cover to avoid direct skin contact with mattress. Consumer may contact Apex Medical Corp for optional mattress covers which have passed skin sensitization and skin irritation test.
2. Hang the pump onto the footboard and adjust hangers so the pump is secured in an upright position; or place the pump on a flat surface.
3. Connect air hose connectors from air mattress to the pump unit.
   ⚠NOTE: Check and ensure the air hoses are not kinked or tucked under mattress.
4. Plug the power cord into electrical outlet

⚠NOTE: 1. Make sure the pump unit is suitable for the local power voltage.
2. The plug is also served to disconnect the device. Do not position the equipment so that it is difficult to disconnect the device.

⚠CAUTION: The pump should only be used with mattress recommended by the manufacturer. Do not use it for any other purpose.

5. Turn the main power switch found from the right side of the pump to ON position.

Several installation tips are listed below:

After installation, the extra length of the power cord, if any, should be neatly arranged to avoid any tripping accidents. The EQUIPMENT should be firmly placed at position where users/doctors can access easily.

4. OPERATION

⚠**NOTE:** Always read the operating instruction before use.

4.1 General operation

1. Switch on the main power switch on right side of the pump.
2. Adjust the pressure setting based upon patient comfort level by turning the pressure adjustment knob clockwise to increase firmness.

⚠**NOTE:** Every time the mattress is set up for use, it is recommended that the pressure first to be set to the max. The user / career can then adjust air mattress weight levels to the desired softness after set up has been completed

4.2 Emergency operation

When there is a need to perform emergency CPR on the patient, pull and disconnect the tube from the pump unit.. Be sure to reconnect the quick connector to the pump unit once restore the power supply.

5. CLEANING

It is important to follow the cleaning procedures before using the equipment on human bodies; otherwise, patients and/or doctors may have the possibility of getting infection.

⚠**CAUTION -** Do not immerse or soak pump unit.

Wipe the pump unit with a damp cloth and a mild detergent. If other detergent is used, choose one that will have no chemical effects on the surface of the plastic case of the pump unit.

Wipe down the mattress with warm water containing a mild detergent. The cover may also be cleaned by using sodium hypochlorite diluted in water. All parts should be air dried thoroughly before use.

⚠**CAUTION -** Do not use phenolic based product for cleaning.
⚠**CAUTION -** After cleaning, dry the mattress without direct exposure sunlight.

6. STORAGE

1. Lay the bubble pad or mattress on a flat surface and upside down.
2. Roll-up the mattress from the head end towards the foot end.
3. Foot-end strap can then be stretched around the rolled pad/ mattress to prevent unrolling.

⚠**NOTE :** Do not fold, crease or stack the mattresses.

7. MAINTENANCE

1. Check main power cord and do not plug it if there is an abrasion or excessive wear.
2. Check mattress cover for signs of wear or damage. Ensure mattress cover and tubes are stubbed together correctly.
3. Check the airflow from the air hose. The airflow should alternate between each connector every half-cycle time.
4. Check the air hoses if there is kink or breaks. For replacement, please contact Apex Medical Corp. or your suppliers.

8. EXPECTED SERVICE LIFE

The products are intended to offer safe and reliable operation when used or installed according to the instructions provided by Apex Medical. Apex Medical recommends that the system be inspected and serviced by authorized technicians if there are any signs of wear or concerns with device function. Otherwise, service and inspection of the devices generally should not be required.

9. TROUBLESHOOTING

Problem	Solution
Power is not ON	• Check if the plug is connected to mains.
Patient is bottoming out	• 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.
Mattress form is loose	• 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.
No air produced from some air outlets of the air tube connector	• This is normal since there is alternating mode. Air outlets take turns to produce air during their cycle time.

⚠ **NOTE :** If the pressure level is consistently low, check for any leakage (tubes or air hoses). If necessary, replace any damaged tubes or hoses or contact your local qualified dealer for repair.

10. TECHNICAL SPECIFICATION

Item		Specification		
Model		Domus1 (9P-047580)	Domus1 (9P-047500)	Domus 1 (9P-047000)
Power Supply (Note: See rating label on the product)		AC220~240V 50Hz, 0.05A	AC220~240V 60Hz, 0.05A	AC100~120V 60Hz, 0.1A
Fuse Rating		T1AL, 250V		
Dimension (L x W x H)		25 x12.5 x 8.5 cm / 9.8" x 4.9" x 3.3"		
Cycle Time		12min/50Hz	10min/60Hz	10min/60Hz
Weight		1.0 Kg	1.1 Kg	1.1 Kg
Environment	Atmospheric Pressure	700 hPa to 1013.25 hPa		
	Temp.	Operation: 10°C to 40°C (50°F to 104°F) Storage: -15°C to 50°C (5°F to 122°F) Shipping: -15°C to 70°C (5°F to 158°F)		
	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		
Mattress		**Specification**		
Model		Bubble Pad		
Dimension (L x W x H)		196 x 90 x 6.4 (cm)/ 77.2"x35.4"x 2.5"		
Weight		2.1 Kg		

⚠ **NOTE: Please follow national requirements to dispose the unit properly.**

Appendix A: EMC Information

Guidance and Manufacturer's Declaration- Electromagnetic Emissions:
This device is intended for use in the electromagnetic environment specified below. The user of this device should make sure it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment-Guidance
RF emissions CISPR 11	Group1	The device 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
RF emissions CISPR 11	Class B	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network
Harmonic emissions IEC61000-3-2	Class A	
Voltage fluctuations / Flicker emissions IEC61000-3-3	Complies	

⚠**Warning:**
1. The device should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used.
2.Use of accessories, transducers and cables 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.
3. 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 Pump, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Guidance and Manufacturer's Declaration- Electromagnetic Immunity:
This device is intended for use in the electromagnetic environment specified below. The user of this device should make sure it is used in such an environment.

Basic EMC standard	Immunity Test Levels: Professional healthcare facility environment	HOME HEALTHCARE ENVIRONMENT	Compliance Levels	Electromagnetic Environment-Guidance
Electrostatic Discharge (ESD) IEC61000-4-2	±8kV contact ±15kV air		±8kV contact ±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 transient/ burst IEC61000-4-4	±2kV for power supply line ±1kV for input/output line		±2kV for power supply line ±1kV for input/output line	Mains power quality should be that of atypical commercial or hospital environment
Surge IEC61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s)	± 1 kV line(s) to line(s)	Mains power quality should be that of atypical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11	Voltage Dips: i) 100% reduction for 0.5 period, ii) 100% reduction for 1 period, iii) 30% reduction for 25/30 period, Voltage Interruptions: 100% reduction for 250/300 period		120/230V	Mains power quality should be that of a typical commercial or hospital environment. If the user of this device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC61000-4-8	30 A/m	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6	3 Vrms 0.15 MHz – 80 MHz 6 Vrms in ISM bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz	3 Vrms 0.15 MHz – 80 MHz 6 Vrms in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz	6Vrms	Portable and mobile RF communications equipment should be used no closer to any part of this device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \sqrt{P}$ 150kHz to 80MHz $d = 0.6\sqrt{P}$ 80MHz to 800MHz $d = 1.2\sqrt{P}$ 800MHz to 2.7 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).b Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey a, should be less than the compliance level in each frequency ranged. Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF EM Fields IEC61000-4-3	3 V/m 80 MHz to 2.7 GHz 80 % AM at 1 kHz 385-6000 MHz, 9-28V/m, 80% AM(1kHz) pulse mode and other modulation	10 V/m 80 MHz to 2.7 GHz 80 % AM at 1 kHz 385-6000 MHz, 9-28V/m, 80% AM(1kHz) pulse mode and other modulation	10V/m	

NOTE 1: UT is the a.c. mains voltage prior to the application of the test level
NOTE 2: At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 3: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people

a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.
b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

Recommended separation distances between portable and mobile RF communications equipment and this device:
This device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of this device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and this device 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		
	150 kHz to 80 MHz $d = \sqrt{P}$	80 MHz to 800 MHz $d = 0.6\sqrt{P}$	800 MHz to 2,7 GHz $d = 1.2\sqrt{P}$
0.01	0.1	0.06	0.12
0.1	0.31	0.19	0.38
1	1	0.6	1.2
10	3.1	1.9	3.8
100	10	6	12

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.
Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

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