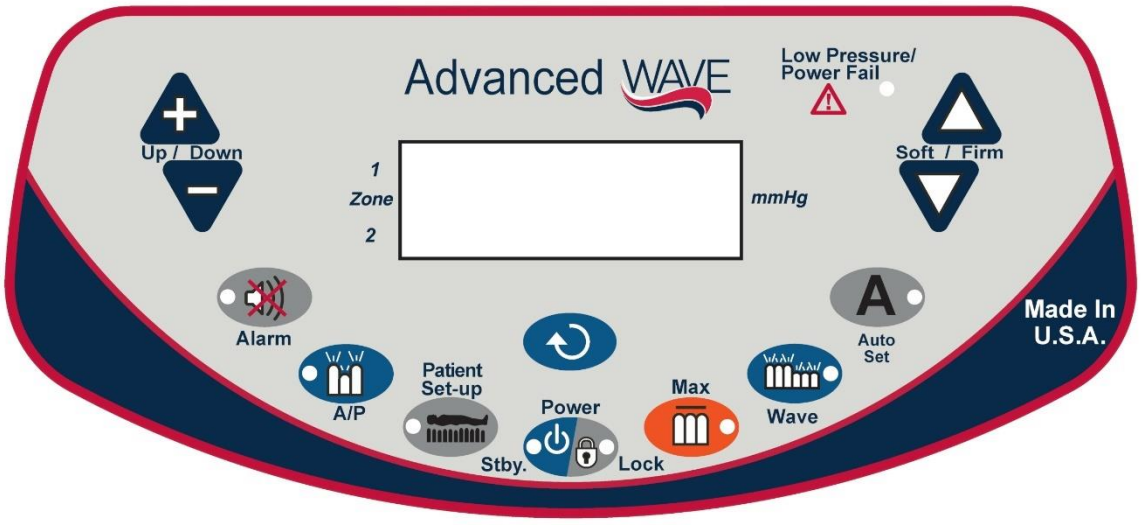
FREEDOM MEDICAL

Advanced Wave

Low Air Loss / Wave Immersion Pulsation Therapy /
Alternating Pressure / Massage Therapy



USER MANUAL

Introduction

This manual contains instructions and information that are necessary for the normal use of the Advanced Wave Mattress System. Reading and understanding the instructions and information included in this manual is required prior to usage. This product is FDA listed.

Product Description & Intended Use

The Advanced Wave is for the treatment and prevention of complicated wounds, flaps, grafts, and burns. It features Low Air Loss, Wave immersion pulsation, Alternating pressure, and massage therapy modes. It is available in both Standard and Bariatric models.

Contact

Please contact your local Freedom Medical office should you require assistance setting up the mattress or experience any operational issues.

Corporate office:

Freedom Medical Inc.
484.879.4272
bedservice@freedommedical.com

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DANGER, CAUTION AND WARNINGS

Warnings are used in this manual to signify hazards and unsafe practices which could result in personal injury or property damage. See the definitions below for information relating to each term.

NOTE / IMPORTANT
Indicates a hazardous situation that could result in property damage, if not avoided.

DANGER
Danger indicates an imminently hazardous situation, which, if not avoided, will result in serious injury or death.

CAUTION
Caution indicates a potentially hazardous situation which, if not avoided, may result in property damage, minor injury, or both.

WARNING
Warning indicates an imminently hazardous situation which, if not avoided, will result in serious injury or death.

RISK OF ELECTRICAL SHOCK
Do not remove control unit cover**.**

EXPLOSION HAZARD
Do not use the control unit in the presence of flammable anesthetics or in the proximity of an oxygen tent.

There is no known risk of adverse effects on the control unit caused by other electromagnetic devices, present at the time of treatment.

- Refer servicing to qualified service personnel.
- Never drop or insert objects into any opening of the control unit.
- DO NOT SMOKE while using this product and do not use in the presence of smoking materials or open flame. Smoking by visitors in the room will contaminate the system. Air flowing through the mattress will support combustion. Failure to observe this warning can result in severe fire, property damage and cause injury or death.
- Entrapment may occur. Patient entrapment with bed side rails and mattress may cause injury or death. Mattress MUST fit bed frame and side rails snugly to prevent patient entrapment. Follow the manufacturer's instructions and monitor the patient frequently. Proper patient assessment and monitoring, and proper maintenance and use of equipment is required to reduce the risk of entrapment. Variations in bed rail dimensions, and mattress thickness, size, or density could increase the risk of entrapment. Visit the FDA website at http://www.fda.gov to learn about the risks of entrapment. Refer to the owner's manual for beds and rails for additional product and safety information. Mattress MUST fit bed frame and bed rails snugly to reduce the risk of entrapment.
- To avoid risk of electric shock, this equipment must only be connected to a grounded supply main using the supplied 14-foot (427cm), or optional 3-foot (91cm) hospital-grade power cord.
- Do not heat, steam autoclave, or spill liquids or food on or into the control unit. In the event of any spillage, immediately turn off the control unit and disconnect it from the power source. Return the control unit for servicing to a factory authorized service center.
- Care should be taken such that the power cord of the control unit is not pinched and does not have any objects placed upon it. Make certain the control unit and power cord are not located where they can be stepped on or tripped over.

DANGER, CAUTION AND WARNINGS (continued)

- Do not modify this equipment.
- Not for use in oxygen-rich environments.
- Before opening or cleaning the control unit enclosure, make certain that the unit is turned off and unplugged from its power source. The control unit enclosure should only be opened by factory authorized qualified technical service personnel.
- Please read this manual before operating any of Freedom Medical's air therapy systems. If you are unable to understand the manual, please contact your dealer or the manufacturer before attempting to use this equipment. Personal injury or property damage may result.
- When installing the Freedom Medical mattress system, do not exceed the manufacturers rated weight of the mattress on the bed frame. See the bed frame manufacturer's manual for bed frame weight rating.

FCC Statements:

This device complies with FCC part 15.231 for license exempt radio apparatus. Operation is subject to the following two conditions:

(1) This device may not cause harmful interference, and

(2) This device must accept harmful interference received, including interference that may cause undesired operation.

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

MANUFACTURER'S LIABILITY

The warranty on the Advanced Wave will remain in effect during the warranty period, provided any changes, readjustments, or repairs have been carried out by Freedom Medical, and only when the mattress system has been used according to the operating instructions.

Original Warranty = 1 year on control unit/coverlet, 5 years on all internal components (incl. foam, manifolds, valves, connectors)

Freedom Medical's liability under the warranty is the repair or replacement provided and, in no event, shall Freedom Medical's liability exceed the purchase price paid by the customer for the product. Under no circumstances shall Freedom Medical be liable for any loss, direct, indirect, incidental, or special damages arising out of or in connection with the use of this product.

CONTRAINDICATIONS

Unstable Head and neck injuries. Always consult the patient's physician before using any of Freedom Medical's Air Therapy Systems.

TECHNICAL SPECIFICATIONS

Electrical Specifications:

Note: The control unit power inlet is used as the means of isolating the equipment from the supply mains on all poles simultaneously.

	U.S. / INTL.
Input Voltage AC:	90 ~ 240 VAC
Input Frequency:	60 / 50 Hz
Maximum Power Consumption:	180 W ± 30 W
Circuit Protection:	Dual fused, 250V, 5A FAST blow fuses
Fuse Type:	Bussmann S500-5-R
Breaking Capacity:	(BRK.CAP.) @125 VAC is 10kA @250 VAC is 200A
Mode of Operation:	Continuous

Performance Specifications:

Weight Capacity:

Standard Mattress (UMS, VL):	360 lbs. (163 Kg.) maximum.
Bariatric Mattress (XMS):	1000 lbs. (455 Kg.) maximum.

Patient Contact:

Control unit and the mattress are constructed from lead free, mercury free, and latex free components. Optional Dartex top sheet is Halogen-free (bromide-free).

Mechanical Specifications - Control Unit:

Dimensions, LxWxH:	12” x 11” x 8” (30cm x 28cm x 20cm)
Weight:	13.6 lbs. (6.2 Kg)
Power Cord:	14 ft. or optional 3 ft. long Hospital Grade
Connection:	Magnetic quick connect
Packaging:	1 piece per box
Air Filter	Rear mounted, washable

Support Surface:

The Advanced Wave mattress has high frequency sealed, urethane lined, nylon air cell inside a durable nylon base cover. Under the air cells is a 2” foam, or air pad (depending on model) enclosed in washable, zippered nylon cover. The patented top sheet is a low friction, low shear, low force producing, breathable, liquid resistant and highly vapor permeable nylon. The Advanced Wave UMS, XMS, and VL models feature adjustment dials for special configuration, or comfort adjustments.

Description	Inflated Dim. (LxWxH)
UMS Mattress:	84” x 36” x 8”
VL Mattress:	90” x 36” x 8” (length adjustable)
Bariatric Mattress (XMS):	90” x 48” x 10” (width, and length adjustable)

Environmental Specifications:

Operating Conditions:

Ambient Temperature:	40° ~ 104° F (10° ~ 40° C)
Relative Humidity:	30% ~ 75% Non-Condensing
Atmospheric Pressure:	700 hPa to 1060 hPa

Storage and Shipping Conditions

Ambient Temperature:	-40° ~ 158° F (-40° ~ 70° C)
Relative Humidity:	10% ~ 100%
Atmospheric Pressure:	500 hPa to 1060 hPa

Protection against Harmful Ingress of Liquids:
Ordinary Protection (IPXO)

Mattress Sanitation:

The complete support surface is made out of superior quality materials and is modular in construction. All components such as the manifold assembly, air cushions, top sheet, and base cover are interchangeable and can be easily cleaned. Most items can be laundered.

Disposal Requirements:
This equipment should be disinfected, and disposed of at your local recycling center (Non-hazardous waste) when it has reached the end of its service life.

SAFETY AGENCY APPROVALS

ETL Listed: 2nd Edition

The standard for safety of Medical Electrical Equipment

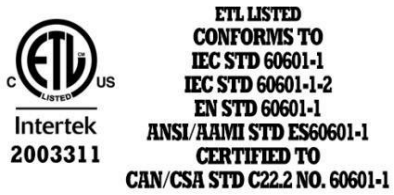
Conforms To: UL STD 60601-1 with respect to Electrical Shock, Fire and Mechanical Hazards

Certified To: CAN/CSA STD C22.2 No. 601.1

CE Mark: CE

Class 1 equipment (Europe); Class 2 equipment (USA)

Optional 3rd Edition Compliant Systems available:



ETL Listed: 3rd Edition

Class 1 equipment (Europe); Class 2 equipment (USA)

3rd Edition CE Mark: CE

Flame Resistance:

Unit components meet UL 94V-0 and Mattress components pass California117.

Optional California TB 106, TB 129, 16 CFR 1632, 16 CFR 1633, BS 6607 (CRIB 5), BS 597-1, & BS-597-2 compliant mattresses lined with Kevlar fire barrier available (Kevlar lining based on flammability standard).

SAFETY INSTRUCTIONS

-  To avoid damage and before operating the control unit, be certain the AC power available at your location matches the power requirements printed on the product identification label on the rear of the unit.
-  To avoid electric shock, always plug the power cord of the control unit into a properly grounded power source.
-  Do not insert items into any openings of the control unit. Doing so may cause fire or electrical shock by shorting internal components.
-  Do not spill liquids or food on or into the control unit. In the event of any spillage, immediately turn off the control unit and disconnect it from the power source. Return the control unit for servicing to a factory authorized service center.
-  Care should be taken such that the controls on the footboard of the bed frames are not obstructed by the control unit.
-  Care should be taken such that the control unit is not blocked, and kept away from any heat sources or radiators during the operation of the unit.
-  Care should be taken such that the power cord of the control unit is not pinched, or has any objects placed on it. Make certain it is not located where it can be stepped on or tripped over.
-  Check that all air hoses and power cord are clear of moving bed components before placing a patient on the bed and that the mattress system is fully inflated. Operate all bed frame motorized functions through their full range of motion to be certain that there is no pulling, interference or pinching. Mattress MUST fit bed frame and side rails snugly to prevent patient entrapment.
-  Do not attempt to service the control unit except as explained in this operating instruction manual. Contact factory for servicing instructions. Always follow operating and service instructions closely.
-  Do not place the patient directly on the mattress without the top sheet. The breathable nylon or 4-way stretch top sheet is water repellent; highly vapor permeable, anti-microbial, low friction and low shear, quilted and reusable.
-  **WARNING:** Before opening the control unit enclosure, make sure the control unit is turned off and unplugged from its power source. The control unit enclosure should only be opened by a factory authorized qualified service technician.
-  Smoking by the patient or anyone else around the system is prohibited. The Advanced Wave uses room air for circulation through the mattress. Smoking will permanently contaminate the system.

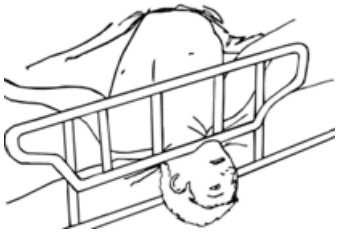
BED RAIL ENTRAPMENT RISK NOTIFICATION

NOTICE TO PATIENT, PATIENT'S FAMILY AND/OR PRIMARY DAY-TO-DAY CAREGIVER

DO NOT use this product without first completely reading and understanding this Bed Rail Entrapment Risk Notification and any additional instructional material such as owner's manual, instruction sheets and on-product warnings supplied with this product. If you are unable to fully understand this Bed Rail Entrapment Risk Notification, the on-product warnings or any additional instructional materials, contact the patient's health care provider and/or your equipment provider before using this equipment. Failure to understand and comply with the information contained in this Bed Rail Entrapment Risk Notification can result in serious injury or death.

Entrapment within the bed rail

Entrapment under the bed rail



Entrapment between the bed rail and mattress

Entrapment between the head or foot board and the end of the mattress

Entrapment under the bed rail at the ends of the bed rail

Entrapment between split bed rails

Entrapment between the end of the rail and the side edge of the headboard or foot board

RISK OF ENTRAPMENT

Bed Rail Entrapment is a known risk in the use of bed's equipped with bed rails.

Every patient is unique. Only the patient's medical care provider is familiar with the patient's unique medical condition and needs. Only the patient's medical care provider and/or the dealer from whom you obtained this equipment, upon proper assessment of the patient's medical condition and needs, can evaluate whether this equipment is appropriate for use by any particular patient and assist the patient, the patient's family and/or the patient's primary day-to-day caregiver in assessing the Risk of Entrapment.

Proper patient assessment, equipment selection, frequent patient monitoring, and compliance with instructions, warnings and this Bed Rail Entrapment Risk Notification is essential to reduce the risk of entrapment.

Accessories have been developed in the industry to reduce the openings in existing bed systems that could cause entrapment. Any modification through the use of accessories must be used in conjunction with proper patient assessment prior to intervention. For a full discussion on this topic, see the Hospital Bed Safety Workgroup's "A Guide for Modifying Bed Systems and Using Accessories to Reduce Risk of Entrapment" found at http://www.fda.gov.

Conditions such as restlessness, mental deterioration and dementia or seizure disorders (uncontrolled body movement), sleeping problems, and incontinence can significantly impact a patient's risk of entrapment, Pediatric patients or patients with small body size may also have an increased risk of entrapment.

BED RAIL ENTRAPMENT RISK NOTIFICATION (continued)

- Bed rails are intended to prevent an individual from inadvertently rolling out of bed, provide assistance to a patient when repositioning and to provide a sense of security. NEVER use bed rails for restraint purposes where “restraint” means preventing or hindering the patient within the bed from exiting the bed as they wish. Use of rails as a means of restraint significantly increases a patient’s risk of entrapment.
- Bed rails are intended to be used as a pair in a bed system. When in use, both side rails must be in the up position, except when the patient is entering or exiting the bed. Use with one side rail up and one side rail down could create an increased risk of entrapment.
- Bed rails and/or their mountings should not be used if they are bent or otherwise deformed. Bent or deformed bed rails and/or bed rail mountings increase gaps and increase the risk of entrapment. DO NOT place pressure upon bed rails while moving the bed. Although bed rails are not rated to any specific patient weight limitation, the bed rails or their mountings may become deformed or broken if excessive side pressure is exerted on the bed rails.
- Mattress overlays or active therapeutic support surfaces (TSS), which support the patient on an air mattress or specialized foam layer, may present an increased risk of entrapment for some patients. The benefit of TSS product use must be weighed against the potential increased risk of entrapment. The risk judgment must be performed by a Medical professional.

The U.S. Food and Drug Administration in partnership with the U.S. Department of Veterans Affairs, Health Canada’s Medical Devices Bureau and representatives from national health care organizations and provider groups, patient advocacy groups, and Medical bed and equipment manufacturers including the Hospital Bed Safety Workgroup, a collection of experts from the United States FDA, health care professionals and manufacturers of hospital beds, published guidelines regarding body part dimensions as they relate to a bed system’s safety. These guidelines, **“Hospital Bed System Dimension and Assessment Guidance to Reduce Entrapment”** contain additional information on the risk of entrapment. Visit the FDA website at *http://www.fda.gov* and search for “bed rail entrapment” to learn about the risk of entrapment or to view the FDA guidelines document.

The above statements are not intended to be a complete or comprehensive list of all risks of entrapment. Freedom Medical recommends that whenever bed products are used that the patient, the patient’s family and/or the patient’s primary day-to-day caregiver discuss entrapment risks with the patient’s medical care provider

UNIT OVERVIEW

These systems are designed to provide continuous air therapy support at required patient comfort levels and are used to inflate a replacement mattress. The Thermoplastic 94V-0 fire retardant enclosure houses a blower motor, main PCB, display panel, lithium-ion batteries, a short circuit / over voltage protection with fuse, and, real time pressure monitoring sensors. The unit is supplied with a 14 ft. or 3 ft. detachable 16 AWG hospital grade power cord.

EXPLANATION OF SYMBOLS USED ON THIS DEVICE

FUNCTION	SYMBOL	EXPLANATION
POWER / LOCK		Press: Power on / off Press and hold (3 seconds) locks the controls
SOFT / FIRM		Adjusts patient comfort pressure in 1 mmHG increments
PLUS / MINUS		Adjusts therapy duration times, and settings within specific menus.
PATIENT SET-UP		Begins Manual setup, based on height and weight of patient.
MODE		Select between available therapy modes.
AUTO SET		Begins simplified setup
ALARM SILENCE		Mutes the audible alarm
WAVE		Begins Wave immersion pulsation therapy
ALTERNATING PRESSURE		Begins alternating pressure therapy.
LOW PRESSURE/ POWER FAIL		Low Pressure/Power Failure warning LED
MAX Inflate (W)		Inflates mattress rapidly (15-minute timer)
	Indicates the point of attachment of the equipment to earth (Grounding Point).	
	Attention: Instructs end user / care giver / operator to refer to the manual.	
	Indicates that the degree of protection against electrical shock is TYPE BF.	
	Not for use in presence of flammable anesthetics.	
	Consult Instructions for Use	
	Waste electrical and electronic equipment (recycle).	
	Risk of electrical shock. Do not remove back cover.	

EXPLANATION OF SYMBOLS USED ON THIS DEVICE (CONT.)

Not all features included on each model.

SYMBOL	EXPLANATION
	No Sharp Objects
	Low Heat Setting
	Do Not Dry Clean
	Do Not Bleach
	No Open Flames
	Normal Cycle
	Do Not Iron
	Latex-Free

UNPACKING THE SYSTEM

⚠ **Note: When opening the large system box or the small control unit box, ensure that the object used to open the box does not penetrate and damage the components inside.**

Components Supplied:

- Control Unit Box
  1 Control Unit
  1 Operating Instruction Manual
  1 Power Cord

- Mattress Box
  1 Mattress
  1 Control Unit (if ordered with Mattress)

Unpacking and Inspection:

Before accepting and signing for your shipment, please inspect the box or boxes for external/internal damages or missing items. Verify that the number of boxes listed on the packing list matches the number of boxes received. Report any missing boxes, components and or damages to the transportation carrier immediately.

MATTRESS SYSTEM SET-UP

⚠ **Note**: Make sure that the hose connection of the mattress is towards the foot of the bed.

⚠ **Note**: When installing the Advanced Wave mattress system, do not exceed the manufacturer's rated weight of the mattress or the bed frame. See the bed manufacturer's manual for bed frame weight rating.

⚠ **Note:** Ensure the control unit is not placed on the floor in such a manner that it is a hazard for flow of traffic or lowering of bed frame.

⚠ **Note:** Before using the Advanced Wave mattress system, remove all other mattresses from the bed.

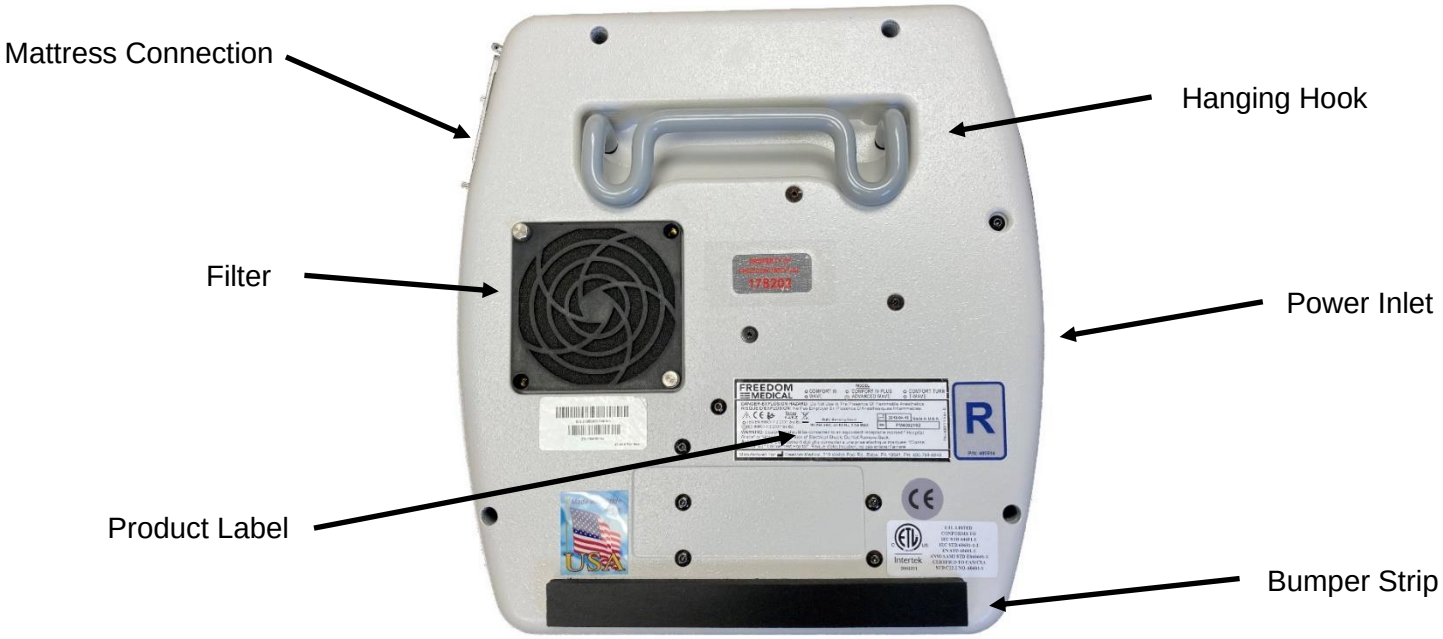
Replacement mattress system:

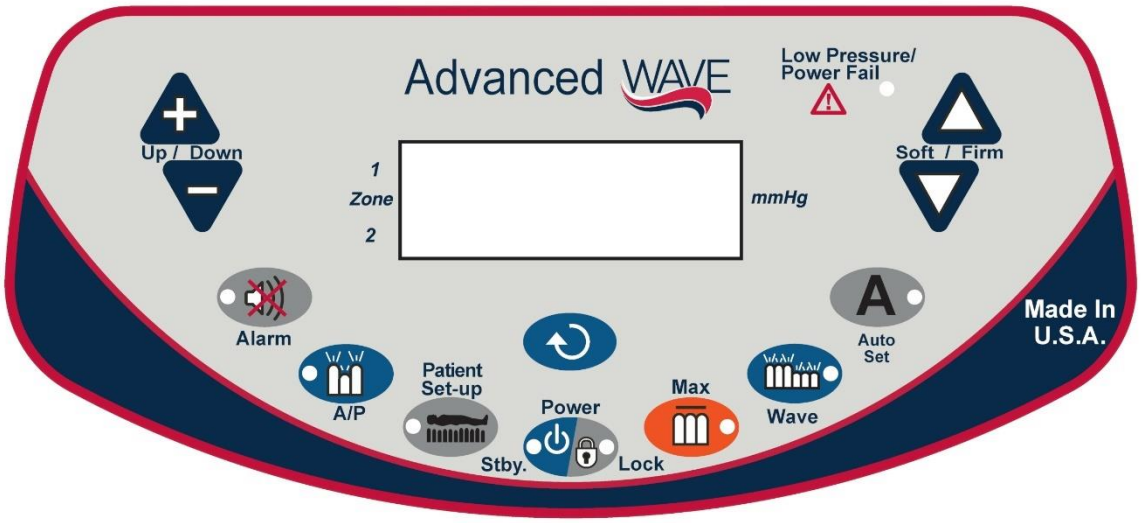
- Unroll the Advanced Wave Mattress and place it directly on the bed frame.
- There are multiple nylon straps with D-rings on the mattress base to secure the mattress to the bed deck. Loop each strap around the bed deck and secure using the D-ring. Note: Make sure the head, knee and foot sections of the bed can be raised and that straps are secured to the movable deck and not to the frame. Once the mattress is securely strapped, tuck the exposed straps under the mattress.
- Extend the hanging hook from the rear of the control unit and suspend the control unit from the foot board of the bed. An optional hanger bracket may be used if required. If the bed you are using does not have a footboard, place the control unit on its base (not on its back) on a flat surface in front of the bed near the foot of the bed frame. Ensure the control unit cannot be crushed during downward travel of the bed frame.
- Plug the cord into an appropriately grounded, AC power source. Plug the other end of the power cord into the control unit. Use the cord retention sleeve on the right side of the mattress when routing the cord towards the head wall.

⚠ **Note:** Care should be taken so the power cord of the control unit is not pinched, and is free from objects placed over it. Ensure it is not located where it can be stepped on or tripped over. Make sure the control units' power inlet connection is positioned to easily disconnect the power cord from the unit if required.

- Connect the mattress hose to the magnetic connection on the upper right side of the control unit. Ensure it is fully seated.

⚠ **Note:** Care should be taken so that the mattress hose is not being pinched or kinked during use.





OPERATING INSTRUCTIONS/DESCRIPTION OF CONTROLS

Initial Power on

- Connect the power cord to the control unit, and a beep will be heard, as well as a slight “whirring” noise.
- Connect the mattress hose to the magnetic connection on the upper right side of the control unit.

Configuring Auto Set

- You will be prompted to “Configure Auto-Set”. Use the **MODE** key to toggle between the two available choices:
  - Standard mode is appropriate for an anatomically correct adult patient 5’2-6’4, weighing 120lb to 250lbs.
  - Bariatric mode is to be used for patients weighing over 250lb (depending on height).
- Press the **POWER** key to confirm selection. The display will then show “STANDBY”.

*If a selection is not made in roughly 90 seconds, the control unit will default to the mode selected on the screen.

Manual patient setup **(not required, unless a custom setup is necessary)**

- To manually program the control unit, you will need the ACCURATE weight and height of the patient.
  - You will need to first select the appropriate patient category based on the parameters for Auto Set (above).
  - When the display shows “STANDBY”, press the **POWER / LOCK** key to turn the unit on. The mattress will begin inflating.
- Press the **PATIENT SET-UP** key and use the **+ / -** arrows to enter the patients WEIGHT.
  - Press the **MODE** key to confirm the selection.
- Use the **+ / -** arrows to enter the patients HEIGHT.
  - Press the **MODE** key to confirm the selection.
- Verify the Weight and Height are correct, and press the **MODE** key one final time to confirm.

* At any time during the patient set-up, you may press the **PATIENT SET-UP** key to exit the setup and start over.

OPERATING INSTRUCTIONS/DESCRIPTION OF CONTROLS (continued)

POWER / LOCK 

- Pressing the POWER / LOCK key will turn the unit on and off.
- Holding the POWER / LOCK key for 3 seconds will lock (or unlock) the controls to prevent unwanted, or unauthorized button presses.
  *MAX inflate is available even with the lock enabled!

MODE KEY 

- The **MODE**  key is used to cycle between therapy modes.

WAVE THERAPY 

- Press the **WAVE**  key to begin immersion pulsation therapy. The Wave indicator will illuminate.

ALTERNATING PRESSURE THERAPY 

- Press the **A/P**  key, OR the **MODE**  key repeatedly until the “A/P” indicator illuminates.

THERAPY (static pressure) MODE

- Press the **MODE**  key repeatedly until “THERAPY” is shown on the display.
- In static mode, all air cushions in the mattress will be maintained at the same internal pressure.

MAX INFLATE 

- Pressing the **MAX** key will quicky raise the internal pressure of the mattress to 35mmHG.
  - MAX inflate is to be used during ingress, or egress of the mattress, and during all patient contact.
  - A series of beeps will sound every 3 minutes as a reminder that MAX inflate is active.
  - Pressing the **MAX** key a second time will exit MAX inflate, and the unit will revert to WAVE therapy.
    ***MAX inflate will automatically revert to WAVE therapy after 15 minutes if not cancelled sooner.

PATIENT COMFORT LEVEL (CUSTOM MODE) 

- At any point, the pressure in the mattress may be manually adjusted in 1 mmHG increments by pressing the **SOFT / FIRM**  arrow keys.
- Manually adjusting the pressure will maintain the current therapy, and will cancel Auto Set and patient set-up.

OPERATING INSTRUCTIONS/DESCRIPTION OF CONTROLS (continued)

UPRIGHT (Fowler's) MODE

Manual Fowler

- Press the **MODE**  key repeatedly until "UPRIGHT" is shown on the display.
  - The internal pressure of the mattress will be increased by 80% of the current set pressure, up to a MAXIMUM pressure of 32 mmHG (+/-5 mmHG).

Automatic Fowler: (considered a backup, and available ONLY after synchronizing the Fowler transmitter)
*transmitter synchronization will be performed by Freedom Medical personnel upon delivery

- When the head-end of the mattress is brought up above 35° (HOB >35°), a beep will be heard, and the pressure in the mattress will be increased by 80% of the current set pressure, up to a MAXIMUM of 32 mmHG (+/-5 mmHG).

LOW AIR LOSS

- The Advanced Wave supplies constant low air loss at all times, regardless of setting or mode. This feature cannot be turned off.

ALARM SILENCE 

- Mutes the audio alarm. Alarm silence stays enabled as long as the LED is illuminated.

LOW PRESSURE /POWER FAIL 

- In the event of an unplanned internal drop in pressure, the amber "Low Pressure" LED will flash, an audible alarm will sound, and the display will show "LOW PRESSURE Once the unit is able to detect appropriate pressure levels, the unit will resume operation with the previously set therapy.

BATTERY BACKUP

- In the event of an interruption in power, the display will show "AC POWER FAILURE" and an alarm will be heard. The unit will continue to operate, uninterrupted on backup battery power. Press the MODE key to silence the alarm.
  *if the **MODE** key is not pressed to silence the alarm within 30 seconds, the unit will revert to standard operation.

- The battery backup system is intended for intra-hospital transport, and AC power should be reconnected as soon as transport is completed.

CPR FUNCTION

CPR

To deflate the Advanced Wave mattress for CPR:

1. Firmly grasp and PULL the magnetic connection from the control unit.

2. Press alarm silence to mute the alarm.

3. On certain models of Advanced mattresses, you may see other plugs labeled as “DEFLATE”, or “EXPANSION DELFLATE”. These plugs will need to be removed from their fittings to evacuate air inside specific components. ***PLEASE FAMILIARIZE YOURSELF WITH DEFLATE PLUG LOCATION(S) PRIOR TO USE***

⚠ PLEASE NOTE: Before using the mattress please make sure that the deflate plug(s) are connected back into the mattress.

PATIENT TRANSPORTATION

The Advanced Wave system features a backup battery to allow uninterrupted function during transport. When AC power is disconnected, and alarm will sound. Press the **MODE** key to mute this alarm. The control unit should be connected to power when the transport is completed.

*if the **MODE** key is not pressed to silence the alarm within 30 seconds, the unit will revert to standard operation.

CLEANING PROCEDURE

⚠ **WARNING:** Before attempting to clean the control unit, turn off and disconnect the power cord from the power source.

⚠ **WARNING: DO NOT HEAT, STEAM AUTOCLAVE, OR IMMERSE THE CONTROL UNIT IN LIQUIDS**

Control Unit:

1. The air filter on the rear of the unit, should be checked weekly for lint or debris. The filter may be washed with mild detergent, and reused. The filter must be completely dry prior to re-installation, or replaced if it is torn or damaged.
2. Wear eye goggles and protective gloves before starting the cleaning procedure.
3. The following example germicidal detergents / disinfectants are recommended by the EPA as hospital disinfectants.
    a. Johnson Wax, Virex 128, EPA Registration Number 47371-130-4822.
    b. Quaternary Detergent-Disinfectant by Airkem Professional Products, Division of Ecolab, Inc., Ecolab Center, St. Paul, Minnesota. EPA registration number: EPA # 42964-5.
    c. Hi-Tor Germicidal Detergent by Huntington Laboratories, Inc. Huntington, Indiana. EPA registration number: EPA # 303-91.

⚠ **Note: A spray bottle of fresh disinfectant / detergent solution should be prepared daily to clean the control unit.**

4. Prepare the required amount of solution by following the preparation instructions provided with the germicidal detergent /disinfectant solution.
5. Pour required amount into a spray bottle.
6. Use a brush or cloth to wipe off dust. If necessary, spray the exterior of the top and the bottom enclosures, power cord and the cord plug with the prepared disinfectant / detergent solution. Using a damp cloth, wipe down the sprayed surface. **Note: Do not spray excess amount of solution on the control unit.**
7. Once the control unit is clean, wipe the unit, power cord, cord receptacle, and the cord plug with a clean dry cloth.
8. Place the control unit to dry in a cool, dry area for an hour before operating or storing the unit. If the control unit is not used immediately, place the control unit in a plastic bag and store it in a storage area.
9. After the cleaning operations are completed, remove and dispose the protective gloves appropriately. Wash your hands thoroughly with antibacterial soap.

CLEANING PROCEDURE (continued)

Advanced Wave Mattress:

⚠ Care should be taken when removing the cover for cleaning. The mattress should never be opened during patient use.

Before attempting to clean the mattress, remove any bedding from the mattress. The mattress cover (top sheet) must be thoroughly cleaned, disinfected, and laundered between patient uses.

1. Wear eye goggles and protective gloves before starting the cleaning procedure.

2. Follow steps 2 through 4 in control unit cleaning procedure above to prepare disinfectant solution.

3. Clean the top and bottom mattress cover using the prepared disinfectant solution.

4. If a NYLON top cover is used, it must be disinfected, laundered, and dried prior to its next use.

5. Wipe dry with a clean cloth and allow to air dry as needed.

CARE AND STORAGE

1. For on-demand storage, the control unit should be plugged in at all times to keep the battery charged.

2. For long-term storage, turn off the unit, disconnect the power cord from the power source. Once the display goes dark, press both **DOWN ARROW** keys simultaneously to electronically disconnect the batteries from the system. Neatly wrap the power cord around the control unit, and store it in a dry, dust-free location.

3. Open all deflate, or expansion plugs to evacuate the air from the mattress. Carefully place the mattress connector on the top of the now deflated mattress, and roll the mattress up from head to foot end. Nylon straps and D-rings are provided to keep the mattress securely rolled. *do not roll the control unit inside the mattress.

4. Once all air has been evacuated from the mattress, close all expansion, and deflate plugs.

5. Store the control unit and mattress together in an area suitable designated for medical / electronic storage.

TROUBLESHOOTING GUIDE

⚠ **THE FOLLOWING INFORMATION IS FOR FACTORY AUTHORIZED SERVICE FACILITIES AND FACTORY QUALIFIED SERVICE PERSONNEL ONLY.**

Freedom Medical can provide technical support to factory qualified technical personnel. Contact Freedom Medical service department for more information.

PROBLEM	CAUSE	SOLUTION
A. Mattress not inflating properly	1. Mattress hose disconnected 2. Air hose kinked or split 3. Major leak in the air cushion 4. Kinked or split manifold 5. Control unit not working 6. Compressor / blower malfunction	1. Connect hose connectors and lock them in place 2. Inspect hose and replace if required 3. Replace leaking air cushion 4. Unkink manifold or replace split manifold 5. Contact Freedom Medical 6. Contact Freedom Medical
B. No Power	1. Control Unit OFF 2. Power cord disconnected	1. Check power source and press Power / lock button. 2. Connect cord to power source
C. Control Unit not responding	1. Unit locks up	1. Contact Freedom Medical

WARRANTY

Freedom Medical's original warranty on the Advanced Wave will remain in effect during the warranty period, provided any changes, readjustments, or repairs have been carried out by a technician of Freedom Medical and when the control unit and mattress system have been used according to the operating instructions.

Original Warranty = 1 year on control unit/coverlet, 5 years on all internal components (incl. foam, manifolds, valves, connectors)

Freedom Medical standard warranty is extended to the original buyer purchasing the equipment directly from Freedom Medical or through its authorized dealers. All warranty periods, where applicable, commence on the date of purchase from Freedom Medical or its authorized dealers.

Freedom Medical's sole obligation and liability under this warranty is limited to (at Freedom Medical's option) the repair or replacement by Freedom Medical's authorized personnel of any parts or assemblies, which upon test and examination by Freedom Medical, prove to be defective. This equipment may be returned prepaid to Freedom Medical after notification has been given and approval obtained for the return. Please call your Freedom Medical Sales Representative or Customer Service at 484-879-4272 to arrange for warranty services.

Freedom Medical's liability under the warranty is the repair or replacement provided and, in no event, shall Freedom Medical's liability exceed the purchase price paid by the customer of the product. Under no circumstances shall Freedom Medical be liable for any loss, direct, indirect, incidental, or special damages arising out of or in connection with the use of this product.

The control unit warranty does not cover normal maintenance such as cleaning, periodic electrical tests, performance tests, and updating of equipment or parts thereof. This warranty shall be void and not apply if the control unit, including any of its parts, is modified without Freedom Medical's written authorization, is attempted to be repaired by personnel not authorized by Freedom Medical, is not maintained in accordance with the prescribed preventive maintenance schedule, is used with accessories or parts not authorized by Freedom Medical, or is damaged due to misuse, mishandling, abuse, negligence, accident, fire, or inadequate packaging by owner for shipment of the control unit for service, upgrade, repair, retrofit, or product return. All reasonable freight charges for valid factory approved warranty returns will be reimbursed.

♦ **THE WARRANTY STATED ABOVE (INCLUDING ITS LIMITATIONS) IS THE ONLY WARRANTY MADE BY FREEDOM MEDICAL AND IS IN LIEU OF ALL OTHER WARRANTIES, WHETHER EXPRESSED OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. FREEDOM MEDICAL SHALL NOT BE LIABLE FOR CONSEQUENTIAL OR INCIDENTAL DAMAGES OF ANY KIND.**