

## \_\_ UltraMamm



Model 452 User Manual

Owner .	
Model	
Serial #	
Jeriai #	
Data	

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## **Symbols and Definitions**

	Warning, follow instructions for use. Failure to comply may result in injury.
(A)	Warning, sitting is prohibited. Failure to comply may result in injury.
AT .	Warning, standing is prohibited. Failure to comply may result in injury.
Type B Applied Part	Applied Part complying with specified requirements IEC 60601-1 to provide protection against electric shock, particularly regarding allowable patient leakage current.
	Warning/Caution
Protective Earth	Any terminal which is intended for connection to an external protective conductor for protection against electric shock in case of a fault.
	In accordance with the European Directive 2002/96/EC on Waste Electrical and Electronic Equipment (WEEE), the product must not be disposed as unsorted municipal waste but should be collected separately. Consult your instructional policies and local regulations regarding disposal. Contact your Medical Positioning, Inc. Service Representative if additional disposal details are required.
***	Manufacturer
C UL US E476901	Agency Mark

## **Symbols and Definitions**

#### **WARNING / CAUTION / NOTE Definition**

The words WARNING, CAUTION, and NOTE carry special meanings and should be carefully reviewed.



Identifies a situation that could result in injury to the patient or caregiver.



Identifies a situation that could result in equipment damage.

#### Note

Provides special information to make an important instruction clearer.



## **Safety Warnings & Cautions**



#### WARNING:

Obey these safety instructions to help prevent injury and/or equipment damage:

- Read and understand all warnings in this manual and on the unit itself prior to use with a patient.
- The device should be operated by trained persons only.
- Authorized and qualified persons will be those who are approved by Medical Positioning Inc. to repair or modify the product.
- Do not modify this equipment without authorization of the manufacturer.
- Equipment should only be serviced by authorized personnel.
- The procedures in this manual are only manufacturer's suggestions. The final responsibility for patient care with respect to this device remains with the caregiver.
- Do not use in an oxygen rich environment.
- Do not leave patient unattended while using the product.
- To reduce the risk of electric shock, grounding reliability can only be achieved when the equipment is connected to an equivalent receptacle marked "hospital only" or "hospital grade".
- If damage has occurred to the power cord, immediately remove the cord from service. Failure to do so could result in serious injury or death.
- The battery should be periodically inspected for damage. If damage has occurred to the battery, immediately remove the battery from service. Failure to do so could result in serious injury or death.
- Removal of secured covers may increase the risk of electrical shock. Refer servicing to qualified and approved personnel.
- The potential for electrical shock exists with electrical equipment. Failure to follow facility protocols may cause death or serious injury.
- Ensure the patient is properly secured prior to using the equipment.
- To reduce the risk of a potential injury, lock casters before using equipment.
- Once the product and patient have been properly positioned for the procedure, ensure the casters are locked and the hand controller is placed in a safe position to prevent unwanted contact and unwanted movement of the support surface.
- To reduce the risk of the product becoming unbalanced, always position the product in the lowest reasonable height when moving.

## **Safety Warnings & Cautions**

- Verify the area around the product is free of impediments before operating to prevent injury or equipment damage.
- Keep hands and feet clear from beneath the patient surface when lowering surface height or making positioning adjustments in order to avoid possible injury.
- Keep hands clear of any hinges during operation to avoid possible injury.
- Sitting at the end of the patient's surfaces can result in device instability. Do not allow a patient to sit at the head end of the patient surface.
- Standing on the footrest may result in device instability. Do not allow a patient to stand on the footrest while the product is in a chair position.
- Protect vinyl upholstery from sharp objects and abrasion to avoid damage.
- Always read manufacturer's instructions and warnings before using any cleaning product or disinfectant. Refer to instructions located in this manual for vinyl cleaning recommendations.
- Substances such as imaging gels and alcohol will not damage the vinyl surface when immediately removed. Extended exposure for longer than a few minutes can damage the topcoat and will eventually discolor vinyl.
- Do not use abrasives to clean painted surfaces.
- It is recommended that the product be cleaned between patients; please follow your facility's documented policy.
- Keep this manual available for future reference.
- If the product is used adjacent to other electrical equipment, observe the product and the other electrical equipment to ensure they operate as intended.
- Failure to latch Drop Sections may result in patient injury. Verify Drop Section is locked in position before and after use.
- Verify the head rest is secure prior to using the product.
- Verify the back rest is secure prior to using the product.
- Verify the arm rests are secure prior to using the product and after each arm rest adjustment.
- Do not exceed the weight capacity of the product.

## **Intended Use**

This product is intended to be used in an environment where ultrasound and diagnostic equipment is present, including hospitals, and outpatient facilities. The product is intended to be used by healthcare professionals who possess the ability to operate the product safely. The product's movements are controlled both manually and electronically via the product's hand control.

The product is not intended for use in oxygen rich environments.

## **Safety Features**

- This product is equipped with multiple automated safety features to prevent danger or damage during use. The entire system is electrically isolated to UL/IEC 60601-1 and CAN/CSA C22.2 No. 60601-1:14 basic safety standards.
- The actuator assemblies are current overload protected. If overloaded, the actuators will stop and reset automatically.
- The sealed hand control operates the actuators by directing small amounts of low voltage D.C. current to the control box. All actuator drives are equipped with internal limit switches which automatically prevent over-extension.

## Set Up

The product has been shipped in "plug and play" condition. Initial testing should be performed to ensure that all functions are in correct working order. After performing the test and reviewing this manual the product is ready for use.

STEP	ACTION
1	After removing packaging materials, locate the primary power supply cord and attach to a suitable grounded power outlet.
2	To test actuator function, locate the hand control and depress each button one at a time.
3	If any function does not operate, perform the test procedures listed in the Troubleshooting Guide.

## **Transport Position**

It is recommended that the patient surfaces be in a horizontal position if the product is used to transport patients.

## Model 452



Item #	Description
1	Base
2	Seat Section
3	Fowler Section
4	Calf Section
5	Footboard
6	Biopsy Drop Section
7	Caster
8	Head rest
9	Arm rest
10	Pedal

<sup>\*</sup>Optional features may be shown

### **Controls and Indicators**

## Unique Device Identification Label See website for manual and warranty information Patent: www.medicalpositioning.com/patents Serial # Serial Number - ###### ITEM # #### Item# Item Description Item Description Unique Identifier GMDN Code (01) 0 8488710 00633 8 (21) 0123456 MEDICAL POSITIONING, INC. 9738 PFLUMM RD LENEXA, KS 66215 REF Model: Product Weight: Safe Working Load: Electrical: Duty Cycle: Manufactured: This product complies with the applicable standards of Health and Human Services Certification Label 21CFR Subchapter J CUL US E476901 MEDICAL EQUIPMENT WITH RESPECT TO ELECTRICAL SHOCK FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH ANSI/AAMI ES60601-1 (2005)+AMD 1 (2012) AND CAN/CSA-C22.2 No. 60601-1 (2014) Grounding reliability can only be achieved when equipment is connected to an equivalent receptacle marked Hospital Only or Hospital Grade Refer to Manual Label

## **Controls and Indicators**

No Sitting label	
No Sitting/No Standing Label	
Hand Control	M P1  AB P2  AMPI  medical positioning.com  800-593-3246

## **Controls and Indicators**

AC Input	
Battery	
Single Pedal Braking	Liock
Drop Section Release	

#### **Powering the Product**

The product may be powered by AC power from a wall outlet or by DC power via the battery. The product is "on" when plugged into AC power or when a charged battery is installed. The product should not be positioned in a way that would make it difficult to remove power by unplugging the AC power cord or unplugging the battery.

See the section "Battery Information" for indicator information and proper care for batteries.



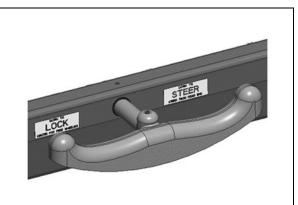
- To reduce the risk of electrical shock, grounding reliability can only be achieved when the
  equipment is connected to an equivalent receptacle marked "hospital only" or "hospital
  grade."
- If damage has occurred to the power cord, immediately remove the cord from service. Failure to do so could result in serious injury or death.
- If damage has occurred to the battery, immediately remove the battery from service. Failure to do so could result in serious injury or death.
- The battery should be periodically inspected for damage. Replace the battery if necessary.

#### **Locking the Casters**

In the locked position casters are prevented from both rolling and swiveling.

#### **Single Pedal Braking**

Pedals are located on each side of the base and are used to adjust the caster function.



## **MARNING**

- To reduce the risk of a potential injury, lock casters before using equipment.
- Once the product and patient have been properly positioned for the procedure, ensure the
  casters are locked and the hand controller is placed in a safe position to prevent unwanted
  contact and unwanted movement of the product surface during the procedure.

#### **Hand Control Functions**

Hand control functions vary depending on the model purchased, your hand control may not include all functions shown.

#### **Surface Height Adjustment**

The surface height may be adjusted between 22" and 38".

Press and hold the applicable hand control function to adjust the seat height.



#### **Fowler Adjustment**

The Fowler section may be adjusted between 0° and 90°.

Press and hold the applicable hand control function to independently adjust the Fowler.



#### **Calf Adjustment**

The calf section may be adjusted between 0° and 83°.

Press and hold the applicable hand control function to independently adjust the calf angle.



#### **Trendelenburg Adjustment:**

The table may be adjusted between 15° Trendelenburg and 15° Reverse Trendelenburg. The Trendelenburg adjustment will pause when seat section is in a level position.

Press and hold the applicable hand control function to independently adjust the Trendelenburg angle.

Press and hold both Trendelenburg buttons simultaneously to activate the "Manual Trendelenburg Leveling" function. This feature will return the table to a level position from any Trendelenburg or reverse Trendelenburg angle.



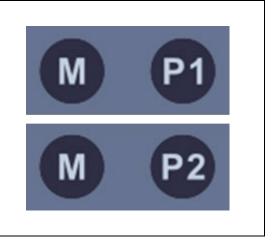
#### **Memory Function**

The product has the ability for the user to set two unique memory positions.

Set the product to the desired position.

To set a memory position, press and hold the "M" button and then simultaneously press and hold either "P1" or "P2". The control box will beep 1 time when the memory position has been set. Setting a memory function takes approximately 3-4 seconds.

The memory positions can be reset by following the instructions above.



#### **Hand Control Lock/Unlock**

The hand control function may be locked to prevent unwanted movement.

Press and hold the lock/unlock button for 3 seconds to lock functions. The control box will beep 2 times to indicate the controls are locked.

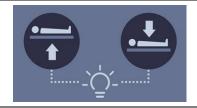
Press and hold the lock/unlock button for 3 seconds to unlock functions. The control box will beep 2 times to indicate the control box is unlocked.



#### **Under-bed Lights**

The product may be equipped with optional under-bed lights.

Press both height up-down buttons to turn on/off the under-bed lights.





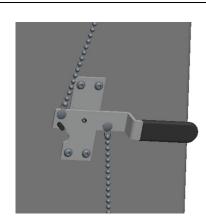
## **MARNING**

- Verify the area around the product is free of impediments before operating to prevent injury or equipment damage.
- Keep hands and feet clear from beneath the patient surface when lowering surface height or making positioning adjustments in order to avoid possible injury.
- Keep hands clear of any hinges during operation to avoid possible injury.

#### **Using the Biopsy Drop Sections**

Drop sections are located on the Fowler section to allow access for imaging equipment.

Pull handle to release drop section latches.



Lift drop section up until latches engage to close the drop sections.



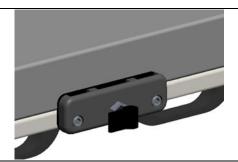


• Failure to latch Drop Sections may result in patient injury. Verify Drop Sections are locked in position before and after use.

#### **Using the Head Rest**

The product is compatible with a head rest that can be attached at the head end of the Fowler.

Rotate cam handle to extend and retract the plunger pin.



Install the head rest at the desired height and lock in place using the plunger pin.



Rotate the plunger pin to the unlocked position to allow for easy removal of the head rest.





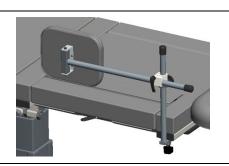
• Verify the head rest is secure prior to using the product or transferring a patient.

#### **Using the Back Support**

The back support can be used to provide stability to the patient during the procedure.

The back rest may be installed at any accessory mounting location.

Install the back rest bracket and secure using the knob.



Adjust the position of the back support by loosening the cam and moving the pad to the desired location. Tighten the cam to lock into position.

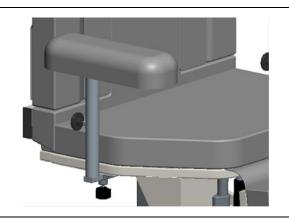




• Verify the back rest is secure prior to using the product.

#### **Arm Rests**

The product may be equipped with arm rests. Place the arm rest bracket into the holder and tighten the knob to secure the arm rest to the chair.

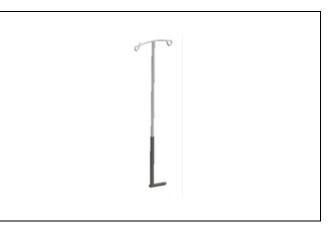




• Verify the arm rests are secure prior to using the product and after each arm rest adjustment.

#### **IV Pole and Holder**

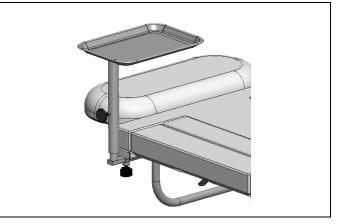
The product may be equipped with an optional IV pole holder. Place the IV pole bracket into the holder and tighten the knob to secure the IV pole to the chair.



#### **Instrument Tray**

The product may be equipped with an optional instrument tray. Place the instrument tray bracket into the mounting bracket and tighten the knob to secure the instrument tray to the chair.

The instrument tray may be installed at any accessory mounting location.



#### **Using the Footboard**

The product may be equipped with an optional footboard.

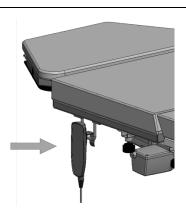
Rotate downward for procedural use.	
<b>Note:</b> The footboard is not intended for standing. The footboard should be raised to its stored position when a patient enters the product in a chair position.	
Raise upward for storage.	



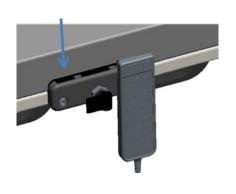
• Standing on the footrest may result in device instability. Do not allow a patient to stand on the footrest while the product is in a chair position.

#### **Storing the Hand Control**

The hand control may be hung on the hook located underneath the support surface.



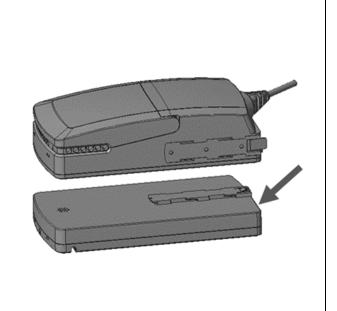
The hand control may be hung from the headrest mount on either side of the lever when not in use.



#### **Battery (Optional)**

The product may be equipped with a battery. If so, the battery is located underneath the control box and will be charged when the product is plugged into AC power.

**Note:** The lifting capacity and speed of the product may be reduced while on battery power.



## **MARNING**

- Equipment should only be serviced by authorized personnel.
- The battery should be periodically inspected for damage. If damage has occurred to the battery, immediately remove the battery from service. Failure to do so could result in serious injury or death.
  - The potential for electrical shock exists with electrical equipment. Failure to follow facility protocols may cause death or serious injury.

#### **Preventative Maintenance**

The following Preventative Maintenance should be performed at a minimum annually. If any of these checks fail, repair or replace the part as applicable.

- Visually inspect all mechanical assemblies and moving parts on the product ensuring smooth, steady operation.
- Visually inspect all fasteners (bolts, nuts, screws, etc.) to ensure all are fully installed. Tighten as necessary.
- Visually inspect all electrical cables and wires for signs of abrasion or other damage. If damaged, replace.
- Visually inspect all electrical connections to ensure they are fully and properly connected. Reconnect as necessary.
- Visually inspect the hand control. If damaged, replace.
- Operate all latch mechanisms to ensure proper engagement of latch into receiver. Adjust if necessary.
- Operate all motors to ensure full extension, retraction and correct operation.
   The motors are permanently lubricated and require no additional lubrication.
- Operate the braking system to ensure proper engagement of the wheel and swivel lock mechanism. Replace as necessary.
- Operate all accessories to ensure proper attachment and operation. Tighten, adjust or replace if necessary.
- Inspect the footboard to ensure that it has resistance to lowering. If necessary, tighten hinge screws to increase resistance.
- Visually inspect the battery for damage. Replace the battery if necessary.
- Unauthorized modification of this product voids any applicable warranty.

## **MARNING**

- No modification of this equipment is allowed.
- Equipment should only be serviced by authorized personnel.
- Removal of secured covers may increase the risk of electrical shock. Refer servicing to qualified and authorized personnel.
- The potential for electrical shock exists with electrical equipment. Failure to follow facility protocols may cause death or serious injury.

## **Battery Information**

The product may be equipped with a Li-Ion rechargeable battery. The battery must be charged periodically to protect the battery from fully discharging. If the battery is not charged for an extended period of time, it may lose its ability to hold a charge and will require replacement. The battery has an integrated charger and must be connected to the control box to be charged. When the battery is connected, plugging the control box into AC power will charge the battery.

The battery buzzer will make a warning when a button on the hand control is pressed, and the battery capacity is low.

<b>Duty Cycle</b>	5 %, 1 minute continuous use followed by 19 minutes not in use	
Charge Time	Approx. 10 hours	
Recharging During Storage	First recharge of the battery must be no later than 12 months after production date stated on the label. Hereafter the battery must be recharged at least every 12 months.	
Operating Temperature	+ 5 °C to + 30 °C	
Storage Temperature	- 10 °C to + 40 °C (+ 10 °C to + 25 °C recommended)  The batteries must be stored in an applicable storage room without direct sunlight.	
Approvals	IEC60601-1, ANSI/AAMI ES60601-1, CAN/CSA-22.2 No 60601-1, IEC62133, UL2054, UN38.3 (needed for transport of lithium batteries)	



LED	Indication of Operation
Solid Yellow	Charging
No LED light	Fully charged
Flashing Yellow	Error during charging

#### Deep discharge protection

- The Li-Ion battery has a deep discharge protection to protect the battery life. The deep discharge protection is activated when the battery is discharged.
- Charge the battery to exit the deep discharge mode. Ensure that the battery is sufficiently charged before use.
- If the battery is completely discharged, the charging will be started at a very small rate to protect the battery. In this case the yellow LED will be flashing. If the battery does not stop flashing and start charging normally within 12 hours (LED ON), the battery is defect and must be disposed according to disposal instructions.

## **Battery Information**

#### Safety feature

The Li-Ion battery contains several mechanisms to protect itself from being damaged due to excessive use.

In case of overheating, the device will activate a thermal protection. No power output will be available until the temperature has returned to normal operating range. Overheating may occur by extensive use at high temperature or by exceeding the 1/19 duty cycle.

#### **BA21** safety

The Li-Ion batteries for medical use are designed and manufactured to be safe throughout the product life. The battery manufacturer has performed various tests of the batteries in normal use, abuse and failure situations to verify the design and production methods. These tests have not shown any unacceptable risks.



### **WARNING**

Lithium-ion batteries differ from the lead acid technology as they have a built-in deep discharge protection.

- Loss of power might happen due to the battery deep discharge protection and will only happen in case of continuous use of the battery despite warnings. In this event, there may be no warning and the application may not be able to move when expected.
- Do not open the battery housing as damaging the cell or circuitry may develop excessive heat. Lithium-ion batteries that are defective, have been damaged or might produce excessive heat or fire are not allowed for transportation. (contact your local transportation provider)
- For safety reasons, please adhere to the indicated charging and operation temperature.
- In case the battery turns hot, disconnect it and evacuate the room and wait for 2 hours before taking further steps.
- Recharge batteries every 12 months at a minimum.
- Dispose of batteries in accordance with local regulations.

#### DO NOT:

- heat or burn the battery
- short circuit the battery
- expose the battery to high impact
- crush or puncture the battery
- use batteries with signs of damage or corrosion
- charge or store the battery near combustible material
- expose the battery to water or other liquids

## **Battery Information**

#### **Disconnecting the Battery**

If equipped, the battery is installed underneath the control box. When storing the product for extended periods, the battery should be disconnected from the control box.

Remove the rear base cover.	
Open the top cover on the control box.	
Unplug the battery cable from port 5 in the control box.	4 3 5 6 6
Replace the control box cover.  Replace the rear base cover.	



- Equipment should only be serviced by authorized personnel.
- Removal of secured covers may increase the risk of electrical shock. Refer servicing to qualified and authorized personnel.

### **Expected Life**

The expected life of the product is 7 years of normal use. Some components may have a shorter life and require replacement.

Note: See Warranty section for warranty information.

#### **Discard the Unit**

Upon reaching the end of its useful life the product may be discarded in accordance with local and federal standards. Recycle when possible.



In accordance with the European Directive 2002/96/EC on Waste Electrical and Electronic Equipment (WEEE), the product must not be disposed as unsorted municipal waste but should be collected separately. Consult your instructional policies and local regulations regarding disposal. Contact your Medical Positioning, Inc. Service Representative if additional disposal details are required.

## Cleaning

#### **Plastic and Painted Surfaces**

The painted metal and plastic surfaces can be cleaned with normal cleaners and disinfectant.

STEP	ACTION
1	Clean and/or disinfect with liquid cleaner of choice being careful to follow label instructions provided with cleaner. (Always test a small area first to determine suitability of solution)
2	Wipe the surface clean with a damp cloth after applying cleaners and disinfectant to remove excess residue buildup.

#### Vinyl

The vinyl upholstered surfaces can be cleaned in one of the following ways:

The preferred method of everyday cleaning is using a soft cloth or sponge with mild soap and water or disinfectant. Spills and accidents require immediate attention for best results. When caught quickly, most stains such as grease, blood and felt tip pens can be wiped right off. Mild soap and water is the preferred method; however, typical hospital-grade antiseptic wipes work as well. For more stubborn stains, a variety of concentrated and solvent type cleansers may be used without damaging the surface as long as they are thoroughly rinsed off with water.

Always start with the mildest cleaning agents first. Never use harsh powdered abrasive cleansers or steel wool. Products containing bleach, ammonia or alcohol should be wiped from the surface with a wet cloth after use. Residue from these products will damage vinyl surfaces.

STEP	ACTION
1	Clean and/or disinfect with liquid cleaner while being careful to follow label instructions provided with cleaner. (Always test a small area first to determine suitability of solution)
2	Wipe the surface clean with a damp cloth after applying cleaners and disinfectant to remove excess residue buildup.

## Cleaning

### RECOMMENDED MAXIMUM CLEANER TO WATER SOLUTIONS 1:1 mix of mild soap and water. Wipe surface with damp cloth with water Mildest only after cleaning. Straight application of common disinfectants. Wipe surface with damp cloth with water only after cleaning. 1:1 mix of ammonia and water. Use a soft cotton cloth saturated with the cleaning material. Wipe surface with damp cloth with water only after cleaning. 1:4 mix of bleach and water. Use a soft cotton cloth saturated with the cleaning material. Wipe surface with damp cloth with water only after cleaning. 1:1 mix of isopropyl alcohol and water. Use a soft cotton cloth saturated with the cleaning material. Wipe surface with damp cloth with water only after cleaning. Straight application of isopropyl alcohol. Use a soft cotton cloth saturated with the cleaning material. Wipe surface with damp cloth with water only after cleaning. 1:1 mix of acetone and water. Use a soft cotton cloth saturated with the Strongest cleaning material. Wipe surface with damp cloth with water only after cleaning.

This information is not a guarantee and does not relieve the user from the responsibility of proper and safe use of the product and all cleaning agents.



• It is recommended that the product be cleaned between patients; please follow your facility's documented policy.



- Substances such as imaging gels and alcohol will not damage the vinyl surface when immediately removed. Studies have shown that exposure for longer than a few minutes can damage the topcoat and will eventually discolor vinyl.
- Always read manufacturer's instructions and warnings before using any cleaning product or disinfectant.
- Do not use abrasives to clean painted surfaces.

#### **Service Calls**

A "Troubleshooting Guide" is included to instruct you in the event of a malfunction. If you are experiencing any of the following symptoms, this guide may help you quickly solve the problem. If, after consulting this guide, you are still unable to operate your product please contact MPI at 1-800-593-3246. Please have the following information ready when you call:

- 1. Model Number or Name of Product
- 2. Serial Number
- 3. Date Received
- 4. Condition When Received
- 5. Symptom (or problem) Encountered & Result of Troubleshooting Procedure

#### **Adverse Event Reporting**

Any serious incident that has occurred in relation to the device should be reported immediately to Medical Positioning. If located in the European Union, please immediately contact Medical Positioning and the competent authority of the Member State in which the user and/or patient is established.

Medical Positioning, Inc. 9732 Pflumm Road Lenexa, KS 66215 www.MedicalPositioning.com 011-816-474-1555 800-593-3246 (ECHO)

## **Troubleshooting Guide**

SYMPTOM	PROBABLE CAUSE	SUGGESTION	
	Power cord not plugged all the way into wall receptacle.	Push power cord securely into receptacle.	
	Power outlet receptacle not supplying AC power.	Check power availability or plug unit into another receptacle.	
	The power cord may be separated from the control box.	Securely press power cord into control box.	
	Battery may be drained.	Replace or charge battery.	
No Actuator Function Actuator(s) Not Running	Actuator cord may be unplugged.	Push actuator cords     securely into actuator     receptacle.	
	Product was overloaded and tripped internal fuse in control box.	Replace control box.	
	Product motion is limited at certain heights and angles.	Return the surface to a level position to restore full range of motion	
	The product will not move when hand control buttons are pressed.	The hand control buttons may be locked. Press and hold the control lock/unlock button for 3 seconds until a beep is heard.	
	Control system limits certain product positions. Beeps indicate limit positions.	Return the surface to a level position to restore full range of motion	
Control box beeps	Control box will beep when memory function is set	Normal operation, no action necessary.	
	Control box will beep 2 times when control lock/unlock function is activated.	Normal operation, no action necessary.	
	Battery may be drained.	Replace or charge battery.	

## **Troubleshooting Guide**

SYMPTOM	PROBABLE CAUSE	SUGGESTION	
Squeaking noises during operation.	<ul> <li>Actuator pins are not sufficiently lubricated</li> </ul>	Apply WD40 or similar lubricant to actuator pins.	
The footrest opens too easily.	Footrest hinge may need to be adjusted.	Tighten footboard hinge bolts.	

## **MARNING**

- Do not modify this equipment without authorization of the manufacturer.
- Removal of secured covers may increase the risk of electrical shock. Refer servicing to qualified personnel.
- The battery should be periodically inspected for damage. Replace the battery if necessary.

# Product Models & Attributes UltraMamm™

ATTRIBUTE	452
Base Width	28.5"
Base Length	33.5"
Surface Width	28"
Surface Length	75"
Surface Height Range *To top of cushion	22" – 38"
Fowler Range	0° – 90°
Calf Range	0° – 83°
Trendelenburg Range	±15°
# of Biopsy Drop Sections	2
Maximum Patient Weight	500lb
Maximum Safe Working Load	527lb
Approximate Product Weight	350lb

#### **Environmental Conditions**

ATTRIBUTE	Range for Use	Range for Storage and Transport
Ambient Temperature	+5° to 40° C	-10° to +40° C
Relative Humidity	20% to 80% @ 30°C non-condensing	20% to 80% @ 30°C non-condensing
Atmospheric Pressure	700 to 1060 hPa	700 to 1060 hPa

### **Upholstery**

ATTRIBUTE	SPECIFICATION	
Foam	California Technical Bulletin 117	
Vinyl	California Technical Bulletin 117	

### **Power Requirements**

ATTRIBUTE	SPECIFICATION	
Electrical, Product	100-240 VAC, 50/60 Hz, max 4.5 A	
Battery Option	25.9V, 2.25Ah, 58.28Wh	
Duty Cycle	10% max, 2 min. on / 18 min. off	
Battery Duty Cycle	5% max, 1 min on / 19 min off	

- All electrical circuitry is isolated from chassis.
- Grounding reliability can only be achieved when the equipment is connected to an equivalent receptacle marked "Hospital Only" or "Hospital Grade."
- The power cord is to be used for mains disconnection.
- Attached power supply cord set is not allowed to be diverted to other equipment.

## **Classifications and Standards**

ATTRIBUTE	SPECIFICATION		
Standards	<ul> <li>IEC 60601-1:2005 + A1:2012</li> <li>ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012</li> <li>CAN/CSA-C22.2 NO. 60601-1:14</li> <li>EN 60601-1:2006 +A11:2011 +A1:2013 +AC:2014</li> <li>IEC 60601-1-2:2007</li> <li>EN/ISO 14971:2012</li> </ul>		
Protection against Electrical Shock	<ul><li>Class I equipment</li><li>Type B applied part</li></ul>		
Degree of protection against Dust and Fluid intrusion	• IPXO		

## **Applied Parts (in accordance with IEC 60601-1)**

- All padded surfaces
- Arm rests

## **Electromagnetic Emissions Guidance**

The product use components that meet the requirements for IEC 60601-1-2. Other products that are used in the vicinity of this product should also comply with this standard. If they do not comply, electromagnetic interference between the products could cause the products to operate incorrectly. If problems do occur, contact the product manufacturer(s).

Make sure the product operates correctly when used near other electronic devices. Portable and mobile radio frequency (RF) communications equipment can affect electrical equipment.



• If the product is used adjacent to other electrical equipment, observe this product and the other electrical equipment to make sure they operate as intended.

## **Electromagnetic Compatibility**

Medical electrical equipment needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in this user manual.

Portable and mobile radio frequency (RF) communications equipment can affect medical electrical equipment.

#### **Guidance and Manufacturer's Declaration - Electromagnetic Emissions**

The product is intended for use in the electromagnetic environments specified below. The customer or the user of the product should assure it is used in such an environment.

user of the product should assure it is used in such an environment.			
Emissions Test	Compliance	Guidance	
RF Emissions CISPR 11	Group 1	This product 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 A		
Harmonic Emissions IEC 61000-3-2	N/A	The product is suitable for use in all establishments other than domestic and those directly connected to the public low-voltag power supply network that supplies buildings used for domestic	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	N/A	purposes.	

#### **Guidance and Manufacturer's Declaration - Electromagnetic Immunity**

The product is intended for use in the electromagnetic environments specified below. The customer or the user of the product should assure it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Guidance
Electrostatic Discharge IEC 61000- 4-2	± 6 kV Contact ± 8 kV Air	± 6 kV Contact ± 8 kV 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 IEC 61000-4-4	± 2 kV on power Supply Lines  ± 1 kV on Input/Output Lines	± 2 kV on Power Supply Lines  ± 1 kV on Input/Output Lines	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	± 1 kV Differential Mode ± 2 kV Common Mode	± 1 kV Differential Mode ± 2 kV Common Mode	Mains power quality should be that of a typical commercial or hospital environment
Voltage Dips, Short Interrupts, & Variations on Power Supply Lines IEC 61000-4-11	$< 5\% \ U_T$ $(95\% \ dip \ in)$ $U_T \ for \ 0.5 \ cycles)$ $< 40\% \ U_T$ $(60\% \ dip \ in)$ $U_T \ for \ 5 \ cycles)$ $< 70\% \ U_T$ $(30\% \ dip \ in)$ $U_T \ for \ 25 \ cycles)$	$< 5\% \ U_T$ $(95\% \ dip \ in)$ $U_T \ for \ 0.5 \ cycles)$ $< 40\% \ U_T$ $(60\% \ dip \ in)$ $U_T \ for \ 5 \ cycles)$ $< 70\% \ U_T$ $(30\% \ dip \ in)$ $U_T \ for \ 25 \ cycles)$	Mains power quality should be that of a typical commercial or hospital environment. If the user of the product requires continued operation during mains interruptions, it is recommended that the product be powered from an uninterruptible power supply or a battery.
Power Frequency Magnetic Fields IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE  $\ \ U_T$  is the a.c. mains voltage prior to application of the test level

#### Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The product is intended for use in the electromagnetic environments specified below. The customer or the user of the product should assure it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Guidance	
			Portable and mobile RF communications equipment should be used no closer to any part of the product, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.	
			Recommended separation distance	
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 Mhz	3 Vrms	$d = 1,2\sqrt{P}$	
Radiated RF IEC 61000-4-3	3 Vrms 80 MHz to 2.5	3 V/m	$d=1,2\sqrt{P}$ 80 MHz to 800 MHz	
	GHz		$d=2,3\sqrt{P}$ 800 MHz to 2.5 GHz	
			Where <i>P</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <i>d</i> is the recommended separation distance in meters (m).	
			Filed strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range. b	
			Interference may occur in the vicinity of equipment marked with the following symbol:	

NOTE 1 At 80 MHz and 800 MHz, 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.

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 product is used exceeds the applicable RF compliance level above, the product should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the product.

Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.

## Recommended separation distances between portable and mobile RF communications equipment and the MPI Echo Products

The product is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the product can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the product as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter	Separation distance according to frequency of transmitter (m)			
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz	
	$d=1,2\sqrt{P}$	$d=1,2\sqrt{P}$	$d = 2,3\sqrt{P}$	
0.01	0,12	0,12	0,23	
0.1	0,38	0,38	0,73	
1	1,2	1,2	2,3	
10	3,8	3,8	7,3	
100	12	12	23	

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

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.

## **Replacement Parts and Upgrade Kits**

The following items are replacements parts or upgrade kits for UltraScan Versa, UltraScan Versa Premier, and UltraMamm. Some of the items below may not be suitable for all models of product.

Part Description	Part #
6 Function Hand Control	15747
1 Function Foot Control (Height) <sup>1</sup>	15755
1 Function Foot Control Bolt-on (H) <sup>1</sup>	15940
2 Function Foot Control (Fowler/Calf) <sup>1</sup>	15756
2 Function Foot Control (Height/Fowler) <sup>1</sup>	15792
2 Function Foot Control (Calf/Trend) <sup>1</sup>	15910
Battery	15757
Positioning Wedge	11943
Arm Rest	16053
Instrument Tray	14084

Kit Description	Part #
Multi-Function Control Kit	15836
Battery Functionality Kit	15837
Underbed Light Kit²	15838
IV Pole Kit	14083
Head Rail Kit	15602
Back Support Kit	15527
Underbed Hook Kit	15510
Safety Strap Kit	15843

<sup>&</sup>lt;sup>1</sup>The Multi-Function Control Kit is required to use multiple foot/hand controls.

<sup>&</sup>lt;sup>2</sup>The Multi-Function Control Kit is required with the Under-bed Light Kit.

## Warranty

#### **Ultra**Mamm™

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#### YEAR WARRANTY

Medical Positioning, Inc. ("MPI") warrants and represents that this product will be free from material and workmanship defects during the period indicated above (the "Warranty Period"), commencing with tender of delivery as defined in Uniform Commercial Code § 2-503, irrespective of any inspection period and provided that the product is maintained and operated in accordance with MPI's specifications.

If the product fails due to a manufacturing defect, MPI will, at its sole expense and discretion, repair the product, authorize repairs to the product, or replace the product. MPI will ship any replacement products or parts using standard shipping rates; if the customer requires expedited shipping of replacement products or parts, the customer is responsible for paying shipping costs above standard rates.

Preventative maintenance and repairs due to damage by use, accident, improper care, negligence, or other non-defect related failures are not covered by this warranty. This warranty is void as to products that have been modified without the advance written permission of MPI.

OTHER THAN AS SET FORTH HEREIN, MPI MAKES NO WARRANTY WHATSOEVER, EITHER EXPRESSED OR IMPLIED, WITH RESPECT TO THIS PRODUCT. MPI SPECIFICALLY DISCLAIMS THE (a) IMPLIED WARRANTY OF MERCHANTABILITY; (b) WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE; AND (c) WARRANTY AGAINST INFRINGEMENT OF ANY PATENT, COPYRIGHT, TRADEMARK, TRADE SECRET OR OTHER PROPRIETARY RIGHTS OF A THIRD PARTY; WHETHER ARISING BY LAW, COURSE OF DEALING, COURSE OF PERFORMANCE, USAGE OF TRADE OR OTHERWISE.

This warranty is nontransferable. The remedies provided under this warranty are the customer's sole and exclusive remedies. In no event will MPI be liable for any direct, indirect, special, incidental, consequential damages or lost profits or income whether based on contract, tort, or any other legal theory.

#### Medical Positioning, Inc.

9732 Pflumm Road Lenexa, Kansas 66215 (816) 474-1555 (800) 593-3246 Fax (816) 474-7755

WAR069-B

## **Return Policy**

MPI accepts returns of unused products within 30 days from the date of delivery, irrespective of any inspection period. Returns are subject to a 30% restocking fee, any applicable duties or taxes and quality inspection. No product may be returned without prior written authorization from MPI. The customer is responsible for all shipping charges and any applicable duties or taxes incurred in connection with a return.

WAR093-A