



# IF 77000S

# **CLINICAL MAX LOW AIR LOSS WITH** ALTERNATING PRESSURE SYSTEM



# **USER MANUAL**

**Important: Do not operate the Mattress System** without first reading and understanding this manual! Save this manual for future use.

Info: The most current version of this manual can be found online at www.grahamfield.com.

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#### INTRODUCTION

Use this manual for set-up and operation of the SIMMONS<sup>™</sup> Clinical Care 770000S Clinical Max Low Air Loss with Alternating Pressure System, a true low air loss mattress system combined with alternating pressure, suitable for the prevention and management of all categories of pressure ulcer. Read all instructions before using the mattress system. Save this manual for future reference.

#### INTENDED USE OF THIS DEVICE

The intended use of the SIMMONS™ Clinical Care 770000S Clinical Max Low Air Loss with Alternating Pressure System is:

- Aid in the treatment and prevention of all categories of pressure ulcer while optimizing user comfort.
- Pain management as prescribed by a physician.
- As described above, in either a homecare or long term care setting.

#### **Contraindication**

Use nasal cannula, face mask, or 1/2 length oxygen tent to deliver oxygen in the presence of this product.

DO NOT use a full length oxygen tent that extends past the top surface of the mattress with this product.

#### **⚠ WARNING:**

This product has a maximum weight capacity of 440 lb (200 kg), EVENLY DISTRIBUTED, in *Static* mode. This product has a maximum weight capacity of 400 lb (180 kg), EVENLY DISTRIBUTED, in *Therapuetic* mode.

### **EQUIPMENT SYMBOLS**

IP20	120V system	Protected against solid foreign objects of 12.5 mm and greater, no protection against vertically falling water drops, KEEP DRY	
IP21 <b>å</b>	230V system	Protected against solid foreign objects of 12.5 mm and greater; protection against vertically falling water drops	
***	Manufactur	er	
	Refer to instruction manual / booklet		
ҡ	"BF"symbol: Indicates that this product is in accordance with the degree of protection against electric shock for type BF equipment		
<u></u>	Attention! Read the instructions!		
Ωi	Consult operating instructions		
	Grounding terminal		
×	Do not bleach		
<b>⋈</b>	Do not iron		
0	Tumble dry, normal, low heat		
(P)	Dry clean, any solvent except trichloroethylene		
95	Machine wash, regular / normal 95°C (203°F)		
X	Disposal of Electrical & Electronic Equipment (WEEE): Do not treat this product as household waste. For more detailed information with regard to returning and recycling this product, please consult your local city office, household waste disposal service, or your Graham-Field authorized distributor.		

#### **STANDARDS**

The system has been tested and successfully approved with the following standards:			
$\triangle$	For U.S. and Canada only		
c Us Intertek	Conforms to UL60601-1, Certified to CAN/CSA C22.2 No. 601.1-M90		

#### IMPORTANT SAFETY PRECAUTIONS

The safety statements presented in this chapter refer to the basic safety information that should be observed by those using this Mattress System. There are additional safety statements in other chapters or sections, which may be the same as or similar to the following, or specific to the operations.

- ▲ NOTICE: Indicates a potential hazard or unsafe practice that, if not avoided, could result in product or property damage.

Info: Provides application recommendations or other useful information to ensure that you get the most from your product.

#### **DANGER**

#### To reduce the risk of electrocution:

- ⚠ DANGER: Always unplug this product immediately after use.

- ⚠ DANGER: Do not place this product in or drop into water or other liquid.

#### **WARNING**

# To reduce the risk of burns, electrocution, fire, or personal injury:

- - a) it has a damaged cord or plug,
  - b) it is not working properly,
  - c) it has been dropped or damaged, or
  - d) it has been dropped into water.

Return the product to your Graham-Field authorized distributor.

- ⚠ WARNING: Do not leave long lengths of tubing around the top of the bed. It could lead to strangulation.

#### 

This product has a maximum weight capacity of 440 lb (200 kg), EVENLY DISTRIBUTED, in *Static* mode. This product has a maximum weight capacity of 400 lb (180 kg), EVENLY DISTRIBUTED, in *Therapuetic* mode.

- MARNING: Patient entrapment with bed side rails may cause injury or death. The bed frame and its components, including the mattress, bed side rails, head and foot board, bedding, and any accessories added to the bed, can all affect the risk of entrapment. Thorough patient assessment and monitoring are necessary to reduce the risk of entrapment, including establishing whether the use of a bed rail is in the best interest of the patient. Read and understand the User Manual before using this equipment. Graham-Field product manuals are available online at www.grahamfield.com.

Visit the FDA's Bed Safety page at <a href="www.fda.gov">www.fda.gov</a> to learn more about the risks of entrapment. It is the responsibility of the facility and provider to be in compliance with these guidelines. Refer to user manuals for beds and rails for additional product safety information.

After any adjustment, repair or service, and before use, ensure all attaching hardware is securely tightened. Bed rails with dimensions different than the original equipment specified by the bed manufacturer may not be interchangeable and may result in entrapment or other injury.

#### **EMC WARNING STATEMENT**

This equipment has been tested and found to comply with the limits for medical devices to the EN 60601-1-2:2007. 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 distance between the equipment.
- Connect the equipment into an outlet on a circuit different from that to which the other device is connected.
- Consult the manufacturer or field service technician for help.
- This system has been tested in compliance with the following volunteer standards: FDA.

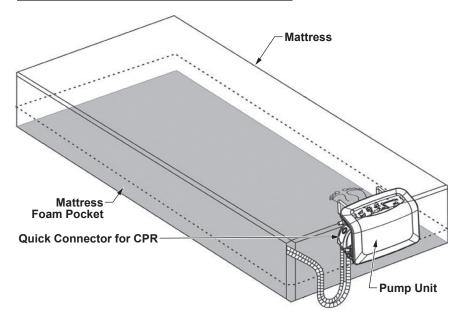
For further information, please see **Appendix A: EMC Information** 

#### **NOTICE**

▲ NOTICE: The pump can be used only with the accompanying mattress. Do not use it for any other purpose.

### **PRODUCT DESCRIPTION**

#### **PUMP AND MATTRESS SYSTEM**



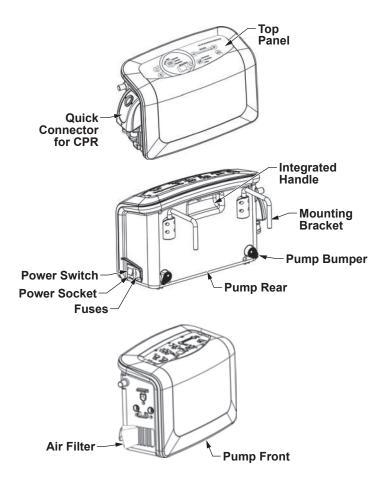


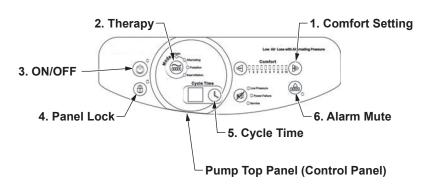




**View of Air Cells** 

### **Pump unit**





### **Pump Top Panel (Control Panel)**

The pump **Top Panel** / **Control Panel** is shown at bottom of previous page. **Button** and **Indicator** descriptions follow.

### 1. Comfort Setting

The Comfort Setting controls the air pressure output. When the firmness is increased ( $\triangleright$ ), the output pressure will increase, and when the firmness is decreased ( $\triangleleft$ ) the output pressure will decrease. The mattress should be firm enough to support the patient, yet soft enough so the patient will sink down to eliminate pressure points. Please consult your physician for an appropriate setting.

# 2. Therapy

#### A. Static

Redistributes body mass over a greater surface area. Caregivers can also use this function during patient transfer or for better support.

#### **B. Alternating Pressure**

1-in-2 alternating cell cycle achieves periodic pressure relief. There are four selectable cycle time settings available. Caregivers can select one of the four cycle settings based on patient comfort and desired outcome.

#### C. Pulsation

Encourages lymph and blood flow for increased oxygenation. The mattress pulsation alternates between a decrease and increase of the pressure in all cells every fifteen seconds.

#### D. Seat Inflation

Features additional support for the patient during upright position to prevent bottoming out.

Info: When the patient is in the raised position, the caregiver should readjust the pressure setting and patient sitting posture to prevent possible bottoming out.

# 3. **ON/OFF**

Press ON to turn the unit ON. Press OFF to turn the unit to OFF/STANDBY.

Info: The power switch on the side of the pump must first be turned on.

## 4. (1) Panel Lock

Should the panel remain untouched for five minutes, the **Panel Lock** feature will lock the panel adjustments and the green LED will illuminate to prevent accidental changing of the settings during normal operation. To unlock the panel, press the **Panel Lock** button for three seconds.

## 5. Cycle Time

There are four selectable cycle times: 5, 10, 15, and 20 minutes. By pressing the **Cycle Time** button, the user can select one of the four cycle times based on patient comfort and desired outcome.

### 6. Alarm Mute

Press the **Alarm Mute** button to temporarily suspend the CPR and low pressure alarm. Should the situation not be resolved within three minutes, the alarm will resume to notify the caregiver.

#### A. Low Pressure Indicator

When the low pressure indicator (yellow LED) illuminates continuously with an alarm sounding, the pressure inside the air mattress body section is abnormal. Ensure quick connector is attached, all tubing is correctly installed per instructions, and all tubing is properly secured.

Info: The Low Pressure Indicator will not work if mattress air cells are purposely disconnected.

#### B. **PFA (Power Failure Alarm)**

During power failure situation, the Power Failure LED will illuminate and an alarm will sound. Press the Mute Button to disable both LED and alarm.

### C. Tech Support

The Service Indicator LED will illuminate if a motor issue occurs with the system. If this occurs, consult your Graham-Field authorized distributor for help.

## 7. Max Firm / Nursing Key

The system will go into Max Firm mode automatically when the power switch is turned on, to ensure the pump quickly reaches its maximum operating pressure. Once the maximum pressure level is reached, the pump will automatically switch into the previously selected comfort level in STATIC mode, or the caregiver can press the THERAPY button to return to the previous mode. The user can also use this function as full mattress inflation during patient ingress / egress or normal nursing procedure for better support. There is a twenty-minute timeout mode to return to the previous selected comfort level.

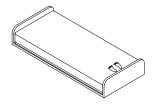
#### **INSTALLATION**

#### **UNPACKING**

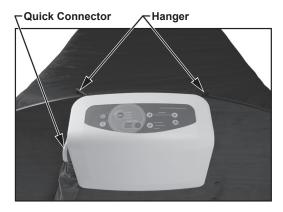
- 1. Carefully remove all components from the carton.
- 2. Inspect all components.
- 3. If damage is evident to the contents, please notify the carrier and your Graham-Field authorized distributor.

#### **PUMP AND MATTRESS SETUP**

1. Place the mattress on top of the bed frame. Note that mattress foot end symbol is placed at foot end of mattress.



- 2. Fasten the securing straps on the base of the mattress firmly by fixing the straps to the bed frame, ensuring that moving sections of the bed are still free to move.
- 3. Hang the pump on the bed rail at foot end, and adjust hangers on rear of pump for best upright position of the pump.
- NOTICE: Do not place the pump on a flat surface; this might block the pump unit air intake.



- ▲ NOTICE: Place the device in a position where the caregiver and / or doctor can access it easily.
- 4. Connect Quick Connector from air mattress to pump unit. Ensure the connector is in the correct position as shown above. When you hear or feel a click, the connection is complete and secured.

Info: The pump is only operable when the Quick Connector is connected to the system.

- ▲ NOTICE: Ensure the pump unit is suitable for local power voltage.
- 5. Plug the power cord into a properly grounded electrical outlet.

*Info: The power plug also serves to disconnect device.* 

- ▲ NOTICE: The pump can only be applied to the mattress recommended by the manufacturer. Do not use it for any other purpose.
- 6. Turn the power switch to the ON position.
- ▲ NOTICE: Ensure air hoses are not kinked or tucked under mattress.

#### **OPERATION**

Info: always read the operating instructions before use.

#### **GENERAL OPERATION**

- 1. Turn the main power switch on the side of the pump **ON** and press **ON** on the control panel to turn on the power.
- 2. The system will automatically go into **Max Firm** mode for a few minutes of inflation.
- 3. Every time the mattress is set up for use, it will execute Max Firm for the quickest inflation. The low pressure indicator (yellow LED) will illuminate before the mattress reaches appropriate pressure; when appropriate pressure is reached, the low-pressure indicator (yellow LED) will de-illuminate.
- 4. When the initial inflation (Max Firm process) is completed, the system will automatically enter into Static mode.
- 5. According to the weight and height of the patient, adjust the pressure setting to the most suitable level without bottoming out.

#### **CPR**

When CPR needs to be performed, press the **Quick Connector Release** Button and quickly detach the connector from the system to release the air.

#### PRESSURE SETUP

The caregiver can adjust air mattress pressure to the desired softness by adjusting the **Comfort Level**. Consult the patient's physician for a suitable setting.

#### **MARNING:**

This product has a maximum weight capacity of 440 lb (200 kg), EVENLY DISTRIBUTED, in *Static* mode. This product has a maximum weight capacity of 400 lb (180 kg), EVENLY DISTRIBUTED, in *Therapuetic* mode.

#### **AUDIBLE AND VISIBLE ALARM**

When the following situations occur, the LEDs will illuminate and the alarm will sound.

#### **Power Failure**

When electrical shortage occurs or the power cord is disconnected without turning off the pump first, the **Power Failure Indicator** (orange LED) will illuminate and an alarm will sound. Ensure power cord is connected properly.

### **Low Pressure**

When abnormally low mattress pressure occurs, the **Low Pressure Indicator** (orange LED) will illuminate and an alarm will sound. Refer to **Troubleshooting** section if this happens. The **Low Pressure Indicator** will illuminate continuously until the low pressure fault condition is resolved.

#### **Service Indicator**

The **Service Indicator** will illuminate during mechanical failure. Please contact your Graham-Field authorized distributor if this occurs.

#### **ALARM MUTE**

When the situations described in **AUDIBLE AND VISIBLE ALARM** occur, the LED will illuminate and an alarm will sound to warn the patient and caregiver. Pressing the **Alarm Mute** button will temporarily mute the alarm buzzer (CPR and Low Pressure) to enable the caregiver to check for possible causes. If the CPR and Low Pressure situation are not resolved within three minutes, the alarm will resume. When in a **Power Failure** situation, pressing the **Alarm Mute** button will turn off the buzzer and deilluminate the **Power Failure** indicator.

#### **MAINTENANCE**

#### **CLEANING**

**Pump**: Wipe the pump with a clean, damp cloth pre-soaked with mild detergent, and keep it away from dust. Air dry.

- ▲ NOTICE: Do not use phenolic products or corrosive or powdered cleansers to clean the pump.
- ▲ NOTICE: Do not immerse or soak the pump.

**Mattress**: Wipe the mattress unit with a clean, damp cloth pre-soaked with warm water (not to exceed 149°F (65°C) and mild detergent, and keep it away from dust. The mattress may also be cleaned using a 10% solution of sodium hypochlorite (bleach) diluted in water. Air dry all parts thoroughly before use.

- ▲ NOTICE: Do not use phenolic products to clean the mattress.
- ▲ NOTICE: After cleaning, air dry the mattress without direct exposure to sunlight.

**Carrying bag (if available):** Turn the carrying bag inside out and wipe it down completely using disinfectant. Allow it to air dry thoroughly. Once the inside is dry, turn it back and wipe down the outside with disinfectant.

#### **GENERAL MAINTENANCE**

- Check power cord and plug for abrasion or excessive wear. For replacement, please contact your Graham-Field authorized distributor.
- 2. Check mattress cover for signs of wear or damage. Ensure mattress cover and tubes are connected correctly.
- 3. Check air hoses for any kinks or breaks. For replacement, please contact your Graham-Field authorized distributor.

#### **Fuse replacement**

Tools needed: small screwdriver

- 1. If you suspect a blown fuse, disconnect the plug from the wall outlet immediately.
- 2. Use a small screwdriver to remove the cover of the fuse holder (fuse locations are shown in picture at right).
- 3. Insert a new fuse of the correct rating (5A / 250V for 120V system, and T3.15A / 250V for 230V system).
- 4. Replace the fuse holder cover. Ensure the fuse holder cover is securely installed.



#### Air filter replacement

- 1. Remove the air filter (shown at right) located at the side of the pump.
- 2. The filter is reusable, if not torn, and can be washed gently with a mild detergent and water. Dry the filter before replacement.
- 3. Replace the filter. Ensure the filter is securely installed. Replace the air filter regularly if it is gray, torn, or the environment is dirty.



### Rechargeable battery

Info: The rechargeable battery is designed to support power failure alarm.

- 1. To check if the rechargeable battery has been drained of charge, unplug the power cord; the Power Failure indicator should illuminate, and the alarm should sound, and last for several minutes.
- 2. If the Power Failure indicator does not illuminate nor the alarm sound, or the battery needs replacement (approximate life expectancy is six months), contact your Graham-Field authorized distributor.

#### **STORAGE**

- To quickly deflate the mattress for storage, click on the Quick Connector release button to remove the connector.
- 2. Lay the mattress out flat with CPR valve open, ensuring tubing is not kinked.
- 3. Roll from the foot end toward the head end.
- 4. Stretch the foot-end strap around the rolled mattress to prevent unrolling. Fasten the buckle strap to secure the packed mattress.
- 5. Wrap the power cord around the pump bumper (on back of pump) for storage.
- 6. Place the whole system in the carrying bag for storage.
- ▲ NOTICE: Do not store the mattress system in direct sunlight, high temperature, dust or moisture.
- ▲ NOTICE: Do not crease or stack the mattresses.

#### **TROUBLESHOOTING**

Problem	Solution		
Power is not ON	Ensure the plug is connected to a power source     Check if fuse is blown		
Low Pressure Alarm is on	Check if the Quick Connector is tightly secured     Ensure all tubing connections along mattress are secure     Check if air hoses are kinked or broken		
Power Failure Alarm is on	Check if power has suddenly shut off     Ensure power cord is properly connected		
Patient is bottoming out	Pressure setting might be inadequate for patient; adjust comfort range one to two levels higher and wait a few minutes for maximum comfort		
If the problem still occurs, contact your Graham-Field authorized distributor			

#### **SERVICE**

If a problem occurs with the SIMMONS<sup>™</sup> Clinical Care 770000S Clinical Max Low Air Loss with Alternating Pressure System that you are unable to resolve, contact your Graham-Field authorized distributor for service.

#### **SPECIFICATIONS**

Pump				
Power Supply (Info: see		120V system: AC 110-120V 60 Hz, 4.5A		
rating label on product)		230V system: AC 220-240V 50/60 Hz, 3.15A		
Fuse Rating		120V system: T5A / 250V		
		230V system: T3.15A / 250V		
Cycle Time		5 / 10 / 15 / 20 minutes		
Dimensions (L	x W x H)	12.3 x 10.2 x 6.3" (31.2 x 26 x 16 cm)		
Weight		11 lb (5 kg)		
Classification		120V / 230V system: Class I, Type BF Applied Part: Air Mattress Not suitable for use in the presence of a flammable anesthetic mixture (No AP or APG protection)		
		120V system: IP20. Protected against solid foreign objects of 12.5 mm and greater, no protection against vertically falling water drops, KEEP DRY		
		230V system: IP21. Protected against solid foreign objects of 12.5 mm and greater, protection against vertically falling water drops		
Environmental Information				
Environment	Temperature	Operation: 50°F to 91°F (10°C to 33°C) Storage: 5°F to 122°F (-15°C to 50°C) Shipping: 5°F to 158°F (-15°C to 70°C)		
	Relative Humidity	Operation: 10% to 90% non-condensing Storage: 10% to 90% non-condensing Shipping: 10% to 90% non-condensing		
Mattress				
Model		8" mattress, 2" foam pocket is provided, standard (35.4") width		
Dimensions (L	x W x H) *	78.7" x 35.4" x 8" (200 x 90 x 20.3 cm)		
Weight *		16.5 lb (7.5 kg)		
Maximum Weight Capacity		Static mode: 440 lb (200 kg), EVENLY DISTRIBUTED		
		Therapeutic mode: 400 lb (180 kg), EVENLY DISTRIBUTED		
Standard Cover		Stretch		
Cell Material		Polyurethane-coated nylon		
Base Material		Polyurethane-coated nylon		
Optional Cover Material		Antimicrobial stretch fabric		

<sup>\*</sup> Mattress dimensions and weight are measured without optional foam cushion.

#### LIMITED WARRANTY

#### **SCOPE OF WARRANTY**

GF Health Products, Inc. ("GF") warrants to the original purchaser only that it will replace or repair components, at GF's sole discretion, that are defective in material or workmanship under normal use and service. All warranties are conditioned upon the proper use of the products strictly in accordance with good commercial practice and applicable GF instructions and manuals, including proper use and maintenance. To the extent that a component is warranted by a third party, GF conveys all of its rights under that warranty to the original purchaser, to the extent permitted. This limited warranty shall only apply to defects that are reported to GF's customer service team within the applicable warranty period and which, upon examination by GF or its authorized representative, prove to be a warranty item. This limited warranty is not transferable. The warranted components and time period are set forth below:

Control unit....two years

Mattress .....one year

The applicable warranty period shall commence from date of shipment to the original customer, unless there is an expiration date on the component in which case the warranty shall expire on the earlier of warranty period or the expiration date.

#### **OBTAINING WARRANTY SERVICE**

A GF Customer Service Representative must authorize warranty service. Please contact the GF Customer Service department by calling 678-291-3207, sending a fax request to 770-368-2386 or by e-mailing a request to cs@grahamfield.com. Specific directions will be provided by the Customer Service Representative. Failure to abide by the specific directions will result in denial of the warranty claim.

#### **EXCLUSIONS**

The warranty does not cover and GF shall not be liable for the following:

- Defects, damage, or other conditions caused, in whole or in part, by misuse, abuse, negligence, alteration, accident, freight damage, tampering or failure to seek and obtain repair or replacement in a timely manner;
- Products which are not installed, used, or properly cleaned and maintained as required in the official manual for the applicable product;
- Products considered to be of a non-durable nature including, but not limited to: casters, filters, fuses, gaskets, lubricants, and charts;
- 4) Accessories or parts not provided by GF;
- 5) Charges by anyone for adjustments, repairs, replacement parts, installation or other work performed upon or in connection with such products which are not expressly authorized in writing, in advance, by GF:
- 6) Any labor or shipping charges incurred in the replacement part installation or repair;
- 7) Costs and expenses of regular maintenance and cleaning; and
- 8) Representations and warranties made by any person or entity other than GF.

ENTIRE WARRANTY, EXCLUSIVE REMEDY AND CONSEQUENTIAL DAMAGES DISCLAIMER THIS WARRANTY IS GF'S ONLY WARRANTY AND IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED. GF MAKES NO IMPLIED WARRANTIES OF ANY KIND INCLUDING ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

IF ANY MODEL OR SAMPLE WAS SHOWN TO THE CUSTOMER, SUCH MODEL OR SAMPLE WAS USED MERELY TO ILLUSTRATE THE GENERAL TYPE AND QUALITY OF THE PRODUCT AND NOT TO REPRESENT THAT THE PRODUCT WOULD NECESSARILY CONFORM TO THE MODEL OR SAMPLE IN ALL RESPECTS.

THIS WARRANTY IS LIMITED TO THE REPAIR OR REPLACEMENT OF THE DEFECTIVE PARTS. GF SHALL NOT BE LIABLE FOR AND HEREBY DISCLAIMS ANY DIRECT, SPECIAL, INDIRECT, INCIDENTAL, EXEMPLARY OR CONSEQUENTIAL DAMAGES, INCLUDING, BUT NOT LIMITED TO: DAMAGES FOR LOSS OF PROFITS OR INCOME, LOSS OF USE, DOWNTIME, COVER, OR EMPLOYEE OR INDEPENDENT CONTRACTOR WAGES, PAYMENTS AND BENEFITS.

The warranties contained herein contain all the representations and warranties with respect to the subject matter of this document, and supersede all prior negotiations, agreements and understandings with respect thereto. The recipient of this document hereby acknowledges and represents that it has not relied on any representation, assertion, guarantee, warranty, collateral contract or other assurance, except those set out in this document.

For additional information on this product or this warranty, please contact a GF Customer Service Representative.

#### NOTES:

- 1) Additional terms and conditions may apply.
- 2) Freight claims must be notated on the Bill of Lading and must be made with immediacy. The ICC regulations govern specific requirements for freight claims. Failure to abide by those regulations may result in a denial of the freight claim. GF will assist you in filing the freight claim.
- 3) Claims for any short shipment must be made within thirty (30) days of the invoice date.

GF Health Products, Inc. 2935 Northeast Parkway Atlanta, GA 30360 Tel 770-368-4700 Fax 770-368-2386 www.grahamfield.com

#### **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
Harmonic emissions IEC61000-3-2	Class A	domestic establishments and those directly connected to the public low-voltage power supply network.
Voltage fluctuations / Flicker emissions IEC61000-3-3	Complies	

#### **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.

Immunity Test	IEC60601 Test Level	Compliance	Electromagnetic Environment-Guidance
Electrostatic Discharge (ESD) IEC61000-4-2	±6kV contact ±8kV air	±6kV contact ±8kV 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/out line	±2kV for power supply line ±1kV for input/out line	Mains power quality should be that of a typical 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) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11	$40 \% U_T (60 \% \text{ dip in } U_T)$ for 5 cycles $70 \% U_T (30 \% \text{ dip in } U_T)$	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 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	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 the application of the test level			

#### **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.

Immunity Test	IEC60601 Test Level	Compliance	Electromagnetic Environment-Guidance
			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 $d = 1.2 \sqrt{P}  \text{150kHz to 80MHz}$
Conducted RF IEC 61000-4-6	3Vrms150 kHz to 80 MHz outside ISM bands <sup>a</sup>	3 Vrms	$d = 1.2\sqrt{P}  \text{150kHz to 80MHz}$ $d = 2.3\sqrt{P}  \text{80 MHz to 2.5G MHz}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	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). <sup>b</sup>
			Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey c, should be less than the compliance level in each frequency ranged.
			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.

a/ The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz;13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.

b/ The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.

c/ 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.

d/ Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 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	Separation distance according to frequency of transmitter m			
of transmitter	150 kHz to 80 MHz 80 MHz to 800 MHz 800 MHz to 2,5 GHz			
W	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$	
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.

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