LUMEX®

A Graham-Field Brand

AltaDyne® Sensor Plus 765000

ALTERNATING PRESSURE MATTRESS SYSTEM WITH ACTIVE SENSOR TECHNOLOGY

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.

765000-INS-LAB-RevC11

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INTRODUCTION

Use this manual for set-up and operation of the Lumex® AltaDyne® Sensor Plus 765000 Alternating Pressure Mattress System with Active Sensor Technology. Read all instructions before using the mattress system. Save this manual for future reference.

INTENDED USE OF THIS DEVICE

The intended use of the Lumex® AltaDyne® Sensor Plus 765000 Alternating Pressure Mattress System with Active Sensor Technology is:

- Aid in the treatment and prevention of stage 1, 2, 3 and 4 pressure ulcers while optimizing user comfort.
- Pain management as prescribed by a physician.
- As described above, in either a homecare or long-term care setting.

Contraindication

⚠ **WARNING: DO NOT use this product in the presence of flammable anesthesia. There is a possible fire hazard when this product is used with certain oxygen delivery equipment.**

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.

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.

⚠ **DANGER: Indicates an imminent hazard situation that, if not avoided, will result in death or serious injury.**

⚠ **WARNING: Indicates a potential hazard situation or unsafe practice that, if not avoided, could result in death or serious injury.**

⚠ **CAUTION: Indicates a potential hazard or unsafe practice that, if not avoided, could result in minor or moderate personal injury.**

▲ **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 use this product while bathing.**

⚠ **DANGER: Do not place or store this product where it can fall or be pulled into a tub or sink.**

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

⚠ **DANGER: Do not reach for a product that has fallen into water. Unplug it *immediately*.**

WARNING

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

⚠ **WARNING: Do not leave this product unattended when plugged in.**

⚠ **WARNING: Always use close supervision when this product is used by, on, or near children or those who require close supervision.**

⚠ **WARNING: Use this product only as intended and described in this manual. Do not use attachments or accessories not recommended by Graham-Field.**

⚠ **WARNING: Never operate this product if:**

a) **It has a damaged cord or plug.**
b) **It is not working properly.**
c) **It has been dropped or damaged.**
d) **It has been dropped into water.**

Return the product to your Graham-Field equipment provider.

⚠ **WARNING: Keep the cord away from heated surfaces.**

⚠ **WARNING: Never block the air openings of this product or place it on a soft surface, such as a bed or couch, where the openings may be blocked. Keep the air opening free of lint, hair, and other similar particles.**

⚠ **WARNING: Never drop or insert any object into any opening or hose.**

⚠ **WARNING: Connect this product *only* to a properly grounded power outlet.**

⚠ **WARNING: Maximum patient weight capacity for this product is 400 lb (189 kg).**

⚠ **WARNING: 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. GF Health Products, Inc. product manuals are available online at www.grahamfield.com.**

Visit the FDA's Bed Safety page at www.fda.gov 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.

NOTICE

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

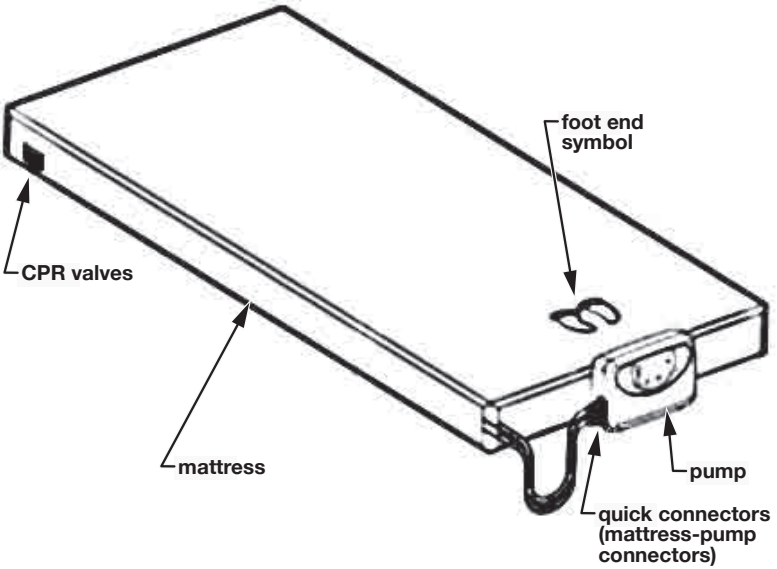
EQUIPMENT SYMBOLS

	**Manufacturer**
	**“BF”symbol: Indicates that this product is in accordance with the degree of protection against electric shock for type BF equipment**
	**Functional earth (for UL only)**
	**Attention! Read the instructions!**
	**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 Graham-Field equipment provider.**
	**Consult operating instructions**
	**Class II (for UL only)**

The system has been tested and successfully approved with the following standards:		
CE 0197	**EN 60601-1, EN 60601-1-2, EN 550011 Class B, IEC61000-3-2, IEC61000-3-3**	
For U.S. and Canada only		
E228589 53DG		**Medical Equipment: Air Pump with respect to electrical shock, fire and mechanical hazards only in accordance with UL60601-1 and CAN/CSA C22.2 No. 601.1**

PRODUCT DESCRIPTION

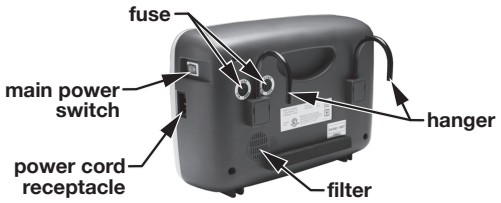
PUMP AND MATTRESS SYSTEM



pump and mattress system

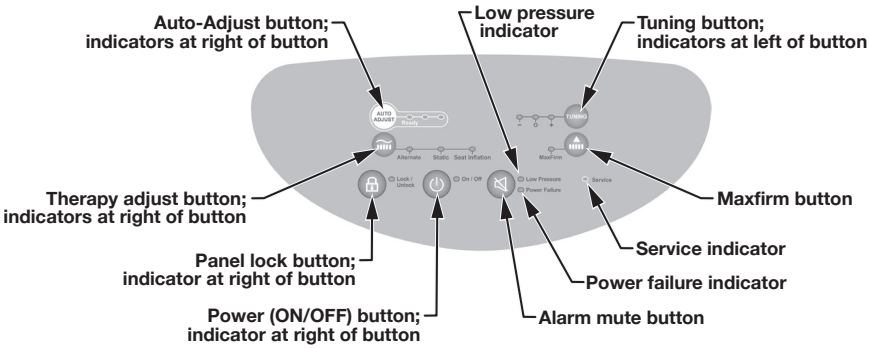
PUMP: FRONT

PUMP: REAR

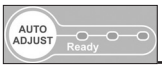


PUMP: FRONT PANEL

Front panel of pump is shown below. Descriptions of buttons and indicators follow.



Front panel, first row



Auto-Adjust button: The auto-adjust button adjusts the mattress pressure automatically based on the patient's weight. To remind the user that the auto-adjust process is ongoing, the auto-adjust indicator LEDs will periodically flash from left to right until the Ready LED illuminates to show the process is complete. Three conditions trigger the auto-adjust function:

1. Press the auto-adjust button for two seconds; the mattress system automatically readjusts pressure setting.
2. When initial mattress inflation is complete, the mattress system automatically starts the auto-adjust function.
3. When the mattress system detects a significant change in patient's weight on the mattress (e.g. patient egress or ingress), the system automatically starts the auto-adjust function.

When auto-adjust is complete, the Ready indicator will illuminate. To disable the auto-adjust function, press the auto-adjust button until auto-adjust indicators de-illuminate.

Info: During the auto-adjust operation, it is normal for the mattress system to cycle through a series of inflation and deflation.

Tuning button: The tuning button fine-tunes the mattress system's auto-adjusted pressure. Three tuning settings are available:

0 System auto-adjusted pressure

- One level softer than auto-adjusted pressure

+ One level firmer than auto-adjusted pressure

Info: The tuning function is only available in alternate and static therapy modes.

Front panel, second row

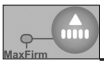
Therapy adjust button: The therapy adjust button selects the therapy mode. After power-up, the system automatically inflates the mattress, auto-adjusts the pressure, and enters alternate therapy mode. To then cycle among the therapy settings, press the therapy adjust button to select static therapy mode; press again to select alternate + seat inflation therapy mode; press again to select static + seat inflation therapy mode; press again to select alternate therapy mode, etc.

Alternate: Each tube fills for 10 minutes, then deflates for 10 minutes, alternately to the next tube. When selected, the alternate indicator illuminates.

Static: The pressure inside all tubes is adjusted to the same pressure. When selected, the static indicator illuminates.

Alternate + Seat Inflation: For use when the head is raised, to increase pressure under the buttocks — in alternating pressure therapy mode. When selected, both the alternate and seat inflation indicators illuminate.

Static + Seat Inflation: For use when the head is raised, to increase pressure under the buttocks — in static therapy mode. When selected, both the static and seat inflation indicators illuminate.



Maxfirm button: The pump will automatically enter maxfirm mode every time the power is turned on. Maxfirm mode ensures the pump is able to reach its maximum operating pressure. Maxfirm mode will last for 20 minutes, and then the system will automatically enter auto-adjust mode. To disable maxfirm mode, press the maxfirm button. When enabled, the maxfirm indicator, at left of button, illuminates.

Front panel, third row

Panel lock button: The panel lock button sets the panel lock to protect the panel settings from accidental change. Press for two seconds to lock; press FIRMLY for two seconds to unlock. After the panel has been untouched for five minutes, the panel lock locks automatically. When the panel is locked, the panel lock indicator will illuminate.

Power (ON/OFF) button: The power button turns power to the mattress system ON or OFF. Press to turn ON; press to turn OFF. When power is on, the power (ON/OFF) indicator will illuminate. When power is turned OFF, the mattress system will slowly deflate.

*Info: Main power switch on side of pump, previously shown in **PUMP: REAR**, must be ON in order for the front panel power button to function.*

Alarm Mute button: The alarm mute button temporarily suspends the LED indicator and buzzer when either the low-pressure alarm or power failure alarm is activated. Should the problem not be resolved within three minutes, the alarm will resume.

Low Pressure **Low pressure indicator:** The low pressure indicator (yellow LED) illuminates, and the alarm sounds, when an abnormally low pressure level occurs. If the low pressure indicator persistently illuminates inappropriately:

1. Check to ensure all connections are properly and securely connected per installation instructions.
2. Check for any leakage (tubes or connecting hoses). If necessary, contact your Graham-Field equipment provider to replace any damaged tubes or hoses.
3. If problem persists, contact your Graham-Field equipment provider.

Info: Sometimes the low pressure indicator will illuminate when a patient gets up to leave the bed. This is normal. The indicator will turn off automatically after a short time.

The low pressure indicator will illuminate until the low-pressure condition is resolved.

Power Failure **Power failure indicator:** The power failure indicator illuminates, and the alarm sounds, when there is a power failure. Depress the alarm mute button to disable both alarm and LED.

Service **Service indicator:** Mechanical failure, service required; contact your Graham-Field equipment provider.

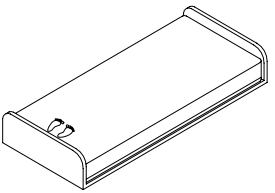
INSTALLATION

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 equipment provider.

PUMP AND MATTRESS SETUP

1. Place the mattress on top of the bed frame; ensure that the foot end symbol faces up at foot end as shown at right. Secure mattress to bed with straps.



2. Fold open the wire hangers on the back of the pump as shown at right.

3. Either hang the pump on the bed's foot end, as shown at right, or place the pump on a flat surface easily accessible to the caregiver and/or doctor.

▲ **NOTICE: Place the device in a position where the caregiver and/or doctor can access it easily.**

4. Connect the mattress-pump air hose quick connector; ensure that the connector has clicked securely into place before continuing.

▲ **NOTICE: Ensure that the air hoses are not kinked or tucked under the mattress.**

⚠ **WARNING: Locate all cords so that they will not be stepped on, tripped over, or otherwise subjected to damage or stress.**

⚠ **WARNING: Do not use a household extension cord if the electrical cord does not reach the power outlet. Use of an improper extension cord could result in fire and electric shock. If an extension cord must be used, use a three conductor cord with ground, properly wired, in good electrical condition, and keep it as short as possible.**

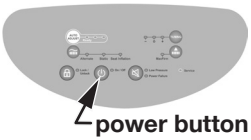
⚠ **WARNING: Ensure that the local power voltage is appropriate for the pump unit.**

5. Plug the power cord into a properly grounded electrical outlet.

OPERATION

GETTING STARTED

1. Turn the main power switch to the ON position.



2. Press the front panel power button. The power indicator will illuminate.

Info: The mattress system will automatically enter maxfirm mode for the quickest inflation at set-up; when inflated, it will then automatically enter auto-adjust mode to select the appropriate pressure.

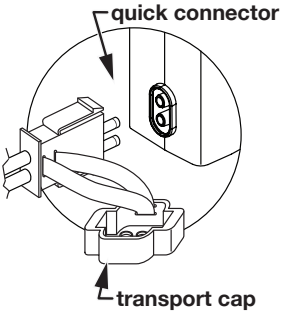
3. The pump will begin delivering air into the mattress. The low pressure indicator and the maxfirm indicator will illuminate for approximately twenty minutes until the mattress is fully inflated.
4. Upon inflation, the system will automatically enter auto-adjust mode to automatically select the appropriate pressure according to the patient's weight. The auto-adjust indicator LEDs will flash from left to right, and the system will cycle through inflation and deflation, until the Ready LED illuminates to show the process is complete, and the mattress system automatically enters alternate therapy mode.
5. Replace all sheets, blankets, and pillows on the bed.
6. You can now adjust therapy modes or tuning. Please see earlier section, **PUMP: FRONT PANEL**, for a complete description of available adjustments, buttons and indicators.

QUICK DISCONNECT

Pull the power plug from the wall connector to disconnect the device quickly.

TRANSPORT CAP

In case of power failure or transport: Disconnect the quick connector and cap the mattress with the transport cap to slow deflation.

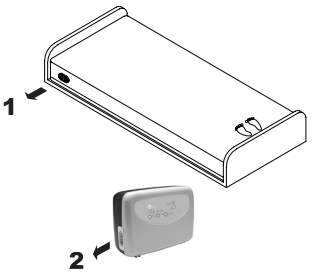


Info: This system is equipped with cell-on-cell technology to provide added support and prevent bottoming out in the event of a power failure. Lower cells will hold air for approximately eight hours.

CPR FUNCTION

If CPR must be performed on the patient while the mattress is in use, to immediately deflate the mattress, either:

1. Pull the CPR valves from the mattress in the location of the arrow shown at right, or
2. Disconnect the quick connector from the pump in the location of the arrow shown at right.



MAINTENANCE

CLEANING

⚠ **WARNING: To reduce the risk of increased bacterial growth, infection, illness, or injury from contamination, thoroughly clean and dry the mattress system before use and as necessary during use as follows:**

Pump: Wipe the pump with a clean, damp cloth and 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 and mild detergent. 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.**

GENERAL MAINTENANCE

1. Check main power cord for abrasion or excessive wear.
2. Check mattress cover for signs of wear or damage. Ensure mattress cover and tubes are connected correctly.
3. Check airflow from the air hose connector. The airflow should alternate between each connector every half-cycle time while in alternating mode.
4. Check the air hoses for any kink or break. For replacement, please contact your GF equipment provider.

Fuse replacement

tool 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 (T1A/250V, VDE approved).
4. Replace the fuse holder cover. Ensure that fuse holder cover is securely installed.

Air filter replacement

tool needed: small screwdriver

1. Use a small screwdriver to remove the air filter plate located at rear of pump (filter location is shown in picture at right).
2. Remove the filter. The filter is reusable, if not torn, and can be washed gently with a mild detergent and water. Dry the filter before use.
3. Replace the filter and cover. Ensure that filter cover is securely installed. Replace the air filter regularly if it is gray, torn, or the environment is dirty.

STORAGE

1. Lay the mattress out flat and upside down.
2. Roll from the head end toward the foot end.
3. Stretch the foot-end strap around the rolled mattress to prevent unrolling.
4. Store mattress and pump in a dust-free environment with no exposure to direct sunlight.

▲ NOTICE: Do not fold, crease or stack the mattress.

SPECIFICATIONS

Pump		Specification
Power Supply (Info: see rating label on product)		AC 120V 60 Hz 0.17A (for 120V system)
Fuse Rating		T1A, 250V
Cycle time		Fixed / 10 minutes
Dimensions (L x W x H)		11.4" x 7.9" x 4.6" (29.1 x 20 x 11.7 cm)
Weight		5 lb (2.2 kg)
Environment	Temperature	Operation: 50°F to 104°F (10°C to 40°C) Storage: 5°F to 122°F (-15°C to 50°C) Shipping: 5°F to 158°F (-15°C to 70°C)
	Humidity	Operation: 10% to 90% non-condensing Storage: 10% to 90% non-condensing Shipping: 10% to 90% non-condensing
Classification		Class II with functional earth, Type BF, IPX0 Applied Part: Air Mattress Not suitable for use in the presence of a flammable anesthetic mixture (No AP or APG protection)

Mattress	Specification
Dimensions (L x W x H)	78.7" x 35.4" x 8" (200 x 90 x 20.3 cm)

Info: Specifications are subject to change without notice.

LIMITED WARRANTY

GF Health Products, Inc. warrants the Lumex® AltaDyne® Sensor Plus 765000 Alternating Pressure Mattress System with Active Sensor Technology for a period of twelve months for defects in workmanship and materials. If a product is deemed to be under warranty, GF Health Products, Inc. shall provide, at its option, (1) replacement of any defective part or product or (2) a credit of the original selling price made to GF Health Products, Inc.'s initial customer. The warranty does not include any labor charges incurred in replacement part(s) installation or any associated freight or shipping charges to GF Health Products, Inc.

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.

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
Harmonic emissions IEC61000-3-2	Class A	The device is suitable for use in all establishments, including 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 atypical commercial or hospital environment
Surge IEC61000-4-5	±1kV for differential mode ±2kV for common mode	±1kV for differential mode ±2kV for common mode	Mains power quality should be that of atypical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11	<5 % UT(>95 % dip in UT)for 0,5 cycle 40 % UT(60 % dip in UT)for 5 cycles 70 % UT(30 % dip in UT)for 25 cycles <5 % UT(>95 % dip in UT)for 5 sec	<5 % UT(>95 % dip in UT) for 0,5 cycle 40 % UT(60 % dip in UT) for 5 cycles 70 % UT(30 % dip in UT) for 25 cycles <5 % UT(>95 % dip in UT) for 5 sec	Mains power quality should be that of atypical 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 atypical 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.
Conducted RF IEC 61000-4-6	3Vrms150 kHz to 80 MHz outside ISM bands[a]	3Vrms	Recommended separation distance $d = 1.2\sqrt{P}$ 150kHz to 80MHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3V/m	$d = 1.2\sqrt{P}$ 150kHz to 80MHz $d = 2.3\sqrt{P}$ 80 MHz to 2.5G MHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).[b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[c], should be less than the compliance level in each frequency range[d]. 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 of transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2,5 GHz** $d = 2.3\sqrt{P}$
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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