Patient **Support** Systems

MEDICAL • DESIGN • INNOVATION

USER MANUAL

Alliana Bluetooth Control Unit with Cushion

9700N+SQNTSC02F

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Thank you for choosing to use the Alliana alternating wheelchair cushion system.

The package includes:

1 x Main Control Unit
1 x Carry Bag
1 x Mains Charging System with Plug Adapter
1 x Foam Seat Cushion with 6 internal cells

Installation

1. The Control Unit is powered with a long lasting Lithium-Polymer battery. In order to protect the battery during transport or long periods of storage the internal battery cable is disconnected. To access and connect the battery, access the battery compartment at the rear of the control unit. Use a screw driver to open the battery case and re-connect the cable. (please see the photo below), you will hear the beeping sound to indicate that there is power in the battery..

Dis-connect

Re-connect

2. Place your cushion on the chair and the connect the air tubes to the rear of the chair. Ensure that the tube is positioned through the wheelchair system to avoid kinking or interfering with the normal working of the chair.
   Important! The carer must insure that the chair is re-adjusted to take account of the higher seating position provided by the cushion. It is the responsibility of the carer or suitable health professional to ensure that the user is comfortable, stable and well supported.

3. Place the control unit into the carry bag then place the control system behind the chair using both side straps to secure the case to both handles of the wheel chair. Adjust the strap length to ensure the optimal height for the system.

4. Connect the air hoses to the control unit – it does not matter which hose is connected to which outlet.

● Starting The System

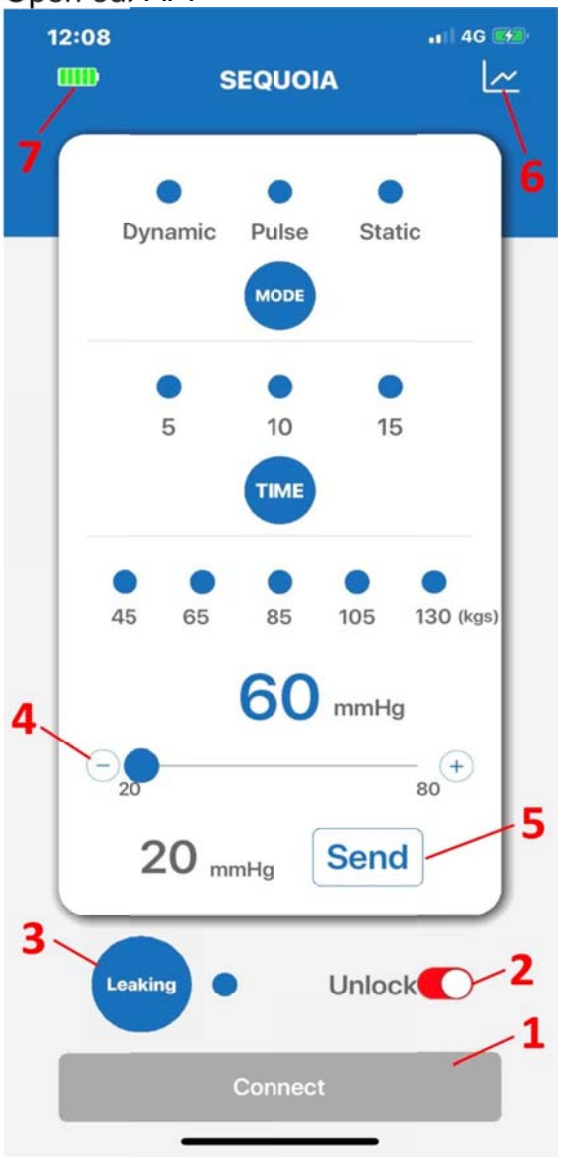
1. Press and hold the power button until you will hear a beeping sound then release your finger from the button. The panel LEDs will then flash twice and the system will begin to inflate.

2. Pump default setting: power on but without any setting, pump's default setting program will be "static" and middle pressure(85kgs)

3. Blue tooth(option item):
   If you has purchased this unit with Blue tooth control then our blue tooth device already building in our main board, so, when you turn on this unit's power you also turn on blue tooth.
   To use Blue tooth control then you have to download our APP(name : iPMAP Cushion) from Apple store or Google store for free

   How to use APP to control

   a. Open our APP



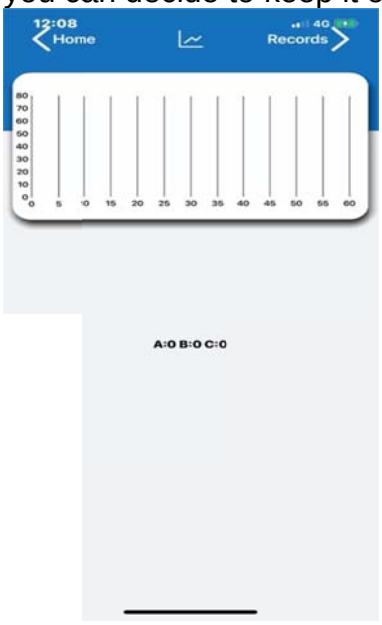
   1. As when you turn on power then our blue tooth also started, please make sure your mobile device's Blue Tooth also turn on.
      Press "connect" (1) then interface will show you our Blue Tooth ID there.. just press Blue Tooth ID then it'll automatic to connect for you, when it connected you will see a chain icon next to our Blue Tooth ID.

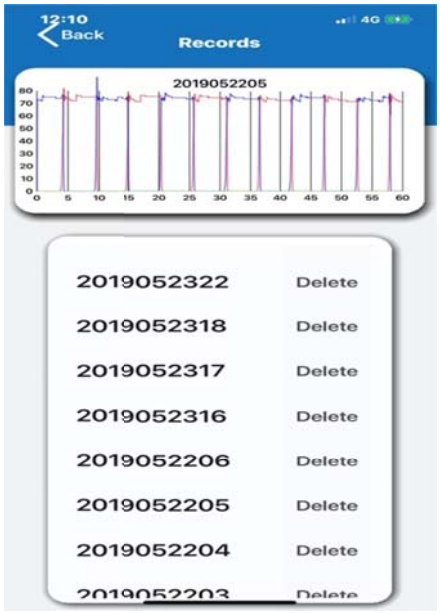
Before connect connected

If you want to disconnect Blue tooth connect, just press “disconnect” then press “yes”, Blue tooth will release to connect with your mobile device.

2. The Locking bar always in the locking position, when you want to operate, please remember to unlock first
3. When pressure are lower or even fail to reach to your setting pressure, you also can see from our APP and APP also will text to warning user.

4. Although the control unit has several weight range for user to select but maybe the pressure setting we offered maybe can't match all user demand, so, we created another Pressure selection from our APP, this function allow user free to choice any his/her preferable pressure(min:20mmHg Max.80mmHg)
5. You may use your finger to slip pressure to your prefer then press "send"(5) and your Control unit will carry out your own and unique pressure for yourself.
6. This unit will auto-recording since you connected with our Blue Tooth, press(6) can show you our internal pressure chart running,if you press interface's "Records",then it'll show you all list you already has,these records will saved every hour to your mobile
you can decide to keep it or not to keep it





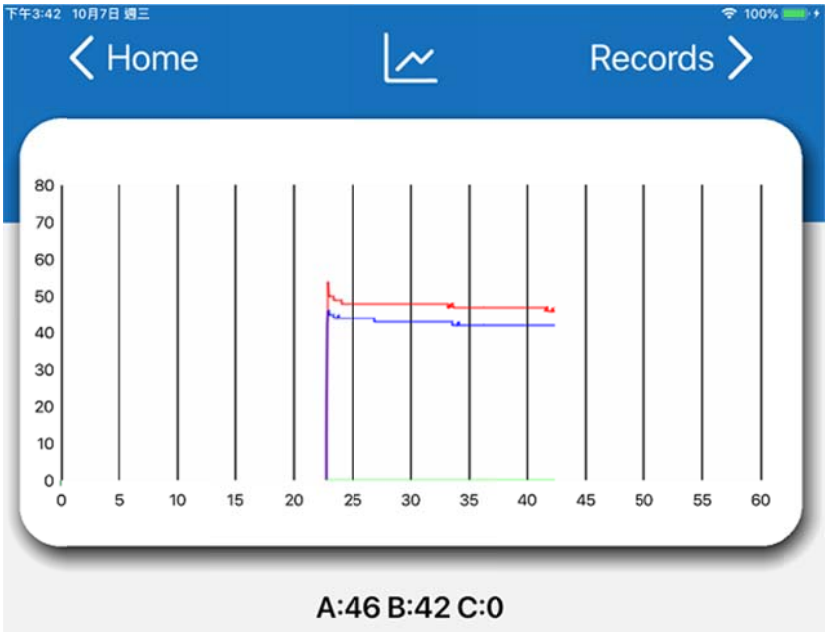
7. The APP also can show you battery status.

Remark: APP's functions explanation same as below.

The Alianna Seating System has three modes – **Static and Dynamic,Pulsate for user to select.**
Modes functions description:

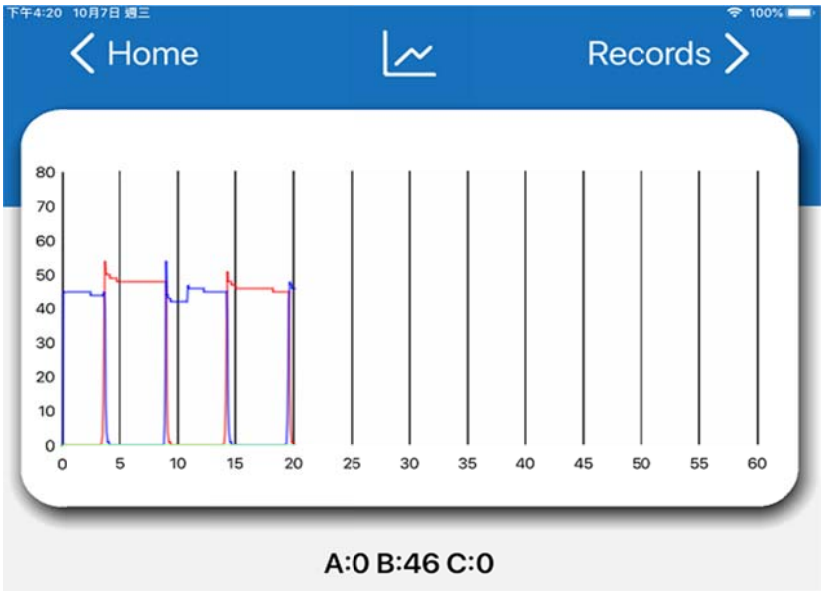
STATIC: this mode designed to make all cells inflated to support patient's weight, under this mode the static will keep pressure all the time.

The pressure operate curves charts as following



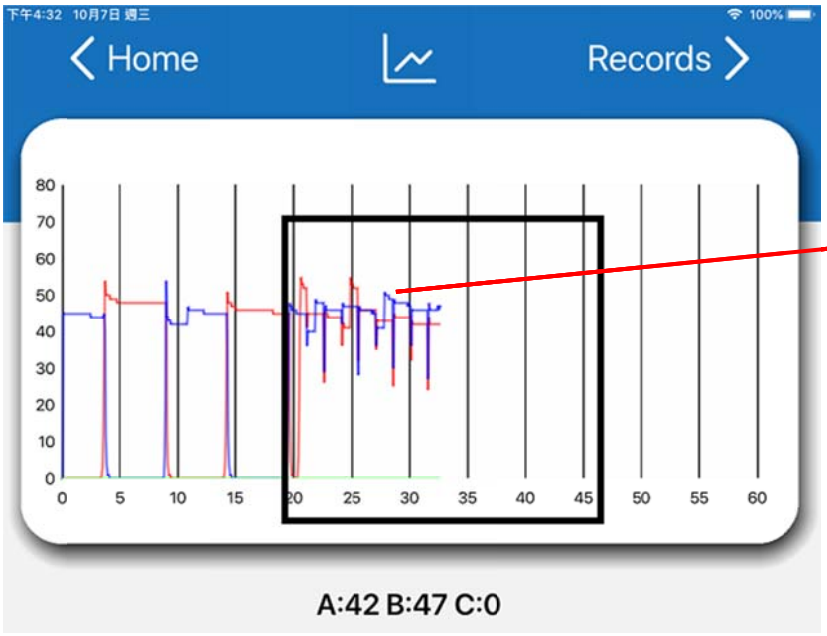
Dynamic Mode: this function designed 1 cells zone holding pressure and 1 cell deflated with this mode also can select cycle time for 5-10-15mins

The pressure operate curves charts as following



Pulsate: this mode designed similar like static, but added in every 45sec. reduce 10mmHg from setting pressure then increase 10mmhg again, the main intention just designed for the user only can use static mode but can't sit too long time with same pressure.

The pressure operate curves charts as following



Pulsate pressure operate curves charts

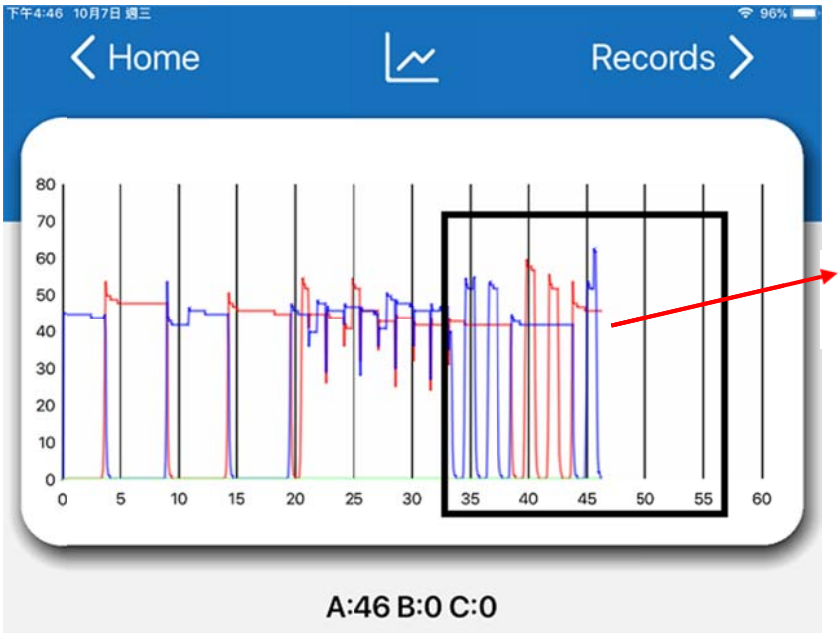
Dynamic+Pulsate : this function designed under alternating status, the cells still can help user to reach to massage features

The way we designed, A cells zone holding pressure, B cells zone deflated, so, during cycle time, every 1 min, the deflated cells zone will inflate 10mmHg more than holding cell zone's pressure and lasting for 1min then deflate pressure again to 0.

For example, if A cells zone holding pressure at 30mmhg, B cells zone are deflated to 0, so, under this mode and during cycle time, every 1 min, the deflated cells zone will inflate 10mmHg more(it's means 40mmHg) than holding cell zone's pressure and lasting for 1min then deflate pressure again to 0.

Please also note this function will consume more battery power from control unit, we will recommend you use this mode also plugging charger together.

The pressure operate curves charts as following



Dynamic + Pulsate pressure operate curves charts

Pressure Leaking Alarm

if within 3 mins , if pump fails to reach the pressure will cause the alarm on.

This alarm will also be accompanied by a LED light flashing. If this occurs, check the air hoses are properly seated onto the Control Unit connectors and unzip the seat cover to also check the connections to the cell hoses.

Panel Locking:

if without any operate on the panel, the pump will automatic lock within 40sec. if want to lock/unlock then long press locking button for 2 sec.

● Charging

The Alianna Control Unit is equipped with a long lasting Lithium Ion battery. In STATIC mode, the battery gives a remote operation time of more than 24 hours. In Dynamic Mode, the system can last at least one day.

The battery power if too low, the pump will alarm 2 different times to warn, first time ,alarm will lasting for 30sec. then if not charging in time, the pump will alarm again and change pump's mode to "static" & middle pressure to inflate cushion again then power will shut off.

When the Control Unit is charging, the charging light will activate, the battery indicator lights will gradually increasing and decrease to show you that it under charging and also the charging light and charging box's indicator lights at this moment is red color .

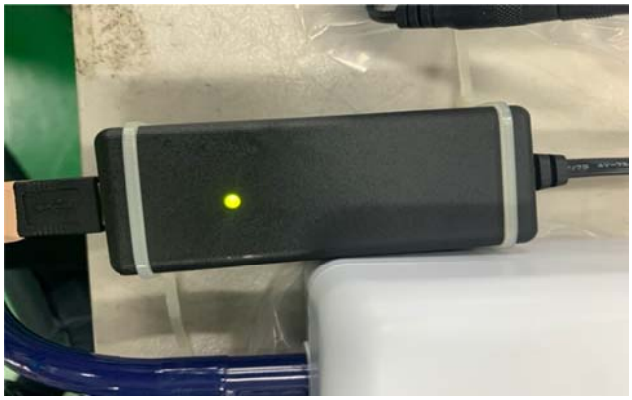
Under charging:

Pump are charging and power still on

Pump are charging but power is off

charging box's indicator are in RED

Charging completed



When power charging completed, you will see the charging light on the panel and changing box will turn to green color and battery indicator bars are full

CAUTION
RISK OF EXPLOSION IF BATTERY IS REPLACED
BY AN INCORRECT TYPE.
DISPOSE OF USED BATTERIES ACCORDING
TO THE INSTRUCTIONS

Complete System General Precautions

※ Ensure this equipment is not setup or used in close proximity to sources of high heat or excessive electromagnetic, electrostatic or radiation fields. Do not use outdoors or expose to direct sunlight over long periods of time as excessive UV radiation can degrade external materials.
※ Do not use system in the presence of any flammable anaesthetic mixture with air, nitrous oxide or oxygen or in the presence of smoking materials or open flame - risk of explosion.
※ Do not use this equipment for anything other than what it is specifically designed for. The use of accessories or parts not recommended or specifically designed for this equipment is prohibited and will void the warranty.
※ Do not modify or connect this equipment to other parts or equipment not specifically designed for use with this system.
※ Do not allow young children to operate, play with or remove any part of this medical system.
※ Do not use this equipment near sources of excessive moisture such as nebulisers or steam kettles.
※ Do not use corrosive cleaning products such as industrial degreasers or even acetone solvents.
※ It can cause material damage.
※ Use a cloth impregnated with a detergent product solution or a surface detergent/disinfectant with the CE* mark following the usage concentrations recommended by the manufacturer. Follow the endurance times.
※ Obligatory CE marking referring to the 93/42/CEE directive for products for use on surfaces of Medical Devices.
※ The product can only be operated by personnel's who are qualified to perform general nursing procedures and has received adequate training in knowledge of prevention and treatment of pressure ulcer
※ Close supervision is necessary when this product is used on or near children. Electrical burns or choking accident may result from a child swallowing a small part detached from the device.
※ The covers have passed skin sensitization and skin irritation test. However, If you suspect that you may have had or are having an allergic reaction, please consult a physician immediately.

Control Unit

※ Do not open the control unit as there is risk of electric shock. Control units should only be opened by approved technicians or warranty will be voided.
※ Avoid blocking the air intake filter at the rear of the control unit.
※ The Control Unit has a rating of IP 22.
※ However, do not spill any liquids onto the control unit. If a spillage occurs then:
- ■ Turn off power to the control unit at the wall.
- ■ Disconnect the power cord from the control unit.
- ■ Wipe dry any excess moisture on the external casing.
- ■ Check that the interior of the power connector, plug and switch is dry.

※ Failure to do the above may lead to component corrosion and or electrical safety hazards to care giver and patients.
※ Ensure that the power lead are undamaged, properly connected and positioned so that it does not:
- ■ Pose a risk of strangulation or asphyxiation to small children.
- ■ Is positioned away from any moving bed part which may kink or damage the power cord.
- ■ Is positioned such that there is no trip hazard presented by excessive lengths of cord on the floor around the bed.

※ The cord does not interfere with cleaning around the bed or the use of cleaning liquids especially on the floor.

● Specifications:

Electronic:AC100-240V, 50-60Hz;0.4A (For Adapter)

DC12.0V ⎓ 1A(For EUT)

Battery:Li-polymer 606696 3S1P 11.1V 4300mAh

● Operate environment:

Storage temperature: -10°C to 55°C ; humidity: 10-90%

Transport temperature: -20°C to 65°C ; humidity: 10-90%

Normal temperature: 10°C to 40°C ; humidity: 10-90% ; Atmospheric pressure: 700hPa to 1013.25hPa

● Product lifetime: 2 years after end user receives the product.

Symbol	Definition of Symbol
	**Attention: See Instructions for use**
	**CE Marking indicating conformance to EC Directive No. 93 42/EEC conceming medical devices**
	**Type BF Applied Part (patient isolation from electrical shock)**
	**Class II Product**
	**Operation Instructions**
	**Indicates separate collection for electrical and electronic equipment (WEEE)**

Note: Follow The National Requirement to dispose unit

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	
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 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)	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	<5 % U_T (>95 % dip in U_T)for 0,5 cycle 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 5 sec	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 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 5 sec	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
Conducted RF IEC 61000-4-6	3Vrms150 kHz to 80 MHz outside ISM bands[a]	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of this device, including cables, than there commended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ 150kHz to 80MHz $d = 1.2\sqrt{P}$ 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: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

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

or 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.