



SIERRA COLD THERAPY SYSTEM™

Directions for Use



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Indications for Use

THIS DEVICE CAN BE COLD ENOUGH TO CAUSE SERIOUS INJURY. SERIOUS ADVERSE REACTIONS AND SAFETY HAZARDS MAY OCCUR WHEN USING THIS DEVICE.

Caution: Federal Law restricts this device to sale by or on the order of a licensed health care practitioner. Follow the recommendations of your health care provider.

Sierra Cold Therapy System™ is intended to treat post-surgical and acute injuries to reduce edema, swelling, and pain where cold therapy is indicated. It is intended to be used by or on the order of healthcare professionals in hospitals, outpatient clinics, athletic training or home settings.

The intended use of Sierra Cold Therapy System is for the temporary reduction of swelling and pain after surgery or injury. This is a non-sterile prescription device for single patient use to provide localized external application of cold therapy. This device may not be used for any other purpose.

Contraindications

WARNING: DO NOT use this device on patients with Raynaud’s phenomenon or other vasospastic conditions; Buerger’s disease, cold allergy or hyper-sensitivity, cryoglobulinemia, paroxysmal cold hemoglobinuria or other cold agglutinin disorders, pheochromocytoma, sickle cell anemia or history of cold injury.

Severe cardiovascular disease, anesthetic skin, hypercoagulation disorders, poor circulation, extremely low blood pressure that are incapacitated.

Local tissue infection. Localized unstable skin condition (e.g., dermatitis, vein ligation, gangrene, or recent skin graft or pheochromocytoma) in the affected region.

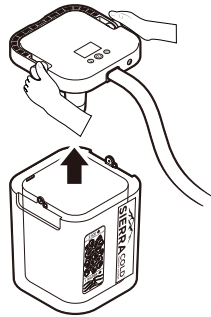
Limitations on Special Patient Population

Limit the use of this device with patients who are unresponsive, incapacitated, have altered mental status, or altered pain perception. Post-surgical patients under sedation or on analgesics or anesthetics, as well as patients taking hypnotics, anxiolytics, or antidepressants, must be monitored frequently during use of this device. These patients may not be able to perceive pain, burning, numbness, tingling or decreased sensation and may be susceptible to injury. Discontinue cold therapy immediately at the first sign of cold injury.

Operating Instructions

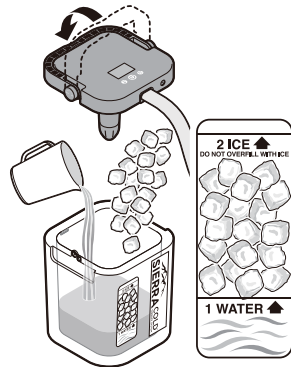
Scan the QR code on top of the lid to watch an instructional video on using Sierra Cold Therapy System.

1. Turn the two knobs to unlock the lid if necessary. Put your thumbs on the top of the knobs and use your other fingers to lift the lid. Then remove the lid from the unit.

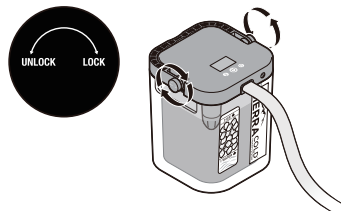


2. Next, Add water to the indicated line. Then add ice to the indicated line.

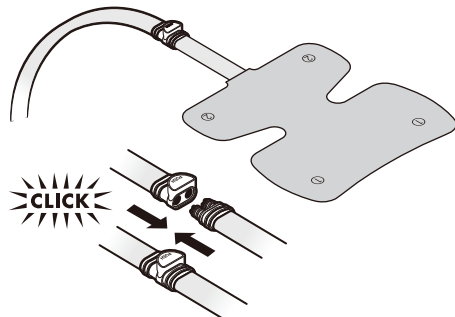
DO NOT overfill with ice. DO NOT run Sierra Cold Therapy System without water. Running without water will cause permanent damage.



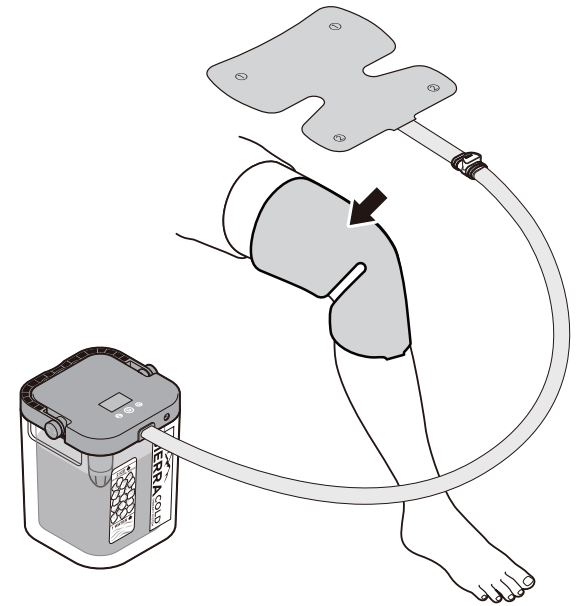
3. The handle can remain in the lowered position and the lid can be locked by turning the knobs clockwise. Unlock the lid by turning the knobs counter clockwise. “LOCK” and “UNLOCK” are printed on each knob to indicate which direction to turn the knobs.




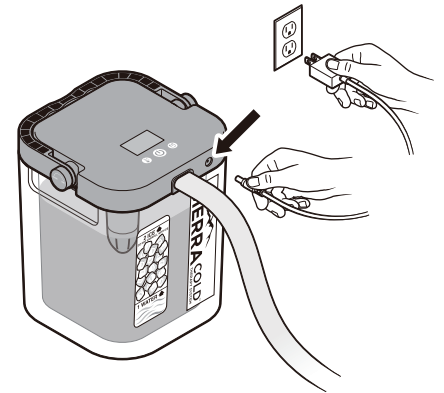
4. Connect the cold therapy pad to the tubing of the Sierra Cold Therapy System. To ensure a solid connection, push the male/female couplings together, listen and feel for a “click”.





5. Before applying the cold therapy pad to the treatment area, place a barrier between the pad and skin. **DO NOT place the pad directly on the skin as this may lead to a cold injury.**




6. Plug the AC Adapter into the wall outlet and then into the unit. Press the  button to turn the unit on, you should see the display on the screen appear.



7. To operate the unit for a treatment session, press the  button to select the temperature setting. Choose between 45°F (High Flow), 50°F (Medium Flow) and 55°F (Low Flow). **Caution, the higher the flow rate, the lower the temperature.**

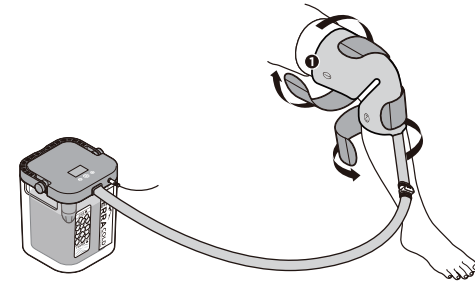
8. After the temperature setting is chosen, press the  button to set the timer. Select a 20, 40 or 60 minute timed session.
Note: the Sierra Cold Therapy System defaults to 50°F and 20 minute session if no temperature or time setting is selected for the first time use. If the temperature or timer settings are changed for a timed session, the unit will retain the last used temperature and timer settings for the next session unless changed by the user.

Quick Start Instructions

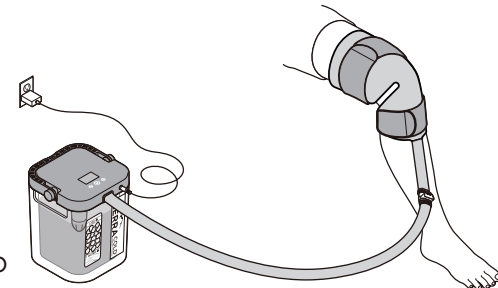
1. With AC Adapter plugged into the wall and unit, press the  button to power on the unit and start treatment at the default settings of 50°F and 20 minute timed session.
NOTE: For best product performance, keep pad and unit in close and level proximity to treatment area.
WARNING: During treatment, check the skin frequently to avoid any possible injury. When treatment is complete, remove the pad from the area and do a thorough skin inspection.
2. When the timed session is complete, the unit will sound a beep and automatically shut off.
3. When treatment is completed, remove the pad and barrier from the skin. Inspect the treatment area for any signs of a cold injury.
CAUTION: STOP USING the unit if there is any evidence of an adverse reaction, such as: increased pain, burning, increased swelling, itching, blisters, increased redness, discoloration, welts, other changes in skin appearance, or any other reaction identified by your practitioner.
4. After use of the Sierra Cold Therapy System, unplug the AC Adapter from the unit and wall. Separate the cold therapy pad from the unit tubing by depressing the button labelled "PUSH". To empty water from the cold therapy pad, hold over a sink and depress the male coupling until all water has drained from the pad. To empty the unit, pour water into a sink, once emptied wipe down the unit of any excess water.

Pad Application

WARNING: Use only pads that comply with this device. Other pads may get colder, increasing risk of serious cold induced injury, including tissue necrosis.

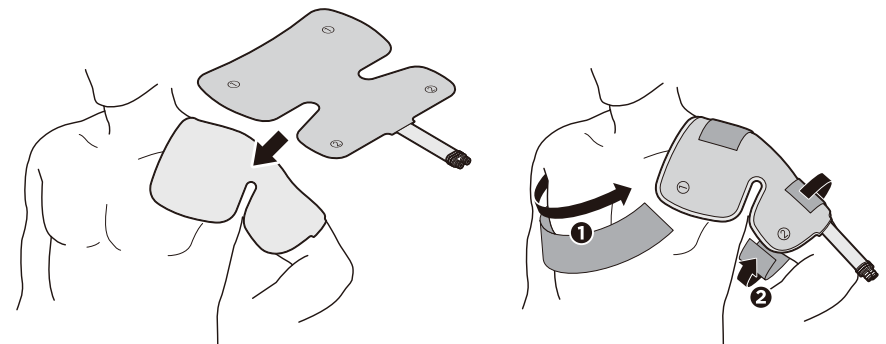


Before applying the cold therapy pad to the treatment area, place a barrier between the pad and skin. **DO NOT place the pad directly on the skin as this may lead to a cold injury.**



To apply the Knee pad, place the pad on top of a protective barrier with the hose pointed toward the foot. Take strap **#1** above the knee and wrap around the leg. Use the hook and loop to attach strap to the pad. The strap should be snug but not uncomfortable. Next, take strap **#2** and wrap around the leg below the knee using the hook and loop to attach to the pad.

To apply the Shoulder pad (example shown), place the pad on top of a protective barrier with the hose facing downward. Take the **#1** strap and wrap around the torso underneath the axilla or armpit and attach to the pad using the hook and loop. Next, take strap **#2** and wrap around the arm using the hook and loop to secure the strap in place.



Pad Application (continued)

A Multi-use pad is also available and may be used for other areas of treatment as prescribed by a healthcare professional. Three straps are included with the pad and can be used to secure the pad to the treatment area.

Product Specifications

1. Unit dimensions and volume

- a. Device size : 9.25in Length, 9.25in Width, 11in Height
- b. Maximum Volume : 6.2L

2. Weight

- a. Unfilled (Empty) : 2.4kg/5.3lbs
- b. Filled : 8.6kg/18.95lbs

3. Flow Rate

- a. High flow rate : .5L/min
- b. Med flow rate : .3L/min
- c. Low flow rate : .2L/min

4. AC Adapter

- a. AC 50-60Hz, 200mA MAX
- b. AC Input : 100-240 Volts
- c. Output : DC 5V/1A
- d. Adapter Type : Switching Power Adaptor
- e. Adapter Model: HNBI05010OWU/ LC-H050100

5. Use Mode

- a. Timed sessions of 20, 40 or 60 minutes with automatic shutoff.

Storage and Transportation

- Unplug the power supply from the electrical outlet.
Caution: To avoid danger of electrical shock, DO NOT unplug the power supply with wet hands.
- Disconnect cold therapy pad from hose.
- Drain the unit and wipe dry.
- Drain the cold therapy pad by ensuring the hose is hanging downward.
- Press the male couplings at the end of the hose and allow the water to drain out completely.
- Storage and Transportation Conditions: -25°C -70°C (-13°F - 158°F).
- Storage and Transportation Relative Humidity: 10% - 90% Non-condensing.
- Keep the power supply and connection areas free from dust. With the unit unplugged, remove any accumulated lint or dust.

Caution: Do not keep in extreme hot or cold temperatures (above 50°C/120°F or below 0°C/33°F). Do not leave in a hot or freezing automobile. Do not leave the lid with LCD display in direct sunlight. The UV light may damage or discolor the LCD display.

Nominal Operating Environment

- Ambient Temperature: 4°C - 40°C (39°F - 104°F)
- Relative Humidity: 15% - 90%
- Atmosphere Pressure: 800-1060 hPa
- Altitude: <2000m

Power Supply

Domestic Power Supply 100-240 Volts, AC 50-60Hz, 200mA MAX.

Warranty











Top Shelf warrants that this product is free from defects in workmanship and materials for 6 months from initial purchase under normal use for which it was intended and under direct supervision of a licensed health care practitioner.













Top Shelf's obligation under this warranty is limited to the replacement or repair of any defective part or parts of this product.

Top Shelf expressly disclaims any and all other warranties and representations, including without limitation, the warranty of merchantability and fitness for a particular purpose.

Warnings and Precautions

WARNING: This device can be cold enough to cause serious injury. Serious adverse reactions and safety hazards may occur when using this device.

WARNING! Read and understand all warnings and Directions For Use before operating this device	
WARNING! The adapter plug is the only part of the device that is separated from the power supply. The power button is only for device control.	
WARNING! DO NOT exceed the maximum fill level when adding water and/or ice into the unit.	
WARNING! DO NOT use this device without a prescription from a physician. Rx only. Your prescription must state a temperature, how long and how often the device should be used and the length of breaks between uses. DO NOT use this device if a prescription has not been provided to you or if you do not understand the prescription. Use of this device without a prescription or failure to follow the prescription may result in serious injury, including tissue necrosis.	 
WARNING! This device can be cold enough to cause serious injury, including tissue necrosis. You must be able to check your skin condition under the cold therapy pad frequently (at least once every hour). DO NOT use this device if you cannot check your skin condition frequently (at least once every hour). Check for increased pain, burning, numbness, tingling, increased redness, discoloration, itching, increased swelling, blisters, irritation, or other changes in skin condition under the cold therapy pad or around the treatment area. If you experience any of these conditions, immediately discontinue use of this device and contact your physician.	
WARNING! This device is intended for single patient use. Secondary use can cause serious injury, including infection.	
WARNING! Application of the cold therapy pad directly on the skin may result in serious injury, including tissue necrosis. DO NOT let any part of the cold therapy pad touch your skin. ALWAYS use with a barrier between your skin and the cold therapy pad.	
WARNING! Taking medications that have a negative effect on peripheral vascular circulation, including beta adrenergic blockers and local epinephrine use.	
WARNING! DO NOT use the Sierra Cold Therapy System near flammable anesthetics, which may result in explosion and serious injury.	

WARNING! The barrier between your skin and the cold therapy pad may develop moisture during use, which may create colder temperatures on the skin. Temperatures that are too cold may result in serious injury, including tissue necrosis. ALWAYS check for moisture on the barrier between your skin and the cold therapy pad. If moisture is present on the barrier, immediately discontinue use of the device.	
WARNING! Poor connections between hoses may cause leaking, which may result in serious injury, including infection and tissue necrosis. ALWAYS listen for a “snap” or a “click” when connecting a cold therapy pad to the Sierra Cold Therapy System.	
WARNING! Use of the Sierra Cold Therapy System with wet hands or in a wet location may result in electrical shock and serious injury. DO NOT handle transformer or power cord with wet hands or in a wet location.	
WARNING! Do not attempt to sterilize the unit by any means.	
WARNING! When using the Sierra Cold Therapy System, keep the tubing from the unit to the pad straight for optimal water flow from the unit to the pad.	
WARNING! DO NOT attempt any unauthorized alteration or modification to this device. This can create new unknown safety risks.	
WARNING! Use of accessories, detachable parts and materials not described in the Directions for Use should be avoided as they can create unknown new risks	
WARNING! Precautions to be taken in the events of changes in the performance of the Sierra Cold Therapy System: Read the instructions carefully. If you encounter any abnormal behavior of the device, turn off the device and contact your healthcare practitioner or customer support.	
WARNING! DO NOT attempt to service or maintain this device while in use.	
PRECAUTIONS! Do not use hot water or any other fluids beside water in this unit. It may be unsafe or damage the unit since it has not been designed or tested with use of other liquid.	
PRECAUTIONS! Do not subject the ice bucket to extreme shocks, such as dropping the ice bucket.	
PRECAUTIONS! Portable and mobile Radio Frequency Communication Equipment can be affected by this device.	



Patient Information

- Inform your physician if any of the following apply to you; under the age of 12, peripheral vascular disease, decreased or hyper skin sensitivity, poor circulation or compromised local circulation, hyper-coagulation disorders, diabetes or neuropathies, or other disease that may lead to cold injury.
- The patient should be educated on how to operate this device in a home setting. A properly educated patient can safely connect the cold therapy pad to the device. Any operation not intended for the patient to operate should be clearly defined by the health practitioner. Contact your health practitioner with any questions about this device.

Electrical Safety

- ⚠ Like all electrical products, you must follow precautions to avoid electrocution, fire, burns, or other injuries.
- ⚠ Do not touch exposed transformer pins and patient at the same time. Use only the transformer provided with the Sierra Cold Therapy unit.
- ⚠ Keep electrical connections dry and free of debris. Even though the Sierra Cold Therapy System is designed to hold and pump water, the electrical connections at the power outlet and from the power cord to the unit must be kept dry. Do not handle the transformer or electrical cord with wet hands. Always keep the unit in a place where the connections will not fall into water (e.g., a tub, sink, etc.). If the electrical connections fall into water, do not touch any wet part of the product. Unplug only at dry electrical connections.
- ⚠ Protect the power cord and transformer. Always use a grounded outlet. Keep the cord and transformer away from heated surfaces. Setup and use this equipment in a low traffic location away from children and pets. Never operate this product if it has a damaged cord, transformer, or plug, which could result in electric shock. If the cord, transformer, or plug is damaged, unplug and contact Customer Service at 866-592-0488.
- ⚠ Unplug to stop the product when not in use. Unplugging the unit turns it off. Always unplug immediately after use. Never leave it plugged in while unattended.
- ⚠ This unit may cause electromagnetic or other interference with other electrical devices. To check whether the unit is interfering with another device, unplug the unit. If this corrects the problem, move the unit or other device, or use an outlet on a different circuit.
- ⚠ Keep cords and hoses away from the neck to avoid risk of strangulation. No modification of this equipment is allowed. Keep hoses out of pathways to avoid the risk of tripping. There are no user serviceable parts.

Safety Classifications

Mode of operation is timed sessions of 20, 40 or 60 minutes with automatic shutoff	
External Electrical Power Source-Class II Equipment	
Degree of Protection Against Electric Shock-Type BF applied parts are extension tubing and the cold therapy pads	
Ordinary Equipment Degree of protection against harmful ingress water or particular.	IP21
CONFORMS TO AAMI STD ES 60601-1, IEC STD 60601-1-6: CERTIFIED TO CSA STD C22.2 NO. 60601-1 C22.2 NO. 60601-1-6 IEC60601-1-2(EMC standard)	

Cleaning and Disinfecting

- **NOTE: Inspect the device and follow the cleaning and disinfecting procedures prior to each use. Cleaning and Disinfecting are recommended when required.**
- **WARNING: Device must be turned off and disconnected from the wall outlet prior to and during cleaning or disinfecting.**
- Clean the outer surface of the device as well the exterior of the wraps using a soft cloth, moistened with soapy water or mild detergent and let air dry.
- Do not use abrasive or volatile cleaners.
- Do not place device and the wrap in the autoclave, dryer or microwave.
- Do not use a hair dryer to accelerate drying.
- Do not place the device on top of or in front of portable or stationary radiators to accelerate drying.

Troubleshooting

Pump will not turn on:

- Check all electrical connections and make sure the AC Adapter is plugged into a wall outlet that is receiving power.

Cold therapy pad is not getting cold:

- Make sure trapped air is out of the cold therapy pad once the unit is running.
- Make sure the device is filled to the correct line with the indicated amount of water and ice.
- Check all hose connections and make sure the cold therapy pad is aligned correctly to allow optimal water flow from the device.

Cold therapy pad pressure is low:

- Check the water level. If it is low, add water to the indicated line.

No water flow from unit to the cold therapy pad:

- The cold therapy pad may be wrapped too tightly or the hose may be kinked. Unwrap and rewrap the cold therapy pad over a barrier to the treatment area while the unit is running, ensuring water is circulating through the cold therapy pad and the hose is properly aligned with the unit.
- Make sure the connection between the cold therapy pad and the hose from the unit is properly connected. Make sure to listen and feel for a “snap” or “click when connecting the hose the cold therapy pad.
- Clean filter: Disconnect pad. Remove unit lid. Pull filter cap from bottom of lid. Remove foam filter. Rinse filter cap and filter to remove clogs. Reassemble and power the unit to run.

Troubleshooting (continued)

Water leak at couplings:

- Check the connection at the coupling of the hose and cold therapy pad. Stop the device, disconnect the couplings and reconnect. Make sure to listen and feel for a “snap” or “click”, then restart the unit.
- Check the barrier between the pad and your skin for dryness. If needed, replace with a dry barrier between the skin and the cold therapy pad.

Water leak at the cold therapy pad:

- The cold therapy pad may be damaged or defective. Contact your health practitioner/customer support to get a replacement.
- Check the barrier between the pad and your skin for dryness. If needed, replace with a dry barrier between the skin and the cold therapy pad.

Condensation:

- To reduce condensation, minimize air exposure by using material to cover the pad.
- Protect the wound site by using a dressing with a waterproof barrier, inspect frequently to maintain a dry wound site.

Magnetic or Electromagnetic Interference:

- Reposition or relocate the device. Increase the separation from other electrical devices.
- Plug the AC Adapter into an outlet on a different circuit than other powered electrical devices.

Disposal

Dispose of product according to local regulations

Product Support

No product maintenance should be performed by the user. If your Sierra Cold Therapy System requires maintenance, please contact your health practitioner or customer support at (866) 592-0488.

Items included in the package:

















- (1) Ice bucket *1pc
- (2) Manual *1pc
- (3) Charger *1pc
(Input: AC100-240V; Output: DC5.0V--1A)

Optional Items:

- (1) Shoulder pad *1pc with elastic straps *2pcs
- (2) Knee pad *1pc with elastic straps *2pcs
- (3) Multi-use pad *1pc with elastic straps *3pcs
- (4) Non woven fabric barrier for shoulder pad *1pc
- (5) Non woven fabric barrier for knee pad *1pc
- (6) Non woven fabric barrier for multi-use pad *1pc

Symbol Interpretation

Information essential for proper use shall be indicated by using the corresponding symbols. The following symbols may be seen on the device and labeling.

Symbol	Title
	ON/OFF button
	Temperature setting
	Timer setting
	Refer to instructions for use
IP21	IP of the device
	Disposal in accordance with Directive 2002/96/EC (WEEE)
	This way up
	Date of manufacture
	Batch code
	Manufacturer
	Type of BF applied part
	Fragile, handle with care
	Keep the product in a dry place away from water and rain
	Product packaging is able to be recycled
	Symbol for Class II Equipment
	Non sterile product
R _x only	CAUTION: Federal Law restricts this device to sale by or on the order of a physician
	Warning

Electromagnetic Compatibility

Warning:

- Do not use near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 12 inches (30 cm) to any part of the equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

FCC Statement:

This device complies with part 18 of the FCC Rules.

Technical description:

All necessary instructions for maintaining BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to electromagnetic disturbances for the expected service life.

Guidance and manufacturer's declaration -electromagnetic emissions and immunity.

Electromagnetic Compatibility (continued)

Guidance and manufacturers declaration - electromagnetic emission	
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.	
Emission test	Compliance
RF emissions CISPR 11	Group 1
RF emission CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies

Guidance and manufacturers declaration - electromagnetic immunity		
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
Immunity test	IEC 60601 test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2kV for power supply lines
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV differential mode

Guidance and manufacturers declaration - electromagnetic immunity		
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle	<5% U_T (>95% dip in U_T) for 0.5 cycle
	40% U_T (60% dip in U_T) for 5 cycles	40% U_T (60% dip in U_T) for 5 cycles
	70% U_T (30% dip in U_T) for 25 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 5 sec
Power frequency (50Hz/60Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m
NOTE: U_T is the AC mains voltage prior to application of the test level.		

Electromagnetic Compatibility (continued)

Recommended separation distances between portable and mobile RF communications equipment and the device.

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the 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	80 MHz to 800 MHz	800 MHz to 2.5 GHz
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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