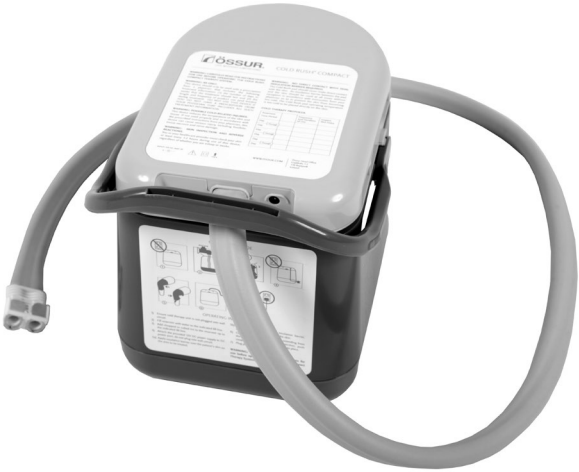
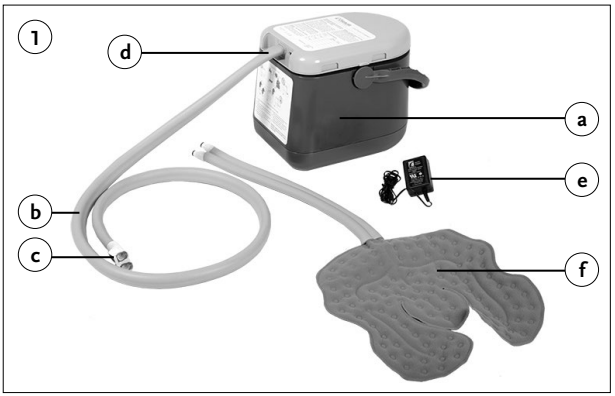
ÖSSUR®
LIFE WITHOUT LIMITATIONS



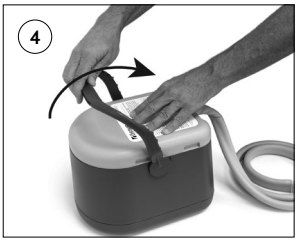
Instructions for Use

COLD RUSH® COMPACT


1
d
a
e
b
c
f


2
Fill Water Here
FIRST
NEXT
1st
2nd


3
Fill Ice Here
TO HERE WITH WATER
TO HERE WITH ICE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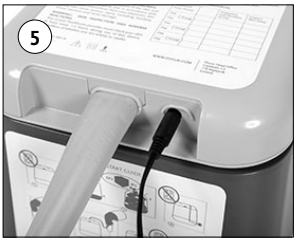
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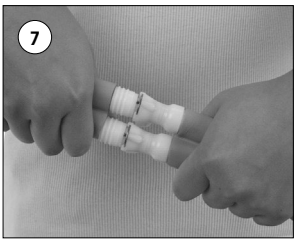
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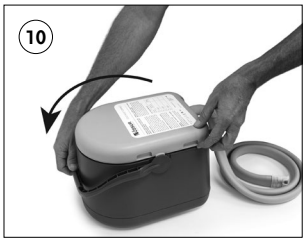
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SYMBOLS

Caution Symbol
Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences

BF Applied Part

Manufacturer address

Consult instructions for use

Device contains electronic components and/or batteries that should not be disposed of in regular waste. The device and packaging must be disposed of in accordance with respective local or national environmental regulations.

IP21

Protected against solid foreign objects of 12.5mmø and greater. Protected against vertically falling water drops.

Negative center connection (ISO. 5926)

Preferred Output Polarity Symbol

Class II Equipment

For indoor use only

UL's Recognized Component Mark for Canada and USA

DESCRIPTION

Cold Rush Compact is a mechanical circulation cold therapy device. The device is composed of a bucket holding a mixture of water and ice, a circulation pump that forces the coolant through a closed-loop hydraulic circuit and a cooling pad that is used to apply cold therapy to the region that is being treated. The system operates on a 12-volt power which is supplied via an external wall-mounted power supply.

LIST OF PARTS

Fig. 1:

a. Cold Rush Compact Cold Therapy System
b. Hose
c. Couplings
d. DC Connector
e. 12V Power Supply
f. Cold Rush Pad (Sold Separately)

INTENDED PURPOSE

The device is non-invasive, intended for single patient use and designed to reduce localized pain and swelling following surgical procedures or trauma.

Indications for use

- Provides cold therapy
- Indications requiring the application of cold therapy to a joint or limb such as post-surgical, trauma pain, and swelling

Contraindications

The device should not be used on patients with the following conditions:

- Known hematological dyscrasias that predispose to thrombosis (e. g., paroxysmal cold hemoglobinuria, cryoglobulinemia, sickle cell disease, serum cold agglutinins)
- Compromised local circulation (including arteriosclerosis, ischemia)
- Neurologic impairment (including paralysis or localized compromise due to multiple surgical procedures or diabetes) in the affected region, polyneuropathy, or other nerve damage causing decreased skin sensitivity
- Cognition or communication impairments that prevent the user/patient from giving accurate and timely feedback including incapacitated patients with severe cardiovascular disease, anesthetic skin, hypercoagulation disorders, poor circulation, extremities sensitive to pain, extremely low blood pressure
- Raynaud's disease, phenomenon, or other vasospastic conditions
- Buerger's disease, significant vascular impairment
- Hypersensitivity to cold (cold urticaria) or history of cold related injury (including chilblains or frostbite)
- Severe cardiovascular disease, anesthetic skin, hypercoagulation disorders, poor circulation, extremities sensitive to pain, extremely low blood pressure, incapacitation, decreased skin sensitivity, vein ligation or recent skin grafts, or pheochromocytoma
- Localized unstable skin condition (e. g., dermatitis, vein ligation, gangrene, or recent skin graft) in the affected region or potential impairment of healing in the treatment area, including infection
- Tissues inflamed as a result of recent injury or exacerbation of chronic inflammatory condition

Warnings and Cautions:
Warning: This product has been designed and tested based on single patient usage and is not recommended for multiple patient use.
If any problems occur with the use of this product, immediately contact your healthcare professional.

Warning: The device can be cold enough to seriously injure skin. Read the instructions which are located inside the unit, the instructions for the pad, and the labels on the device carefully before operating the device.

Warning: RX ONLY
This device should only be used with a prescription from a physician that includes the following treatment information: (1) the number of days or weeks that the treatment should last and (2) the length and frequency of product use (and breaks) during treatment, (3) instructions about how to inspect the skin, and (4) frequency of skin checks. A blank treatment protocol to be filled out by your healthcare provider is provided on top of the device. **DO NOT USE THIS DEVICE IF YOU DO NOT HAVE A PRESCRIPTION FROM YOUR PHYSICIAN THAT INCLUDES ALL SUCH TREATMENT INFORMATION**

Warning: POSSIBLE COLD-RELATED INJURIES
This device reduces the temperature of the skin and tissue. If not used properly and in accordance with the prescribed instructions from your physician, this device can cause serious injury, non-freezing cold injury, tissue necrosis and nerve damage.

Warning: SKIN INSPECTION AND ADVERSE REACTIONS
You or your healthcare provider must check your skin at least every 1–2 hours during use of this device, regardless of whether you are asleep or awake, for any change in skin condition, including for any increase in pain, burning, blistering, itching, increased swelling, discoloration of the skin, increased redness, welts or any other changes in the appearance of the skin. If you experience any of these reactions, you should immediately discontinue use of your device and contact your healthcare provider. Any dressing, casting, bracing or wrapping must not interfere with your ability to check your skin condition. If you are unable to check your skin condition for any reason, do not use the device.

Warning: NO DIRECT CONTACT WITH SKIN: INSULATION BARRIER REQUIRED (not included).
The Cold Rush Pad should never make direct contact with the skin. The pad operating temperature is too cold to be placed directly on the skin. An insulation barrier between the pad and the skin should be used at all times without exception so as to prevent the skin from becoming too cold. Failure to use an insulation barrier between the pad and the skin can lead to a cold-related injury.

- Unit is not suitable for use in the presence of flammable anesthetic mixture with air, oxygen, or nitrous oxide.
- Follow local ordinances or regulations for proper disposal of device, accessories, and packaging

Caution: Federal law requires this device to be sold by a physician or by the order of a physician.

Warning: USE ONLY ÖSSUR COLD RUSH PADS
Competitive brand cold therapy pads should not be used with the device as the temperature may become too cold when using competitive pad and the pads may not otherwise function properly, causing injury. Only Össur Cold Rush Pads should be used with the device.

Warning: NO MOISTURE IN INSULATION BARRIER
If the moisture is present in the insulation barrier, the skin may become colder than intended. The insulation barrier should be inspected regularly to check for moisture caused by bleeding, sweating or condensation. If moisture is found on the insulation barrier between the pad and the skin, immediately discontinue use of the device until the moisture is removed and a fresh barrier is placed between the pad and the skin.

Risk factors
Physicians should carefully consider the following conditions or factors before prescribing the device:

- Sensitivity to cold;
- General impaired circulation;
- Use of medications that may negatively affect peripheral vascular circulation, including beta adrenergic blockers and local epinephrine use (such as local anesthetics);
- Poor nutrition, smoking, tobacco use, excessive use of caffeine or alcohol and any other behavior negatively affecting circulation;
- Desensitization of the treatment area due to local anesthesia or regional nerve blockers;
- Cognitive impairment and use of medications that have a negative effect upon mental capacity or judgment;
- Moisture at the application site due to excessive bleeding, sweating or condensation;
- Diabetes;
- Use of product on hand, wrist, foot or ankle; and
- Young children and elderly.

Warning: Water level should not exceed the reference mark on the sticker inside the bucket to avoid risk of overflow when closing the cover.

Warning: Make sure the ice level does not exceed the reference mark on the sticker. Failure to comply will cause device overflow when closing the lid.

Healthcare provider responsibilities

- The prescribing physician must determine (1) the number of days or weeks that the treatment should last and (2) the length and frequency of product use (and breaks) during treatment. All such information should be included in the patient's prescription.
- Appropriate training must be provided by the healthcare provider, in the proper application, use and operation and care of the device.
- The healthcare provider must monitor the patient's use of the device to assure compliance with the prescribed protocol, appropriate use, proper application, and operation of the device, including but not limited to application and maintenance of an insulation barrier between the patient's skin and the pad.

Treatment Time Period	Frequency and Duration of Use	Inspect Skin Every
Day Through Day		
Day Through Day		
Day Through Day		

Additional warnings

- The device should never be left unattended when plugged in.
- Do not place the tubes or the power cord where your or other's feet can get entangled, causing a fall.
- Never drop or insert any object into any opening or hose.
- Do not operate where aerosol (spray) products are being used or where oxygen is being administered.
- Do not attempt to drag or reposition the device by pulling or tugging on the insulated hoses, as this may cause damage to the device and/or cause the hoses to disconnect. Use handle when moving the device.
- Do not place the tubes or the power cord by the top of your bed where they could twist around your neck while you are sleeping.
- The pump in the device is designed to run with water. Running the device without water will cause permanent damage to the pump.
- A wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies can affect the device and should be kept at least a distance 3.3 m away from the device.

Safety standards

The device is tested and certified to comply with the IEC60601-1 standard of electrical safety of medical devices and IEC/EN60601-1-2, electromagnetic compatibility for medical electrical devices. IEC 60601-1-11, requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment. The company fulfills the requirements of ISO13485.

Electric shock hazard

To create the safest operating conditions possible, Össur has designed the device to operate on a 12-volt power supply, significantly reducing the chance of dangerous electric shock. Avoid use near any water source.

- Only use the power supply provided with the device.
- Unplug device before filling it with ice and water.
- To avoid danger of electric shock be certain that hands are dry before inserting or removing the power supply from wall socket.
- Avoid getting water or ice on the power adapter.
- Always unplug this product immediately after each use.
- Never use the device while bathing.
- Do not place or store product where it can fall or be pulled into a tub or sink.
- Do not place in or drop into water or other liquid.
- Do not reach for a product that has fallen into water. Unplug immediately.

- Keep cord & device away from heated surfaces.
- Never operate this product if:
  - The device has a damaged electrical cord or plug;
  - The device has been dropped or damaged;
  - The has been dropped into water; or
  - The device is not working properly.
- If any of the above have occurred, immediately discontinue use of the device and return the product to your healthcare provider for examination and repair.

USAGE

Setup and operation

1. Do NOT plug unit into wall socket until steps 2–7 are completed.
2. Fill reservoir with water to the indicated fill line **(Fig. 2)**.
   Warning: water level should not exceed the reference mark on the sticker inside the bucket to avoid risk of overflow when closing the cover.
3. Add chopped or cubed ice to the reservoir up to the indicated fill line **(Fig. 3)**.
   Warning: Make sure the ice level does not exceed the reference mark on the sticker. Failure to comply will cause device overflow when closing the lid.
4. Close the reservoir. With handle in the open position, press lid firmly onto unit making certain that the lid is in full contact with the vessel and the seal is engaged, then pull handle into the locked position **(Fig. 4)**
5. Attach the provided 12V power supply to DC power port, but do not plug into wall socket **(Fig. 5)**.
6. Apply insulation barrier (not included) over the patient's skin in the area to be treated **(Fig. 6)**.
7. Connect Cold Rush Pad to hose extending from the device. To ensure proper connection, push couplings together until they snap into place **(Fig. 7)**.
8. Apply pad over insulation barrier (not included). The pad should never be applied directly over the patient's skin **(Fig. 8)**.
9. Plug the provided 12V power supply to wall socket (120V US, 240V Europe) **(Fig. 9)**.
10. To turn off the cold therapy device, unplug the power supply unit from wall socket.
11. Always turn the cold therapy device off before disconnecting the pad or any hoses. To disconnect the hoses, press the release tabs on the coupling and pull the connectors apart.
12. To open lid, press handle down to disengage lid seal, then lift to remove **(Fig. 10)**
13. Drain all of the water out of the cold therapy device after each use.
14. Follow directions 2–8 before each use.

Cleaning and prolonged storage

When you have finished all of your cold therapy treatments, prior to prolonged storage, fill the device so the water level is at the ice fill line.

- Add 2 tablespoons of liquid bleach or 3 ounces of 3% hydrogen peroxide to the water and mix.
- Connect hoses to the Cold Rush Pad, plug in the device to start.
- Allow water mixture to circulate for 5 minutes.
- To turn device off, unplug power supply.
- Carefully drain the water mixture out of the device and store in a dry, cool, and dark place leaving the lid slightly open. (Exposure to sunlight and extreme heat may damage hoses and device.)

- When reusing the device after storage, fill the reservoir with clean water and turn the pump on to circulate the water through the hoses and flush the remaining water mixture out of the system (use old pad for this procedure, discard the pad after cleaning is completed).
- Dispose water and refill the reservoir with fresh ice and water combination to begin cold therapy treatment. Follow operating instructions 2–9 before each use.
- Before you use the device, inspect hoses and new pad for any tears or breaks. Contact your healthcare provider to purchase new Cold Rush Pad.
- Clean or replace insulation barrier as recommended by your healthcare practitioner.

Environmental Conditions

- Operating Temperature: +10 °C (+50 °F) to 40 °C (104 °F)
- Operating Humidity: 30% - 75% Relative Humidity
- Operating Atmospheric Pressure: 700–1060 h Pa
- Shipping and Storage Temperature: -20 °C (-4 °F) to 60 °C (140 °F)
- Shipping and Storage Humidity: 10% - 90% Relative Humidity, non- condensing
- Shipping and Storage Atmospheric Pressure: 700–1060 h Pa

MAINTENANCE

Do not attempt to repair your device as this may create a user hazard and put the user at risk. Any attempt of repairing the device will automatically void warranty.

Power supply specifications

Do not use any other power supply other than the one provided with the unit.

- Model no: UES06WU-120050SPA
- Input: 120V US, 240V EU
- Input frequency: 60Hz US, 50Hz EU
- Output power: 6W
- Output Voltage: 12V
- Output Current: 0.5A

ELECTROMAGNETIC COMPATIBILITY PRECAUTIONS AND WARNINGS

The Cold Rush Compact Cold Therapy System needs special precautions regarding electromagnetic compatibility (EMC). Specifically, it needs to be installed and put into service according to the EMC information provided as follows:

- The Cold Rush Compact Cold Therapy System should not be used adjacent to or stacked with other equipment. In case adjacent or stacked use is necessary, the Cold Rush Compact Cold Therapy System should be observed to verify normal operation in the configuration in which it will be used.
- The Cold Rush Compact Cold Therapy System may be susceptible to electromagnetic interference from portable and mobile RF communications devices such as mobile (cellular) telephones.
- The Cold Rush Compact Cold Therapy System may be interfered with by other equipment, even if that other equipment complies with CISPR EMISSION requirements.

Cold Rush accessories, various pads, will not negatively affect EMC performance of the Cold Rush Compact Cold Therapy System. To maintain basic safety, do not use any other power supply other than the one provided with the unit. Cold Rush Compact Cold Therapy System is intended for use in EM environment tabulated below

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The device is intended for use in the electromagnetic environment specified below. The customer or user of device should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment – Guidance**
RF Emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are 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 domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonics Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration – Electromagnetic Emissions			
The device is intended for use in the electromagnetic environment specified below. The customer or user of device should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst IEC 61000-4-4	±2 kV	±2 kV	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±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 lines IEC 61000-4-12	0 % UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0°	1 % UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0°	Mains power quality should be that of a typical commercial or hospital environment. If the user of the 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 (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Proximity magnetic fields IEC 61000-4-39	30 kHz at 8 A/m 134.2 kHz at 65 A/m 13.56 MHz at 7.5 A/m	30 kHz at 8 A/m 134.2 kHz at 65 A/m 13.56 MHz at 7.5 A/m	
Note: UT is the a.c. mains voltage prior to application of the test level.			

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 d=1,2√P	80 MHz to 800 MHz d=1,2√P	800 MHz to 2,7 GHz d=2,3√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.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions			
The device is intended for use in the electromagnetic environment specified below. The customer or user of device should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance:
Conducted RF IEC 61000-4-6	3 Vrms, 150 kHz to 80 MHz	3 Vrms	$d=1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m, 80 MHz to 2.7 GHz	10 V/m	$d=1.2\sqrt{P}$ 80 MHz to 800 MHz $d=2.3\sqrt{P}$ 800 MHz to 2.7 GHz
			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). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey*, should be less than the compliance level in each frequency range**.
			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 situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.		
*	Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the 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 re-orienting or relocating the device.		
**	Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.		

RF Wireless Communication Compliance Information					
Test Frequency (MHz)	**Band (MHz)**	**Service**	**Modulation**	**Distance (m)**	**Immunity test level (V/m)**
385	380-390	TETRA 400	Pulse modulation 18 Hz	0,3	27
450	430-470	GMRS 460, FRS 460	Pulse modulation 18 Hz	0,3	28
710	704-787	LTE Band 13, 17	Pulse modulation 217 Hz	0,3	9
745					
780					
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	0,3	28
870					
930					
1720	1700-1990	GSM 1800, CDMA 1900, GSM 1900, DECT, UMTS LTE Band 1, 3, 4, 25	Pulse modulation 217 Hz	0,3	28
1845					
1970					
d2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	0,3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0,3	9
5500					
5785					

DISPOSAL

The device and packaging must be disposed of in accordance with respective local or national environmental regulations.

LIABILITY

Össur does not assume liability for the following:

- Device not maintained as instructed by the instructions for use.
- Device assembled with components from other manufacturers.
- Device used outside of recommended use condition, application, or environment.

Limited Warranty

Qualified returns/exchanges must be processed by the original seller and be in accordance with their return policy.