



Cryotherapy



TRIMED

OPERATING MANUAL



Please read fully before operating

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PRODUCT SPECIFICATIONS

Items included:

- (1) Ice bucket (Tru- U109) *1pc
- (2) Manual (Tru-M109 Rev A) * 1pc
- (3) AC Adapter (Tru- AC109) * 1pc (Input: AC100-240V; Output: DC5.0V--1A) BHI-004
- (4) Universal pad (Tru-UP109) *1pc
- (5) Elastic straps (Tru-ES109) *3pcs
- (6) Non-woven fabric barrier (Tru-FB109) *1pc

INTRODUCTION

Indications for Use

The ice bucket can provide constant circulation of cold water for cold therapy and reduce post-surgery swelling and inflammation, joint pain and facilitate post-workout recovery.

The ice bucket can be cold enough to cause serious injury including full skin necrosis. Read and understand all warnings and follow this information, the Operating Instructions in this product insert prior to using this device. Always keep the manual for easy reference.

United States federal law restricts this device to sale by or on the order of a healthcare professional. This device is intended for single patient only. Dispensed with a prescription.

SAFETY WARNING

Contraindications

Cold Therapy

Patients with any of the following conditions should not use BigHorn.

- History of cold injury, frostbite/chilblains, or adverse reactions to local cold application. Hypersensitivity to cold/cold allergy, extremities sensitive to pain, decreased skin sensitivity.
- Patients who are incoherent due to general anesthesia, sedation, or coma. Cognition or communication impairments that prevent them from giving accurate and timely feedback.
- Application areas with compromised local circulation or potential wound healing problems, including paralysis or localized compromise due to multiple surgical procedures Or diabetes or neurological impairment in the affected region.
- Circulatory syndromes, including Raynaud's disease or cold hypersensitivity (cold urticaria), Buerger's disease, peripheral vascular disease, vasospastic disorders, sickle cell anemia, and hyper-coagulable clotting disorders.
- Severe cardiovascular disease, anesthetic skin, hyper-coagulation 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.
- Tissues inflamed as a result of recent injury or exacerbation of chronic inflammatory condition.
- Hand/wrist or foot/ankle surgery with polyneuropathy.
- Diabetes/ Diabetic Polyneuropathy.
- Decompensated hypertonia in the affected region.
- Known hematological dyscrasias that predispose to thrombosis (e.g., Cold agglutinin disorders like paroxysmal cold hemoglobinuria, cryoglobulinemia, sickle-cell disease, serum cold agglutinins).

WARNINGS

Do not use this device if you did not receive or do not understand the instructions. Use only according to your healthcare professional's instructions regarding the frequency, duration, and settings of cold application and length of breaks between uses, the pressure, how and when to inspect the skin, and total length of treatment.

A healthcare professional is responsible for providing warning instructions and precautions to other healthcare professionals, care providers involved in the patient's care, and the patient.

The healthcare provider must monitor the patient's use of this device, assuring appropriate use and application of all therapies.

If it is appropriate for the patient to use the therapy garment with this device at home, the healthcare provider must provide adequate and appropriate instructions for use to the patient.

Patients with any of the following should only use the product under direct supervision of a medical professional:

- Cognitive disabilities.
- Communication barriers.
- Use of medications that have a negative effect upon mental capacity.
- Young children and the elderly.
- Visually impaired.

Exercise special precautions for children, pregnant users, hyper-coagulation disorders, diabetes, neuropathies, arthritic conditions, diabetes peripheral vascular disease, and patients with decreased skin sensitivity.

If the patient has any of the following clinical risk factors, use of the device may result in serious cold- induced injury, including full thickness skin necrosis:

- Pathologic sensitivity to cold.
- Behaviors that negatively affect circulation, including poor nutritional status, smoking and tobacco use, excessive caffeine use, and excessive alcohol use.
- Cold application area desensitization due to local anesthesia or regional nerve blocks. Diabetes.
- Hand/wrist or foot/ankle surgery.
- Taking medications that have a negative effect on peripheral vascular circulation, including beta adrenergic blockers and local epinephrine use.

Excessive moisture at the application site due to excessive bleeding, sweating, or condensation may increase the risk of serious cold-induced injury, including full thickness skin necrosis.

Individuals may vary in sensitivity to cold, regularly inspect the skin under the cold pad (by lifting the edge) as prescribed. You may need to check more frequently according to your situation and the suggestions from your healthcare professionals. Do not use the unit if skins checks are inhibited by a barrier.

Stop using and consult your healthcare professional immediately if you experience any adverse reactions, such as: increased pain, burning, increased swelling, itching, blisters, increased redness, discoloration, welts, irritation and other changes in skin appearance, or any other reaction identified by your healthcare professional.

Therapy garments are to be initially selected by a healthcare professional familiar with their purpose.

Therapy garments are non-sterile unless specifically labeled as sterile. Non-sterile therapy garments should never be directly applied to an open wound or breached skin. Use only sterile therapy garments over wounds or breaks in the skin.

Garments should be inspected for cleanliness and damage for each treatment. Do not use a garment if there are signs of damage as the garment may leak. If the garment is dirty, clean as indicated in the cleaning section of each garment IFU.

Do not attempt to sterilize this device or therapy garments by any means.



Do not use abrasive or solvent-based cleaners on the unit.

Do not allow the therapy garment or tubes to contact sharp objects that could puncture them.

Observe all warning and caution labels. Never remove the labels.

Ensure the therapy wrap is applied correctly before initiating any therapy. Allowing the wrap to inflate when not applied correctly may cause the wrap to “balloon” which may cause damage to the wrap.

Immediately stop ice therapy if you experience any sense of discomfort, numbness or tingling of the limb.

The power must be turned OFF when the wrap is removed from the patient.

Precautions

When using this device, basic safety precautions should always be followed to reduce the risk of fire, electric shock and personal injury. Please read the entire manual carefully before trying to operate the unit. Precautions include:

- Use only accessories (such as power adapter, pads, tubes) that have been designed, approved and supplied for use with this device.
- This device (including the pad) is only for single patient use.
- Do not use BigHorn on infants. It may cause an accident.
- Always unplug immediately after each use. Never run pump without water, which may damage BigHorn.
- Do not operate this device with a damaged or frayed power cord.
- If a leak or a steady stream of water is flowing from any part of the unit, tubing or cold pad, discontinue use and contact Customer Care. Excess moisture could result in a slip hazard or unwanted moisture at an injury site.
- 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.
- Do not attempt to repair/disassemble/modify the device. NEVER attempt any service while the device is in use. Service and maintenance is restricted only to authorized service personnel.
- Do not operate in a wet environment or operate the transformer or electrical cord with wet hands. The electrical connections at the power outlet and from the power cord to the unit must be kept dry.
- If this device gets wet, unplug from the wall, wipe the outer surface with a dry cloth, and allow it to dry before use.
- Do not subject BigHorn to extreme shocks, such as dropping BigHorn.
- Portable and mobile Radio Frequency Communication Equipment can be affected by this device. Do not use near equipment that generates electromagnetic or other interferences as this may be harmful to this device.
- This device is intended to be used indoors. Not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
- Do not smoke while using therapy garments or use garments by an open flame.
- If exposed to temperatures below 5°C or above 40°C, allow the device to warm up or cool down to room temperature.
- All equipment and accessories should be kept out of reach of children and pets.
- Keep the cords and tubes away from neck to avoid risk of strangulation and put them away avoid tripping

Reminder for healthcare professionals:

Review the contraindications, warnings and precautions prior to discharging the patient from facility care to home use.

Screen the patient for any contraindications and/or applicable warnings. If the patient has any contraindications (see Contraindications), do not dispense this device to the patient. If any of the warnings apply to the patient (see Warnings), determine the appropriateness of application of this device to that patient.

Instructions For Use. Instruct the patient on how to properly use this device. Review the Operating Instructions in this document and affixed to the unit with each patient.

Prescription. Instruct the patient regarding the healthcare professional's prescribed protocol: frequency, temperature level and duration of use, length of breaks between uses, how and when to inspect the skin, and total length of treatment. A protocol template is included in this document to fill in and provide to the patient. The duration of application, temperature may vary depending upon the patient. If the patient does not experience pain relief, the physician may increase the duration of application and/or adjust temperature levels. As the application duration is increased, the frequency of the skin inspections should increase.(see Warnings). Instruct the patient to take breaks by turning off the unit for a specified period of time.

Potential For Injury. Inform the patient that improper use can result in serious skin injury, including full thickness skin necrosis. Emphasize the importance of following the prescribed protocol, proper cold pad application, and skin inspection.

Proper Cold Pad Application. Instruct the patient to use only the cold pad designed for the body part being treated; other pads may not connect or may be colder, increasing the risk of serious cold-induced injury, including full thickness skin necrosis. Do not use this unit if skin checks are inhibited by a barrier.

Skin Inspection. Instruct the patient to inspect the skin receiving treatment per the practitioner's instructions, typically at least every 1 hour. Do not use this unit if skin checks are inhibited by a barrier.

Discontinue. Instruct the patient to stop using this device and consult his/her healthcare professional immediately if he/she experiences any adverse reactions, such as: increased pain, burning, increased swelling, itching, blisters, increased redness, discoloration, welts, or other changes in skin appearance.

Documentation. Provide the patient a prescription. The prescription must include:

- The frequency, duration, and settings of the cold application
- Length of breaks between uses
- How and when to inspect the skin
- Total length of treatment

Cold Protocol for reference

Cold Therapy Protocol (To be completed by a licensed healthcare professional)			
Treatment Period	Awake/Sleep	Frequency/Duration/Cold Setting	Inspect Skin Frequency/ Breaks between uses
Day:			
Day:			
Day:			
Day:			

If you prescribe this product to patients with risk factors, consider taking special measures to control the risk, such as:

- Recommending more frequent skin checks. If patient has cognitive risk factors, healthcare professional or

caretaker should provide skin checks.















- Requiring more frequent follow-up examinations.
- Adding an insulation barrier between the cold pad and skin.
- Prescribing shorter durations of application, less frequent application, or eliminating nighttime application.
- Prescribe the warmer temperature setting.

Condition of Working, Storage and Transportation

- Normal working ambient temperature: 5~40°C
- Normal working ambient humidity: 15%~90%
- Store and transport ambient temperature: -25~70°C
- Store and transport ambient humidity: 0~90%
- Atmospheric pressure: 70~106kPa

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
	Refer to instructions for use
	Temperature setting
	Timer setting
IP20	IP code of the device
	Disposal in accordance with Directive 2002/96/EC (WEEE)
	This way up
	Date of manufacture
	Batch code
	Manufacturer
	Type BF applied part
	Fragile, handle with care
	Keep the product in the dry place. Away from water and rain.
	Symbol for Class II Equipment
	Caution: Federal law restricts this device to sale by or on the order of a licensed practitioner.

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 in (30 cm) to any part of the equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Technical description:

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

Guidance and manufacturers declaration -electromagnetic emissions and Immunity

Guidance and manufacturer's 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 manufacturer's 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
Conducted RF IEC 61000-4-6	3 V _{rms} 150 kHz to 80 MHz	
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	

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 Field strength 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.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Guidance and manufacturer's declaration – electromagnetic immunity

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U _T for 0.5 cycle (>95% dip in U _T) 40% U _T for 5 cycles (60% dip in U _T) 70% U _T for 25 cycles (30% dip in U _T) <5% U _T for 5 sec (>95% dip in U _T)	<5% U _T for 0.5 cycle (>95% dip in U _T) 40% U _T for 5 cycles (60% dip in U _T) 70% U _T for 25 cycles (30% dip in U _T) <5% U _T for 5 sec (>95% dip in U _T)
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.

Recommended separation distances between portable & 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.

TECHNICAL INFORMATION

Model/type	Ice bucket	Weight	Approx. 2670g
Power supply	Powered by an internal 5V 1A adapter	Degree of protection against electric shock	Type BF applied part
Effective Volume	6.2L	Type of protection against electric shock	Class II
Warranty	1 year	Grade of waterproof	IP22
Temperature range	45°F-50°F-55°F	Mode of operation	Continuous operation
The time required for the equipment to warm from the minimum storage temperature between uses until it is ready for intended use	30 minutes	The time required for the equipment to cool from the maximum storage temperature between uses until it is ready for intended use	15 minutes
Timer	20-60 min	Controller size (±2mm)	235 x 235 x 280mm
Typical battery operation time	Approx. 2 hours	Adapter for charging	Input: AC100-240V, Output: DC5.0V--1A

Note: Not intended to be sterilized.

Not for use in an OXYGEN RICH ENVIRONMENT

OPERATING INSTRUCTIONS



Set up and operation the ice bucket

1. Unlock the handle and Open the lid.
2. First fill the bucket with cold water up to the indicated water line. Then fill the ice to the indicated ice line. Do not overfill the water or ice to avoid water spill out. Use cubed or chunked ice for optimal performance. **DO NOT RUN PUMP WITHOUT WATER!**
3. Put the lid back and keep the handle in the lower position and turn the knobs to lock the lid.
4. Connect the wrap to the connector of the ice bucket tubing by pushing the coupling button. When the female and male ends are connected securely, you will hear a “click”.
5. A barrier is always needed to be added between the pad and skin to avoid cold injury. Not any part of the pad should contact with skin. Apply the pad to the treatment area and secure it with the elastic straps.
6. Connect the ice bucket to the outlet using the supplied adapter.
7. Press the ON/OFF button on the ice bucket lid to power it on. The ice bucket will work automatically.



You can also set up the temperature and timer by pressing the timer setting button and the temperature button on the lid. The timer option is 20 min, 40 min and 60 min. The temperature range is 45°, 50° and 55°.

If it's initial start-up, the unit will work at default to 20 min and 50°. If the unit was previously in use, it will default to the last settings selected when the unit was turned off.

8. After treatment, press and hold the power button to power off. Remove the wraps from treatment area. Then disconnect the adapter from the outlet. Disconnect the wrap from the tube and ice bucket. Dry the wrap first before storage.



Usages Tips

1. Consult with your licensed health care practitioner before treatment.

Federal law restricts this device to sale by or on the order of a licensed health care practitioner.

Provide a complete medical history including any reactions to cold to your practitioner. Certain medical conditions make cold-induced injury more likely. Ask your practitioner about potential adverse reactions and cold-induced injuries.

2. Use Only as Prescribed

Use only according to your practitioner's instructions regarding the frequency and duration of cold, application and length of breaks between uses, how and when to inspect the skin, and total length of treatment. Do not use this device if you do not receive or do not understand the instructions.

3. Always apply insulation barrier & pad during use.

Do not let any part of the pad touch the skin. Always use an insulation barrier between the pad and skin.

The barrier material that comes with the packing is biologically compatible while not sterilized. It's breathable but not waterproof. Protect the wound site by using a sterile dressing with waterproof barrier first before using this barrier and pad over the treatment area or you can consult your professional healthcare practitioner for advice.

If a sterile dressing has been applied to the treatment site that does not completely cover the skin under the pad, use an additional insulation barrier.

If you are very sensitive to cold, thicker barriers should be used to avoid cold injury or ask your healthcare practitioner for advice.

4. Pad applications

The ice bucket may come with compatible pads according to your needs. Below are the instructions for use for the universal pad.

Use only with the pads comply with the device. Other pads may be colder, increasing the risk of serious cold-induced injury, including full thickness necrosis.

The universal pad

Place a barrier over the treated area. Then place the cold pad over the barrier. Secure the top part of the pad using one of the straps with hook attached on the loop pad surface. Then secure the bottom part of the pad by attaching another strap to the loop surface of the pad. Make sure not to wrap the straps too tight so that it restricts movement or circulation. You can check the skin when needed. Always make sure to wear a barrier between the pad and skin.

5. Inspect the skin under the pad (by lifting the edge) as prescribed.

If you are very sensitive to cold or any situation that needs to be checked frequently, you can check more often to avoid potential injuries caused by cold. Ask your practitioner to instruct you on how to inspect the skin area which is being treated by the device. Do not use this unit if dressing, wrapping, bracing, or casting over the pad prevents skin checks. Contact your practitioner immediately if you experience any adverse, for example, itching, blisters, increased redness, increased pain, swelling, burning, discoloration, welts, other changes in skin appearance, or any other reaction identified by your practitioner.

6. Check for moisture on the barrier between your skin and the cold pad. Discontinue use if the barrier is moist.

Change to a dry skin barrier before resuming use. Excessive moisture at the application site due to excessive bleeding, sweating or condensation may increase the risk of serious cold-induced injury, including full thickness necrosis.

7. Regarding Condensation

If the pad isn't properly applied and the surface is exposed to air, condensation may appear. The surface of the pad may appear to be leaking water. Condensation on the pad is normal due to the temperature difference between the air and the cold water inside the pad. However, to avoid condensation causing excessive moisture, which may cause side effects as mentioned above, wrap barrier over pad to minimize air exposure. And the pads should be wrapped well to the treated area before turning on the device.

Remarks: Wounds should be protected by using a sterile dressing with waterproof barrier over the wound site.

8. It is highly recommended that the pads are drained between uses.

To drain the pad, hold the pad upright with the hose pointed toward the ground. Depressed run with water. Running the unit without the black plunger and allow the water to drain out of the pad.



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 70% prophylaxis alcohol 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 the 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

The ice bucket does not work or water can't flow to wraps or not feeling cold:

- Ensure there is both water and ice in the device.
- Ensure enough water has been added according to the water level instruction.
- Use more ice for optimal performance.
- Allow 10 minutes for flow and pressure to stabilize.
- Ensure power outlet is working and plugs are fully engaged.
- Ensure the tubing is not folded or kinked.
- Disconnect and reconnect the pad and unit.
- Release air by depressing the white plus-shaped part inside the unit connector. Note: water may be released.
- Decrease tension of straps around the wraps.
- Remove wraps and lay it flat. Allow wrap to fill; reapply.
- Clean filter: Disconnect wrap. Take the lid off, screw out filter cap from bottom of lid. Remove foam filter. Rinse or replace foam filter, put the foam filter back to the lid. Try again.
- If the recommended action does not solve the problem, please contact the seller.

Leaking:

- If the pad is leaking (Not condensation as mentioned above), stop using the pad and replace the pad.
- If the lid is leaking, stop using the unit and contact the seller.
- If the leaking appears at the coupling area, disconnect the connectors and reconnect. You can hear a "Click" if the connectors match well. If this is not working, contact the seller for help.

MAINTENANCE AND DISPOSAL

- The device contains no serviceable parts.
- Inspect the device and all components for any damage that may have occurred prior to each use (for example, frayed or cut charging cord, cracked plastic housings, torn wraps, etc.). Refer to this manual for description of all components.
- Do not attempt to connect the wall supply if any damage is noticed.
- Avoid subjecting the device to shocks, such as dropping the device.
- Do not handle the wrap that contains water bladder with any sharp objects. If the water bladder is punctured or you notice a leak, do not attempt to repair the device or wrap. Replacement devices are available through customer service.
- Avoid folding or creasing the water bladder during use and transportation of the device. Contact the manufacturer or seller to receive replacement instructions for any damaged item.
- If not in use for a long time, empty and dry the wraps with soft cloth. This device is an electromagnetic device that includes printed circuit boards. Dispose of it according to the local, state, or corresponding laws.
- Do not discard in landfill. Do not discard the device in regular waste.

WARRANTY

This device carries a limited warranty of one year from the date of delivery. The warranty applies to the device only, and the accessories are not covered by this warranty.

During the warranty period, defective items will be repaired or replaced at no charge. Any evidence of misuse, abuse, alternations, or externally caused damage may have this warranty invalid.

For more information, please contact the manufacturer or seller.

CONTACT INFORMATION

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