

ARTEK | SPORT™

Cold Therapy Unit

INSTRUCTIONS FOR USE



Indications for Use

The ARTEK Sport is indicated to aid in the reduction of pain and swelling post-injury, or surgery, through the application of cold therapy. This single-patient use system, and its components, are non-sterile and are for prescription use only.

Contraindications

DO NOT use the ARTEK Sport on patients experiencing any of the following:

- Raynaud's phenomenon
- Vasospastic conditions
- Cold allergy or hypersensitivity
- Cryoglobulinemia
- Cold agglutinin disorders
- History of cold injury
- Limited mobility
- Reduced perception of pain
- Medication affecting sensation

Precautions

Special care and attention should be made when prescribing the ARTEK Sport for the following patients diagnosed with the following:

- Arthritis
- Peripheral vascular disease
- Compromised circulation
- Children under the age of 12
- Decreased skin sensitivity
- Hypercoagulation disorders
- Diabetes

Cold Injury Warning

Prolonged exposure to cold has the potential to cause injury to tissue. There is a potential for cold tissue injury even when providing cooling within your prescribed treatment. If unusual swelling, irritation, skin discoloration or discomfort occurs, immediately discontinue use of the ARTEK Sport and consult your health care professional.

General Warnings

Attention: The potential for cold injury is greater with extremity application. With foot/ankle or hand/wrist application, be sure to perform frequent checks of the toes or fingers for discoloration or numbness. If changes are observed, discontinue use immediately and consult your physician.

- This device is intended for single-patient use only. Secondary use can cause risk of infection or injury.
- Do not apply wrap directly against bare skin. Always use a skin barrier or thin piece of clothing between skin and wrap.
- The skin barrier must be kept dry. If barrier develops moisture, stop therapy and change barrier.
- Be sure to connect wrap and hose with audible click. Failure to connect may cause system to leak.
- Do not attempt to service this device. Attempting to do so may lead to electric shock.
- Only use the ARTEK Sport system with the power cord and accessories provided with the device. The use of other accessories may result in serious injury.
- Do not use in a sterile environment or place wraps directly over an open wound or breached skin.
- Do not drop the device or use if system is physically damaged. Keep wrap/hose away from sharp objects.
- Do not place therapy hose or power cord near/around your neck; strangulation risk.
- Do not cast or bandage over the ARTEK Sport therapy wraps.
- Do not spill water over the top of the device. Dry any excess water on the outside of the device prior to use.
- Use only water and water based ice in the system.
- Do not smoke near system or use system near open flame.

Operating Principle

ARTEK Sport provides cold therapy to a localized area by flowing cold water, from an ice bath, through an applied therapy wrap. The intended user is a licensed medical professional, a patient, or a caregiver. The user should be able to read and understand directions, warnings, and cautions provided in these user instructions. The user should be physically capable of performing all the instructions provided in this user manual.

Before using the ARTEK Sport

- Read and understand all warnings and instructions for use before using the device.
- The system set-up requires 3 – 4 lbs. of ice. Each set-up will allow for up to 6 hours of continuous use.
- The ARTEK Sport is prescription use only. Do not use without a prescription.
- It is the responsibility of the prescribing physician to define the therapy use parameters for each patient, including application site and therapy duration.
- If you are a patient, and are unclear as to the details of your prescribed therapy, contact your prescribing physician. This single-patient use system, and its components, are non-sterile and are for prescription use only.

How to read your prescription

Your prescription will include on the prescribed treatment ON time, either 20 or 40 min.

If your prescribed therapy is 'as tolerated,' you should choose therapy ON time that works best for you.

Therapy Rest/OFF time is not adjustable by the user; it is important for your safety that you do not skip the rest period.

Example Prescriptions

Example Prescription for Knee Application



Active Treatment ON Time	☐ As tolerated (choose 20 or 40 min ON)
	☐ 20 min ON
	☐ 40 min ON
Treatment Rest/OFF Time	☐ 20 min OFF
Duration of Need	☐ 30 days or greater as needed
	☐ Duration _____

The patient should use this therapy during their recovery as tolerated unless a specific therapy time is specified below.

Thermal Prescribed Therapy (Check as appropriate)	
☐ COLD Therapy 20 min. ON / 20 min. OFF	☐ COLD Therapy 40 min. ON / 20 min. OFF

If you have any questions regarding the details of your prescription, contact your physician.

ARTEK Sport System

The ARTEK Sport Therapy System is a single-patient use cooling system, designed to deliver effective and safe cooling therapy. These user instructions describe the operating and safety procedures for the ARTEK Sport. Read these user instructions in their entirety, prior to using the ARTEK Sport.



Unpacking the System

The ARTEK Sport system is provided with the following components. If the packaging is damaged, or any listed pieces are missing, please contact your medical equipment provider.

ARTEK Sport Device

- **Keypad:** Allows user to select therapy options and displays therapy state.
- **Hose:** Connects the device to the therapy wrap.
- **Hose Connectors:** Located at the end of the hose and used to connect the wrap to the device.
- **Lid:** Remove the lid by rotating the handle backward to put water and ice in the device.
- **Tank:** Holds water and ice – fill instructions are printed on the inside of the tank.
- **Power Input:** Located on the back of the device.

Universal Therapy Wrap Kit

- Includes 1 wrap, 4 straps, 2 connection tabs, and wrap instructions for use.
- Using the wrap instructions, apply wrap to the injured body part to deliver therapy.

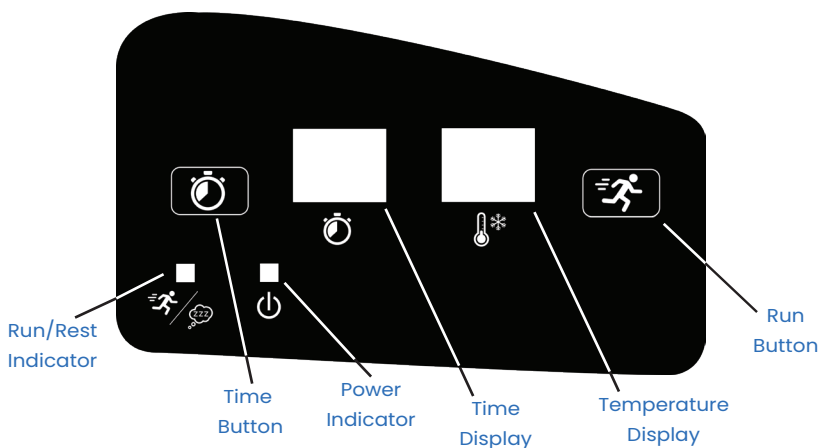
Power Cord

- Connects wall power to the device.
- Only use the manufacturer's supplied or recommended power cord with this system.

If your ARTEK Sport or any system components are damaged, do not use and contact your medical provider immediately

ARTEK Sport Keypad

The ARTEK Sport device is controlled using a simple, touchpad operation. The touchpad provides the following information and control. Refer to this section during set-up and therapy instruction.



Power Indicator: The power indicator will illuminate when the system is supplied with wall power.

Run Button: Starts and pauses therapy. Therapy will initiate from the state when last paused.

Time Button and Display: The time button changes the active therapy run time between 20 and 40 minutes. This button is disabled once a therapy session is started. The display indicates the time remaining in the current active or rest period.

Run/Rest Indicator: Indicates the current state of operation. The light illuminates when the system is in the active therapy state. During rest state, the light will blink. When system is paused, the light will de-illuminate.

Temperature Display: Displays the water temperature in the tank. It is recommended that when the system indicates the water temperature above 50F, ice should be added to ensure continued therapy delivery.

Setting up the ARTEK Sport

See our instructional videos on how to set up your ARTEK Sport



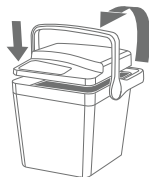
1. Remove all system components from the packaging. It is recommended to keep the packaging for one week in case the system needs to be returned. To prevent microbial growth, DO NOT store the system, or its components, in the plastic bags/packaging after using the system.

2. To set up the ARTEK Sport, remove the lid from the tank by rotating the handle toward the back of the device. The lid will lift from the tank.

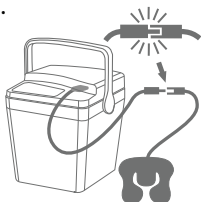
3. Fill the tank with water to the water line indicated inside the tank. Fill with ice to indicated ice line and place the lid back on the tank.



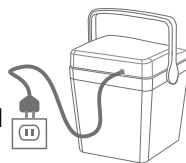
4. Secure the lid back on the tank by working the cylindrical pump down into the ice bath until the handle can be rotated back to the upright position. If this operation is difficult, remove some of the ice and repeat the process.



5. Once the lid is secured, connect the wrap to the hose. You will hear an audible click.



6. Connect the power cord into the back of the device and connect to wall power. The LEDs will illuminate and the device will beep.



7. Press the Run button on the keypad. The device will beep and the wrap will begin to fill with fluid (should take ~10 seconds).



8. Pick up the wrap by the hose and shake it to remove any major bubbles. Smaller bubbles will evacuate over time.

9. Once the wrap is full of fluid, press the Run button again to stop water flow.

The ARTEK Sport is now ready to use.

Cleaning and Maintenance

General Cleaning

The device can be wiped down with a damp rag or mild disinfecting cleaner. The wrap can be hand washed with soap and water. Dry fully before using for therapy. DO NOT use the wrap if it is wet.

To store the system

1. Unplug the power cord from the electrical outlet and disconnect from the back of the device.
2. Disconnect the wrap from the device hose.
3. Remove the lid and empty tank. Leave lid off of reservoir when storing the system.
4. The wrap cannot be drained, however the fluid will evaporate over time.
5. The system can be stored open on a shelf or in a breathable container. DO NOT store in a closed container or in a plastic bag. This may cause mold to form inside the unit.

Using the ARTEK Sport

The ARTEK Sport system delivers cold therapy in durations of 20 and 40 minutes. Refer to your physician's instructions on which therapy you should use and their instructions on the duration and frequency of use.



Apply the wrap to the site of injury. For instructions, see the instructions provide in the wrap kit or see our Universal Wrap instructional videos.

1. Disconnect and reconnect to wall power to re-set any previously set parameters.
2. Press the Time button to set the therapy time to 20 or 40 minutes, according to your prescription details. 
3. Confirm that the system temperature is below 50F when starting therapy (if not, add ice to the tank).
4. If not previously applied, use the wrap instructions and apply the wrap to the affected area.
5. Press the Run button to initiate the flow of fluid. The system will beep and the Run/Rest indicator will illuminate. 
6. The system will deliver therapy for the set therapy time. During therapy, you may notice occasional pauses in the fluid flow, followed by bursts of cool. This is normal.
7. Once the set therapy time has expired, the system will transition to a 20 minute rest period where the Run/Rest indicator will blink. The timer will display the remaining rest time.
8. Once the rest period is over, the system will automatically transition back into active therapy.
9. To pause therapy, press the Run button again. The Time Display will remain on the time at which the system was paused.
10. To resume therapy, press the Run button. The system will continue in the state and from the time at which it was previously paused.
11. To change therapy settings, disconnect and reconnect to wall power.

Attention: The rest period is important for the safety of therapy. Do not skip the rest period.

Troubleshooting



Device Set up
and Use

Need Help?

See our instructional videos
on how to set up your and
use your ARTEK Sport



Wrap
Application

The ARTEK Sport system (device and accessories) carries a 90-day manufacturer warranty. Physical damage not incurred during shipping or use of non-manufacturer provided accessories will void warranty.

If a problem with the system presents, refer to the Problem/Resolution table below. If the problem cannot be resolved as described below, contact your medical equipment provider.

Therapy skin area is discolored, tingly, numb, blistered or is otherwise physically altered.

- Terminate therapy immediately and remove the wrap.
- Contact your physician.
- Do not re-initiate therapy without first contacting your physician.

Device will not turn on.

- Check power at the wall. Try new wall connection.
- Disconnect and reconnect power cord at device power inlet.

Keypad LED's do not illuminate when device is powered or LEDs do not illuminate correctly.

- Disconnect and reconnect power to the device.
- Power LED and Time/Temperature displays will illuminate when power is supplied.
- Check power at the wall connection.

Run button does not operate.

- Check for power and keypad issues as above.
- Pressing the Run button should cause the system to beep and water to start flowing from the device to the wrap. When the system starts, the pump should initiate and emit a soft hum sound.

Time button does not function or change treatment time.

- Check for power and keypad issues as above.
- The Time button is disabled when therapy is active. Stop the active therapy and retry.

The handle will not rotate freely or lid will not close or secure.

- Check that the lid sits low enough in the ice bucket so that it can close. If needed, remove some ice, especially any large chunks.
- Be sure that the lid is on in the correct direction. The touch pad should face forward and the fill instructions should be visible on the back of the tank.
- Confirm that no cords are in the way.

Troubleshooting

Water flow to the wrap starts and stops during active cold therapy.

- These pauses in water flow during active therapy are designed to help protect your skin during active therapy.
- The water stops flowing every 5 min 1 min to give your skin mini breaks from cold therapy.
- If changes in flow create a repeated pulsing feeling near the wrap tubing, this can indicate fluid flow issues. See below for troubleshooting tips.

Water is not flowing to the wrap or the wrap does not feel cool.

- Make sure the system is full of ice and the temperature display indicates that the fluid is cold.
- When troubleshooting water flow issues, remove the wrap and place open on a flat surface. If flow issues resolve after doing this, re-apply wrap being sure the wrap is applied with no kinks or folds and the wrap is not applied too tightly.
- Disconnect/reconnect wall power. Press the run button and listen for the hum.
- With the wrap laying open, confirm water flows to the wrap. If this fixes the issue, note the following:
 - The system may have been in rest mode – during Run mode, the Run/Rest light is on. The light blinks in Rest mode and turns off when paused.
 - During Run mode, the flow will stop every 5 min for 1 min, this is normal.

My device wrap or hose is leaking.

- If the leak is coming from the wrap/hose connections, disconnect, check that the black o-rings on the wrap connectors are in place, and re-connect to the hose. Good connection will result in an audible click.
- If the leak is coming from the wrap or hose, check for damage/cuts in the material.
- Leaks from the device may come from damage to the device. Do not use the device if it is physically damaged.

Disposal Information

Do not dispose of the device or its accessories in household waste.

All therapy wraps are for single patient use only. Discard the therapy wraps per local government / city laws on acceptable method of disposal.

**For further information about your ARTEK Sport,
visit us at www.directekusa.com/artek-sport
or call us at 866.280.5844**

Technical Information

The ARTEK Sport system (device and accessories) comes with a 90-day manufacturer’s warranty.

1.1 Safety Signed Marked on the Equipment

PN: 0P2BATSPTRL_B



ThermoTek, Inc.
1200 Lakeside Parkway, #200
Flower Mound, Texas 75028
Tel: 866-280-5844

 **ARTEK SPORT™** 

Conf. to IEC60601-1:2012
Cert. to CAN/CSA-22.2 No. 60601-1
No User Serviceable Parts
Made in China

Rx ONLY





12 VDC, 1.0A

For Assistance, Please Visit www.directekusa.com

1.2 Technical Specifications

ARTEK Sport Part Number	0V9PTSPRT01UNV01
Operating Environment	41F - 80F [5C - 27C]
Relative Humidity	30% to 60%, Non-Condensing
Operating Altitude	< 2000 meters
Thermal Therapy Temperature Range	41F - 80F [5C - 27C] 41F - 80F [5C - 27C]
Dimensions	10"H x 8.5"D x 8"W [254mmH x 215mmD x 203mmH]
Weight	4 lbs [1.81 kg]
Circulatory Pump	12 VDC
Reservoir Fluid Capacity	144.0 fl oz [4.2L]
Temperature Accuracy	+/- 3.6F [+/- 2C]
Input Voltage	12 VDC [Only use the power adaptor provided]
Input Current (Max)	1.0A
Recommended Coolant	100% water and ice
Transport & Storage Environment	-13F - 158F [-25C - 70C] 10% - 90%, Non-Condensing

1.3 Classification Information

US FDA Medical Device	21 CFR 878.4360
Protection Against Electric Shock Hazard	Class II per UL/EN/IEC 60601-1
Applied Protection Against Fluid Ingress	IP21
Applied Part	Type BF

1.4 Conformance Information

Quality Assurance	FDA 21 CFR 820 QSR, ISO 13485
Safety	IEC 60601-1, IEC 60601-1-11
Electromagnetic Compatibility (EMC)	IEC 60601-1-2

1.5 Guidance and Manufacture Declaration – Electromagenic Emissions

Emission Test	Compliance	Electromagnetic Environment – Guidance
Radiated Emissions EN 55011	Complies to Group 1, Class B	The equipment uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause interference to nearby electronic equipment.
Conducted Emissions EN 55011	Complies to Group 1, Class B	
Harmonics Emission EN 61000-3-2	Complies	
Voltage fluctuations / flicker emissions EN 61000-3-3	Complies	The equipment is suitable for use in all hospitals, health service clinics and homes connected to the public low voltage power adapter network that supplies buildings used for domestic purposes.

1.6 Guidance and Manufacture Declaration – Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	IEC 60601 Test Level	Electromagnetic Environment – Guidance
Electrostatic Discharge EN 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 in synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient / Burst EN 61000-4-4	+/- 2 kV for power supply lines +/- 2 kV for power supply lines	+/- 2 kV for power supply lines +/- 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge EN 6100-4-5	+/- 1 kV line to line +/- 2 kV line to earth	+/- 1 kV line to line +/- 2 kV line to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power adapter lines EN 61000-4-11 (per EN 60601-1-2, 4 th ed)	< 5% UT, (95% dip in UT) for 0.5 cycle 40% UT, (60% dip in UT) for 5 cycles 70% UT, (30% dip in UT) for 25 cycles < 5% UT, (95% dip in UT) for 5 sec	< 5% UT, (95% dip in UT) for 0.5 cycle 40% UT, (60% dip in UT) for 5 cycles 70% UT, (30% dip in UT) for 25 cycles < 5% UT, (95% dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) Magnetic field EN 61000-4-8	30 A/m (60 Hz)	30 A/m (60 Hz)	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF EN 61000-4-6 Radiated RF EN 61000-4-3	3Vrms 0.15 MHz to 80 MHz 3V/m 80 MHz – 27 GHz	3Vrms 0.15 MHz to 80 MHz 3V/m 80 MHz – 27 GHz	Portable and mobile RF communications equipment should be used no closer to any part of the equipment, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Technical Information

1.7 EMC Notice

This equipment generates, uses, and can radiate radio frequency energy. If not installed and used in accordance with the instructions in this manual, electromagnetic interference may result. The equipment has been designed to provide reasonable protection against electromagnetic interference when operated in the intended use environments described in this manual.

1.8 Electromagnetic Interference

This device has been tested and found to comply with the limits for Medical Devices according to IEC60601-1-2. These limits are designed to provide reasonable protection against harmful interference in typical medical installations. This equipment generates and radiates radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. There is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment on and off, the user can try to correct the interference by one or more of the following measures:

- Re-orient or relocate the receiving device.
- Increase the physical separation between the equipment and other device(s).
- Connect the equipment into an outlet, or circuit, different from the one where the other device(s) are connected.

1.9 MRI Notice

This equipment contains electronic and ferrous components, whose operation can be affected by intense electromagnetic fields. Do not operate the system in an MRI environment or in the vicinity of high-frequency surgical diathermy equipment, defibrillators, or shortwave therapy equipment. Electromagnetic interference could disrupt the operation of the device.

1.10 Calibration

This equipment is comprised of components that are of high accuracy and low drift. Under normal operation, during its useful life, the therapy unit does not require calibration.

Symbols



Risk of cold injury



Serial Number



Refer to the instruction/user manual



Batch Code

Rx ONLY

Prescription Device



Direct current
Polarity of d.c. power connector.



Do not reuse



Caution



Catalogue number



Keep Dry



DO NOT use near explosives or an open flame. Do not smoke around device.



Product compliance with North American safety standards.

IP21

Protected against solid objects over 12.5mm (e.g., a finger) and protected against vertically falling drops of water or condensation



Non-sterile



Manufacturer



Type BF applied part.



Keep away from sunlight.



Class II



Temperature limit / Humidity limit



Not for general waste.

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