Rx ONLY

Models: KLV10002

KLV10003

kelvi PRO^{e}

User Manual

Kelvi Pro^{e} Console

Table of Contents

This manual may be updated periodically. The most current manual can be found at kelvi.com

Introduction 1

Indications for Use

The Kelvi Pro™ System provides cryotherapy (cold), thermotherapy (heat), and contrast therapies to treat post surgical and acute injuries for which cold or heat therapies are indicated. It is also intended to treat conditions for which localized thermal therapy (heat, cold, or contrast) is indicated. It is to be used by, or on the order of, licensed or certified healthcare professionals in rehabilitation facilities, outpatient clinics, athletic training settings, and at home.

Clinical Effects

Contrast therapy is the repetitive alternating application of cold (cryotherapy) and heat (thermotherapy). Cryotherapy has been shown to decrease skin, subcutaneous, and muscle temperature leading to vasoconstriction of the blood vessels and a decrease in swelling and inflammation through the slowing of metabolite production. Thermotherapy has been shown to increase tissue temperature, metabolite production and muscle elasticity, stimulate local blood flow and reduce muscle spasms.*

Contact

Kelvi
Hypothermia Devices Inc.
413 N Oak St
Inglewood, CA 90302, USA

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(310) 492-5886
info@kelvi.com

For assistance in using the Kelvi Pro™ System, contact your licensed or certified healthcare professional.

*References available upon request.

Safety 2

IMPORTANT: Read complete instructions including indications, contraindications, cautions, and warnings before using this product.

The Kelvi Pro™ System should only be used under the care and/or direction of a licensed or certified healthcare professional. During the course of Kelvi Pro™ System treatment, the skin surrounding the treated region or the digits of the extremities of the treated limb should be monitored for uncomfortable burning or itching sensations, increased swelling, or pain. For longer treatments, Smart Wrap™ should be removed every 90 minutes or less to inspect the skin. If any of these signs are present, or any changes in skin appearance occur (such as blisters, increased redness, discoloration, or other noticeable skin changes), immediately discontinue use and consult a physician. Follow the treatment recommendations of your health care practitioner for duration and frequency of use for this device.

Contraindications

The Kelvi Pro™ System should be used only under the direct supervision of a licensed or certified healthcare practitioner in patients who:

- Experience or have been diagnosed with hypertension or extreme low blood pressure.
- Experience or have been diagnosed with rheumatoid arthritis in or around the treatment area.
- Experience or have been diagnosed with known and uncontrolled peptic ulcer (if the affected region is the abdominal region).
- Have been diagnosed with type I or type II diabetes.
- Have compromised local circulation or neurological impairment (including paralysis or localized compromise due to multiple surgical procedures) in or around the treatment area.
- Have been diagnosed with a localized unstable skin condition (e.g., dermatitis, vein ligation, gangrene, or recent skin graft) in the affected region.
- Have recently had surgery in or around the treatment area.
- Are under 18 years old.

The Kelvi Pro™ System should NOT be used in patients who:

- Experience or have been diagnosed with any vascular impairment in or around the treatment region. This includes, but is not limited to, tissue that has experienced frostbite, arteriosclerosis, type II diabetes, or ischemic tissue of any type or cause.
- Have current clinical indications of deep vein thrombosis and/or significant peripheral edema in or around the treatment region.
- Have areas of skin deterioration or damage that may produce uneven heat conduction across the skin.
- Have impaired sensitivity to pain or temperature.
- Have cognitive or communicative impairments that prevent them from giving accurate and/ or timely feedback.
- Have poor circulation, or over sensitive skin areas.

The cryotherapy (cold) and contrast settings should NOT be used in patients who:

- Experience or have been diagnosed with hematological dyscrasias which affect or modify thrombogenic processes. This includes, but is not limited to, sickle-cell disease, paroxysmal cold hemoglobinuria, serum cold agglutinins, and cryoglobulinemia.
- Have current clinical indications of cellulitis, inflammatory phlebitis, or venous ulcers.
- Have current clinical indications or any risk factors suggestive of embolism. This includes, but is not limited to, pulmonary embolism, cerebral infarction, atrial fibrillation, endocarditis, myocardial infarction, and atheroma.
- Have any condition in which modified venous or lymphatic return may have adverse effect in or around the treated extremity. This includes, but is not limited to, carcinoma.
- Experience or have been diagnosed with Raynaud's disease or cold hypersensitivity (cold urticaria).
- Have been diagnosed with decompensated hypertonia in or around the treatment area.

The thermotherapy (hot) and contrast settings should NOT be used in patients who:

- Have inflamed tissue as a result of recent injury or exacerbation of chronic inflammatory condition.
- Have an acute, untreated fracture in the treatment region.
- Have local malignancy.
- Have actively bleeding tissue or hemorrhagic conditions.
- Have recently radiated tissue or areas affected by heat-sensitive skin diseases (e.g., eczema, psoriasis, vasculitis, dermatitis).
- Have any active local or systemic infection.
- Are pregnant.

The air pressure settings should NOT be used in patients who:

- Have hypertension, extreme low blood pressure, cardiac failure, or decompensated cardiac insufficiency.
- Have any active local or systemic infection.
- Have current clinical indications of cellulitis, inflammatory phlebitis, deep vein thrombosis, or venous ulcers.
- Have current clinical indications or any risk factors suggestive of embolism. This includes, but is not limited to, pulmonary embolus, cerebral infarction, atrial fibrillation, endocarditis, myocardial infarction, and atheroma.
- Have any condition in which modified venous or lymphatic return may have an adverse effect in or around the treated extremity. This includes, but is not limited to, carcinoma.
- Have diabetes mellitus, multiple sclerosis, rheumatoid arthritis, poor circulation, or spinal cord injuries.

Cautions

- Do not attempt to operate the Kelvi Pro™ System if there is any mechanical damage to the Console, cord, or accessories.
- Be careful not to trip over power cord or Umbilical. Always position the device such that the power cord or Umbilical cannot pose a hazard to you or others in the surrounding area.
- Never wrap any Umbilical or power cord around anyone's body, as this may pose a risk of strangulation. Keep power cord and Umbilical out of the reach of children.
- During use, always place Kelvi Pro^{e} Console such that the device is quickly and easily accessible to the user. In the event of an emergency, it may be necessary to disconnect the power cord from the Console or wall outlet to terminate functions of the System.
- Smart Wraps™ are designed for use on unbroken skin for time periods set by your healthcare practitioner. If the skin is broken or appears otherwise damaged, contact your healthcare practitioner before use. Your healthcare practitioner may determine that your Smart Wrap™ may be used with a layer of gauze or insulation between the skin and Smart Wrap™.
- The Kelvi Pro™ System should not be used in or near pooled bodies of liquid such as swimming pools or bathtubs. Do not spill liquids on the Kelvi Pro™ System or accessories.
- The Kelvi Pro™ System is not to be disassembled or serviced by the user, except as expressly directed in this manual. If service or repairs are needed, contact Kelvi™ support.
- When using a Smart Wrap™, the KelviTEC™ Insert should not be removed from its Sleeve. Do not use the KelviTEC™ Insert directly against the skin under any circumstances. If the Sleeve becomes torn or damaged, replacement Sleeves are available.
- Do not puncture or otherwise damage Smart Wraps™. Damage may cause the system to operate incorrectly. If a Smart Wrap™ begins leaking water for any reason, discontinue use of that Smart Wrap™ and contact Kelvi™ support.
- Do not step on, stack, or compress the Smart Wrap™. Doing so may damage the Smart Wrap™ and may cause system to operate incorrectly.
- The Kelvi Pro^{e} Console is designed to be carried by its handle or transported using a Kelvi™ carry case. Do not use the Smart Wrap™ or Umbilical to carry or transport the Console.
- Do not apply undue force when connecting the Smart Wrap™ to the Kelvi Pro^{e} Console.
- The Kelvi Pro^{e} Console should be handled with care. Damage sustained by inappropriate handling or impact may result in reduced Kelvi Pro™ System performance and will void all Kelvi™ warranties.
- Smart Wraps™ are meant to be used by one stationary person at a time. Do not transport the device or move the Kelvi Pro^{e} Console while the device is attached to the body. The Kelvi Pro^{e} Console and Smart Wraps™ contain hard components which can cause injury upon bodily impact.
- Keep the Kelvi Pro™ System out of reach of small children or pets.
- Operating the Kelvi Pro^{e} Console while connected to a Wi-Fi network that includes other electronic medical equipment or to a cellular network in the presence of other electronic medical equipment may result in previously unidentified risks to patients, operators, or third parties. These risks should be evaluated by the operator or responsible organization before use. Changes to the IT network during or after usage may introduce additional risks. Examples of changes to the IT network include changes in network configuration, update or upgrade of equipment, connection or removal of other items on the network.
- The use of a mobile device connected to an unsecured network is a security vulnerability and can result in a breach of Personal Health Information (PHI).
- The Kelvi Pro™ System should only be used under the care and/or direction of a licensed or certified healthcare professional.
- In addition to the precautions listed above, additional warnings and safety precautions are posted throughout this manual. Read and carefully follow these instructions prior to operating the Kelvi Pro™ System.

WARNING: If at any time the user experiences discomfort or the skin around the treated are feels burning or itching sensations, immediately remove the Smart Wrap™ from the body or disconnect it from the Console.

Warnings

- Smart Wraps™ are not sterile; do not place directly against open wounds, sores, rashes, infections, or stitches. The Kelvi Pro™ System is not intended for use in a sterile environment.
- Smart Wraps™ are rated for sufficient biocompatibility with healthy human skin. If the patient develops any signs of allergic reaction during normal use, discontinue use of the device immediately. Consult the Care and Storage section of this manual and ensure that the device has been properly cleaned and maintained. Replace the Smart Wrap™ Sleeve as necessary.
- During the course of Kelvi Pro™ System treatment, the skin surrounding the treated region or the digits of the extremities of the treated limb should be monitored for uncomfortable burning or itching sensations, increased swelling or pain. For longer treatments, the Smart Wrap™ should be removed every 90 minutes or less to inspect the skin. If any of these, or other signs, are or become present, or any changes in skin appearance occur (such as blisters, increased redness, discoloration, or other noticeable skin changes), immediately discontinue use of the device and consult a physician.
- Each Smart Wrap™ is designed to fit the unique contours of specific anatomical regions. Only use the Kelvi Pro™ System on the area indicated for each Smart Wrap™ (i.e. the Knee Pro should only be used on the left or right knee). Do not use the Kelvi Pro™ System outside of these anatomical guidelines.
- Do not use the Kelvi Pro™ System in conjunction with any treatment outside of the intended use.
- To avoid electrical shock or risk thereof, do not remove any panels from the device or otherwise open the device except as directed in this manual.
- Do not use any power cord other than those provided directly by Kelvi™. Use of any other power cords presents the risk of electrical shock and will void the Kelvi™ warranty.
- Do not use the Kelvi Pro™ System with any components or accessories other than those described in this manual. The Kelvi Pro™ System is not compatible with accessories from any other manufacturer.
- If damage occurs resulting in small parts or components becoming dislodged from the device or accessories, these parts may pose a risk of inhalation or swallowing. If damage occurs, discontinue use of the device and contact a Kelvi™ representative.
- Rough handling or transport conditions may result in loosened connections which can impair or degrade system performance. In the event of any unexpected or irregular performance, discontinue use of the device immediately and contact Kelvi™ support for further guidance.
- No modifications to this equipment may be made. Modifications without the authorization of the manufacturer may result in unsafe usage conditions and will void the product warranty.

WARNING: This product can expose you to chemicals including Antimony oxide, phthalates, Lead, Cobalt oxide, or Nickel (Metallic) which are known to the State of California to cause cancer or birth defects or other reproductive harm. For more information, visit www.P65Warnings.ca.gov.

Using the Kelvi Pro™ System

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The Kelvi Pro™ System is made up of a Kelvi Proᵉ Console and a Kelvi Smart Wrap™.
Both parts are required to perform a treatment

Console

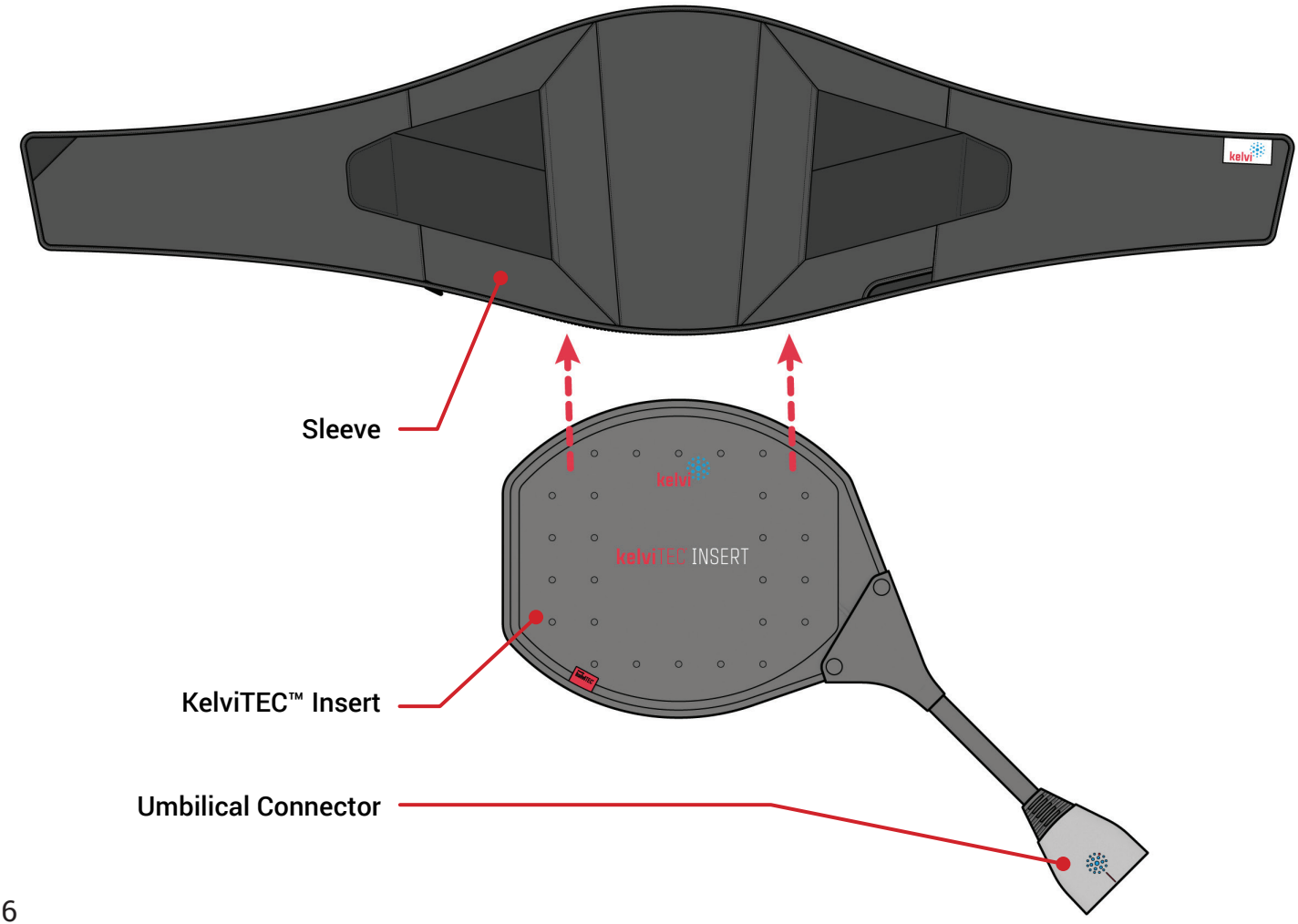
A Kelvi Proᵉ Console includes the following:

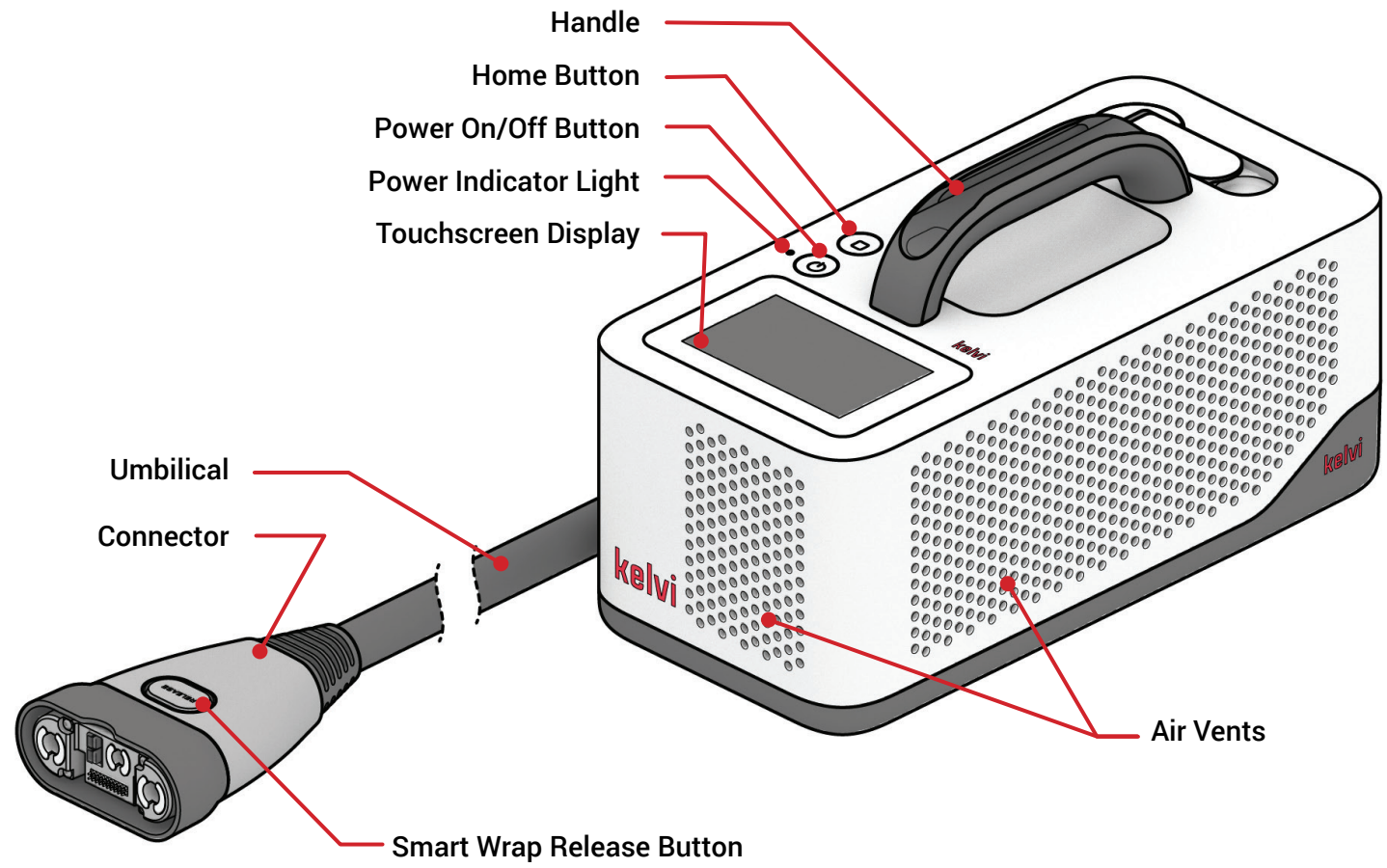
- Power Supply
- User Manual
- Copper Sulfate Solution

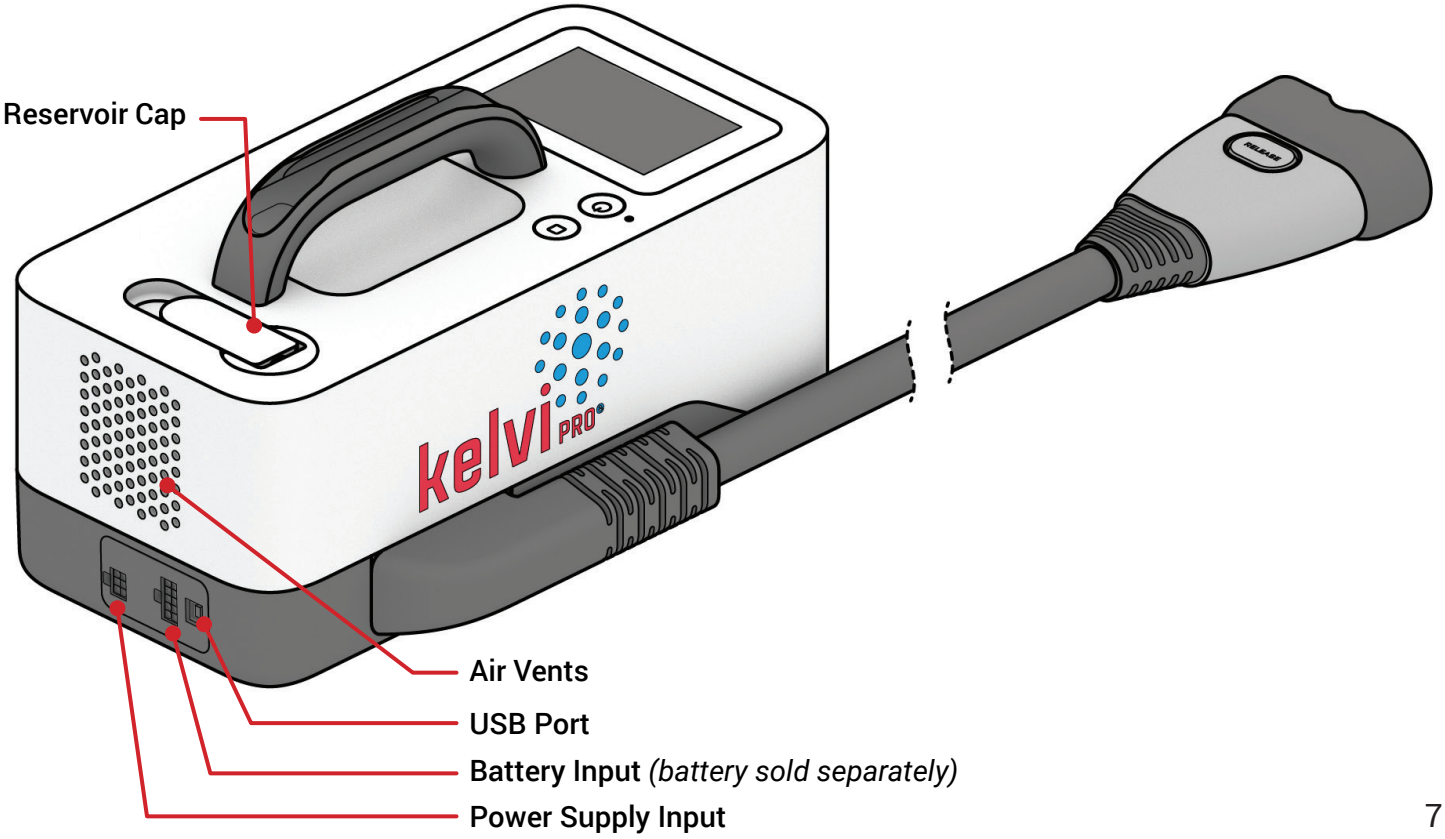
Smart Wrap™

A Kelvi Smart Wrap™ (sold separately) includes the following:

- KelviTEC™ Insert
- Sleeve

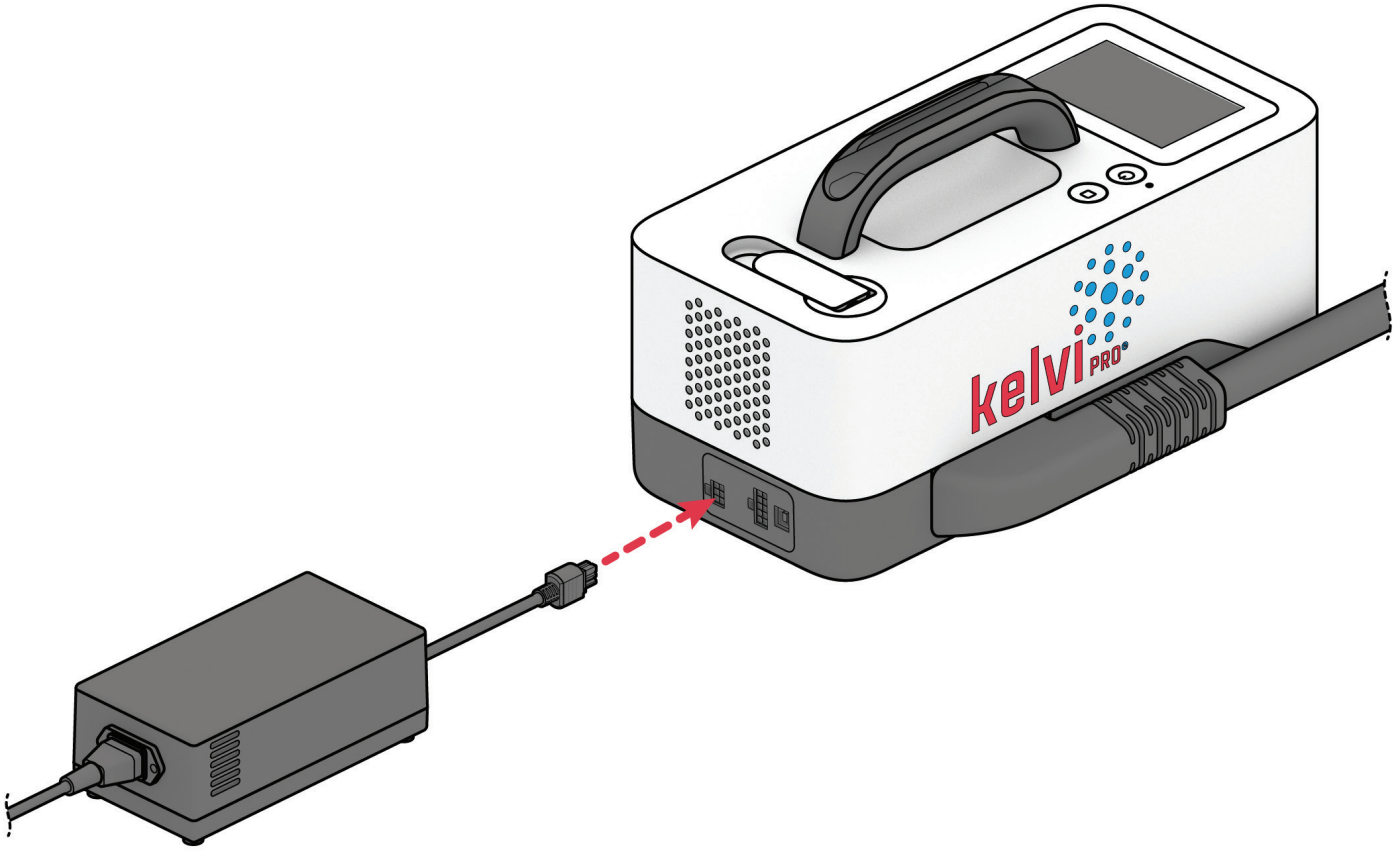



Handle
Home Button
Power On/Off Button
Power Indicator Light
Touchscreen Display
Umbilical
Connector
Smart Wrap Release Button
Air Vents
kelvi


Reservoir Cap
Air Vents
USB Port
Battery Input (battery sold separately)
Power Supply Input
kelvi PRO

Setting Up

1. Remove the Kelvi Pro^{e} Console from its packaging by lifting it from the handle.
2. Place the Console on a flat dry surface to prepare for treatment.
3. Attach the included power supply to the port on the back of the Console.
4. Connect the power supply to an appropriate power outlet.
5. Place the power supply in a safe location to avoid tripping hazard.
6. Press the On/Off button on the top of the Console to turn on the device. The power light will turn on to indicate that the system is starting up.
7. The Console will take up to 60 seconds to start up, during which time the Kelvi™ logo will appear on the screen.

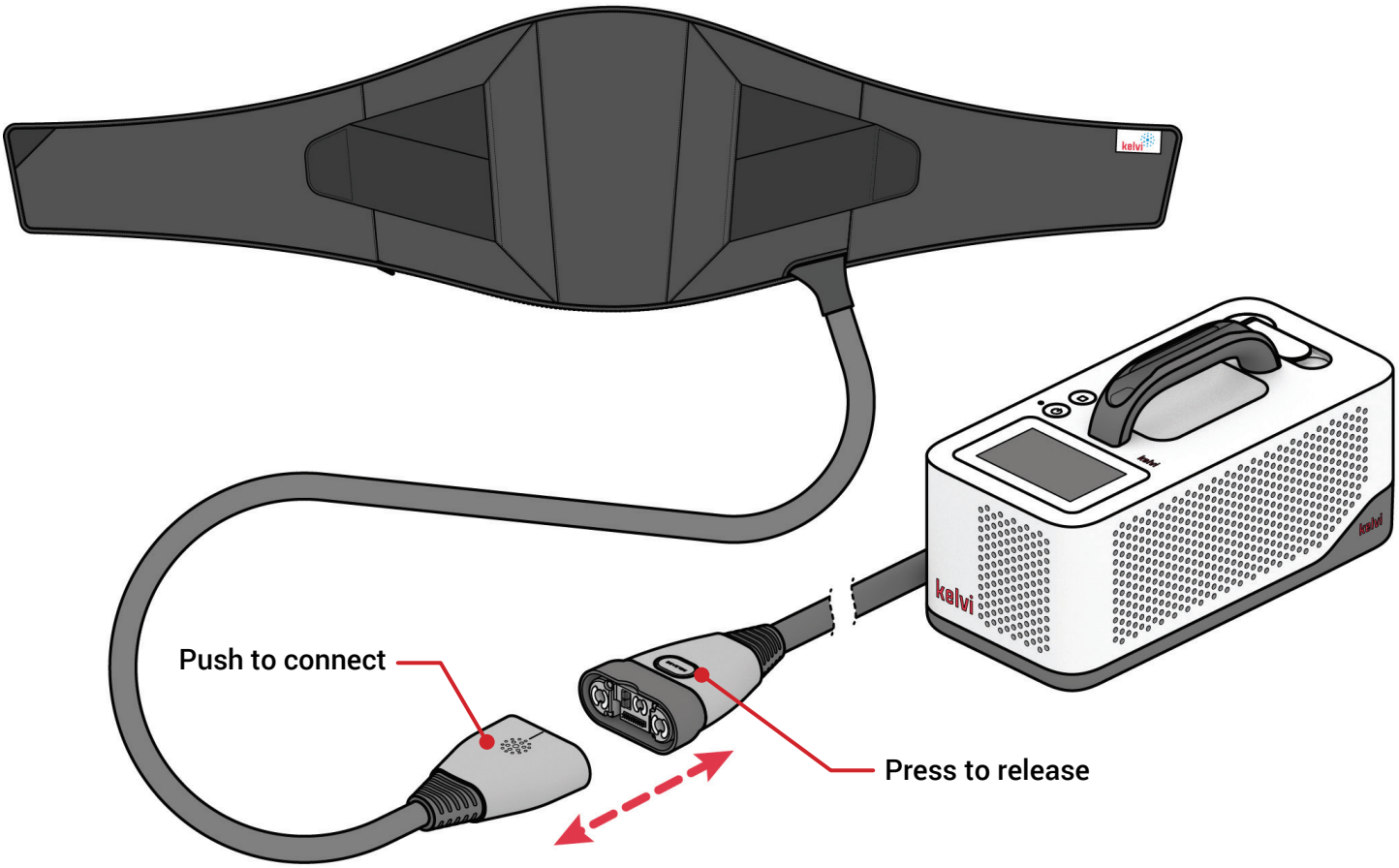


Connect power supply to Console

Connecting a Smart Wrap ™

1. To connect a Smart Wrap™, insert the Smart Wrap™ connector into the Umbilical connector. An audible click will occur when the connectors engage.
2. To disconnect a Smart Wrap™, press the Release button on the Umbilical connector and pull the connectors apart.

It is normal for a few drops of water to drip from the fittings when disconnecting. Facing the connectors down helps direct the water away from pooling in the connectors. Remove any remaining drops of water in the connector by shaking lightly.

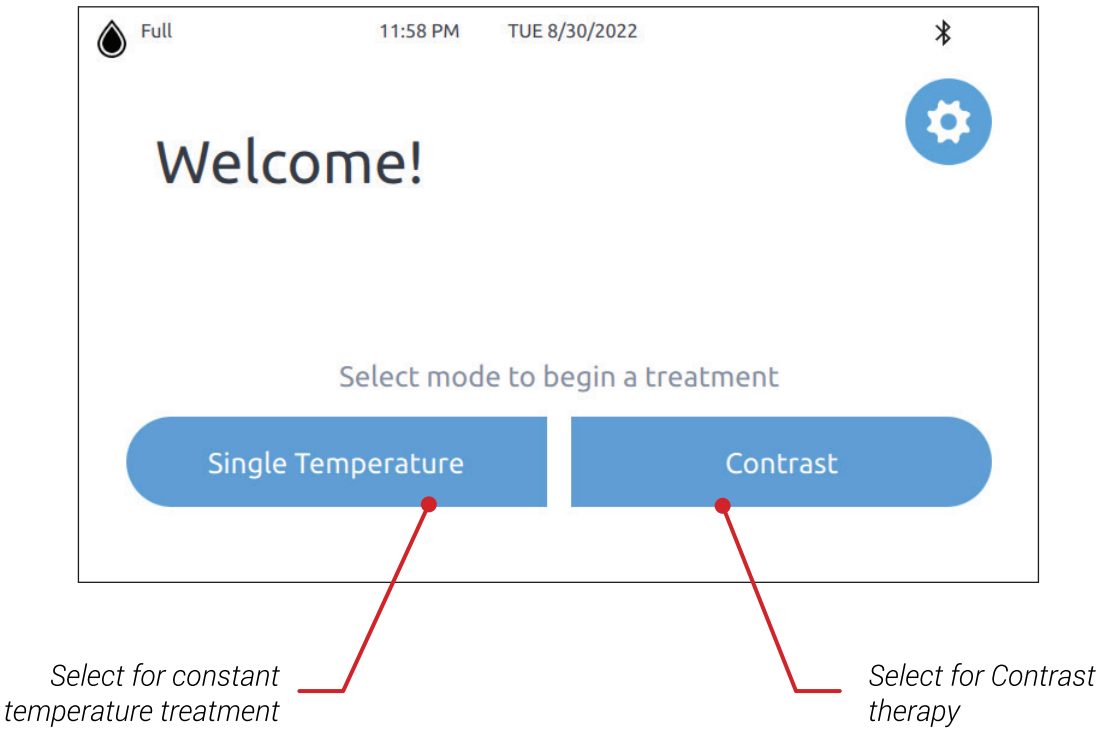


Connect Smart Wrap™ to Console

Starting a Treatment

Before running a treatment, make sure the Console is powered on and the Smart Wrap™ is connected.

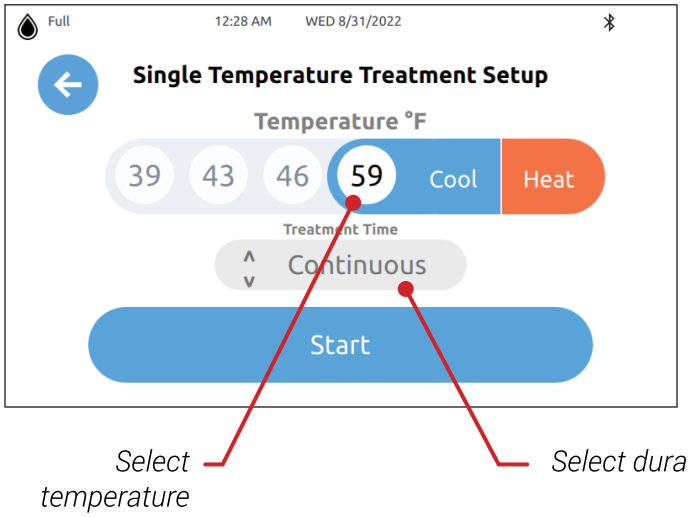
1. Power on the Kelvi Pro[e] Console. When the Welcome screen is visible, place the connected Smart Wrap™ on the patient. For instructions on fitting and adjusting the Smart Wrap™, consult the User Guide provided with each Smart Wrap™.
2. Select **Single Temperature** for continuous cooling or heating at a single temperature for a set treatment time.
3. Select **Contrast** for alternating hot and cold therapies at preset temperatures for a selected number of treatment cycles.
4. For additional treatment programming options, download the Kelvi™ Mobile App on your iOS or Android mobile device.



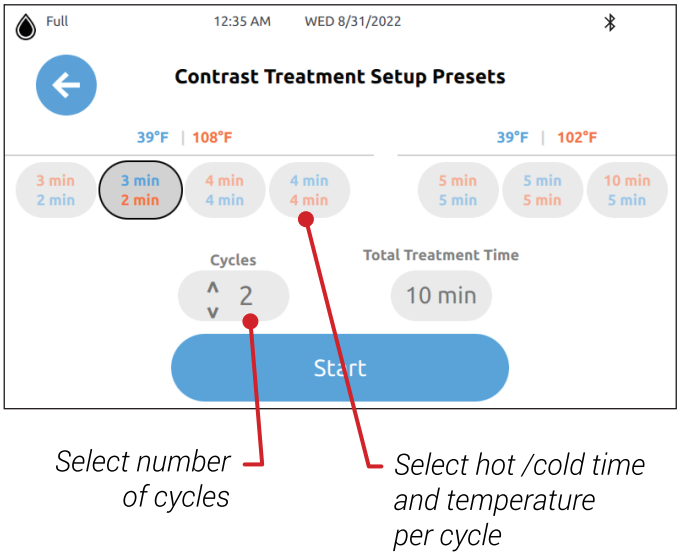
Understanding Temperature Settings

The Kelvi Pro™ System measures an average of multiple temperature sensors in each Smart Wrap™. For the most accurate and beneficial treatment, maintain direct and complete contact between the Smart Wrap™ and the user's skin. Clothing can be worn, but will adversely affect accuracy of treatment. Please see **Safety** for situations where wraps should not be placed directly on skin.

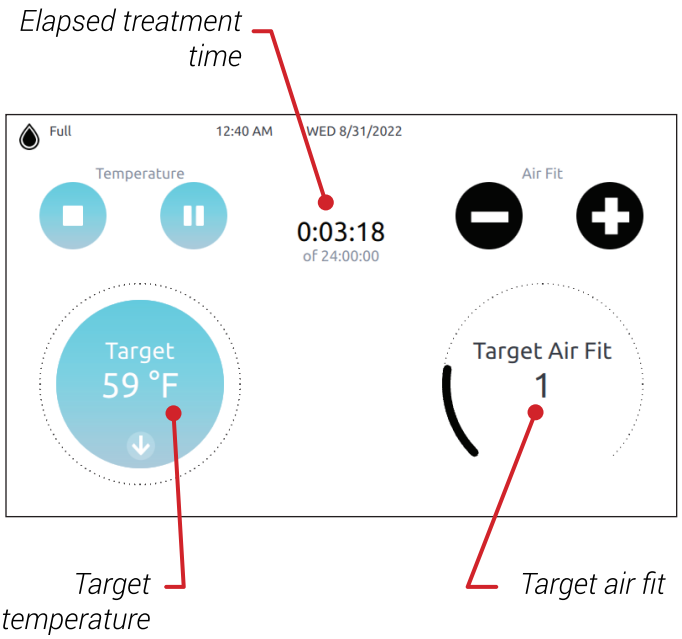
Single Temperature Setup



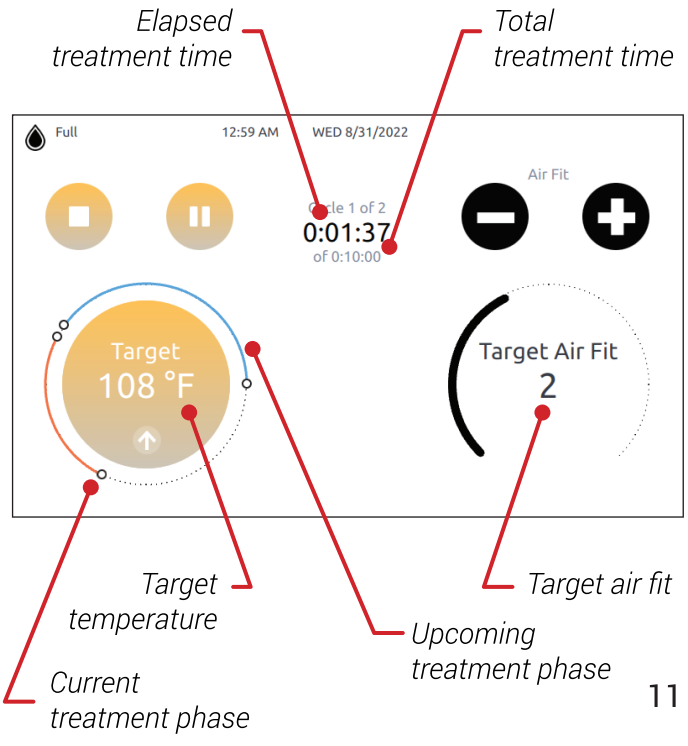
Contrast Therapy Setup



Single Temperature Treatment Screen



Contrast Treatment Screen



Single Temperature Treatment

1. Select your type of treatment by choosing **Cool** or **Heat**.
2. Choose the target temperature by selecting the desired value.
3. Select the treatment time:
   a. Continuous treatment will run up to 24 hours or until stopped by the user.
   b. Up and down arrows can be used to specify a duration. Treatment will stop automatically after this time.
4. Select **Start** to begin treatment.
5. The treatment screen will display the current status of treatment.
6. To pause the treatment at any time, press the **Pause** button on the screen. Press the **Resume** button on the screen to continue treatment.
7. To end the treatment, perform any of the following actions:
   a. Press the **Stop** button on the screen. You will be asked to confirm before ending the treatment.
   b. Press the **Home** button on the top of the Console.
   c. Disconnect the Smart Wrap™ from the Umbilical.
8. Remove the Smart Wrap™ from the patient as indicated in Smart Wrap™ User Guide.

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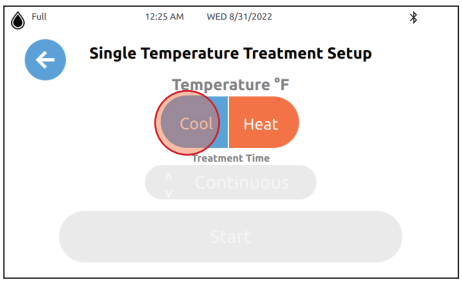

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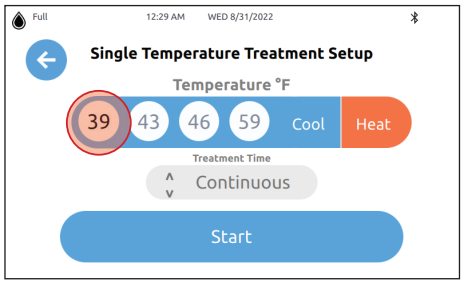

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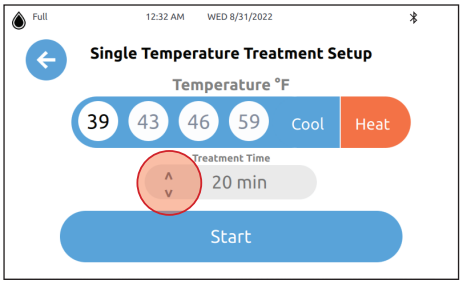

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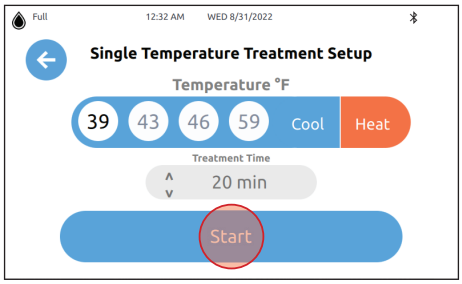

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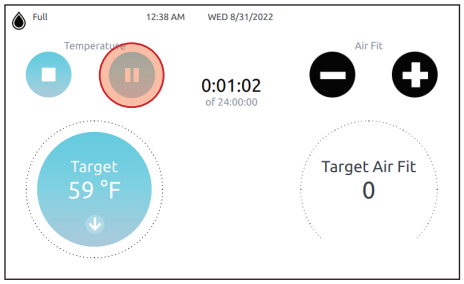

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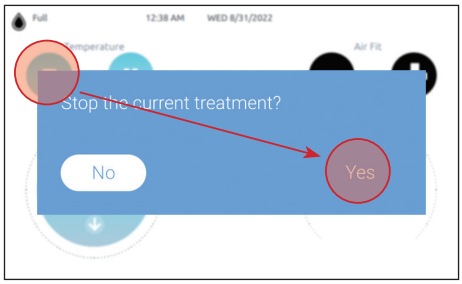

Contrast Therapy Treatment

1. Select your treatment parameters from the available options.
   a. Orange color indicates Hot phase, blue color indicates Cold phase.
   b. Treatment phases will occur in the order they appear.
2. Choose the number of treatment cycles. The total treatment time will be displayed automatically.
3. Select **Start** to begin treatment.
4. The treatment screen will display the current status of treatment.
5. To pause the treatment at any time, press the **Pause** button on the screen. Press the **Resume** button on the screen to continue treatment.
6. To end the treatment, perform any of the following actions:
   a. Press the **Stop** button on the screen. You will be asked to confirm before ending the treatment.
   b. Press the **Home** button on the top of the Console.
   c. Disconnect the Smart Wrap™ from the Umbilical.
7. Remove the Smart Wrap™ from the patient as indicated in Smart Wrap™ User Guide.

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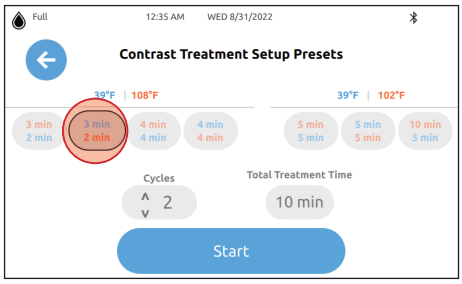

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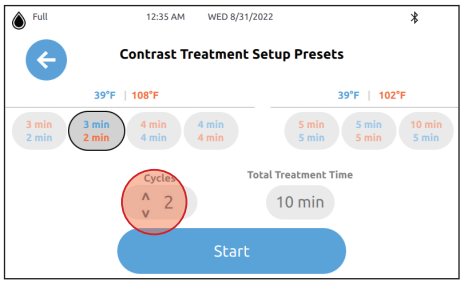

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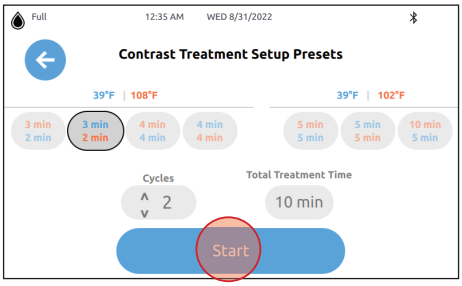

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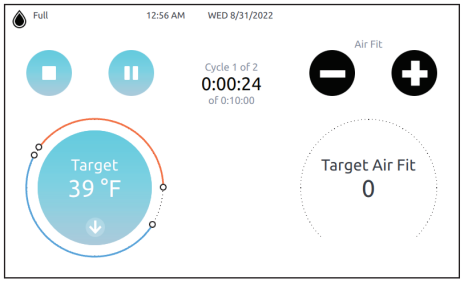

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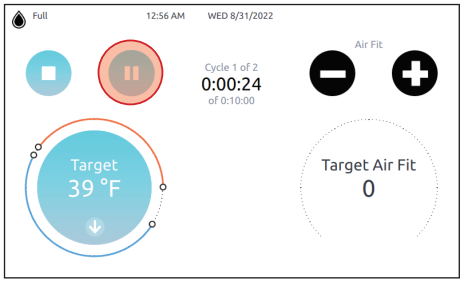

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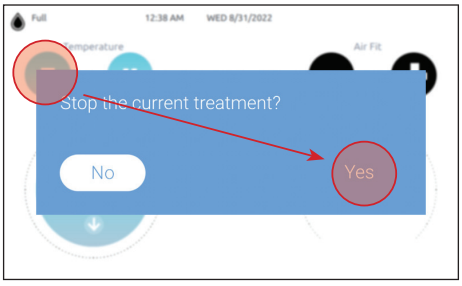
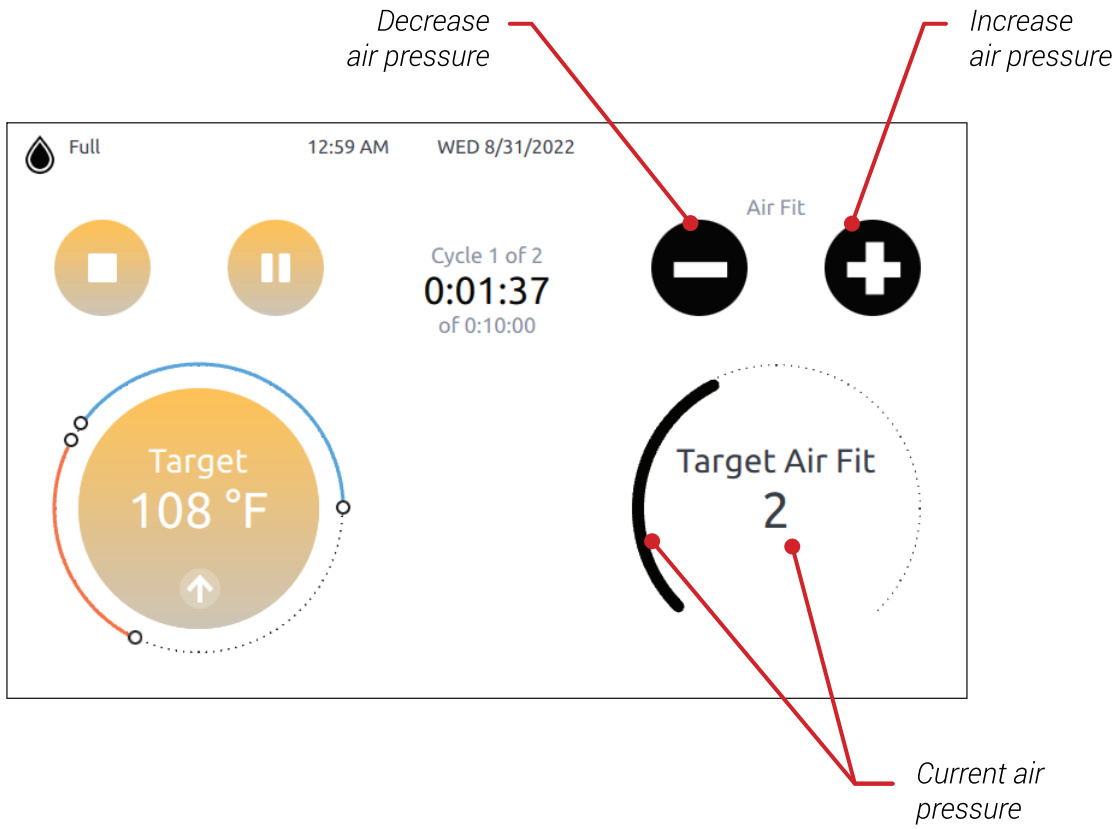


Adjusting Fit

The Kelvi Pro™ System allows you to apply air pressure to adjust the Smart Wrap™ fit, ensuring optimal comfort and skin contact for effective treatment. Air pressure can be adjusted at any time during a treatment.

1. To increase air pressure, press the **+** button on the screen.
2. To decrease air pressure, press the **–** button on the screen.
3. At the end of treatment, release all air pressure from the Smart Wrap™. Air pressure will drop automatically when the Smart Wrap™ is disconnected.



WARNING: Do not increase the air pressure to the point that blood flow stops, pain is experienced, or the surrounding area becomes discolored.

WARNING: Release air pressure after every use by decreasing the pressure using the onscreen controls or by disconnecting the Smart Wrap.™

Ending a Treatment

A treatment in progress can be ended at any time by pressing the **Home** button on the top of the Console, selecting the **Stop** button on the touchscreen, or through the Mobile App (if connected). When a treatment stops, the Smart Wrap™ will return to ambient temperature. Disconnect the Smart Wrap™ and remove it from the body.

If you are finished using the Kelvi Pro™ System, power off the Console by pressing and holding the Power On/Off button on the top of the Console. When the system has powered down, it is safe to disconnect the power supply.

See **Care and Storage** for further instructions on maintaining and storing your Kelvi Pro™ System.

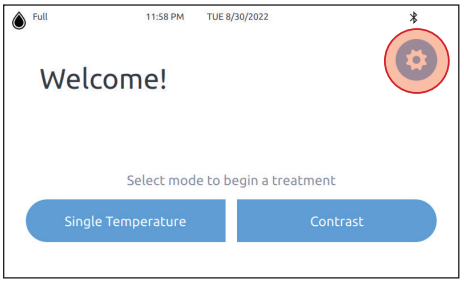
> **IMPORTANT:** The Home button on the top of the Console may be pressed at any time to stop treatment. The Smart Wrap™ may also be removed from the user or disconnected from the Console at any time.

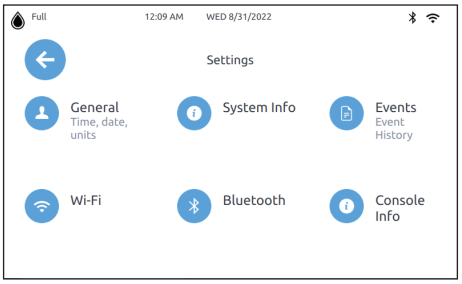
Configuring System Settings

The Kelvi Pro[e] Console allows you to change settings through the System Settings screen. On the Welcome screen, select the gear icon to access System Settings. Settings include the following:

1. General
   a. Adjust the date and time settings
   b. Select the default temperature display °C or °F
2. System Info
   a. Display system information
   b. Update system software (requires an internet connection)
3. Wi-Fi
   a. Enable or disable Wi-Fi connection
   b. Select the desired Wi-Fi network and enter the security credentials
4. Bluetooth
   a. Enable or disable Bluetooth connection
   b. Change the Console name

> **IMPORTANT:** Kelvi™ will periodically provide system updates for the Kelvi Pro[e]. It is recommended that the user connect the Console to Wi-Fi and check for updates regularly. Keeping system software up to date can help improve performance and prevent errors.





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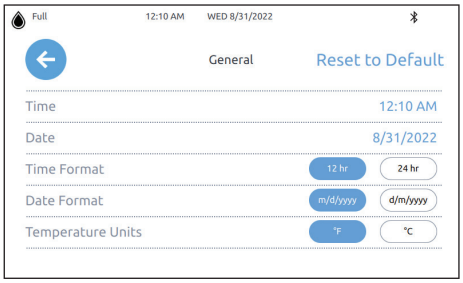

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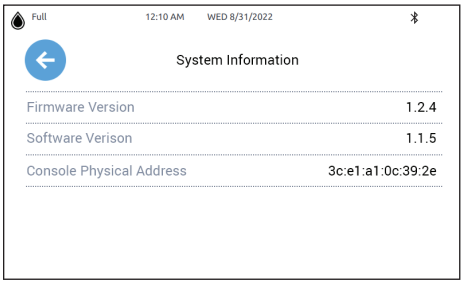

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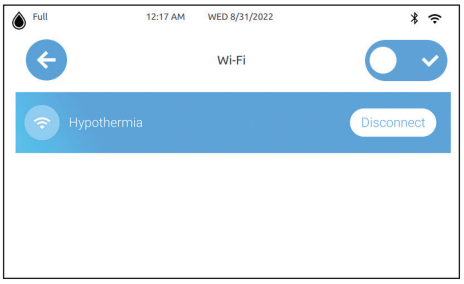

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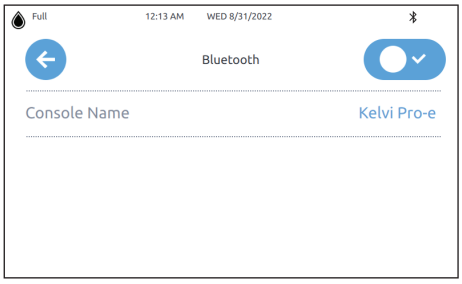
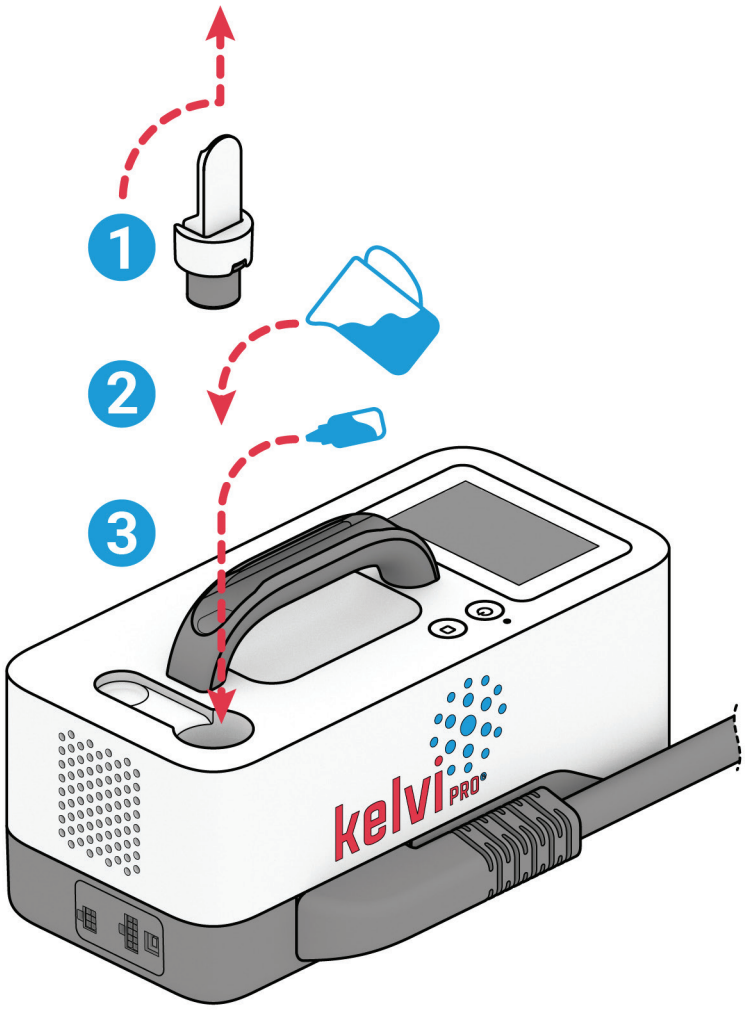


Refilling the Reservoir

The Kelvi Pro™ System uses flowing water to cool the electronic systems that provide cryotherapy for increased performance. The Kelvi Pro^{e} Console comes pre-filled with distilled water but may occasionally need to be refilled. If the water level is too low, treatment will stop and a notice will be displayed on the device. Refill the reservoir with the following steps:

1. Open the reservoir cap by lifting up on the lever and pulling straight up to remove it.
2. Pour distilled water into the reservoir until water is visible inside the mesh filter or until the Fill Reservoir screen on the device reads “Full.” Take care not to overfill the reservoir. If the reservoir is overfilled, water will drain out through the overflow drain located on the bottom of the Console.
3. Add 1-2 drops of Copper Sulfate Solution to the reservoir. This solution prevents bacterial growth in the water supply.
4. Replace the reservoir cap and lower the lever to seal it. The Kelvi Pro^{e} Console may not operate properly if the reservoir cap is not installed correctly.



IMPORTANT: Use distilled water only. Do not use deionized water or tap water. Failure to use distilled water may void the warranty.

IMPORTANT: Add 1-2 drops of Copper Sulfate Solution every time the reservoir is refilled. Failure to add Copper Sulfate Solution may void the warranty.

WARNING: Do not drink or ingest the water from the system.

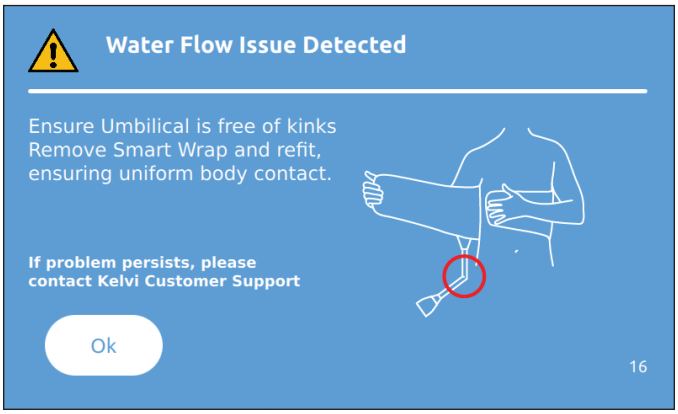
Troubleshooting 4

In the event that the Kelvi Pro™ System exhibits any irregular or unexpected performance, discontinue use of the Kelvi Pro™System immediately and contact Kelvi™ Support for additional guidance. At any time, the device can be deactivated by disconnecting the power cord from the wall outlet, or by removing power cord from the Console's power inlet. The Smart Wrap™ may also be removed from the user's body or disconnected from the Console at any time to end treatment.

Maintaining Water Flow

The Kelvi Pro™ System uses flowing water to cool the electronic systems that provide cryotherapy. An obstruction in the system can restrict water flow and cause a drop in performance. Obstructions are often the result of a kink in the Smart Wrap™ or Umbilical. If a water flow error occurs, the following steps can be taken to correct it:

1. Adjust the Smart Wrap™ on the user. When applying the Smart Wrap™, ensure that no creases or folds are present. The Smart Wrap™ should conform to the contours of the user's body without any folds that may constrict the device.



2. Adjust the user's body position. Applying pressure to the Smart Wrap™ may cause pinch points that reduce flow rate. Try shifting the user's body position to ensure that there are no obstructions.

3. Adjust the Umbilical position. Verify that the Umbilical is not kinked or folded over on itself. Also verify that the Umbilical is connected securely to the Smart Wrap™.

4. Decrease air pressure. Even when applied correctly, increased air pressure may limit water flow. If the Smart Wrap™ is transferred from one user to another, make sure that the air bladder is fully deflated before applying the Smart Wrap™ to the new user to ensure a proper fit.

Error Messages

The Kelvi Pro™ System reports errors or events that may prevent proper treatment. If an error occurs, a notification will be displayed on Console and treatment may be stopped if necessary. The table below will help to correct and reset the Kelvi Pro™ System. If any issue persists, please contact Kelvi™ Support.

> **IMPORTANT:** Errors are notifications about the device's operation - not necessarily an indication of an unsafe condition.

Message	What to Do
Unable to read Smart Wrap. Please ensure that Smart Wrap and Umbilical are firmly connected.	Disconnect the Smart Wrap™ from the Console. Reconnect evenly and firmly. An audible click will occur when the connectors engage.
Improper Smart Wrap Fit Detected. Remove Smart Wrap and refit, ensuring uniform body contact.	Remove the Smart Wrap™ from the user's body and refit, ensuring uniform body contact.
Console Airflow Issue Detected. Ensure vents are free from obstructions.	Ensure the back and side panels of the Console are not blocked. Place the Console at least 6 inches from any wall or solid object that might block air flow.
Console Error. Please unplug, disconnect Console and Smart Wrap connections, and restart the system.	Disconnect the Smart Wrap™ from the Console. Unplug Console for 15 seconds and restart the system. Reconnect and try again.
Console Error. Unplug Console power, wait 15 seconds, and try again.	Unplug the Console from power source. Wait 15 seconds, plug in the Console, and try again.
Flow Issue Detected. Ensure Umbilical is free of kinks. Remove Smart Wrap and refit, ensuring uniform body contact.	See **Maintaining Water Flow**
Environmental Temperature Alert. Leave Smart Wrap attached, Console idle, and try again in 15 minutes.	Leave Console running with Smart Wrap™ attached, but not on body. Wait up to 15 minutes and try again.
Console Error. Please ensure the Console is level on a flat surface.	The Console must be placed on a flat surface with the black base facing down. Relocate Console to a flat, even surface and try again.
Smart Wrap Issue Detected. We've noticed you've experienced repeated disruption in treatment.	Disconnect the Smart Wrap™ from the Console. Reconnect evenly and firmly. An audible click will occur when the connectors engage.
Software Update Failed. Please try again.	A Software Update failure may be due to poor internet connection. Either try again later when there may be fewer users on the network or try a different network.

Care and Storage

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It is important that the Kelvi Pro^{e} Console and Smart Wraps™ are properly cleaned and stored after every use. Be sure the Kelvi Pro^{e} Console is disconnected from the electrical outlet and disconnect the power supply from the unit before cleaning. Regular cleaning and maintenance will help to keep the Kelvi Pro^{e} Console operating at peak performance.

Console

(clean and maintain regularly)

Keep all parts of Kelvi Pro^{e} Console clean and as dust-free as possible. Clean the exterior of the Kelvi Pro^{e} Console with a soft cloth and either a mild detergent or 70% isopropyl alcohol.

Debris such as lint or dust can accumulate in the vents of the Console and affect performance of the system. Use a soft cloth to remove dust and lint. If necessary, compressed air may be used to remove dust and debris.

Smart Wrap™

(clean after each use)

Remove the KelviTEC™ Insert from the Smart Wrap™ Sleeve. Wipe away any condensation with a dry towel. Wipe the KelviTEC™ Insert clean with a soft cloth and either a mild detergent or 70% isopropyl alcohol. Dry the KelviTEC™ insert after wiping down.

The Sleeve should be cleaned after each use, especially for multi-patient use. Close all zippers and hand wash or machine wash cold with mild detergent and hang dry. Always remove the KelviTEC™ Insert before washing.

Maintenance

(anually)

To maintain optimal performance, the O-rings on the Smart Wrap™ should be lubricated periodically. Apply a thin layer of silicone O-ring lubricant to the black O-rings. Three O-rings are present on each Smart Wrap™ connector.

Storage

To store the Kelvi Pro™ System, first disconnect the Smart Wrap™. Disconnect the Console from the wall outlet and power supply. The Umbilical can be coiled around the Console and snapped into the recess in the carrying handle. Take care not to fold or crease the Smart Wrap™ when storing it, as this may cause kinks that will adversely affect the performance of the device permanently.

The Kelvi Pro™ System can be stored on a shelf or in a Kelvi™ carrying case in a cool, dry place. Do not store the Kelvi Pro™ System in extreme hot or cold temperatures or high humidity.

WARNING: Do not excessively dampen or wet the KelviTEC™ Insert or submerge it in any way. Do not hand wash or machine wash the KelviTEC™ Insert. Doing so will void the warranty.

Smart Wraps™ may have condensation on the surface after cryotherapy (cooling) or contrast therapy treatments. Allow the Smart Wrap™ to fully dry before storing to prevent bacterial growth.

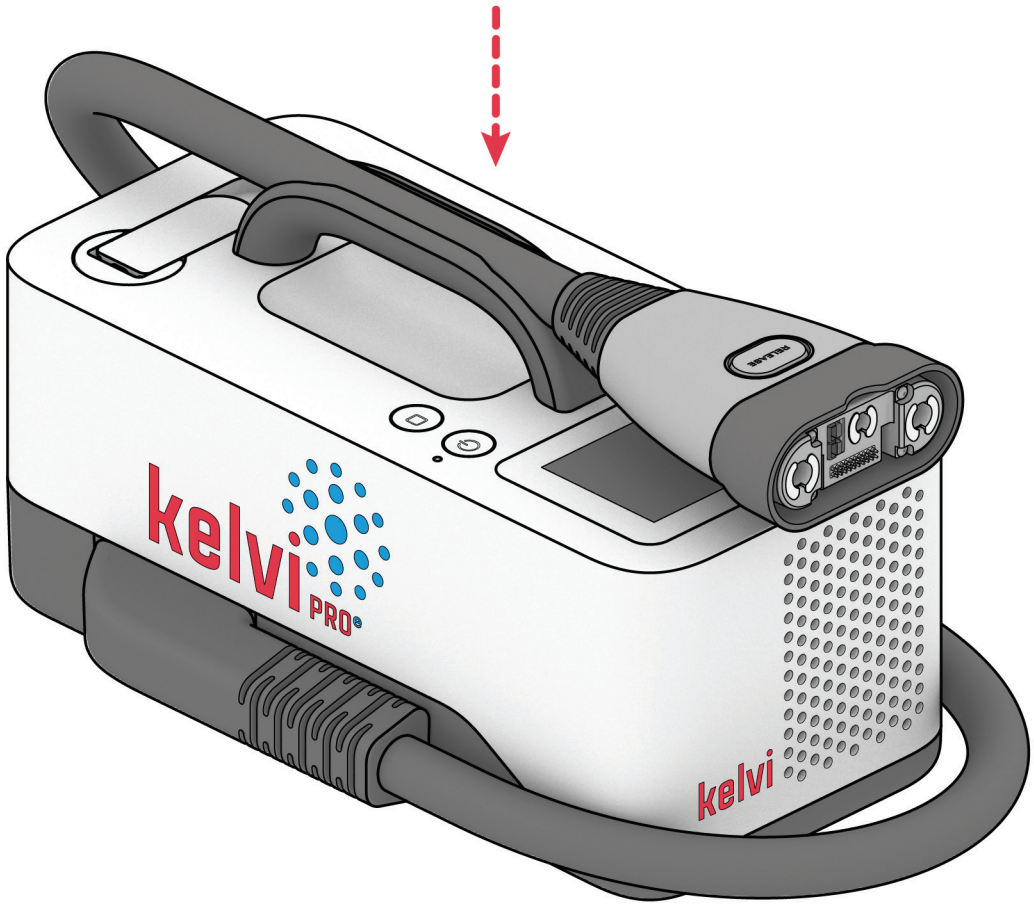
Transportation

Make sure that the Kelvi Pro[e] Console is powered off and disconnected from the power supply or battery pack before moving it. In order to prevent tripping hazards, it is recommended that the Smart Wrap™ be disconnected from the Console before moving.

To move the device around the facility or area of treatment, coil the Umbilical around the Console and snap it into the recess in the carrying handle. Lift the Console only by using the carrying handle. Smart Wraps™ can be carried by hand, but should never be carried while attached to a user.

If the Kelvi Pro™ System is damaged during transport due to lack of proper care or shipping of materials during transportation, the warranty may be voided. Kelvi™ cases are recommended for storage and travel. Please contact Kelvi™ or visit kelvi.com to learn more.

When setting up the Kelvi Pro™ System after transportation or storage conditions outside of the specified operating temperature range (see **Specifications**), please allow 15-20 minutes for the device to return to operating temperature to ensure proper performance.



Coil umbilical and snap into handle for transportation

Symbols

6

	ETL Classified. Conforms to all applicable standards.
	Type BF applied parts
	Double insulation
	Consult user manual
	Consult user manual and follow instructions for use
	Warning
	Manufacturer
	Date of manufacture
	Reference number
	Serial number
	Lot number
	Ingress protection
	Wi-Fi connected
	Bluetooth enabled
	Cellular connected

	Power On/Off
	Home
	Water level
	Battery
	Wash gentle cycle
	Line dry
	Do not iron
	Do not dry clean
	Do not tumble dry
	Do not bleach
	Keep dry
	Do not use if damaged
	Transportation & storage temperature limits
	Transportation & storage humidity limits
	Separate collection for waste electrical and electronic equipment

Specifications

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General Specifications

Size	15.2 x 7.3 x 8.2 in (38.7 x 18.5 x 20.8 cm) + 6 ft (2 m) umbilical
Weight	21.5 lbs (9.8 kg) with full reservoir
Input Voltage	100-240V ~ 6A, 50/60Hz
Power Supply	400W, Class II
Reservoir Capacity	1 L (0.26 gal)
Smart Wrap™ Temperature Range	4-42 °C (39-108 °F)
Air Pressure	5-75 mmHg
Operating Temperature & Humidity	6-30 °C (43-86 °F) 30-90% relative humidity
Storage Temperature & Humidity	1-52 °C (34-126 °F) 10-90% relative humidity
Operating Altitude	0-9842 ft (0-3000 m)
Expected Service Life	Kelvi Pro^{e} Console: 3 Years KelviTEC™ Insert: 1-2 Years, varying by rate of use
Applied Part	Smart Wrap™
Applied Part Type	Type BF
Equipment Classification	Class II ME Equipment
Ingress Protection	IP22
Bluetooth Support	2.4 GHz
Cellular Support (model KLV10002 only)	4G LTE Category 4
Oxygen Safety	Not suitable for use in an oxygen enriched environment or in the presence of flammable substances.

Applicable Standards

The Kelvi Pro™ System conforms to the following standards:

AAMI ES60601-1 / CSA C22.2 #60601-1	Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance
IEC 60601-1-2	Medical Electrical Equipment: Electromagnetic Compatibility
IEC 60601-1-6	Medical Electrical Equipment: Usability
IEC 60601-1-1	Medical Electrical Equipment: Home Healthcare

Essential Performance

If Essential Performance is lost, the device may stop treatment, display an error notification, and/or shut down.

Cold and Heat Therapy	4-42 °C (39-108 °F)
Contrast Therapy	Transition between cold and heat within the above temperature range
KelviTEC™ Insert Average Temperature Accuracy	±1 °C (2 °F)

Supplied Power Cord: North America

Cord	18 AWG
Plug	NEMA 1-15P
Connector	IEC 60320 C17
Approvals	UL

Supplied Power Cord: European Union

Cord	18 AWG
Plug	CEE 7/7
Connector	IEC 60320 C13
Approvals	VDE

IMPORTANT: Use only the power supply and power cord provided with your Kelvi Pro™ System.

Accessories and replacement parts

Accessories and replacement parts can be purchased by contacting Kelvi™ or at kelvi.com.

Accessories

- Smart Wraps™ are available for various parts of the body including ankle, back, knee, and shoulder
- Travel cases are available for the Kelvi Pro^{e} Console and Smart Wraps™
- Batteries and battery charger

Replacement Parts

- Power Supply
- Power Cord
- Copper Sulfate Solution

Electromagnetic Compatibility

This equipment has been tested and found to comply with the electromagnetic compatibility limits for the Medical Device Directive 93/42/EEC (EN 55011 Class B and EN 60601-1-2). These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. The equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with these instructions, may cause harmful interference to other devices in the vicinity. The emissions characteristics of this equipment make it suitable for use in residential environments (CISPR 11 Class B).

If this equipment does cause harmful interference with other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device.
- Increase the separation between the equipment.
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) is connected.
- Consult the manufacturer for help.

The Kelvi Pro™ System is intended for use in the electromagnetic environment specified below. The user should ensure that it is used in such an environment.

Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Environment
RF Emissions CISPR 11	Group 1	The Kelvi Pro^{e} uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The Kelvi Pro^{e} 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 IEC 61000-3-2	Complies	
Flicker IEC 61000-3-3	Complies	

Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment
ESD (IEC 61000-4-2)	±8kV Contact ±15kV Air	±8kV Contact ±15kV Air	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the r/h should be at least 30%
EFT (IEC 61000-4-4)	±2kV Mains ±1kV I/O's	±2kV Mains N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge (IEC 61000-4-5)	±1kV Differential ±2kV Common	±1kV Differential ±2kV Common	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips (IEC 61000-4-11	>95% Dip for 0.5 Cycle >95% Dip for 1 Cycle 30% Dip for 25/30 Cycles >95% Dip for 250/300 Cycles	>95% Dip for 0.5 Cycle >95% Dip for 1 Cycle 30% Dip for 25/30 Cycles >95% Dip for 250/300 Cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Kelvi Pro^{e} requires continued operation during power mains interruptions, it is recommended that the Kelvi Pro^{e} be powered from an uninterruptible power supply or a battery.
Power Frequency 50/60Hz Magnetic Field (IEC 61000-4-8)	30 A/m	30A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.
Conducted RF (IEC 61000-4-6)	3 V 0.15 MHz-80 MHz 6 V[1] in ISM between 0.15 MHz and 80 MHz[2] 80 % AM at 1 kHz	3 V 0.15 MHz-80 MHz 6 V[1] in ISM between 0.15 MHz and 80 MHz[2] 80 % AM at 1 kHz	Mains power quality should be that of a typical commercial or hospital environment.
Radiated RF (IEC 61000-4-3)	3 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz	3 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz	Mains power quality should be that of a typical commercial or hospital environment.

1) r.m.s. before modulation is applied
2) The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz

Test Frequency (Mhz)	Band[1] (Mhz)	Service[1]	Modulation	Max Power (W)	Distance (m)	Immunity Test Level (V/m)
385	380-390	TETRA 400	Pulse modulation [2] 18 Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM [3] ± 5 kHz deviation 1 kHz sine	2	0.3	28
710 745 780	704-787	LTE Band 13, 17	Pulse modulation [2] 217 Hz	0.2	0.3	
810 870 930	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [2] 18 Hz	2	0.3	28
1720 1845 1970	1700-1900	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [2] 217 Hz	2	0.3	28
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [2] 217 Hz	2	0.3	28
5240 5500 5785	5100-5800	WLAN 802.11a/n	Pulse modulation [2] 217 Hz	0.2	0.3	9

1) For some services, only the uplink frequencies are included.
2) The carrier shall be modulated using a 50 % duty cycle square wave signal.
3) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 in) to any part of the Kelvi Pro™ System to ensure proper functionality.

WARNING: Use of accessories or cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic compatibility issues and result in improper operation.

WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided as it may result in improper operation. If such use is necessary, all equipment should be observed to verify that they are operating normally.

WARNING: A noisy environment or mobile device with low battery power can lead to intermittent Bluetooth connection and may require operation of the Kelvi Pro™ System using the Console touchscreen.

Wireless Connectivity

The Kelvi Pro™ System uses Bluetooth for control capability via the Kelvi™ Mobile App and relies on the mobile device having a connection to the Internet either through a Wi-Fi network or a Cellular network in order to:

- Create an account
- Add a patient or invite a clinician
- Assign a treatment to a patient

The Kelvi Pro® Console uses an 802.11 b/g/n secure Wi-Fi connection to download software updates.

The Kelvi™ Mobile App sends the following over Bluetooth:

- Treatment sets (temperature settings, time durations, and number of cycles)
- Pause or Stop treatment commands
- Temperature unit display preferences (°C or °F)

The Kelvi Pro® Console sends the following over Bluetooth:

- Notifications if an error occurs (error information is displayed on a message on Console screen)

The Kelvi™ Mobile App sends the following over Wi-Fi or Cellular Data Network:

- Account authentication and verification
- Treatment history
- Treatment library
- Patient and/or Clinician list

Data is sent over a secure connection using either the mobile device Wi-Fi or a cellular data network. This information is used to provide a secure login, user-associated settings and libraries, and a history of treatments run.

NOTE: Mobile device Bluetooth connectivity allows for an enhanced set of features and is not essential to the operation of the Kelvi Pro™ System.

Software Updates

Software updates will be sent over a Wi-Fi or cellular data connection when manually selecting the option in System Settings. The Kelvi Pro™ System uses standard FCC certified wireless connections. However, it is always recommended to validate that the Kelvi Pro™ System is not interfering with any devices where wireless capability is a required function.

Disposal

This product and its accessories contain electronic components and should not be disposed of with household/consumer waste. Contact your local city or municipal waste disposal service to learn where to drop off electrical and electronic waste.

Water inside the Kelvi Pro™ System is not potable. Any excess water should be drained into a sink or external receptacle for disposal. Do not drink or ingest the water that has been circulating in the system.

Intellectual Property

The Kelvi Pro™ System and all accessories are covered by intellectual property rights including, but not limited to, patents, trademarks, trade names, and copyrights, owned and/or licensed by Hypothermia Devices, Inc., dba Kelvi™. No license under such intellectual property rights are granted to users, and all such rights are hereby expressly reserved by Kelvi™. Without the express, written consent of Kelvi™, user shall not (i) modify any Kelvi™ product or documentation Kelvi™ provides to user or (ii) reverse engineer, decompile, or disassemble any Kelvi™ product, or encourage or assist any third party in doing so.

Software License

Kelvi™ products use software code owned and/or licensed by Kelvi™ from third parties. Each sale of a Kelvi™ product is not a sale of the software contained therein but rather is a license to use the software in the Kelvi™ product in which the software was initially installed. Any license granted by Kelvi™ to use the software contained in its Kelvi™ products does not give the user/licensee the right to copy, alter, disassemble, reverse engineer, create derivative works of such software or to use such software in either original or modified form in any product other than the Kelvi™ product in which the software was initially installed by Kelvi™.

Warranty Information

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To obtain warranty support, please visit kelvi.com

Kelvi™ warrants that the Kelvi Pro^{e} Console, if properly used, will be free from defects in material and workmanship for a period of two (2) years after the date of purchase. Kelvi™ warrants that the KelviTEC™ Insert, if properly used, will be free from defects in material and workmanship for a period of one (1) year after the date of purchase.

Item	Standard Warranty
Kelvi Pro^{e} Console	2 years
KelviTEC™ Insert	1 year
Sleeve	If defective, report or return within 14 days from receipt
Hard Case	If defective, report or return within 90 days from receipt
Soft Case	If defective, report or return within 90 days from receipt

If the Kelvi Pro^{e} Console and/or KelviTEC™ Insert, which is the subject of this limited warranty, fails during the warranty period for reasons covered by this Limited Warranty, Kelvi™ will, at its sole discretion, repair or replace the Kelvi Pro^{e} Console and/or KelviTEC™ Insert with a separate Kelvi Pro^{e} Console and/or KelviTEC™ Insert. This limited warranty and any implied warranties that may exist under state law apply only to the original purchaser of the device and are non-transferable.

This limited warranty does not cover damage due to external causes, including, but not limited to, storage, usage, or handling not in accordance with product instructions, accident, misuse, neglect alteration, and/or unauthorized repair. Kelvi™ may elect, at its sole discretion, to replace or repair the Kelvi Pro^{e} with a new or reconditioned product. Any product returned to Kelvi™ that is the subject of replacement or repair becomes the property of Kelvi™. Any replacement Kelvi Pro^{e} Console and/or KelviTEC™ Insert provided to the original purchaser is warranted under the same warranty as the original Kelvi Pro^{e} Console and/or KelviTEC™ Insert, and only for the remaining period of the original warranty.

How to Obtain Warranty Service

To obtain warranty service, contact Kelvi™ Support at or at kelvi.com. If Kelvi™ authorizes the return of the Kelvi Pro^{e}, you will be issued a Return Merchandise Authorization (RMA) number. Customers are not to return any product without prior written authorization from Kelvi™. Instructions on how to pack and send the Kelvi Pro^{e} will be provided in writing once the return is approved. You should keep this RMA number for your records. Kelvi™ will cover the cost of the return if the Kelvi Pro^{e} Console and/or KelviTEC™ Insert is under warranty. If the Kelvi Pro^{e} Console and/or KelviTEC™ Insert is outside the time frame of the warranty, the customer is responsible for all associated costs. If the Kelvi Pro^{e} Console and/or KelviTEC™ Insert is not packaged per the given instructions, Kelvi™ is not responsible for any damage which occurs during shipping.

Warranty Disclaimers

All Kelvi™ warranties are in lieu of any and all other warranties, express or implied including, but not limited to, the implied warranties of merchantability and fitness for a particular purpose. Kelvi™ makes no express warranties beyond those stated here. Kelvi™ disclaims all other warranties, express or implied including, without limitation, implied warranties of merchantability and fitness for a particular purpose. Some jurisdictions do not allow the exclusion of implied warranties so this limitation may not apply to you. All express and implied warranties are limited in duration to the limited warranty period. Unless required, no warranties apply after that period. Some jurisdictions do not allow limitations on how long an implied warranty lasts, so this limitation may not apply to you. Kelvi™ warranties are non-transferable.

Limitations of Liability

The responsibility of Kelvi™ under this, or any other warranty, implied or express, is limited to repair or replacement, as set forth above. These remedies are the sole and exclusive remedies for any breach of warranty. In no event shall Kelvi™ be liable to any person for any incidental, special, punitive or consequential damages, including lost profits, cost of procurement of substitute goods, downtime, goodwill, damage to or replacement of equipment or property or any indirect damages even if Kelvi™ has been informed of the possibility thereof and notwithstanding the failure of essential purpose of any limited remedy stated herein. Some jurisdictions do not allow the exclusion or limitation of incidental or consequential damages, so the above limitations or exclusions may not apply to you. This limited warranty gives you specific rights, and you may also have other rights that vary from jurisdiction to jurisdiction.

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PNT-0012 Rev: 00