



kelvi™

User Manual

Rx ONLY
Model: KLV10001



Kelvi Pro™ Console 1.0

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Updates

This manual may be updated periodically. The most current manual can be found at Kelvi.com, or please call (310) 492-5886 to request a paper copy.

Mission

Kelvi™ embodies a platform of technologies for hypothermia/normothermia and heat application therapy that stem from research in a physiology lab of the medical school at a major American university. A talented team of physicians and engineers have worked together to transform innovative ideas on efficient methodologies to apply or withdraw heat from patients into patented, commercial products.



Visit Kelvi.com to learn more about KelviTEC™ and the entire range of Kelvi™ devices and accessories.

Contact

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

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

Kelvi.com
(310) 492-5886
info@kelvi.com



Introduction

1

Kelvi™ provides heating and cooling therapy products. The Kelvi Pro™ System, powered by KelviTEC™, gives licensed healthcare professionals and healthcare providers unprecedented treatment accuracy.

Indications for Use

The Kelvi Pro™ System provides cryotherapy (cold), thermotherapy (heat), and contrast therapies to treat postsurgical and acute injuries for which cold or heat therapies are indicated. It is also intended to treat conditions for which localized thermal therapy (hot, cold or contrast) is indicated. It is to be used by, or on the order of, licensed 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. Heat is also commonly used to reduce pain and promote healing in soft tissue injuries.

Safety

2



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

IMPORTANT: The Kelvi Pro™ System should only be used under the care and/or direction of a licensed healthcare professional. During the course of Kelvi Pro™ therapy, 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 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 neurologic 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 hypertension 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 Kelvi Pro™ includes air pressure functionality for enhanced fit. 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 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.
- Have diabetes mellitus, multiple sclerosis, rheumatoid arthritis, poor circulation, or spinal cord injuries.

General Warnings and Cautions

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™ Console such that the device is quickly and easily accessible to this manual. In the event of emergency, it may be necessary to disconnect power cord from the 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™ customer service.
- When using a Smart Wrap™, KelviTEC™ Insert should not be removed from its sleeve. Do not use 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 for any reason, discontinue use of that Smart Wrap™ and contact customer service.
- Do not step on, stack, or compress Smart Wrap™. Doing so may damage Smart Wrap™ and may cause system to operate incorrectly.
- Kelvi Pro™ Console is designed to be carried by its handle or transported using a Kelvi™ carry case. Do not use Smart Wrap™ or Umbilical to carry or transport Console.
- Always check Smart Wrap™ connector and the connector pocket on Console for debris

before connecting. Do not apply undue force when connecting Umbilical to any part of the Kelvi Pro™ System or accessories. Application of undue force will void the warranty.

- Kelvi Pro™ 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 Kelvi Pro™ Console while the device is attached to the body. Kelvi Pro™ Console and Smart Wraps™ contain hard components which can cause injury upon bodily impact.
- Keep Kelvi Pro™ System out of reach of small children or pets.
- 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.
- Operating Kelvi Pro™ Console while connected to a Wi-Fi network that includes other electronic 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 healthcare professional.

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 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™ therapy, 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, 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 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 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.



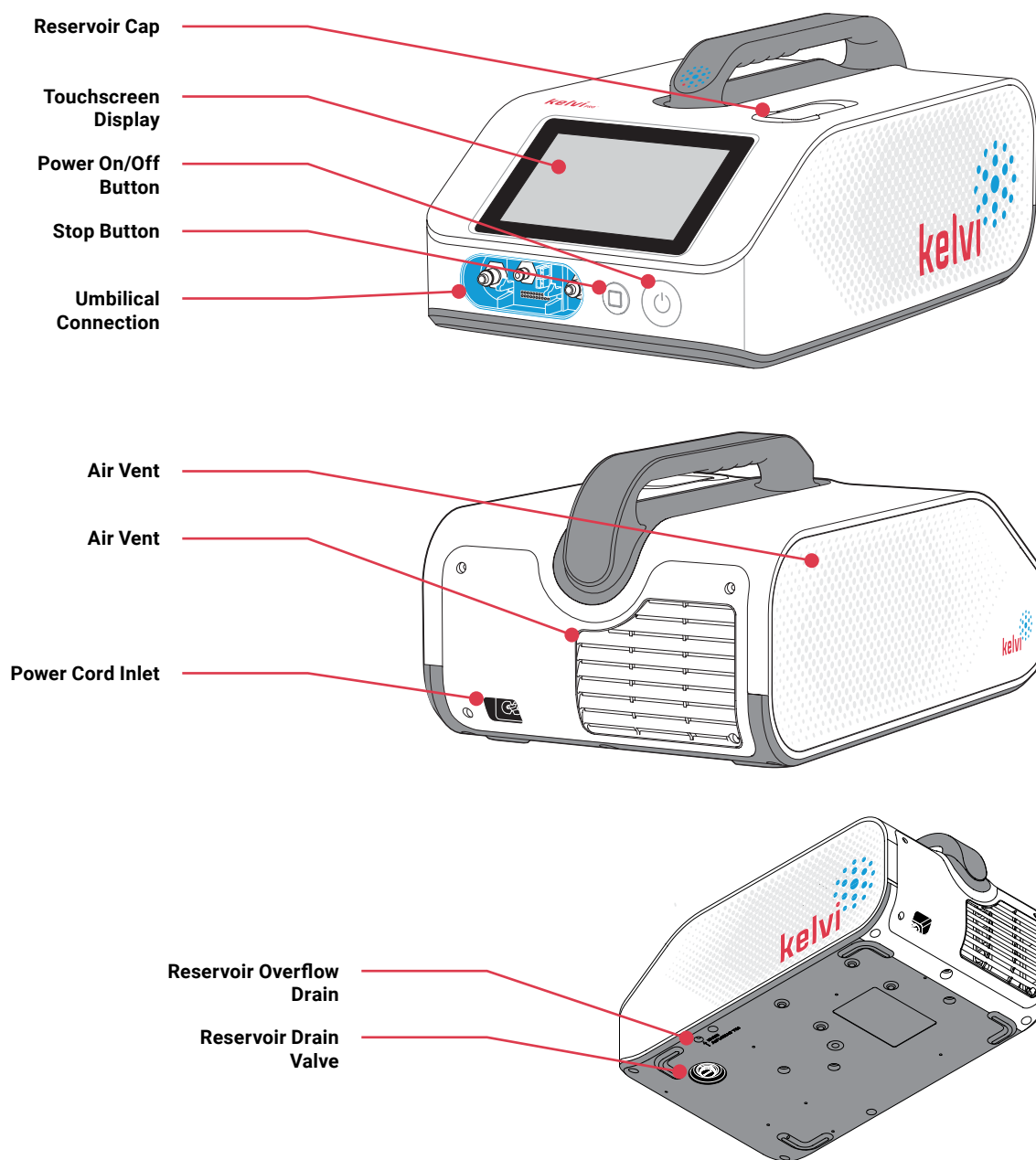
WARNING: This product can expose you to chemicals including Antimony oxide (Antimony trioxide), Lead, Nickel (Metallic) which are known to the State of California to cause cancer or birth defects or other reproductive harm. For more information, visit www.P65Warnings.ca.gov.

Console

The following items are included with your Kelvi Pro™ Console:

1. Kelvi Pro™ Console 1.0
2. Power Cord
3. User Manual
4. Copper Sulfate Solution

A complete Kelvi Pro™ System is needed for a treatment. The Kelvi Pro™ System is defined as a Console, Umbilical, Smart Wrap™, and power cord.



Umbilical

An Umbilical (sold separately) is required to begin treatment using the Kelvi Pro™ System.



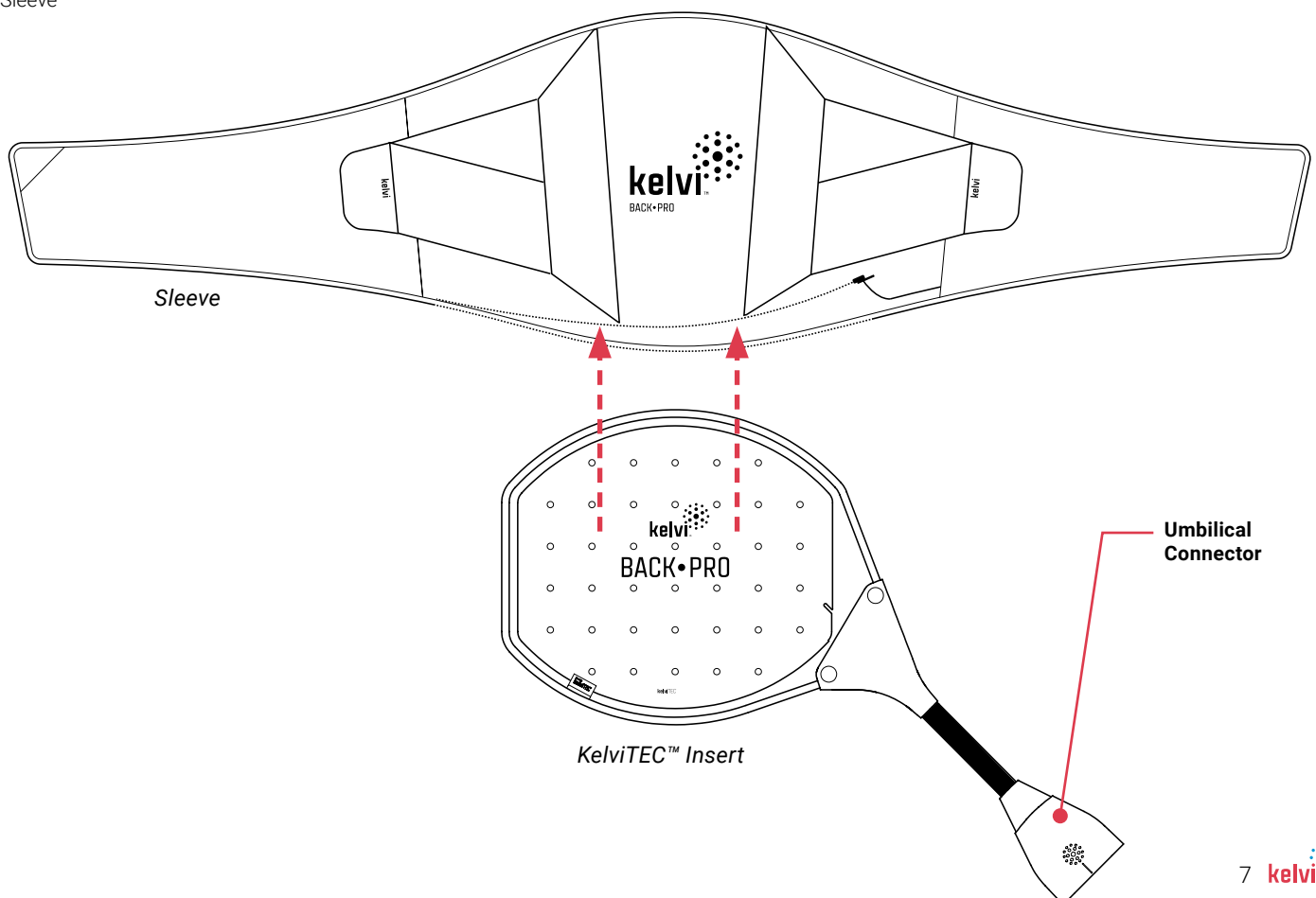
WARNING: Deflate air bladder after every use. Deflate air bladder by hitting Decrease Air Pressure button, (-) or disconnecting Smart Wrap™.

Smart Wrap™

A Smart Wrap™ (sold separately) is required to begin treatment using the Kelvi Pro™ System. The Kelvi Pro™ System is compatible with any Smart Wrap™.

The following items are included with a Smart Wrap™:

1. KelviTEC™ Insert
2. Sleeve



Setting Up

Please read the instructions carefully before powering up and operating Console.

1. Remove Kelvi Pro™ Console from its packaging by lifting it from the handle.
2. Place Console on a flat dry surface to prepare for treatment.

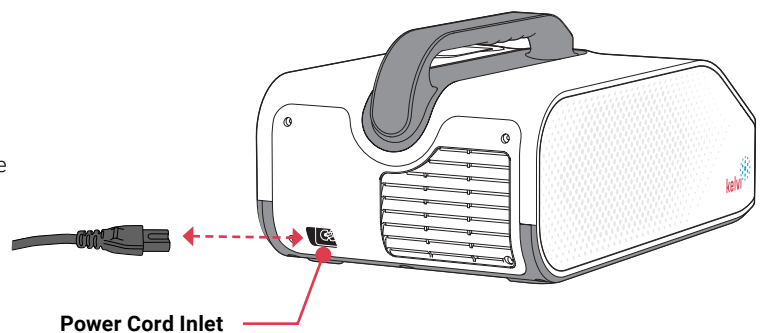
IMPORTANT: Place Console at least one foot away from any adjacent wall or barrier to ensure that the front and side Air Vents are not obstructed.

IMPORTANT: Ensure Console is on a stable, level surface during operation. It will not function if placed on its side, and its functionality may be compromised if placed at a substantial angle.

Powering Up

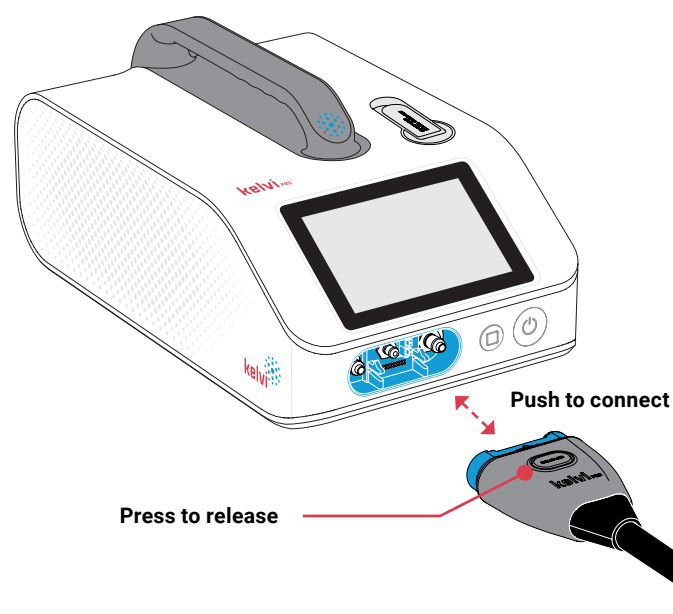
The Kelvi Pro™ Console comes with a six foot power cord.

1. Attach the supplied power cord to the power cord inlet on the back of Console.
2. Plug power cord into an appropriate power outlet.
3. Place power cord in a safe location to avoid tripping hazard.
4. Press "On/Off" button on the front of Console to turn on the device. The power button will light up to indicate System startup is in progress.
5. Console will take up to 60 seconds to start up, during which time the Kelvi™ logo will appear on the display.



Connecting a Smart Wrap™

To connect and disconnect Smart Wrap™, follow these steps:



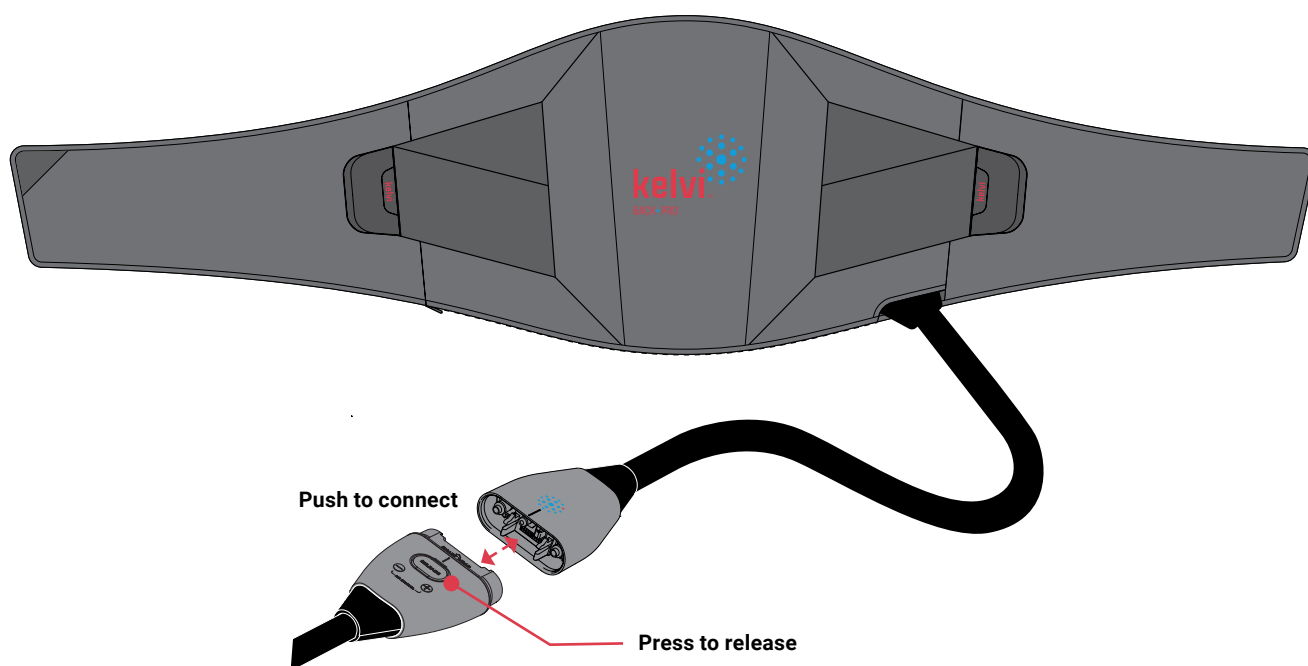
To connect:

1. Insert the blue Umbilical connector into the blue receptacle on the front of Console. An audible "click" will occur when the connectors engage.
2. Connect Smart Wrap™ to the opposite end of Umbilical. An audible "click" will occur when the connectors engage.

To disconnect:

1. Disconnect Smart Wrap™ by pressing the "Release" button on Umbilical connector and pull the connectors apart.
2. Disconnect Umbilical from Console by pressing the "Release" button on Umbilical connector and pulling away from Console.

NOTE: 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.



NOTE: Point connectors down when pulling apart, allowing any excess water to drain out.

Starting a Treatment

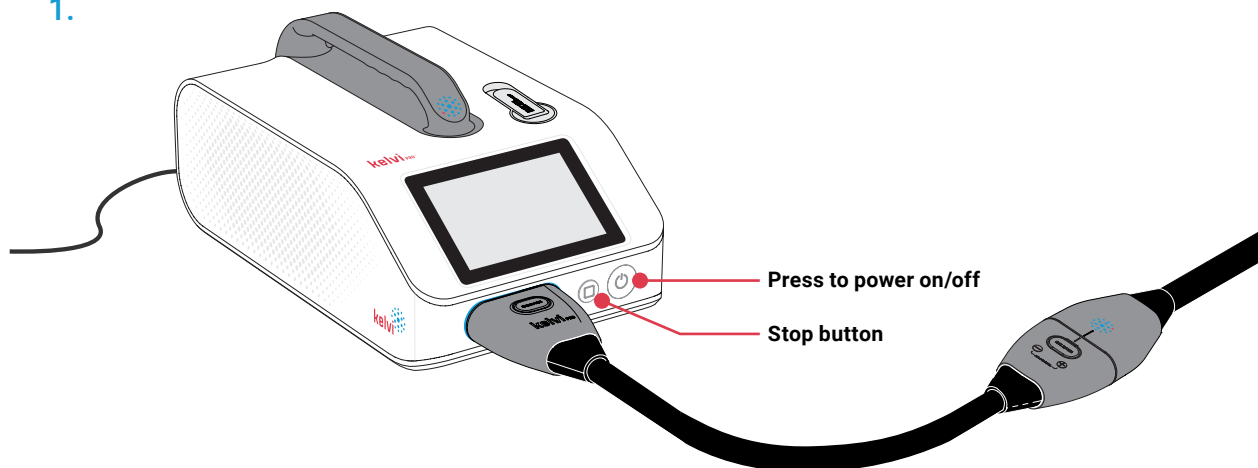
For specific instructions on wearing and adjusting Smart Wrap™ for optimal fit, please consult the User Guide provided with each Smart Wrap™.

To run a treatment, Umbilical, Smart Wrap™, and power cord must all be connected and Console must be powered on.

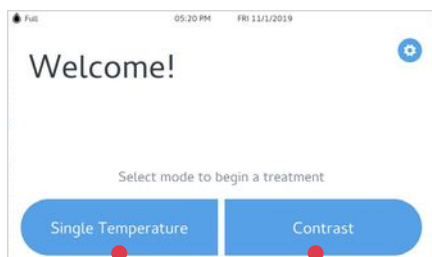
1. Plug in power cord to power cord inlet on the back of Console. Connect the blue end of the Umbilical to the front of Console, and the grey end to Smart Wrap™. Press Power On/Off button to power Console. Once you are at the "Welcome" screen, place Smart Wrap™ on the patient.
2. On the "Welcome" screen of Console, select your mode of treatment
 - a. Single Temperature allows for continuous cooling or heating at a single temperature for a set treatment time.
 - b. Contrast provides six preset contrast therapies at preset temperatures for a selected number of treatment cycles.
3. For additional treatment programming options, turn to page 17 to start a treatment using the Kelvi™ Mobile App. Make sure Bluetooth is enabled on your Console.

IMPORTANT: Do not excessively compress Smart Wraps™. This may cause errors.

1.



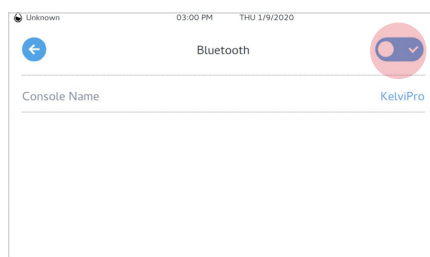
2.



Select for Single Temperature

Select for Contrast

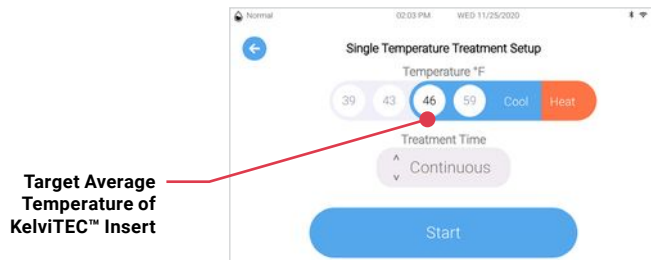
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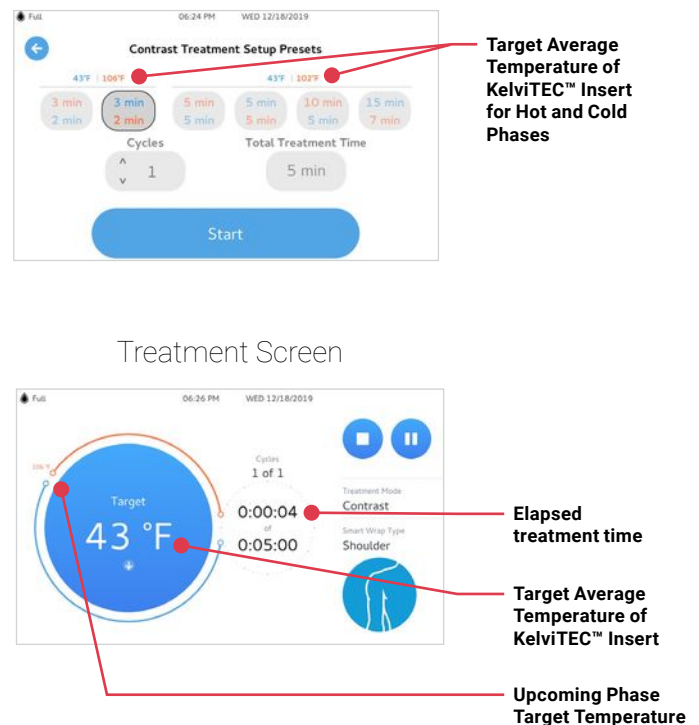
Understanding Temperature Settings

Kelvi™ temperature reading reports an average of the temperature sensors embedded in each KelviTEC™ Insert. For most accurate therapy readings, ensure direct, consistent, and complete contact between Smart Wrap™ and skin.

Single Temperature Treatment



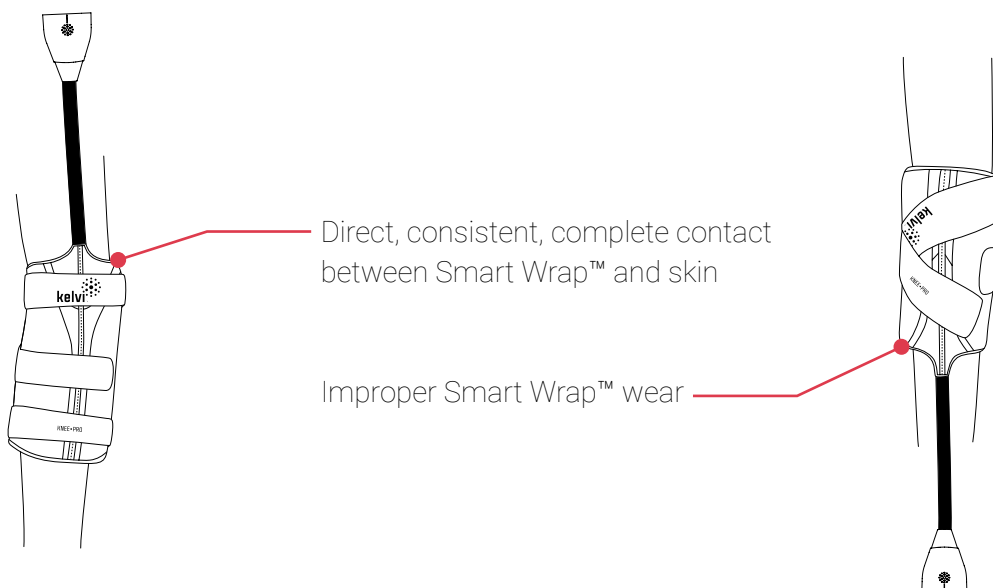
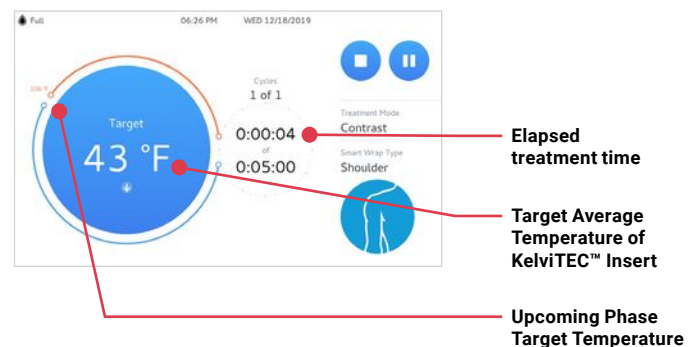
Contrast Therapy Treatment



Treatment Screen



Treatment Screen



IMPORTANT: For accurate temperature reading, Smart Wrap™ should be worn directly on skin. Clothing can be worn, but will adversely affect accuracy of therapy. Please see Warnings and Cautions for situations where wraps should not be placed directly on skin.

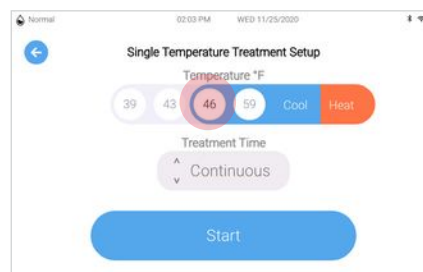
Single Temperature Treatment

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 indefinitely until stopped by the user.
 - b. Up and down arrows can be used to specify a fixed treatment duration if desired.
4. Select "Start" to begin treatment.
5. 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.
7. To end treatment:
 - a. Press the "Stop" button on the screen and confirm that you wish to end the treatment.
 - b. During treatment press the Stop button located next to the Power On/Off button.
 - c. Disconnect Smart Wrap™ from Umbilical.
8. Remove Smart Wrap™ from the patient as indicated in Smart Wrap™ User Guide.

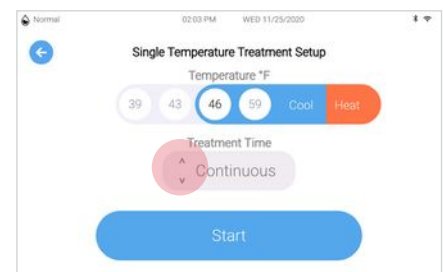
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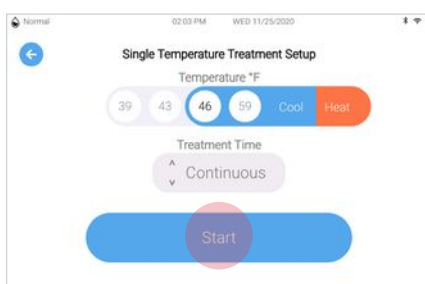
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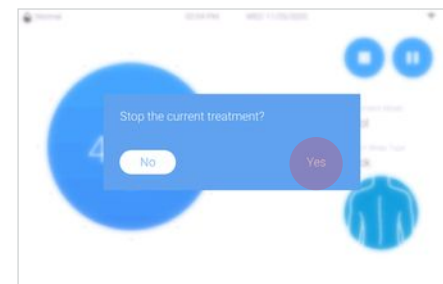
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5-6.



7.



Contrast Therapy Treatment

- Choose your contrast treatment parameters by selecting one of the six options.
 - Orange color indicates Hot phase, Blue color indicates Cold phase.
 - Treatment Phases will occur in the order they appear in each grey button.
- Choose the number of treatment cycles. The total treatment time will be displayed automatically.
- Select "Start" to begin treatment.
- Treatment screen will display the current status of treatment.
- To pause the treatment at any time, press the "Pause" button on the screen. Press the "Resume" button on the screen to continue.
- To end treatment:
 - Press the "Stop" button on the screen and confirm that you wish to end the treatment.
 - During treatment press the Stop button located next to the Power On/Off button.
 - Disconnect Smart Wrap™ from Umbilical.
- Remove Smart Wrap™ from the patient as indicated in Smart Wrap™ User Guide.

1.



2.



3.



4.



5.

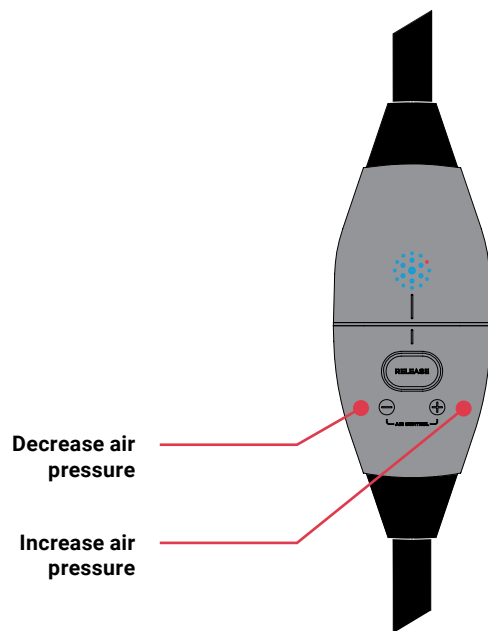


6.



Adjusting Fit

The Kelvi Pro™ System allows you to apply air pressure to adjust the fit and ensure optimal comfort and skin contact for effective treatment. Controls for fit adjustment are found on Umbilical.



1. Air pressure may be applied to adjust the fit of Smart Wrap™ before or during treatment.
2. To increase air pressure, press the (+) button on Umbilical connector.
3. To release air pressure, press the (-) button on Umbilical connector.
4. At the end of treatment, release all air pressure from Smart Wrap™. Air pressure will drop automatically when Smart Wrap™ is disconnected.



WARNING: Never use air pressure to the point that blood flow stops, pain is experienced, or the surrounding area becomes discolored.



WARNING: Deflate air bladder after every use. Deflate air bladder by hitting Decrease Air Pressure button, (-) or disconnecting Smart Wrap™.

Ending a Treatment

A treatment in progress can be ended at any time by pressing the Stop button on Console, stop on the touchscreen, or through the Mobile App (if connected). When a treatment programmed through the mobile app reaches its conclusion, Console will automatically stop and Smart Wrap™ will return to ambient temperature.

1. If you are finished using the Kelvi Pro™ System, power off Console by pressing and holding the Power On/Off button on the front of Console.
2. When Console has fully powered down, it is safe to disconnect power cord from wall outlet.
3. Disconnect Smart Wrap™ and remove from the body.

See pg 24: Care and Storage for further instructions on maintaining and storing your Kelvi Pro™ System.



IMPORTANT: The Stop button on the front of Console may be depressed at any time to stop treatment. Smart Wrap™ may also be removed from the user's at any time should it be necessary.

Configuring System Settings

Kelvi Pro™ Console allows you to change the factory settings through System Settings screen.

1. Power Console and select the gear icon from the Welcome screen to access System Settings.
2. General
 - a. Adjust the date and time settings.
 - b. Select the default temperature display to °C or °F.
3. Bluetooth
 - a. Enable or disable Bluetooth connection.
4. Wi-Fi
 - a. Enable or disable Wi-Fi connection. Wi-Fi is on by default.
 - b. Select the Wi-Fi network you wish to join from the list and enter the security credentials.
5. System Info
 - a. Display System information.
 - b. If a System update is available and you are connected to WiFi, an "Update" button will appear on this screen.

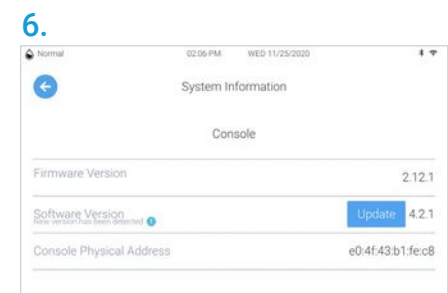
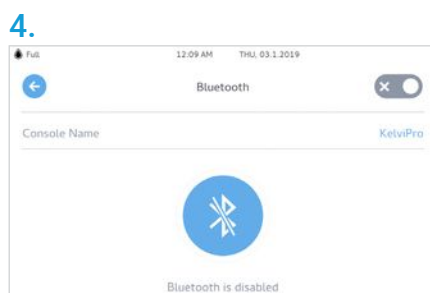
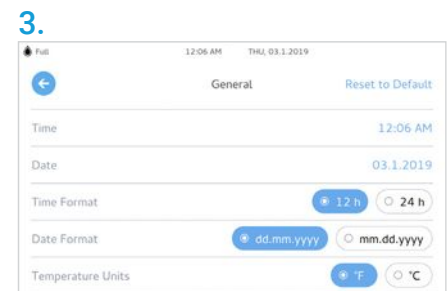
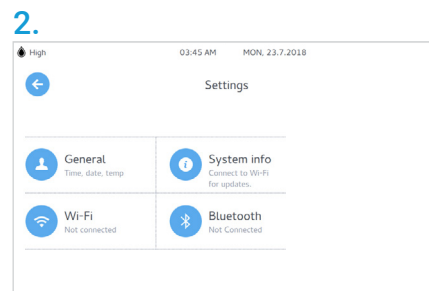
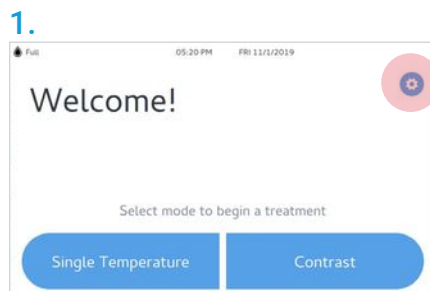
Naming your Console:

The user has the ability to provide a distinctive name to Console. This is the name that will appear when using Mobile App to connect to Console. To name your Console:

1. Navigate to your Bluetooth Screen.
2. Click on the name.
3. Input desired name.
4. Press "Enter" on keyboard.

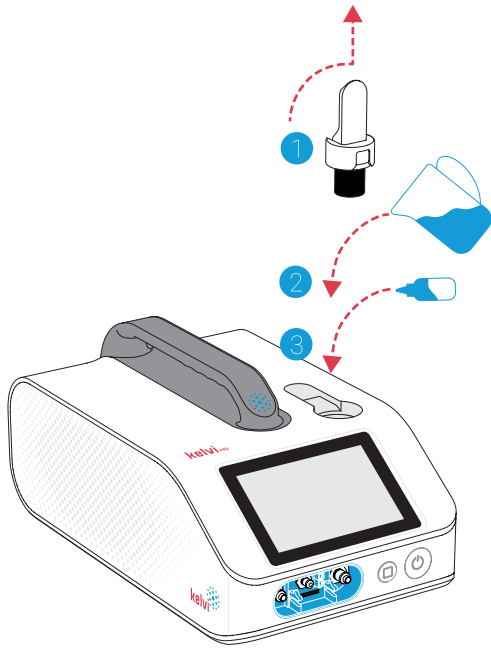
IMPORTANT: Kelvi™ will periodically provide system updates for Console. We highly recommend that the user connect Console to Wi-Fi and periodically check for updates. Failure to update may cause functionality issues, including but not limited to, issues connecting to the Kelvi™ Mobile Apps.

IMPORTANT: Mobile App temperature settings for °C or °F override Console settings



Refilling the Reservoir

The Kelvi Pro™ System arrives filled with distilled water* to dissipate heat from the solid state electronics used to provide cryotherapy. If the water level in the System is too low, the System will stop treatment and display a warning. The reservoir can hold up to one liter of water and be refilled by following these steps:



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

1. Open Reservoir Cap on the top of Console by lifting up on the lever and pulling straight up to remove.
2. Pour distilled water into the reservoir until the water reaches the blue line or the Fill Reservoir screen reads "Full".
3. Add one (1) drop of Copper Sulfate Solution to reservoir each time water is refilled. This solution acts as an antimicrobial.
4. When the reservoir is full, replace Reservoir Cap and lower the lever to seal the valve.
5. The Kelvi Pro™ System will not operate if Reservoir Cap is not properly installed.

*IMPORTANT: Console comes filled with antimicrobial treated water. When you need to refill your Console with water, add one drop of Copper Sulfate Solution per refill. Failure to add Copper Sulfate Solution may void the warranty. To purchase more visit Kelvi.com.



WARNING: Do not drink or ingest the water that has been circulating in the System.

IMPORTANT: Take caution to not overfill Console. If you do over fill the reservoir, water will drain out through the fill overflow drain located at the bottom of Console. The System may periodically release excess water through this overflow drain.

Using Kelvi™ Mobile Apps:

4

The Kelvi Pro™ Console can be controlled (1) directly from Console screen, (2) through the use of the Kelvi™ Clinician App on your phone or tablet or (3) through the use of the Kelvi™ Patient App on your phone or tablet. The app gives clinicians and patients easy access to some of the more powerful functions of the Kelvi Pro™ System, including contrast therapies. Clinicians can create a library of treatments and prescribe them to patients remotely. Patients can recall treatments prescribed to them at any time or run a manual treatment. The apps let you enjoy the full functionality of the Kelvi Pro™ System from the palm of your hand.

NOTE: A smartphone or tablet supporting Bluetooth BLE and running Android or iOS is required to use the Kelvi Pro™ mobile app. The mobile device must have its bluetooth enabled and be connected to the Internet either through Wi-Fi or Cellular network, in order to access saved account information (user information, saved treatments, saved patients). It is recommended that the device be connected using a secure network connection. Some Android devices may have connectivity issues. Contact Kelvi™ Customer Support if you have problems connecting your device.

IMPORTANT: Update Apps regularly.

Setting up the Apps

To download either the Kelvi™ Patient App or the Kelvi™ Clinician App, visit the Apple App Store or Google Play Store. Once downloaded, you will need to create a Kelvi™ account. Click the blue "Sign Up" button to create an account. A Kelvi™ account allows you to create, store, and run treatments using your Kelvi Pro™ System.

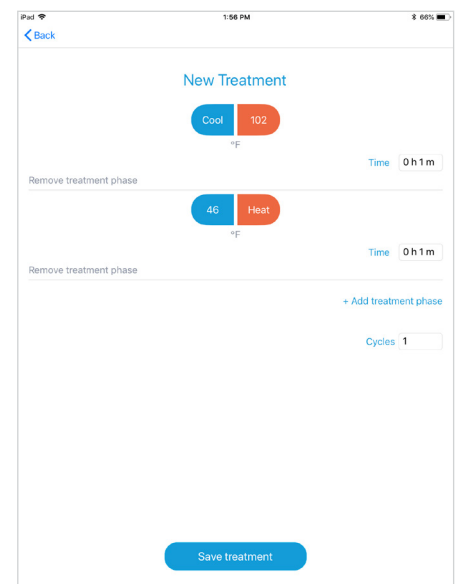
Kelvi™ Clinician App

The Kelvi™ Clinician App allows licensed healthcare professionals to create a library of treatments and prescribe them to patients remotely.

IMPORTANT: In environments where multiple Consoles are used, follow instructions on page 15 to assign distinctive names to each Console.

Creating a Treatment

1. To start a treatment, select the "Start New Treatment" button on the home screen.
2. The app will display Kelvi Pro™ Consoles available to execute the treatment.
3. Select the "Pair" button to connect to your Console via Bluetooth. If your Console does not appear in the list make sure your Console is running and has Bluetooth enabled in the System Settings.
4. Console will display a message indicating successful connection to the Kelvi™ Mobile App.
5. On the app, select "Cool" or "Heat" to indicate the type of treatment phase desired.
6. Select the desired treatment temperature.
7. Select the desired treatment duration.
8. If you wish to add additional steps to the treatment or perform a contrast therapy, select "Add treatment phase". You can add up to 5 treatment phases.
9. Repeat steps 5-8 as necessary.
10. Select the desired number of cycles. Treatments can include up to 15 cycles.
11. Select "Run Treatment".
12. Fill out and submit the pre-treatment survey to begin.

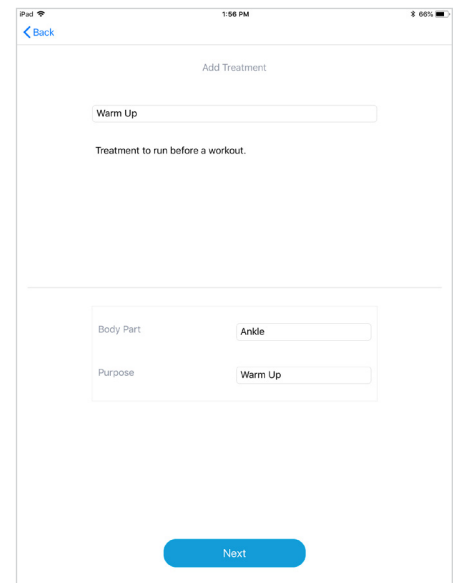


Running a Treatment

1. Select "Start a Treatment" or "Run Treatment" on a saved treatment.
2. The app will display Kelvi Pro™ Consoles available to execute a treatment. If necessary specify treatment.
3. Select "Pair" button to connect to your Console via Bluetooth. If your Console does not appear in the list make sure the Console is running and has Bluetooth enabled in the System Settings.
4. Treatment will begin immediately when the app connects to the Console.
5. Mobile App treatment may be stopped or paused as a manual treatment. The treatment may also be stopped by the Mobile App.

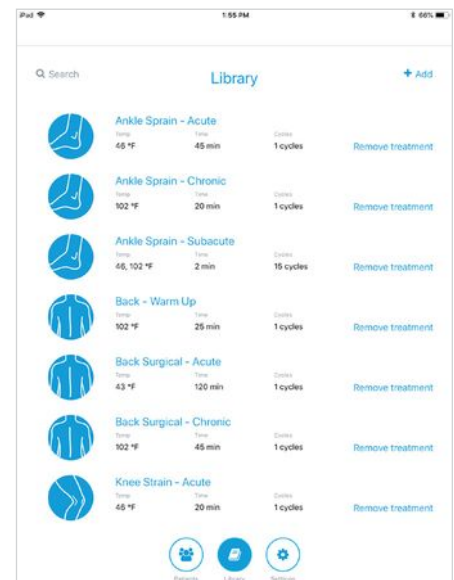
Adding a Treatment to Library

1. To access the treatment library, select the "Library" button on the home screen.
2. To add a new treatment select "+Add" at the top of the screen.
3. Enter a Treatment name.
4. Enter a description of the treatment.
5. Select the Body Part to which the treatment will be applied.
6. Select the purpose of the treatment.
7. Select "Next" to complete the treatment setup.
8. Select "Cool" or "Heat" to indicate the type of treatment phase you want to perform.
9. Select the desired Smart Wrap™ temperature.
10. Select the desired treatment duration.
11. If you wish to add additional steps to the treatment or perform a contrast therapy, select "Add treatment phase".
12. Repeat steps 8-11 as needed.
13. Select the desired number of cycles. Treatments can include up to 15 cycles.
14. Select "Save Treatment" to save it to the Library.



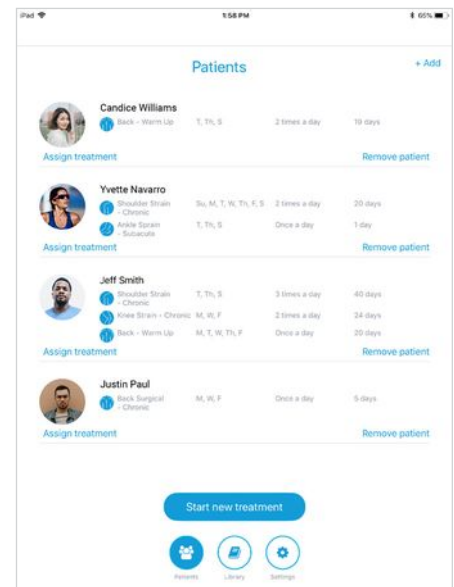
Recalling a Treatment from Library

1. To access Treatment Library, select the "Library" button on the home screen.
2. Select a saved treatment from the list or use the Search function to locate a saved treatment to run.
3. On the treatment screen you can view details of the saved treatment and choose to run the treatment or assign it to a patient.



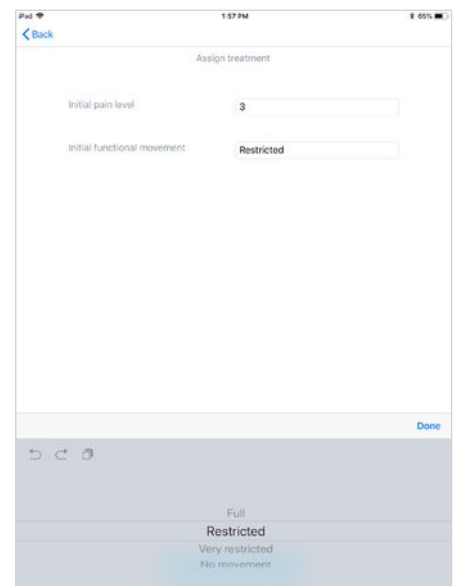
Adding a Patient

1. Select "+Add" at the top of the home screen.
2. Type the patient's email address and select Invite.
3. If a user already has a Kelvi™ account their information will appear in your patient library immediately. If they do not have a Kelvi™ account, their email will be displayed in your patient library and they will be sent an email inviting them to create a Kelvi™ account.



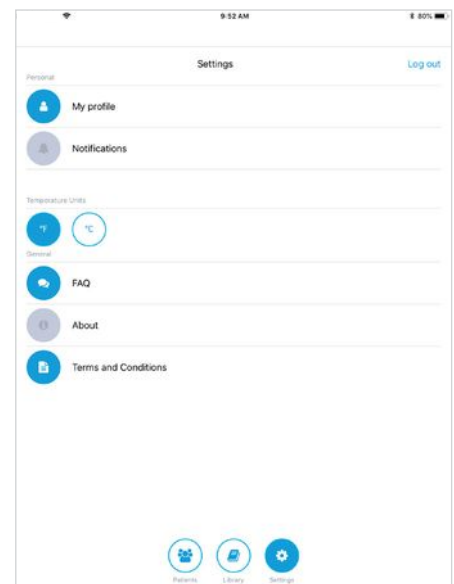
Assigning a Treatment to a Patient

1. Select a saved treatment from the Treatment Library.
2. Select "Assign Treatment" to assign it to a patient.
3. Select "Assign" for the patient you would like to assign the treatment to.
4. Enter the patient's initial pain level and functional movement.
5. Enter a prescribed treatment schedule and duration.
6. Enter any custom treatment directions.
7. Enter the start date of treatment.
8. Select "Save Treatment" to complete the assignment.



Changing Settings

1. Select the "Settings" button from the home screen.
2. On the Settings screen you can view and edit your profile, change your notification and temperature unit settings, or view information about the Kelvi Pro™ System and Mobile App.
3. To view or edit your profile select "My profile".
 - Select "Change Photo" to add or change your profile photo.
 - Edit your name as it appears to others.
 - Select "Save" to save changes.
4. To view or edit your notification settings, select "Notifications".
5. To change temperature units, select °F for Fahrenheit or °C for Celcius. Note that temperature unit selected in Mobile App settings will override the Console settings during a mobile treatment.
6. To view information about the Kelvi Pro™ System, select "FAQ".
7. To view information about the Kelvi™, select "About".
8. To log out of the Kelvi™ select "Log out" at the top of the screen. You will be taken back to the login screen.



Kelvi™ Patient App

To simplify the experience of patients under the care of a licensed healthcare professional, Kelvi™ offers a Kelvi™ Patient App tailored to the patient experience. Patients can create custom treatments or recall treatments prescribed by a clinician.

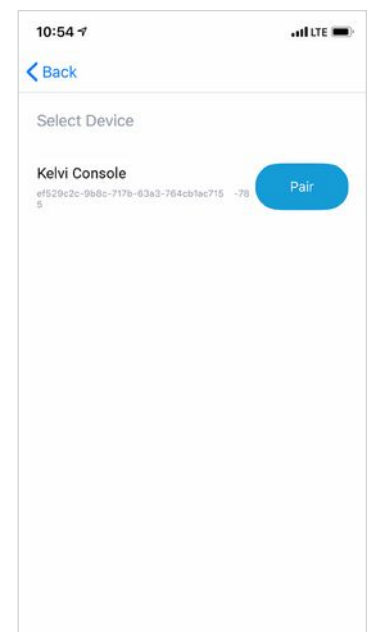
Creating a Treatment

1. To start a treatment, select the "Start new treatment" button on the home screen.
2. The app will display all available Kelvi Pro™ Consoles to execute the treatment.
3. Select the "Pair" button to connect to your Console via Bluetooth. If your Console does not appear, make sure your Console is running and Bluetooth is enabled in the System Settings.
4. Console will display a message indicating successful connection to the Kelvi™ Mobile App.
5. On the app, select "Cool" or "Heat" to indicate the desired treatment type.
6. Select the desired treatment temperature.
7. Select the desired treatment duration.
8. If you wish to add additional steps to the treatment or perform a contrast therapy, select "Add treatment phase". You can add up to 5 treatment phases.
9. Repeat steps 5-8 as needed.
10. Select the desired number of cycles. Treatments can be run up to 15 times.
11. Select "Run Treatment".
12. Fill out and submit the pre-treatment survey to begin.



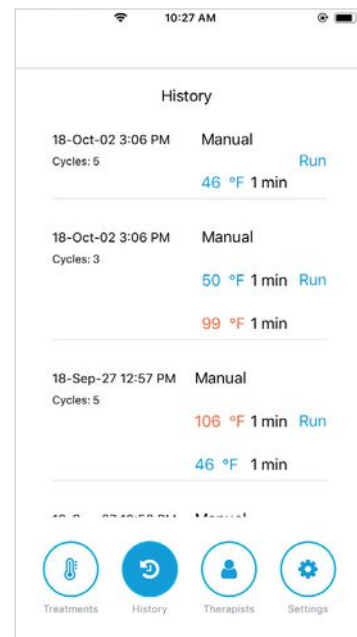
Running a Treatment

1. Select "Start a Treatment" or "Run Treatment" on a saved treatment.
2. The app will display Kelvi Pro™ Consoles available to execute the treatment.
3. Select the "Pair" button to connect to your Console via Bluetooth. If your Console does not appear, make sure Console is running and Bluetooth is enabled in System Settings.
4. Treatment will begin immediately when the app connects to Console.
5. The Mobile App treatment may be stopped or paused as a manual treatment. The treatment may also be stopped by the Mobile App.



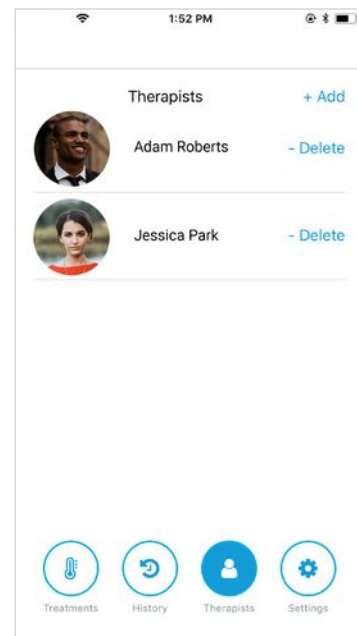
Viewing Treatment History

1. To view a history of recent treatments select the "History" button on the home screen.
2. A list of previous treatments will be displayed. Select "Run" to repeat a previous treatment.



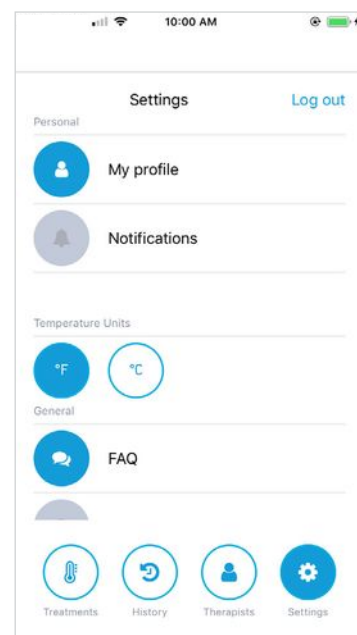
Adding a Clinician

1. To add a clinician who can assign you treatments select the "Clinician" button from the home screen.
2. Select "+Add" at the top of the home screen.
3. Type the clinician's email address and select "Invite".
4. If a user already has a Kelvi™ account their information will appear in your patient library immediately. If they do not have a Kelvi™ account, their email will be displayed in your patient library and they will be sent an email inviting them to create an account.
5. Treatments assigned to you by a clinician will appear on your home screen.



Changing Settings

1. Select the "Settings" button from the home screen.
2. On the Settings screen you can view and edit your profile, change your notification settings, or view information about the Kelvi Pro™ System and mobile app.
3. To view or edit your profile select "My profile".
 - Select "Change Photo" to add or change your profile photo.
 - Edit your name as it appears to others.
 - Select "Save" to save changes.
4. To view or edit your notification settings select "Notifications".
5. To view information about the Kelvi Pro™ System select "FAQ".
6. To view information about the Kelvi™ Patient App select "About".
7. To log out of the Kelvi™ Patient App select "Log out" at the top of the screen. You will be taken back to the login screen.



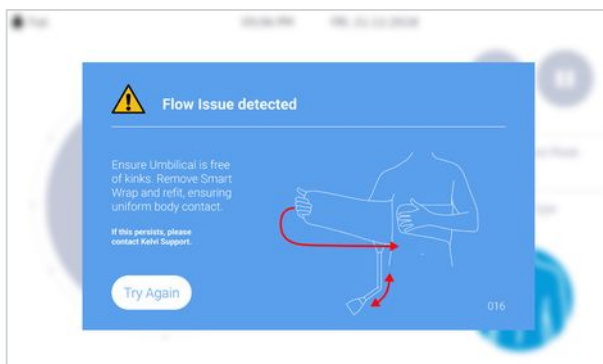
The Kelvi Pro™ System is designed to end treatment and display a notification if conditions are not met for proper usage.

Water Flow Obstruction

To prevent water flow or temperature errors, users must follow these guidelines:

The Kelvi Pro™ System uses flowing water to dissipate heat from the solid state electronics during treatment. A reduction in flow rate can occur when there is a blockage in the flow path. This is often the result of a kink in Smart Wrap™ or Umbilical. If a water flow error occurs (shown below), the following can be done:

1. Adjust Smart Wrap™. When applying Smart Wrap™, ensure that no creases or folds are present. Smart Wrap™ should conform to the contours of the user's body without any significant folds that may cause the fluid flow rate to drop.
2. Adjust body position. Applying pressure to Smart Wrap™ may cause pinch points that reduce flow rate. Try shifting the user's body position to ensure that no obstructions are present.
3. Decrease air pressure. Even when applied correctly, increased air pressure may exacerbate folds or creases in Smart Wrap™ and limit fluid flow rate. If Smart Wrap™ is transferred from one user to another, make sure that the air bladder is fully deflated before applying Smart Wrap™ to the new user to ensure a proper fit.
4. Ensure proper operation of Umbilical. Verify that Umbilical is not kinked or folded over on itself. Also verify that Umbilical is connected securely to Smart Wrap™ and Console. A proper connection is required to ensure there is no drop in water flow.



Error Messages

The Kelvi Pro™ System reports errors or events that may impede proper treatment. If an error occurs, a notification will be displayed on Console and treatment may be stopped if necessary. Errors are a notification about the device's operation - not necessarily an indication of an unsafe condition. The table below will help you correct and reset your Kelvi Pro™ System.

Message	What to Do
Unable to read Smart Wrap. Please ensure that Smart Wrap and Umbilical are firmly connected.	Disconnect Umbilical from Console and Smart Wrap. Reconnect evenly and firmly. An audible "click" will occur when the connectors engage. If this persists with all connections firmly attached, please contact Kelvi Support.
Improper Smart Wrap Fit Detected. Remove Smart Wrap and refit, ensuring uniform body contact.	Remove Smart Wrap from body and refit, ensuring uniform body contact. If this persists, please contact Kelvi Support.
Console Airflow Issue Detected. Ensure vents are free from obstructions.	Ensure the back and side panels of Console are free from obstructions. If vents are blocked or jammed, or if the problem persists, please contact Kelvi Support for assistance
Console Error. Please unplug, disconnect Console and Smart Wrap connections, and restart entire system.	Disconnect Umbilical from Console. Unplug console for 15 seconds and restart the entire system. Reconnect and try again. If this persists, please contact Kelvi Support.
Console Error. Unplug Console power, wait 15 seconds, and try again.	Unplug Console from power source. Wait 15 seconds, plug in Console, and try again. If this persists, please contact Kelvi Support.
Flow Issue Detected. Ensure Umbilical is free of kinks. Remove Smart Wrap and refit, ensuring uniform body contact.	Ensure Umbilical and Smart Wrap are free of kinks. Remove and refit Smart Wrap to ensure uniform body contact. If the problem persists, please contact Kelvi Support
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. If this persists, please contact Kelvi Support.
Console Error. Please ensure Console is level on a flat surface.	The console is designed to function only on flat surfaces with the gray bottom facing down. Relocate Console to a flat, even surface and select "Try Again." If this persists, please contact Kelvi Support
Smart Wrap Issue Detected. We've noticed you've experienced repeated disruption in treatment.	Disconnect Umbilical from Console and Smart Wrap. Reconnect evenly and firmly. An audible "click" will occur when the connectors engage. If this problem persists with all connections firmly attached, please contact Kelvi Support.
Update required. Please perform an update from the Settings > Update Software screen. Console cannot be used without update.	Select the gear icon in the upper right hand corner to enter the Settings menu. Click on "System Settings." Scroll down to "Software Version" and select the blue button displaying an available update.
Bluetooth Not Detected. Unplug Console power, wait 15 seconds, and try again.	Unplug Console from power source. Wait 15 seconds, plug in Console, and try again. If this persists, please contact Kelvi Support.
Wi-Fi Not Detected. Unplug Console power, wait 15 seconds, and try again.	Turn off Console using the Power button and disconnect the power cord from the wall outlet. Reconnect the power cord after 15 seconds. Power on Console and try again. Wifi signal strength is important when downloading software updates. Please ensure that your Wi-Fi signal is strong and consistent and try again. If the problem persists, contact Kelvi Support.
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. If the problem persists, please contact Kelvi Support.
Wi-Fi Not Configured. Configure your Wi-Fi settings and try again.	Clear the message by selecting "OK" then Select the gear icon in the upper right hand corner to enter the Settings menu. Click on the Wi-Fi section and select an available network to connect.
Mobile App Error. Treatment received is outside the Console's allowable temperature range. Please retry sending or select another treatment.	Clear the error by selecting "OK" and completely restart the Kelvi Mobile App. Delete the previous treatment from your Library and reprogram a treatment within the allowable temperature parameters of 43°F (6°C) to 106°F (41°C). Try again. If this message persists, please contact Kelvi Support

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 at (310) 492-5886 for additional guidance.
At any time, the device can be deactivated by disconnecting power cord from the wall outlet, or by removing power cord from Console's power inlet. Smart Wrap™ may also be removed from the user's body or disconnected from Console at any time.

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

Console and Umbilical

(clean and maintain regularly)

Keep all parts of Kelvi Pro™ Console and Umbilical clean and as dust-free as possible. It is recommended that you clean the exterior of the Kelvi Pro™ System with a soft cloth and either a mild detergent or 70% isopropyl alcohol.

Debris such as lint or dust can accumulate in the vents on the side and rear of the Console ports 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)

Care of KelviTEC™ Insert

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



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 damage the device and void its warranty.

Care of Sleeve

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

IMPORTANT: Do not tumble dry, dry clean, iron, or use bleach on the Sleeves.

Maintenance

To maintain optimal performance, the O-rings on Console and 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 in the blue Console connector pocket and three are present on each Smart Wrap™ connector.

Storage

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

If Kelvi Pro™ Console is to be stored for an extended period of time it is recommended that the reservoir be drained and not refilled.

1. Turn off and unplug Console from the outlet.
2. Place Console over a sink or bucket to catch the water.
3. Unscrew the Reservoir Drain Plug (see pg 6)
4. Allow the water to fully drain.
5. Replace and tighten Reservoir Drain Plug

To refill reservoir, follow instructions on pg 16

IMPORTANT: The water inside Console should be disposed of safely. Do not drink or ingest the water that has been circulating in the system. Avoid prolonged skin contact.

IMPORTANT: The Kelvi Pro™ Console comes filled with an antimicrobial treated water. With each refill, please add one drop per liter of Copper Sulfate Solution.

Transportation

Make sure that the Kelvi Pro™ System is powered off and disconnected from the wall outlet before moving. In order to prevent tripping hazards, it is recommended that Smart Wrap™ and Umbilical be disconnected from Console before moving. To move the device around the facility or area of treatment, disconnect from Umbilical and lift Console by using the carrying handle. Smart Wraps™ can be carried by hand, but should never be carried while attached to a user.

To store the Kelvi Pro™ System, disconnect Smart Wrap™ and Umbilical. Disconnect Console from the wall outlet. Umbilical can be gently coiled and stored. Take care not to fold or crease Smart Wrap™, as this may cause kinks that will adversely affect the performance of the device permanently.

Kelvi cases are recommended for storage and travel. Kelvi cases are available for purchase through Kelvi.com

- Hard Console Case: Protective hard shell travel case for your Kelvi Pro™ Console.
- Soft Console Carrier: Carries Kelvi Pro™ Console. Not designed for transportation as a checked bag on airlines.
- Large Smart Case: Protective case sized for Back Pro or Ankle Pro Smart Wraps™.
- Small Smart Case: Protective case sized for Knee Pro or Shoulder Pro Smart Wrap™.
- Soft Smart Case Carrier: Carries array of large and small Smart Cases.

If Kelvi Pro™ System is damaged during transport due to lack of proper care or shipping of materials during transportation the warranty may be voided.

When setting up Kelvi Pro™ System after transportation or storage conditions above or below the specified operating temperature range (see Specifications), please allow 15-30 minutes for the device to return to operating temperature to ensure proper performance.

Labels & User Manual

Symbol	Meaning
	The Kelvi Pro System: Conforms to AAMI ES60601-1 & IEC 60601-1-6 & IEC 60601-1-11 Certified to CSA C22.2 # 60601-1
	Type BF Applied Parts
	Equipment Protection Class II
	Attention: Consult User Manual
	Consult User Manual and follow instructions for use
	Do not dispose of this product or accessories with household/ consumer waste. Contact your local city or municipal waste disposal service to learn where to drop off electrical and electronic waste.
	Manufacturer
	Date of Manufacture
	Serial Number
IP	Ingress Protection
Rx ONLY	Prescription only device
	Warning

Washing

Symbol	Meaning
	Wash gentle cycle at 30°C
	Line dry
	Do not iron
	Do not dry clean
	Do not tumble dry
	Do not bleach

Console

Symbol	Meaning
	Power On/Off
	Stop Button
	Increase air pressure
	Decrease air pressure
	Water Level
	Bluetooth enabled
	WiFi connected

Size	18 x 10.8 x 8.1 in (46 x 27.5 x 21 cm)
Weight	21.5 lbs (9.8 kg) with full reservoir
Input Voltage	100-240V ~ 6A, 50/60Hz
Reservoir Capacity	1 L (0.26 gal)
Smart Wrap™ Temperature Range	4-42 °C (39-108 °F)
Air Pressure	5-75 mmHg
Operating Temperature and Humidity	6-30 °C (43-86 °F) 30-90% relative humidity
Storage Temperature and Humidity	1-52 °C (34-126 °F) 10-90% relative humidity
Operating Altitude	0-9842 ft (0-3000 m)
Classification	Class II ME Equipment
Applied Part	SmartWrap™
Applied Part Type	Type BF Applied Part
Electric Shock Protection	Conforms to AAMI ES60601-1 Certified to CSA C22.2 # 60601-1
Ingress Protection	IP22
Electromagnetic Compatibility	Conforms to IEC 60601-1-2
Bluetooth Support	2.4 GHz
Oxygen Safety	Not suitable for use in an oxygen enriched environment or in the presence of flammable substances.

Essential Performance:

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

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

Supplied Power Cord Specifications: North America

Cord	18 AWG
Plug	NEMA 1-15P
Connector	IEC 60320 C7
Approvals	UL
RoHS	Compliant

IMPORTANT: Use only the power cord supplied with your Kelvi Pro™ System. Replacement power cords can be purchased by contacting Kelvi at (310) 492-5886.

Wireless Connectivity

The Kelvi Pro™ System uses Bluetooth for control capability via the Kelvi™ Mobile Apps 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 therapy to a patient

Kelvi Pro™ Console uses an 802.11 b/g/n secure Wi-Fi connection to download software updates. It requires a Wi-Fi network with a WEP, WPA-PSK, or WPA2-PSK password.

Information Sent over Wireless Communication

Kelvi™ Mobile Apps to Kelvi Pro™ Console over Bluetooth:

1. Kelvi™ Mobile Apps send treatment sets (temperature settings, time durations, and number of cycles).
2. Kelvi Pro™ Console sends the Kelvi™ Mobile Apps notification if an error occurs on Console (error information is displayed on a message on Console screen).
3. Kelvi™ Mobile Apps can send Console a Pause or Stop Treatment command.
4. Kelvi™ Mobile Apps will also send Console instructions on what temperature units to display (°C or °F).

Mobile Device over Wi-Fi or Cellular Data Network:

The Kelvi™ Mobile Apps send:

1. Account authentication and verification.
2. Treatment history.
3. Library and list information (patient list, clinician list, and treatment library).

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 for starting and stopping a Manual Treatment.

Kelvi Pro™ Console over Wi-Fi:

Software updates will be sent over a Wi-Fi 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.

Applicable Standards

The Kelvi Pro™ System conforms to the following standards:

- AAMI ES60601-1 Medical Electrical Equipment - General Requirements for Basic Safety and Essential Performance
- IEC 60601-1-2 Medical Electrical Equipment - Electromagnetic Disturbances
- IEC 60601-1-6 Medical Electrical Equipment - Usability
- IEC 60601-1-11 Medical Electrical Equipment - Home Healthcare

The Kelvi Pro™ System is certified to the following standards

- CSA C22.2 # 60601-1 Medical Electrical Equipment - General Requirements for Basic Safety and Essential Performance.

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 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 environment (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.



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



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



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 Console touchscreen.

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.

Warranty Information

To obtain warranty support, please visit Kelvi.com

Kelvi™ warrants that the Kelvi Pro™ Console, Umbilical, and/or 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. If the Kelvi Pro™ Console, Umbilical, 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™ Console, Umbilical, and/or KelviTEC™ Insert with a separate Kelvi Pro™ Console, Umbilical, 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™ 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™ Console, Umbilical, and/or KelviTEC™ Insert provided to the original purchaser is warranted under the same warranty as the original Kelvi Pro™ Console, Umbilical, and/or KelviTEC™ Insert, and only for the remaining period of the original warranty.

ITEM	STANDARD WARRANTY
Kelvi Pro™ Console	1 Year
Umbilical	1 Year
KelviTEC™ Insert	1 Year
Sleeve	If defective, report within 14 days from receipt for return or repair
Hard Case	If defective, report within 90 days from receipt for return or repair
Soft Case	If defective, report within 90 days from receipt for return or repair

Expected Service Life for the Kelvi Pro™ Console, Umbilical, and KelviTEC™ Insert is 3 Years.

How to obtain warranty service:

To obtain warranty service, contact Kelvi™ Support at (310) 492-5886 or at Kelvi.com. If Kelvi™ authorizes the return of the Kelvi Pro™, 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™ 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™ Console, Umbilical, and/or KelviTEC™ Insert is under warranty. If the Kelvi Pro™ Console, Umbilical, and/or KelviTEC™ Insert is outside the time frame of the warranty, the customer is responsible for all associated costs. If the Kelvi Pro™ Console, Umbilical, and/or KelviTEC™ Insert is not packaged per the given instructions, Kelvi™ is not responsible for any warranty work or 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-transferrable.

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.

Accessories and replacement parts:

Accessories and Replacement Parts can be purchased by contacting Kelvi™ Customer Service. In the U.S. call (310) 492-5886.

Accessories:

- Smart Wraps™ are available for various parts of the body including ankle, back, knee, and shoulder
- Kelvi™ also offers a line of travel cases for the Kelvi Pro™ Console and Smart Wraps™
- Umbilical

Replacement Parts:

- Power Cord
- Copper Sulfate Solution

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:

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© Hypothermia Devices, Inc.
413 N Oak St, Inglewood, CA 90302
Kelvi.com
(310) 492-5886

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