
THERM-X

No Ice Required

The Therm-X does not need ice to stay cool. It uses a special coolant that allows the Therm-X to get colder and stay colder.

Thermal Technology

Using proprietary thermoelectric technology, the Therm-X can provide digitally controlled heating or cooling, along with contrast and compression.

Low Maintenance

The Therm-X does not require constant refilling with ice, or emptying and cleaning the tank. The Therm-X coolant stays in the machine to keep the tank and lines clean.

We Don't Melt

Ice melts over time as ice-based machines pass water over the warm patient. The Therm-X can set a specific cycle temperature and maintain that same temperature for as many treatment cycles required.

You Control It

The Therm-X has a wide variety of treatment presets for temperature, compression, and treatment time. If you don't like presets, the control can be in your hands with customizable cycles.

Smaller Is Better

The Therm-X was born portable, weighing only 14 lbs and fitting in a convenient travel case. It can travel with an athlete or be carried from therapy room to patient room.

Welcome to the Team.

We're glad you're with us.

QUICK START

1

Remove cap, add fluid to red line if necessary, replace cap.

2

Attach the power cord from the power brick to the back of the machine until a “click” is heard.

3

Attach fittings from hose to front of machine until a “click” is heard.

4

If using DVT, fully insert open end of tubing into DVT connector on front of machine.

5

If using DVT, securely attach appropriate DVT garment(s) to foot or calf.

6

Firmly secure the thermal garment to the body.

7

Attach fittings from hose to thermal garment until a “click” is heard.

8

Press “Start Treatment” button on touch screen to begin treatment.

CONTENTS

1 INDICATIONS FOR USE

Therm-X (Therm-X Home and Therm-X AT) combines cold, heat, contrast, and compression therapy. Therm-X is intended to treat post-surgical and acute injuries to reduce edema, swelling, and pain for which cold and compression are indicated. It is intended to treat post traumatic and post-surgical medical and/or surgical conditions for which localized thermal therapy (hot or cold) are indicated.

Therm-X Home systems also provide DVT therapy. Therm-X Home systems with DVT therapy are intended to reduce the risk of the formation of deep venous thrombosis (DVT) by aiding blood flow back to the heart via lower extremity limb compression.

Therm-X (Therm-X Home and Therm-X AT) is intended to be used by, or on the order of, licensed health care professionals in rehabilitation facilities, outpatient clinics, athletic training settings, and home settings.

2 THERM-X FEATURES

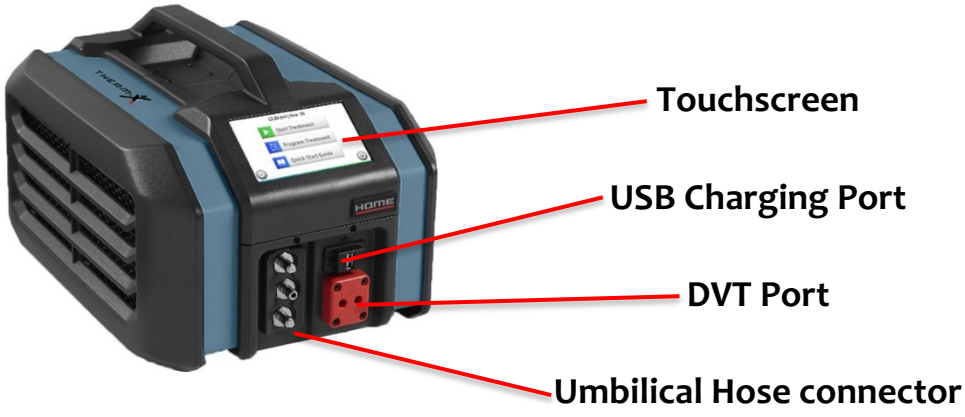
Please read the entire User Manual before operating the Therm-X. There are no user serviceable components inside the Therm-X.

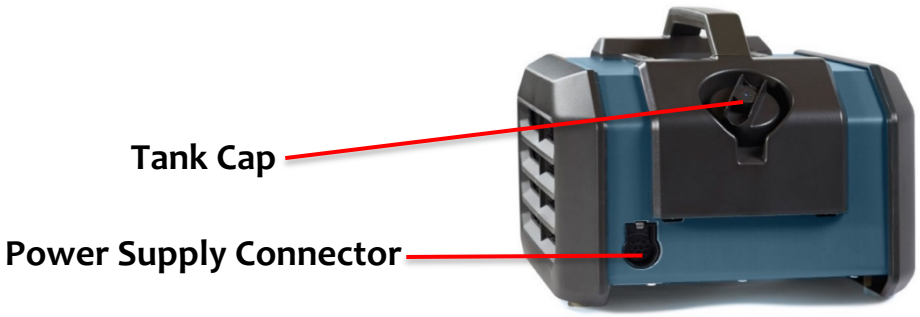
Features

- Easy to use and read touch screen display
- Quiet operation
- Quick Pick therapies commonly used for extended treatments in the home setting
- Programmable therapies, including the ability to have two different treatments stored at once, one to start at a later date
- USB port for charging handheld devices
- Coolant temperature range between 34°F-55°F and 105°F-110°F
- DVT prophylaxis modality for the calf (50 mmHg – 70 mmHg) and foot (90 mmHg – 120 mmHg) *(Home model only)*
- Treatment of edema and lymphedema with compressions of Lite (5 mmHg), Low (20 mmHg), Medium (45 mmHg), and High (70 mmHg)
- 100 V AC-240 V AC, 50/60 Hz operation.
- The option for password protection for the stored treatment to increase patient compliance to the prescribed treatment

3 System Components

What's in the Box?





4 GARMENTS

Instructions for use are provided with each garment.

5 ICONS

	Power Off		**Exit**		**Compression**
	Back		**Help**		**Stop Treatment**
	Select Tool		**Confirm**		**Pause Treatment**
	Scroll		**Resume**		**Temperature**

6 PREPARING YOUR THERM-X SYSTEM FOR USE

These instructions are supplemented by the Quick Start Guide available from the Therm-X home screen.

Unpacking your System

Your Therm-X package will include a Therm-X unit, a power supply, a power cord, a 16-oz. coolant bottle, a Therm-X umbilical hose, and a user manual. Ensure you have all parts of the Therm-X system before proceeding. Please reference the figure in Section 3 for device and components images.

Additionally, you will need a Therm-X garment (sold separately) to operate Therm-X.

Filling the Device

For optimal device performance, purchase Therm-X coolant from your distributor. If you have no coolant available, the easiest way to make it is by purchasing the 91% isopropyl alcohol solution available at most drug stores. Mix 1 gallon (128 ounces) of distilled water with 1 pint (16 ounces) of 91% isopropyl alcohol to create the Therm-X coolant; it is recommended to use the Therm-X coolant sold by Zenith Technical Innovations, LLC.

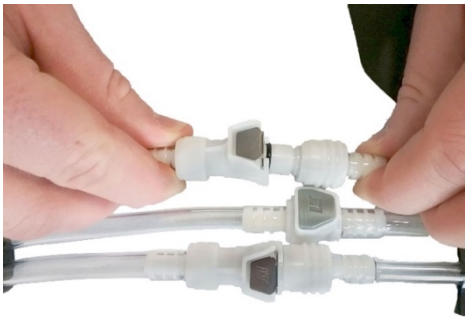
Once you have prepared the coolant mixture, open the tank located at the back of the Therm-X and fill the tank to the red line inside the tank filler neck. It is important whenever filling the Therm-X to fill to the red line.

Attaching the Hoses

Press the 3-in-1 connector into place on the main unit until you hear a click. If you are unable to attach the connector, try pressing and releasing the red button on the side of the hose connector and then trying again.

Attaching the Garments

To attach the garments, align the 3 fittings to their relative ports on the umbilical hose. Press until an audible 'click' is heard. For further instruction, please reference individual garment guides, available with the garment or for download at thermxtherapy.com.

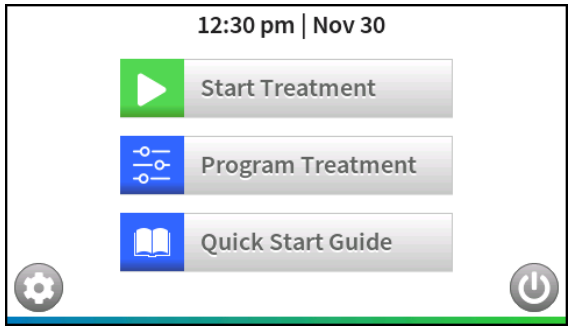


7 OPERATING INSTRUCTIONS FOR PATIENTS

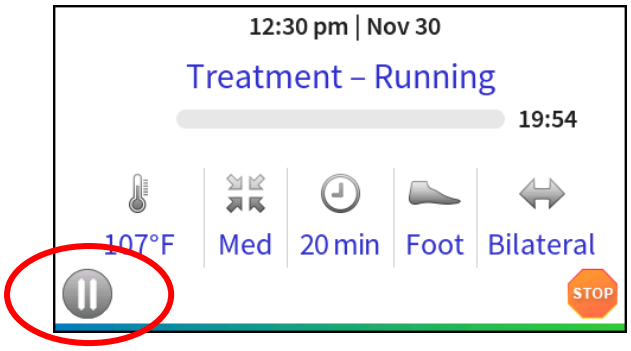
Before use, please read Section 16, "Contraindications" and Section 17, "General Precautions and Warnings"

Connect the power supply to the Therm-X main unit and an AC outlet. When the unit initiates, it will beep briefly and the Therm-X logo will briefly appear followed by the Home Screen.

The Therm-X will come pre-programmed by your healthcare provider with a custom cycle for use. To initiate the pre-programmed therapy, follow all instructions in the 'Preparing your Therm-X for Use', including unpacking the machine, filling the coolant tank, and attaching the hose and garment. Then select the "Start Treatment" button from the Home screen.



Once the cycle has been initiated you will feel the garment inflate and fluid flow. The 'Treatment Running' screen will appear and will show the current cycle settings, a progress bar, timer, and 'Stop' and 'Pause' buttons. The unit will run through the end of the prescribed cycle automatically.

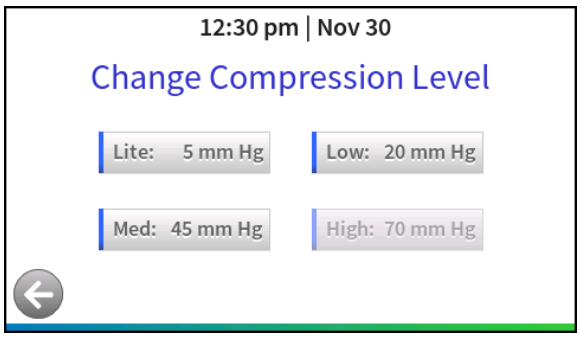


You may stop the cycle and return to the 'Home' screen at any time by selecting the "Stop" button.

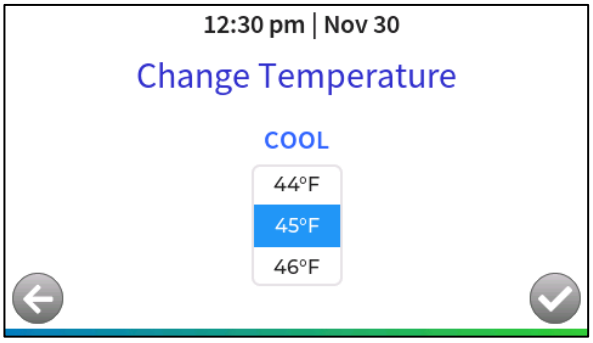
You may pause the cycle at any time by selecting the 'Pause' button, and resume the cycle by again pressing the 'Resume' button.

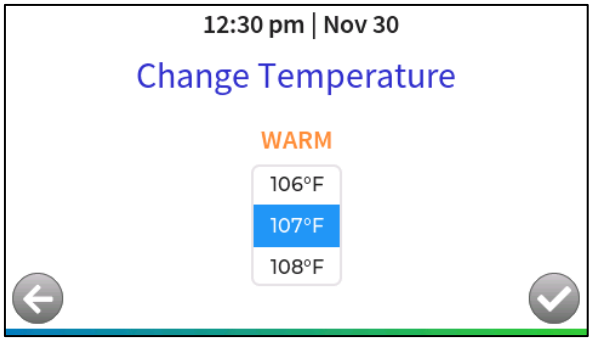
You may adjust the temperature or compression level of the treatment cycle during a running treatment by selecting the 'Compression' or 'Temperature' symbol.

To change the compression level, select the 'Compression' symbol then select one of the available compression levels. You may adjust the 'Compression' level as many times as needed during a cycle. Note: compression levels may only be changed to a compression level equal to or lower than the programmed treatment. If compression was programmed, compression may not be turned off.

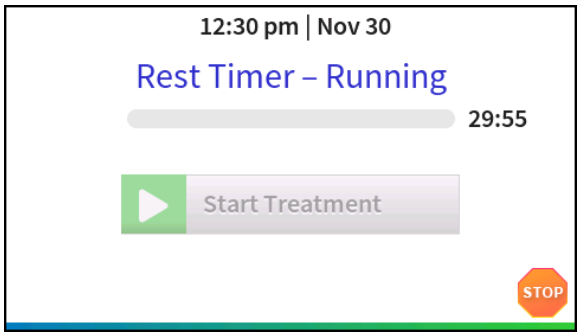


To change the temperature of a treatment, select the 'Temperature' symbol, then select one of the available temperatures. You may adjust the temperature as many times as needed during a cycle. *Note: Temperatures may only be changed to a temperature equal to or closer to room temperature than the programmed treatment.*





Once the prescribed treatment is complete, the machine will beep, and the prescribed Rest Timer will begin. The amount of time remaining in the rest cycle will display to the right of the progress bar.

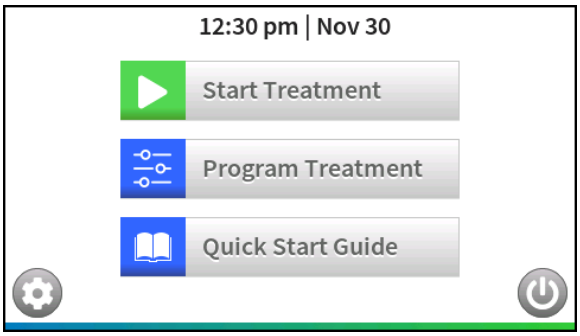


8 Operating Instructions For Healthcare Providers

Before use, please read Section 17, "Contraindications", and Section 18, "Precautions and Warnings"

If you are a certified healthcare provider, you may program the device for therapy using the following instructions:

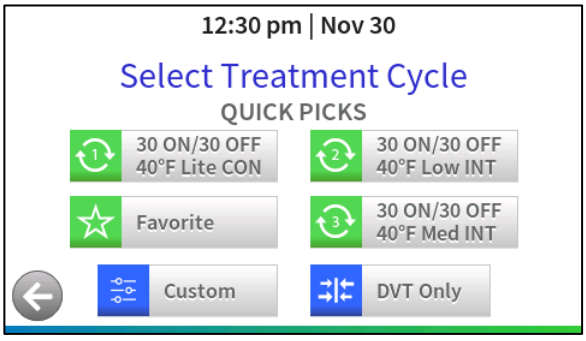
Connect the power supply to the Therm-X main unit and an AC outlet. When the unit initiates it will beep briefly and the Therm-X logo will briefly appear followed by the Home Screen.



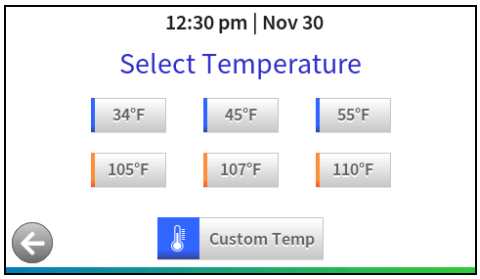
Programming a Therapy

Certified users will be able to program a variety of therapies for Therm-X using cryotherapy, thermotherapy, and DVT prophylaxis options.

From the Home Screen, select "Program Treatment". If the password is enabled, you must enter it before proceeding. Use the password you received with your machine. For more information on passwords, please see System Tools on page **16**. The 'Select Treatment Cycle' screen will then appear. This screen will have a variety of Quick Picks available for selection based on commonly prescribed treatments. There will also be a "Custom" button, a "DVT Only" button, and a "Back" button that will return you to the home screen.

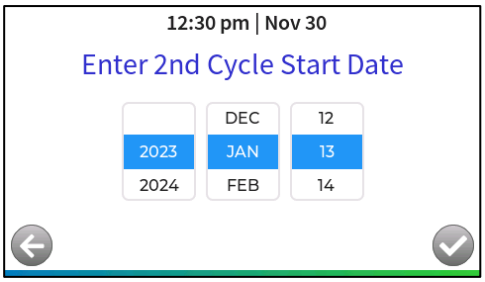


Upon selecting a Quick Pick, the temperature, compression level, and time of the cycle will be preloaded. On this screen, you will be able to select buttons for "Add 2nd Cycle" (if available), "Add DVT" (if available), "Confirm", or "Back" to return to the 'Select Treatment Cycle' screen. The "Confirm" button will enter the chosen cycle into the system's memory. See more about Quick Picks on page **14**.

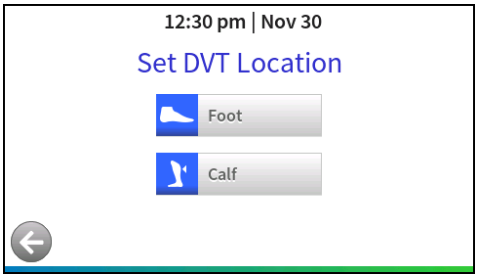


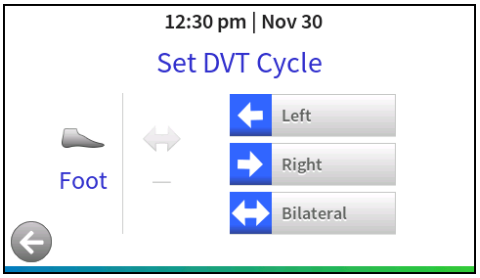
When the "Add 2nd Cycle" button is selected, the unit will present the 'Select Temperature' screen. The purpose of this button is to program a second cycle that will initiate at a future date.

After entering the treatment specifics, you will then be asked to identify a 2nd program start date. This is the date at which the prescribed cycle in the machine will switch from the 1st programmed cycle to the 2nd. Use the scrolling wheels to change the date, the "Confirm" button to save the cycles, and the "Back" button to return to the 2nd cycle selection screens.



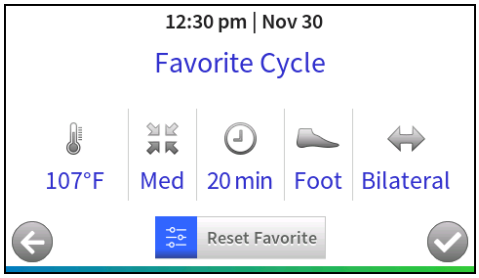
When the "Add DVT" button is selected, the unit will present the 'Set DVT Location' screen. This screen will have options available for "Foot" and "Calf" DVT locations, as well as a "Back" button that will return you to the "Cycle Selection" screen. Selecting a DVT location will allow you to proceed to the next step in setting a DVT cycle.





After the location is selected, you will be prompted to choose between a "Left", "Right", or "Bilateral" (both left and right) cycle on the 'Set DVT Cycle' screen. This choice will indicate on which side the DVT prophylaxis occurs. There is also a "Back" button to return to the 'Set DVT Location' screen. Once a DVT choice is made, the Therm-X will redirect to the 'Finish 1st Programmed Cycle' Screen.

On the 'Finish 1st Programmed Cycle' screen, icons are available for "Back" and "Confirm". "Confirm" will store the cycle and return you to the Home screen, and "Back" will return you to the 'Set DVT Cycle' screen.

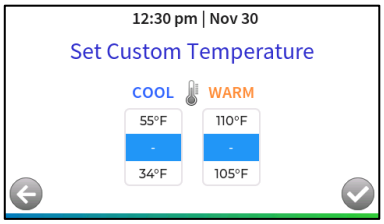


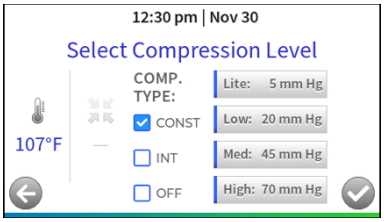
Customizing a Cycle

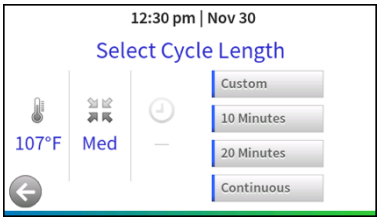
If a cycle other than a Quick Pick or Favorite is desired, you will be able to customize a cycle from the "Custom" button on the Select Treatment Program screen. *(Please note: Custom cycles are single-use only. If you would like to retain your custom cycle for future use, please see the "Quick Picks and Favorites" section.)*

Once the "Custom" button is chosen, you will navigate to the 'Select Temperature' screen. "Custom" will allow a choice from the range of either 34°-55°F or 105-110°F, unless the cycle chosen will be Continuous, which will alternate between active and resting treatment continuously until the Stop icon or Pause icon is pressed. The temperature range available for Continuous treatment is more conservative; 40°-55°F for cold, and 105°-107°F for warm therapy. For more information, see the "Continuous Treatment" section on page 14.

After the temperature in the custom cycle is chosen, the Therm-X will prompt you to select a pressure value on the 'Select Compression Level' screen. There are four levels of compression available to select, as well as a toggle button to turn the compression off, or select either constant or intermittent compression. There is also a "Back" button to return to the 'Select Temperature' screen. The compression range available for Continuous treatment is more conservative; High pressure is not available. Intermittent compression is not available during a cycle with Lite compression.



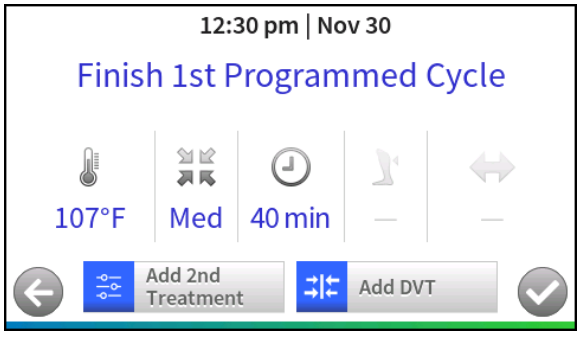




After the compression level is chosen, the Therm-X will prompt you to select a cycle length value on the 'Select Cycle Length' screen. You may select either of the preset times, create a custom duration, or access the continuous option. There will also be a "Back" button to return to the 'Select Compression Level' screen.

After the cycle length cycle is made, a complete cycle will have been created. On the 'Finish 1st Programmed Cycle' Screen you will then have options to "Add 2nd Cycle", "Add DVT", "Confirm" to return to the 'Home' screen and store the cycle, or "Back" to return to the 'Select Cycle Length' screen.

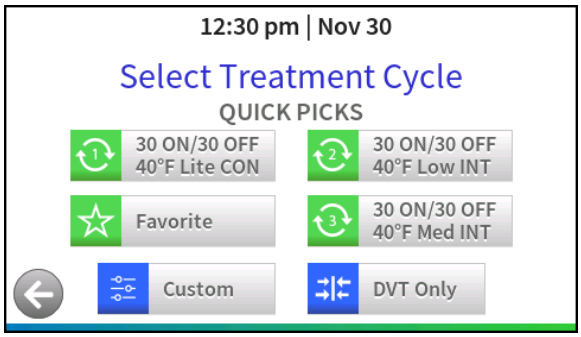
At this point it is possible to use the "Add 2nd Treatment" or "Add DVT" options if they are accessible. Please refer to page **13** for itemized instructions.

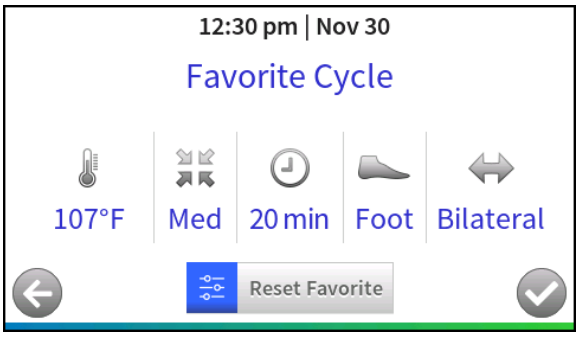


Quick Picks and Favorites

Your Therm-X will come preloaded with 3 commonly-prescribed therapies.

- Quick Pick 1, 30 minute treatment, 30 minute rest, 40°F, lite constant compression, continuous treatment.
- Quick Pick 2, 30 minute treatment, 30 minute rest, 40°F, low intermittent compression, continuous treatment.
- Quick Pick 3, 30 minute treatment, 30 minute rest, 40°F, medium intermittent compression, continuous treatment.

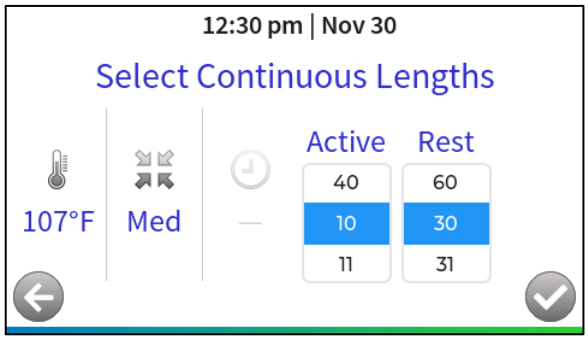




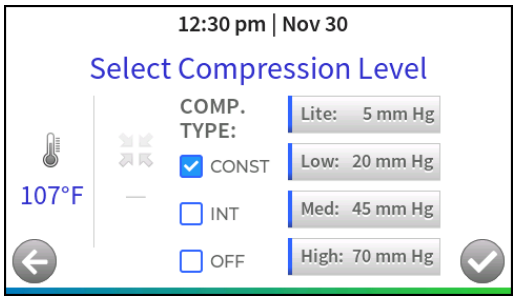
You may add a favorite program quick pick. This allows you to program a favorite treatment for quicker selection when treating multiple patients. The software will allow you to program one treatment along with DVT on your Home model. You can reprogram the Favorite treatment by selecting the Favorite treatment and pressing "Reset Favorite."

Continuous Treatment

You may select the "Continuous" button to set the duration of treatment (10-40 minutes) and the duration of rest (30-60 minutes). A continuous treatment will alternate between active and resting treatment continuously until the Stop icon or Pause icon is pressed. This treatment will apply 5 mm Hg compression to the thermal garment during the rest timer.



In you have already selected a temperature lower than 40°F or higher than 107°F, or a compression level of 'High' while programming a 'Continuous' treatment, the software will automatically adjust the temperature and compression to a more conservative choice; 40°F for a cold cycle, 107°F for a warm cycle, and Medium pressure. A continuous cycle cannot be run outside of these parameters.



Thermal Garment Compression

For thermal garment compression, no compression, constant, or intermittent pressure may be selected.

If constant pressure is selected, the thermal garment will fill to the selected pressure, and remain at that pressure for the duration of the treatment cycle.

If intermittent pressure is selected, the thermal garment will fill to the selected pressure, will hold and then release the selected pressure in cyclic fashion for the duration of the treatment. Intermittent compression is not available during a cycle with Lite compression.

DVT Garment Compression

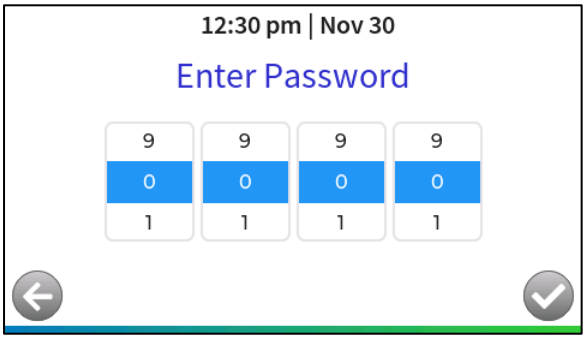
DVT treatment may be programmed with any thermal treatment cycle, or selected as an independent treatment from the Select Treatment Cycle screen. If one DVT garment is being used, compression will increase and release throughout the course of the treatment (one minute of pulsing compression, one minute of rest). If two DVT garments are being used, treatment will alternate from one garment to another and pressure will increase and release throughout the course of the treatment.

Pause Treatment

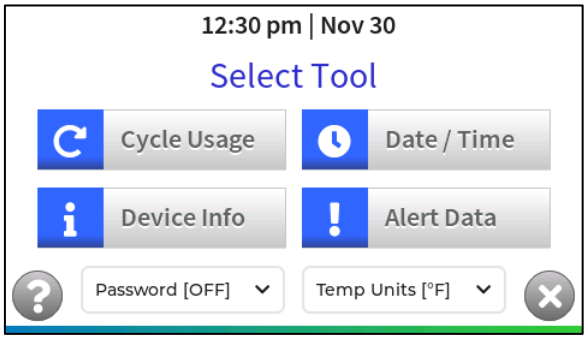
You may pause treatment at any time, using the Pause button on the bottom left corner of the Therm-X touchscreen. Pausing treatment will release all garment pressure and stop warming or cooling the thermal garment. You may resume treatment by pressing "Resume."

9 System Tools

To navigate to the System Tools screen from the Home screen you must first select the "Settings" button in the lower left corner of your Therm-X touchscreen. A password screen will appear if the password is enabled. Use the password that you received with your machine. You will have a maximum of 5 attempts to input the correct password. If too many incorrect attempts are made, the machine will display an error and you will need to restart it before resuming use of the machine. The Settings screen will display immediately if the password is disabled. The password may be toggled on and off by selecting the "Password" button. By enabling the password, you will be able to ensure that unauthorized users are unable to change the stored cycle.



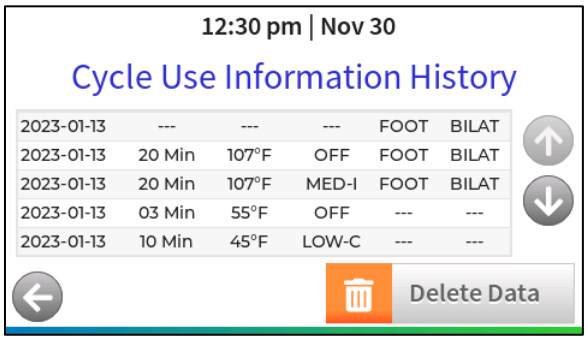
Once you reach the Select Tool screen you will be given the selections of "Cycle Usage", "Date/Time", "Device Info", "Alert Data", "Toggle Password", "Temperature Units", "Help", and "Cancel".

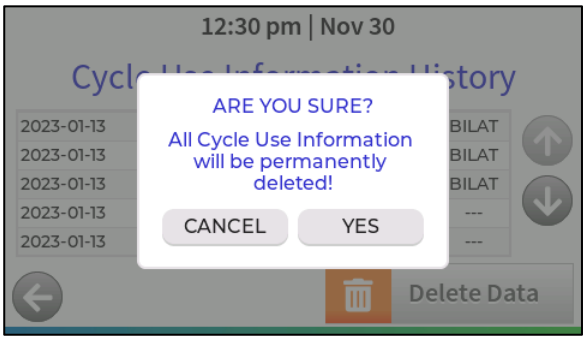


The password may be toggled on and off by selecting the "Toggle Password" button. Each time the button is selected the password status will change. By enabling the password, you will be able to ensure that unauthorized users are unable to change the stored cycle.

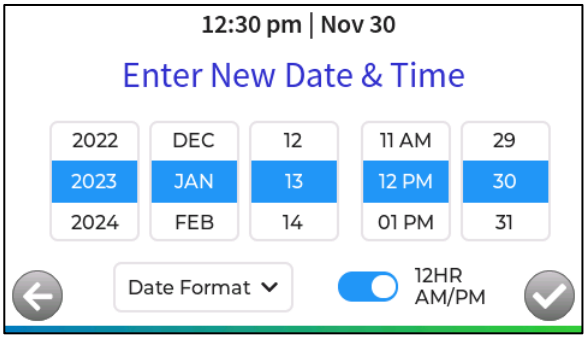
The format in which the temperature is displayed, Fahrenheit or Celsius, can be toggled by selecting the "Temp Units" button, and selecting the desired unit of display.

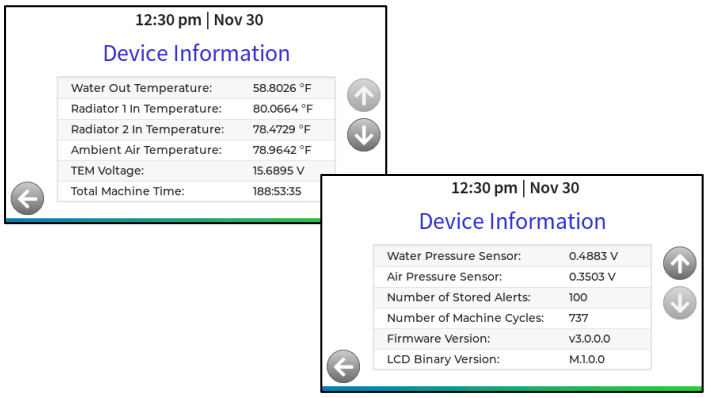
The Cycle Use Information History screen can be reached by selecting the "Cycle Usage" button. It will display the past cycles run on the unit which may be scrolled through using the arrows on the right of the screen. Additionally, there will be a "Back" button to return you to the Select Tool screen and a "Delete?" button. The "Delete?" button will prompt an alert to confirm the previous cycle's information is deleted.





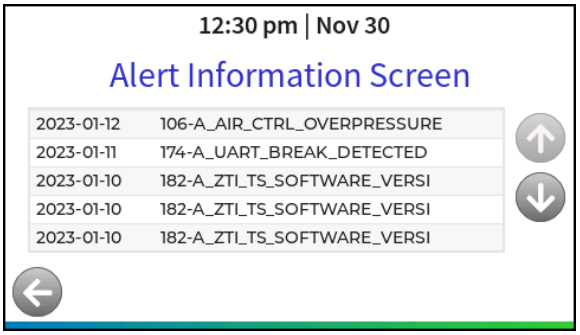
The ‘Enter New Date & Time’ screen can be reached by selecting the “Date/Time” button. On this screen you may select the date and time by scrolling the desired value. There will also be a “Back” button to return to the ‘Select Tool’ screen, and a “Confirm” button to store the date and time you have chosen. This screen also provides the option to toggle the date on/off or into different formats, and to toggle the 12HR AM/PM format off and display time in the 24HR format.

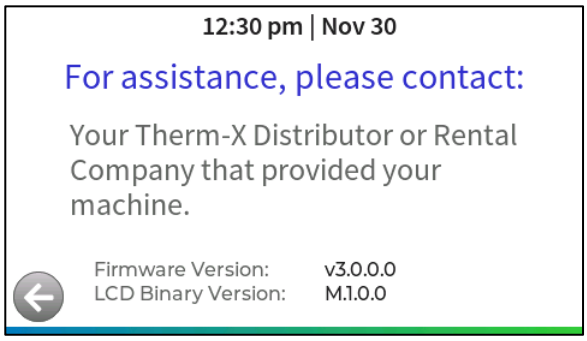




The Device Information screen can be reached by selecting the “Device Info” button. This screen will display a variety of metrics about the unit and its environment. You may navigate through these metrics using the “Up” and “Down” arrow buttons on the right of the screen. There will also be a “Back” button to return to the Select Tool screen.

The Alert Information screen can be reached by selecting the “Alert Data” button. This screen will display the alerts that have occurred for this unit. You may navigate through these past alerts using the “Up” and “Down” arrow buttons on the right of the screen. There will also be a “Back” button to return to the Select Tool screen.





The Assistance screen may be reached by selecting the “Help” button. It will also have a “Back” button to return you to the Select Tool screen.

10 CARING FOR YOUR THERM-X SYSTEM

Cleaning

Therm-X Device

The interior of the Therm-X does not need to be cleaned; there is no need to empty and replace the coolant in the tank.

To clean the exterior of the device, wipe down the exterior with an alcohol cleaning pad or equivalent soft cloth with a mild cleaning product. The device should be cleaned whenever it encounters bodily fluids or between patients. Do not use solvent based cleaners or abrasive materials.

Use compressed air to ensure the radiator grill of the Therm-X device remains clear of dust and debris as needed.

Garments

Please refer to the individual Garment Manual that came with your garment for cleaning instructions.

Umbilical Hose

Between uses, the umbilical hose may be wiped down with an alcohol cleaning pad or equivalent soft cloth with a mild cleaning product. Do not use solvent based cleaners or abrasive materials to clean the umbilical hose.

Storage

Therm-X Device

The device should be stored without coolant in a temperature range of +33°F to +122°F in below 60% non-condensing humidity. Devices with coolant content must be stored above +32°F (0°C).

To drain the unit, first turn the unit off and unplug it from its electrical source. Disconnect all hoses from the unit. Remove the coolant reservoir cap from the unit by twisting it counter-clockwise. Lift the unit with both hands and tip it backwards to empty the coolant into a bucket or sink. Continue to tip the unit until the reservoir is completely empty.

Garments

Garments without coolant contents may be stored in the same environment as the device, in a temperature range of +33°F to +122°F in below 60% non-condensing humidity. Garments with coolant content must be stored above +32°F (0°C).

Disposal

Therm-X Device

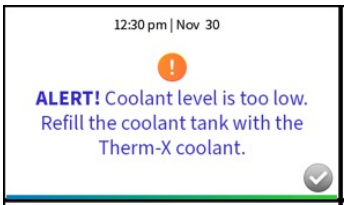
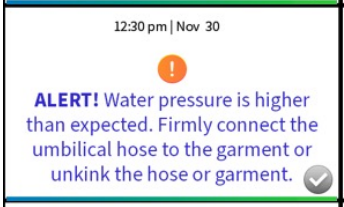
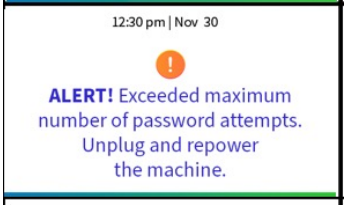
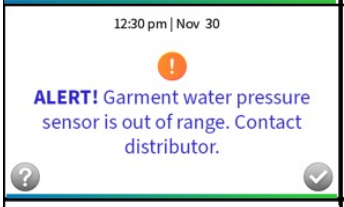
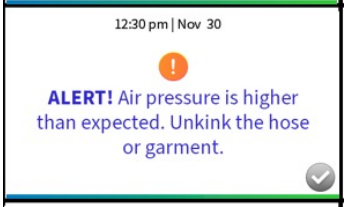
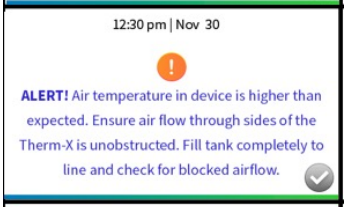
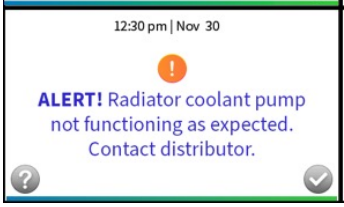
The device and device components can be disposed in accordance with local regulations.

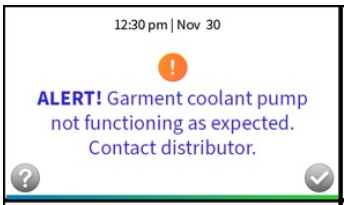
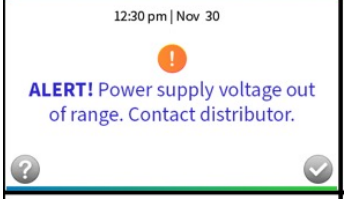
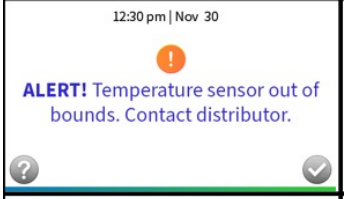
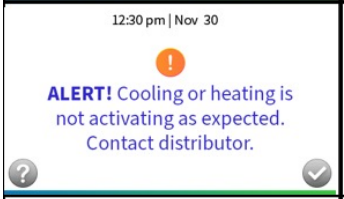
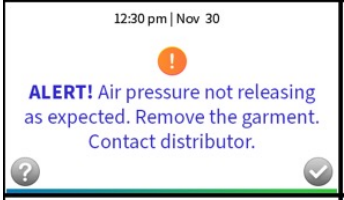
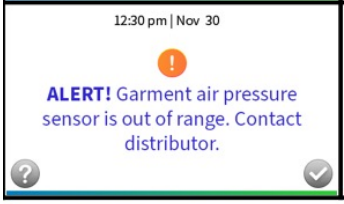
Garments

Garments may be disposed of as regular waste.

11 ALERTS

The table below can guide you through possible alerts you may observe while using your Therm-X Home device.

	This alert occurs when the Therm-X senses that the fluid level in the device is low. Refill the device's tank to address the problem.
	This alert occurs when the pressure level in the device is high. Ensure that the umbilical hose is firmly connected on both the garment and device end. Detach and reattach the garment to the user.
	This alert occurs when the Therm-X is used in a room outside of the temperature range required. Ensure that you are using the device within the required temperature range.
	This alert occurs when too many attempts are taken to surpass the password screen. Power down the device and restart it to unlock the device. Do not attempt to access the password loop if you are not a certified user.
	This alert occurs when the garment water pressure sensor is detecting an unexpected pressure. Ensure that the umbilical hose is firmly connected on both the garment and device end. Detach and reattach the garment to the user. Turn off and repower the device on.
	This alert occurs when the air pressure is higher than expected. Ensure that the umbilical hose or DVT hoses are unkinked. Detach and reattach the garment to the user.
	This alert occurs when the air temperature in the device is higher than expected. This error usually occurs when the vents on the side of the device are blocked, ensure that airflow through the device is not obstructed.
	This alert occurs when the radiator coolant pump is not functioning correctly. Try restarting the device. If the alert persists, contact the distributor.

	This alert occurs when the garment coolant pump is not functioning correctly. Try restarting the device. If the alert persists, contact the distributor.
	This alert occurs when the power supply is out of the expected range. Try restarting the device. If the alert persists, contact the distributor.
	This alert occurs when the temperature sensor is reading an unexpected temperature. Try restarting the device. If the alert persists, contact the distributor.
	This alert occurs when the device is not cooling or heating as it is expected to. Try restarting the device. If the alert persists, contact the distributor.
	This alert occurs when the device is unexpectedly retaining air pressure. Immediately remove all garments. Try restarting the device and reattaching the garments. If the alert persists, contact the distributor.
	This alert occurs when either the garment is wrapped too loosely to apply pressure or the air pump is not functioning correctly. Detach and reattach the garments to the user. Try restarting the device. If the alert persists, contact the distributor.
	This alert occurs when the air pressure sensor is detecting an unexpected pressure. Try restarting the device. If the alert persists, contact the distributor.

12 ACCESSORIES AND REPLACEMENT PARTS

Replacement parts may be ordered by contacting Zenith Technical Innovations at:

customerservice@thermxtherapy.com

847.672.7481

Device Accessories

Model Number	Description
TX0206	**Therm-X Coolant (1 quart) –** The coolant that is recommended for use in the Therm-X device
TX0208	**Split Umbilical Hose –** Hose for simultaneous treatment of two patients or anatomical areas* **The Split Umbilical Hose is only compatible with the Therm-X AT device* 
TX0202	**Carrying Case –** The carrying case for your Therm-X device
TX0207	**Hospital Grade Power Supply**
TX0109	**Therm-X Extender Straps** – Fabric hook and loop straps to increase the overall length of garment straps 

Garments

Model Number	Description
TX0107	**Calf DVT Garment –** The DVT prophylaxis garment designed for your calf
TX0106	**Foot DVT Garment –** The DVT prophylaxis garment designed for your foot
TX0102	**Knee Thermal Garment –** The multi-patient use thermal garment designed for your knee
TX0105	**Back Thermal Garment –** The multi-patient use thermal garment designed for your back
TX0101	**Shoulder Thermal Garment –** The multi-patient use thermal garment designed for your shoulder
TX0110	**XL Shoulder Thermal Garment** - The multi-patient use extra large thermal garment designed for your shoulder
TX0104	**Ankle Thermal Garment –** The multi-patient use thermal garment designed for your ankle
TX0103	**Elbow Thermal Garment –** The multi-patient use thermal garment designed for your elbow
TX0108	**Hip Thermal Garment –** The multi-patient use thermal garment designed for your hip
TX0111	**Half-Leg Thermal Garment –** The multi-patient use thermal garment designed for your lower leg
TX0112	**Hand Thermal Garment –** The multi-patient use thermal garment designed for your hand/wrist

Model Number	Description
TX0302	**Knee SPU Thermal Garment –** The single-patient use thermal garment designed for your knee
TX0301	**Shoulder SPU Thermal Garment –** The single-patient use thermal garment designed for your shoulder
TX0304	**Ankle SPU Thermal Garment –** The single-patient use thermal garment designed for your ankle
TX0305	**Back SPU Thermal Garment -** The single-patient use thermal garment designed for your back
TX0308	**Hip SPU Thermal Garment –** The single-patient use thermal garment designed for your hip
TX0312	**Hand SPU Thermal Garment** - The single-patient use thermal garment designed for your hand/wrist
TX0313	**Cervical SPU Thermal Garment** - The single-patient use thermal garment designed for your neck
TX0314	**Butterfly Knee Large, SPU Thermal Garment** - The large single-patient use thermal garment designed for your knee
TX0315	**Butterfly Knee Small, SPU Thermal Garment** - The small single-patient use thermal garment designed for your knee

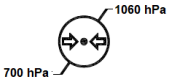
13 Acronyms and Definitions

Acronym/ Term	Definition
DVT	Deep Vein Thrombosis
ESD	Electrostatic discharge
IFU	Instructions for Use
RF	Radio Frequency
USB	Universal Serial Bus; USB interface
Certified User	User with the ability to create or modify treatment cycles

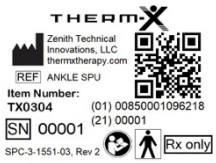
14 Symbols and Abbreviations on Product and Packaging

Therm-X Device

Symbol/Term	Significance
A	Ampere
Hz	Hertz
IP21	Degree of protection against: Touch by fingers and objects with Ø ≥ 12.5 mm Vertically falling drops shall have no harmful effect
VA	Volt-ampere (power)
V~ / VAC	Alternating current
VDC	Direct current
	Identification label
REF	Product number
SN	Serial number
	Manufacturer
	Caution! There are specific warnings and precautions associated with this device.
	Consult the instructions for use
	USB connection
	On/Off button
	Temperature Limitation (Temperature must be between 60°F - 80°F)

Symbol/Term	Significance
	Humidity Limitation (Humidity must be below 60%)
	Atmospheric pressure Limitation (Atmospheric pressure must be between 700 hPa and 1060 hPa)
	Class II ME equipment
Rx only	Caution: Federal law restricts this device to sale by or on the order of a physician

Garments

Symbol/Term	Significance
	Identification label
REF	Product number
SN	Serial number
LOT	Lot number
	Manufacturer
	Caution! There are specific warnings and precautions associated with this device.
	Follow instructions for use
	Type BF applied part
Rx only	Caution: Federal law restricts this device to sale by or on the order of a physician

Packaging

Symbol/Term	Significance
	Temperature Limitation
	Humidity Limitation
	Pressure Limitation

15 PRODUCT SPECIFICATIONS AND TECHNICAL DATA

Device Functional Specifications

Parameter	Value
Cold Therapy Temperature Range	
Default	34°F, 45°F or 55°F
Custom	34°F - 55°F
Continuous Cycle Length	40°F - 55°F
Heat Therapy Temperature Range	
Default	105°F, 107°F or 110 °F
Custom	105°F - 110°F
Continuous Cycle Length	105°F - 107°F
Cycle Length	
Default:	10 or 20 minutes
Custom:	3-40 minutes
Continuous Cycle Length:	Active: 10-40 minutes, rest: 30-60 minutes
Edema Pressure Range	
Off	0 mm Hg
Lite	5 mm Hg
Low	20 mm Hg
Medium	45 mm Hg
High	70 mm Hg
DVT Pressure Range	
Calf	50 - 70 mm Hg
Foot	90-120 mm Hg
Measured Skin Temperature	
Maximum Skin Temperature	Skin temperature measured as high as 107.61°F (42°C) when set to maximum Heat Reservoir set point for a 40 minute cycle length (110°F)
Minimum Skin Temperature	Skin Temperature measured as low as 40°F (4.44°C) when set to minimum Cold Reservoir set point for a continuous cycle length (40°F)

Device Physical Specifications

Parameter	Value
Dimensions of Device	
Dimensions (L x W x H)	10" W x 9" H x 15" L
Weight	14lbs. maximum when empty and 15 lbs. maximum with fluid.
Umbilical Hose (with Therm-X AT)	
Length	5 ft +/- 0.5 ft
Type	3-in-1 connector for multi-patient use garments
DME Umbilical Hose (with Therm-X Home)	
Length	5 ft +/- 0.5 ft
Type	3 individual connectors for single-patient use garments
Split Umbilical Hose (purchased separately)	
Length	1 ft hose connected to two discreet sections of 4 ft +/- 0.5 ft hose
Type	Two 3-in-1 connectors for multi-patient use garments
Classifications	
Information about IEC 60601-1 classification	
Class of protection against electric shock	II
Protection against accidental contact and ingress of solid foreign bodies Protection against penetration of liquids	IP21 Degree of protection against: Touch by fingers and objects with Ø ≥ 12.5 mm Vertically falling drops shall have no harmful effect
Degree of safety in the presence of flammable anesthetics or oxygen:	Not suitable for use in an oxygen enriched environment or in the presence of flammable anesthetics
Power Supply	
Type:	IEC 60601-1 compliant, 2x MOPP medical grade
Line Voltage:	100 V AC – 240 V AC
Frequency	50/60 Hz (automatic)
Coolant	
Formulation	90% Distilled Water, 10% Isopropyl Alcohol
Capacity	650 ml
Standards	
Structural safety	IEC 60601-1

Parameter	Value
EMC	IEC 60601-1-2
Interference suppression	EN 55011: Class B
Interference immunity	IEC 61000-3, Part 2, Part 3 IEC 61000-4, Parts 2-6, Part 8, Part 11

Garment Specifications

Parameter	Value
Applied part type	BF
Patient contacting material	Multi-Patient Use Thermal Garment: 30 Denier Nylon Ripstop coated in urethane Single-Patient Use Thermal Garment: 200 Denier Nylon Oxford coated in urethane DVT Garment: 200 Denier Nylon Oxford coated in urethane

Environmental Conditions for Operating Your Therm-X Device

Parameter	Value
Temperature range	
In operation	+60°F to +80°F
During storage/transport	+33°F to +122°F
Humidity	
In operation	Below 60% non-condensing
During storage/transport	Below 60% non-condensing
Atmospheric pressure	
In operation	700 hPa – 1060 hPa
During storage/transport	700 hPa – 1060 hPa

16 CONTRAINDICATIONS

Pneumatic Compression Therapy

Do not use the device without a licensed healthcare practitioner prescription.
NOTE: The prescription must show the time, temperature range, pressure, duration, and frequency of use of the device. Make sure you fully understand the use of the device before starting.

The patient should NOT use the therapy system if the patient is suspected of or observed to have any of the following pre-existing conditions.

- Presumptive evidence of congestive heart failure
- Pre-existing DVT condition
- Deep acute venal thrombosis (Phlebothrombosis)
- Inflammatory phlebitis process
- Episodes of pulmonary embolism
- Pulmonary edema
- Acute inflammation of the veins (Thrombophlebitis)
- Decompensated cardiac insufficiency
- Arterial dysregulation
- Erysipelas
- Carcinoma and carcinoma metastasis in the affected extremity
- Decompensated hypertonia
- Acute inflammatory skin diseases or infection
- Venous or arterial occlusive disease
- Venous or lymphatic return is undesirable
- Poor peripheral circulation
- Severe arteriosclerosis, or active infection

Contraindications for Heat and Cold Therapy

Do not use the device without a licensed healthcare practitioner prescription.
NOTE: The prescription must show the time, temperature range, pressure, duration, and frequency of use of the device. Make sure you fully understand the use of the device before starting.

The patient should NOT use the therapy system if the patient is suspected of or observed to have any of the following pre-existing conditions.

Do not use on patients with Raynaud's phenomenon or other vasospastic conditions, cold allergy, cold agglutinin disorders like paroxysmal cold hemoglobinuria, Buerger's disease, Chilblains, cryoglobulinemia, sickle cell anemia, diabetes, hypersensitivity to cold or heat, history of cold injury, severe cardiovascular disease, anesthetic skin, hypercoagulation disorders, poor circulation, extremities sensitive to pain, extremely low blood pressure that are incapacitated, decreased skin sensitivity, vein ligation or recent skin grafts, or pheochromocytoma.

While using the device you should check the skin condition every hour for increased redness, discoloration, itching, swelling, blisters, irritation and other changes. If any unusual conditions occur, immediately discontinue using Therm-X and contact your physician.

Exercise special precautions for children under 12, pregnant users, hypercoagulation disorders, diabetes, neuropathies, arthritic conditions, diabetes peripheral vascular disease, and patients with decreased skin sensitivity.

Check for moisture on the therapy garment before placing on the skin. Remove any moisture before use.

The following patients must use Therm-X for temperature therapy under the supervision of a physician if they are:

- Patients with extremities not sensitive to pain
- Patients with Extremely low blood pressure
- Patients with Raynaud's disease
- Hypersensitivity to cold
- Children under 12
- Diabetics
- Incapacitated patients
- Patients with decreased skin sensitivity
- Patients with poor circulation
- Patients with vein ligation or recent skin grafts

17 General Precautions and Warnings

Precautions

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

- Never push objects of any kind into Therm-X through the exterior case.
- Never spill liquid of any kind on Therm-X. If a spill occurs, clean immediately.
- Do not overfill the Therm-X reservoir - fill only to the red line inside the filler neck.
- If Therm-X gets wet, unplug from the wall, wipe the outer surface with a dry cloth, and allow it to dry before use.
- Only operate Therm-X with the supplied power cord and power supply model.
- Unplug the Therm-X from the wall if it is not in use.
- Do not operate Therm-X if it has any noticeable, physical damage or is leaking fluid.
- Do not operate Therm-X with a damaged or frayed power cord.
- Therm-X is intended to be used indoors. Therm-X is not intended to be used in a wet environment or when relative humidity is greater than 60%.
- Do not spray Therm-X with any water solvents or cleaners.
- Do not drop or cause impact to Therm-X.
- Do not pull cords or hoses attached to Therm-X or otherwise put undue stress on Therm-X.
- Do not use near equipment that generates electromagnetic or other interferences as this may be harmful to Therm-X.
- Do not smoke or use garments by an open flame.
- Do not stick a finger or any other foreign objects into the reservoir.
- Do not drink or ingest the coolant.
- Ensure that the side vents of the Therm-X are not blocked. Use compressed air to remove dust from the air vents once a year.
- Do not attempt to modify the Therm-X. Service and maintenance is restricted only to authorized service personnel.

Warnings

⚠ If unusual swelling, skin discoloration or discomfort occurs, immediately discontinue use of Therm-X and consult your healthcare professional.

⚠ Follow the prescribed instructions of your healthcare professional for treatment regimen(s), area, frequency, and duration.

⚠ A licensed healthcare practitioner must select the correct regimen for use.

⚠ Patients vary in sensitivity to cold. Make regular checks on the patient's comfort.

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

⚠ Do not apply the therapy garment so tightly as to restrict blood or fluid flow.

⚠ Use only Zenith Technical Innovations approved therapy garments.

⚠ Therapy garments are non-sterile unless specifically labeled as sterile.

⚠ Non-sterile therapy garments should never be directly applied to an open wound or breached skin.

⚠ Use only sterile therapy garments over wounds or breaks in the skin.

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

⚠ If it is appropriate for the patient to use the therapy garment with Therm-X at home, the healthcare provider must provide adequate and appropriate instructions for use to the patient.

⚠ The healthcare provider must monitor the patient's use of Therm-X, assuring appropriate use and application of all therapies.

⚠ Multi-patient use garments must be cleaned and disinfected as outlined in the cleaning section of each garment IFU. Use of a garment with multiple patients without proper cleaning and disinfection may lead to risks of infection.

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

⚠ Do not attempt to sterilize Therm-X or therapy garments by any means.

⚠ Dressings used under the therapy garment should be applied lightly.

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

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

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

⚠ Use only the approved coolant recommended for Therm-X.

⚠ All therapies using compression must be turned OFF when the wrap is removed from the patient.

⚠ Do not drink or ingest the coolant.

⚠ Do not stick foreign objects into the coolant reservoir.

⚠ Do not smoke while using therapy garments or use garments by an open flame.

⚠ Slots and openings in the console are provided for ventilation to protect the unit from overheating. These openings must not be blocked or covered at any time.

⚠ The Therm-X is intended for use only in an environment of 60°-80° F with lower than 60% humidity.

⚠ The Therm-X is not to be used in a confined space; ensure that adequate air flow can be maintained through the side of the unit.

⚠ Air bubbles trapped in the unit's system may negatively affect the Therm-X's performance.

⚠ The use of the calf DVT therapy while using the foot DVT garment is not an effective or approved treatment to reduce the risk of clot formation.

⚠ The use of the foot DVT therapy while using the calf DVT garment may cause harm to the patient.

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

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

⚠ Use carefully. May cause serious burns. Do not use over sensitive skin areas or in the presence of poor circulation. The unattended use of Therm-X by children or incapacitated persons may be dangerous.

Electromagnetic Compatibility (EMC)

Table 1. *Electromagnetic Emissions Declaration*

Declaration – Electromagnetic Emissions		
Therm-X is intended for use in the electromagnetic environment specified below. The customer or the user of Therm-X should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment – Guidance**
RF emissions CISPR 11	Group 1	Therm-X 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	Therm-X is suitable for use in all establishments including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 2. *Electromagnetic Immunity Declaration I*

Declaration – Electromagnetic Immunity			
Therm-X is intended for use in the electromagnetic environment specified below. The customer or the user of Therm-X should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment –Guidance**
Electrostatic discharge (ESD) EN61000-4-2 (IEC 1000-4-2)	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material the relative humidity should be at least 30%.
Electrical fast transient/burst EN61000-4-4 (IEC 1000-4-4)	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge EN61000-4-5 (IEC 1000-4-5)	±1 kV differential mode ±2 kV common mode	±1 kV ±2 kV	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines. IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of Therm-X requires continued operation during power mains interruptions, it is recommended that Therm-X be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) Magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note UT is the a.c. mains voltage prior to application of the test level.			

Table 3. *Electromagnetic Immunity Declaration II*

Declaration – Electromagnetic Immunity			
Therm-X is intended for use in the electromagnetic environment specified below. The customer or the user of Therm-X should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
Conducted RF IEC 61000-4-6	3 V 150kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of Therm-X, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m) Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which Therm-X is used exceeds the applicable RF compliance level above, Therm-X should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating Therm-X.

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

Table 4. *Separation Distances*

Recommended separation distances between portable and mobile RF communications equipment and Therm-X			
Therm-X is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of Therm-X can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and Therm-X as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz $d = 1.2kH$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	.12	.12	.23
.10	.38	.38	.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacture. Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

18 SERVICE AND CUSTOMER SUPPORT

When reporting problems, provide the Unique Device Identification number (e.g. S/N) of the device (as identified on the device label) and the affected garment, in addition to the corresponding alert information, if any.

Contact Information:

Zenith Technical Innovations
1396 St. Paul Ave.
Gurnee, IL 60031

customerservice@thermxtherapy.com

847.672.7481

19 MASTER PRODUCT WARRANTY

Zenith Technical Innovations, Inc. ("Zenith") warrants that the Therm-X machine, umbilical hose and power supply (a "Therm-X Unit"), if properly used, will operate in accordance with its specifications as described by Zenith, and will be free from defects in material and workmanship for a period of one (1) year following its date of purchase. Zenith warrants that the Therm-X garments (the "Therm-X Attachments"), if properly used, will function in accordance with their specifications as described by Zenith, and will be free from defects in material and workmanship as follows:

Durable (multi-patient use) garments:	six (6) months following date of purchase
Disposable (single-patient use) garments:	warranty terminates upon end of first garment use

A "Product," as that term is used in this Warranty, means either a Therm-X Unit or a Therm-X Attachment. There are no warranties applicable to any of the supplemental items (e.g., the refill bottle) included with the sale of Products.

RECIPIENT OF WARRANTY

This Warranty covers only a new Product and is only for the benefit of a customer ("Customer") who purchases a Product directly from Zenith or from an authorized distributor or authorized seller of Zenith Products.

SCOPE

This Warranty covers only defects in operation, materials and workmanship. This Warranty does not cover any claim, service, defect, condition, loss or damage arising from, without limitation: installation; set-up or use instructions not coming from Zenith; recommendations on use (including but not limited to recommendations from health care professionals); representations regarding therapeutic or other results of use; accidents; tampering; improper product selection; misuse, neglect, or abnormal use; use of parts, accessories or components that are incompatible or adversely affect Product operation, performance or durability; unauthorized service, repair or alteration; normal wear and tear; improper storage; cleaning or any condition caused by any dirt or foreign substance on or in a Product; and damage resulting from shipping. INSTALLATION, SET-UP OR USE OF A PRODUCT, OR ANY PORTION THEREOF, IN A MANNER THAT DOES NOT COMPLY WITH OPERATING INSTRUCTIONS OR USER MANUALS PROVIDED BY ZENITH VOIDS THIS WARRANTY. ANY UNAUTHORIZED ALTERATION OR MODIFICATION VOIDS THIS WARRANTY.

REPAIR OR REPLACEMENT IS EXCLUSIVE REMEDY

If a Product malfunctions during the applicable Warranty Period as a result of a defect in operation, material or workmanship, Zenith will either, at its sole option:

- Repair the Product; or
- Replace the Product with another equivalent product.

Repair or replacement is Customer's sole and exclusive remedy. Zenith may elect to replace or repair the Product with either a new or reconditioned equivalent Product. Any repaired or replaced Product is warranted only for the remainder of the original Warranty Period that covered the original Product and is subject to the same limitations and exclusions. Warranty repairs or replacement will require Customer to deliver at Customer's expense the Product to Zenith or return the Product through the authorized Zenith distributor from which it was purchased. Zenith will pay the expense to return to Customer any repaired or replaced Product receiving Warranty service. Customer is responsible for and will be assessed a fee and costs of return if, upon testing and calibration, there are no defects discovered in the Product. If Zenith elects to replace the defective Product, the returned Product shall become Zenith's property upon receipt.

REGISTRATION AND WARRANTY SERVICE

Zenith recommends registration of the Therm-X to assure Warranty support. To register a Product, Customer must, within thirty (30) days after purchase, contact Zenith in writing, by mail or email (customerservice@thermxtherapy.com), and provide Zenith with Customer's contact information, model and serial number(s) of the Product(s) purchased, date of purchase, seller's name (if purchased from authorized Zenith distributor), order confirmation number (if applicable) and shipment identification number (if applicable). Registration will be deemed made when received by Zenith at 1396 St. Paul Ave, Gurnee, IL, 60031.

THIS WARRANTY APPLIES ONLY TO THE ORIGINAL CUSTOMER AND IS NOT TRANSFERABLE.

To obtain Warranty service, Customer must contact Zenith's customer service team as set forth below to receive instructions, including but not limited to instructions regarding Customer's shipment of the defective Product(s) for repair or replacement:

Service team contact:

Telephone:	847-672-7481
Mail:	ATTN Warranty Service, 1396 St. Paul Avenue, Gurnee, IL 60031
Email:	customerservice@thermxtherapy.com

DISCLAIMERS OF WARRANTY

EXCEPT FOR THE WARRANTIES AS EXPRESSLY PROVIDED HEREIN, ZENITH MAKES NO WARRANTY THAT A PRODUCT IS OR WILL BE ACCURATE, COMPLETE, UNINTERRUPTED, OR WITHOUT ERROR.

ZENITH DISCLAIMS AND MAKES NO WARRANTIES OR REPRESENTATIONS AS TO THE ACCURACY, QUALITY, RELIABILITY, SUITABILITY, COMPLETENESS, USEFULNESS, OR EFFECTIVENESS OF ANY PRODUCT.

ZENITH DISCLAIMS ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, WITH RESPECT TO ANY PRODUCT, INCLUDING WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

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THIS AGREEMENT IS NOT TRANSFERABLE OR MADE TO ANY PERSON OTHER THAN THE ORIGINAL CUSTOMER.

TO THE EXTENT ANY DISCLAIMER OF WARRANTY IS NOT PERMITTED BY APPLICABLE LAW, ANY WARRANTY SHALL EXPIRE UPON THE EXPIRATION OF THE WARRANTY PERIOD INDICATED ABOVE, AND RECOURSE IS LIMITED TO REPAIR OR REPLACEMENT AS PROVIDED ABOVE.

EXCEPT FOR THE EXPRESS WARRANTIES PROVIDED HEREIN, EVERY PRODUCT IS SOLD "AS-IS" AND NO WARRANTY, PROMISE OR AFFIRMATION OF FACT, OTHER THAN AS SET FORTH HEREIN ABOVE, IS MADE OR AUTHORIZED BY ZENITH.

ANY WARRANTY OF A THERAPEUTIC OR HEALTH RESULT ARISING FROM USE OF A PRODUCT IS EXPRESSLY DISCLAIMED

LIMITATION OF LIABILITY

Zenith will not be liable to Customer with respect to this Warranty or otherwise, whether in an action based on a contract, tort (including negligence and strict liability) or any other legal theory, however arising, for any incidental, special, exemplary or consequential damages, including but not limited to damages resulting from lost profits, interruption of business, loss of goodwill, injury to Customer or patients or clients of Customer, or injury to other users of a Product or bystanders to any use, even if Zenith is advised of the possibility of such damages.

ZENITH DISCLAIMS AND IS NOT RESPONSIBLE FOR DIRECT, SPECIAL, INCIDENTAL, CONSEQUENTIAL, OR OTHER DAMAGES, COSTS OR LOSS. ZENITH'S LIABILITY IS LIMITED TO REPAIR OR REPLACEMENT AS PROVIDED ABOVE. IN THE EVENT THE REMEDY OF REPAIR OR REPLACEMENT IS DETERMINED TO BE INADEQUATE AT LAW OR EQUITY, THE REMAINING TERMS AND PROVISIONS OF THIS WARRANTY APPLY EXCEPT THAT IN SUCH EVENT THE EXCLUSIVE REMEDY IS ZENITH'S REPAYMENT TO CUSTOMER OF THE PURCHASE PRICE OF THE WARRANTED PRODUCT.

SEVERABILITY

If any provision of this Warranty is held to be invalid or unenforceable under the laws of any jurisdiction, such provisions shall be fully severable and the remaining portions of the Warranty shall remain in full force and effect.

UPDATES AND ADVANCEMENTS

Zenith reserves the right to modify and improve the design of any Product without assuming any obligation to modify any previous model of a Product previously manufactured, distributed or sold by Zenith and without assuming any obligation to modify this Warranty.


THERM-X