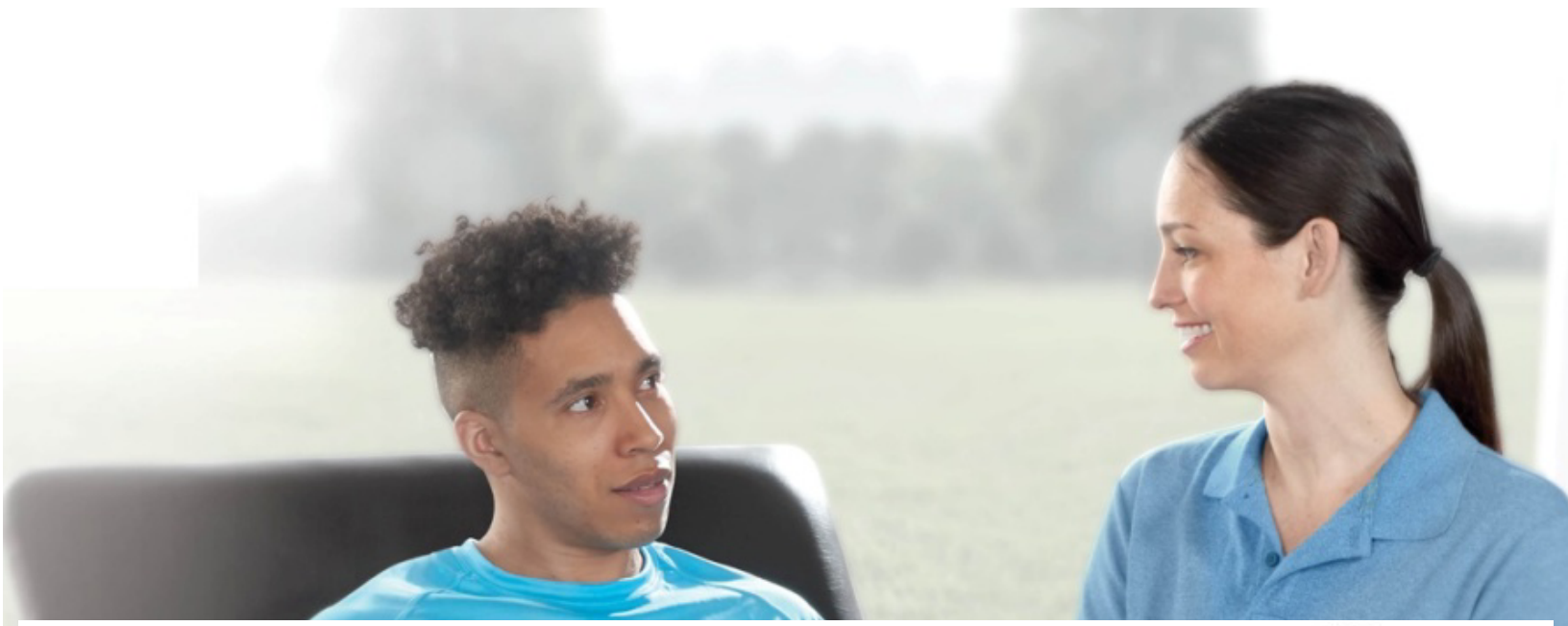


THERM-X

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.

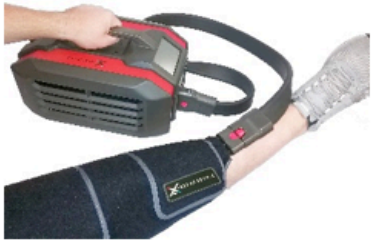
2

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

3

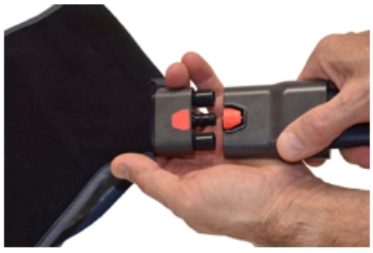
Attach fittings from hose to front of machine until a “click” is heard.

4



Firmly secure the thermal garment to the body.

5



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

6

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

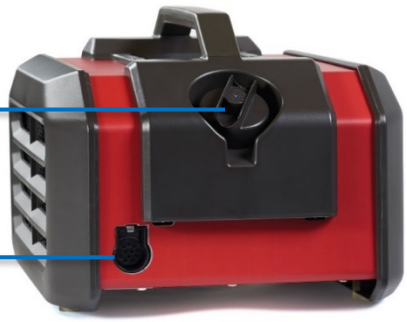
Please read the entire User Manual before operating the Therm-X. There are no user-serviceable components inside the Therm-X.

Features

- Easy to use and read touch screen display
- Quiet operation
- Coolant temperature range between 34°F-55°F and 105°F-110°F
- Treatment of edema and lymphedema with compressions of Lite (5 mmHg), Low (20 mmHg), Medium (45 mmHg), and High (70 mmHg)
- 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
- The option for password protection for the stored treatment to increase patient compliance to the prescribed treatment
- 100 V AC – 240 V AC, 50/60 Hz operation
- Conveniently preloaded quick pick treatment cycles informed by commonly-prescribed treatment therapies

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 AT 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 component 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.

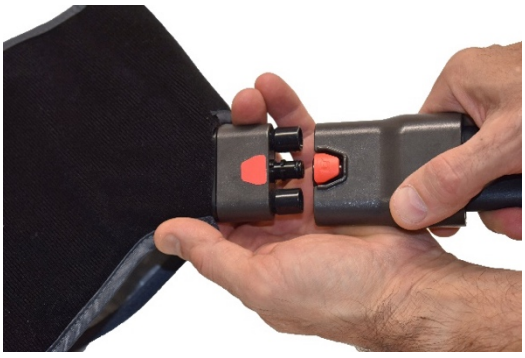
Once you have prepared the coolant mixture, open the tank located at the back of the Therm-X and fill the tank to the red line inside the tank filler neck. It is important whenever filling the Therm-X to fill to the red line.

Attaching the Hoses

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

Attaching the Garments

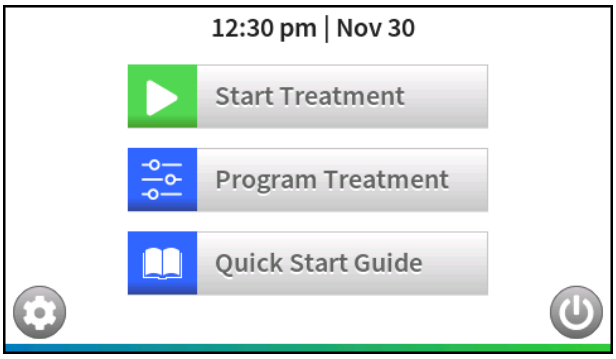
To attach the garments, align the red button on the garment with the red button on the hose and press together until an audible 'click' is heard. For further instruction, please reference individual garment guides, available with the garment or for download at thermxtherapy.com.



7 OPERATING INSTRUCTIONS

Before use, please read Section 17 "Contraindications", and Section 18 "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 and model type will briefly appear followed by the Home Screen. Once a selection has been made, press the touchscreen directly over the button or icon. An audible beep will confirm the selection.

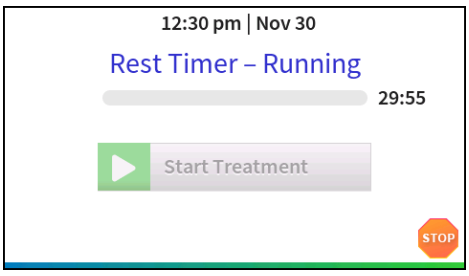


If you have already programmed the therapy treatment, follow all instructions in the 'Preparing the Therm-X for Use', including unpacking the machine, filling the coolant tank, and attaching the hose and garment. Then select the "Start Treatment" button from the Home screen.

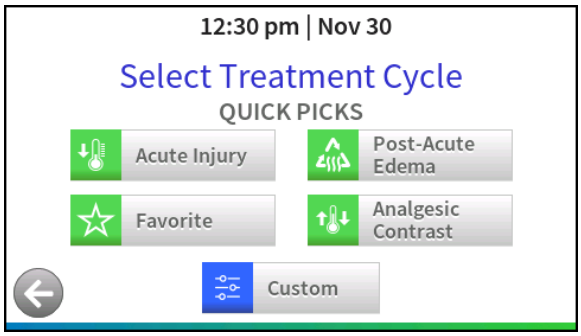
Once the cycle has been initiated you will feel the garment inflate and fluid flow. The 'Treatment Running' screen will appear and will show the current cycle settings, a progress bar, timer, and 'Stop' and 'Pause' buttons. The unit will run through the end of the prescribed cycle automatically.

> ***You may stop the cycle and return to the 'Home' screen at any time by selecting the "Stop" icon. You may pause the cycle at any time by selecting the 'Pause' icon, and resume the cycle by again pressing 'Resume.'***

Once the prescribed treatment is complete, the machine will beep three times, 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.

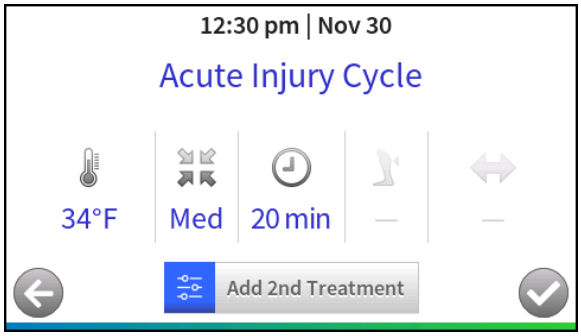


8 PROGRAMMING A THERAPY

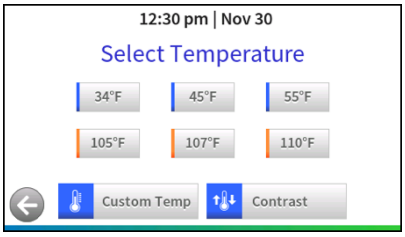


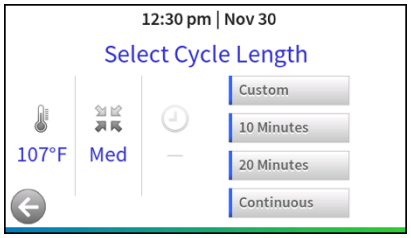
From the Home screen, select Program Treatment. If the password is enabled, you must enter it before proceeding. For more information regarding your password, please see Section 10 System Tools. The Select Treatment Cycle screen will then appear. This screen will have a variety of "Quick Picks" available for selection including "Acute Injury", "Post-Acute Edema", "Analgesic Contrast", and "Favorite". There will also be a "Custom" button, and a "Back" button which will return you to the previous screen.

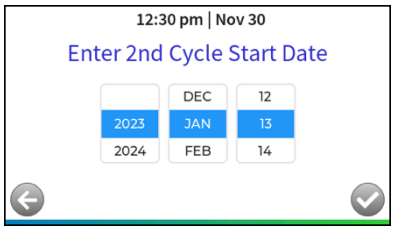
Upon selecting a Quick Pick, the temperature, compression level, and time of the cycle will be preloaded. On this screen, you will be able to select buttons for "Add 2nd Treatment" (if available), "Confirm", or "Back" to return to the Select Treatment Cycle screen. The "Confirm" button will enter the chosen cycle into the system's memory. See Section 9 for more information about Quick Picks.



The purpose of a 2nd program cycle is to build an additional treatment that will initiate on a future date. When the "Add 2nd Treatment" button is selected, you will be guided through a series of program screens to select both the temperature and the duration of the programmed cycle. After programming the treatment specifics, you will 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 scrolling wheels to change the date, the "Confirm" icon to save the cycles, and the "Back" icon to return to the 2nd cycle selection screens.

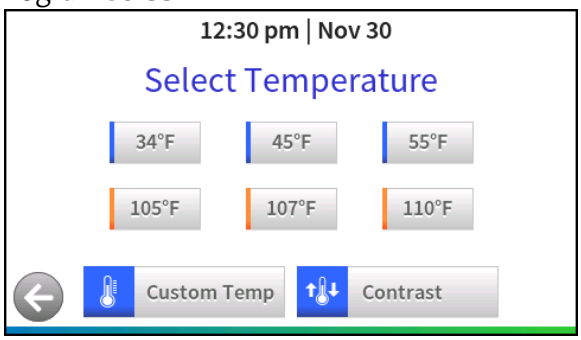






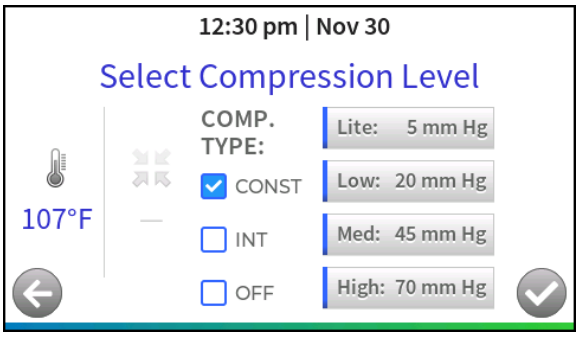
Customizing A Cycle

If a cycle other than the Quick Picks is desired, you will be able to customize a cycle from the "Custom" button on the Select Treatment Program screen.

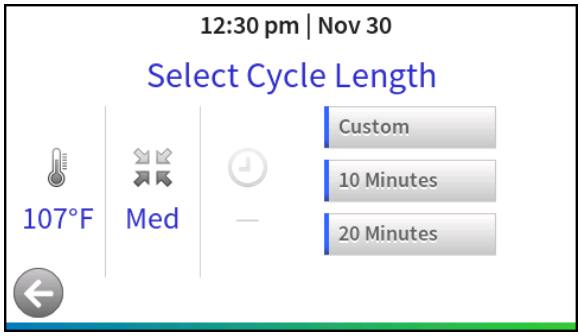


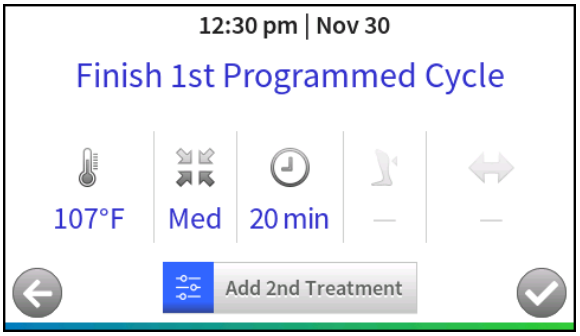
Once the "Custom" button is chosen, you will be taken to the Select Temperature screen. This will allow the choice of a variety of pre-chosen temperatures, as well as a "Custom Temp" and "Contrast" option. "Custom" will allow a choice from the range of either 34-55°F or 105-110°F. "Contrast" will set a cycle that alternates between temperatures of 38°F and 105°F. (You can set which temperature is initiated and the durations.)

After the temperature cycle is chosen, the Therm-X will prompt you to select a pressure value on the Select Compression Level screen. There will be 4 levels of compression available to select. To the left you can choose to turn the compression off, or choose either constant or intermittent compression. There will also be a "Back" button to return to the Select Temperature screen.



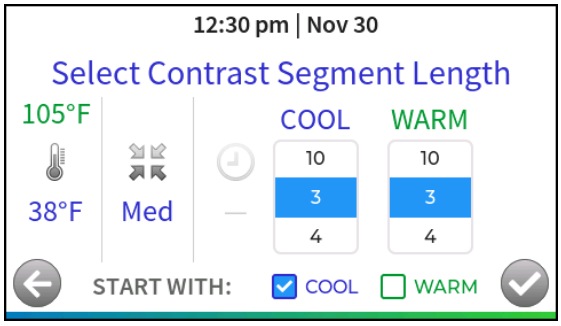
After the compression level is chosen, Therm-X will prompt you to select a cycle's duration on the Select Cycle Length screen. There will be 2 lengths of time available to select, as well as the option to create a custom length. The "Back" button will return you to the Select Compression Level screen.

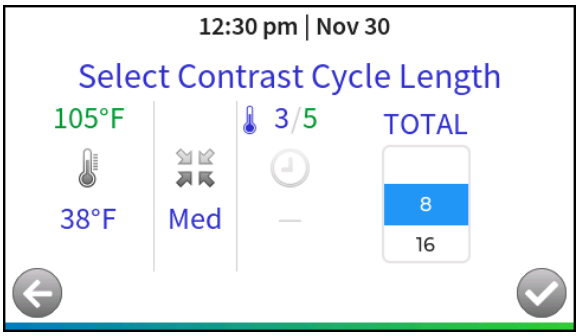




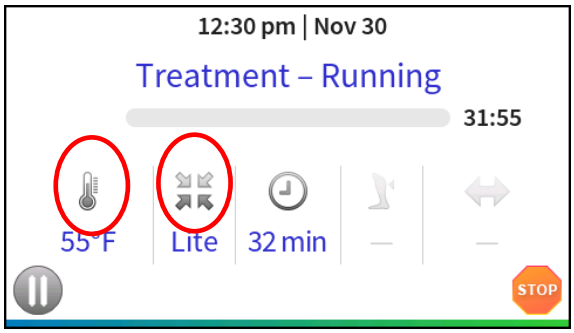
After the cycle length is chosen, a complete cycle will have been created. On the Finish 1st Programmed Cycle screen you will then have the option to "Confirm" to lock in the treatment and return to the Home screen, or "Back" to return to the Select Cycle Length screen.

If you chose the "Contrast" button on the original Select Temperature screen, the Therm-X will ask you to choose a compression level, separate contrast durations for heat and cold, which temperature (heat or cold) to start the treatment with, and total treatment time (I.E. number of heat/cold cycles).

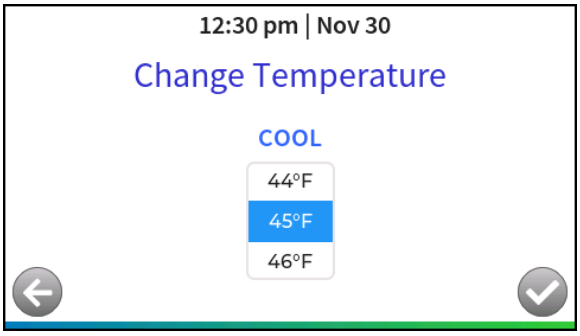


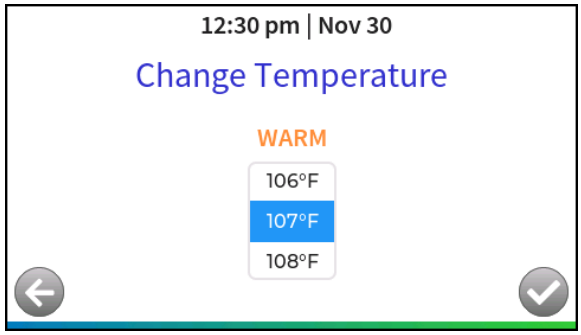


9 MAKING CHANGES TO A RUNNING TREATMENT



You may make changes during a running treatment for garment temperature and compression. You may access the "Change Temperature" or "Change Compression" screen (during a running treatment only) by selecting the 'Compression' or 'Temperature' icons (see figure to the left). ***Changes may not exceed the limits set by the prescribed or programmed treatments.***





Temperature

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. Select the "Confirm" icon to lock in new temperature.

Password Disabled

Any cold temperature adjustment will be allowed for a cold treatment, within the range of 34°F to 55°F. Your Therm-X AT will allow any temperature change for a warm treatment from 105°F to 110°F.

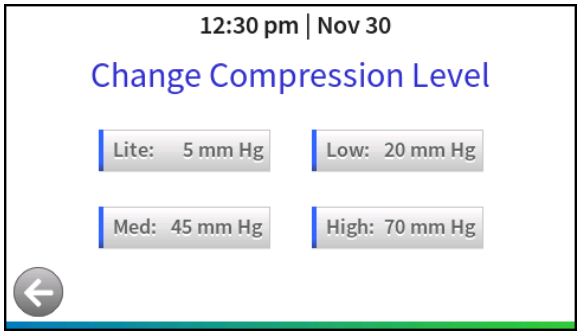
Password Enabled

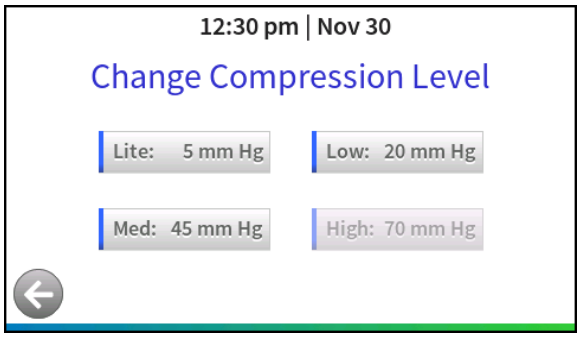
Only conservative temperature adjustments will be allowed, and are relative to the originally programmed treatment. For example, if the COLD treatment was programmed to 45°F, you may select a temperature between 45°F and 55°F.

If the treatment program for WARM therapy was 107°F, you can select a temperature from 105°F to 107°F.

Pressure

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. If compression was programmed, it may not be turned off. Select the "Confirm" icon to lock in new compression level.





Password Disabled

Constant Compression: Any compression level will be allowed. Your Therm-X AT will allow Lite, Low, Medium, and High.

Intermittent Compression: Low, Medium, and High compression are available.

Password Enabled

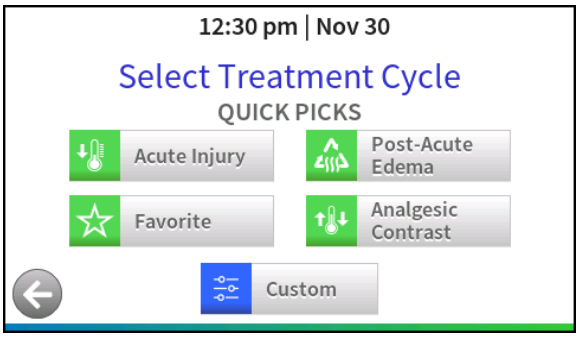
Only conservative compression level adjustments are allowed, and are relative to the originally programmed treatment. For example, if the prescribed treatment was Medium, you may select Lite, Low and Medium. If the originally programmed treatment was Low, you may select Lite or Low.

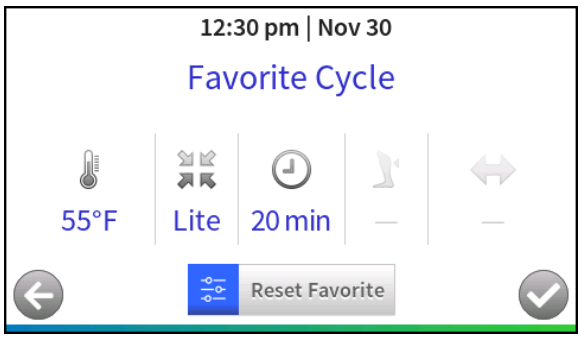
Constant Compression: All compression levels at or below the originally programmed compression level are available.

Intermittent Compression: Lite compression not available.

Favorite Quick Picks for Programming a Treatment

You may program the "Favorite" quick pick button with a preferred treatment that you use regularly. To do this, press the "Favorite" button and it will lead you through the custom programming choices and lock them in when you press the "Confirm" icon. To reprogram the favorite quick pick button, simply press the button and on the next screen press "Reset Favorite".

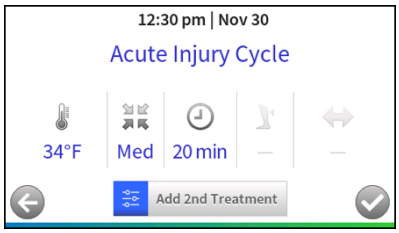


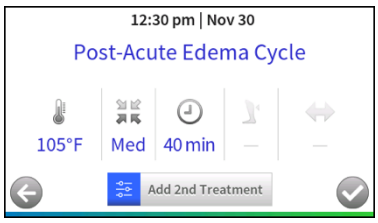


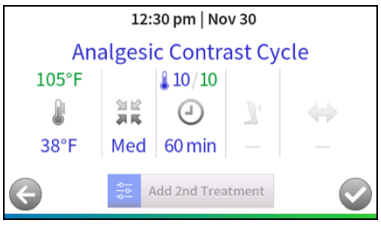
Selecting from pre-programmed quick picks

Three commonly prescribed treatment options will come pre-programmed on your Therm-X AT. If the cycle allows for you to add a 2nd treatment, the icon will appear in full color.

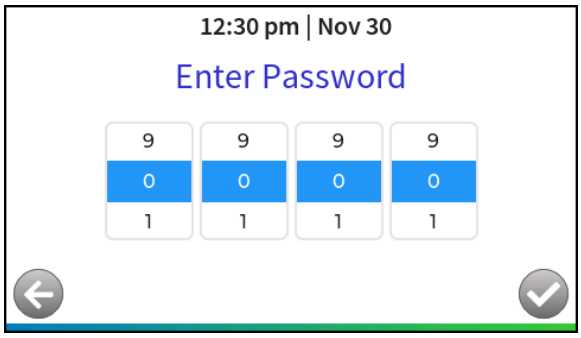
- *Acute Injury Cycle*: 20 minute treatment, 34° F, medium compression, no rest period.
- *Post-Acute Edema Cycle*: 40 minute treatment, 105° F, medium compression.
- *Analgesic Contrast Cycle*: 60 minute treatment, medium compression, 6 cycles of contrasting temperatures alternating between 105° F and 38° F.







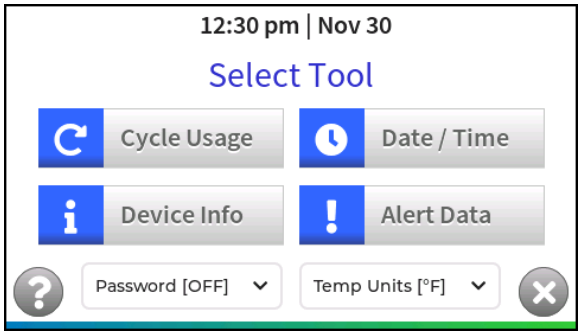
10 System Tools



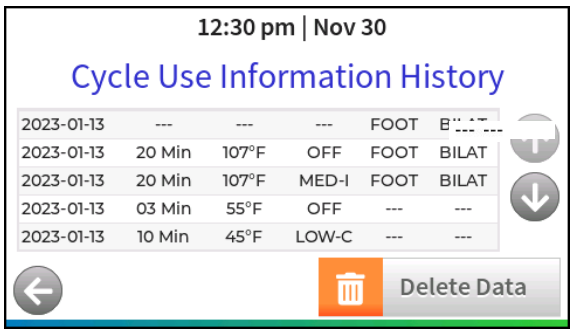
To navigate to the System Tools screen from the Home screen you must first select the "Settings" button in the lower left corner of your Therm-X touchscreen. A password screen will appear if the password is enabled. Use the password that you received with your machine. You will have a maximum of 5 attempts to input the correct password. If too many incorrect attempts are made, the machine will display an error and you must restart before you resume use of your Therm-X. 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.

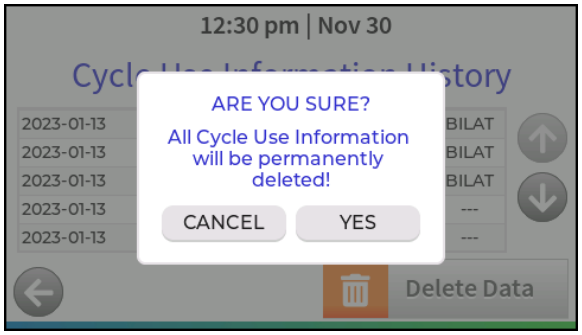
Once you reach the Select Tool screen you may access "Cycle Usage", "Date/Time", "Device Info", "Alert Data", "Password", "Temp Units", "Help", and "Cancel".

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.

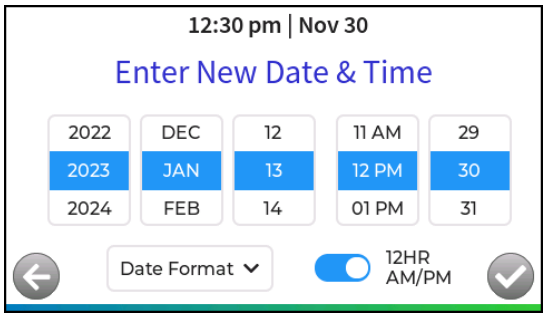


The Cycle Use Information History screen can be reached by selecting the "Cycle Usage" button. It will display the past cycles run on the unit which may be scrolled through using the arrows on the right of the screen. Additionally, there will be a "Back" button to return you to the Select Tool screen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

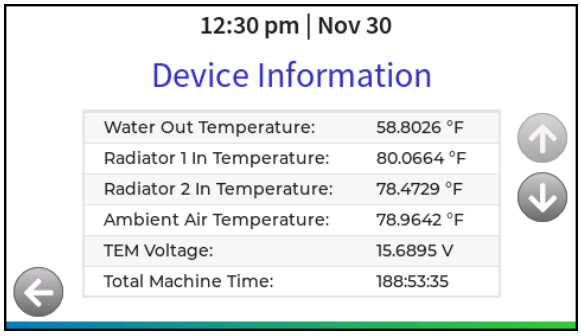


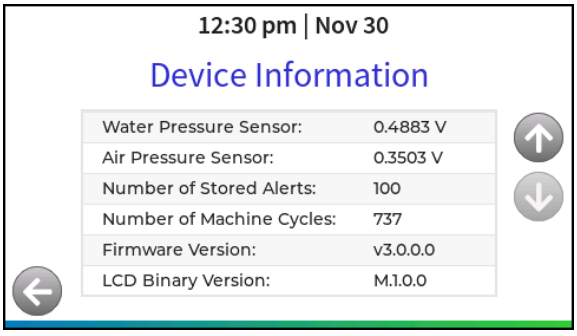


The Enter New Date & Time screen can be reached by selecting the "Date/Time" button. On this screen you may select the date and time by scrolling to the desired values. This screen also provides the option to toggle the date on/off or into different formats, and to toggle the 12HR AM/PM format off and display time in the 24HR format. 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.

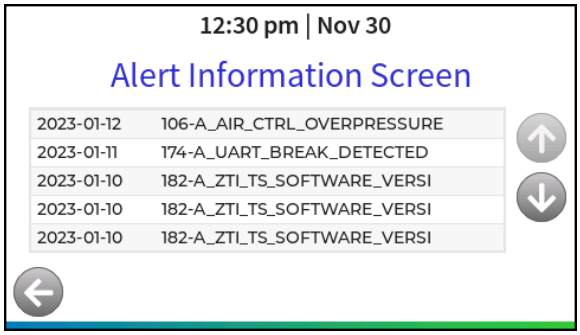


The Device Information screen can be reached by selecting the "Device Info" button. This screen will display a variety of metrics about the unit and its environment. You may navigate through these metrics using the "Up" and "Down" arrow buttons on the right of the screen. There will also be a "Back"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

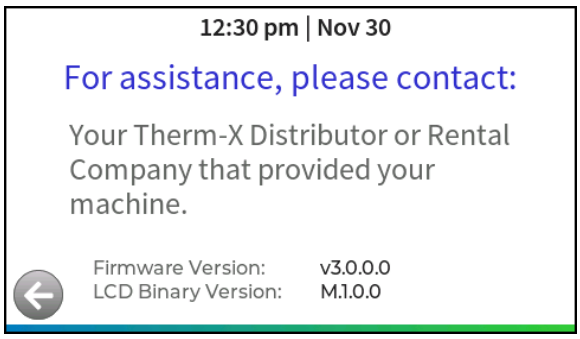




The "Alert Data" button navigates to the historical Alert data screen. This screen will display the alerts that have occurred for this unit. You may navigate through these past alerts using the "Up" and "Down" arrow buttons on the right of the screen. There will also be a "Back" button to return to the Select Tool screen.



If you press the "Help" icon, you will reach the Assistance Screen. The Assistance screen will have information regarding the device to use when contacting your distributor. It will also have a "Back" button to return you to the Select Tool screen.



11 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

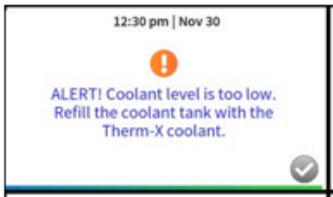
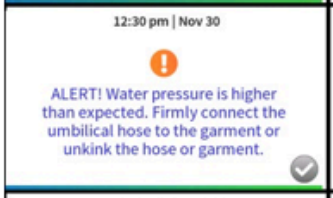
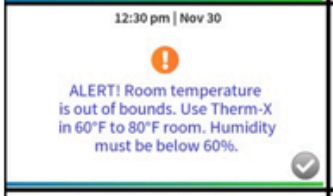
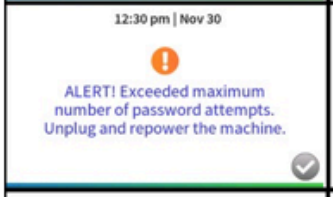
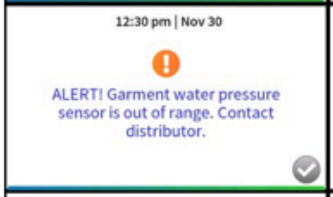
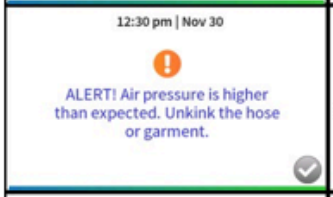
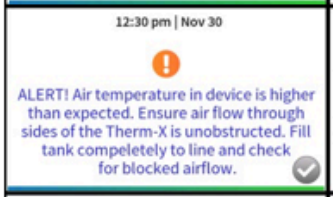
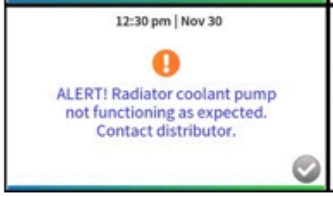
The device and device components can be disposed in accordance with local regulations.

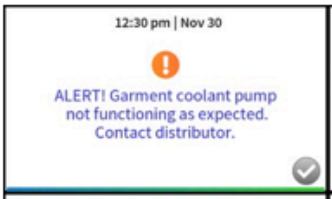
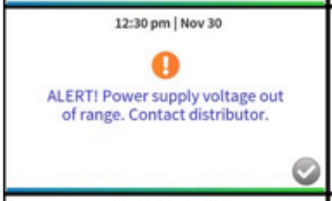
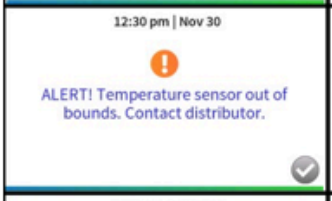
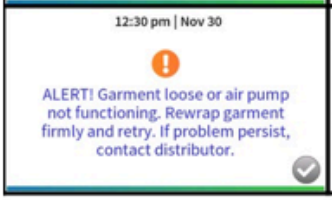
Garments

Garments may be disposed of as regular waste.

12 ALERTS

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

13 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

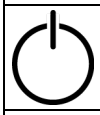
Model Number	Description
TX0302	**Knee SPU Thermal Garment –** The single-patient use thermal garment designed for your knee
TX0301	**Shoulder SPU Thermal Garment –** The single-patient use thermal garment designed for your shoulder
TX0304	**Ankle SPU Thermal Garment –** The single-patient use thermal garment designed for your ankle
TX305	**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

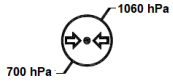
14 ACRONYMS AND DEFINITIONS

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

15 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)
	Humidity Limitation (Humidity must be below 60%)

Symbol/Term	Significance
	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

16 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
Heat Therapy Temperature Range	
Default	105°F, 107°F or 110 °F
Custom	105°F - 110°F
Cycle Length	
Default	10 or 20 minutes
Custom	3-40 minutes
Contrast Therapy Temperature Range	
Temperature	Alternating between 38°F and 105°F
Cycle Length	Cold: 3-10 minutes, Heat: 3-10 minutes, Total: 6-60 minutes
Edema Pressure Range	
Off	0 mm Hg
Lite	5 mm Hg
Low	20 mm Hg
Medium	45 mm Hg
High	70 mm Hg
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 48.63° F (9.24° C) when set to minimum Cold Reservoir set point for a 40 minute cycle length (34° 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)	

Parameter	Value
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
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 and +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

17 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

18 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.

⚠ 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√P	**800 MHz to 2.5 GHz** d = 2.3√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.			

19 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

20 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.

ZENITH HAS NOT MADE ANY AFFIRMATION OF FACT OR PROMISE RELATING TO A PRODUCT THAT A CUSTOMER CAN BE RELY UPON OR THAT MAY BECOME THE BASIS OF A BARGAIN.

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