

# THERM-X

Manufactured by:  
**Zenith Technical Innovations, LLC**

## User Manual



# 1 About these Instructions for Use







## 1.1 Glossary of Terms and Abbreviations








Abbreviation / 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

# 2 Symbols and Abbreviations on the Product and Packaging









## 2.1 Product


### 2.1.1 Device

Symbol/Term	Significance
A	Ampere
Hz	Hertz
IP21	Degree of protection against: Touch by fingers and objects with $\varnothing \geq 12.5$ mm Vertically falling drops shall have no harmful effect
VA	Volt-ampere (power)
V~ / VAC	Alternating current
VDC	Direct current
	Identification label
	Product number
	Serial number
	Manufacturer
	Caution! There are specific warnings and precautions associated with this device.
	Consult the instructions for use

Symbol/Term	Significance
	USB connection
	On/Off button
	Temperature Limitation (Temperature must be between 60°F - 80°F)
	Humidity Limitation (Humidity must be below 60%)
	Atmospheric pressure Limitation (Atmospheric pressure must be between 700 hPa and 1060 hPa)
	Class II ME equipment
	Caution: Federal law restricts this device to sale by or on the order of a physician




### 2.1.2 Garments

Symbol/Term	Significance
	Identification label
	Product number
	Serial number
	Manufacturer
	Caution! There are specific warnings and precautions associated with this device.
	Follow instructions for use
	Do not re-use
	Type BF applied part

Symbol/Term	Significance
	Caution: Federal law restricts this device to sale by or on the order of a physician

## 2.2 Packaging

### 2.2.1 Device

Symbol/Term	Significance
	Temperature Limitation
	Humidity Limitation
	Pressure Limitation

## Indications for Use

Therm-X (Therm-X Pro 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) is indicated.

Therm-X Pro system also provides DVT therapy. Therm-X Pro is 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 Pro 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.

## 3 Contraindications

### 3.1 Pneumatic Compression Therapy

Do not use the device without a licensed healthcare practitioner prescription. **NOTE:** The prescription must show the time, temperature range, pressure, 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

### **3.2 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, 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

## **4 General Warnings and Cautions**

### **4.1 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.
- 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 as needed.

- Do not attempt to modify the Therm-X. Service and maintenance is restricted only to authorized service personnel.
- Therm-X is expected to function and operate for a minimum of 2000 hours. With proper care and maintenance, Therm-X may operate for longer than this expected service life.

## 4.2 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 and frequency.
- ⚠ 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.
- ⚠ Garments are designed for single patient use only. Re-use of single patient use garments may lead to risks of infection.
- ⚠ The garment should be inspected for cleanliness and damage for each treatment. Do not use garment if there are signs of damage as the garment may leak. If the garment is dirty, clean as indicated in the cleaning section.
- ⚠ Do not attempt to sterilize Therm-X or therapy garment 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.

## 5 Therm-X Device Description

### 5.1 Overview

Therm-X is an AC powered, software-controlled multimodality device, designed to be used in a clinical or home-use setting, and under the direction, prescription, or supervision of a licensed healthcare professional. The device is available in two configurations: Therm-X Pro and Therm-X AT.

Therm-X (Therm-X Pro and Therm-X AT) features iceless cold therapy, heat therapy, and contrast (alternating heat and cold) therapy. Therm-X Pro system also provide DVT prophylaxis therapy.

Therm-X consists of various single-patient use inflatable wraps for thermal treatment of the back, elbow, shoulder, ankle, or knee and DVT prophylactic treatment applied to the foot or calf. The thermal garments are flexible coolant circulating garments that apply to the body to deliver cold, heat, or contrast therapy in combination with pneumatic compression. The Foot and calf DVT prophylactic garments apply pneumatic compression alone and are intended for use by Therm-X Pro system only.

Therm-X is controlled by an intuitive touch screen computer interface, allowing the user to manage the therapy modalities as well as easily adjust and monitor treatment times, temperature and compression settings. Therm-X AT and Therm-X Pro models provide an optional password protection feature that allows for a home user to use a stored cycle without being able to change it, giving health care providers an ability to ensure

compliance to a chosen cycle. The device also provides functionality to allow the health care provider to assign a date at which the user will be able to access a second stored cycle instead of the first.

The Therm-X is approximately 15 lbs. when filled with coolant and has a handle placed on the top of the device. It has a centralized coolant reservoir accessible through a cap located at the back of the device that supplies its coolant and radiator systems. The reservoir, pumps, fans, circuit board, and other components of the Therm-X are located inside a covered enclosure made out of plastic and metal components, accessible only using a specialized tool.

## 5.2 Features

- 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)
- Treatment of edema and lymphedema with compressions of low (20 mmHg), medium (45 mmHg), and high (70 mmHg)
- Chronic pain management and acute injury treatment functions
- Programmable therapies, including the ability to have two therapies stored at once, one to start at a later date of your choosing
- Lightweight and portable
- User-friendly interface
- Easy to use and read touch screen display
- Quiet operation
- 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

## 5.3 Models

- **Pro** – The Therm-X Pro is a full-featured model that provides heat, cold, and DVT treatment. This model shall have password protection. This model shall provide the ability for configuration of 2 prescriptions.
- **AT** – The Therm-X Athletic Trainer provides heat and cold treatment but does not include DVT treatment ability. This model has password protection and provides the ability for configuration of 2 prescriptions. For the Therm-X Athletic Trainer there are a few notable deviations from the typical user interface and machine functionality:
  - The DVT Only button on the Select Treatment Cycle Screen will be grayed out
  - The DVT icons will be grayed out on all run screens depicting run settings
  - After a cycle length is selected, the Add DVT or Complete Cycle Screen will display for the user to program a second cycle

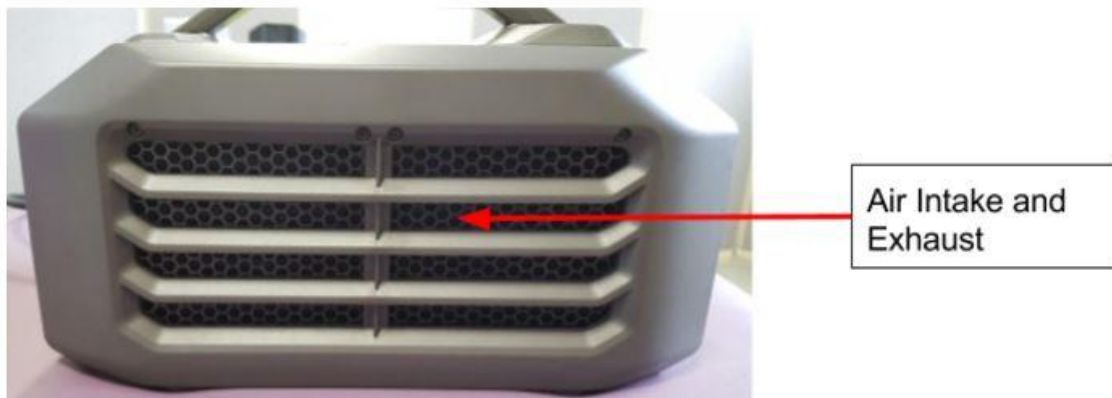
## 5.4 Therm-X System Components

### 5.4.1 Device Schematics

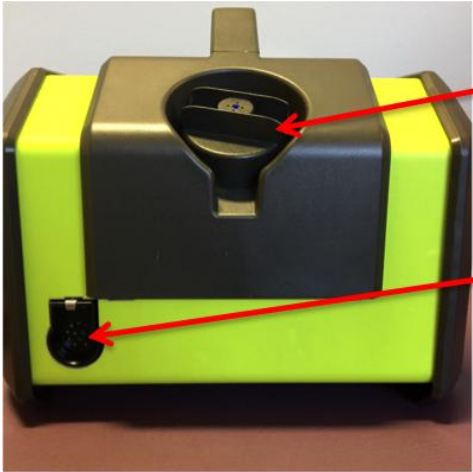
Front View



Side View



**Back View**

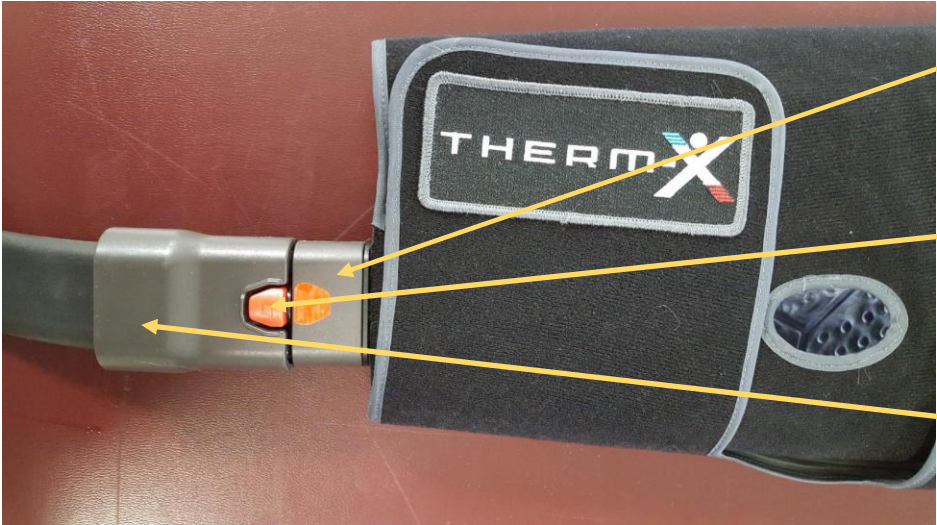


Coolant Tank Cap

Power Cord Connection

**5.4.2 Garment Schematics**

**Hose View**



Garment Side 3-in-1 connector

Quick Release Button

Hose Side 3-in-1 connector















### Back-of-Garment View










## 5.5 Control Panel

### 5.5.1 Display Configuration

Icon	Name	Color	Significance
<b>Round Action Buttons</b>			
	Power Off	Grey	Enables the user to Power Off the device
	Back	Grey	Enables the user to return to the previously viewed screen
	Current Settings	Grey	Shows the currently programmed treatment cycle
	Exit	Grey	Exits the user from an area
	Help	Grey	Renders the Assistance Screen, which provides contact information to the user
	Ok	Grey	Enables the user to confirm a setting
	Yes	Green	Confirms that the user wishes to delete information
	Stop Treatment	Orange	Enables the user to stop the treatment

Icon	Name	Significance
<b>Other Buttons</b>		
	Scroll	Enables the user to scroll through screens displaying information
	Increase Value	Allows the user to increase the value of a unit when setting the date or second cycle start
	Decrease Value	Allows the user to decrease the value of a unit when setting dates or entering a password
 Delete?	Delete	Allows the user to delete the stored cycle information
 Toggle Password <input checked="" type="checkbox"/> ON <input type="checkbox"/> OFF	Toggle Password	Allows the user to turn the password on or off
 Quick Start Guide	Quick Start Guide	Accesses the Quick Start Guide
 Access Tools	Access Tools	Accesses the Device Tools
 Settings	Settings	Accesses the Settings screen
 Start Treatment	Start Treatment	Starts the stored treatment
 Device Info	Device Information	Displays the current device information
 Alert Data	Alert Data	Displays the previous stored alerts
 Cycle Usage	Cycle Usage	Displays the previously run cycles
 Date / Time	Date/Time	Allows the user to set the date and time
 Program Treatment	Program Treatment	Allows the user to program a treatment
 Add 2 <sup>nd</sup> Cycle	Add 2 <sup>nd</sup> Cycle	Allows the user to add a 2 <sup>nd</sup> cycle to be run at a future date

Icon	Name	Significance
<b>Other Buttons</b>		
 Custom	Custom Temperature	Allows the user to select a custom temperature for a given cycle
 Add DVT	Add DVT	Allows the user to add a DVT prophylaxis cycle to a thermal cycle
 DVT Only	DVT only	Allows the user to select a cycle that does only DVT Prophylaxis
 Acute Injury	Acute Injury	Allows the user to select a preloaded “Acute Injury” cycle
 Analgesic Contrast	Analgesic Contrast	Allows the user to select a preloaded “Analgesic Contrast” cycle
 Chronic Pain Analgesia	Chronic Pain Analgesia	Allows the user to select a preloaded “Chronic Pain Analgesia” cycle
 Post-Acute Edema	Post-Acute Edema	Allows the user to select a preloaded “Post-Acute Edema” cycle

## 5.6 Garments

The following garments are available with Therm-X. Instructions related to application are provided with each garment.

- Back – Thermal Garment
- Knee – Thermal Garment
- Shoulder – Thermal Garment
- Elbow – Thermal Garment
- Ankle – Thermal Garment
- Calf – DVT Prophylaxis Garment
- Foot – DVT Prophylaxis Garment

## 6 Preparing your Therm-X System for Use

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

- 6.1 Unpacking your System** – Your Therm-X package will include a Therm-X unit, a power supply, a power cord, and a Therm-X umbilical hose. It will also include a user manual. Ensure you have all parts of the Therm-X system before proceeding. You should have all the items shown below.



You will also need a Therm-X garment to use the Therm-X.

- 6.2 Filling the Device** – Before filling the Therm-X unit, make sure that you have the correct coolant prepared. The Therm-X must be operated with a 90% water, 10% isopropyl alcohol mixture for maximum performance and microbial resistance; it is recommended to use the Therm-X coolant sold by Zenith Technical Innovations, LLC. Once you have obtained this mixture, you should open the tank located at the back of the Therm-X and fill the tank to the lower lip.



**6.3 Making the Therm-X coolant** – 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. If you wish to, you may add 1-2 drops of green food coloring per gallon to the coolant to show that it is Therm-X coolant.

**6.4 Attaching the Hoses** – Once the Therm-X unit is full and prepared to run under the correct settings (reference Section 8 to change the settings), you must attach the Therm-X hose to the front of the unit. Simply press the 3-in-1 connector into place until you hear a click. If you are unable to press the connector in, try pressing and releasing the button on top of the hose connector and then trying again. You will then attach the other end of the hose to the garment. Once again, simply press in the 3-in-1 connector until you hear a click.



**6.5 Attaching the Garments** – To attach the garments to yourself in the most effective way, reference the garment guide that came with them. If you have misplaced this guide, please reference the garment guide accessible at [thermxtherapy.com](http://thermxtherapy.com).

## 7 Operating Instructions – Setting up the Device

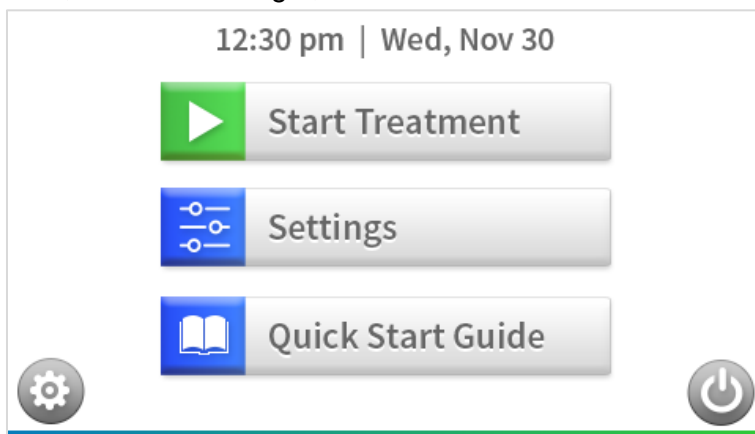
**7.1 Turning on the Device for the First Time** – The Therm-X system can be programmed by a healthcare provider to provide a custom therapy. Your unit may have been programmed in this manner. If you are not a certified user, you will be unable to change a custom therapy. If you are a certified user, you may set the unit up for therapy using the instructions below.

**7.1.1** Connect the power supply to the Therm-X unit and an AC outlet.

- 7.1.2 When the unit is powered up it will beep briefly and the Therm-X logo will appear. Underneath the Therm-X logo an icon for the Therm-X model type (Pro or AT for Athletic Trainer) will appear.



- 7.1.3 The selections on the Home screen will be “Start Treatment”, “Settings”, “Quick Start Guide”, “Current Settings”, and “Power”.

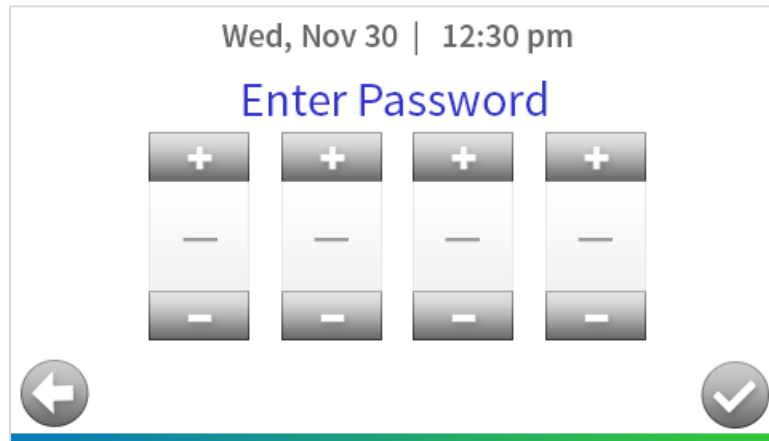


- 7.1.4 The selections may be made by pressing the touchscreen directly over the button. Buttons will indicate that they have been selected by emitting an audible beep.

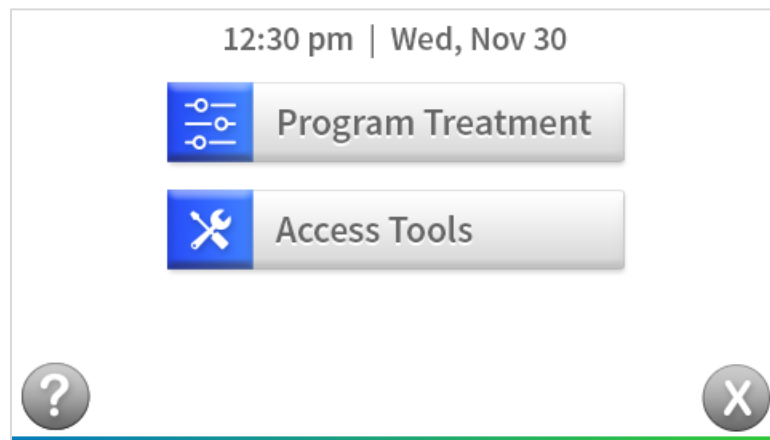
**7.2 System Tools** – System tools include “Cycle Usage”, “Date/Time”, “Device Info”, “Alert Data”, and “Toggle Password”. These tools will be accessible only after selecting the “Settings” button.

- 7.2.1 To navigate to the System Tools screen from the Home screen you must first select the “Settings” button. For the Pro and AT models 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

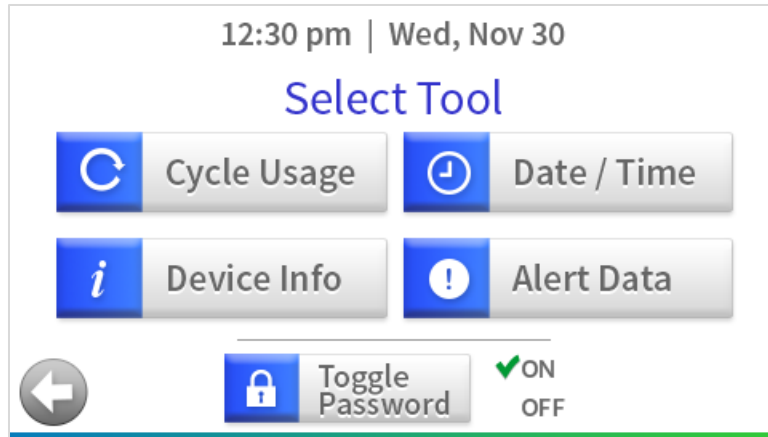
Program Treatment and Access Tools Screen will appear immediately for the Therm-X Pro and Therm-X AT models if the password is disabled.



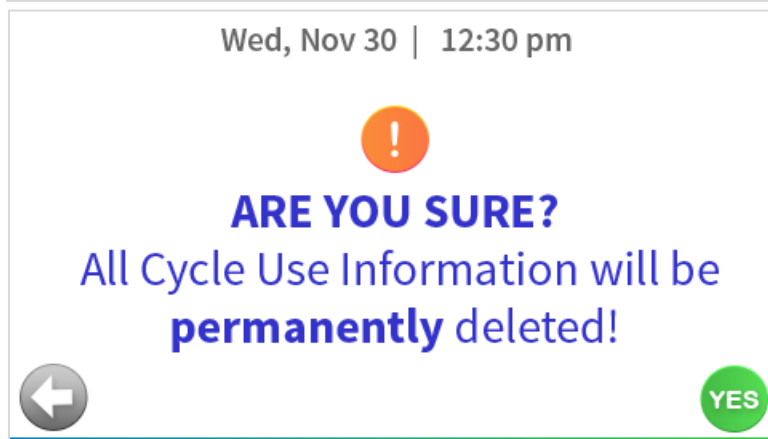
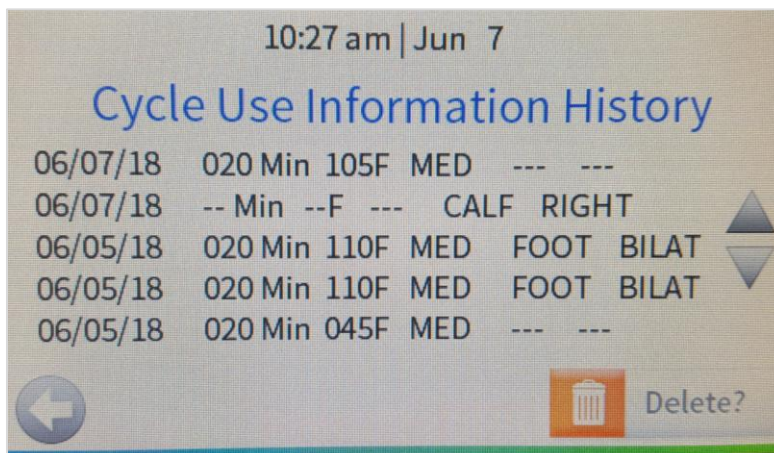
**7.2.2** The selections on the Program Treatment and Access Tools screen are “Program Treatment”, “Access Tools”, “Help”, and “Back”. To continue to the tools, select the “Access Tools” button.



**7.2.3** Once you reach the Select Tool screen you will be given the selections of “Cycle Usage”, “Date/Time”, “Device Info”, “Alert Data”, “Toggle Password”, and “Back”.



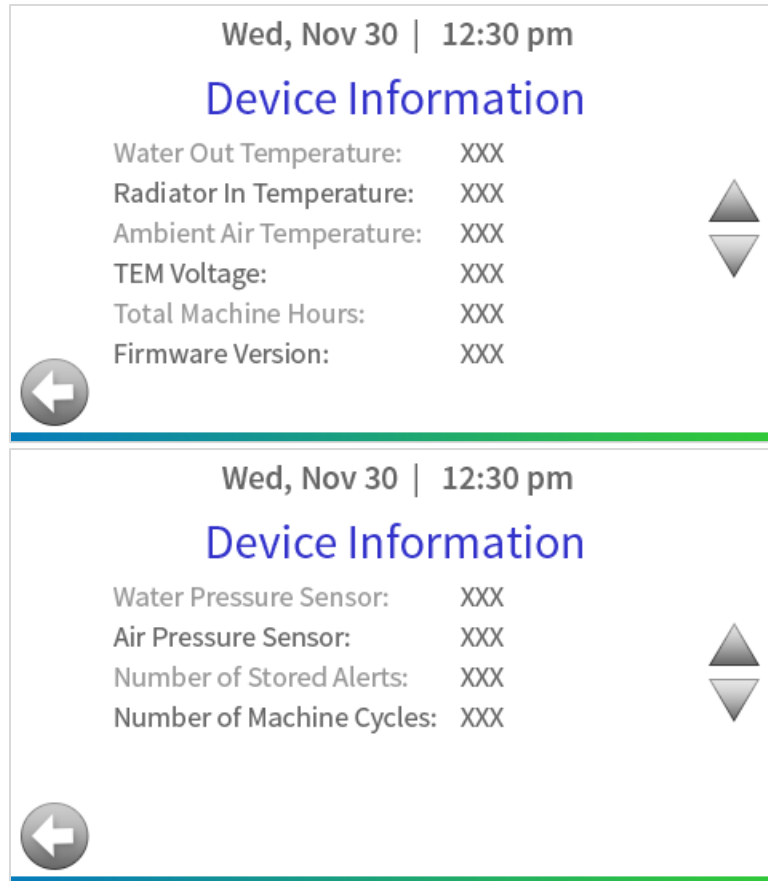
**7.2.4** The Cycle Use Information History screen can be reached by selecting the “Cycle Usage” button. It will display the past cycles run on the unit which may be scrolled through using the arrows on the right of the screen. Additionally, there will be a “Back” button to return you to the Select Tool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



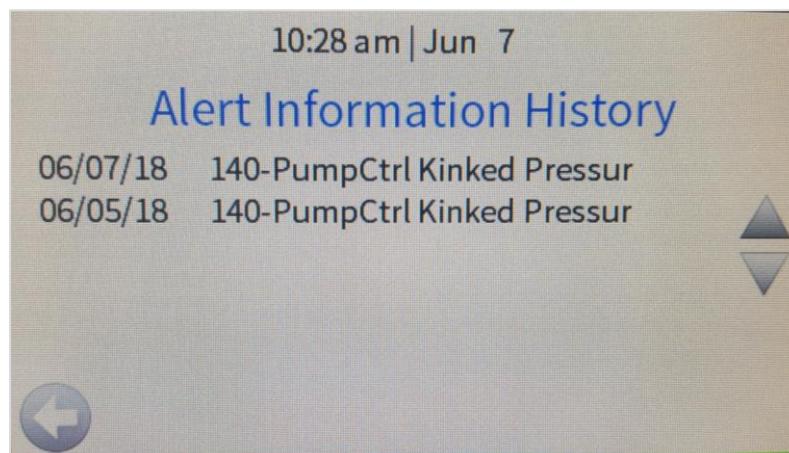
**7.2.5** The Enter New Date & Time screen can be reached by selecting the “Date/Time” button. On this screen you may select the correct date and time by using the “+” or “-” buttons to change the displayed values to the correct values. There will also be a “Back” button to return to the Select Tool screen and a “Confirm” button to store the date and time you have chosen.



**7.2.6** 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.

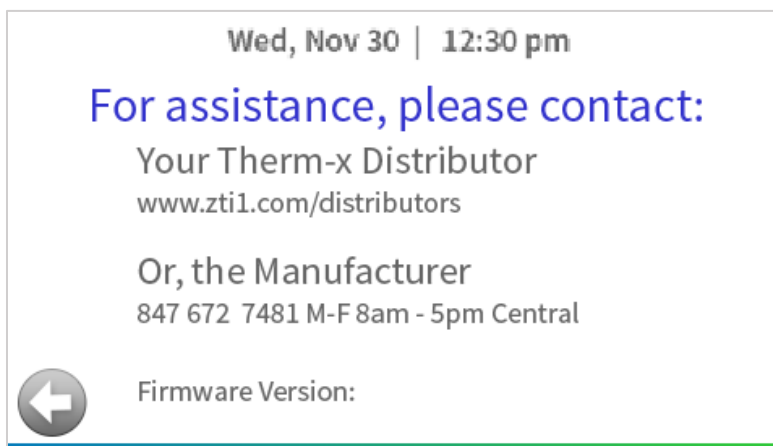


**7.2.7** The Alert Information screen can be reached by selecting the “Alert Data” button. This screen will display the alerts that have occurred for this unit. You may navigate through these past alerts using the “Up” and “Down” arrow buttons on the right of the screen. There will also be a “Back”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



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

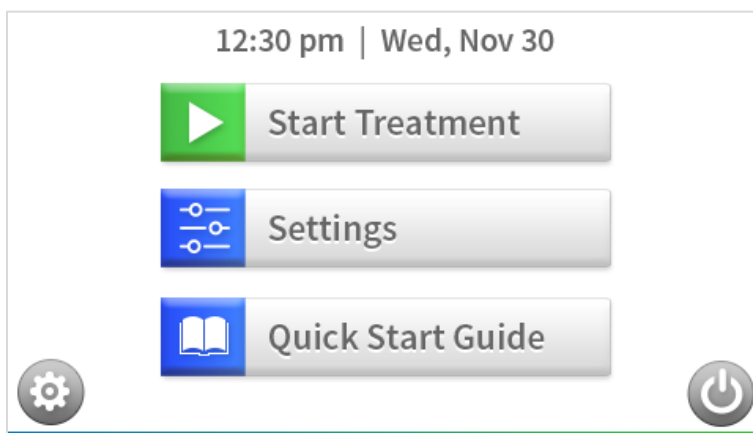
**7.2.9** The Assistance screen may be reached by selecting the “Help” button. The Assistance screen will have contact information for Therm-X manufacturers and distributors. It will also have a “Back” button to return you to Select Tool screen.



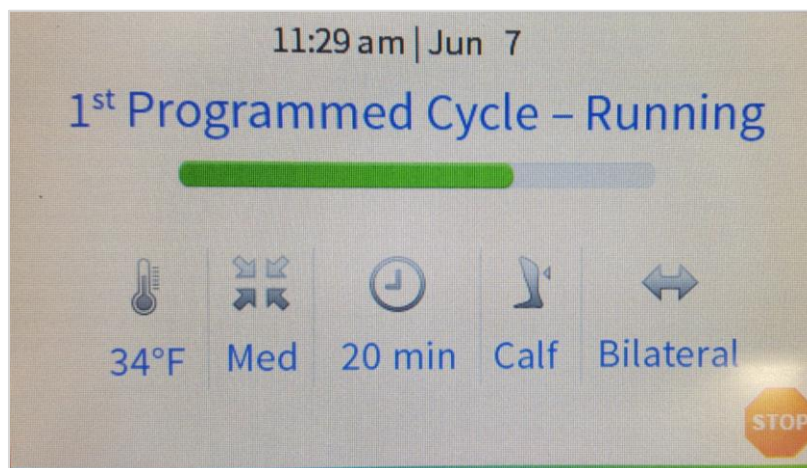
## 8 Automatic Pre-Programmed Therapy

**8.1** If the Therm-X has been prescribed to you, the unit will come pre-programmed with a cycle for your use. The Therm-X stores the last cycle programmed into it until it is overwritten.

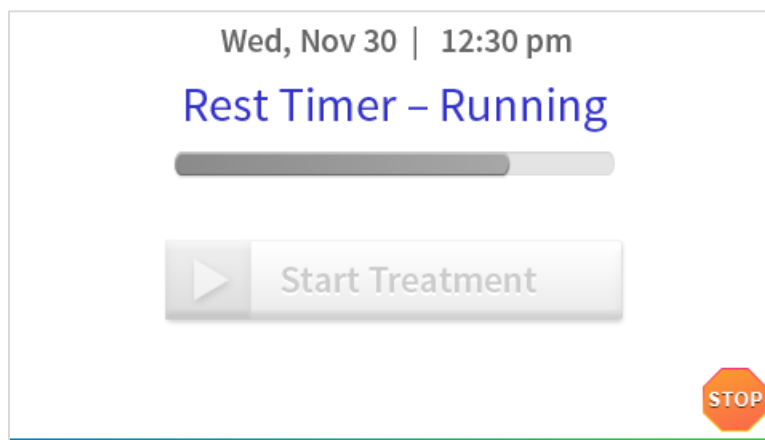
**8.1.1** To initiate the pre-programmed therapy, you will select the “Start Treatment” button from the Home screen. You should be wearing the appropriate garments and have them plugged into the unit before initiating the cycle.



- 8.1.2** Once the cycle has been initiated you should expect to begin feeling garment inflation and fluid flow. The Run screen will appear and will show the current cycle settings, a progress bar, and a “Stop” button. 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.



- 8.1.3** Once the prescribed treatment is complete, with the exception of the Acute Injury Quick Pick Cycle and all Contrast Cycles, a 30-minute rest timer will begin to run on the Rest Timer Run screen. At the end of this rest period, the prescribed cycle will again begin to run. To exit this rest timer and return to the Home screen you may select the “Stop” button.

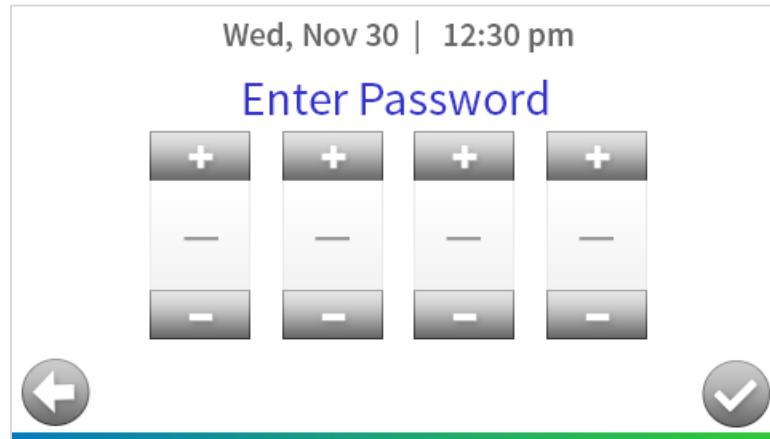


## 9 Programming a Therapy

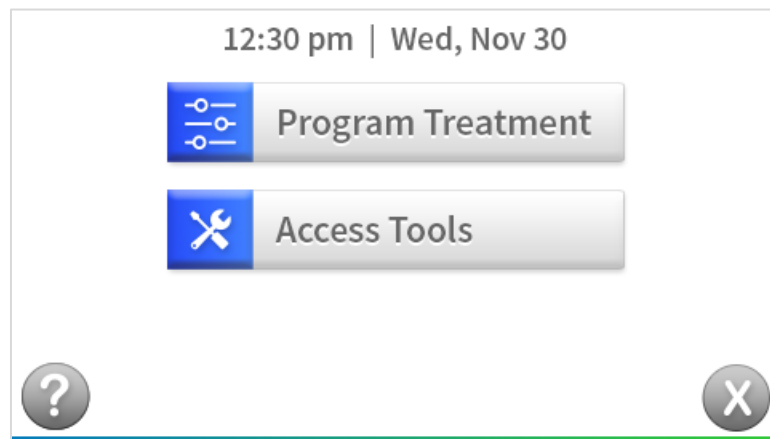
- 9.1** Certified users will be able to program a variety of therapies for Therm-X using cryotherapy, thermotherapy, and DVT prophylaxis options.

- 9.1.1** To navigate to the System Tools screen from the Home screen you must first select the “Settings” button. For the Therm-X Pro and Therm-X AT models 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 Program Treatment and Access Tools Screen will appear immediately for the Therm-X Pro and Therm-X AT models if the password is disabled.



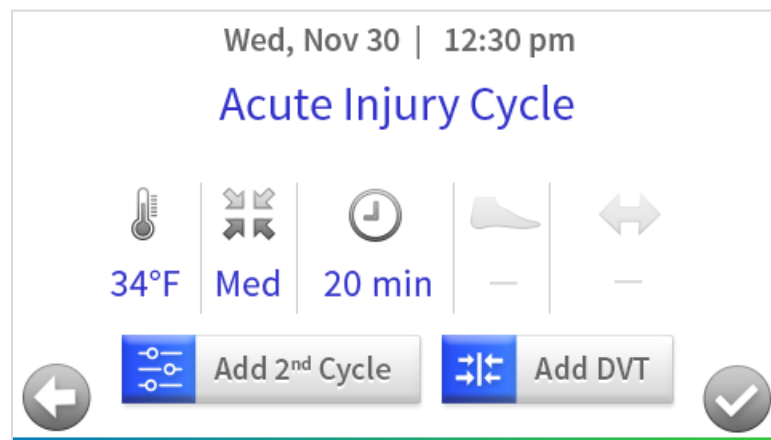
- 9.1.2** The selections on the Program Treatment and Access Tools screen are “Program Treatment”, “Access Tools”, “Help”, and “Back”. To continue to the tools, select the “Program Treatment” button.



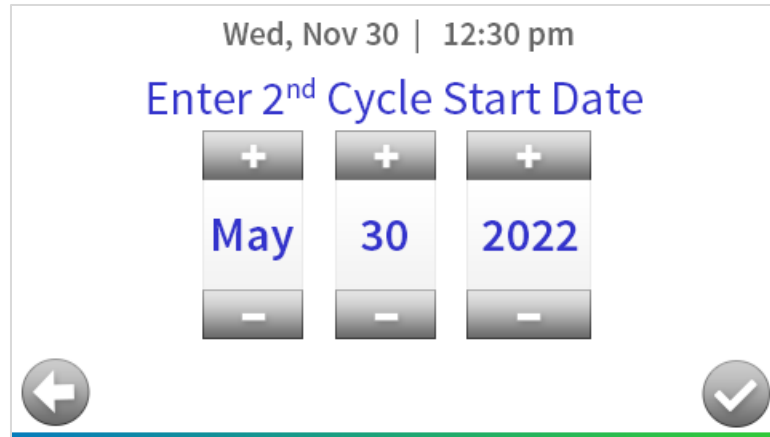
- 9.1.3** The Select Treatment Cycle screen will then appear. This screen will have a variety of “Quick Picks” available for selection including “Acute Injury”, “Post-Acute Edema”, “Chronic Pain Analgesia”, and “Analgesic Contrast”. There will also be a “Custom” button, a “DVT Only” button, and a “Back” button that will return you to the Program Treatment and Access Tools screen.



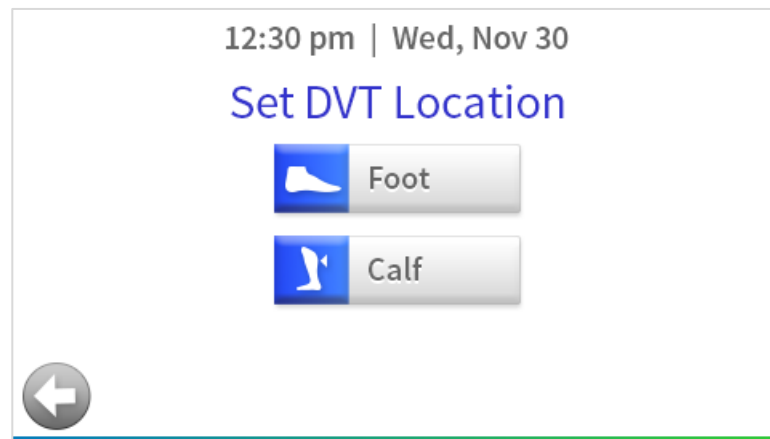
**9.1.4** When one of the Quick Picks is selected the temperature, compression level, and time of the cycle will be preloaded. On this screen, you will be able to select buttons for “Add 2nd Cycle”, “Add DVT”, “Confirm”, or “Back” to return to the Select Treatment Cycle screen. The “Confirm” button will enter the chosen cycle into the system’s memory.



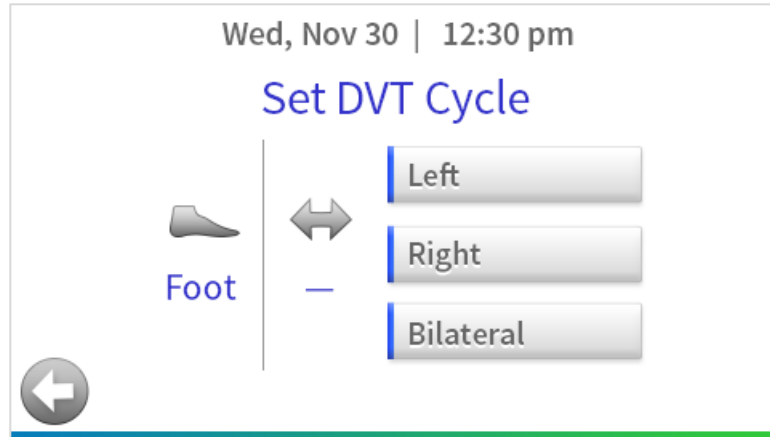
**9.1.5** When the “Add 2nd Cycle” button is selected, the unit will present the Select Temperature screen. The purpose of this 2nd cycle is to prescribe a cycle for later use. You will then proceed through a series of cycle identification screens that define temperature, compression, time of cycle. After identifying the cycle, you will then be asked to identify a 2nd cycle start date. This is the date at which the prescribed cycle in the machine will switch from the 1st programmed cycle to the 2nd. This Enter 2nd Cycle Start Date screen will have “+” and “-” buttons to change the date, a “Confirm” button to save the cycles, and a “Back” button to return to the 2nd cycle selection screens.



- 9.1.6** 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.



- 9.1.7** 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 will also be 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 Cycle Screen.

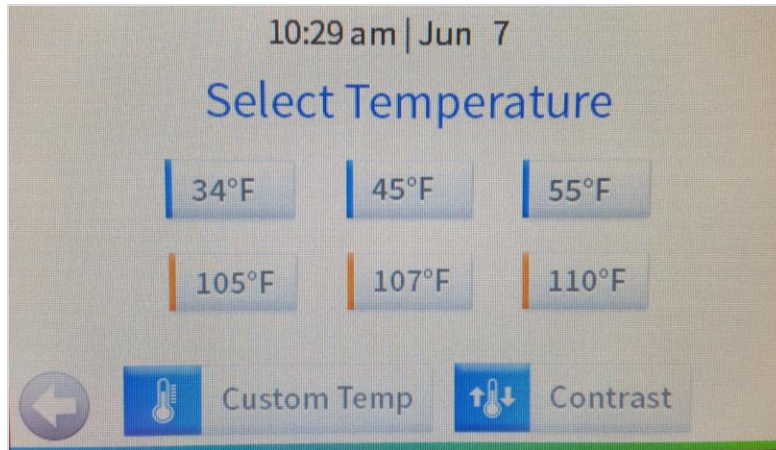


**9.1.8** On the Finish 1st Cycle screen (Section 9.1.13) buttons are available for “Back” and “Confirm”. “Confirm” will store the cycle and return you to the Home screen, and “Back” will return you to the Set DVT Cycle screen.

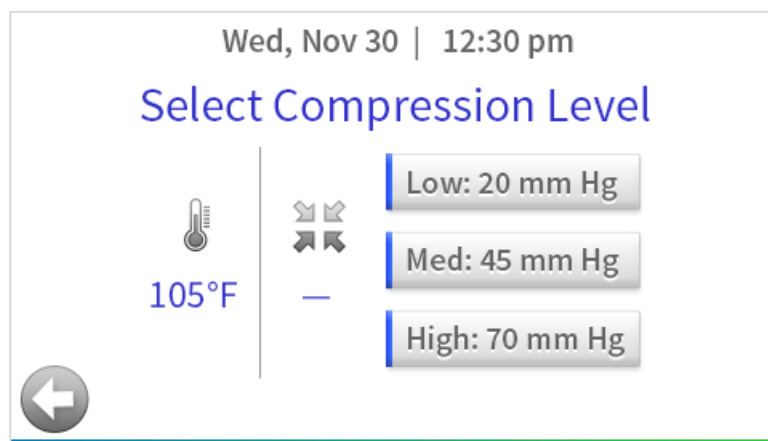
**9.1.9** If a cycle other than the Quick Picks is desired, you will be able to customize a cycle from the “Custom” button on the Select Treatment Cycle screen.



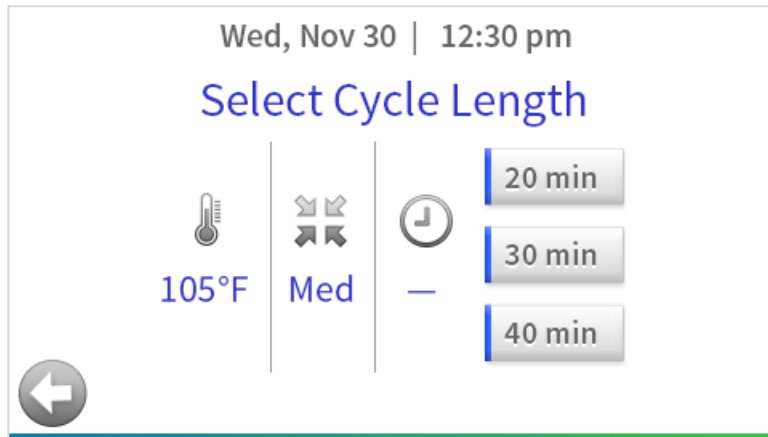
**9.1.10** Once the “Custom” button is chosen, you will be taken to the Select Temperature screen. This will allow the choice of a variety of pre-chosen temperatures, as well as a “Custom Temp” and “Contrast” option. “Custom” will allow a choice from the range of either 34-55°F or 105-110°F. “Contrast” will set a cycle that begins with temperatures of 50°F for 10 min followed by 105°F for 10 min.



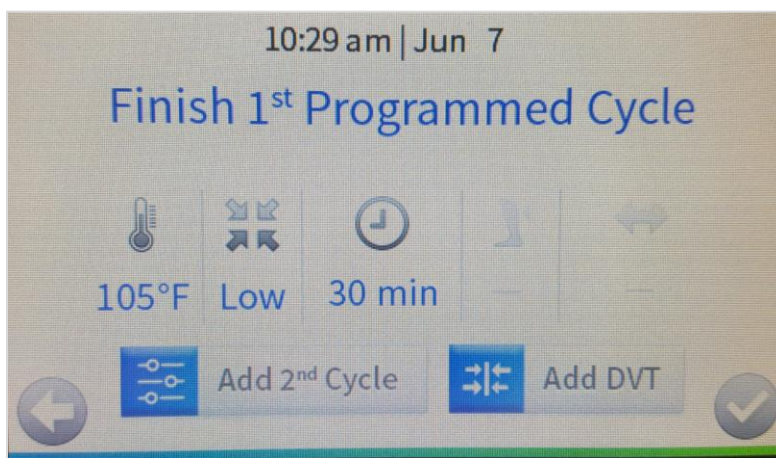
**9.1.11** After the temperature cycle is chosen, the Therm-X will prompt you to select a pressure value on the Select Compression Level screen. There will be 3 levels of compression available to select. There will also be a “Back” button to return to the Select Temperature screen.



**9.1.12** After the compression level is chosen, the Therm-X will prompt you to select a cycle length value on the Select Cycle Length screen. There will be 3 lengths of time available to select. There will also be a “Back” button to return to the Select Compression Level screen.



**9.1.13** After the cycle length cycle is made, a complete cycle will have been created. On the Finish 1<sup>st</sup> Programmed Cycle you will then have options to “Add 2nd Cycle”, “Add DVT”, “Confirm” to return to the Home screen and store the cycle, and “Back” to return to the Select Cycle Length screen.



**9.1.14** At this point it is possible to use the “Add 2nd Cycle” or “Add DVT” options. These options are discussed in length in 9.1.5 - 9.1.8.

## 10 Caring for your Therm-X System

### 10.1 Cleaning

#### 10.1.1 Device

To clean the device, you should 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 to clean the Therm-X unit.

### **10.1.2 Garments**

Garments should never be used by multiple patients. Between uses, a garment may be wiped down with an alcohol cleaning pad or equivalent soft cloth with a mild cleaning product. **DO NOT MACHINE WASH.**

Do not use solvent based cleaners or abrasive materials to clean the garment.

### **10.1.3 Umbilical Hose**

Between uses, an 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.

## **10.2 Storage**

### **10.2.1 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.

### **10.2.2 Garments**

Garments without coolant contents may be stored in the same range 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).

## **10.3 Disposal**

### **10.3.1 Device**







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






### **10.3.2 Garments**







Garments may be disposed of as regular waste.







## 11 Alerts






The table below guide you through addressing the alerts you may potentially receive during use of the Therm-X device.

Alert Type	Alert Explanation
<p style="text-align: center;">Wed, Nov 30   12:30 pm</p> <p style="text-align: center;"></p> <p style="text-align: center;"><b>ALERT!</b> Coolant level is too low. Refill the coolant tank with the Therm-X coolant.</p> <p style="text-align: right;"></p>	<p>This alert occurs when the Therm-X senses that the fluid level in the device is low.</p> <p>Refill the device's tank to address the problem.</p>
<p style="text-align: center;">Wed, Nov 30   12:30 pm</p> <p style="text-align: center;"></p> <p style="text-align: center;"><b>ALERT!</b> Water pressure is higher than expected. Firmly connect the umbilical hose to the garment or unkink the hose or garment.</p> <p style="text-align: right;"></p>	<p>This alert occurs when the pressure level in the device is high.</p> <p>Ensure that the umbilical hose is firmly connected on both the garment and device end. Detach and reattach the garment to the user.</p>
<p style="text-align: center;">Wed, Nov 30   12:30 pm</p> <p style="text-align: center;"></p> <p style="text-align: center;"><b>ALERT!</b> Room temperature is out of bounds. Use Therm-X in 60° to 80°F room. Humidity must be below 60%.</p> <p style="text-align: right;"></p>	<p>This alert occurs when the Therm-X is used in a room outside of the temperature range required.</p> <p>Ensure that you are using the device within the required temperature range.</p>

Alert Type	Alert Explanation
<p data-bbox="402 268 756 302">Wed, Nov 30   12:30 pm</p>  <p data-bbox="269 436 886 646"><b>ALERT!</b> Exceeded maximum number of password attempts. Unplug and repower the machine.</p> <hr data-bbox="196 684 959 688" style="border: 1px solid green;"/>	<p data-bbox="992 323 1425 426">This alert occurs when too many attempts are taken to surpass the password screen.</p> <p data-bbox="992 453 1419 625">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.</p>
<p data-bbox="402 739 756 772">Wed, Nov 30   12:30 pm</p>  <p data-bbox="256 907 899 1062"><b>ALERT!</b> Garment water pressure sensor is out of range. Contact distributor.</p>  <hr data-bbox="196 1152 959 1157" style="border: 1px solid green;"/>	<p data-bbox="992 758 1425 898">This alert occurs when the garment water pressure sensor is detecting an unexpected pressure.</p> <p data-bbox="992 926 1419 1134">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</p>
<p data-bbox="402 1209 756 1243">Wed, Nov 30   12:30 pm</p>  <p data-bbox="263 1377 893 1533"><b>ALERT!</b> Air pressure is higher than expected. Unkink the hose or garment.</p>  <hr data-bbox="196 1623 959 1627" style="border: 1px solid green;"/>	<p data-bbox="992 1304 1425 1371">This alert occurs when the air pressure is higher than expected.</p> <p data-bbox="992 1398 1419 1539">Ensure that the umbilical hose or DVT hoses are unkinked. Detach and reattach the garment to the user.</p>

Alert Type	Alert Explanation
<p style="text-align: center;">Wed, Nov 30   12:30 pm</p> <p style="text-align: center;"></p> <p style="text-align: center;"><b>ALERT!</b> Air temperature in device is higher than expected. Ensure air flow through sides of the Therm-X is unobstructed.</p> <p style="text-align: right;"></p>	<p>This alert occurs when the air temperature in the device is higher than expected.</p> <p>This error usually occurs when the vents on the side of the device are blocked, ensure that airflow through the device is not obstructed.</p>
<p style="text-align: center;">Wed, Nov 30   12:30 pm</p> <p style="text-align: center;"></p> <p style="text-align: center;"><b>ALERT!</b> Radiator coolant pump not functioning as expected. Contact distributor.</p> <p></p>	<p>This alert occurs when the radiator coolant pump is not functioning correctly.</p> <p>Try restarting the device. If the alert persists, contact the distributor.</p>
<p style="text-align: center;">Wed, Nov 30   12:30 pm</p> <p style="text-align: center;"></p> <p style="text-align: center;"><b>ALERT!</b> Garment coolant pump not functioning as expected. Contact distributor.</p> <p></p>	<p>This alert occurs when the garment coolant pump is not functioning correctly.</p> <p>Try restarting the device. If the alert persists, contact the distributor.</p>

Alert Type	Alert Explanation
<p style="text-align: center;">Wed, Nov 30   12:30 pm</p> <p style="text-align: center;"></p> <p style="text-align: center;"><b>ALERT!</b> Power supply voltage out of range. Contact distributor.</p> <p></p>	<p>This alert occurs when the power supply is out of the expected range.</p> <p>Try restarting the device. If the alert persists, contact the distributor.</p>
<p style="text-align: center;">Wed, Nov 30   12:30 pm</p> <p style="text-align: center;"></p> <p style="text-align: center;"><b>ALERT!</b> Temperature sensor out of bounds. Contact distributor.</p> <p></p>	<p>This alert occurs when the temperature sensor is reading an unexpected temperature.</p> <p>Try restarting the device. If the alert persists, contact the distributor.</p>
<p style="text-align: center;">Wed, Nov 30   12:30 pm</p> <p style="text-align: center;"></p> <p style="text-align: center;"><b>ALERT!</b> Cooling or heating is not activating as expected. Contact distributor.</p> <p></p>	<p>This alert occurs when the device is not cooling or heating as it is expected to.</p> <p>Try restarting the device. If the alert persists, contact the distributor.</p>

Alert Type	Alert Explanation
<p style="text-align: center;">Wed, Nov 30   12:30 pm</p> <p style="text-align: center;"></p> <p style="text-align: center;"><b>ALERT!</b> Air pressure not releasing as expected. Remove the garment. Contact distributor.</p> <p></p>	<p>This alert occurs when the device is unexpectedly retaining air pressure.</p> <p>Immediately remove all garments. Try restarting the device and reattaching the garments. If the alert persists, contact the distributor.</p>
<p style="text-align: center;">Wed, Nov 30   12:30 pm</p> <p style="text-align: center;"></p> <p style="text-align: center;"><b>ALERT!</b> Garment loose or air pump not functioning. Rewrap garment firmly and retry. If problems persist, contact distributor.</p> <p> </p>	<p>This alert occurs when either the garment is wrapped too loosely to apply pressure or the air pump is not functioning correctly.</p> <p>Detach and reattach the garments to the user. Try restarting the device. If the alert persists, contact the distributor.</p>
<p style="text-align: center;">Wed, Nov 30   12:30 pm</p> <p style="text-align: center;"></p> <p style="text-align: center;"><b>ALERT!</b> Garment air pressure sensor is out of range. Contact distributor.</p> <p></p>	<p>This alert occurs when the air pressure sensor is detecting an unexpected pressure.</p> <p>Try restarting the device. If the alert persists, contact the distributor.</p>

## 12 Accessories and Replacement Parts

### 12.1 Ordering Address -

Replacement Parts – ZTI  
 1396 St Paul Ave  
 Gurnee, IL 60031

Phone: (847) 672-7481

Email: customerservice@thermxttherapy.com

### 12.2 Device Replacement Parts and Accessories

Catalog number	Description
TX0001	<b>Therm-X Model 1 – Pro</b> – The Therm-X Pro Device
TX0002	<b>Therm-X Model 2 – AT</b> – The Therm-X AT Device
TX0201	<b>Umbilical Hose</b> – The hose that attaches the garment to the front of the Therm-X device
TX0202	<b>Travel Case</b> – The carrying case offered custom made for your Therm-X device
TX0203	<b>Power Supply and Power Cord</b> – The cord and power supply that provide electricity to your Therm-X device
TX0204	<b>Coolant Bottle</b> – The bottle that originally came with your Therm-X system and is specially chosen to conveniently refill your system
TX0205	<b>Therm-X Coolant (1 Quart)</b> – The coolant recommended for use in the Therm-X system for best long-term durability and performance

### 12.3 Replacement Garments

Catalog number	Description
TX0101	<b>Shoulder Thermal Garment</b> – The thermal garment designed for your shoulder
TX0102	<b>Knee Thermal Garment</b> – The thermal garment designed for your knee
TX0103	<b>Elbow Thermal Garment</b> – The thermal garment designed for your elbow
TX0104	<b>Ankle Thermal Garment</b> – The thermal garment designed for your ankle
TX0105	<b>Back Thermal Garment</b> – The thermal garment designed for your back
TX0106	<b>Foot DVT Garment</b> – The DVT prophylaxis garment designed for your foot
TX0107	<b>Calf DVT Garment</b> – The DVT prophylaxis garment designed for your calf

## 13 Product Specifications and Technical Data

### 13.1 Device Functional Specifications

Parameter	Value
<b>Cold Therapy Temperature Range</b>	
Default	34°F, 45°F or 55°F
Custom	34°F - 55°F
<b>Heat Therapy Temperature Range</b>	
Default	105°F, 107°F or 110 °F
Custom	105°F - 110°F
<b>Cycle Length</b>	
Default:	20, 30 or 40 minutes
<b>Contrast Therapy Temperature Range</b>	
Temperature	Alternating between 50°F and 105°F for 10 minutes each
Cycle Length	100 minutes
<b>Edema Pressure Range</b>	
Low	20 mm Hg
Medium	45 mm Hg
High	70 mm Hg
<b>DVT Pressure Range</b>	
Calf	50 - 70 mm Hg
Foot	90 - 120 mm Hg
<b>Measured Skin Temperature</b>	
Maximum Skin Temperature	Skin temperature measured as high as 107.61° F (42° C) when set to maximum Heat Reservoir set point (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 (34° F)

### 13.2 Device Physical Specifications

Parameter	Value
<b>Dimensions of Device</b>	
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.

Parameter	Value
<b>Umbilical Hose</b>	
Length	5 ft +/- 0.5 ft
Type	3 in 1 connector
<b>Classifications</b>	
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 $\varnothing \geq 12.5$ 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
<b>Power Supply</b>	
Type:	IEC 60601-1 compliant, 2x MOPP medical grade
Line Voltage:	100 V AC – 240 V AC
Frequency	50/60 Hz (automatic)
<b>Coolant</b>	
Formulation	90% Distilled Water, 10% Isopropyl Alcohol
Capacity	650 ml
<b>Standards</b>	
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

### 13.3 Garment Specifications

Parameter	Value
Applied part type	BF
Patient contacting material	Thermal Garment: 30 Denier Nylon Ripstop DVT Garment: 200 Denier Nylon Oxford

### 13.4 Environmental Conditions for Operating Your 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

### 13.5 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**

<b>Declaration – Electromagnetic Immunity</b>			
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.			
<b>Immunity Test</b>	<b>IEC 60601 Test Level</b>	<b>Compliance Level</b>	<b>Electromagnetic Environment – Guidance</b>
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**

<b>Declaration – Electromagnetic Immunity</b>			
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.			
<b>Immunity Test</b>	<b>IEC 60601 Test Level</b>	<b>Compliance Level</b>	<b>Electromagnetic Environment – Guidance</b>
Conducted RF IEC 61000-4-6	3 V 150kHz to 80 MHz	3 V	<p>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.</p> <p>Recommended separation distance</p> $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz <p>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,<sup>a</sup> should be less than the compliance level in each frequency range.<sup>b</sup></p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 

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**

<b>Recommended separation distances between portable and mobile RF communications equipment and Therm-X</b>			
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.			
<b>Rated maximum output power of transmitter</b>	<b>Separation distance according to frequency of transmitter</b>		
	<b>m</b>		
<b>W</b>	<b>150 kHz to 80 MHz</b>	<b>80 MHz to 800 MHz</b>	<b>800 MHz to 2.5 GHz</b>
	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$
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.

## 14 Service and Customer Support

When reporting problems, provide the UDI numbers of the device (as identified on the nameplate on the back of each device) 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

Email: [customerservice@thermxttherapy.com](mailto:customerservice@thermxttherapy.com)

Phone: (847) 672-7481

## 15 Warranty

### MASTER PRODUCT WARRANTY

#### WARRANTY

Zenith Technical Innovations, Inc. (“**Zenith**”) warrants that the Therm-X machine 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 defect in material and workmanship for the Warranty Period applicable to the Therm-X Unit. The “**Warranty Period**” for a Therm-X Unit is the period of one (1) year after its date of purchase. Zenith warrants that the Therm-X umbilical hose and garments (the “**Therm-X Attachments**”), if properly used, will operate in accordance with their specifications as described by Zenith, and will be free from defect in material and workmanship for the Warranty Period applicable to the Therm-X Attachments. The “**Warranty Period**” for a Therm-X Attachment is the period of six months from the date of purchase. 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 THE WARRANTY. ANY UNAUTHROIZED 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; or  
Mail: 1396 St. Paul Avenue, Gurnee, IL 60031, ATTN Warranty Service  
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 THERAPUETIC 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.