



U.S. Army Medical Materiel Agency (USAMMA)/Distribution Operations Center (DOC)

Equipment Used to Support Cold Chain Distribution



Background:

The Distribution Operations Center (DOC) of the U.S. Army Medical Materiel Agency (USAMMA) is a core group of highly skilled specialists recognized within the Department of Defense (DoD) for the management, coordination and execution of distribution services. Specifically the packing and storage of medical temperature sensitive products requiring refrigeration or other special handling requirements while maintaining close in-transit visibility in support of our internal and external customers. The DOC operates under the clinical and technical direction of USAMMA's Pharmacy Consultant who is also the Deputy Director for Distribution Operations of the Defense Health Agency Immunization Healthcare Branch (DHA-IHB) formally known as Military Vaccine Office (MILVAX).

The DOC has been assigned the exclusive mission of the distribution management of Anthrax/Smallpox/Adeno Virus vaccines for the entire DoD. The branch's expertise expanded with missions to support the distribution of a variety of other specialty pharmaceuticals, including refrigerated, non-refrigerated and frozen items. With each of these pharmaceuticals, packing and shipping protocols were specifically designed to meet the unique requirements for each product.

In addition to managing pharmaceutical shipments for both medical and non-medical units, the DOC provides both on-site and on-line training of key principles of Cold Chain Management of temperature sensitive pharmaceuticals. This training provides state of the art information on tools, techniques, and procedures for moving pharmaceuticals within narrow temperature ranges.



**U.S. Army Medical Materiel Agency
Distribution Operations Center
USAMMA/DOC**

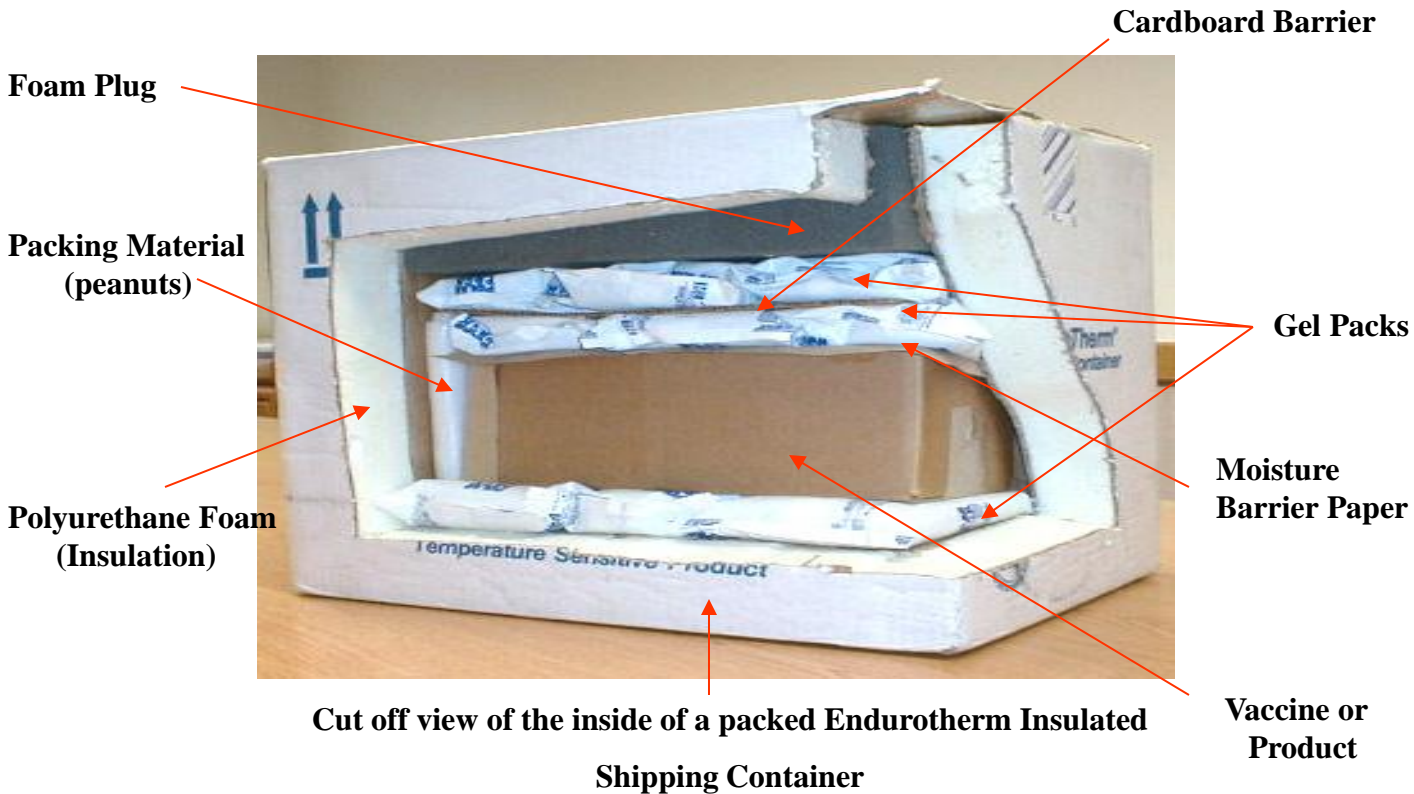
**Insulating Shipping Containers
(ISCs)
and Packing Protocols for
Temperature Sensitive
Products**



ThermoSafe Insulating Shipping Container specifications:

- **Extra Large Box (Model E-327)**
Outer dimensions: **23 1/4" L x 23" W x 24" H**
Cargo area dimensions: **18 1/2" L x 18 1/4" W x 16 3/4" H**
- **Large Box (Model E-186)**
Outer dimensions: **23 1/4" L x 19 1/4" W x 19 1/4" H**
Cargo area dimensions: **18 1/2" L x 14 1/2" W x 12" H**
- **Medium Box (Model E-65)**
Outer dimensions: **18 3/4" L x 12 3/4" W x 17 1/4" H**
Cargo area dimensions: **14" L x 8" W x 10" H**
- **Small Box (Model E-36)**
Outer dimensions: **15 3/4" L x 12 3/4" W x 14 1/4" H**
Cargo area dimensions: **11" L x 8" W x 7" H**

Cold Chain Management employs a common sense approach that keeps products in the correct temperature ranges from the initial entry into DoD channels until administration/issue to the patient or end user. The Distribution Operations Center at USAMMA developed and validated many of the principles and methods from lessons learned during the initiation of the Anthrax Vaccination Immunization Program (AVIP).



Endurotherm Box:

Material: It is comprised of two corrugate layers injected with 2 inches of polyurethane foam within a mold. The end product is a rigid, one piece, three layer laminated container.

The following are approximate weight and amount of gel packs for each complete box:

- **Small Box:** packed weight - 25 lbs, with (8) 24 oz Gel packs.
- **Medium Box:** packed weight - 35 lbs, with (13) 24 oz Gel packs.
- **Large Box:** packed weight – 85 lbs, with (17) 48 oz Gel packs.
- **Extra Large Box:** packed weight - 145 lbs, with (27) 48 oz Gel packs.

A complete packing system was designed using the ThermoSafe boxes to ensure the cold chain distribution process is not broken. There are four different sizes small, medium, large and extra large. The boxes have gone through various testing protocols and they can maintain the required temperature for up to 7 days.

E-327 (Ex-Large container) has an inside dimension of 18-1/2" (length) by 18-1/4" (width) by 16-3/4" (depth) .

E-186 (Large container) has an inside dimension of 18 1/2" in (length) by 14 1/2" (width) by 12" (depth)



E-65 (Medium container) has a inside dimension of 14 " (length) by 8" (width) by 10" (depth).

E-36 (Small container) has a inside dimension of 11" (length) by 8" (width) by 7 in (depth).

Refrigerants

Polar Gel packs are coolant or refrigerants used to maintain desired temperature levels (refrigerated or frozen) inside the ThermoSafe boxes during shipping. When packing refrigerated products gel packs must be refrigerated at +4° Celsius and for frozen products the temperature should be at -17° Celsius for at least 24 hours prior use.



Gel Packs

Medium Gel Packs (24 oz ea)
are used in Small and
Medium ThermoSafe Boxes

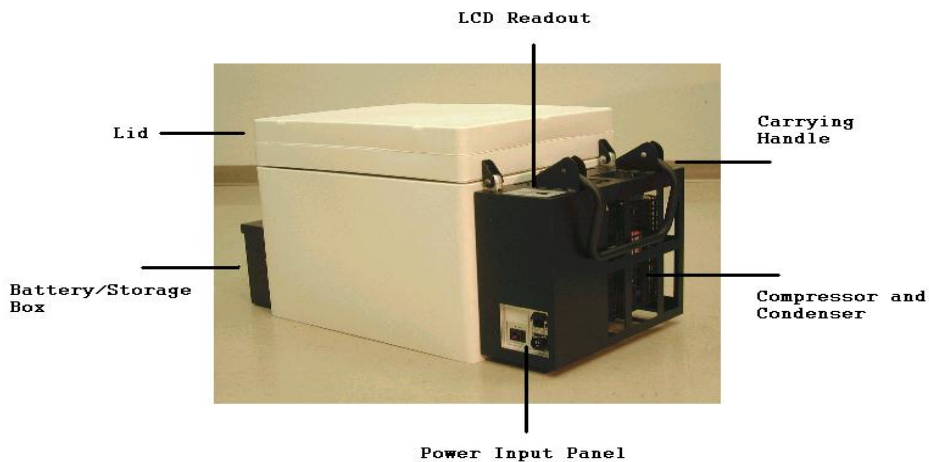
Large Gel Packs (48 oz ea) are used
in Large ThermoSafe Boxes only.

<u>SIZE</u>	<u>WEIGHT</u>	<u>DIMENSIONS (in inches)</u>
1.	24 OZ	8 x 6 x 1 ¼”
2.	48 OZ	10 ¼ x 8 x 1 ½”



**U.S. Army Medical Materiel Agency
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**VaxiCool
Refrigerator/Freezer**



**Manufacturer:
AcuTemp
2900 Dryden Road
Dayton, OH 45459
(937) 312-0114**

The VaxiCool is a commercially procured, high-efficiency refrigerator or freezer system designed for the local transport, temporary storage and re-distribution of temperature-sensitive pharmaceuticals.

Model: AX27L **NSN:** 4110-01-518-6521

Material: It is comprised of Vacupanel Insulation designed to maintain vaccine at 2° - 8° Celsius.

Payload area: Approximately 1 cubic foot.

Alternate Power sources: 110 AC (220 w/special cable), car battery, solar panels, car cigarette lighter and HMMWV tactical vehicle cable.

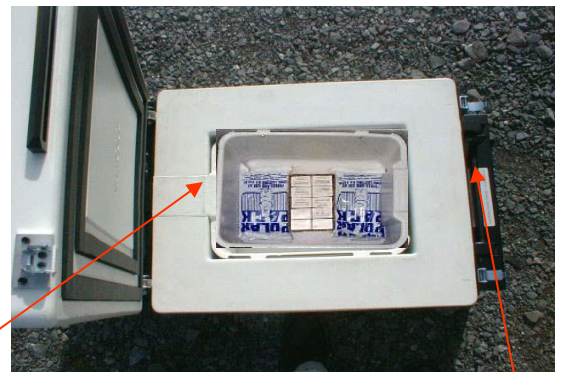
Batteries: 2-12Volt/20 Amp gel cell batteries.

When Amp batteries are installed and fully charged, the VaxiCool can maintain temperatures on internal batteries for up to 5 days, when using 2-12 Volt/20 Amps it can maintain temperature for up to 5 days after being disconnected from an AC power source. Due to its insulation capabilities it can possibly add 16-24 hours more if the lid is kept closed.



Power panel contains solar input plug, AC power from 90-270 Volts and accessory plug for car battery and car cigarette lighter.

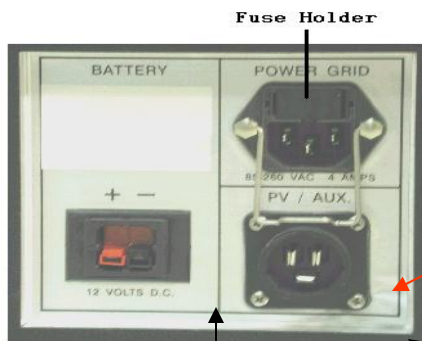
*** Intra-Theater Distribution utilizes Express Carriers to transport the Vaxicools which are strategically pre-position throughout the world to help with intra-theater distribution.**



The VaxiCool has an inside dimension of 14" (length) by 10-1/2" (width) by 10" (depth), its payload can be from 1 to 400 Vials.

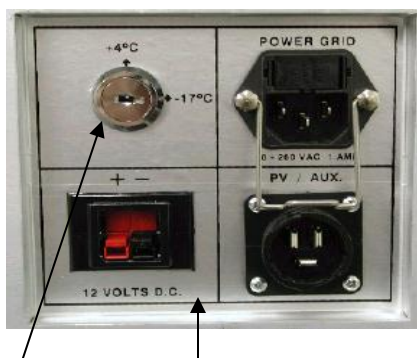
Battery box contains 2-12 Volt/20 Amp dry gel-cell batteries.

The system is comprised of a super efficient compressor and a super insulated container using Vacupanel insulation designed to maintain vaccines at appropriate temperatures from 2°C to 8°C.

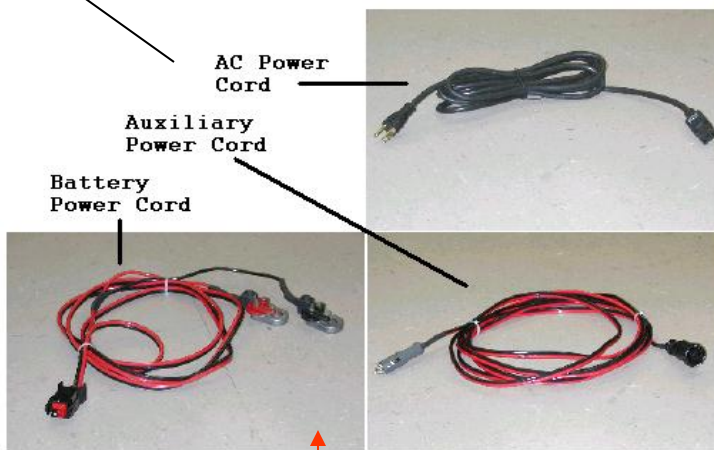


Power Input Panel (VXC-1)

The plugs for the various power sources are clearly marked. The receptacle for the power grid has a fuse holder above the plug. The wire frame that is hanging from the receptacle is used to hold an electrical cord more firmly, making it difficult to accidentally knock the cord loose.

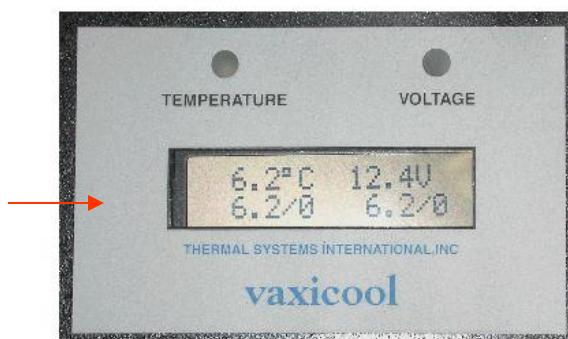


Power Input Panel (VXC-2) w/key switch for refrigeration mode +4C and freezer mode -22C



Examples of the various power cords for the unit are shown above. There is one example of each type of plug used with the power input panel. Note that the battery cord has fittings for a typical lead acid battery, and the auxiliary power cord has a plug that fits into the common cigarette lighter receptacle.

Once the unit has power, the LCD readout will begin to function. The upper left line displays the payload area current temperature and the upper right will display current voltage. The lower line will display the high and low temperatures readings that the unit experienced during the preceding seven day period. There are temperature and voltage alarms. If the temperature or voltage has exceeded safe operating ranges the unit will produce a beeping sound.





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VaxiPac (PX1L) Shipping Container



Manufacturer: AcuTemp, Dayton, OH

The VaxiPac is a commercially procured, high-efficiency small insulated container used for transport of vaccines and other temperature sensitive pharmaceuticals. It is used for the re-distribution of products for short movements of less than 24 hours. The container is designed to maintain the product at the appropriate temperature (2° – 8° Celsius).

----NSN: 6515-01-475-8145

----Material: It is comprised of a rugged, hard plastic material filled with Vacupanel insulation.

----Payload: 1 to 24 vials maximum.

It utilizes a specific refrigerant called VaxiSafe which is composed of a Phase Change Material (PCM) that hardens at 6° degrees Celsius and protects against varying temperatures. The VaxiSafe is an approved replacement for ice in a passive container that does not freeze products. The VaxiPac comes with 5 VaxiSafes from the manufacturer.



Exterior dimension of 15" (length) by 7.75" (width) by 11.38" (depth).

← Walls are comprised of VacuPanel insulation



A maximum of 24 vials can be placed in the VaxiPac (a full layer consists of 12 vials).



↑ VaxiSafe is a Phase Change Material (PCM) that starts to harden or freeze at 6°C.

VaxiPac (VX1L)/Shipping Container

PERFORMANCE OF ACUTEMP PXC (+7°C)

• **AcuTemp PXC (+7°C) is a safe replacement for ice to keep vaccines and other**

temperature sensitive goods cold in the AcuTemp PX1L without accidental freezing.

• **Used according to the instructions, the AcuTemp PX1L system will maintain**

vaccines/products between 2-8°C (35 – 46°F) for more than 20 hours at an ambient temperature of 24°C (75°F).

• **As the ambient temperature increases, the hold time will decrease:**

a. 15 hours @ 30°C (86°F)

b. 12 hours @ 37°C (99°F)

c. 9 hours @ 48°C (118°F)



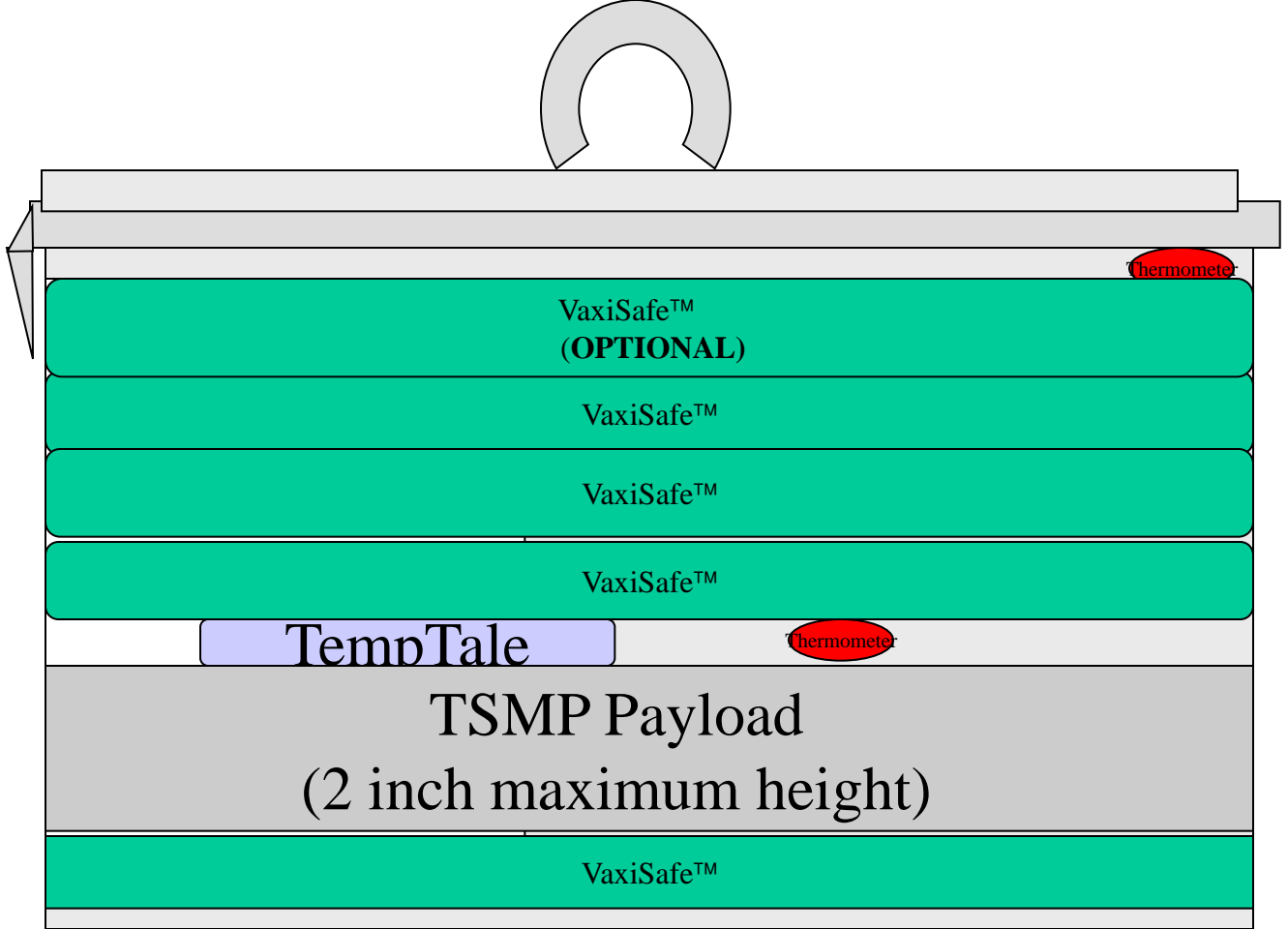
PXC (+7°C) must be chilled at 3°C (±1°C) for 24 hours.

When placing PXCs in the PX1L, be sure to keep the pull-tab“UP” so that the pack can be removed easily



A maximum of 24 vials can be placed in the VaxiPac (a full layer consists of 12 vials).





Packing Instructions for the VaxiPac™

1. The VaxiSafe™ (PCM) must be chilled for at least 24 hours in an accurate temperature-controlled cooler/refrigerator that maintains 4°C (± 1°C) before being packed.
2. The diagram above is the only tested and approved method for packing the VaxiPac™ container.
3. The bottom layer will always be one (1) chilled VaxiSafe™ PCM. Be sure to keep the pull-tab “UP” so that PCM can be removed easily. Never put payload directly in the bottom of the container.
4. The next layer will be the evenly distribute payload with the payload height not to exceed 2.0” d
5. Place a thermometer on top of or next to the payload. If a TempTale is used, start the TempTale and place the TempTale on top of or next to the payload along with the thermometer.
6. Place the remaining 4 VaxiSafe™ PCM packs on top of the payload area being careful to keep the removal tabs of the PCM in the up position for easy removal.
8. Additional information can be obtained from the Distribution Operations Center at (301) 619-7235/3017/1197/4318 or DSN 343-7235/3017/1197/4318.

DO NOT PLACE VaxiSafe™ PCM IN FREEZER



TempTale[®]4 Bio

Temperature Monitor

The TempTale[®]4 BIO (TT4 BIO) helps to ensure the quality, safety, and efficacy of temperature-sensitive products in storage and transit by accurately monitoring and recording environmental conditions experienced by medicinal products throughout the cold chain. The TT4 is a compact, battery powered, electronic monitor designed with a high degree of accuracy to meet critical pharmaceutical applications. With its increased accuracy (see specifications), the TT4 BIO can significantly improve the efficiency and quality of shipment dispositions, thereby reducing operating costs while effectively managing risk. The TT4 BIO features an LCD display that provides shippers and receivers with an immediate indication that a shipment has maintained its specified temperature limits or that a shipment has exceeded the pre-programmed thresholds established for a particular product. The monitor quickly and easily downloads to a PC for viewing, printing, saving, and analyzing trip data recorded by the monitor.



Temperature Accuracy Range:

- ±1.1°C from -30°C to -18°C
- ±0.55°C from -18°C to -1°C
- ±0.22°C from -1°C to 10°C
- ±0.55°C from 10°C to 50°C
- ±1.1°C from 50°C to 70°C

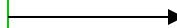
Manufacturer:

Sensitech Inc.
800 Cummings
Center
Suite 258X
Beverly, MA 01915-
6197
(484) 530-2656

Instructions for Starting a TempTale 4 BIO

- Press and release the **Start** button.
- The Sunshine Icon appears in the upper left corner of the display.
- The TempTale will begin to record data after the start-up delay has passed.

Start Button



Instructions for Reading a TempTale 4

- Press and release the **Start** button, each time the **Start** button is pressed it will display the following information in the same order:

- Highest temperature reached during the recording cycle.
- Cumulative amount of time above the high temperature alarm.
- Lowest temperature reached during the recording cycle.
- Cumulative amount of time below the low temperature alarm.

**Start
Button**

