

USER INFORMATION

For

AcuTemp[®] PX1L Carrying Case and AcuTemp[®] PXC Coolant Packs (Formerly VaxiPac[®] and VaxiSafe[™])



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AcuTemp® PX1L and AcuTemp® PXC Coolant Packs WARRANTY

The **AcuTemp PX1L** (formerly VaxiPac®) carrying case and **PXC** (formerly VaxiSafe™) coolant packs are warranted by AcuTemp Thermal Systems to be free from defects in manufacturing and workmanship for a period of one (1) year from the date of purchase. This limited warranty covers repair or replacement, at AcuTemp's option, of components only. It does not cover any costs related to or damage resulting from the use of the **PX1L** or **PXC** packs. The repair or replacement must take place at AcuTemp Thermal Systems or a designated service center. Shipping charges to return **PX1L** or **PXC** units to AcuTemp Thermal Systems or a designated service center are the responsibility of the shipper. The unit must be packaged to avoid damage in transit; AcuTemp is not responsible for any such damage.

AcuTemp reserves the right to change product specifications, materials used in construction, component parts, suppliers and product design elements at any time without notice.

AcuTemp makes no representation or warranty, express or implied, with respect to the suitability of such container and its phase change materials for holding or carrying any particular items or for any other purpose, including, without limitation, any implied warranty of merchantability or fitness for a particular purpose.

AcuTemp AX27L (formerly VaxiCool®), **AcuTemp PX1L** (formerly VaxiPac®), and **AcuTemp PXC** (formerly VaxiSafe™) are products of AcuTemp Thermal Systems, 2900 Dryden Road, Dayton, Ohio 45439 USA. For information, contact AcuTemp toll-free at 866-312-0114 or at 937-312-0114, by fax at 937-312-1277, or email to support@acutemp.com.

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)

HOW TO CORRECTLY CHILL* ACUTEMP PXC (+7°C) PHASE CHANGE MATERIAL (PCM)

- **PXC (+7°C)** must be chilled at 3°C ($\pm 1^\circ\text{C}$) for 24 hours.
- Do not use a household type cooler or refrigerator unless you have documented that it operates at a uniform internal temperature of $3 \pm 1^\circ\text{C}$ or below.
- Use accurate, temperature-controlled coolers or refrigerators (such as the **AcuTemp AX27L** (formerly VaxiCool[®])) for chilling this material. In order to properly chill the **PXC (+7°C)** material, place it in the bottom half of the **AcuTemp AX27L**.

HOW TO USE PXC (+7°C) PHASE CHANGE MATERIAL (PCM) WITH THE ACUTEMP PX1L CARRYING CASE

- Avoid deforming the physical shape or the packaging of the **PXC (+7°C)**.
- Note that each **PXC (+7°C)** will have a pull-tab available for ease of removal/use with the **PX1L** carry case. When placing **PXCs** in the **PX1L**, be sure to keep the pull-tab “UP” so that the pack can be removed easily.
- Place one chilled **PXC (+7°C)** on the bottom of the **PX1L**. This is the bottom PCM layer.
- Evenly distribute the payload on top of the first layer of PCM material with the payload height (H) not exceeding 2.0”. (See Figure 1)
- Place the remaining four **PXC (+7°C)** packs on top of the payload being careful to keep the removal tabs “UP”.
- In case of damage to **PXC (+7°C)**, clean up and disposal may be handled in the same way as any environmentally benign petroleum-based product.

* For purposes of using the **PX1L** carrying case and **PXC** coolant packs, “correctly chilled” means to cool a **PXC** pack to the temperature required to change the contents from a liquid phase to a solid phase. The change (a phase change) may occur at the freezing temperature of water, or it may occur at a different temperature either higher (as in the case of the **PXC (+7°C)**), or lower as with **PXC (-15°C)**). At room temperature the **PXC** packs will feel slightly soft when depressed gently with the fingers. When correctly chilled they will feel very firm. Please be certain to read and follow the instructions for the **PXC** packs you are using to ensure that they are chilled at the proper temperature.

PERFORMANCE OF ACUTEMP PXC (-10°C)

- **AcuTemp PXC (-10°C)** packs are used with frozen vaccines or other frozen payloads.
- Used according to the instructions, **PXC (-10°C)** coolant packs will maintain vaccines/products at or below -10°C in the **PX1L** carrying case for more than 22 hours at 24°C (75°F).
- The hold time noted above requires the use of five pieces of **PXC (-10°C)** packs. If three **PXC** packs are used, the temperature maintenance time is reduced.
- As the ambient temperature increases, the hold time will decrease.

HOW TO FREEZE ACUTEMP PXC (-10°) PHASE CHANGE MATERIAL (PCM)

- The **PXC (-10°C)** may be frozen in a standard freezer operating at -14°C or below.
- An accurate temperature-controlled freezer (such as the **AcuTemp AX27L** refrigerator/freezer) may also be used for freezing this material.
- **PXC (-10°C)** requires 48 hours at -14°C to freeze completely.
- In order to properly freeze the **PXC (-10°C)** material in the **AcuTemp AX27L**, place it in the bottom half of the **AX27L** unit with unit set to “freeze”.

HOW TO USE PXC (-10°) PHASE CHANGE MATERIAL (PCM) WITH THE ACUTEMP PX1L CARRY CASE

- Avoid deforming the physical shape or the packaging of the **PXC (-10°C)**
- Note that each **PXC (-10°C)** will have a pull-tab available for ease of removal/use with the **PX1L** carry case. When placing **PXC** coolant packs in the **PX1L** carry case, be sure to keep the pull-tab “UP” so that the pack can be removed easily.
- Place one frozen **PXC (-10°C)** on the bottom of the **PX1L** carrying case. This is the bottom PCM layer.
- Evenly distribute the payload on top of the first layer of PCM material with the payload height (H) not exceeding 2.0”. (See Figure 1)
- Place the remaining four **PXC (-10°C)** packs on top of the payload being careful to keep the removal tabs “UP”.
- In case of damage to **PXC (-10°C)**, clean up and disposal may be handled with common soap and water.

PERFORMANCE OF ACUTEMP PXC (-15°C)

- **AcuTemp PXC (-15°C)** packs are used with frozen vaccines or other frozen payloads.
- Used according to the instructions, the **PX1L** system will maintain vaccines/products at or below -15°C for more than 12 hours at 24°C (75°F).
- The hold time noted above requires the use of five **PXC (-15°C)** coolant packs. If three **PXC** packs are used, the temperature maintenance time is reduced.
- As the ambient temperature increases, the hold time will decrease.

HOW TO FREEZE ACUTEMP PXC (-15°C) PHASE CHANGE MATERIAL (PCM)

- Must be frozen in a freezer maintaining -21°C or below.
- **PXC (-15°C)** requires 48 hours at -21°C to freeze properly.

HOW TO USE PXC (-15°C) PHASE CHANGE MATERIAL (PCM) WITH THE ACUTEMP PX1L CARRYING CASE

- Avoid deforming the physical shape or the packaging of the **PXC (-15°C)**.
- Note that each **PXC (-15°C)** will have a pull-tab available for ease of removal/use with the **PX1L** carry case. When placing **PXC** coolant packs in the **PX1L** carrying case, be sure to keep the pull-tab “UP” so that the pack can be removed easily.
- Place one frozen **PXC (-15°C)** on the bottom of the **PX1L** carrying case. This is the bottom PCM layer.
- Evenly distribute the payload on top of the first layer of PCM material with the payload height (H) not exceeding 2.0”. (See Figure 1)
- Place the remaining four **PXC (-15°C)** packs on top of the payload being careful to keep the removal tabs “UP”.
- In case of damage to **PXC (-15°C)**, clean up and disposal may be handled with common soap and water.

PERFORMANCE OF ACUTEMP PXC (-20°C)

- **AcuTemp PXC (-20°C)** packs are used with frozen vaccines or other frozen payloads.
- Used according to the instructions, the **AcuTemp PX1L** system will maintain vaccines/products at or below -20°C for more than 12 hours at 24°C (75°F).
- The hold time noted above requires the use of five **PXC (-20°C)** coolant packs. If three **PXC** packs are used, the temperature maintenance time is reduced.
- As the ambient temperature increases, the hold time will decrease.

HOW TO FREEZE ACUTEMP PXC (-20°C) PHASE CHANGE MATERIAL (PCM)

- May be frozen in a freezer maintaining -28°C (-18.4°F) or below.
- **PXC (-20°C)** requires 48 hours at -28°C to freeze properly.

HOW TO USE PXC (-20°) PHASE CHANGE MATERIAL (PCM) WITH THE ACUTEMP PX1L CARRYING CASE

- Avoid deforming the physical shape or the packaging of the **PXC (-20°C)**.
- Note that each **PXC (-20°C)** will have a pull-tab available for ease of removal/use with the **PX1L** carrying case. When placing **PXC** coolant packs in the **PX1L** carrying case, be sure to keep the pull-tab “UP” so that the pack can be removed easily.
- Place one frozen **PXC (-20°C)** on the bottom of the **PX1L** carrying case. This is the bottom PCM layer.
- Evenly distribute the payload on top of the first layer of PCM material with the payload height (H) not exceeding 2.0”. (See Figure 1)
- Place the remaining four **PXC (-20°C)** packs on top of the payload being careful to keep the removal tabs “UP”.
- In case of damage to **PXC (-20°C)** packs, clean up and disposal may be handled with common soap and water.

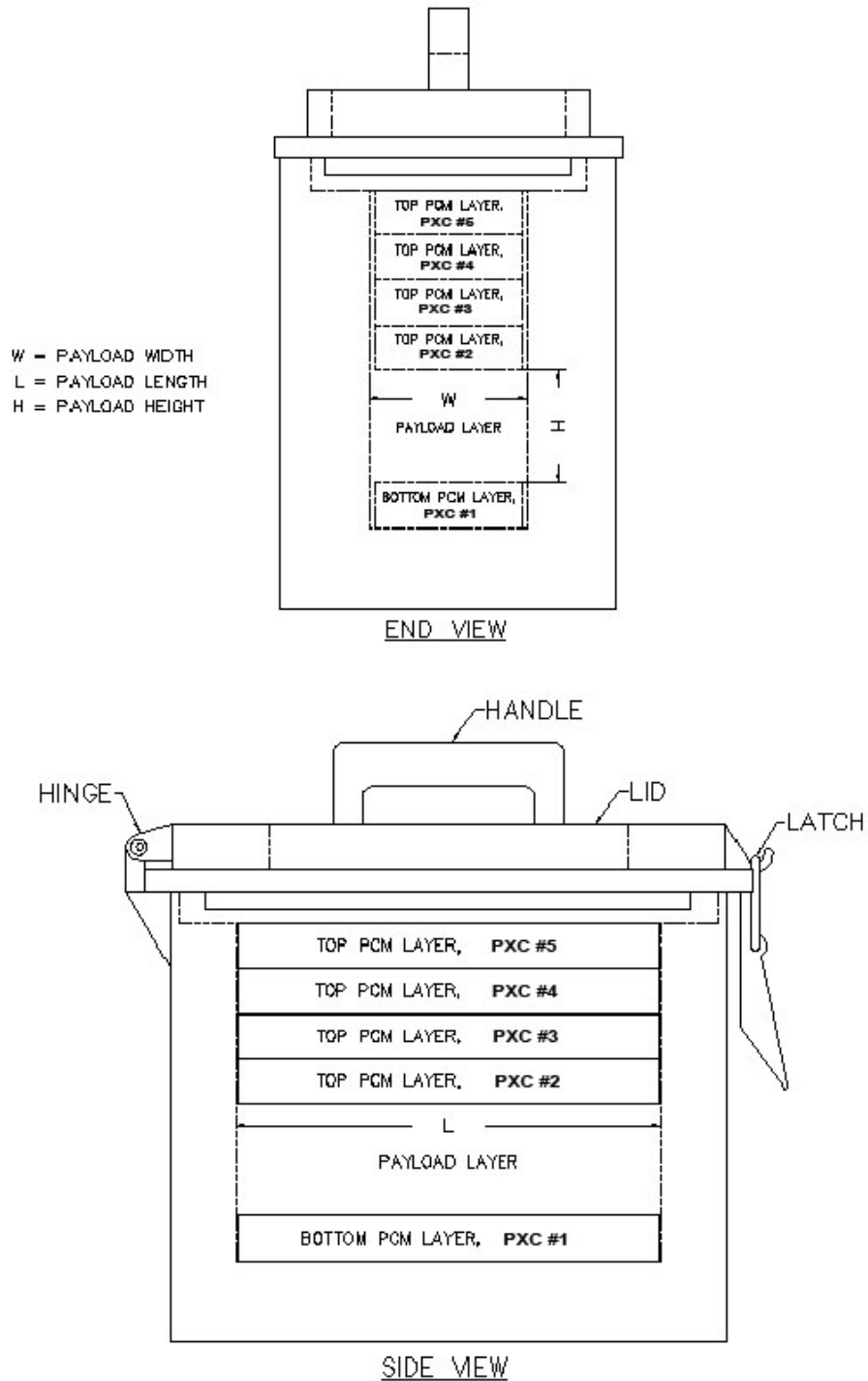


Figure 1



Brief AcuTemp PX1L Instructions

(Please read entire manual before using the **AcuTemp PX1L** carrying case and **AcuTemp PXC** coolant packs.)

Use of the **AcuTemp PX1L** and **AcuTemp PXC** system is easy, but requires an understanding of the term “freeze.” For purposes when using the **PX1L** carrying case and **PXC** coolant packs, “freeze” means to cool a **PXC** pack to the temperature required to change the contents from a liquid to a solid. The change (a phase change) may occur at the freezing temperature of water, or it may occur at a different temperature either higher (as in the case of **PXC (+7°C)**), or lower as in the case of **PXC (-15°C)**). At room temperature the **PXC** packs will feel slightly soft when depressed gently with the fingers. When frozen they will feel very firm. Please be certain to read the instructions for the **PXC** packs you are using to ensure that they are frozen at the proper temperature.

Procedure:

- 1) Freeze the **PXC** coolant packs according to the instructions that are included in this manual.
- 2) Place one **PXC** pack in the bottom of the **PX1L** carrying case. Please be certain to keep the pull-tab “UP”.
- 3) Place your payload on top of the **PXC** pack making certain that there is enough space on top to add the remaining four **PXC** packs (or 2 if you are only using 3 packs) with their pull tabs up.
- 4) Close and latch the **PX1L** carrying case and you are ready to go.

Determining the number of **PXC** coolant packs to use with the **PX1L** carrying case will depend on a number of factors:

- Ambient temperature
- Volume and shape of the material that needs to be kept cold, and
- The number of times the **PX1L** will be opened and closed during use.

It is recommended that you begin with all five **PXC** packs until you have gained experience with the **AcuTemp PX1L** system. We also recommend that you keep a temperature monitoring device in the unit along with the temperature sensitive payload so that you will be able to tell when any warming begins to take place as the **PXC** packs begin to thaw.

For technical help call AcuTemp at 937-312-0114.

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GENERAL SPECIFICATIONS

PX1L Carrying Case:

Dimensions (maximum): 11.5" (292 mm) H x 7.9" (200 mm) W x 13.7" (348 mm) L
13.4" (341 mm) height with handle
Payload Area: 2.0" (51 mm) H x 3.3" (84 mm) W x 9.3" (236 mm) L
Weight (empty): 5.5 lbs (2.5 kg)

PXC (+7°C):

Dimensions (maximum): 1.1" (28 mm) H x 3.3" (84 mm) W x 9.3" (236 mm) L
Weight, one piece: 1.0 lb (450 gm) maximum, 0.84 lb (380 gm) minimum
Weight, five pieces: 5.0 lbs (2.3 kg) maximum

PXC (-10°C):

Dimensions (maximum): 1.1" (28 mm) H x 3.3" (84 mm) W x 9.3" (236 mm) L
Weight, one piece: 1.4 lbs (630 gm) maximum, 1.2 lbs (530 gm) minimum
Weight, five pieces: 7.0 lbs (3.2 kg) maximum

PXC (-15°C):

Dimensions (maximum): 1.1" (28 mm) H x 3.3" (84 mm) W x 9.3" (236 mm) L
Weight, one piece: 1.1 lbs (500 gm) maximum, 0.8 lbs (370 gm) minimum
Weight, five pieces: 4.4 lbs (2.0 kg) maximum

PXC (-20°C):

Dimensions (maximum): 1.1" (28 mm) H x 3.3" (84 mm) W x 9.3" (236 mm) L
Weight, one piece: 1.3 lbs (590 gm) maximum, 1.0 lbs (495 gm) minimum
Weight, five pieces: 6.5 lbs (3.0 kg) maximum