IncuBlanket Kit User Manual (Full Version)





Spread the warmth Save lives

Spread the warmth. Save lives. *Warmth when you need it most.*

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Product Description

Used for infant thermal management to prevent and treat hypothermia following surgery, during transport (in external referral or intrahospital ward-to-ward), labor and delivery, or as an alternative source of infant warming. Simply click disk for instant non-electric 5-8 hours of heat anywhere. Average warming temperatures derived from Warmilu clinical data.

- Range of Warming Temperatures: 100.4° F (38°C) to 104°F (40°C)
- Average Temperature: 39°C (102.2°F)



Activator

Disk

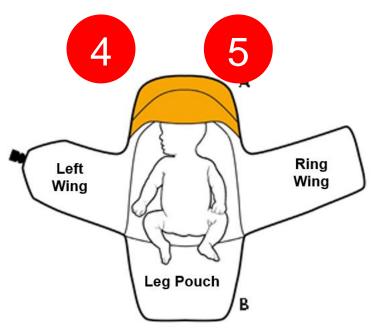
Using Your InstaWarmer 1. Activating Your InstaWarmer Pack

1. Activating Your Instavvarmer Pack

To activate your warming pack, please follow the instructions written below.

- Step 1: Roll the warming pack up to push clear liquid into the corner with the metal disk (located in one corner of the pack).
- **Step 2:** To heat, grasp the activator and press (pulse) a few times with the thumb and forefinger of both hands. You will hear an audible click.
- **Step 3:** The pack begins heating! You will see the pack change from liquid to solid as the heat spreads.
- **Step 4:** Knead pack to distribute heat.
- Step 5: Mark the pack to keep and track the number of use cycles. If you have difficulty activating the InstaWarmer, roll the pack up from the top opposite the activator disc, to push the clear phase change fluid around the activator disc. Press the activator disc again.





To place your pack and the baby into the blanket, follow these instructions.

Step 1: Unzip the back pocket of your IncuBlanket.

- Step 2: Place your InstaWarmer in the pocket. DO NOT USE THE INSTAWARMER PACK IMMEDIATELY AFTER BOILING. IT MUST BE ALLOWED TO COOL TO ROOM TEMPERATURE BEFORE ACTIVATING.
- Step 3: Zip the pocket closed completely.
- **Step 4:** Flip the blanket so the pack is on the bottom. Open the blanket.
- Step 5: Positioning the Infant Open blanket flaps before placing infant. Place the infant in the blanket on their back with the head at end A and feet pointing towards end B. The infant's head should be in a neutral position and their airway must be clear and unblocked. Legs and hips should be in a relaxed, flexed position.
- Step 6: When the infant is correctly positioned, fold the leg pouch up over the infant's torso. Fold the right wing across the infant's body. Repeat with left wing and clip buckle. Make sure the infant can breathe freely.
- **Step 7:** Pull the nylon strap down to tighten the flaps. Make sure the blanket is closed snuggly around the infant AND the infant can BREATHE freely.



3. Resetting (Option No.1): Boiling Your InstaWarmer

	5,000 ft 524 m
35 Minutes	3,000-5,000 ft 914.4 – 1,524 m
30 Minutes	1,000 - 3,000 ft 304.48– 914.4 m
25 Minutes	500 - 1,000 ft 152.4 - 304.48 m
20 Minutes	0 - 500 ft 0 - 152.4 m

Step 1: To boil your pack, fill a medium to large metal pot 2/3 with water to completely cover the InstaWarmer, and heat until it begins to boil.

Step 2: Roll your pack into thirds and carefully place into the boiling water.

Step 3: Boil the pack for 20-45 minutes. The length of time is determined by your altitude. Please refer to the image (left) to find the correct boiling time.

Step 4: Stir the pack during the boiling process to ensure the pack is heated, and that the pack does not stick to the metal pot. **DO NOT let pack touch ANY open flames.**

Step 5: When the pack has finished boiling, remove it from the water and check to make sure the entire contents of the pack have become a clear liquid. If white crystals or cloudiness (cloudy liquid) are observed, continue boiling for another 5 minutes, then check again. CAUTION: PACK WILL BE HOT, USE A PLASTIC OR WOOD UTENSIL TO REMOVE IT FROM THE WATER. Once the pack has cooled to room temperature, you will see two distinct materials within the pack: 1) The clear liquid phase-change material 2) The semi-solid thermal buffer that is a semi-transparent white color.

Step 6: Before use, the pack **MUST BE COOLED TO ROOM TEMPERATURE**. Lay the boiled pack flat with the activator disk slightly lower than the rest of the pack (such as off the edge of a counter or shelf). Once the pack feels room temperature to the touch (approximately 25°C), it is ready for use. Packs can be stored for up to 1 year and used when needed.



To watch a video on how to boil the pack, visit: https://www.youtube.com/watch?v=qnYURGBWICI

3. Resetting (Option No.2): Microwaving Your InstaWarmer

Instructions Video: https://www.youtube.com/watch?v=KMxMwzkusBA&feature=youtu.be **Step 1:** Roll the pack into thirds.

Step 2: Place the pack into a microwavable bowl filled to at least the middle (50%) with water. Make sure that the part of the pack with the DISK is BELOW (UNDER) the water.

Step 3: Place the bowl of water and the warming pack into the microwave. Set the timer for 25 minutes for a full pack OR 15 minutes for a half pack on the HIGH power setting based your microwave.

Step 4: Carefully remove the HOT pack from bowl. Shake the pack back and forth vigorously to mix solid chunks. Feel bottom of the pack. IF there are any solid salt-like chunks or cloudiness, keep microwaving for additional 5-minute increments until fully melted. You have successfully microwaved the pack when it looks like your pack is crystal clear. CAUTION: PACK WILL BE HOT, USE A PLASTIC OR WOOD UTENSIL TO REMOVE IT FROM THE WATER.

Step 5: Let the pack cool on the edge of a table for 45 minutes or until the pack's temperature is room temperature. The pack will have a gel-like interior with a jelly and clear liquid. Now, your pack is ready to activate!



3. Resetting (Option No.3): Autoclaving Your InstaWarmer Equipment: Tuttnauer Autoclave 1730

Step 1: Roll up each warming pack into thirds.

Step 2: Grab a bread loaf pan that is 9" x 5.5" x 3" (228.6 mm x 139.7 mm x 76.2 mm) in size.

Step 3: Place each pack rolled up with the disk at the very bottom of a non-stick bread loaf pan filled with about 0.5 inch (12.77 mm) of water to cushion the warming pack.

Step 4: Place the pan and pack into the autoclave. Set the autoclave settings to 104 degrees Celsius for 25 minutes on the sterilize-only cycle.

Step 5: Upon cycle completion, remove and shake the packs. Place the pack with the disk off the edge of a flat surface to cool to room temperature. **CAUTION: PACK WILL BE HOT, USE A PLASTIC OR WOOD UTENSIL TO REMOVE IT FROM THE WATER.**



4. Cleaning, Disinfecting, and Sterilization of Blanket and Pack

FREQUENCY FOR CLEANING, DISINFECTION, AND STERILIZATION OF INCUBLANKET: REMOVE infant from IncuBlanket. Ensure that the blanket is sterilized after each patient and BEFORE using this medical device on another patient. The Warmilu products can be stored at 0-50°C / 90% relative humidity. The Warmilu products can be operated at 10-40 °C / 90% relative humidity.

IncuBlanket Materials Overview

The interior fabric material is medical grade and waterproof. The IncuBlanket is made from certified CPSIA compliant fabrics. The fabric materials are certified nontoxic, safe, and medical-grade. The IncuBlanket can be stored in standard humidity and room temperature. Durable and survives more than 100 hot water sterilization washes.

External Fabric: 64% polyester, 36% polyurethane. CPSIA certified. Contains no lead, BPA, phthalates or other harmful chemicals | **Lining Fabric:** Face – Medical Grade Vinyl **Back**: Wicking polyester | **Batting Fabric One:** 65% olefin, 35% polyester **Batting Fabric Two:** 93.75% polyester and 6.25% metalized polyethylene film

INCUBLANKET WASHING INSTRUCTIONS

Step 1: Remove the InstaWarmer pack from the back pocket of your IncuBlanket, and leave the pocket unzipped. Open blanket wing and leg flaps.

Step 2: Wipe down the inside vinyl layer to remove ALL bodily fluids using standard hospital-grade cleaning solution and

disinfectant, like bleach.

Step 3 IF Hand



Washing: Wash in tub of hot water (a minimum of 160°F or 70°C) by hand for a minimum of 25 minutes with mild detergent. Agitate frequently.

Step 3 IF Machine Washing: Wash on a normal cycle on hot with mild detergent. DO NOT BLEACH, WILL DISCOLOR EXTERIOR FABRIC. Machine dry on low heat or hang dry. Store in a clean, dry location.

INSTAWARMER WIPE DOWN ONLY

Step 1: DO NOT wash the InstaWarmer in the washing machine.

Step 2: Wipe down with sanitizing solution like hospital-grade bleach and rinse with water. Do not use acetone to clean your InstaWarmer. Return to the ready-to-activate liquid state by boiling before storing. Store out of direct sunlight in a clean, dry location.

5. Specific Maintenance Requirements and Disposal of Blanket and Pack

The Blanket and InstaWarmer Pack do not have specific maintenance requirements for users beyond cleaning. The infant warming blanket materials can be recycled/made into secondary products such as pillow cases or purses. The warming pack disk is made from metal and can be recycled or sent back to Warmilu for reuse. The remaining materials can be disposed of in a normal (general) waste stream. The Blanket and InstaWarmer materials can be disposed of as solid general waste and are food grade, medical grade, and non-toxic. Warmilu Recycling Program Overview | https://www.warmilu.com/faqs

Safety Provisions

- a. When boiling your InstaWarmer, do not grab the pack directly or touch the metal pot or boiling water. Use appropriate safety gear, such as hot pads or non-metallic utensils, to protect hands and body from making contact with heated surfaces.
- b. Do not stab, cut, or perforate the external material of your InstaWarmer. If pack contents come in contact with skin, rinse immediately under cool water. If the pack is damaged or leaking, discontinue use immediately and allow the pack contents to return to room temperature before disposing of the pack with general waste. Do not place pack contents into the sink.
- c. Monitor the infant's temperature frequently while using the IncuBlanket. Temperature can be monitored with an external thermometer. If the infant's core body temperature reaches 38°C or above and does not return to a safe range within 30 minutes, remove the infant from the blanket. Do not place the infant directly on InstaWarmer.
- d. Follow proper cleaning and sanitizing instructions for your IncuBlanket and InstaWarmer to prevent cross-infection or damage to the product.
- e. Do not use IncuBlanket on infants who are febrile, having seizures, at risk for respiratory or cardiac arrest, have a brain injury, or are experiencing internal hemorrhage.
- f. Only activate the InstaWarmer once it has completely cooled to room temperature to prevent overheating.

Disclaimer

All intellectual property belongs to Warmilu LLC. **Warmilu reserves the right to make changes to the specifications shown herein. Please contact Warmilu to receive updates** and learn about changes to our products and procedures. A medical professional must always rely on his or her own professional clinical judgment when deciding whether to use the IncuBlanket and InstaWarmer when treating a particular patient. Warmilu does not dispense medical advice and recommends that medical professionals be trained in the use of the IncuBlanket and InstaWarmer before using it with a patient. **Do not use the IncuBlanket and InstaWarmer on infants without first seeking advice from a medical professional.**

Contact Information

If there are any questions, please contact the team by email (<u>info@warmilu.com</u>), phone or WhatsApp (+1 248 835 8703), or by mail correspondence to the following address (326 West Liberty Street, Ann Arbor MI 48103).