

IncuBlanket Kit User Manual



warmilu™

Spread the warmth. Save lives.



Our Mission

At Warmilu LLC, our goal is to provide non-electric, safe and instant warmth to infants around the world.

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Product Description

The Warmilu IncuBlanket kit is safe, non-electric, and reusable. This kit consists of a blanket which has been specially designed to accommodate an infant. This blanket provides instant warmth to assist in maintaining an infant's body temperature (between 97.5-99.5°F (36.4-37.5°C)) by using an InstaWarmer pack which is installed in the back zipper pocket.

Specifications for Preterm IncuBlanket and InstaWarmer:

Total Weight: 5 lbs (2.3 kg)

IncuBlanket Weight: 1.1 lbs (0.5 kg)

IncuBlanket Dimensions: 17.5 in x 10 in x 2.5 in
(44.45 cm x 25.4 cm x 6.35 cm)

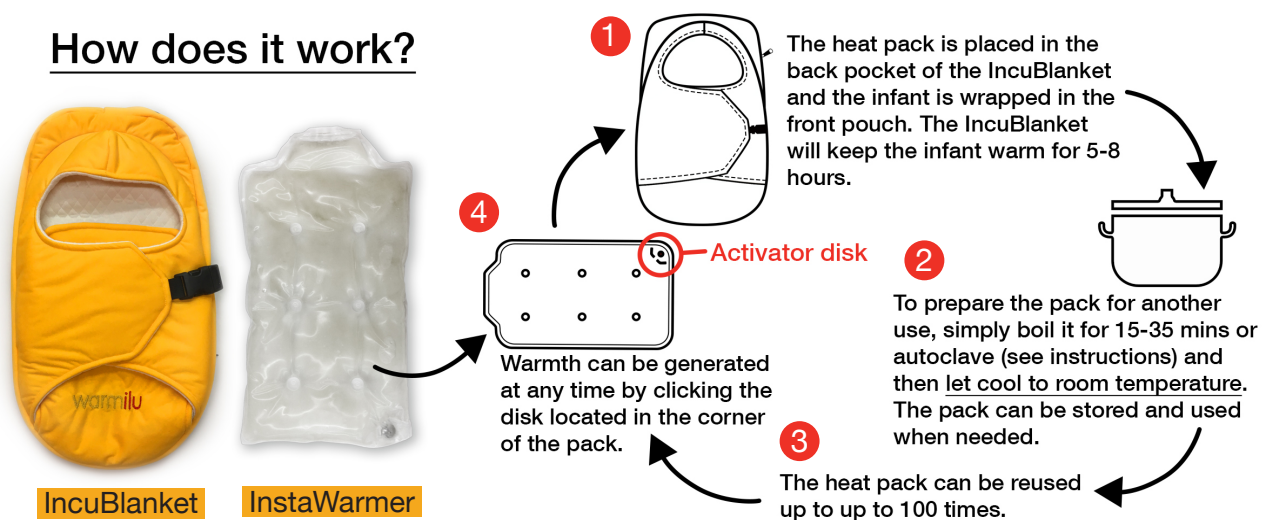
InstaWarmer Weight: 3.9 lbs (1.8 kg)

InstaWarmer Dimensions: 16 in x 9 in x 1 in
(40.6 cm x 22.8 cm x 2.5 cm)

Peak Temp: 102.2°F (39°C)

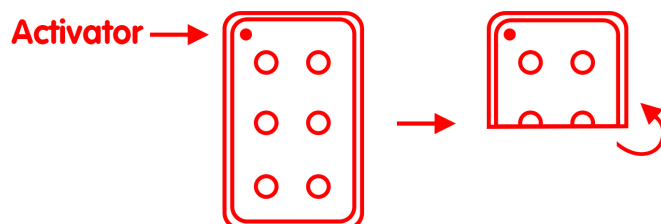
Time Duration: 5-8 Hours

How does it work?

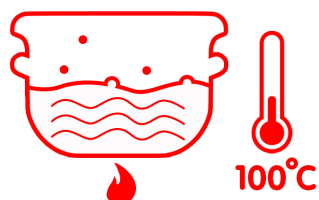


Use Instructions (Visual Guide)

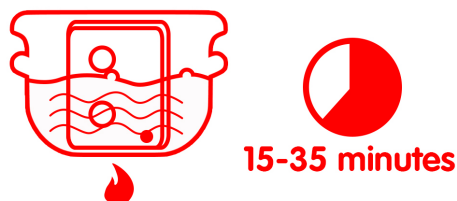
1. Fold InstaWarmer pack



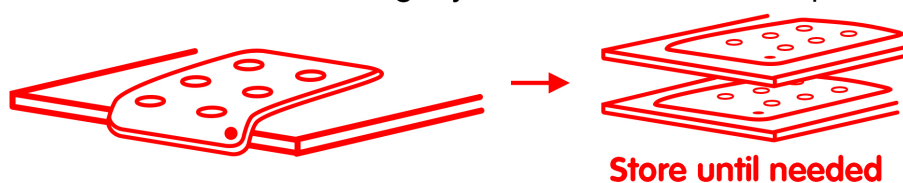
2. Boil enough water to cover pack in large fufuria (metal pot)



3. Place InstaWarmer in fufuria (metal pot) and boil for 15 - 35 minutes



4. Allow InstaWarmer to cool to room temperature on a flat surface with disk slightly lower than rest of the pack



5. When ready to use, press disk, check off use on label and place InstaWarmer into back of IncuBlanket (the InstaWarmer will generate heat for 5-8 hours and can be used up to 100 times).



Intended Use

The Warmilu IncuBlanket is intended to assist in maintaining an infant's core body temperature for 5-8 hours. Upon receiving the Warmilu IncuBlanket, please check to make sure you have received its two components including:

- 1) InstaWarmer: Warmilu warming pack
- 2) IncuBlanket: Warmilu infant warming blanket.

Newborns, infants, preterm infants, and young children are more likely to develop hypothermia. Neonates particularly low birth weight infants (2,500 g or less), very low birth weight infants (1,500 g or less), extremely low birth weight infants (less than 1,000 g), and preterm infants (<37 weeks) are more likely to develop hypothermia due to limited capacity to thermoregulate. Infants up to about 32 weeks of gestation do not have the ability to warm themselves effectively. Normal infants weigh 2,500 - 4,200 g at term delivery. Infants risk hypothermia if they are left in close proximity to cold surfaces, are stressed, or exposed to room temperature air and if the infant is not immediately dried and swaddled to prevent evaporative, conductive, and convective heat losses. Hypothermia may be caused by environmental factors, disorders that impair thermoregulation (i.e. sepsis, intracranial hemorrhage, drug withdrawal, and/or combinations of the above). The World Health Organization suggests different temperature values to assess the degree of hypothermia in infants:

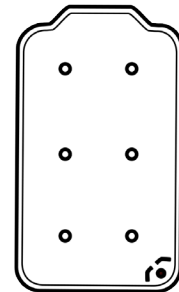
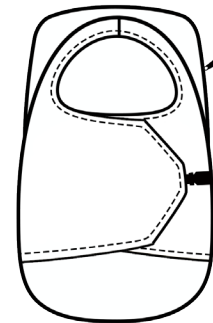
Cold stress or mild hypothermia: 36.0°C to 36.4°C (96.8°F - 97.5°F)

Moderate hypothermia: 32.0°C to 35.9 C (89.6°F to 96.6°F)

Severe hypothermia: <32°C (89.6°F)

Risk factors for hypothermia in infants include maternal hypertension, Cesarean section, and low Apgar scores. IncuBlankets and InstaWarmers may be used on infants weighing 2,500 g or less. Babies keep a normal heart rate when their body temperature is between 36.7-36.8°C.

IncuBlanket

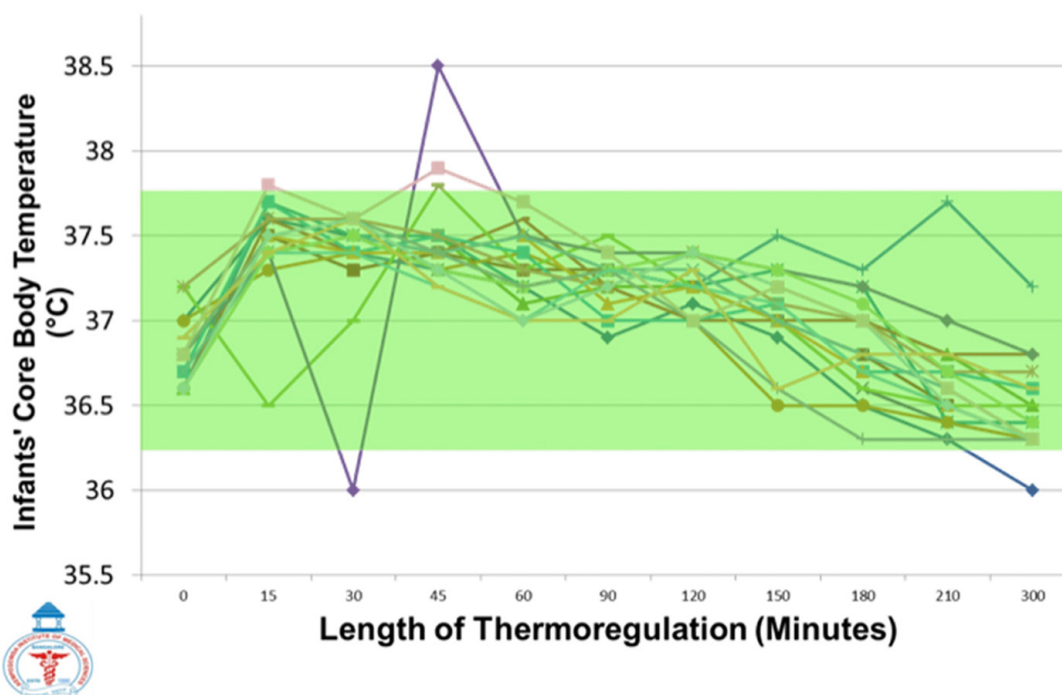


InstaWarmer

Warmilu IncuBlanket Clinical Trials

Clinical trials were conducted January – March 2013 at the Kempegowda Institute of Medical Sciences (KIMS) in Bangalore, India. The IncuBlanket kept 20 low birthweight and preterm infants warm between 36.4°C – 37.5°C. (97.5°F – 99.5°F) for 5 hours and successfully prevented hypothermia. The average weight of the infants was 1.75 kg (range 1.3 kg – 2.4 kg) and average gestational age 35.25 weeks (range 31-38 weeks). The trial was conducted on 10 boys and 10 girls. There was no case of overheating, skin rashes, hypothermia, hyperthermia, or erythema of significance noticed during or immediately after the study period. The interior temperature of the IncuBlanket will not exceed 39°C.

Infant Core Temperatures vs. Time



The Warmilu IncuBlanket and InstaWarmer have successfully cleared the Kenya Pharmacy and Poisons Board. Application Number: 9737.

The Warmilu InstaWarmer is a registered FDA Class I reusable device.

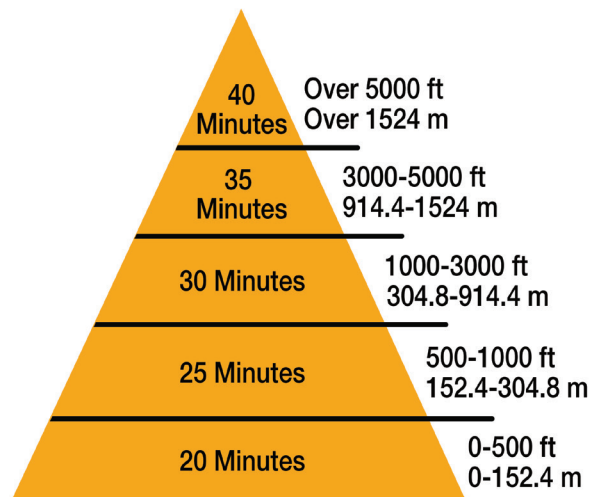
The Warmilu is in the process of filing for USA FDA 510(k) clearance and CE Mark for the IncuBlanket and InstaWarmer.

Using Your InstaWarmer

The InstaWarmer is activated before shipping to help prevent damage. When you receive your InstaWarmer pack you will need to reset it before use by boiling or autoclaving.

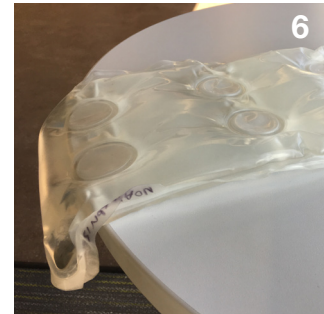
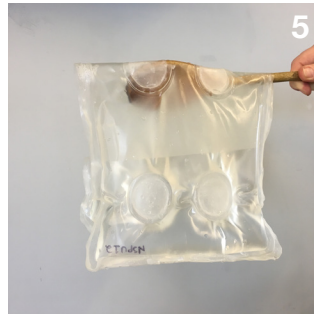
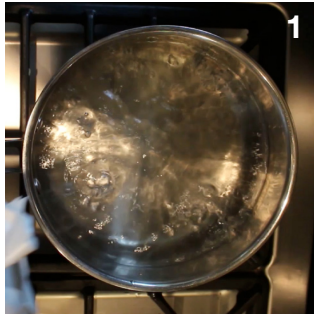
Resetting Option 1: Boiling Your InstaWarmer

Step 1: To boil your pack, fill a medium to large fufuria (metal pot) with enough water to completely cover the InstaWarmer, and heat until it begins to boil. Reduce heat. **Step 2:** Roll your pack into thirds and carefully place into the boiling water. **Step 3:** Boil the pack. The length of time needed to reset your pack by boiling is determined by your altitude. Please refer to the image below to find the correct boiling time for your location.



Step 4: Stir the pack several times during the boiling process to ensure all of the warming solution is heated, and that the pack does not stick to the fufuria (metal pot). **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 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>



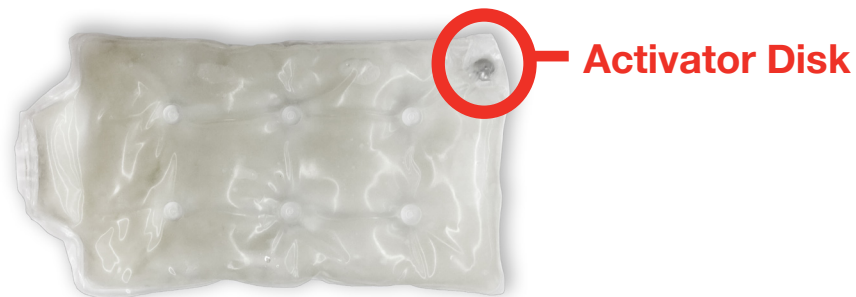
Resetting Option 2: Autoclaving Your InstaWarmer

The InstaWarmer pack can be reset in a hospital autoclave as an alternative to boiling. **Step 1:** Wipe InstaWarmer clean with soap and water. **Step 2:** Wrap InstaWarmer in a sterilization pouch or autoclave wrap.

Autoclave Settings: Use gravity cycle at 121°C for 15 minutes, and a 15 minute dry time.

Activating Your InstaWarmer Pack

When you are ready to use your InstaWarmer pack, lay it on a surface and grasp the metal activator disk (located in one corner of the pack) between both thumbs. Click it a few times to activate the phase change and generate heat. You will hear a clicking sound. The liquid in the pack will begin turning into a solid. You will feel warmth in seconds. Knead the InstaWarmer for 30 seconds to evenly distribute the thermal buffer before using the InstaWarmer in the IncuBlanket. If you experience any difficulty in activating the InstaWarmer pack, roll the pack starting from the end opposite the activator, to force the phase-change liquid into the space around the activator disk. Then click the disk again.



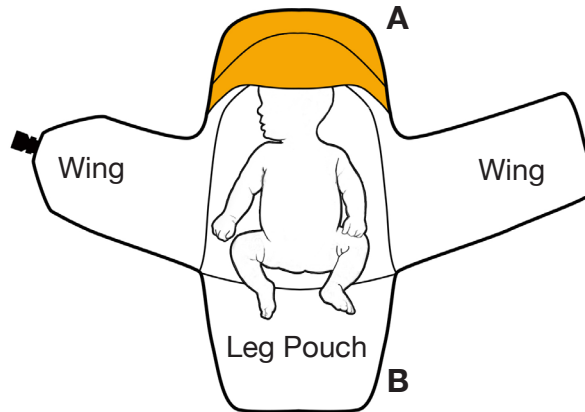
Prepping and Using the IncuBlanket

- Step 1:** Unzip the back pocket of your IncuBlanket.
- Step 2:** Place your InstaWarmer in the pocket.
DO NOT USE THE INSTAWARMER 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:** Place the infant into the blanket on their back. Make sure the infant's head is in a neutral position, and their legs and hips are in a relaxed, flexed position. Fold the leg pouch over the infant's torso.
- Step 6:** Fold the right wing across the infant's body. Repeat with the left wing and clip buckle. Pull the nylon strap down the tighten flaps. Make sure the blanket is closed snugly around the infant, but that they are able to breath freely.



Positioning the Infant

Completely open blanket flaps before placing infant. Place infant in the blanket on their back with 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. Their legs and hips should be in a relaxed, flexed position. When infant is correctly positioned, fold leg pouch up over infant, and close wings. Make sure infant is able to breathe freely.



Caring for your IncuBlanket and InstaWarmer

Caring for your IncuBlanket

Remove the InstaWarmer pack from the back pocket of your IncuBlanket, and leave the pocket unzipped. Open blanket flaps. Wash in hot water (a minimum of 160°F or 70°C) by machine or by hand for a minimum of 25 minutes with mild detergent. Agitate frequently. DO NOT BLEACH. Machine dry on low heat or hang dry. Store in clean, dry location.

Washing your InstaWarmer

DO NOT wash the InstaWarmer in the washing machine; wipe down with sanitizing solution and rinse with water. Do not use acetone to clean your InstaWarmer. Return to ready-to-activate liquid state by boiling before storing. Store out of direct sunlight in clean, dry location.



WASHABLE

WIPE DOWN ONLY

IncuBlanket Information

Materials are all 100% non-toxic. All materials are made in the USA.
All components are assembled and manufactured in Ann Arbor, MI, in the United States.
This product does not contain any rubber or latex.

IncuBlanket Materials

External fabric:

64% polyester, 36% polyurethane

CPSIA certified

Contains no lead, BPA, phthalates or other harmful chemicals

Lining fabric:

Face: 70% bamboo viscose, 30% organic cotton

Back: wicking polyester

CPSIA certified

Contains no lead, BPA, phthalates or other harmful chemicals

Batting fabric one:

65% olefin, 35% polyester

Batting fabric two:

93.75% polyester and 6.25% metalized polyethylene film

InstaWarmer Materials

External flexible polymer film:

100% medical grade polyurethane

Pack contents:

Non-toxic materials

Metal disk

Safety

- a. When boiling your InstaWarmer, do not grab pack directly or touch the fufuria (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 pack is damaged or leaking, discontinue use immediately and allow pack contents to return to room temperature before disposing of pack with general waste. **Do not place pack contents into sink.**
- c. Monitor infant's temperature frequently while using the IncuBlanket. Temperature can be monitored with an external thermometer. If infant's core body temperature reaches 38°C or above and does not return to a safe range within 30 minutes, remove infant from blanket. Do not place 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 over heating.

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.

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