



Instruction for Use

1.Product Name

Infant Heel Warmer

2.Specification/Main contents

EL085120A, ML085120A, EL095140A

Sodium acetate, water

3.Use Method

- 1.Find a metal plate and bend it with your hand to make it react.
- 2.Apply to affected area for 5min.

4.Temperature performance

Item		Target
Maximum temperature	The maximum temperature measured from the beginning to the end of heating.	$\leq 40^{\circ}\text{C}$
Temperature guarantee time	The total amount of time that the heating temperature is maintained 37- 40°C.	≥ 10 min

5.Intended Purpose

The Infant Heel Warmer is intended to provide controlled, localized warming to the heel of infants prior to capillary blood sampling procedures.Suitable for in medical institutions. Refer to the warning instructions for restrictions.

6.Intended patient population

The Warmer is applied to infants.

7.Intended user

Warmer shall only be used by the people who can read and understand the instruction manual.

8.Indications

The device is indicated for neonates and infants requiring heel-stick capillary blood sampling when localized warming of the sampling site is desired.

9.Contraindications

- Compromised peripheral circulation
- Skin infection, inflammation, dermatitis
- Recent burn injury in the heel area

- Infants with severe hemodynamic instability
- Known hypersensitivity to device materials

10.Undesirable side-effects

- Mild transient erythema (redness of the skin).
- Local skin irritation or discomfort.
- Blistering or superficial skin burns due to excessive warming.
- Contact dermatitis related to material sensitivity.

11.Intended clinical benefits

- To deliver safe and controlled warming to the heel prior to sampling.
- To support preparation of the heel for capillary blood collection.
- To reduce the risk of overheating and skin injury associated with non-controlled warming methods.
- To provide a standardized and reliable warming method for clinical use.

12. Warnings

- For external use only.
- Check the packaging bag without leakage and product within expiry date before using.
- Do not use if heel skin temperature $\geq 37^{\circ}$ C.
- Do not exceed the recommended warming time.
- Do not reheat, microwave, or use unauthorized heating methods.
- Do not use on damaged or compromised skin.
- Monitor the heel continuously during use and stop if redness or irritation occurs.
- For professional use only; not for unattended home use.
- Harmful swallowed. If accidentally swallowed, contact poison control center or physicians immediately.
- If bag breaks and fluid comes in contact with skin or eyes, flush with water immediately.

13. Cautions

- Consult instructions for use.
- Prior to use, store at room temperature.
- Patients should not lie with their full body weight on top of a warmer.
- Verify device temperature before application.
- Apply only to intact skin.
- Follow recommended warming duration strictly.
- Inspect skin before and after use.
- Dispose after single use (if applicable).
- Do not open the warmer.
- Keep out of reach of children.

14.Disposal

Dispose of contents/container in accordance with local/regional/national/international regulations.

15.Storage/Transportation conditions

Store at room temperature in a dry place. Avoid direct sunlight..

16.Shelf life

3 years

17.Importer



Name

Address [Note: the specific importer information will be printed in the printed version of IFU]

18.Manufacturer



JIANGSU INTCO MEDICAL PRODUCTS CO., LTD.

No. 298 Yandunshan Road, Zhenjiang New District 212132 Jiangsu P.R. China

19.EU Authorized Representative



MedNet EC-REP C IIb GmbH

Address: Borkstrasse 10, 48163 Muenster, Germany

20.Effective Date

2025-10-13

21.Revision

A/1

22.Contact information

- JIANGSU INTCO MEDICAL PRODUCTS CO., LTD.
- ADD: No. 298 Yandunshan Road, Zhenjiang New District, 212132 Jiangsu P.R. China

Email: sunguihua@intco.com

For a patient/user/third party in the European Union and in countries with identical regulatory regime (Regulation 2017/745/EU on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorized representative and to your national authority.

The contacts of national competent authorities (Vigilance Contact Points) and further information can be found on the following European Commission website:

https://ec.europa.eu/growth/sectors/medical-devices/contacts_en.

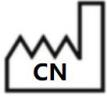
23.



<https://www.intcomedical.com/download.html>

Website: www.intcomedical.com

24.Symbol

No.	Symbol	Meaning
1		Date of Manufacture Country of Manufacture
2		Use-by date
3		Manufacturer
4		EU authorized representative
5		Batch Code
6		CE Marking, and Notified Body Code
7		Caution
8		Do not reuse
9		Do not use if package is damaged
10		Catalogue number
11		Medical device
12		Importer
13		Unique device identifier
14		Model number

No.	Symbol	Meaning
15	 A black icon of a sun with rays, positioned above a simple house silhouette.	Keep away from sunlight
16	 A black icon of an open umbrella with several raindrops falling from it.	Keep dry
17	 A black icon of an open book with a lowercase letter 'i' inside a square on the right page.	Consult electronic instructions for use