

KOOL-KIT® Neonate

REF 950

KIT CONTAINS:

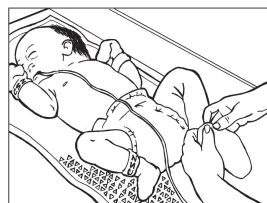
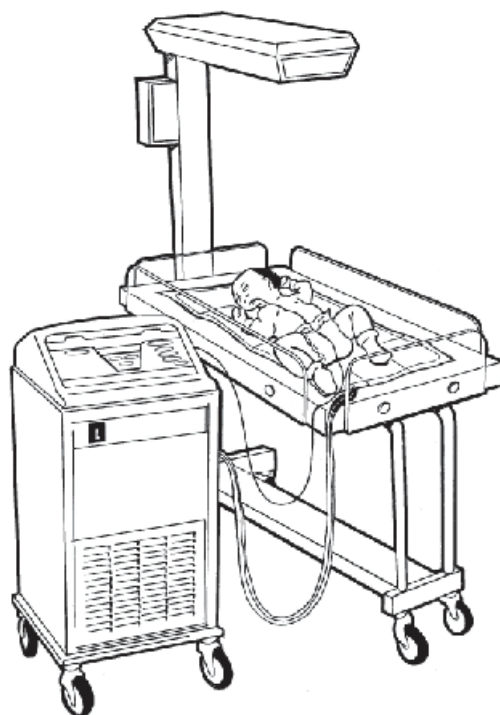
1. TRANSLATED INSTRUCTIONS

1. 33"x25" (83.8cm x 63.5cm) PAD (CE 0344)

1. TEMPERATURE PROBE INSTRUCTIONS
(English Only. For translations visit www.gentherm.com)

1. ESOPH/RECTAL TEMPERATURE PROBE (STERILE EO)
(MEDLINKET CE 2460)

1. MITTENS AND SOCKS (NOT CE MARKED)



WARNINGS

- Licensed healthcare practitioner's order is required for temperature setting and for use of therapy. Patients should be checked at least every 20 minutes or as directed by a licensed healthcare practitioner. Higher risk patients should be checked more frequently.
- Monitor patient skin temperature and condition paying particular attention to bony prominences. Notify licensed healthcare practitioner for changes in patient condition.
- Follow licensed healthcare practitioner's order /hospital policy for discontinuation of therapy. Notify licensed healthcare practitioner for changes in patient condition.
- Leaky blankets or hoses should never be used. Water leaks present a risk of infection and should be handled accordingly.
- Do not position patient on insulated tubing. Patient injury may occur.
- Do not allow the pad to be pulled out from under the patient. Check to make sure the pad is secure at all times to ensure patient's safety.
- Do not place sharp objects in contact with the blanket or hose as punctures may occur. Do not use pins to secure the blanket.
- Do not place several layers of sheets or other materials that will reduce the heat transfer between the blanket and patient. Conductive therapy effectiveness will be reduced if the patient is not placed directly on the blanket. Do not wrap patient with blanket.
- The Kool-Kit® Neonate is single patient use only. Reuse may result in biocontamination or cross-infection.
- Do not use the device distal to arterial cross clamping. Non-observance can lead to thermal injury.
- Do not use with a patient with an ischemic limb. Thermal injury may occur.
- If the patient is in contact with the mittens and socks, check the contact area per Hospital protocol or as directed by a licensed healthcare practitioner. Check that the mittens and socks do not restrict circulation.
- Ensure that the patient's mouth stays clear of the product. Patient injury may occur.

PRECAUTIONS

- Caution: Federal law restricts the device to sale by or on the order of a licensed healthcare practitioner.
- Presence of water or gel on the blanket while the unit is not operating may cool the patient.
- Use of unapproved equipment or hoses is not recommended. The Kool-Kit® Neonate has been designed and tested for use with Gentherm Blanketrol® thermal regulating system.
- Caution: Only the temperature probe is sterile. Do not use the Kool-Kit® in a sterile or aseptic area without proper precautions.
- If warranted, use pressure relieving or pressure reducing devices under the patient to protect from skin injury.
- Do not place bean bags or other firm positioning devices under the blankets/pads. Skin damage may occur.
- Keep the area between the patient and the blanket dry. Excessive moisture may result in skin damage.

INDICATIONS FOR USE

The Kool-Kit® Neonate is intended to be used by trained healthcare professionals as part of Gentherm's thermal regulating system, specifically, the Blanketrol®. The Blanketrol® Hyper-Hypothermia Temperature Management System is used to lower or to raise a patient's temperature and/or maintain a desired patient temperature through conductive heat transfer.

CONTRAINDICATIONS

- None Known.

SET UP

- Check the reservoir in the hyper-hypothermia unit to ensure it is full of sterile water or water that has been passed through a filter of less than or equal to 0.22 microns. Check Kool-Kit® integrity prior to each use.
- Lay the blanket on the patient care surface.
- Attach the male and female coupling from the Cat#286 hose to the unit. Make sure they "click" as they lock together.
- Attach the blanket to the Cat#286 hose by inserting the blanket connectors into the hose connectors. Connectors should "click" as they lock together.
- Turn the unit on and select the desired temperature setting.
- Allow time for the blanket to fill with water. Place the patient on blanket.
- Connect temperature probe to the device via an interconnect cable. Insert temperature probe according to hospital/institution protocol.
- Optional: place mittens and socks on patient.

OPERATING INSTRUCTIONS

- Follow Gentherm Blanketrol® operation manual for operating instructions.
- To discontinue therapy: Turn off unit and allow water to drain back into the reservoir. Hold the connector above the level of the blanket and disconnect the blanket from the connecting hoses.
- Discard the blanket after each patient use according to hospital/institution protocol. Retain the connecting hose for next use.
- Discard the temperature probe after each use according to hospital/institution protocol. Retain the interconnect cable.
- Discard the mittens and socks after each use according to hospital/institution protocol.

CLEANING

- The Kool-Kit® is single patient use only. Discard the Kool-Kit® according to hospital/institution protocol after each use. Do not reprocess or sterilize.

STORAGE

- Store unused Kool-Kit® in a cool, dry environment, free from items that may puncture Kool-Kit® components.

GENTHERM

Gentherm Medical, LLC
12011 Mosteller Road
Cincinnati, Ohio, USA 45241
1-800-989-7373
www.gentherm.com



CEpartner4U, BV
Esdoornlaan 13
3951 DB Maarn
The Netherlands
www.CEpartner4U.com