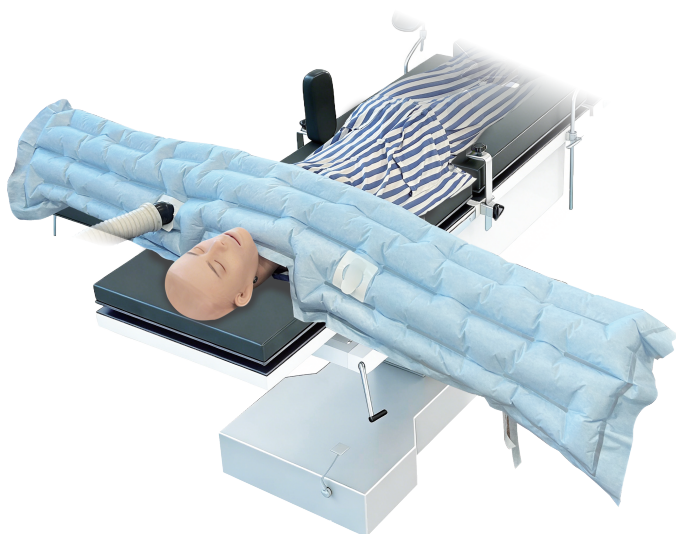


Air Flow Blanket



REF

GC2004A201

GC2004B102

GC2004C103

GC2004F106

User Manual

CE

Contents

Contents	1
Intended Use	2
Indications for Use	2
Intended User	2
Intended Patient Population and Settings	2
Contraindications, Warnings, and Cautions	2
Intraoperative Warming	4
Directions for Use	4
Technical product specifications	7
Symbol Glossary	8

Intended Use

The Air Flow Temperature Management System is intended to prevent and treat hypothermia. In addition, the temperature management system can be used to provide patient thermal comfort when conditions exist that may cause patients to feel too warm or too cold.

Indications for Use

The Air Flow Temperature Management System is intended to prevent and treat hypothermia. In addition, the temperature management system can be used to provide patient thermal comfort when conditions exist that may cause patients to feel too warm or too cold.

The temperature management system can be used with adult and pediatric patients.

Intended User

The Air Flow temperature management system should only be used by trained medical professionals.

Intended Patient Population and Settings

Adult and pediatric patients being treated in operating rooms, emergency departments and other departments in the hospital setting where patient temperature management is required.

Contraindications, Warnings, and Cautions

WARNING: Indicates a hazardous situation which, if not avoided, could result in death or serious injury.

CAUTION: indicates a hazardous situation which, if not avoided, could result in minor or moderate injury.

Contraindications: To reduce the risk of thermal injury

- Do not apply heat to lower extremities during aortic cross-clamping. Thermal injury may occur if heat is applied to ischemic limbs.

WARNING: To reduce the risk of thermal injury

- Do not treat patients with the Air Flow Warming Device hose alone. Always attach the hose to an Air Flow Blanket before providing warming therapy.
- Do not allow the patient to lie on the Air Flow Warming Device hose.
- Do not allow the Air Flow Warming Device hose to directly contact the patient's skin during warming therapy.
- Do not leave neonates, infants, children and other vulnerable patient populations unattended during warming therapy.

- Do not leave patients with poor perfusion unmonitored during prolonged warming therapy.
- Do not place the non-perforated side of the Air Flow Blanket on the patient. Always place the perforated side (with the small holes) directly on top of the patient in contact with the patient's skin.
- In the operating room, Air Flow Blanket can be used in conjunction with GCMEDICA Air Flow Warming Device. If combined use with other heating devices is necessary, please ensure that the inflation interface of other heating devices can be connected and used normally with Air Flow Blanket, and thorough safety test and other compatibility assessment must be performed prior to operation.
- Do not continue warming therapy if the red Over-temp indicator light illuminates and the alarm sounds. Unplug the Air Flow Warming Device and contact a qualified service technician.
- Do not place patient securement device (i.e. safety strap or tape) over the Air Flow Blanket.
- Do not place the Air Flow Blanket directly over a dispersive electrode pad.

WARNING: To reduce the risk of patient injury or death due to altered drug delivery

- Do not use an Air Flow Blanket over transdermal medication patches.

WARNING: To reduce the risk of injury due to interference with ventilation

- Do not allow the Air Flow Blanket or head drape to cover the patient's head or airway when the patient is not mechanically ventilated.

WARNING: To reduce the potential for injury due to patient falls

- Do not use an Air Flow Blanket to transfer or move the patient.

CAUTION: To reduce the risk of Product damage

- Store the device away from sunlight in a dry place.

CAUTION: To reduce the risk of cross-contamination

- This Air Flow Blanket is not sterile and is intended for single patient use ONLY. Placing a sheet between the Air Flow Blanket and the patient does not prevent contamination of the product.

CAUTION: To reduce the risk of fire

- Do not use this product within a high pressure oxygen therapy device.
- Do not use in a flammable anesthesia gas and high concentration oxygen atmosphere.

CAUTION: To reduce the risk of thermal injury

- Do not use if primary packaging has been previously opened or is damaged.

CAUTION: To reduce the risk of thermal injury, hyperthermia or hypothermia

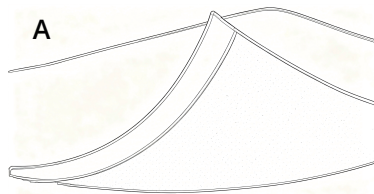
- GCMEDICA recommends continuously monitoring core temperature. In the absence of continuous monitoring, monitor the temperature of patients who are incapable of reacting, communicating and/or who cannot sense temperature a minimum of every 15 minutes or according to institutional protocol.
- Monitor cutaneous responses of patients who are incapable of reacting, communicating and/or who cannot sense temperature a minimum of every 15 minutes or according to institutional protocol.
- Adjust air temperature or discontinue therapy when the therapeutic goal is reached, if elevated temperatures are recorded or if there is an adverse cutaneous response under the Air Flow Blanket.

Intraoperative Warming

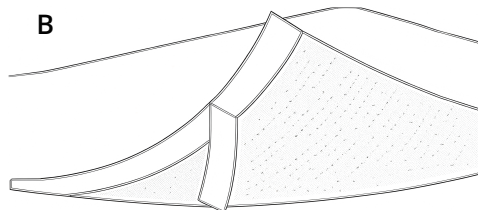
Follow your institution's protocols and adhere to guidelines for sterile technique, including good surgical draping practice.

Directions for Use

1. Place the perforated side of the Air Flow Blanket (the side with small holes) directly on top of the patient in contact with the patient's skin (see Figure A).



2. Where applicable, to help secure the Air Flow Blanket, remove the backing from the adhesive tape strip and adhere the Air Flow Blanket to the patient (see Figure B). The Air Flow Blanket should be placed with the adhesive strip towards the surgical site.

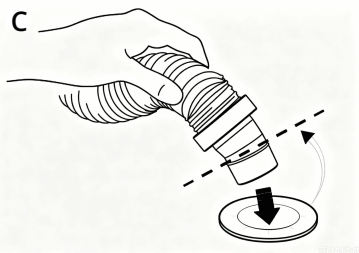


Warning: Do not place patient securement device (i.e. safety strap or tape) over the Air Flow Blanket.

Warning: Do not place the Air Flow Blanket directly over a dispersive electrode pad.

Warning: Do not treat patients with the Air Flow Warming Device hose alone. Always attach the hose to an Air Flow Blanket before providing warming therapy.

3. Insert the end of the Air Flow Warming Device hose in the hose port (see Figure C). Use a twisting motion to ensure a snug fit. A visual marker is located around the mid-section of the hose end to guide the depth of hose insertion. Support hose to ensure secure attachment.



NOTE: See special considerations for blankets shown below.

4. Select the desired temperature setting on the Air Flow Warming Device to initiate warming therapy. (See the IFU for your Air Flow Warming Device)

Caution: Patient Monitoring Recommendations

—GCMEDICA recommends continuously monitoring core temperature. In the absence of continuous monitoring, monitor the temperature of patients who are incapable of reacting, communicating and/or who cannot sense temperature at a minimum of every 15 minutes or according to institutional protocol.

—Monitor cutaneous responses of patients who are incapable of reacting, communicating and/or who cannot sense temperature a minimum of every 15 minutes or according to institutional protocol.

—Adjust air temperature or discontinue therapy when the therapeutic goal is reached, if elevated temperatures are recorded or if there is an adverse cutaneous response under the Air Flow Blanket.

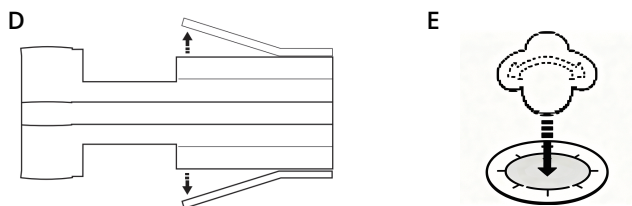
5. Based on the Air Flow Warming Device utilized, turn the unit off or to standby mode to discontinue warming therapy. Disconnect the Air Flow Warming Device hose from the blanket and discard the Air Flow Blanket per hospital policy.

Special Considerations

Upper Body GC2004A201 Air Flow Blanket

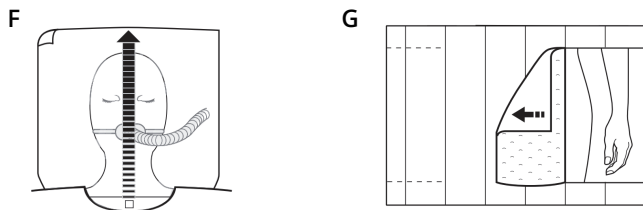
Where applicable, in order to help secure the Air Flow Blanket, use the tie strips to secure the patient to the blanket(see Figure D).

Two hose ports are provided for clinician preference. Place the removable card in the hose port that is not being used during warming therapy(see Figure E).



If the patient is intubated and ventilated, lay the head drape over the patient's head and neck(see figureF) otherwise, tuck the drape between the channels of the Air Flow Blanket, away from the patient's head.

Warning: Do not allow the Air Flow Blanket or head drape to cover the patient's head or airway when the patient is not mechanically ventilated.



Full Body Surgical GC2004C103 Air Flow Blankets

To use the access panels, tear the uncut tab at the edge of the Air Flow Blanket. Remove the backing from the tape strip on the center of the blanket. Fold the access panel back and press against the exposed tape. Pull the panel away from the tape to release (see Figure G).

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.





Technical product specifications





Product code	Size	Blanket Type	Description
GC2004A201	212cm×64cm	Upper Body	Adapts to multiple surgical positions and procedures
GC2004B102	163cm×120cm	Lower Body	Cover and warming the lower body of the patient, adapts to upper body surgical procedures
GC2004C103	212cm×120cm	Full Body Surgical	Adapts to chest, arm, trunk, and lower body surgical procedures
GC2004F106	212cm×120cm	PACU Full Body	Indicated for postoperative




Note:





The shelf life of all styles of blankets is **5 years**.

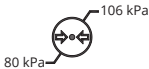
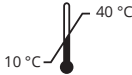


Symbol Glossary






Symbol	Symbol reference number	Standard – Title and Designation	Description
	5.1.11	ISO 15223-1 Medical devices–Symbols to be used with information to be supplied by the manufacturer–Part 1: General requirements	To identify the country of manufacture of products. GCMEDICA also uses this symbol to state the date of manufacture
	5.4.3	ISO 15223-1 Medical devices–Symbols to be used with information to be supplied by the manufacturer–Part 1: General requirements	Indicates the need for the user to consult the instructions for use
	5.7.7	ISO 15223-1 Medical devices–Symbols to be used with information to be supplied by the manufacturer–Part 1: General requirements	Indicates the item is a medical device
	5.1.5	ISO 15223-1 Medical devices–Symbols to be used with information to be supplied by the manufacturer–Part 1: General requirements	Indicates the manufacturer's batch code so that the batch or lot can be identified

Symbol	Symbol reference number	Standard – Title and Designation	Description
	N/A	ISO 15223-1 Medical devices–Symbols to be used with information to be supplied by the manufacturer–Part 1: General requirements	Indicates conformity to European Union Medical Device Regulation or Directive
	5.1.1	ISO 15223-1 Medical devices–Symbols to be used with information to be supplied by the manufacturer–Part 1: General requirements	Indicates the medical device manufacturer
	5.1.4	ISO 15223-1 Medical devices–Symbols to be used with information to be supplied by the manufacturer–Part 1: General requirements	Indicates the date after which the medical device is not to be used
	5.2.1	ISO 15223-1:2021/Amd 1: 2025 Medical devices- Symbols to be used with information to be supplied by the manufacturer-Part 1: General requirements AMENDMENT 1: Addition of defined term for authorized representative and modified EC REP symbol to not be country or region specific	Indicates the authorized representative in the identified country or jurisdiction Name: Kingsmead Service B.V. Address: Zonnehof 36, 2632 BE, Nootdorp, Netherlands

Symbol	Symbol reference number	Standard – Title and Designation	Description
	5.4.2	ISO 15223-1 Medical devices–Symbols to be used with information to be supplied by the manufacturer–Part 1: General requirements	Indicates a medical device that is for one single use only
	5.2.8	ISO 15223-1 Medical devices–Symbols to be used with information to be supplied by the manufacturer–Part 1: General requirements	Indicates that a medical device should not be used if the package has been damaged or opened, and that the user should consult the instructions for use for additional information
	5.2.7	ISO 15223-1 Medical devices–Symbols to be used with information to be supplied by the manufacturer–Part 1: General requirements	Indicates a medical device that has not been subjected to a sterilization process
	5.4.5 and Annex B	ISO 15223-1 Medical devices–Symbols to be used with information to be supplied by the manufacturer–Part 1: General requirements	Indicates natural rubber or dry natural rubber latex is not present as a material of construction within the medical device or the packaging of a medical device

Symbol	Symbol reference number	Standard – Title and Designation	Description
	5.3.2	ISO 15223-1 Medical devices–Symbols to be used with information to be supplied by the manufacturer–Part 1: General requirements	Indicates a medical device that needs protection from light sources
	5.3.4	ISO 15223-1 Medical devices–Symbols to be used with information to be supplied by the manufacturer–Part 1: General requirements	Indicates a medical device that needs to be protected from moisture
	5.3.1	ISO 15223-1 Medical devices–Symbols to be used with information to be supplied by the manufacturer–Part 1: General requirements	Indicates a medical device that can be broken or damaged if not handled carefully
	0623	ISO 7000 Graphical symbols for use on equipment	Packages Transport packaging design and materials handling. To indicate correct upright position of the transport package

Symbol	Symbol reference number	Standard – Title and Designation	Description
	5.3.9	ISO 15223-1 Medical devices–Symbols to be used with information to be supplied by the manufacturer–Part 1: General requirements	Indicates the range of atmospheric pressure to which the medical device can be safely exposed
	5.3.7	ISO 15223-1 Medical devices–Symbols to be used with information to be supplied by the manufacturer–Part 1: General requirements	Indicates the temperature limits to which the medical device can be safely exposed
	5.3.8	ISO 15223-1 Medical devices–Symbols to be used with information to be supplied by the manufacturer–Part 1: General requirements	Indicates the range of humidity to which the medical device can be safely exposed
	5.7.8	ISO 15223-1 Medical devices–Symbols to be used with information to be supplied by the manufacturer–Part 1: General requirements	Indicates that the original medical device information has undergone a translation which supplements or replaces the original information Name: YGYM Translation Service Co., Ltd. Address: Room 1007, No. 21, Jizheng Road, Nansan Community, Buji Subdistrict, Longgang District, Shenzhen, China

Symbol	Symbol reference number	Standard – Title and Designation	Description
	5.4.4	ISO 15223-1 Medical devices–Symbols to be used with information to be supplied by the manufacturer–Part 1: General requirements	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action to avoid undesirable consequences
	M002	EN ISO 7010– Graphical symbols –Safety colours and safety signs– Registered safety signs (ISO 7010:2019) ISO 20417 Medical devices–Information to be supplied by the manufacturer	Indicates that, according to the manufacturer's risk analysis, not reading the instructions can cause a hazard
	5.2.6	ISO 15223-1 Medical devices–Symbols to be used with information to be supplied by the manufacturer–Part 1: General requirements	Indicates a medical device that is not to be resterilized
	2794	ISO 7000 Graphical symbols for use on equipment	To indicate the number of pieces in the package. Note: A number is inserted in the symbol to indicate the number of pieces in the package
	5.1.6	ISO 15223-1 Medical devices–Symbols to be used with information to be supplied by the manufacturer–Part 1: General requirements	Indicates the manufacturer's catalogue number so that the medical device can be identified



Kingsmead Service B.V.
Zonnehof 36, 2632 BE, Nootdorp, Netherlands



GCMEDICA ENTERPRISE LTD.(WUXI)
Loujin Industrial Park, Shuofang,
Wuxi 214143, Jiangsu, P.R. China

Made in China