

# Sterisets

Medical Products

## Blanket Warming Unit Operator Manual

Model: WB1000F

REF: 85000



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PART OF STI GROUP





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# Instruction Manual

## General Description

The Sterisets® Blanket Warming System is a forced-air warming system, using convective warming to prevent and treat hypothermia. It consists of two components: a Blanket Warming unit and a single-use blanket.

The blanket is connected to the flexible hose of the warming unit. Warm air from the warming unit passes through the hose into the blanket.

Through the small holes in the underside of the blanket the warm air is distributed evenly over the patient.

The clinical staff using the device are anesthetists, anesthetic assistants, operating department practitioners and nurses in theatre, the recovery room and critical care unit.



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**Read this manual carefully before use. Failure to follow may cause severe injuries.**

| Indications                             | Contraindications  |
|---|--|
| Prevention and treatment of hypothermia | DO NOT apply heat directly to open wound or ischemic limb.<br>DO NOT apply to extremities during surgeries when an artery to the extremity is clamped. |



**Warnings** Failure to follow may cause personal injuries

To avoid the risk of electric shock, this equipment must only be connected to a grounded electrical outlet.

To prevent electromagnetic interference from other devices to the unit, the other devices must meet EMC requirements.

The Blanket Warming Unit meets medical electronic interference requirements. If radio frequency interference with other equipment should occur, connect the unit to a different power source.

Continuously monitor temperature and skin when used on unconscious patients, elderly patients, or pediatric patients.

Risk of electrical shock, always unplug power cord before cleaning.

DO NOT use on circulatory problem individuals, unless managed and monitored by healthcare professional.

DO NOT use unit hose directly to patient without a blanket.

DO NOT use hose under the patient or put any pressure on it.

DO NOT obstruct vents of the device. Temperatures will vary according to the room temperature and blanket sizes.

DO NOT operate damaged or malfunctioning device.

DO NOT position the device where it is difficult to operate the appliance plug and socket.

Device must only be opened or serviced by qualified personnel such as certified electronics technicians or certified clinical engineers familiar with repair practices for servicing medical devices, and in accordance with the Instruction manual.



**Caution** Failure to follow may cause damage to product

DO NOT use this unit in any other manner other than the purpose or the operation method described in this instruction manual.

Use only the power cord specified for this product.

DO NOT submerge, spray, pour, or spill any liquid on the unit.

DO NOT drop or hit the product. Store in a cool dry place.

DO NOT open or disassemble the unit.

No modification of this unit is allowed.

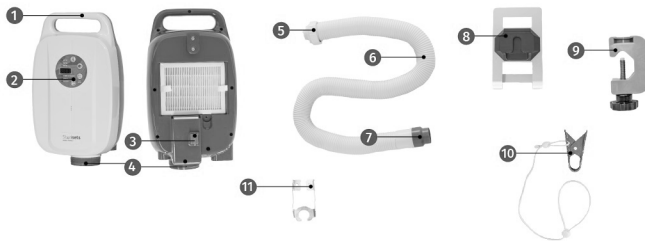
The device can only be operated by qualified and trained personnel.

DO NOT operate if the hose is ruptured.

DO NOT operate in a wet or moist condition.

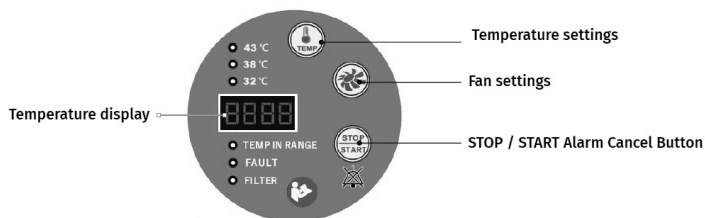
**This document was made taking into account post market surveillance and clinical evaluation data.**

## Overview



- 1 Handle
- 2 Control Panel
- 3 Trolley / I.V. Pole Bumper
- 4 Hose Port
- 5 Proximal Extremity
- 6 Distal Extremity
- 7 Hose Connector
- 8 Bedrail Bracket
- 9 Trolley / I.V. Pole Clamp
- 10 Securing Clip
- 11 Power Cord Holder

## Control panel



## Attach Flexible Hose

1. Place the unit on a stable surface, make sure the power is not connected.
2. Connect the electrical plug from the hose.
3. Take the proximal end of the Flexible Hose and attach it to the Hose Port.
4. Turn the outer ring clockwise until it is well secured.
5. Attach the power cord and tighten security support.

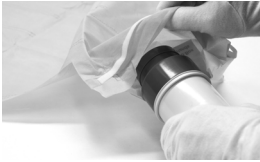


## Mount on an I.V. Pole

1. Pull out the I.V. Pole Clamp and release the screw lock.
2. Place the Warming Unit on the I.V. pole and align the I.V. Pole Bumper.
3. Tighten the screw lock and make sure it is securely clamped to the pole.
4. The Flexible Hose can be placed over the unit when not using it.

## Attach Blanket

1. Insert the Distal End of the Flexible Hose into the selected Sterisets Blanket.
2. Tie up the blanket on the Flexible Hose.
3. Ensure that it is well secured.



## Instructions for Use

1. Connect the unit to the power source. It will run a 1 second power-on self light test and finish with the standby light ON (orange) and the preset High Fan light ON (green).

2. Select the desired Temperature  
It will start blowing and the Standby light will go OFF.  
Once the temperature Display reaches the selected temperature +/- 2°C, the TEMP. IN RANGE light will light up.



3. Select the desired Fan setting.  
It can be changed anytime while operating.  
Ensure the blanket is well inflated.



4. Press Standby button to stop operating.  
Standby will light up (orange).  
Reselect the temperature to start.



## Over Temperature Alarm

If the temperature reaches > 48°C, it will automatically shut down the heater and the fan. The OVER TEMP light will light up and the alarm will go of. Press any button (except FAN settings button) to turn OFF the sound.

In case of OVER TEMP:

1. Disconnect the Power cord.
2. Contact Technical Support.

## User Requirements

The device is to be operated by a skilled professional only. Please request your supplier for any additional training if desired.

## System Fault Troubleshooting

When the system fails, it will automatically turn off the heater and fan. The screen will display fault code, OVER TEMP and TEMP IN RANGE light indicator will flash simultaneously. Press any button (except FAN settings button) to turn OFF the sound.

## If system fault occurs

- 1 . Unplug the power cord and wait for 5 minutes.
- 2 . Reconnect the power cord. The device will start the power-on-reset operation and stay on standby mode.
- 3 . Reselect the desired temperature.
- 4 . If it doesn't return to normal operating condition, contact technical support.

## Routine Maintenance

Maintenance on the device should be performed by qualified personnel such as certified electronics technicians or clinical engineers. Additional service maintenance is available. Please request your distributor for a digital copy.

## Filter Change

The FILTER light will light up after 500 hours or every 12 months of use to remind to replace the filter. Replacing the filter should be done by qualified service personnel only.

## Diagnostics

A qualified service technician can perform over-temperature detection system testing, temperature output testing, operating temperature calibration and fault code troubleshooting.

## Cleaning

**ALWAYS** power off the device and unplug the power cord from the outlet before cleaning.

- Device can be cleaned with a neutral disinfectant wipe or with a damp cloth, no residue of detergent may be left on the control panel.
- DO NOT wash the device or hold under running water.



**Do not use aggressive cleaning materials.**

## Operating Environment

- Operating temperature
- Relative Humidity: 2,000 -> 2.000 M
- Altitude: Max 2,000m

## Transportation and Storage

- Temperature: +5 to +/-45°C
- Relative Humidity: 80% RH maximum

## Disposal



Please dispose the device in accordance with EC Directive - WEEE (Waste Electrical and Electronic Equipment).

If you have any questions, please contact the local authorities responsible for waste disposal.

## Specifications

- Temperature Setting (°C) : Low 32 / Med 38 / High 43
- Fan Setting: HIGH / LOW
- Input: 220~240V, 50/60Hz, Max. 4.5 A
- Heating Element: 500W
- Power Consumption: 500W (1.000W peak)
- Fuses: Fast acting ceramic fuses, 250 VAC / 5A
- Device Classification: Class IIa
- The device complies with the following standards: EN 60601-1-2, EN 60601-1
- Dimensions: H 373 x W 223 x D 172 mm
- Weight: 2.3 kg
- Hose: 1.8 meters length, flexible
- Power Cord: 4.5 meters
- Filter: HEPA 0.2 µm

## Labeling Symbols



Consult operators manual



Warning / Caution



European Union WEEE Directive Logo



Device type BF (Protection against electric shock)



Item number



Batch number



Serial number



CE mark



Manufacturer



# Annex I HEPA filter replacement

## HEPA Filter Replacement - Instruction Manual

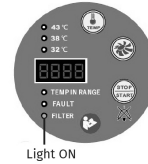
The FILTER light will light up after 500 hours or every 12 months of use to remind to replace the filter.

### Warnings

- . ALWAYS power off the device and unplug the power cord from the outlet before filter replacement.
- . DO NOT operate the warming system with the back cover removed.

### Caution

- . ONLY qualified service personnel should replace the filter.



## Equipment Required for HEPA Filter Replacement

| Equipment            | Description / Use    |
|----------------------|----------------------|
| Phillips Screwdriver | Removing Screwdriver |
| Replacement Filter   | REF. 85011           |

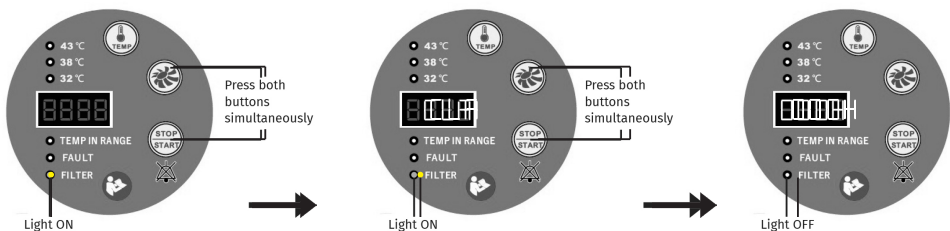
## HEPA Filter Change

1. Unplug the blanket warming unit.
2. Remove the filter cover screws, remove the old filter.
3. Place the new filter into the blanket warming unit.
4. Place the filter cover and install the screws holding the filter cover to the blanket warming unit






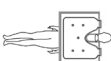
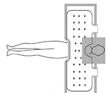





## Filter Timer & Light Reset

1. Plug the blanket warming unit.
2. Press both buttons together, until «CLA» display ON release both buttons immediately.
3. If display «0000», means RESET success and FILTER light will turn OFF.



## Annex II Blanket Assortment

|   | Ref   | Description        | Size (cm) | Packaging |
|---|-------|--------------------|-----------|-----------|
|    | 85100 | Full Body          | 195 x 100 | 4 x 10    |
|    | 85110 | Multi Access       | 195 x 100 | 4 x 10    |
|    | 85120 | Abdominal Access   | 192 x 180 | 4 x 10    |
|    | 85150 | Adult Tube         | 217 x 91  | 4 x 10    |
|    | 85200 | Lower Body         | 120 x 100 | 4 x 10    |
|    | 85300 | Upper Body ARM IN  | 124 x 94  | 4 x 10    |
|    | 85310 | Upper Body ARM OUT | 192 x 57  | 4 x 10    |
|    | 85400 | Pediatric Neonatal | 92 x 89   | 4 x 10    |
|   | 85410 | Pediatric Child    | 99 x 136  | 4 x 10    |
|  | 85450 | Pediatric Tube     | 113 x 56  | 4 x 10    |

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