Paciento šildytuvas - šaldytuvas

BLANKETROL® III

Operation and Technical Manual

Model 233 Hyper-Hypothermia System

Įrenginio modelis

Gamintojas

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www.gentherm.com

Manual 56201 Rev. AM

external features of the BLANKETROL III and Section (3-10.) describes display messages. These sections should be consulted if questions arise over the terminology used in this manual.

Operating modes are described in Section (1-5.1.) and are highlighted throughout the manual in italics and capital letters. Button names and display messages are shown in all capital letters.

1-2. GENERAL DESCRIPTION OF THE BLANKETROL III SYSTEM

2.1.1. paciento temperatūros kontrolė bei hipotermijos, normotermijos ir hipertermijos užtikrinimui

INDICATIONS FOR USE

The BLANKETROL III 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. The system is composed of a heater, a compressor, a circulating pump and blankets/pads.

BLANKETROL III Model 233

This unit requires no field adjustments or calibrations to maintain the precise board measurement of temperature and temperature limits.

Sterile water or water that has been passed through a filter less than or equal to 0.22 microns is heated or cooled and pumped from the unit to a blanket. The blanket* rests under and/or on top of the patient and is designed so that the water circulates through the blanket and returns to the unit.

If water that is at a lower temperature than the patient's temperature is circulated through the blanket, the desired effect is to reduce the patient's temperature. If water that is at a higher temperature than the patient's temperature is circulated through the blanket, the desired effect is to elevate the patient's temperature.

The BLANKETROL III unit can be set so that it operates based on the temperature of the water in the BLANKETROL III equipment (*MANUAL CONTROL MODE*) or it can be set so that it operates based upon the patient's temperature (Automatic Modes). The three Automatic modes include:

1) *AUTO CONTROL MODE*
2) *GRADIENT 10C SMART MODE*
3) *GRADIENT VARIABLE SMART MODE*

2.1.8. Temperatūros kontrolės režimai: rankinis, automatinis, gradientas

The BLANKETROL III System can also be used solely to monitor the temperature of the patient (*MONITOR ONLY MODE*).

The BLANKETROL III is intended for use in ambient temperatures of 15°C – 30°C (59°F – 86°F). The maximum contact surface temperature is 41°C (105.8°F).

* The recommended blanket(s) for use are described in Table 6-8.

1-3. PHYSICAL DESCRIPTION OF THE BLANKETROL III UNIT

See Section (7.) for specifications and certifications of the BLANKETROL III.

1-3.1. External Features - Front View

The external features in Figure (1-1.) of the BLANKETROL III unit are described as follows:

2.1.2.4. Ekranas temperatūrų atvaizdavimui

A. The control panel is composed of pressure sensitive touch switches, nine LED indicators, a liquid crystal display, and two LED displays. An expanded description of the membrane control panel is presented in Section (1-3.4.).

B. The recessed handle permits the operator to grip the unit when moving it.

C. The power switch is a bevel rocker switch labeled “I” (on) at the top and “O” (off) at the bottom. The switch illuminates green when the unit is on. A circuit breaker is built into the switch to protect against overload conditions.

D. The storage drawer tilts out from the top to provide storage space for items such as probes, connecting cables, connecting hoses, the drain hose, and the Operator's Manual.

E. The grill permits air to be drawn into the unit and pass over the condenser. The air is then discharged through the bottom of the unit. The grill and compressor should be kept clear from blockage and cleaned regularly as described in Section (4-4.).

F. The protective bumper guard surrounds the lower edge of the unit and protects the unit as well as the walls.

G. Four swivel casters are specially designed to permit the unit to move easily and to prevent it from tipping. The unit is equipped with two locking casters to prevent unintended movement during operation.

2.1.2.2. Dėtuvė dokumentams ir priemonėms integruota prietaiso priekinėje dalyje

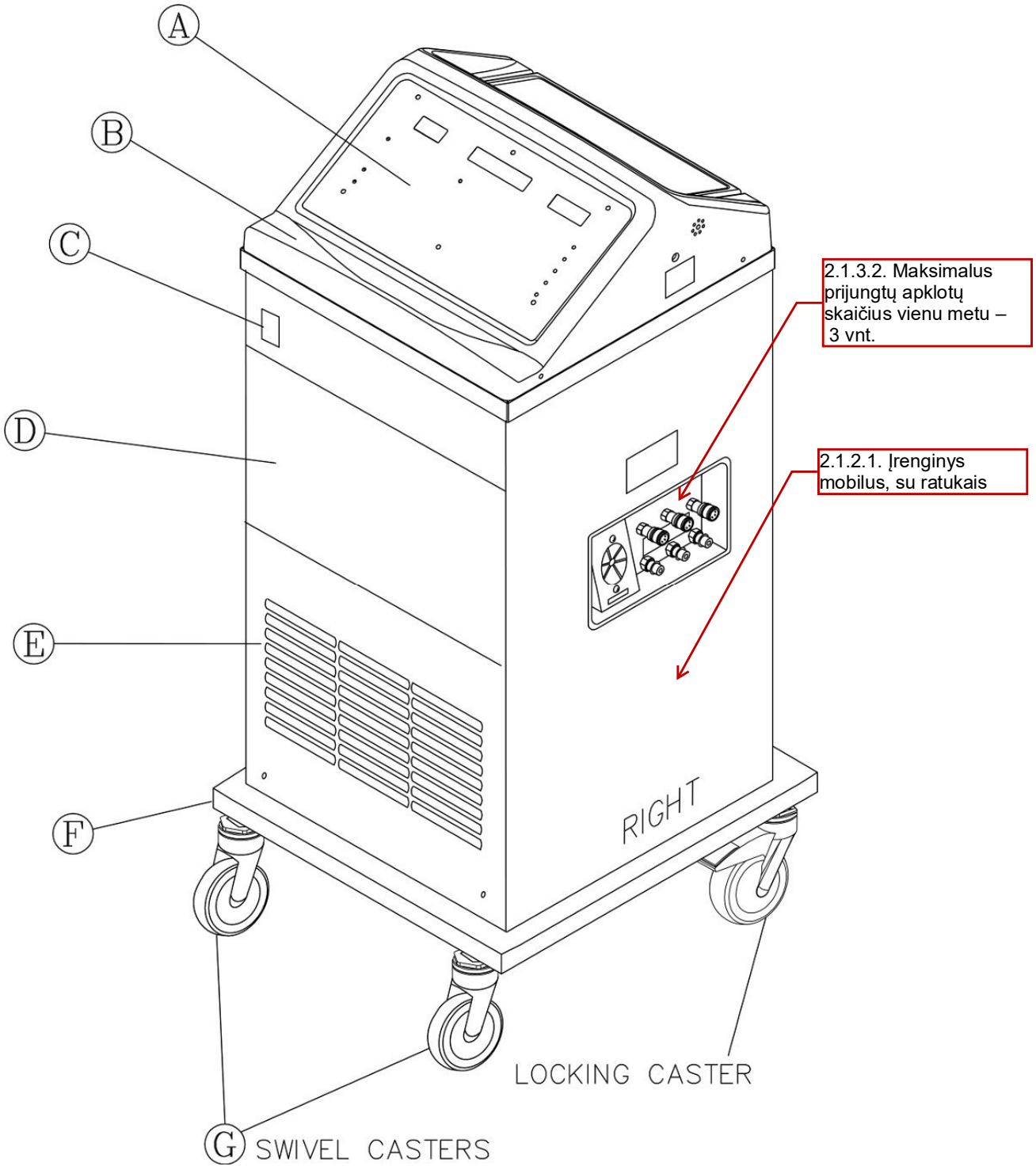


FIGURE 1-1. BLANKETROL III - FRONT VIEW

1-3.2. External Features – Right Side View

The external features in Figure (1-2.) of the BLANKETROL III unit are described as follows:

A. The water flow indicator is a paddle wheel immersed in the path of the circulating water with a window to the outside. As water is circulated through the system, it passes over the paddle wheel causing it to spin (like a pinwheel). The water flow indicator provides a visual display of the general rate at which the water is circulating. For example, if the unit is circulating water but the connecting hose is pinched, the circulation of the water is restricted. The restriction in water flow decreases the speed of the paddle wheel.

   The water flow indicator only spins when a blanket or by-pass hose is connected to the unit. It will not spin while the water is being circulated internally to pre-condition the water to the 'preset" water temperature chosen by the operator.

   A total obstruction of the water path will cause the paddle wheel to stop completely.

B. The air vents, on both the right and left side of the unit, provide air circulation for the microprocessor.

C. The four capped screws on the right and left side of the unit secure the top to the base.

D. The patient 1/4-inch receptacle is where the 400 Series probe (refer to Table 6-8 for a list of temperature probes) is connected to the unit. Only one patient probe can be connected at a time.

E. Three female, quick-disconnect return fittings on the top row are designed for water to flow in when the male coupling of the connecting hose is attached.

F. The three male quick-disconnect outlet fittings on the bottom row are designed for water to flow out when the female coupling of the connecting hose is attached.

G. The power cord with a hospital-grade plug should only be plugged into a properly grounded hospital grade receptacle. Electrical Specifications are described in Section (7.).

H. The isolation label indicates that the BLANKETROL III and the blanket (applied part) are BF rated as a system. Contact with other parts (i.e. the quick-disconnect fittings) at the same time as contacting the patient will negate the type of BF rating.

2.1.3.2. Maksimalus prijungtų apklotų skaičius vienu metu – 3 vnt.

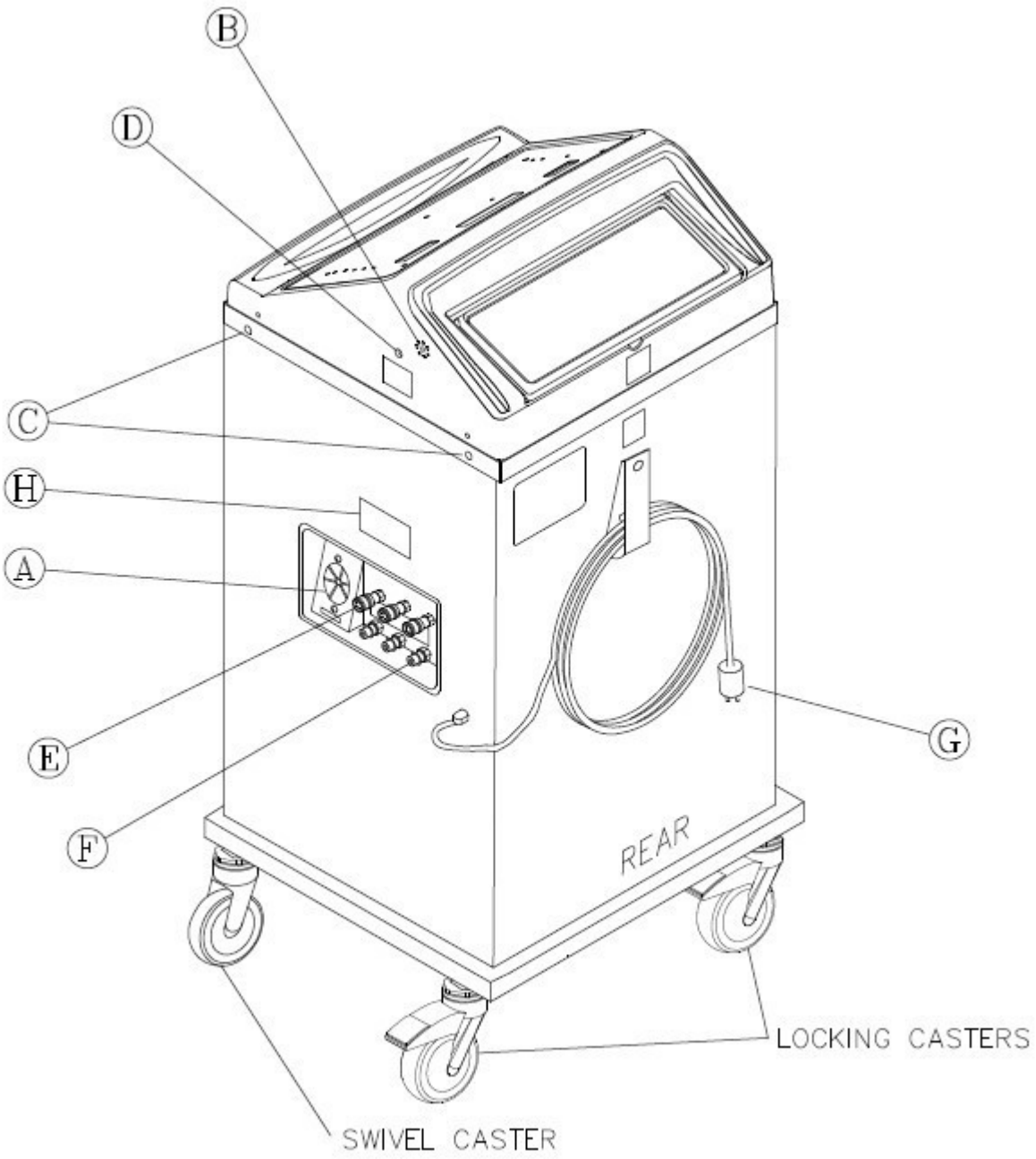


FIGURE 1-2. BLANKETROL III - RIGHT SIDE

The water circulates through the blanket(s) and returns to the unit. The water then passes through the water flow indicator, through the water filter, through the flow switch, and returns to the circulating reservoir to be re-heated or re-cooled and then recycled.

An internal by-pass inside the BLANKETROL III by-passes the quick-disconnect fittings, the flow indicator, the water filter, and the flow switch for water circulation during preconditioning of the water.

The circulating water system contains a flow switch to alert the operator when an occlusion prevents water flow through the blanket(s). The flow switch will only activate an alarm when flow is interrupted after normal flow has been detected. Therefore, the operator should check the flow indicator for proper flow when operation is first begun.

In addition, the replenishing reservoir contains a low water level sensor which shuts down the unit and sounds the alarm if the water level drops below a preset amount. The unit becomes operational only after the water level is restored to normal. (After the unit is refilled with water, the system must be returned to the previous operational settings.)

1-5.5. Temperature Safety Control System

The BLANKETROL III System is designed to carefully measure and control the temperature of the water in the BLANKETROL III equipment. The system is engineered so that when the temperature of the water in the BLANKETROL III equipment reaches the desired Set Point temperature, the unit cycles between heating and cooling the water in order to maintain the Set Point temperature. The unit is designed not to exceed or fall below the desired temperature.

As a safety precaution, the BLANKETROL III System has three high temperature safety devices and two low temperature safety devices.

2.1.9.2.Trijų lygių apsauga nuo per aukštos temperatūros;
2.1.9.3.Dviejų lygių apsauga nuo per žemos temperatūros

Each safety device continuously monitors the temperature of the water in the BLANKETROL III equipment. As an additional precaution, if the water temperature sensor fails, the unit shuts down and indicates SENSOR FAULT REMOVE FROM SERVICE. In this manner, both the patient and the unit are protected from injury or damage caused by extreme temperatures.

The operator must regularly monitor the patient (according to hospital/institution policy/protocol) whenever hyper-hypothermia therapy is used.

SAFETY CONTROLS FOR PROTECTION FROM HIGH TEMPERATURE

The microprocessor controls the temperature when the water in the BLANKETROL III equipment reaches 42.0°C ± 0.5°C (107.6°F ± 1.0°F).

If water in the BLANKETROL III equipment reaches 44.0°C ± 2.0°C (111.2°F ± 3.6°F), the safety device shuts off the unit, the Status Display flashes HIGH LIMIT REMOVE FROM SERVICE and the trouble alarm sounds.

If software fails and water in the BLANKETROL III equipment reaches 44.0°C ± 2.0°C (111.2°F ± 3.6°F), the back-up safety device shuts off the unit, Status Display flashes HIGH LIMIT REMOVE FROM SERVICE, and the trouble alarm sounds.

TABLE 6-8. BLANKETROL III SYSTEM ACCESSORIES

WARNING
• Use of accessories other than specified below **may result in increased electromagnetic emissions or decreased immunity to electromagnetic emissions** of the BLANKETROL III unit. This could affect the BLANKETROL III's compatibility with other electrical equipment. Electromagnetic compatibility refers to electronic devices unintentionally affecting the operation of each other by emitting electromagnetic energy.

ACCESSORIES – BLANKETS

Blankets, Pads, and Hoses, Approved for Use with the BLANKETROL III are listed below.

2.1.3.1.Šildymo-šaldymo apklotai ir priedai: Galimi įvairių dydžių vienkartiniai šildymo–šaldymo apklotai suaugusiems, vaikams ir naujagimiams

MAXI-THERM Single-Patient Use Blankets

276 Adult or O.R. Table Size (24" x 60")
274 Pediatric Size (22" x 30")
273 Infant Size (12" x 18")
Contents: 5/box, 4 boxes/case
286 Reusable Connecting Hose (for GENTHERM Unit)

MAXI-THERM LITE Single-Patient Use Blankets

876 Adult Size (25" x 64")
874 Pediatric Size (25" x 33")
873 Infant Size (12.5" x 18")
872 Pediatric Size (25" x 19")
871 Pediatric Size (25" x 17.25")
870 Localized Therapy (25" x 4")
300 Staff Vest
800 Patient Vest

PLASTIPAD Reusable Molded Plastic Blankets (Polyurethane)

196 Adult Size (24" x 60")
195N Narrow Adult Size (20" x 60")
194 Pediatric Size (22" x 30")
193 Infant Size (12" x 18")
193CPC Infant Size with CPC Connectors (12" x 18")
186 9' Blanket Extension Hose with Couplings

Head Wrap Single-Patient Use Pad

600 Adult Head Wrap

KOOL KIT Single-Patient Use Convenience Kits

900 Kool Kit (Adult Head Wrap, Patient Vest and Lower Body Pad)
910 Head Wrap Kit (Adult Head Wrap and Lower Body Pad)
920 Patient Vest Kit (Patient Vest and Lower Body Pad)
930 Large Kool Kit (Adult Head Wrap, Patient Vest and Full Body Pad)
950 Kool Kit Neonate (Pediatric Pad and Esophageal/Rectal Temperature Probe)

Gelli-Roll Reusable Blankets

195P Adult Size (73.5" x 21.5")
194P Pediatric Size (31.25" x 23.75")
193P Infant Size (20" x 13")

SECTION 7. SPECIFICATIONS AND CERTIFICATIONS OF THE BLANKETROL III

BLANKETROL III MODEL 233 FEATURES

PHYSICAL

Dimensions: 17"W x 17"D x 37.5"H
(43.18 cm.W x 43.18 cm. D x 95.25cm. H)

Weight: Empty -131 lbs. (59.5kg)
Shipping – 151 lbs. (68.5kg)

Cabinet Construction:
Powder coated steel with plastic top. Divided reservoir. Bottom air discharge. Built-in handle. Bumper guard. Storage Compartment. Two 4" conductive, 360° swivel-type casters and two 4" non-conductive, 360° swivel-type locking casters.

Ambient Temperature (during use):
15°C – 30°C (59°F – 86°F)

Humidity (during use):
20% - 60%

Maximum Contact Surface Temperature:
41°C (105.8°F)

THERMAL SYSTEM

Compressor: 1/3 HP
Heater: 800 Watts
NOTE: Maximum expected heating capability approximately 3°C (5.4°F) per minute. Maximum expected cooling capability approximately 5.5°C (9.9°F) per minute. Time to heat from 23 ± 2°C to 37ºC is approximately 12 minutes with a blanket attached.

CIRCULATING SYSTEM

Divided Compartment Reservoir, 2 gallon (7.5 liters) total capacity. Error proof, quick-disconnect fittings.

ELECTRICAL SYSTEM

Electrical Characteristics:
115V-127V±10%, 60Hz., 10.2 Amps
220V-230V±10%, 50Hz., 5.2 Amps

Power Cord: 14/3 SJT (115V), Hospital grade plug
Standard European Cord (230V)

…urrent: Under 300 µa (115V)
Under 500 µa (230V)

Circuit Breaker: In Power Switch
Mains Isolation: Two-Pole Mains Switch

2.1.11.Elektros energijos šaltinis, tinkamas aparato maitinimui: 230V, 50Hz ±10%

SAFETY SYSTEM

Maximum High Control Setting:
42.0°C (107.6°F)

High Limit Safety:
44.0°C ± 2.0°C (111.2°F ± 3.6°F)

High Limit Secondary Back-up Safety:
44.0°C ± 2.0°C (111.2°F ± 3.6°F)

Thermostatic Snap Disc:
46.0°C ± 2.0°C (114.8°F ± 3.6°F)

Minimum Low Control Setting:
4.0°C (39.2°F)

Low Limit Safety:
2.0°C ± 2.0°C (35.6°F ± 3.6°F)

Low Limit Secondary Back-up Safety:
2.0°C ± 2.0°C (35.6°F ± 3.6°F)

Defective or Dislodged Probe Alarm:
Audible & Visual

Primary & Secondary High and Secondary Low Limit Failure Alarm:
Audible & Visual

2.1.9.1.Garsiniai ir vizualiniai aliarmai

Low Water Alarm:
Audible & Visual

Defective Water Temp Sensor:
Audible & Visual

Water Flow Indicator:
Visual

Low Flow Alarm:
Audible & Visual

Water Temperature Sensor Fault Alarm:
Audible & Visual

BLANKETROL III MODEL 233 FEATURES (CONT.)

CONTROL SYSTEM

Microprocessor controlled, Lighted "OFF-ON" power switch, Digital LED Read Outs, Alarm Indications, and Mode Indications.

2.1.7. Vandens temperatūros nustatymo ribos: 4.0°C – 42.0°C

Controller Range:

Water Temp.: 4°C to 42°C (39.2°F to 107.6°F)

Patient Temp.: 30°C to 40.0°C (86°F to 104°F)

2.1.6. Paciento temperatūros nustatymo ribos: 30.0 °C – 40.0 °C

Display Accuracy:

Water Temp. ± 0.5°C (± 1°F) (measured at 37°C)

Patient Temp. ± 0.3°C (± .5°F)

2.1.5. Paciento temperatūros matavimo paklaida: ± 0.3 °C

Display Range:

Water Temp.: 0°C - 52°C (32°F – 126°F)

Patient Temp.:

MANUAL CONTROL: 10°C – 50.0°C (50°F - 122°F)

AUTO MODES: 30.0°C – 43.5°C (86.0°F – 110.3°F)

MONITOR ONLY: 10°C – 50.0°C (50°F - 122°F)

Service Life

The expected service life/ lifetime of the Blanketrol III, Model 233 unit is twelve (12) years from the date of manufacture provided the product is not subject to misuse, negligence, accident or abuse and under the conditions that the device is properly used as intended and serviced and maintained according to the Operation /Technical Manual provided with the device.

CONTROL SYSTEM (cont'd)

Display Type: LED

Temp. Settings:

Water Temp.: 0.1°C (0.1°F)

Patient Temp.: 0.1°C (0.1°F)

Patient Probe ¼ inch receptacle: One

Probe Type: 400 Series

ENVIROMENTAL CONDITIONS (during storage and transportation)

Ambient Temperature (transportation and storage):

-40°C – +50°C (-40°F – +122°F)

Humidity (transportation and storage):

20% – 95%

WARRANTY

2 yr. parts (Labor if returned to GENTHERM)
Additional warranties available at time of purchase.
Contact GENTHERM.

CLASSIFICATION

Equipment is Class I.

Equipment is Type BF.
The blanket is a means of patient protection.

IP22

CERTIFICATIONS

CLASSIFIED C UL US
16HV

MODEL 233 MEDICAL ELECTRICAL EQUIPMENT WITH RESPECT TO ELECTRIC SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH UL60601-1, IEC60601-1, IEC60601-2-35, ASTM F2196-02, IEC60601-1-2, AND CAN/CSA-C22.2 No. 601.1

CE 0344

GENTHERM

Blanketrol III

Specifications

- Dimensions: 43.2cm W x 43.2cm D x 95.3cm H
- Weight: 59.4kg
- Water temperature range: 4 to 42°C
- Patient temperature control: 30 to 40°C
- Primary high temperature safety: 44±2°C
- Secondary high temperature safety: 46±2°C
- Low temperature safety: 2±2°C
- Water capacity: 7.6 L
- Flow rate: approx. 136L/hr
- Temperature display accuracy:
  - *Water temp ±0.5°C*
  - *Patient temp ±0.3°C*

2.1.2.3. Vandens rezervuaro talpa 7,6l

2.1.4. Vandens tėkmė: 2,666 l/min

ensoETM

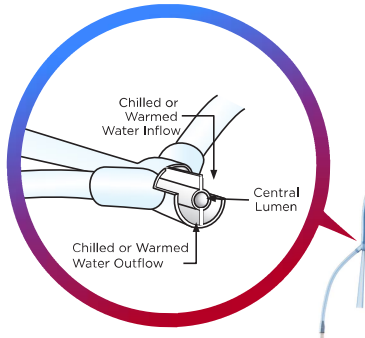
The EnsoETM works with your existing heat exchange unit..

...so there's no new capital to purchase.

How it works

Two lumens attach to existing heat exchange units commonly used in the care environment. Distilled warm or cool water circulates within the EnsoETM just like a water blanket.

A third, independent lumen allows enteral administration of fluid and gastric decompression.



1) Find your current heat exchange unit

2) Select enteral feeding connector type

Altrix
(Stryker Altrix Temperature Management System)

Medi-therm III
(Stryker Altrix Temperature Management System)

ENFit® Enteral Feeding + Suction — ECD03

Suction only — ECD01

Blanketrol II or III
(Cincinnati Sub-Zero Blanketrol II or Blanketrol III Hyper-Hypothermia System)

ENFit® Enteral Feeding + Suction — ECD04

Suction only — ECD02

2.1.3.3. Prietaisas suderinamas su stempliniais šildymo–šaldymo zondais

SPECIFICATIONS

	ECD01	ECD02	ECD03	ECD04
External Heat Exchanger	Stryker Altrix Temperature Management System Gaymar/Stryker Medi-Therm III Hyper/Hypothermia System	Cincinnati Sub-Zero Blanketrol II or Blanketrol III Hyper-Hypothermia System	Stryker Altrix Temperature Management System Gaymar/Stryker Medi-Therm III Hyper/Hypothermia System	Cincinnati Sub-Zero Blanketrol II or Blanketrol III Hyper-Hypothermia System
Heat Exchange Connector	Gaymar/Stryker Clik-Tite	Colder Products Company PLCD22004	Gaymar/Stryker Clik-Tite	Colder Products Company PLCD22004
Enteral Feeding Connector	None	None	ENFit®	ENFit®
Intended Duration of Use	72 h in the US / 120 h outside the US	72 h in the US / 120 h outside the US	72 h in the US / 120 h outside the US	72 h in the US / 120 h outside the US
Material	Medical-grade silicone	Medical-grade silicone	Medical-grade silicone	Medical-grade silicone
Water Volume	55 mL (1.9 fl oz.)	55 mL (1.9 fl oz.)	55 mL (1.9 fl oz.)	55 mL (1.9 fl oz.)
Outside Diameter	12.0 mm (0.47 in, 36 Fr)	12.0 mm (0.47 in, 36 Fr)	12.0 mm (0.47 in, 36 Fr)	12.0 mm (0.47 in, 36 Fr)
Inside Diameter of Gastric Lumen	2.6 mm (.10 in)	2.6 mm (.10 in)	2.6 mm (.10 in)	2.6 mm (.10 in)
Length	758 mm (29.8 in)	758 mm (29.8 in)	758 mm (29.8 in)	758 mm (29.8 in)

The ECD01 and ECD02 are approved for sale in the United States, Europe, and Australia.

The ECD03 and ECD04 are approved for sale in the United States, Europe, and Australia.