

NORM-O-TEMP[®]

Operation / Technical Manual

Model 111W Hyperthermia System



GENTHERM

Gentherm Medical, LLC • 12011 Mosteller Road • Cincinnati, Ohio 45241, U.S.A.

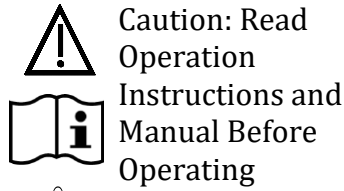
www.gentherm.com

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Manual 56430 Rev. AI

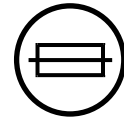
SYMBOLS



Caution: Read
Operation
Instructions and
Manual Before
Operating



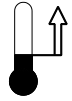
Temperature Set



Fuse



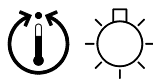
Water Temperature



Increasing
Temperature



Silence Alarm



Temp. Set Point
Indicator



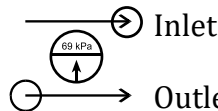
Decreasing
Temperature



Fill to Strainer



Water Flow Indicator



Inlet

Outlet



Heat



Risk of Explosion:
Do not use in the
Presence of
Flammable
Anesthetics



Disconnect Power
Before Servicing



Power Cord Holder

I / O On / Off

~ AC Voltage



Danger; Risk of
Electric Shock



Type BF
Equipment



Separate
collection for
electrical and
electronic
equipment



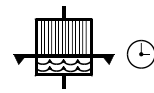
Protective Earth
(Ground)



Earth
(Ground)



Equipotentiality



Clean Water
Filter Quarterly



Caution



Low Water
Level



High Limit /
Over-Temperature
Safety Limit



Change Water
Monthly

Gentherm Medical, LLC, reserves the right to make changes to the device, which may not be reflected in this manual.

WARNING

- A physician's order is required for the use of the device and setting the temperature of the blanket/pad. At least every 20 minutes, or as directed by physician, check patient's temperature and skin condition of areas in contact with blanket/pad; also, check blanket/pad water temperature. Pediatric patients, temperature-sensitive patients with vascular disease, surgical patients, and diabetic patients are at greater risk for developing tissue injuries, and this should be considered when selecting the temperature, duration of therapy and frequency of skin checks. If patient's temperature does not reach desired set point or differs drastically from recommended set point, notify physician. **Notify the physician promptly of any change in patient status in order to avoid serious injury or death.**

 1. Pediatrics – Infants' and children's body temperatures are often more responsive to surface heating and cooling than adults. Due to their size, the effect of heating or cooling a child is likely more pronounced because of their higher ratio of skin contact area to body mass.
 2. Temperature Sensitive Patients – Patients with impaired peripheral blood circulation and patients who are incapacitated may be more sensitive to temperature changes than patients with normal circulation.
 3. Surgical Patients – Patients with poor circulation due to inadequate heart function, loss of blood, or impaired peripheral blood circulation may be more sensitive to temperature changes.
- The method of temperature control provided by all hyperthermia units presents the danger of heating body tissues, particularly the skin, to a point where they are injured. The clinician is responsible for determining the appropriateness of the temperature limits in dependency to time. Exceeding 40°C water temperature for extended periods can cause tissue damage and burns. Clinical judgment should be used to determine the safe maximum contact periods base on patient age, clinical condition, and current medications. **Avoid placing additional heating or cooling sources between the patient and blanket/pad. Depending on the extent and severity of a burn, very serious and even fatal complications may arise.**
- Do not use the NORM-O-TEMP® System distal to arterial cross clamping. **Thermal injury may result.**
- Prevent excessive and/or prolonged tissue pressure and shearing forces, especially over bony prominences, **to prevent skin damage that may result.**
- Do not place additional heat sources between the patient and blanket/pad. **Skin damage may result.**
- **The area between the patient and the blanket/pad should be kept dry to avoid injury to patient.** Prep solutions have been reported to injure the skin when allowed to remain between patients and a water-circulating heating blanket/pad during prolonged procedures. If using a vinyl blanket/pad, place a dry absorbent sheet between the patient and the blanket/pad to prevent moisture from accumulating.
- **Proper sanitation procedures must be practiced, and hygienic safety must be maintained, to prevent contamination.** Contamination can affect patient's health, i.e. skin irritation/rash may result.

<ul style="list-style-type: none"> Do not use the NORM-O-TEMP® system in the presence of flammable anesthetics. Risk of explosion can result.
<ul style="list-style-type: none"> Power interruption will cause the NORM-O-TEMP® to revert to Preset Set point Temperature resulting in possible inaccurate therapy to the patient. Follow instructions for First Time Set-Up/System Test Routine to resume operation. Failure to resume therapy could result in serious injury or death.
<ul style="list-style-type: none"> Do not by-pass ground lug. Electrical Hazards may result.
<ul style="list-style-type: none"> Any time water is found leaking into or around the unit, connecting hose, and/or blanket/pad, turn the unit off, disconnect the power cord from its power source, and correct the problem before proceeding. Water leaks could lead to electric shock. Water leaks could also present a slip hazard.
<ul style="list-style-type: none"> Water leaks present a risk of infection and should be handled accordingly. Proper sanitation procedures should be followed including, but not limited to, the preventative maintenance described in this manual. Leaky blanket/pad(s) or hoses should never be used.
<ul style="list-style-type: none"> Exercise extreme caution if the unit is used for patients who are electrically susceptible (probe, catheter, or electrodes connected to the heart).
<ul style="list-style-type: none"> Do not position unit near any objects that can generate a strong electrical/magnetic field. Potential electromagnetic interference may result.
<ul style="list-style-type: none"> To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
<ul style="list-style-type: none"> Always unplug the unit before accessing internal components during service. Failure to unplug the unit could result in electric shock.
<ul style="list-style-type: none"> The repair, calibration, and servicing of the NORM-O-TEMP® should be performed by qualified Medical Equipment Service Technicians, Certified Biomedical Engineering Technicians, or Certified Clinical Engineers familiar with good repair practices for servicing medical devices, and in accordance with instructions contained in the Operation / Technical Manual. Improper repair could result in damage to the NORM-O-TEMP® system and possible patient injury.
<ul style="list-style-type: none"> Before returning the NORM-O-TEMP® to patient use after repairs, the FIRST TIME SET-UP/SYSTEM TEST ROUTINE in Section (3-2.) must always be performed. Improper repair and inadequate maintenance can result in damage to the NORM-O-TEMP® system and patient injury.
<ul style="list-style-type: none"> Remove the NORM-O-TEMP® from service if the outer casing or membrane control panel is cracked or internal components are exposed. Contact with internal components could result in electric shock or thermal injury to the patient or operator and exposure to sharp edges.
<ul style="list-style-type: none"> Keep the vents clean and free of debris and obstruction. Blockage of the vents could result in the unit overheating which could render the unit unable to provide adequate therapy; excessive surface temperatures could cause injury of patient or operator. Keep unit, specifically the vents away from curtains or other obstructions.
<ul style="list-style-type: none"> The warming of transdermal medications (patches) can increase drug delivery, resulting in possible injury to the patient.
<ul style="list-style-type: none"> Thermal injury may occur if heating/cooling therapy is applied to ischemic limbs.
<ul style="list-style-type: none"> Use only hospital grade plug or electric shock may result.

CAUTION

- Federal law (U.S.) restricts this device to sale by or on the order of a licensed healthcare practitioner.
- Use sterile water or water that has been passed through a filter less than or equal to 0.22 microns only. Do Not Use De-Ionized water or Distilled water.
- **Do not** use alcohol. Alcohol may cause blanket/pad and unit deterioration.
- **Do not** overfill. Overfilling may result in overflow when the water in the blanket/pad drains back into the system when the system is turned off.
- Always drain the NORM-O-TEMP® to a sanitary drain because **bacteria** may be present in the unit's water supply.
- Working with electronic boards, plugs, and cables requires careful handling. Proper **Electrostatic Discharge (ESD) handling practices should be followed during replacement of any electronic board.**
- To Discharge the NORM-O-TEMP®, ensure the unit is unplugged and use any metal tool, such as a screwdriver, with an insulated handle to simultaneously touch both pins on the power cord.
- The operator must regularly monitor the patient whenever hyperthermia or normothermia therapy is used.
- For safe handling and use of chemicals follow manufacturer guidelines.
- The device is still energized when the power switch is in the off position. To completely disconnect the device from the power source, remove the power cord plug from the power source.
- **Unapproved blanket/pad(s) or hoses should never be used. Always use GENTHERM recommended blankets/pads.**
- No modification of this equipment is allowed without prior, written authorization from GENTHERM.

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Technical Help

United States and Canada	Telephone	1-513-772-8810
Gentherm Medical, LLC	Toll Free	1-800-989-7373
12011 Mosteller Road	Fax	1-513-772-9119
Cincinnati, OH 45241	(U.S.) 24hr Clinical Support	1-513-460-2038

Visit our Web Site at <http://www.gentherm.com>

Before you call for Service...

To help us better serve you, please have the serial number of your NORM-O-TEMP® unit ready when you call for parts or service. The serial number is located on the specification label on the back of the unit.

In-Warranty Repair and Parts

All parts on your NORM-O-TEMP® unit are covered by a one-year (1) warranty. Additional warranties are available at the time of purchase or during the warranty period. To return defective parts or units, first obtain a Returned Materials Authorization (RMA) number from our Medical Technical Service department.

Receiving Inspection

After unpacking the NORM-O-TEMP® System, be sure to inspect the system for concealed damage. Retain all packing material and carefully describe or photograph any damage. Notify the carrier at once and ask for an inspection (in writing). Failure to do this within 15 days may result in loss of claim. Do not return the equipment to Gentherm. Call our Medical Technical Service department for further instructions.

Important Safety Information

Refer to this manual for instructions and caregiver information. Read and understand all precautionary information before using, prescribing, or servicing the NORM-O-TEMP® unit.

NORM-O-TEMP® Operating Instructions Quick Start Guide

Read Operation Manual before using this device

First Time Use Cleaning:

Refer to section 5-1.1, 5-1.2 and 5-1.3 for cleaning instructions.

Initial Operation:

1. Check reservoir water level and fill if necessary
2. Insert power cord plug into hospital grade outlet
3. Connect hyperthermia blanket or pad
4. Turn power switch "ON"

Unit will go through an 8-10 second calibration cycle to test all indicators and will flash the set point temperature of 37°C. Observe Water Flow Indicator on the side of the unit to verify that the pump is circulating water when blanket/pad is connected. The unit will start heating to a preset temperature of 37°C. To change the desired set point temperature, proceed to step 5 below.

5. Depress the "TEMP SET" button. The display will flash the previous set point temperature or the default temperature of 37°C if the unit has been turned OFF, and then back ON.
NOTE: You have five seconds to depress one of the arrows or the temperature readout will return to the actual reservoir water temperature.
6. Depress the "UP" ▲ or "DOWN" ▼ arrow to raise or lower the set point temperature to the desired setting.

Draining Instructions:

1. Turn “OFF” power switch.
2. Connect drain hose to one of the outlet fittings and allow to gravity drain.

Alarm Conditions:

- If an alarm sounds, check indicator lights or display for problem and take corrective action.
- Alarm may be silenced temporarily for five minutes by depressing the “Silence Alarm” button.
- The “Silence Alarm” button will not silence the alarm when “ERR” appears on the display or “HIGH TEMP” indicator light comes on and does not flash. Power cord should be removed from outlet and the unit sent to Biomedical Engineering for repair.

CAUTION:

- This device should be operated only by trained personnel, under the direction of a physician.
- Patients vary in degree of sensitivity to cold, heat, and pressure.
- The patient’s temperature and skin conditions should be checked at least every 20 minutes, or as directed by a physician, while on a thermal blanket.

Section 1. Introduction

1-0. General Safety Precautions

To provide the patient maximum safety during the use of the NORM-O-TEMP® hyperthermia system, a thorough knowledge and understanding of the system, and the correct application and operating use are required. Each person who is responsible for use or direction of use of the system, such as physicians, nurses, technicians and operators must read and understand this operating manual and all precautions and warnings prior to use. It is recommended this manual be reviewed at least semi-annually as a refresher to safe operation and application. For proper knowledge and understanding, in-service training is available upon request. **Failure to read, understand, or follow operating manual could result in serious injury or death.**

1-1. General Description of this Manual

This manual describes the operation, maintenance, and service of the NORM-O-TEMP® hyperthermia system.

This manual is prepared for professional personnel who use the NORM-O-TEMP® hyperthermia system for patient care as well as technicians and service personnel who are responsible for maintaining the equipment. All personnel who operate or service the unit should be familiar with all parts of this manual.

Physical and functional characteristics are described in Sections 1-3 and 1-5

Maintenance and service activities will sometimes overlap. In general, maintenance refers to any activity that does not require a certified technician. Maintenance may be performed by healthcare personnel or by other trained persons.

The following actions are considered maintenance:

1. Inspecting, cleaning, and disinfecting the exterior
2. Adding or replacing water
3. Replacing hoses
4. Cleaning hoses, blankets
5. Draining reservoirs

Service refers to any activity that requires a Medical Equipment Service Technician, Certified Biomedical Electronics Technician, or a Certified Clinical Engineer.

The following actions are considered service:

1. Equipment or parts replacement
2. Repairs
3. System testing
4. Cleaning & disinfecting water reservoirs
5. Replacing hoses (air, water), cords, and other accessories

1-2. Description of the NORM-O-TEMP® Hyperthermia System

Intended Use

The NORM-O-TEMP® Model 111W hyperthermia system is intended to prevent hypothermia during surgical procedures and to reduce cold discomfort before, during, and after a surgical procedure. The thermal regulating system is used to keep a patient comfortable by maintaining blanket/pad water temperature through conductive heat transfer. The water heated blankets transfer the thermal energy to adult, pediatric, and infant (includes neonates) patients to keep a patient at a comfortable temperature. The NORM-O-TEMP® system is composed of a heater, circulating pump, and blankets/pads. It is intended for use by appropriately trained healthcare professionals in clinical environments.

Intended Environment

The NORM-O-TEMP® hyperthermia system is used in the Operating room, Post Anesthesia Care Units, Recovery rooms, Intensive Care Units and Emergency Rooms.

The NORM-O-TEMP® hyperthermia system 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).

NORM-O-TEMP, Model 111W

The NORM-O-TEMP®, Model 111W hyperthermia System is used to keep a patient comfortable by maintaining blanket/pad water temperature through conductive heat transfer. The NORM-O-TEMP® hyperthermia system is composed of a heater, circulating pump, safety high limit, and microprocessor board.

Sterile water or water that has been passed through a filter less than or equal to 0.22 microns is heated and pumped from the unit to a blanket/pad. The blanket/pad rests under, around, and/or on top of the patient. The water circulates through the blanket/pad and returns to the unit. When warmed water is circulated through the blanket/pad, the patient is warmed. The unit is designed to operate based on the temperature of the circulating water.

The recommended blankets/pads for use are listed in Figure 16 Accessories.

1-3. Physical Description of the Norm-O-Temp® System

See Section 2 for specifications and certifications of the NORM-O-TEMP® system.

1-3.1. External Features and Descriptions – Front View

The external features in Figure 1 of the NORM-O-TEMP® unit are described as follows:

- A. The control panel is composed of pressure sensitive touch switches and an LED display. An expanded description of the membrane control panel is presented in Section 1-3.5.

- B. The operating instructions printed below the control panel describe the necessary steps to operate the unit.
- C. The power switch is a bevel rocker switch labeled “I” (on) at the top and “O” (off) at the bottom.
- D. The four rubber feet help the unit to mount on the I.V. stand (Catalog #118), the low profile stand (Catalog #119) or allow the unit to sit on any flat surface.
- E. The water fill opening is where the operator pours sterile water or water that has been passed through a filter less than or equal to 0.22 microns to fill the reservoir.
- F. The red, Power Fail LED is the visual indicator when power is disconnected with the switch still in its on position or when the independent mechanical (High Limit) safety is activated.

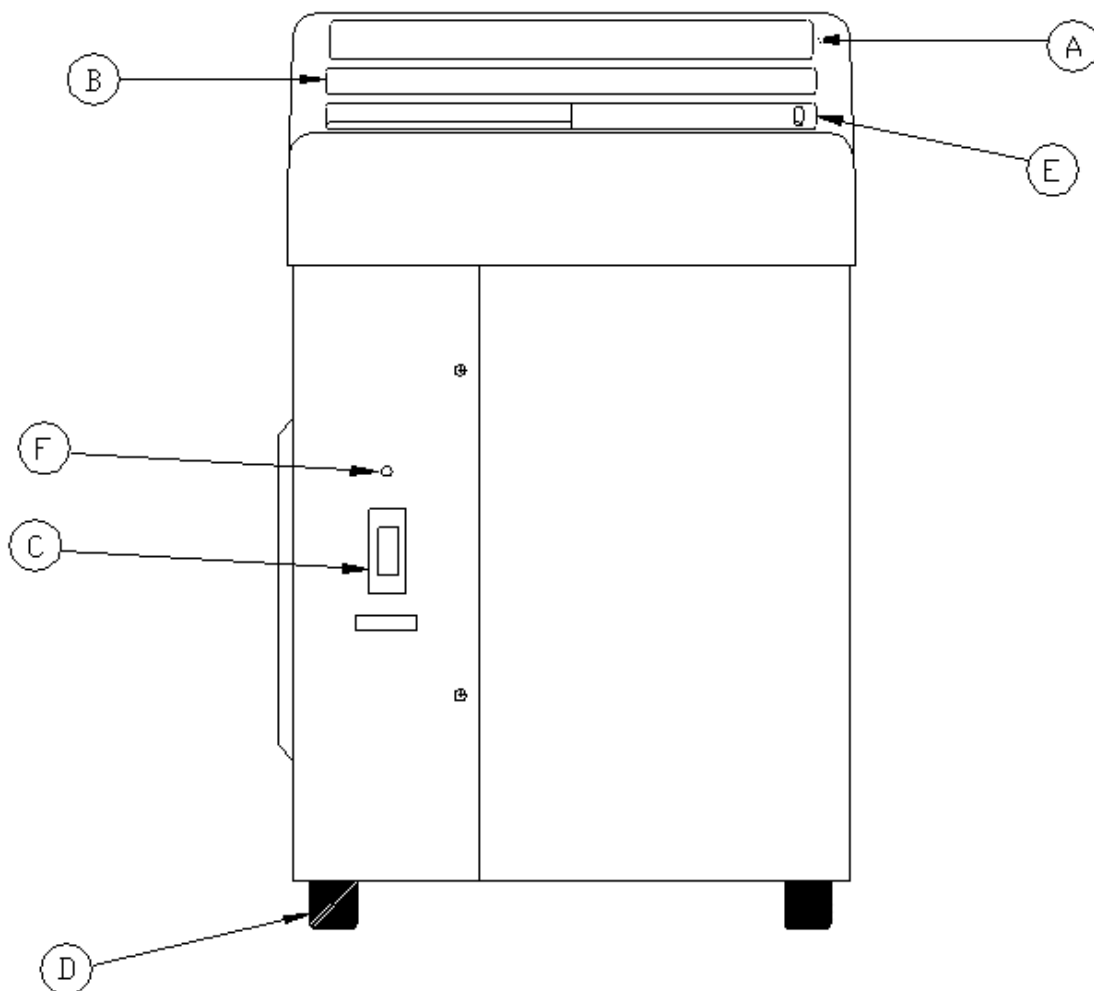


Figure 1. NORM-O-TEMP® unit, Front View

1-3.2. External Features and Descriptions – Left Side View

The external features in Figure 2 of the NORM-O-TEMP® 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 must pass 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 change in water flow decreases the speed of the paddle wheel.

The water flow indicator only spins when a blanket/pad or by-pass hose is connected to the unit. It will not spin when water is circulated internally to pre-condition the water. A total obstruction of the water path will cause the paddle wheel to stop completely.

- B. Two screws on the left and right side of the unit secures the top to the base.
- C. Two female fittings, quick-disconnect return couplings, on the top row are designed for water to flow in when the male coupling of the connecting hose is attached.
- D. Two male fittings, quick-disconnect outlet couplings, on the bottom row are designed for water to flow out when the female coupling of the connecting hose is attached.
- E. The recessed handle, one on each side, is provided to assist in lifting the unit on and off the I.V. stand or when carrying the unit.

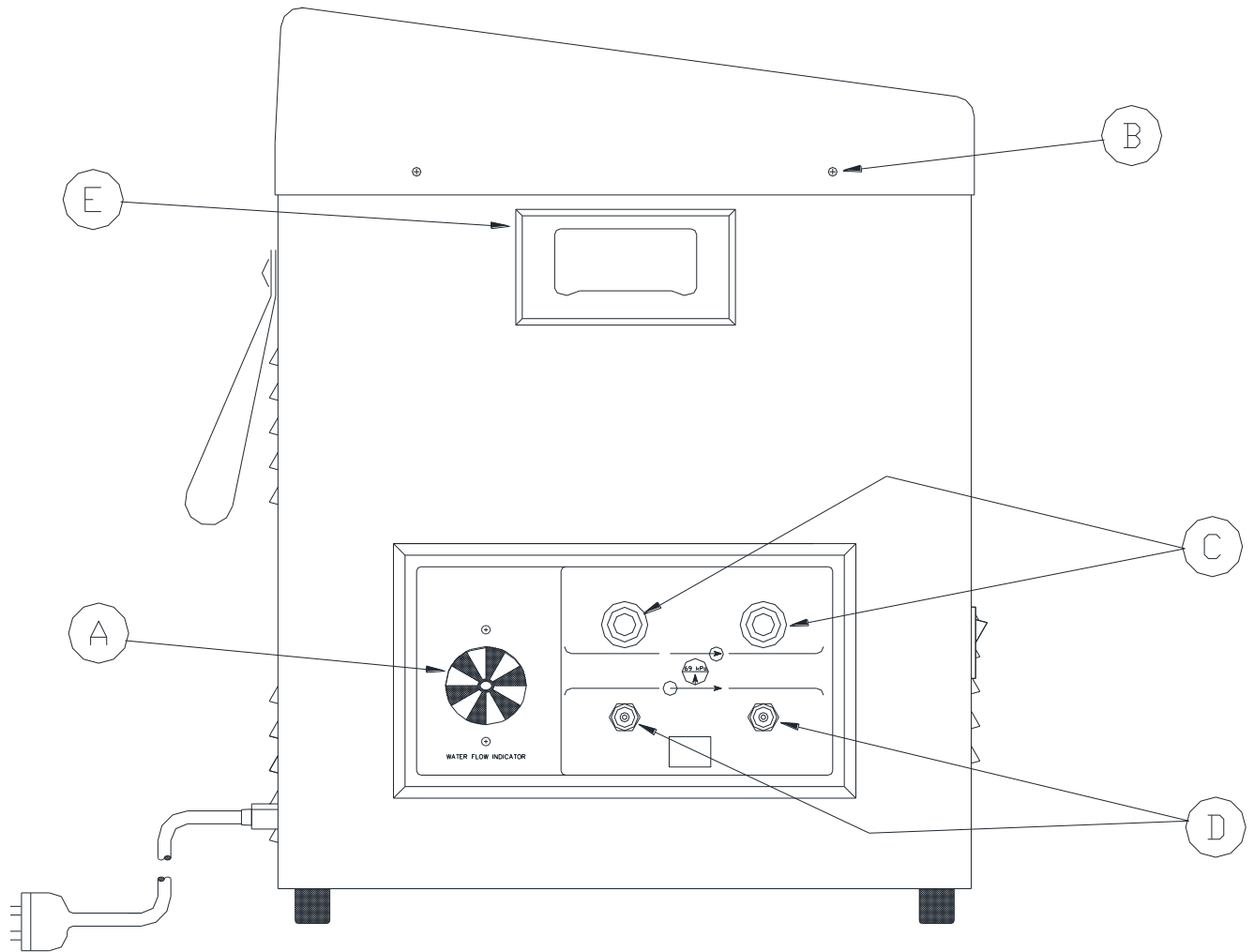


Figure 2. NORM-O-TEMP® unit, Left Side View

1-3.3. External Features and Descriptions – Rear View

The external features in Figure 3 of the NORM-O-TEMP® unit are described as follows:

- A. The specification label outlines the NORM-O-TEMP® unit's electrical requirements.
- B. Sets of air vents provide air circulation for the internal components.
- C. The nylon straps are used to secure and store the coiled power cord and/or the connecting hose when not in use.
- D. The serial number printed on the Spec Label and located just above the power cord.
- E. Units have a power cord that can be disconnected and should only be inserted into a properly grounded mating receptacle of a hospital grade specified by local codes and practices. Electrical specifications are described in Section 1.
- F. Ground Lug.

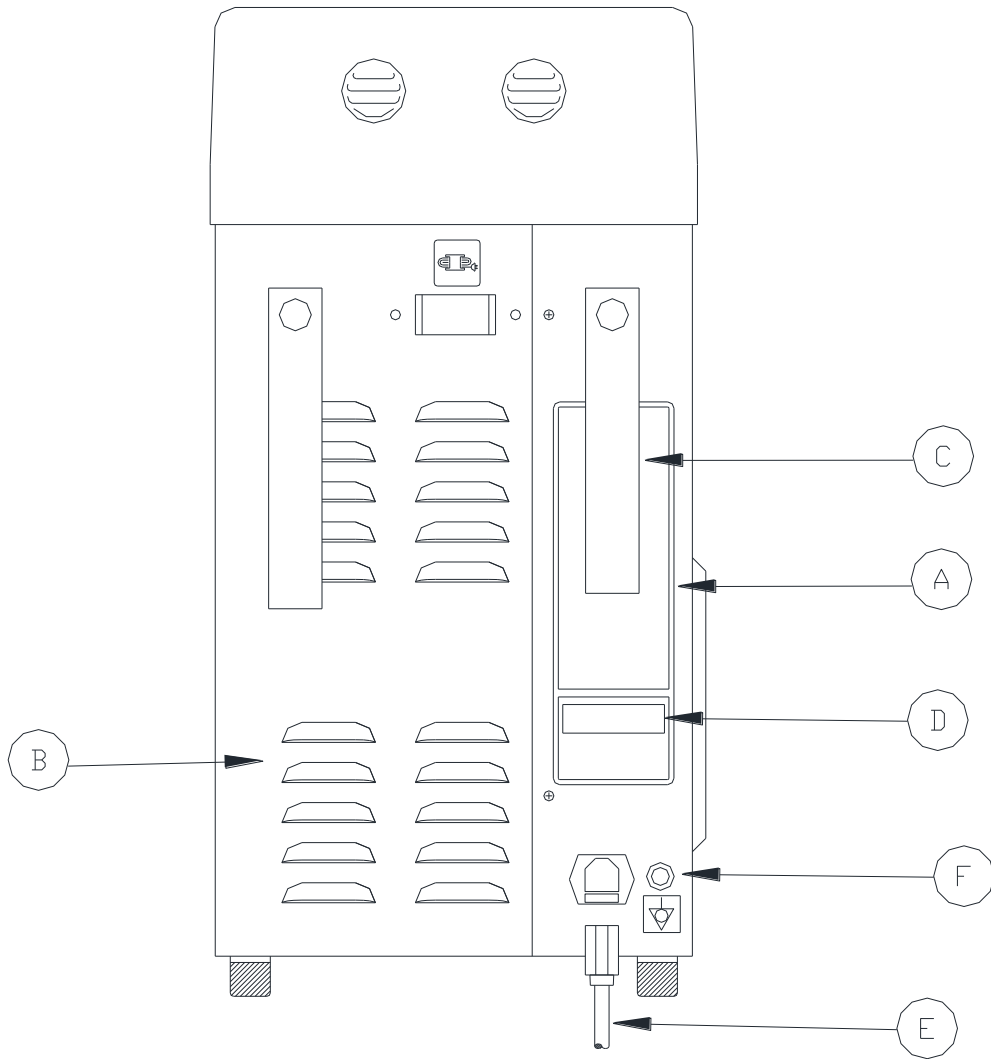


Figure 3. NORM-O-TEMP® unit, Rear View

1-3.4. External Features and Descriptions – Right Side View

The external features in Figure 4 of the NORM-O-TEMP® unit are described as follows:

- A. The three sided enclosure panel, secured with eight screws, provides access to the interior.
- B. The recessed handle is one of two provided to assist in lifting the unit.
- C. Two screws on the right and left side of the unit secure the top to the base.

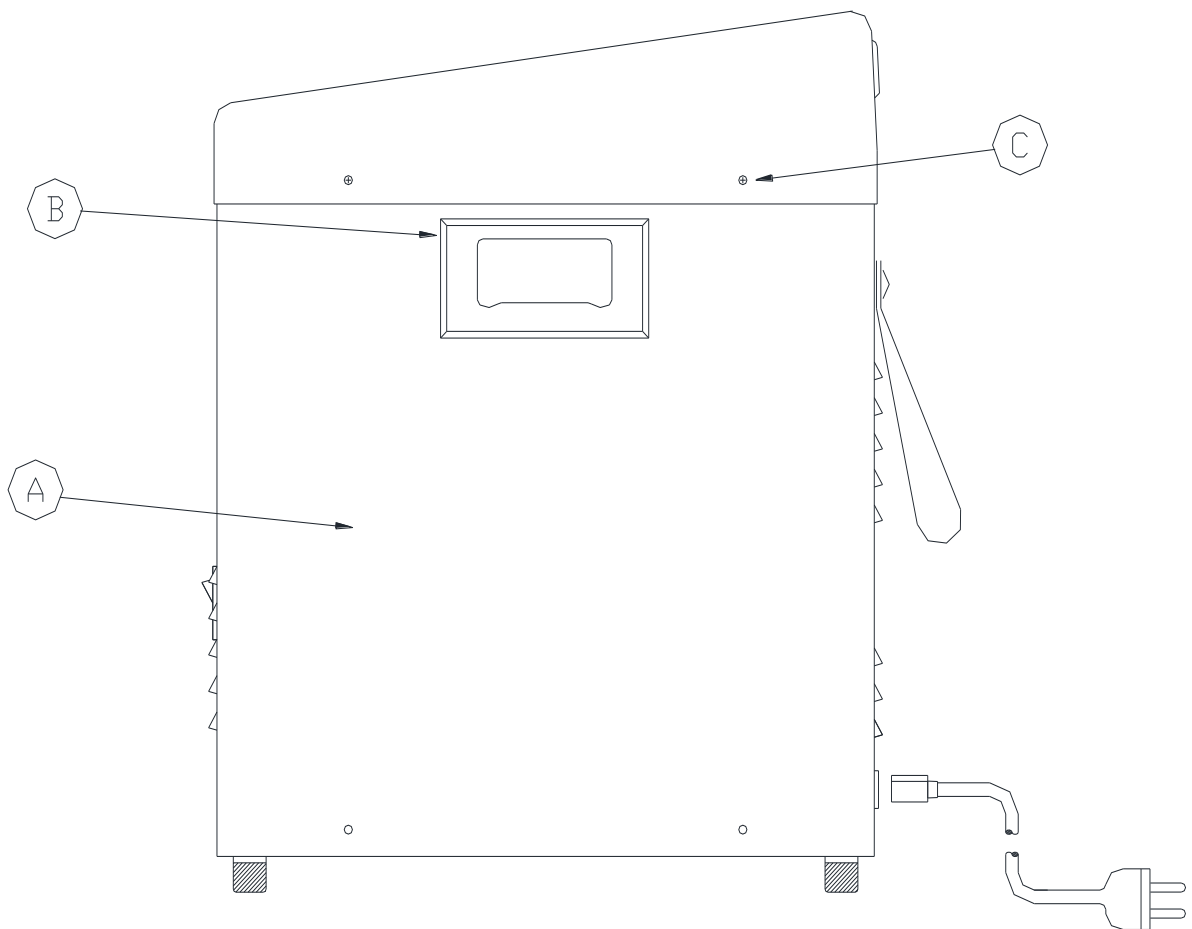


Figure 4. NORM-O-TEMP® unit, Right Side View

1-3.5. External Features and Descriptions – Top View

The membrane control panel as shown in Figure 5 is composed of pressure sensitive touch switches and LED displays.

The membrane control panel is divided into the following sections:

- A. The four digit LED display shows the actual water temperature and set point temperature.
- B. When the HEAT LED is lighted, it indicates that the water is being heated.
- C. The HI TEMP LED will illuminate, the power fail LED will illuminate, and the audible alarm will sound when the water temperature reaches $44^{\circ}\text{C} \pm 0.6^{\circ}\text{C}$. The HI TEMP LED will flash when water temperature reaches $1^{\circ}\text{C} \pm 0.6^{\circ}\text{C}$ above the set point temperature.
- D. When the LO WATER LED is lit it indicates that the unit needs more sterile water or water that has been passed through a filter less than or equal to 0.22 microns to operate. The LED will be accompanied by an audible alarm.
- E. The SILENCE ALARM button will silence the primary HI TEMP alarm and LO WATER audible alarms for five minutes and if the problem is not solved, the alarm will sound again until the button is pressed, or the problem is solved.
- F. The TEMP SET button is used to display and change the desired set point temperature. When this button is pressed, the display will flash the set point temperature for five seconds.
- G. The INCREMENT and DECREMENT buttons are used to raise or lower the set point temperature. The operator has less than ten (10) seconds to set the temperature up or down after pressing the TEMP SET button.
- H. The fill reservoir lid slides to the left to open and to the right to close.
- I. Operating instructions label.

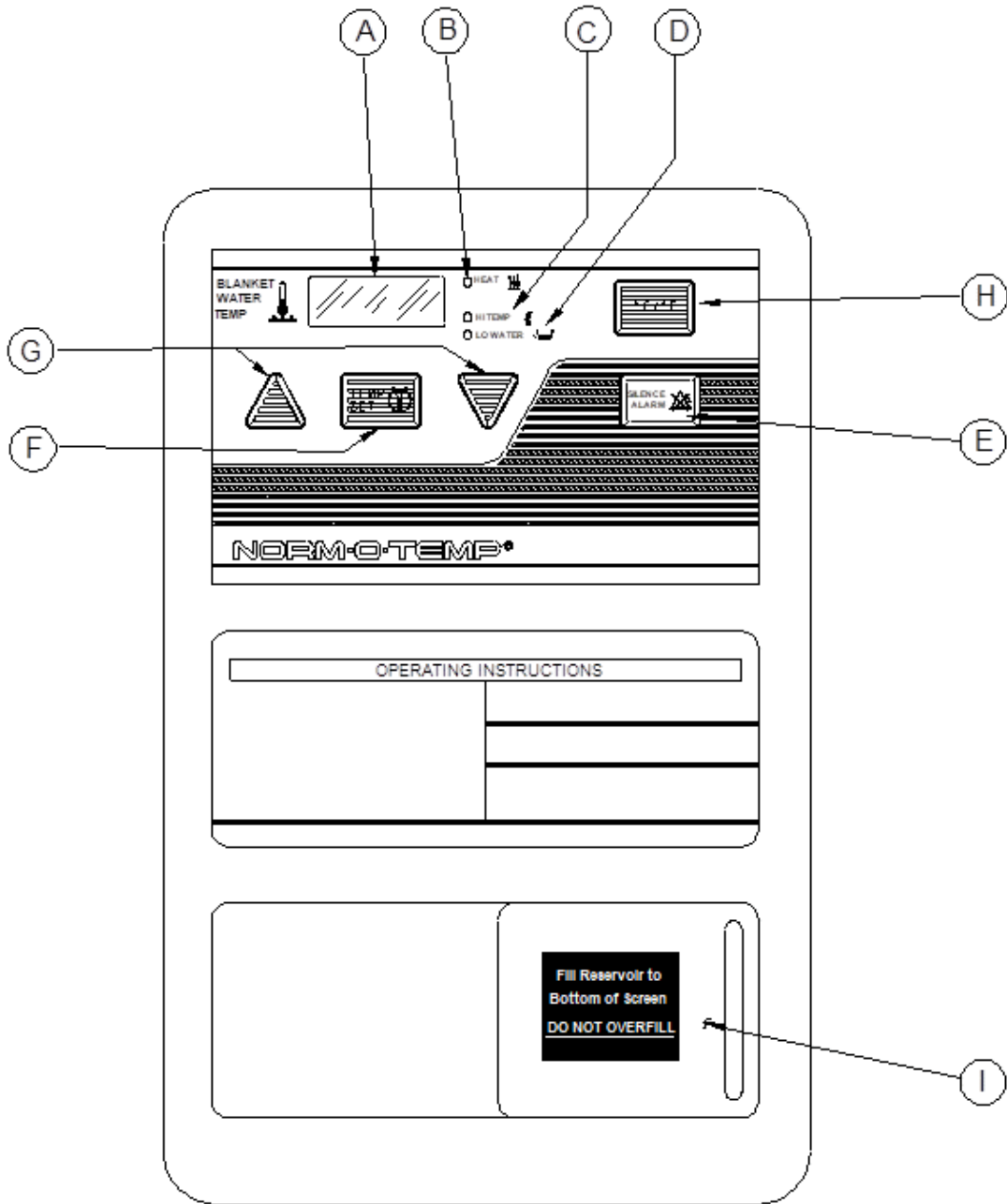


Figure 5. NORM-O-TEMP® unit, Model 111W Top View.

1-4. Required Accessories

Operation of the NORM-O-TEMP® unit requires the use of the blanket/pad(s) designed to circulate warm water via a connecting hose with quick-disconnect male and female couplings. NORM-O-TEMP® System Equipment and accessories are listed in Figure 16.

Note: Some reusable blankets/pads come with a permanently attached hose.

1-5. Functional Description of the NORM-O-TEMP® System

When the unit is turned ON, the NORM-O-TEMP® unit heats the water to reach a preset set point temperature of 37°C unless an alternate temperature is selected by the health care provider. The water circulates through the blanket/pad(s) which keeps a patient comfortable.

1-5.1. Heating System

The NORM-O-TEMP® heating system consists of an immersion heater and water temperature control. The temperature ranges are described in Section 2.

The immersion heater is located in the circulating reservoir. The water circulating in the reservoir flows around the immersion heater and is warmed.

It is important to note that the rate of change in the circulating water temperature is not directly proportional to the rate of change in the temperature of the patient.

1-5.2. Circulating System

The NORM-O-TEMP® 6-quart (5.7 liters) capacity dual compartment reservoir is composed of the circulating reservoir situated under and connected to the replenishing reservoir. When the operator fills the reservoir with sterile water or water that has been passed through a filter less than or equal to 0.22 microns, the circulating reservoir fills first and holds approximately 1 ½ quarts (1.4 liters) of water. The remaining 4 ½ quarts (4.2 liters) are held in the replenishing reservoir. The water moves from the replenishing reservoir to the circulating reservoir by gravitational pull as needed.

The circulating water flows over the heating element located in the circulating reservoir. The heated water then flows out the reservoir to the circulating pump, through the pump housing, over the water temperature sensor, and into the blanket/pad(s). The water circulates through the blanket/pad(s) and returns to the unit. The water then passes through the water flow indicator and returns to the circulating reservoir to be reheated and then recycled.

An internal by-pass inside the NORM-O-TEMP® by-passes the quick-disconnect fittings and the flow indicator for water circulation during preconditioning of the water.

The circulating water system contains a flow indicator. The operator should check the flow indicator for proper flow when operation is first begun.

In addition, the circulating reservoir contains a low water level sensor which shuts down the unit and sounds an alarm if the water level drops below 1 ½ quarts (1.4 liters). The unit becomes operational after the water level is restored to normal.

1-5.3. Temperature Safety Control System

The NORM-O-TEMP® unit is designed to carefully measure and control the temperature of the circulating water by heating. The unit is engineered so that when the temperature of the circulating water reaches the desired set point, the heater cycles on and off to maintain that set point temperature. The unit is designed to stay within 0.6°C of the selected temperature.

The microprocessor board continuously monitors the temperature of the circulating water and each unit is protected by an independent high limit safety. As an additional precaution, if the water temperature sensor itself should fail, the unit shuts down, the alarm sounds, and the display will read ERR (for error). With this safety design, the patient is protected from injury and the unit from damage caused by extreme high temperatures.

CAUTION

- The operator must regularly monitor the patient whenever hyperthermia or normothermia therapy is used.

Safety Controls for Protection from High Temperature

If the circulating water reaches $43.5^{\circ}\text{C} \pm 0.6^{\circ}\text{C}$, the primary high temperature safety will activate to turn off pump, turn off heater, the HI TEMP LED flashes and the trouble alarm sounds.

If the circulating water reaches $44.5^{\circ}\text{C} \pm 0.6^{\circ}\text{C}$, the secondary high temperature safety will activate to turn off pump, turn off heater, the HI TEMP LED illuminates and the trouble alarm sounds.

If the circulating water reaches $46^{\circ}\text{C} \pm 0.6^{\circ}\text{C}$, the independent mechanical high temperature safety will activate to shut off the power to the pump, shut off the power to the heater, the HI TEMP LED and Power Fail LED illuminate, and the trouble alarm sounds.

Section 2. Specifications and Certifications

Specifications for the NORM-O-TEMP® are presented in Figure 6 and are subject to change without notice.

<p style="text-align: center;"><u>Physical</u></p> <p>Dimensions: 22.86 cm Wide 38.14 cm Deep 46.99 cm High</p> <p>Weight: 15.2 kg empty 20.6 kg. filled</p> <p>Ambient Temperature (during use): 15°C - 30°C (59°F - 86°F)</p> <p>Cabinet Construction: Powder-coated steel with plastic top. Dual reservoir. Built-in handles.</p> <p style="text-align: center;"><u>Alarms</u></p> <p>High Temperature: Audible and Visual</p> <p>Low Water: Audible and Visual</p> <p>Defective Water Temperature Sensor: Audible and Visual</p> <p>Water Flow Indicator: Visual</p> <p>Power Failure: Audible and visual</p> <p>Greater than 1° Over Set point: Audible and Visual</p>	<p style="text-align: center;"><u>Control System</u></p> <p>Microprocessor-based temperature control system, and Alarm indications.</p> <p>Controller Range: <u>Water Temperature</u> Heating Only: 32°C - 42°C</p> <p>Controller Accuracy: Water Temperature: ±0.6°C</p> <p>Display Range: Water Temperature Display: 0°C - 52°C</p> <p>Display Type: LED Display.</p> <p>Temperature Settings: Water Temperature increments. 1°C</p> <p style="text-align: center;"><u>Service Life</u></p> <p>The expected service life / lifetime of the NORM-O-TEMP®, Model 111W unit is ten (10) 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.</p>
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Figure 6. NORM-O-TEMP®, Model 111W Features

<u>Electrical System</u>	<u>Safety System</u>
<p>Electrical Characteristics: 230V, 50Hz, 4.8 Amps 240V, 50Hz, 4.6 Amps</p> <p>Heater Power: 800 watts</p> <p>Power Cord: 16/3 Detachable, IEC 320</p> <p>Leakage Current: Under 500µa 230/240 VAC</p> <p>Fuse 5 Amp in IEC 320 connector</p> <p>Mains Supply Isolation: Two-Pole Mains Switch</p> <p>Warranty 1 year parts. Parts and labor if returned to factory. Additional Warranty Available</p>	<p>Maximum High Control Setting 42°C</p> <p>Primary Temperature Limit: 43.5°C ± 0.6°C</p> <p>Secondary Temperature Limit: 44.5°C ± 0.6°C</p> <p>Independent Mechanical Temperature Limit: 46°C ± 0.6°C</p> <p>Environmental Conditions (during storage and transportation)</p> <p>Ambient Temperature (transportation and storage): -40°C – +50°C</p> <p>Humidity (transportation and storage): 20% – 95%</p>
<p align="center">UL Electrical Classification Equipment is Class I. Equipment is Type BF.</p> <div align="center" data-bbox="734 1417 917 1606"> </div>	
<p align="center">CERTIFICATIONS</p> <div align="center" data-bbox="446 1690 641 1879"> </div> <p align="center"> Medical Electrical Equipment In Accordance With: UL 60601-1 2nd Ed. IEC 60601-1-2 3rd Ed. ASTM F-2196-2 </p>	

Figure 6. NORM-O-TEMP®, Model 111W Features

Section 3. General Preparation of the NORM-O-TEMP® System

3-0. Introduction

This section describes the procedures to prepare the NORM-O-TEMP® unit for general use. This entails unpacking the shipment, arranging all the equipment for the first time, and completing a test routine. This section also outlines the cleaning agent preparations, standard safety precautions, and patient preparation/bedside care when using the hyper-hypothermia blanket/pad(s). Technical support is available upon request.

3-1. Unpacking the Shipment

WARNING

- Remove the NORM-O-TEMP® from service if the outer casing or membrane control panel is cracked or internal components are exposed. **Contact with internal components could result in electric shock or thermal injury to the patient or operator.**

Open the top of the carton and remove the top foam insert. Lift the unit from the box. Locate and remove the manual.

During the unpacking process, look carefully for signs of shipping damage. If any unacceptable damage is found, notify the transportation company immediately and file a claim. The transportation company is responsible for the shipment after it leaves the factory. If problems other than shipping damage are found, notify your Gentherm representative or manufacturer (Gentherm Medical, LLC) directly.

3-2. First Time Set-Up / System Test Routine

This section describes the tasks necessary to inspect and arrange the equipment for the first time after unpacking and describes a System Test Routine to check out the membrane control panel.

The System Test Routine can also be used to teach operators unfamiliar with the equipment how to use the unit.

3-2.1. Inspecting and Arranging the Equipment

- A. Place the NORM-O-TEMP® unit on an uncluttered work surface that is accessible to the correct power source. Position the unit so that the membrane control panel faces the operator.

- OPTION: The NORM-O-TEMP® unit can be mounted on an optional Low Profile stand with casters or an optional I.V. Stand. For installation instructions, see insert packaged with the stand.
- B. Visually inspect the NORM-O-TEMP® unit to determine that there are no missing parts, dents, or punctures.
 - C. Examine the power cord for cuts or exposed wires and the power plug for bent or missing prongs.
 - D. Review Section 1-3 to identify the features of the NORM-O-TEMP® unit.
 - E. Collect and arrange the following equipment and supplies:
 1. Hyper-hypothermia blanket/pad(s) Listed in Figure 8.
 2. Connecting hose with quick-disconnect fittings (if applicable).
 - F. Mount the NORM-O-TEMP® unit on the proper stand.
 1. To mount the NORM-O-TEMP® on IV Pole Stand:
 - i. Place the NORM-O-TEMP® on the equipment pan with the rear of the unit facing the IV pole. Slide the NORM-O-TEMP® toward the IV pole until the rubber bumper touches the pole
 - ii. Fasten the NORM-O-TEMP® by turning the knurled knobs (on the underside of the equipment pan) clockwise into the threaded holes on the bottom of the NORM-O-TEMP®. Hand tighten knurled knobs until snug.
 - iii. Fasten the mounting bracket around the lower IV pole near the bumper on the rear of the NORM-O-TEMP® with the two stainless steel machine screws provided.
 2. To mount the NORM-O-TEMP® on the Low Profile Stand:
 - i. Place the NORM-O-TEMP® unit on the equipment pan so that the threaded holes on the bottom of the unit line up with the knurled knobs (on the underside of the equipment pan).
 - ii. Fasten the NORM-O-TEMP® by turning the knurled knobs clockwise into the threaded holes on the bottom of the NORM-O-TEMP®. Hand tighten knurled knobs until snug.
 - G. Slide the lid of the water fill opening and then gradually pour approximately 6 quarts (5.7 liters) of sterile water or water that has been passed through a filter less than or equal to 0.22 microns into the reservoir. **DO NOT USE DE-IONIZED WATER, DISTILLED WATER, OR TAP WATER.** Stop pouring when the water reaches the strainer visible at the bottom of the water fill opening. **DO NOT OVERFILL.**
 - H. Connect the blanket/pad(s) to the NORM-O-TEMP® unit by attaching the quick-disconnect female socket of the connecting hose to a male outlet plug (on the bottom row) of the unit. Attach the male quick-disconnect plug of the connecting hose to a female return socket (on the top row) of the unit. Each blanket/pad

must be connected to one outlet coupling and one return coupling of the connecting hose if necessary.

1. To attach the fittings (quick-disconnect fittings):
 - i. Grasp the quick-disconnect female socket of the connecting hose
 - ii. Slide the collar back towards the hose
 - iii. Push the female socket of the hose over a male plug of the unit
 - iv. Allow the collar to SNAP into place and return to its original position
 - v. Gently pull on the connecting hose to assure a positive connection
 - vi. Next, push back the collar of a female socket on the unit with one hand
 - vii. With the other hand, insert the male plug of the connecting hose
 - viii. Release the collar of the female socket
 - ix. Push the male plug until it SNAPS into position
 - x. Gently pull the connecting hose to assure a positive connection
2. To attach a blanket/pad to the connecting hose (if necessary):
 - i. Insert one end of the blanket/pad to the plastic outlet coupling of the connecting hose
 - ii. Insert the other end of the blanket/pad to the plastic return coupling of the connecting hose
 - iii. Gently pull on the blanket/pad to check that the connection is secure.
- I. Assure that the blanket/pad is laying flat and that the connecting hose to the unit is not twisted or pinched.
- J. Check that the power switch of the unit is in “O” position (unit is off).
- K. Insert the appropriate power cable. DO NOT BY-PASS GROUND LUG AS ELECTRICAL HAZARD MAY RESULT.

3-2.2. Completing a System Test Routine

After arranging the equipment described in Section 3-2.1, complete this System Test Routine which describes what switches to press and the changes to observe.

ALARM NOTE: *If power is removed from the unit without actuating the power switch (I/O switch) a power fail alarm is activated and the LED located on the front panel of the unit flashes. To stop alarm, restore power to the unit and push the SILENCE ALARM button.*

ALARM NOTE: *If at any time the water falls below the minimum level, the LO WATER LED is activated and the alarm sounds. The unit shuts down and the operator cannot proceed until this is corrected by filling the reservoir.*

- A. Make sure that the power switch is in the “I” position (unit is turned on).
 1. A beeper sounds.
 2. The microprocessor board goes through self-test.
 3. The seven segment display reads CAL for several seconds.
 4. All segments of the seven segment display flash on and off (8888's) for a few seconds along with the LED's.
 5. A beeper sounds.
 6. The seven segment display flashes the set point temperature 37°C for a few seconds and the unit begins to pump and heat the water.
 7. The seven segment display will show the actual water temperature.
 8. The HEAT LED will light up if the water temperature is less than 37°C.

- B. Press the TEMP SET button.
 1. A beeper sounds.
 2. The seven segment display will begin to flash the set point temperature 37°C. Each time the operator presses the TEMP SET button after just having turned on the unit, the set point temperature will display 37°C.
 3. After pressing the TEMP SET button, the operator has five seconds to change the set point temperature by pressing either the INCREMENT ▲ or DECREMENT ▼ buttons.

- C. Press the DECREMENT ▼ button during the five second interval after pressing the TEMP SET button.
 1. A beeper sounds each time it is pressed but does not beep when held down continuously.
 2. The set point display changes; the numbers move down the scale. The lowest set point is 20°C. However, the operating range of the device is from 32°C to 42°C.

- D. Press the INCREMENT ▲ button during the five second interval after pressing the TEMP SET button.
 1. A beeper sounds each time it is pressed, but does not beep when held down continuously.
 2. The set point display changes; the numbers move up the scale. The highest setting is 37°C.

- E. To complete this test routine, press the Power switch to the “O” position.
 1. The control panel goes blank.
 2. The water flow indicator stops.

- F. Disconnect the power cord, loosely coil it and attach it to the nylon straps on the back of the unit.

- G. Check the blanket/pad for leaks. Water leaks present a risk of infection to the patient because the water is not sterile. If a leak is found, the blanket/pad should not be used.

- H. Check the couplings at the unit and at the blanket/pad for positive connection.
- I. To drain the water from the reusable blanket/pad simply shut off power to the unit and allow the water to drain from the blanket/pad back into the NORM-O-TEMP® unit.

For reusable PLASTIPAD blanket/pad(s), disconnect the connecting hose from the unit. Loosely coil the hose lengthwise in the center of the blanket/pad. Fold the blanket/pad lengthwise into the center, 1/3 from the left side and 1/3 from the right side.

For reusable Gelli-Roll blankets/pads either lay them flat or roll the blanket/pad. Do not fold the Gelli-Roll blankets/pads as folding may damage blanket/pad.

For single-use blanket/pad(s) follow the instructions packaged with the blanket/pad.

The NORM-O-TEMP® unit, connecting hose, and blankets/pads are now ready for patient use.

3-3. Unit and Patient Related Precautions

This unit requires both sterile water or water that has been passed through a filter less than or equal to 0.22 microns and electricity to operate.

***NOTE:** Please consult pages 4-6 at the beginning of the manual for a complete list of warnings and cautions related to the NORM-O-TEMP® system.*

3-4. Patient Preparation and Bedside Care

Effective use of the NORM-O-TEMP® system must include proper patient care prior to and while using the hyper-hypothermia blanket/pad(s).

- A. A base line recording should be made of vital signs, level of consciousness and responsiveness.
- B. It is recommended that a dry sheet be placed between the hyper-hypothermia blanket/pad and the patient when using PLASTI-PAD, GELLI-ROLL, or MAXI-THERM Blanket/pad(s).

Standard nursing procedures while using a hyper-hypothermia blanket/pad include the following tasks:

- A. Patient core temperature and the condition of the skin in contact with the blanket/pad and blanket/pad water temperature should be checked every twenty minutes. Surgical patients, temperature sensitive and pediatric patients should be checked more frequently. Notify the physician if the patient's core temperature

does not reach the prescribed temperature in the time prescribed or deviates from the prescribed temperature range.

- B. Changes in skin color, edema, inflammation, or indications of pressure, especially over bony prominences, should be noted and treated as ordered. Avoid prolonged tissue pressure and shearing forces over bony prominences.
- C. The patient should be turned and properly positioned frequently.

3-5. Alarms and Error Displays

A. Power Failure Alarm

1. If power is removed from the unit without actuating the power switch (I/O switch) a power fail alarm is activated and the LED located on the front panel of the unit flashes.
2. If the Power Failure alarm occurs, turn the power switch off and unplug the unit if it is not already unplugged. Then, plug the unit into the power source and turn the power switch "ON". If the Power Fail LED flashes and the audible alarm continues to sound, remove the unit from service and send to Biomedical Engineering for repair.

B. Low Water Alarm

1. If at anytime, the water in the reservoir falls below 3 ½ quarts (3.3 liters) a low water level alarm will activate, the LO WATER LED located on the membrane control panel will flash and the unit will shut down.
2. To clear the low water alarm, replenish the reservoir with sterile water or water that has been passed through a filter less than or equal to 0.22 microns as described in Section 5-1.5.

C. Primary High Temperature Safety Alarm

1. If the circulating water reaches $43.5^{\circ}\text{C} \pm 0.6^{\circ}\text{C}$, the primary high temperature safety will activate to turn off pump, turn off heater, the HI TEMP LED flashes and the trouble alarm sounds.
2. If the primary high temperature alarm occurs, the unit should be powered off and the power cord removed from the outlet. The unit should be immediately removed from service and sent to Biomedical Engineering for repair.

D. Secondary High Temperature Safety Alarm

1. If the circulating water reaches $44.5^{\circ}\text{C} \pm 0.6^{\circ}\text{C}$, the secondary high temperature safety will activate to turn off pump, turn off heater, the HI TEMP LED illuminates and the trouble alarm sounds.
2. If the secondary high temperature alarm occurs, the unit should be powered off and the power cord removed from the outlet. The unit should be immediately removed from service and sent to Biomedical Engineering for repair.

E. Independent Mechanical High Temperature Safety Alarm

1. If the circulating water reaches $46^{\circ}\text{C} \pm 0.6^{\circ}\text{C}$ the independent mechanical high temperature safety will activate to shut off the power to the pump, shut off the power to the heater, the HI TEMP LED and Power Fail LED illuminate, and the trouble alarm sounds.
2. If the independent mechanical high temperature alarm occurs, the unit should be powered off and the power cord removed from the outlet. The unit should be immediately removed from service and sent to Biomedical Engineering for repair.

F. 1°C Over Set point Alarm

1. If the set point temperature has been set at least 1°C lower than the actual circulating water temperature, the 1°C Over Set point Temperature Alarm will activate to turn off the heater, the HI TEMP LED flashes, the "WATER" display flashes the actual water temperature and the trouble alarm sounds.
2. The heater will remain off, the HI TEMP LED will continue to flash and the "WATER" display will continue to flash until the actual circulating water temperature is within 1°C of the set point temperature. No additional action is required.

G. Defective Water Temperature Sensor

1. If the "WATER" display reads "ERR" or "PF" the unit may have a defective water temperature sensor.
2. If the "WATER" display reads "ERR" or "PF" the unit should be powered off and the power cord removed from the outlet. The unit should be immediately removed from service and sent to Biomedical Engineering for repair.

Section 4. Operating the NORM-O-TEMP® System

4-0. Introduction

This section describes how to operate the NORM-O-TEMP® system in order to control the blanket/pad water temperature.

For proper knowledge and understanding of the unit, in-service training is available upon request.

4-1. Arranging the System Components

- A. Collect all supplies and equipment
 - a. NORM-O-TEMP® unit
 - b. Hyper-hypothermia blanket/pad(s)
 - c. Dry sheet, if necessary.
 - d. Connecting hose, if necessary.
 - e. Sterile water or water that has been passed through a filter less than or equal to 0.22 microns
- B. Place the NORM-O-TEMP® unit in the patient area, accessible to the correct power source. Ensure the NORM-O-TEMP® unit is positioned to prevent tipping and unintended motion.
- C. Refer to Section 1-3 for features of the unit and membrane control panel.
- D. Check that the power switch is in the “O” position (unit is off).
- E. Check the level of sterile water or water that has been passed through a filter less than or equal to 0.22 microns in the reservoir. To do so, slide the cover of the water fill opening and check if the water is visibly touching the strainer. If needed, carefully add sterile water or water that has been passed through a filter less than or equal to 0.22 microns. Do not use de-ionized water or distilled water. Do not overfill. If the water falls below a preset level, the alarm sounds and the LO WATER LED lights up. The pump and heater shut down and the operator cannot proceed until this is corrected by refilling the unit and resetting the alarm.
- F. Inspect the power plug for bent or missing prongs. Do not by-pass ground lug.
Electrical hazards may result.
- G. Insert the plug into a properly grounded hospital grade receptacle.
- H. Lay the hyper-hypothermia blanket/pad flat with the hose routed, without kinks, towards the unit.
- I. If the blanket/pad is already filled, check that there are no leaks. **Water leaks present a risk of infection. Leaking blankets/pads should never be used.**

- J. Cover the blanket/pad with a dry sheet (if necessary).
- K. Connect the blanket/pad to the NORM-O-TEMP® unit as described in Section 3-2.1.
- L. If a single-patient use hyper-hypothermia blanket/pad is used, connect the couplings of the connecting hose to the blanket/pad as described in the instructions packaged with each blanket/pad.
- M. The hyper-hypothermia blanket/pad may be pre-warmed before positioning the patient. To do so, operate the unit at desired temperature for about 25 minutes.
- N. Place the patient on the hyperthermia blanket/pad.
- O. If a top hyper-hypothermia blanket/pad is to be used, cover with a dry sheet
- P. Connect the blanket/pad to the NORM-O-TEMP® unit following the procedure described in Section 3-2.1.
- Q. If no top hyper-hypothermia blanket/pad is used, cover the patient with a top sheet and/or blanket/pad. Patient preparation and bedside care are further described in Section 3-4.

NOTE: *If at anytime, power is removed from the unit without actuating the power switch (I/O switch) a power fail alarm will activate and the Power fail symbol LED located on the front of the unit will flash. To stop the alarm, restore power.*

NOTE: *If at anytime, the water in the reservoir falls below 1 ½ quarts (1.4 liters) a low water level alarm will activate, the LO WATER LED located on the membrane control panel will flash and the unit will shut down.*

4-2. Operating the NORM-O-TEMP® System

The NORM-O-TEMP® system operates based upon the actual temperature of the circulating water relative to the set point temperature. The NORM-O-TEMP® heats and circulates the water.

Given the many variables such as patient size, weight, or condition, there is no direct relationship between the temperature of the circulating water and patient temperature. Both water temperature and patient temperature should be closely monitored.

4-3. Concluding the Use of the NORM-O-TEMP® System

NOTE: *It is important to drain the unit before placing in dry storage.*

After the patient temperature reaches the prescribed temperature for the prescribed amount of time, discontinue the use of the NORM-O-TEMP® unit as ordered. Patient's temperature can vary slightly up or down after therapy has been discontinued. The operator should continue to monitor the patient's temperature.

When the hyperthermia therapy has concluded and the unit is turned off:

- A. Permit the blanket/pad(s) and hose to remain connected to the unit for about ten minutes. This allows the water to drain back into the unit.
- B. Disconnect the power cord from the power source, loosely coil it and attach it to the back panel using the nylon straps.
- C. Remove the blanket/pad(s).
- D. Loosely coil the connecting hose and attach it to the back panel using the nylon straps, if necessary.
- E. For reusable PLASTIPAD blanket/pad(s), loosely coil the hose lengthwise in the center of the blanket/pad. Fold the blanket/pad lengthwise into the center, 1/3 from the left side and 1/3 from the right side. Maintenance of the blanket/pad is described in Section 5-4.

For reusable Gelli-Roll blankets/pads either lay them flat or roll the blanket/pad. Do not fold the Gelli-Roll blankets/pads.

For Single-Patient Use blanket/pad(s), follow the instructions packaged with the blanket/pad. Dispose of blankets/pads in a manner consistent with hospital policy protocol for patient contact items.

Section 5. General Maintenance of the NORM-O-TEMP® System

5-0. Introduction

Maintenance and service activities will sometimes overlap. In general, maintenance refers to any activity that does not require a certified technician. Maintenance may be performed by healthcare personnel or by other trained persons.

The following actions are considered maintenance:

1. Inspecting, cleaning, and disinfecting the exterior
2. Adding or replacing water
3. Replacing hoses
4. Cleaning hoses, blankets
5. Draining reservoirs

Service refers to any activity that requires a Medical Equipment Service Technician, Certified Biomedical Electronics Technician, or a Certified Clinical Engineer. The following actions are considered service:

1. Equipment or parts replacement
2. Repairs
3. System testing
4. Cleaning & disinfecting water reservoirs
5. Replacing hoses (air, water), cords, and other accessories

This section describes the general requirements maintenance personnel should complete on a regular basis so that the NORM-O-TEMP® system continues to operate within the manufacturer's specifications.

These maintenance requirements include changing and replenishing the water in the reservoir; cleaning the water filter, the exterior of the unit, the back vent, and the hyperthermia blanket/pad(s). Figure 7 provides a convenient checklist to record the required maintenance history of the unit.

The description of each requirement includes the tools, the procedures, and the precautions necessary to complete the requirements. Maintenance, repair and/or service of the NORM-O-TEMP® unit by qualified maintenance/technical personnel will not void the warranty of the unit.

WARNING	
•	Improper repair and inadequate maintenance can result in damage to the NORM-O-TEMP® system and patient injury.
•	Before returning the NORM-O-TEMP® to patient use after repairs, the FIRST TIME SET-UP/SYSTEM TEST ROUTINE in Section 3-2 must always be performed.

The following maintenance procedures should be performed quarterly.

- A. Draining/Replenishing the Reservoir
- B. Cleaning the Vent
- C. Required Preventive Maintenance Checklist
- D. Cleaning the Water Filter
- E. Cleaning Water System
- F. Cleaning the Exterior of the Unit
- G. Cleaning Hyper-Hypothermia Blanket/pad(s)

Required Preventative Maintenance Checklist (Quarterly)

Hospital Control No. _____

Serial Number _____

Check When Completed

- | | |
|---|--------------------------|
| 1. External cabinet in good condition. (No unusual dents or missing parts.) | <input type="checkbox"/> |
| 2. All labels properly affixed. | <input type="checkbox"/> |
| 3. Clean the unit's exterior. (See Section 5-3) | <input type="checkbox"/> |
| 4. Quick disconnect couplings are tight, straight, and not leaking. | <input type="checkbox"/> |
| 5. Power cord (no cuts or exposed wire) and plug (no bent or missing prongs). | <input type="checkbox"/> |
| 6. Indicator lights are operative. | <input type="checkbox"/> |
| 7. Drain and clean reservoir. See Section 5-1. | <input type="checkbox"/> |
| a. Check circulation through each male coupling with drain hose | <input type="checkbox"/> |
| 8. Clean water filter. See Section 5-2. | <input type="checkbox"/> |
| 9. Refill reservoir with sterile water or water that has been passed through a filter
than or equal to 0.22 microns. See Section 5-1.5 | <input type="checkbox"/> |
| 10. Check flow rate. | <input type="checkbox"/> |
| a. Flow rate: Minimum of 0.5 GPM | <input type="checkbox"/> |
| b. Pressure: Maximum of 10 PSI | <input type="checkbox"/> |
| 11. Condition of blanket/pad(s), hoses, and couplings (check for leaks). | <input type="checkbox"/> |
| 12. Check the low water safety. (See Section 5-1.4) | <input type="checkbox"/> |
| 13. All readings should be under 500µa for 230V/240 units: (See Section 6-17.2) | <input type="checkbox"/> |
| a. OFF Normal Polarity | <input type="checkbox"/> |
| b. OFF Reverse Polarity | <input type="checkbox"/> |
| c. ON Normal Polarity | <input type="checkbox"/> |
| d. ON Reverse Polarity | <input type="checkbox"/> |
| 14. Check the high limit safety: (See Section 6-11) | <input type="checkbox"/> |
| a. Primary: 43.5°C ± 0.6°C | <input type="checkbox"/> |
| b. Secondary: 44.5°C ± 0.6°C | <input type="checkbox"/> |
| c. Independent Mechanical: 46°C ± 0.6°C | <input type="checkbox"/> |
| 15. Check the Power Interrupt Safety. (See Section 6-10) | <input type="checkbox"/> |
| 16. Ground Integrity Check: Verify the case to ground pin resistance.
(See Section 6-17.1) | <input type="checkbox"/> |

Signature of Inspector

Date of Inspection

Figure 7. NORM-O-TEMP® Maintenance Checklist

5-1.Maintenance of Water Reservoir

The dual compartment reservoir holds approximately 1½ gallons (5.7 liters) of sterile water or water that has been passed through a filter less than or equal to 0.22 microns that remains in the unit between periods of use.

Once a month the water reservoir should be drained and replenished. The drain hose, included in the packaging of the unit, is attached and the water is pumped out of the unit. When the LO WATER alarm sounds, the remaining water is drained by gravity. Sterile water or water that has been passed through a filter less than or equal to 0.22 microns is then poured into the reservoir.

Quarterly, at a minimum, the Internal Cleaning / Dry Storage Procedure, listed below, should be conducted.

NOTE: DO NOT USE DE-IONIZED WATER, DISTILLED WATER OR ALCOHOL.

CAUTION
For safe handling and use of chemicals follow manufacturer guidelines.
Always drain the NORM-O-TEMP® to a sanitary drain because bacteria may be present in the unit’s water supply.

Chemical Cleaning Circulation Chart

UNIT	MODE	TEMPERATURE	DURATION
NORM-O-TEMP® 111W	Heating	38°C	5 Minutes

5-1.1. Internal Clean using Bleach / Dry Storage Procedure

For circulating water units utilizing household bleach.

The following procedure cleans the fluid circuit in these products. The required tools/supplies are appropriate drain hose(s) and/or hose connector(s), household bleach, sterile water or water that has been passed through a filter less than or equal to 0.22 microns, and the appropriate AC electrical power

Procedure:

- A. Drain the water from the reservoir as described in Section 5-1.4.
- B. Turn unit off (“O” position).
- C. Fill the reservoir with the appropriate amount of household bleach per the below chart.

UNIT	BLEACH	WATER
NORM-O-TEMP®, 111W	168 Milliliters	5.4 Liters

- D. Fill the reservoir with warm sterile water or water that has been passed through a filter less than or equal to 0.22 microns.
- E. Turn the unit on and circulate per the Chemical Cleaning Circulation Chart (above).
- F. Drain the unit as instructed in Step A.
- G. Rinse the unit three (3) times as described in Steps D-F. Be sure to omit the household bleach (sodium hypochlorite).
- H. After the third rinse, drain the unit and fill the reservoir with sterile water or water that has been passed through a filter less than or equal to 0.22 microns and circulate.
- I. Check the water with pH strips or other appropriate test method for detecting bleach. If bleach is detected, repeat Steps F-H.
- J. Continue to fill the water reservoir with sterile water or water that has been passed through a filter less than or equal to 0.22 microns.
- K. If unit is being placed in dry storage skip steps J and K, continue with procedure at step M.
- L. When all fluid has been removed from the unit, disconnect the drain hose(s) and wipe unit clean.
- M. Unit is now ready for storage.
- N. Document unit maintenance.

When you are ready to return unit to service, replenish the reservoir(s) with sterile water or water that has been passed through a filter less than or equal to 0.22 microns. Perform all the checks as described in the respective Manual.

5-1.2. Internal Cleaning and Disinfection Using Gigasept FF / Dry Storage Procedure

For Circulating Water Units Utilizing CE Approved Gigasept FF (Product of Schulke & Mayr) (Contact your local Cleaning Supplier). Gigasept FF Is Not Available In the United States.

The following procedure disinfects the fluid circuit in these products. The required tools/supplies are appropriate drain hose(s) and/or hose connector(s),

Gigasept FF, sterile water or water that has been passed through a filter less than or equal to 0.22 microns, and the appropriate AC electrical power

Procedure:

- A. Drain the water from the reservoir as described in Section 5-1.4.
- B. Turn unit off (“O” position).
- C. Fill the reservoir with the appropriate amount of Gigasept FF per the below chart.

UNIT	Gigasept FF	WATER
NORM-O-TEMP®, 111W	168 Milliliters	5.4 Liters

- D. Fill the reservoir with sterile water or water that has been passed through a filter less than or equal to 0.22 microns.
- E. Turn the unit on and circulate per the Chemical Cleaning Circulation Chart (above).
- F. Drain the unit as instructed in Step A.
- G. Rinse the unit with Sterile water or water that has been passed through a filter less than or equal to 0.22 microns three (3) times as described in Steps D-F. Be sure to omit Gigasept FF.
- H. After the third rinse, drain the unit and fill the reservoir with sterile water or water that has been passed through a filter less than or equal to 0.22 microns and circulate.
- I. Check the water with PH strips or other appropriate test method for Gigasept FF detection. If Gigasept FF is detected, repeat Steps 4-6.
- J. If unit is to be returned to service, replenish reservoir(s) with the appropriate volume of sterile water or water that has been passed through a filter less than or equal to 0.22 microns.
- K. If unit is being placed in dry storage, continue with procedure.
- L. When all fluid has been removed from the unit, disconnect the drain hose(s) and wipe unit clean.
- M. Unit is now ready for storage.
- N. Document Unit Maintenance.

5-1.3. Internal Cleaning and Disinfection Using Maranon H / Dry Storage Procedure

For circulating water units utilizing CE approved Maranon H (Product of Ecolab). Maranon H is not available in the United States.

The following procedure disinfects the fluid circuit in these products. The required tools/supplies are appropriate drain hose(s) and/or hose connector(s), Maranon H, sterile water or water that has been passed through a filter less than or equal to 0.22 microns, and the appropriate AC electrical power.

Procedure:

- A. Drain the water from the reservoir as described in Section 5-1.4.
- B. Turn unit off (“O” position).
- C. Fill the reservoir with the appropriate amount of Maranon H per the below chart.

UNIT	MARANON H	WATER
NORM-O-TEMP®, 111W	168 Milliliters	5.4 Liters

- D. Fill the reservoir with the appropriate amount of water per the above chart.
- E. Turn the unit on and circulate per the Chemical Cleaning Circulation Chart (above).
- F. Drain the unit as instructed in Step A.
- G. Rinse the unit three (3) times as described in Steps D-F. Be sure to omit the Maranon H.
- H. After the third rinse, drain the unit and fill the reservoir with sterile water or water that has been passed through a filter less than or equal to 0.22 microns and circulate.
- I. Check the water with pH strips or other appropriate test method for Maranon H detection. If Maranon H is detected, repeat Steps D-F.
- J. If unit is to be returned to service, replenish reservoir(s) with the appropriate volume of sterile water or water that has been passed through a filter less than or equal to 0.22 microns.
- K. If unit is being placed in dry storage, continue with procedure.
- L. When all fluid has been removed from the unit, disconnect the drain hose(s) and wipe unit clean.

M. Unit is now ready for storage.

N. Document unit maintenance.

5-1.4. Draining the Reservoir

CAUTION
<ul style="list-style-type: none">Always drain the NORM-O-TEMP® to a sanitary drain because bacteria may be present in the unit's water supply.

A. Collect these items:

1. An empty container to drain the water into that can hold at least 3 gallons (11.4 liters).
2. The drain hose with a female quick-disconnect coupling.
3. 2 gallons (7.6 liters) sterile water or water that has been passed through a filter less than or equal to 0.22 microns to replenish the reservoir.

B. Insert the drain end of the hose into the 3 gallon (11.4 liters) container. Set the container on the floor so the hose drains downward.

C. Attach the female coupling of the drain hose to any one of the male outlet couplings on the right side of the unit.

1. Slide back the collar of the female coupling.
2. Insert the female coupling over the male coupling.
3. Release the collar so the coupling 'Snaps' into position.

WARNING
<ul style="list-style-type: none">Do not by-pass ground lug. Electrical Hazards may result.

D. Plug the power cord into a properly grounded power outlet.

E. Place the power switch to the "I" position.

The water is pumped into the container until there is approximately 1½ quarts (1.4 liters) of water remaining to be drained. The LO WATER indicator lights up, the status display flashes and the alarm sounds. The unit shuts down but the water continues to drain into the container because of gravitational pull.

F. Press the power switch to the "O" position.

G. Disconnect the power cord from the power source.

- H. After all the water has drained from the unit, disconnect the drain hose, wipe, clean and store in a dry environment without disinfecting. Refer to Section 5-3 for storage conditions specifications.
- I. Discard the water drained from the unit.
- J. If any other maintenance/repair is to be completed, go to the appropriate section, e.g., cleaning the water filter. If not, go to Section 5-1.5 to replenish the reservoir.

5-1.5. Replenishing the Reservoir / Fixing a Low Water Alarm

- A. Check that the drain hose is disconnected.

CAUTION	
<ul style="list-style-type: none">• Use sterile water or water that has been passed through a filter less than or equal to 0.22 microns only. Do Not Use De-Ionized water or Distilled Water.	
<ul style="list-style-type: none">• Do not use alcohol. Alcohol may cause blanket/pad deterioration.	
<ul style="list-style-type: none">• Do not overfill. Overfilling may result in overflow when the water in the blanket/pad drains back into the system when the system is turned off.	

- B. Slide the water fill opening lid to the left and gradually pour approximately 1½ gallons (5.7 liters) of sterile water or water that has been passed through a filter less than or equal to 0.22 microns into the reservoir (DO NOT USE ALCOHOL, TAP WATER, DISTILLED WATER, OR DE-IONIZED WATER).
- C. Stop pouring when the water reaches the strainer visible at the bottom of the water fill opening.
- D. Proceed with normal operations; always check the water level before starting.

5-2. Maintenance of the Water Filter

The NORM-O-TEMP® circulating system includes a water filter designed to clear the line of any particulate matter as the water is pumped through the system. The water filter assembly is a plastic T-shaped fitting that intersects the hose from the water flow indicator to the reservoir. A stainless steel wire-mesh screen is located inside the clear plastic cap of the water filter assembly.

Quarterly, or more often if deemed necessary, the water filter should be disassembled and cleaned. To do so, the reservoir must first be drained and the three sided enclosure panel removed. The cap of the water filter assembly is unscrewed. The wire mesh and the plastic cap are cleaned. The parts are then reassembled.

CAUTION

- Always drain the NORM-O-TEMP® to a sanitary drain because bacteria may be present in the unit's water supply.

WARNING

- The repair, calibration, and servicing of the NORM-O-TEMP® should be performed by qualified Medical Equipment Service Technicians, Certified Biomedical Electronics Technicians, or Certified Clinical Engineers familiar with good repair practices for servicing medical devices, and in accordance with instructions contained in this manual. **Improper repair can result in damage to the NORM-O-TEMP® system and patient injury.**
- Always **unplug the unit** before accessing internal components during service. Failure to unplug the unit could result in **electric shock**.

After draining the reservoir as described in Section 5-1.4:

- A. Disconnect the unit from its power source.
- B. Remove the three sided enclosure panel.
- C. Locate the water filter assembly.
- D. Firmly grasp the notched rim of the cap of the assembly and turn it counterclockwise. The cap may contain a small amount of water.
- E. Remove the wire mesh.
- F. Clean the wire mesh and the plastic cap. Be careful not to lose the black O-ring in the rim of the plastic cap.
- G. Replace the wire mesh in the plastic cap and position the wire mesh, O-ring and plastic cap.
- H. Screw the cap clockwise onto the fitting until it is secure.
- I. Replace the three sided enclosure panel.
- J. Replenish the water reservoir as described in Section 5-1.5.

5-3. Maintenance of the NORM-O-TEMP® Exterior – Cleaning Instructions

The NORM-O-TEMP® unit is constructed of powder coated steel with a plastic top that should be cleaned quarterly with water and mild detergent solution. For cleaning and disinfecting, always use conventional hospital-approved topical equipment cleaners and disinfectants that do not contain alcohol. Avoid alcohol and other strong, undiluted disinfectants. These may cause staining of the device's outer skin. Thoroughly wipe down device with a damp cloth to remove any residue from cleaning solutions. Ensure that all inaccessible cracks and crevices on the NORM-O-TEMP® unit are reached during cleaning. In addition, ensure that all accessories associated with the NORM-O-TEMP® system, including extension hoses, are cleaned quarterly as well.

5-4. Maintenance of the Hyper-Hypothermia Blanket / Pad(s)

This section describes the general maintenance for the reusable and disposable blankets/pads. General maintenance tasks include cleaning, draining, and storing the reusable blankets/pads.

5-4.1. Cleaning / Maintenance of Reusable Blanket / Pad(s)

Gentherm reusable blankets/pads are constructed from biocompatible polyurethane/urethane. Stains and debris can be wiped away with mild soap and water. For cleaning, always use conventional hospital-approved topical cleaners and disinfectants that do not contain alcohol. Avoid alcohol or strong, undiluted disinfectants. These may cause staining of the device's outer skin. Thoroughly rinse product with clear water to remove any residue from cleaning solutions. DO NOT use gas sterilization or autoclaving for cleaning and disinfecting the blankets/pads.

To drain the water from the reusable blankets/pads simply shut off power to the unit and allow the water to drain from the blanket/pad back into the NORM-O-TEMP® unit.

To store PLASTIPAD blankets/pads, loosely coil the hose lengthwise into the center of the blanket/pad. Fold the blanket lengthwise into the center, 1/3 from the left side and 1/3 from the right side. Do not fold the blankets/pads width-wise, as doing so will crimp the tubing.

To store Gelli-Roll blankets/pads either lay them flat or roll the blanket/pad. Do not fold the Gelli-Roll blankets/pads.

Disposal of blankets/pads are done in a means consistent with hospital policy protocol for patient contact items.

5-4.2. Cleaning / Maintenance of Disposable, Single-Patient Use Blanket / Pad(s)

The reusable blanket/pad maintenance procedures do not apply to the disposable, single-patient use blankets/pads. Disposal of blankets/pads are done in a means consistent with hospital policy protocol for patient contact items.

Section 6. Field Repair / Service of the NORM-O-TEMP®

WARNING

- **The repair, calibration, and servicing of the NORM-O-TEMP® should be performed by a qualified Medical Equipment Service Technicians, Certified Biomedical Electronics Technicians, or Certified Clinical Engineers familiar with good repair practices for servicing medical devices, and in accordance with instructions contained in this manual.** Improper repair can result in patient injury and/or damage to the NORM-O-TEMP®.
- **Always unplug the unit before accessing internal components during service.** Failure to unplug the unit could result in electric shock.

CAUTION

- This device is still energized when the power switch is in the off position. To completely disconnect the device from the power source, remove the power cord plug from the power source.
- The capacitors inside this unit may remain charged after power is disconnected, discharge before servicing. To discharge the NORM-O-TEMP®, ensure the unit is unplugged and use any metal, such as a screwdriver, with an insulated handle to simultaneously touch both pins on the power cord.

6-0. Introduction

Maintenance and service activities will sometimes overlap. In general, maintenance refers to any activity that does not require a certified technician. Maintenance may be performed by healthcare personnel or by other trained persons.

The following actions are considered maintenance:

1. Inspecting, cleaning, and disinfecting the exterior
2. Adding or replacing water
3. Replacing hoses
4. Cleaning hoses, blankets
5. Draining reservoirs

Service refers to any activity that requires a Medical Equipment Service Technician, Certified Biomedical Electronics Technician, or a Certified Clinical Engineer.

The following actions are considered service:

1. Equipment or parts replacement
2. Repairs
3. System testing
4. Cleaning & disinfecting water reservoirs
5. Replacing hoses (air, water), cords, and other accessories

Complete the applicable parts of the First Time Set-Up/System Test Routine as described in Section 3-2 to determine that the unit is operating.

This section describes the repair and service that qualified maintenance personnel can complete in the field if a problem should occur. Only qualified personnel should undertake repairs and service. These tasks include replacing any of the following parts:

1. Heater
2. Pump Housing
3. Pump Motor
4. Water Filter
5. Water Temperature Sensor
6. Outlet Water Manifold
7. Return Water Manifold
8. High Limit Temperature Safety Device
9. Water Flow Indicator
10. Power Switch
11. Water Level Sensor
12. Microprocessor Control Board
13. Membrane Control Panel
14. Power Supply Board

The description of each task includes the tools, the procedures and the precautions necessary to complete the task. Maintenance, repair and/or service of the NORM-O-TEMP® by qualified maintenance/technical personnel will not void the warranty.

Figure 9 and Figure 11 highlight the interior components of the NORM-O-TEMP®.

Any part that is removed from the unit and is still under warranty should be returned to Gentherm as described in Section 8. If not, dispose of the part as required. Before attempting to perform any service or make any repairs, disconnect the NORM-O-TEMP® unit from any power source.

6-1. Access to the Interior

All internal operating components are readily accessible by either removing the top of the unit or the three sided enclosure panel. It is recommended that the reservoir be drained and the power cord disconnected before removing any part of the unit.

6-1.1. Removing the Top of the Unit

CAUTION

- Working with electronic boards, plugs, and cables requires delicate handling. Proper Electrostatic Discharge (ESD) handling practices should be followed during replacement of any electronic board. It is recommended that this section be read before removing the microprocessor board, the power supply board and/or the membrane control panel.

- A. Remove the four phillips head screws from the top assembly.
- B. Carefully lift up the top so that you can see the microprocessor board, the two connecting cables and the power supply board.
- C. Wipe dry the strainer and any water that may have dripped.
- D. Disconnect the 12-pin connector by pinching the sides and pulling apart.
- E. Disconnect the 15-pin connector by pinching the sides and pulling apart.
- F. Lift the top up and put it aside or discard if being replaced.

6-1.2. Replace / Reinstall the Top of the Unit

Re-Install top as it was removed in Section 6-1.1.

NOTE: When securing the top, be sure the fill spout gasket inner lip on the aluminum cover top is in the up position and the fill spout goes directly into it.

6-1.3. Removing the Three-Sided Enclosure Panel

- A. Loosen the top of the unit as described in Section 6-1.1.
- B. If an I.V. pole is attached to the stand, remove the two phillips screws from the U-shaped bracket that secures the I.V. pole to the unit. Put the bracket and screws aside.
- C. Remove the six remaining phillips head screws that secure the three-sided panel to the unit.
- D. Remove the enclosure panel and put aside or discard if it is being replaced.

6-1.4. Replace / Reinstall the Three-Sided Enclosure Panel

Re-Install enclosure as it was removed in Section 6-1.3.

6-2. Replacement of the Heater

- A. Collect the following required items:
 - 1. 7/8 inch wrench
 - 2. Teflon tape
 - 3. Replacement heater
 - 4. 6-32 Kep Nut
 - 5. 5/16 inch Nut Driver
- B. Drain the reservoir as described in Section 5-1.4.
- C. Remove the three-sided enclosure panel as described in Section 6-1.3.
- D. Locate the heater inserted in the lower front part of the reservoir.
- E. Disconnect the two heater wires attached to the power supply board.
- F. Using a 5/16 inch nut driver unscrew the 6-32 kep nut to disconnect the ground wire.
- G. Using a 7/8 inch wrench, unscrew the heater and pull it from the reservoir.
- H. Apply three (3) wraps of teflon tape around the threads of the replacement heater.
- I. Insert and tighten (hand tight plus half turn) the replacement heater into the reservoir.
- J. Connect the ground wire to the grounding stud located on the reservoir frame using a 6-32 kep nut.
- K. Connect both heater wires to the power supply board.
- L. Refill the reservoir as described in Section 5-1.5.
- M. Secure the three-sided enclosure panel as described in Section 6-1.4.

6-3. Replacement of the Pump Housing

- A. Obtain a replacement pump housing.
- B. Drain the reservoir as described in Section 5-1.4.

- C. Remove the three-sided enclosure panel as described in Section 6-1.3.
- D. Locate the pump housing assembly, and the inlet and outlet hose connections at the bottom front of the unit in Figure 9.
- E. Disconnect the hose at the inlet of the pump housing by loosening the screw clamp. Note: There may be small amounts of water in the hose.
- F. Disconnect the hose at the outlet of the pump housing by releasing the clamp near the top of the white pump housing.
- G. Remove the four screws from around the edge of the pump housing
- H. Pull the complete white pump housing forward, remove, and discard.
- I. Insert the replacement housing assembly. Position the housing so that the outlet is pointing upward and the screw holes are aligned.
- J. Reinsert the four screws around the edge of the housing.
- K. Tighten the screws in the following order: Top, bottom, right and left. **Do not tighten the screws sequentially.**
- L. Reconnect the hose of the water manifold to the outlet at the top of the pump housing and tighten the clamp.
- M. Reconnect the hose from the water reservoir to the inlet at the center of the pump housing and tighten the clamp.
- N. Secure the three-sided enclosure panel as described in Section 6-1.4.
- O. Refill the reservoir as described in Section 5-1.5.

6-4. Replacement of the Pump Motor

- A. Obtain a replacement pump motor.
- B. Drain the reservoir as described in Section 5-1.4.
- C. Remove the three-sided enclosure panel as described in Section 6-1.3.
- D. Locate the pump housing assembly with inlet and outlet hose connections at the bottom front of the unit as shown in Figure 9.

- E. Disconnect the hose at the inlet and the outlet of the pump housing by loosening the clamps. Note: There may be small amounts of water in the lines.
- F. Using a phillips screwdriver and an 11/32 inch wrench, remove the four screws from the bottom of the base while holding the 11/32 inch lock nuts on the pump mounting plate. Using a 7/16 inch wrench, remove the four bolts and nuts holding the pump mounting plate to the pump.
- G. Locate the pump wires on the power supply board and disconnect. Locate the ground wire on the unit base and disconnect.
- H. Remove the pump motor from the unit and discard.
- I. Reattach the pump mounting plate to the replacement pump using the four nuts and bolts. Position the pump on the base with the head of the pump towards the front of the unit.
- J. Reattach the pump mounting plate to the base of the unit using the phillips head screws and the kep nuts.
- K. Reconnect the inlet and outlet hoses to the replacement pump. Tighten the clamps securely.
- L. Reconnect the pump wires to the power supply board. Reconnect the ground wire to the base of the unit.
- M. Secure the three-sided panel as described in Section 6-1.4.
- N. Refill the reservoir as described in Section 5-1.5.

6-5. Replacement of the Water Filter Assembly.

- A. Obtain a replacement water filter assembly.
- B. Drain the reservoir as described in Section 5-1.4.
- C. Be sure that the unit is disconnected from any power source.
- D. Remove the three-sided enclosure panel as described in Section 6-1.3.
- E. Locate the water filter assembly as shown in Figure 9.
- F. Disconnect the assembly by loosening the plastic snapper clamps and sliding the hoses off the barbed fittings.
- G. Remove the T-shaped water filter assembly and discard.

- H. Insert the replacement water filter assembly so that the cap and screen point down and the arrow on the top points towards the front of the unit.
- I. Reinstall the plastic snapper clamp.
- J. Secure the three-sided enclosure panel as described in Section 6-1.4.
- K. Refill the reservoir as described in Section 5-1.5.

6-6. Replacement of the Water Temperature Sensor.

- A. Obtain replacement water temperature sensor.
- B. Drain the reservoir as described in Section 5-1.4
- C. Remove the three-sided enclosure panel as described in Section 6-1.3.
- D. Locate the water temperature sensor in the end of the copper outlet (bottom) manifold and the 4 wire connector just below the front half of the reservoir as shown in Figure 9.
- E. Disconnect the water temperature sensor by disconnecting the white, 4 wire plug.
- F. Using a 7/16 inch wrench, unscrew the water temperature sensor at the water manifold and remove the water temperature sensor. Note: There may be small amounts of water in the manifold.
- G. Insert and tighten the replacement water temperature sensor into the copper outlet (bottom) water manifold. The threads of the replacement water sensor should be sealed with teflon tape.
- H. Connect the water temperature sensor. The connectors can be inserted only one way; check that the grooves are aligned.
- I. Secure the three-sided panel as described in Section 6-1.4.
- J. Refill the reservoir as described in Section 5-1.5.

6-7. Replacement of the Water Manifolds

6-7.1. Outlet Manifold

- A. Collect the following required tools:
 - 1. 7/16 inch and 9/16 inch wrench, pliers and phillips screwdriver
 - 2. Teflon tape

3. Replacement water outlet manifold.
 - B. Drain the reservoir as described in Section 5-1.4.
 - C. Remove the three-sided enclosure panel as described in Section 6-1.3.
 - D. Locate the (bottom) manifold to be replaced which is secured on the left side of the unit, shown in Figure 9. The water manifold is connected to the two male quick-disconnect couplings and to the hose from the pump. The water temperature sensor is inserted into the end of the manifold.
 - E. Remove the water temperature sensor, see Section 6-6.
 - F. Disconnect the hose at the copper elbow by cutting the cable tie. Note: There may be small amounts of water in the line.
 - G. Disconnect the 1/8 inch bypass line from the water manifold by removing the cable tie and sliding the tube off the manifold.

NOTE: It is necessary to detach the ground wire connected to the manifold.

- H. Using a 9/16 inch wrench, unscrew and remove the two male quick-disconnect couplings and put aside.
- I. Remove the old manifold and insert the replacement manifold. Apply teflon tape around the threads on the manifold and do not block the openings. Be sure to remove the washers from the old manifold and install onto the replacement manifold. Discard the old manifold.
- J. Attach and tighten the male couplings to the water manifold. Make sure the copper elbow points down.
- K. Reconnect the by-pass line and replace the cable ties.
- L. Connect the hose from the pump housing to the copper elbow of the manifold and tighten the clamp.
- M. Remove the used white teflon tape from around the threads of the water temperature sensor and apply new Teflon tape.
- N. Reinsert the water temperature sensor as described in Section 6-6.
- O. Secure the three-sided enclosure panel as described in Section 6-1.4.
- P. Refill the reservoir as described in Section 5-1.5.

6-7.2. Return Manifold

- A. Collect the required tools.
 - 1. 9/16 inch wrench, pliers, phillips screwdriver
 - 2. Teflon tape
 - 3. Replacement of the water return manifold.
- B. Drain the reservoir as described in Section 5-1.4.
- C. Remove the three-sided enclosure panel as described in Section 6-1.3.
- D. Locate the (top) manifold to be replaced which is secured to the left side of the unit behind the water pump, shown in Figure 9. The manifold is connected to the female quick disconnect fittings and to the water flow indicator via a 5½ inch piece of clear tubing.
- E. Disconnect the hose by loosening the clamp around the copper elbow of the manifold.
- F. Remove the two female quick disconnect fittings from the outside of the unit using the 9/16 inch wrench.
- G. Remove the old manifold from the unit. Remove the washers from the old manifold and install onto the new manifold. Apply Teflon tape around the threads of the new manifold and be careful not to block the openings. Discard the old manifold.
- H. Install the new manifold into the unit and reattach the two quick disconnect fittings. Be sure the copper elbow is in the upward position.
- I. Reconnect the tubing and tighten the clamp.
- J. Secure the three-sided enclosure panel as described in Section 6-1.4
- K. Refill the water reservoir as described in Section 5-1.5.

6-8. Replacement of the Independent High Limit Safety Thermostat

- A. Obtain the replacement Independent High Limit Safety Thermostat.
- B. Drain the reservoir as described in Section 5-1.4.
- C. Remove the three-sided enclosure panel as described in Section 6-1.3.
- D. Locate the Independent High Limit Safety Thermostat which is under the reservoir near the back of the unit as shown in Figure 13.

- E. Unscrew the two screws which secure the thermostat to its bracket.
- F. Disconnect the two wires from the slide-on terminals.
- G. Loosen the compression fitting on the back of the reservoir and remove the copper sensing bulb. Be sure to remove the compression fitting cap, washer, and rubber “O” ring and install them onto the replacement bulb.
- H. Insert the replacement copper sensing bulb and tighten the compression fitting. Do not over-tighten the compression fitting.
- I. Insert the two slide-on connectors to the slide-on terminals on the new Independent High Limit Safety Thermostat.
- J. Secure the Independent High Limit Safety Thermostat to its bracket.
- K. Refill the water reservoir as described in Section 5-1.5.
- L. Calibrate the Independent High Limit Safety Thermostat to $46^{\circ}\text{C} \pm 0.6^{\circ}\text{C}$ as described in Section 6-9.
- M. Secure the three-sided enclosure panel as described in Section 6-1.4.

6-9. Calibration of the Independent High Limit Safety Thermostat

- A. Allow the unit to run for at least an hour with the temperature set to 42°C . This will allow adequate time for the internal ambient temperature of the Norm-O-Temp cabinet to stabilize.
- B. Turn the unit OFF and unplug from the power source. Move the jumpers on the power supply board to the “test” position. Plug the unit into the power source and turn the unit ON.
- C. Locate the Independent High Limit Safety Thermostat adjustment screw mounted to the NORM-O-TEMP® unit base through the hole at the rear of the unit.
- D. The unit will begin to heat, when the temperature reaches $46^{\circ}\text{C} \pm 0.6^{\circ}\text{C}$, turn the adjustment screw counterclockwise until the alarm activates. If it is necessary to raise the limit, turn the adjustment screw clockwise.
- E. Drain some of the water as described in Section 5-1.4 and then replenish. Allow the unit to heat up again to make sure the Independent High Limit Safety Thermostat powers off the heater and the pump at $46^{\circ}\text{C} \pm 0.6^{\circ}\text{C}$.

- F. Turn the unit OFF and unplug from the power source. Move the jumpers to the “normal” position on the power supply board.

6-10. Power Interrupt Test

- A. Leaving the power switch on, disconnect the power cord from its source. The audibly and visual alarm must indicate for at least 10 minutes.

6-11. Hi-Limit Test

- A. Raise the top of the unit and move the jumpers on the power supply board to the “test” position.
- B. Turn the unit on.
- C. Observe WATER display window and HI TEMP LED.
- D. The independent mechanical high limit is at $46^{\circ}\text{C} \pm 0.6^{\circ}\text{C}$. The HI-TEMP LED will illuminate, there will be an audible alarm, it will shut off power to the heater and the pump.
- E. Once the Hi-Limit test is complete, power OFF and unplug the unit.
- F. Then move the jumpers back to the “normal” position.

NOTE: Be sure that the unit is disconnected from any power source before moving the jumpers.

- G. After the water has been allowed to cool below 37°C , verify that the jumpers are in the correct position by turning the unit on and allowing it to heat to 37°C . The heater should turn off once the unit has reached a set point of 37°C .

6-12. Replacement or Cleaning of the Water Flow Indicator Assembly

- A. Obtain a replacement water flow indicator.
- B. Drain the reservoir as described in Section 5-1.5.
- C. Remove the three sided enclosure panel as described in Section 6-1.3.
- D. Locate the water flow indicator assembly shown in Figure 11.
- E. Remove the two screws that hold the water flow indicator to the manifold pan on the outside left wall.

- F. Remove the two screws securing the water flow indicator to the back-up manifold bracket under the rear of the reservoir.
- G. Disconnect the hoses from the plastic elbows. If the water flow indicator is to be replaced, go to step N. If the water flow indicator is to be cleaned and then reinserted, go to step H.
- H. Remove the four remaining screws around the face of the water flow indicator.
- I. Disassemble the parts of the water flow indicator. Do not lose the large black “O” ring.
- J. Rinse thoroughly with clean water. A small, soft brush may be used to clean the parts.
- K. Reassemble the parts.
- L. Reinsert the four screws, two on each side.
- M. Connect the hoses from the return fitting to the top plastic elbow and tighten the clamp.
- N. Secure the water flow indicator to the back-up manifold bracket by inserting the two screws.
- O. Insert and tighten the two screws from the outside left wall.
- P. Secure the three-sided enclosure panel as described in Section 6-1.4.
- Q. Refill the water reservoir as described in Section 5-1.5.

6-13. Replacement of the Power Switch

- A. Obtain the replacement power switch.
- B. Drain the reservoir as described in Section 5-1.4.
- C. Remove the three-sided enclosure panel as described in Section 6-1.3.
- D. Locate the power switch on the front left side of the unit as shown in Figure 9.
- E. Press together the tension clips on the top and bottom of the switch assembly by reaching inside the unit from the right side. Push the switch out through the opening in the enclosure.

- F. Disconnect the four slide-on connectors from the switch. Note which wire goes to which terminal. Remove and discard the old power switch.
- G. Position the replacement power switch into the unit in the same manner and position as the one you removed. Reconnect wires as noted above.
- H. Secure the three-sided enclosure panel as described in Section 6-1.4.

6-14. Replacement of the Water Level Sensor Assembly

- A. Obtain a replacement water level sensor.
- B. Remove the top of the unit as described in Section 6-1.1.
- C. Locate the water level sensor. Facing the unit, it is a square, grey plate located in the center as shown in Figure 9.
- D. Disconnect the water level sensor.
- E. Using a 5/16 inch wrench, remove the four nuts from the screw post in the four corners of the water level sensor.
- F. Remove the water level sensor and discard. Make sure the black gasket remains on the four posts.
- G. Insert the replacement water level so that the holes are aligned with the four screws posts.
- H. Replace and tighten the four nuts on the screw posts.
- I. Reconnect the red, 2-pin connector. It can only be connected one way.
- J. Secure the top of the unit as described in Section 6-1.2.

6-15. Replacement of the Power Supply Board

CAUTION

- Working with electronic boards, plugs, and cables requires delicate handling. Proper **Electrostatic Discharge (ESD) practices should be followed during replacement of any electronic board.**

- A. Obtain a replacement power supply board.

- B. Remove the top of the unit as described in Section 6-1.1.
- C. Unplug the pump wires, the heater wires and the AC wires from the power supply board. Note wire positions for reinstallation. Also unplug the 9 pin connector.
- D. Remove the six screws and discard the old power supply board.
- E. Install the new power supply board in its place using the same screws removed in step D.
- F. Reinstall all of the wires removed in step C.

Secure the top of the unit as described in Section 6-1.2.

6-16. Replacement of the Microprocessor Board and/or the Control Panel

CAUTION

- Working with electronic boards, plugs, and cables requires delicate handling. **Proper Electrostatic Discharge (ESD) practices should be followed during replacement of any electronic board.**

Access to the control panel first requires removing the microprocessor board.

See Section 8 for instructions for the return of the microprocessor board to the factory on the exchange program.

- A. Obtain the required replacement parts:
 - Microprocessor board
 - Membrane control panel
- B. Remove the top of the unit as described in Section 6-1.1.
- C. Position the top of the unit face down on a padded work space.
- D. Using a 5/16 inch wrench, remove the six nuts and star washers on the edge of the board
- E. Slide off the clear strip cable on the left side of the microprocessor board.
- F. Remove the microprocessor board.

- G. Carefully place the microprocessor board aside. If only the microprocessor board is to be replaced, go to step K.
- H. To replace the membrane control panel, use a ¼ inch wrench to remove the six stand-offs and put aside. The control panel is released and falls outward. Put the control panel aside.
- I. Position the replacement control panel from the face side of the top assembly so that the screw posts align with the holes, the writing on the control panel is right side up, and the clear strip connector is on the right side.
- J. Insert and tighten the six stand-offs
- K. Position the new microprocessor board on the six stand offs so that the LED display will be face down and the clear strip connector connects to the left side.
- L. Connect the cable to the 7-pin connector.
- M. Insert and tighten the six nuts and star washers on the edge of the board and tighten using a 5/16 inch wrench.
- N. Secure the top of the unit as described in Section 6-1.2.

6-17. Electrical Safety

The NORM-O-TEMP® unit should be checked quarterly for electrical safety. It is appropriate to perform such inspection upon receipt of a new unit prior to acceptance, and then again during each periodic inspection.

6-17.1. Ground Integrity

Using a Digital Multimeter, measure the resistance between an exposed, unpainted part of the metal case of the NORM-O-TEMP® and the ground conductor of the power plug. Take measurements between ground pin and the quick-disconnect fittings, also between the ground pin and the handle. Verify that the case to ground pin resistance is less than 0.2 ohms.

6-17.2. Leakage Current

Using an Electrical Safety Analyzer, measure electrical leakage current of the under the following conditions: Power ON & OFF, polarity normal and reverse, unit grounded and ungrounded. When measuring power ON, polarity normal and reverse, measure when the NORM-O-TEMP® unit is heating and circulating water (both the heater and pump are ON). When measuring power OFF, normal and

reverse polarity, measure while the NORM-O-TEMP® unit is going through self-calibration, when it is first turned on (both the heater and pump are OFF). The leakage current should be less than 500 microamps. If a NORM-O-TEMP® unit has leakage current that exceeds the appropriate limit or has a significant increase in leakage current, the cause should be investigated.

Excessive leakage current is most commonly caused by a defective heater, but other components can also fail in such a way as to increase leakage current. To find the source of excessive leakage current, suspect components should be sequentially disconnected until the source of the high leakage current is isolated.

Section 7. Troubleshooting Guide

CAUTION	
<ul style="list-style-type: none"> This device is still energized when the power switch is in the off position. To completely disconnect the device from the power source, remove the power cord plug from the power source. 	

Observation	Possible Problem	Action To Be Taken
A. The power switch is pressed to the ON position but it does not light; control panel is blank	Unit is unplugged.	Check that the power cord is plugged into a properly grounded hospital grade outlet.
	Power switch is defective	Replace the power switch. See Section 6-13.
	Fuse is open	Check the circuit breaker for the outlet.
	No line voltage	Check for possible open in electrical system.
B. Each time the power switch is pressed to the ON position, it snaps back to the OFF position	The fuses are defective.	<p>Check amperage at switch.</p> <p>If the current measurement is less than the specified amperage draw check for electrical short in unit.</p> <p>If the current measurement is more than the specified</p>

		amperage draw check the heater and pump amperage.
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Observation	Possible Problem	Action To Be Taken
<p>C. The power switch is pressed to the ON position. It lights up green but the control panel is blank/inoperable.</p>	<p>Power supply board is defective.</p> <p>The cable(s) that connect(s) to the microprocessor control board is (are) disconnected.</p>	<p>Replace the power supply board. See Section 6-15.</p> <p>Reconnect the 12-pin and 9-pin connector cables. See Section 6-1.2.</p>
<p>D. Unit is operating. A switch on the membrane control panel is pressed but nothing happens.</p>	<p>The clear strip cable leading from the membrane control panel to the microprocessor control board is disconnected.</p> <p>Membrane control panel is defective. See Section 6-16.</p>	<p>Reconnect the 7-pin clear stripe cable. See Section 6-16.</p> <p>Replace membrane control panel. See Section 6-16.</p>
<p>E. The unit is ON. The unit sounds the alarm and the indicator lights up either LO WATER or HIGH TEMP, but the silence alarm switch does not stop the alarm.</p>	<p>The membrane control panel has failed.</p>	<p>Replace the membrane control panel. See Section 6-16.</p>
<p>F. The unit is set to operate. When the unit goes through its test indicator cycle, a part of the display or the LED indicator does not light up.</p>	<p>A segment of the display or LED indicator is burned out.</p>	<p>Replace the microprocessor board.</p>

Observation	Possible Problem	Action To Be Taken
<p>G. Unit is set to operate. When the unit goes through its test indicator cycle, the display shows a typical pattern display; e.g. all 333's.</p>	<p>Microprocessor control board malfunctioned.</p>	<p>Replace the microprocessor control board. See Section 6-16.</p>
<p>H. The unit is operating and the unit momentarily blanks and then goes through start up cycle.</p>	<p>Low line voltage or power interruption. A loose connection of the power cord.</p>	<p>Check line voltage and proceed with operation. Check line voltage and proceed with operation.</p>
<p>I. The unit is operating and it will not heat or pump water.</p>	<p>The independent high limit safety thermostat has tripped or it is defective.</p>	<p>Recalibrate the independent high limit safety thermostat: See Section 6-9. Replace the independent high limit safety thermostat if found to be defective; see Section 6-8.</p>
<p>J. The unit is operating, the display reads ERR, the alarm sounds.</p>	<p>Defective water temperature sensor. Defective microprocessor board.</p>	<p>Replace the water temperature sensor. See Section 6-6. Replace microprocessor board. See Section 6-16.</p>

Observation	Possible Problem	Action To Be Taken
<p>K. The unit sounds an alarm. The LO WATER indicator light is on. The water level is correct.</p>	<p>The 2-pin connection cable from the LOW WATER float switch is disconnected.</p> <p>The low water level sensor is defective.</p>	<p>Reconnect the 2-pin connector.</p> <p>Replace the low water level sensor. See Section 6-14.</p>
<p>L. Unit is set to operate. The water flow indicator does not move; i.e. water not circulating.</p>	<p>Disengaged quick-disconnect couplings.</p> <p>Clogged water line.</p> <p>Clogged water filter.</p> <p>Kink in connecting hose and/or blanket.</p> <p>Clogged pad.</p> <p>Pump not running.</p> <p>Defective microprocessor board.</p> <p>Defective power supply board.</p>	<p>Check all couplings for proper fit.</p> <p>Use forced air to drain unit and pad.</p> <p>Clean water filter. See Section 6-5.</p> <p>Straighten hose.</p> <p>Use forced air to clean coupling.</p> <p>Check for voltage to the pump. If measured voltage is approximately the same as line voltage, check pump housing for possible obstruction. See Section 6-4 if pump must be replaced.</p> <p>Check and replace pump motor. See Section 6-4.</p> <p>Replace microprocessor board, See Section 6-16.</p> <p>Replace power supply board, See Section 6-15.</p>

Observation	Possible Problem	Action To Be Taken
<p>M. Unit is set to operate but fluid does not heat.</p>	<p>Water not circulating. Defective heater Defective power supply board.</p>	<p>See observation N. Replace heater. See Section 6-2. Replace power supply board. See Section 6-15.</p>
<p>N. Unit is set to operate. Water temperature not accurate or jumps up and down.</p>	<p>Defective microprocessor board and control board.</p>	<p>Replace microprocessor control board. See Section 6-16.</p>

Section 8. Parts Information

8-0. Introduction

This section outlines information for ordering, shipping and replacing parts. Identification of parts and components are shown in Figure 8, Figure 10, and Figure 12. The numbers in Figure 8, Figure 10, and Figure 12 correspond to the numbers in the left column of the accompanying parts lists in Figure 9, Figure 11, and Figure 13. Diagrams of the functional operation of the NORM-O-TEMP® are shown in Figure 14 and 15.

8-1. Ordering Information for Replacement Parts

Replacement parts are available directly from Gentherm or our authorized NORM-O-TEMP® dealer. When ordering parts, specify the replacement part number listed in the second column of Figure 9, Figure 11, and Figure 13 as well as the serial number of your unit located on the specification label. There is no minimum order requirement when ordering replacement parts.

Forward orders to your local dealer or to:

Gentherm Medical, LLC
12011 Mosteller Road
Cincinnati, OH 45241-1528
Telephone: (513) 772-8810
Fax: (513) 772-9119

Replacement parts from the factory are shipped F.O.B. (freight on board), Cincinnati, Ohio.

It may be desirable to stock strategic parts. Section 8-2 outlines the recommended replacement parts inventory.

It is strongly recommended that all NORM-O-TEMP® parts be replaced with parts purchased from Gentherm or our authorized dealers. Use of other parts could void the warranty on the unit and possibly damage the unit.

8-2. Recommended Replacement Parts Inventory

<u>I.D. #</u>	<u>Qty.</u>	<u>Description</u>
91702	1	Water Level Sensor Assembly
91166	1	Pump Housing Assembly
41002	1	Water Temperature Sensor
37025	1	Independent High Limit Safety Thermostat 230/240 VAC
91735	1	800 Watt Heater Assembly 230/240 VAC
91200	1	Nylon Strap Assembly
55050	2	Rubber Feet
07010	1	1/8 inch Quick-Disconnect Socket Fitting
06017	1	1/8 inch Quick-Disconnect Plug Fitting
37033	2	5 x 20 mm, 5 AMP slo blo fuse 230/240 VAC

8-3. Returning Parts Under Warranty

All parts are covered by a one (1) year warranty. Labor is covered under the one (1) year warranty only if the unit is returned to Gentherm. To replace parts during the warranty period * ship the part to:

Gentherm Medical, LLC
 12011 Mosteller Road
 Cincinnati, OH 45241-1528
 Telephone: 513/772-8810
 Fax: 513/772-9119

* To qualify for credit, warranty parts should be tagged with the following information:

1. The invoice number under which the unit/part was purchased.
2. Cause of Failure.
3. Serial Number.
4. Date of installation or purchase of the unit.
5. Return Material Authorization (RMA) Number. (You must call GENTHERM first to obtain the RMA Number.)

8-4. Shipping Parts

Parts to be returned to the factory should be carefully packaged, especially the micro-processor board and the control panel. Both of these boards should be cushioned in static safe packing material to prevent damage from Electrostatic Discharge.

NOTE: Shipping damage will be the responsibility of the shipper. Insure if necessary.

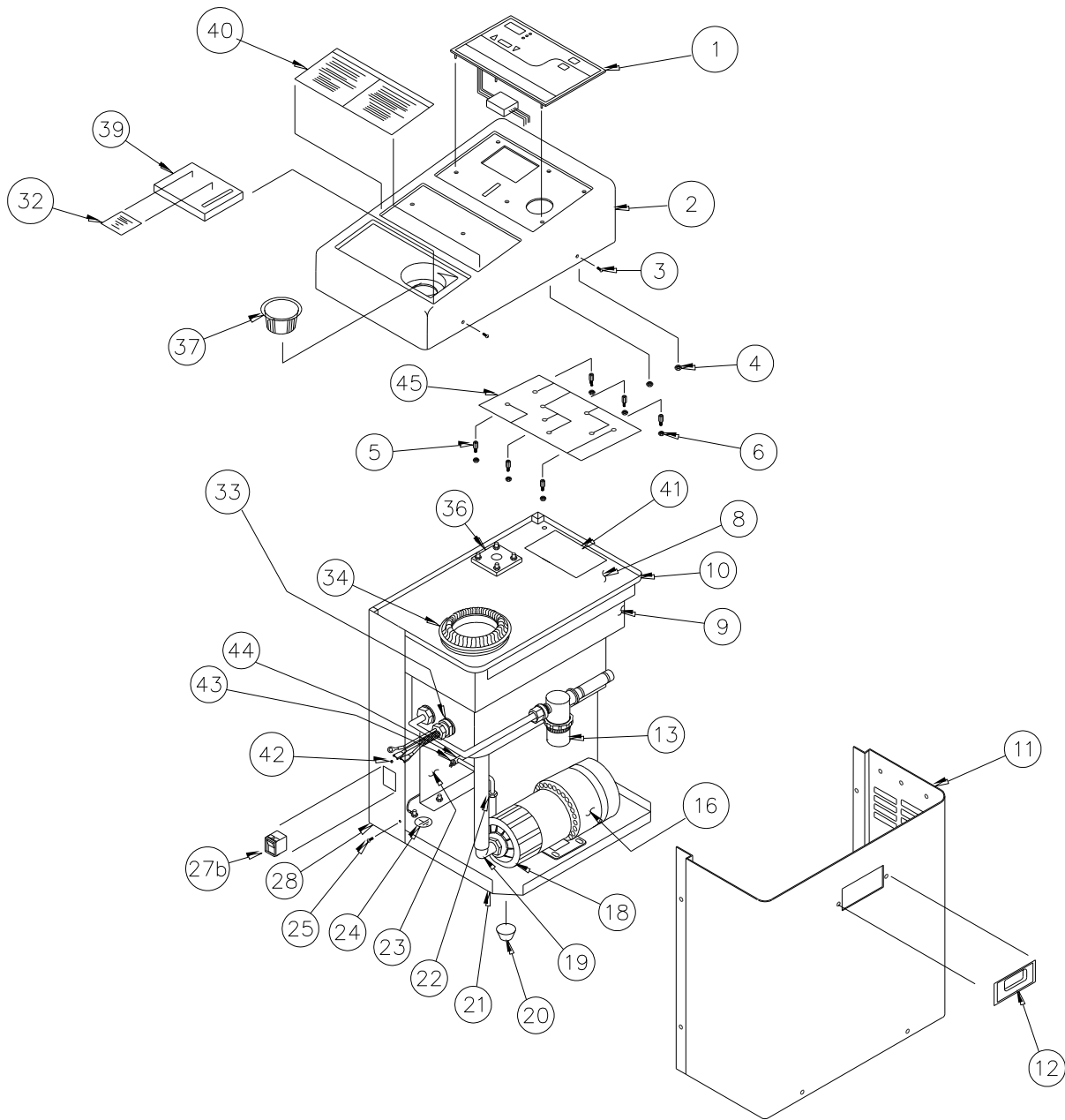


Figure 8. NORM-O-TEMP® Internal Exploded - Front View

<u>Index #</u>	<u>I.D. #</u>	<u>Description</u>
1	57208	Control Panel 230/240 VAC
2	91628	Top Assembly 230/240 VAC
3	60033	(4) #8 Phillips Screws
4	60180	(4) 6/32" Brass Nut
5	57027	(6) 3/8" Stand Off
6	60180	6/32" Brass Nuts
8	06902	Reservoir Cover
9	06644	Reservoir Frame
10	91712	White Plastic Reservoir Assembly
11	06683	Three-Sided Cabinet Wrap
12	56850	Recessed Stainless Steel Handle
13	91717	Water Filter Assembly
16	91178	3C Pump, 230/240 VAC
18	91166	Pump Housing Assembly
19	51444	Inlet Pump Fitting (3/4" elbow)
20	55050	(4) Rubber Feet
21	06442	Cabinet Base
22	51577	Outlet Pump Elbow Fitting
23	06443	Back-Up Manifold Bracket
24	56538	Grounding Point Label
25	60201	(6) 8/32" S.S. Phillips Screws
26 (not shown)	03005	Water Return (top) Manifold
27b	78018	O/I Power Switch
28	06439	Left Side Panel
32	56910	Fill Reservoir Label (symbol)
33	91735	800 Watt Heater Assembly
34	51024	Reservoir Throat Grommet
36	91702	Water Level Sensor Assembly
37	49211	Strainer
39	52370	Reservoir Lid
40	57228	Operating Instruction Label (International)
41	39951	Power Supply Board
42	37028	Red LED
43	41002	Water Temperature Sensor
44	03004	Water Outlet (bottom) Manifold
45	39993	Microprocessor Board
46 (not shown)	53019	Power Inlet Shroud
47 (not shown)	06699	Beeper Board Bracket
48 (not shown)	39968	Beeper Board

Figure 9. Front View Parts List

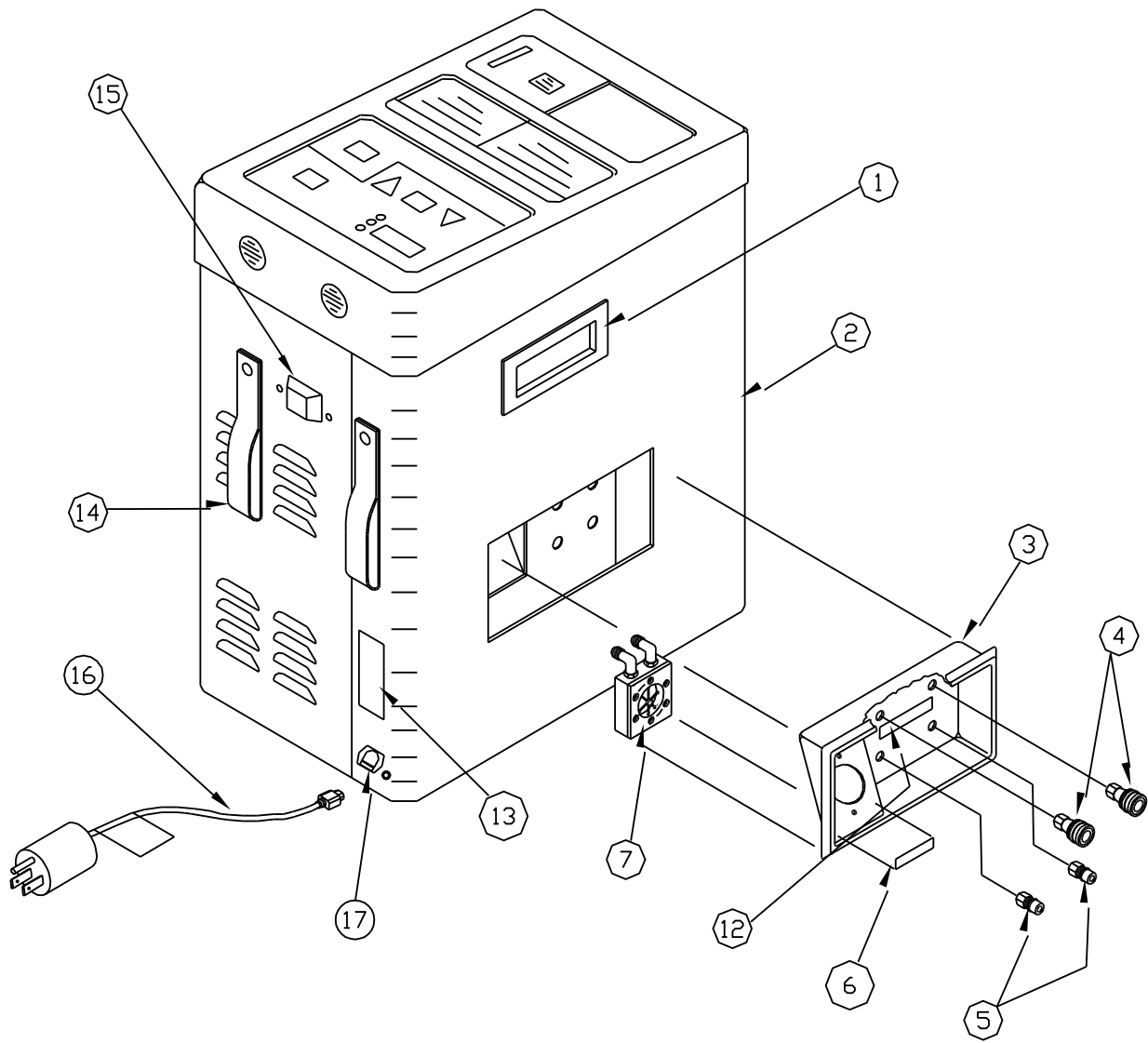


Figure 10. NORM-O-TEMP® Internal Exploded – Rear View

<u>Index #</u>	<u>I.D. #</u>	<u>Description</u>
1	56850	Recessed Stainless Steel Handle
2	06446	Left Side Panel
3	52307	Plastic Manifold Pan
4	07010	1/8" Quick-Disconnect Socket Coupling
5	06017	1/8" Quick-Disconnect Plug Coupling
6	56907	Flow Indicator Label (International)
7	91715	Water Flow Indicator Assembly
12	56908	Outlet and Return Label
13	56541	Specification Label
14	91200	Nylon Strap Assembly(s)
15	55051	Rubber Pole Mount
16	37029	Power Cord
17	35055	Power Inlet
18 (not shown)	37033	(2) 5 AMP, slo blo fuse

Figure 11. Rear View Parts List

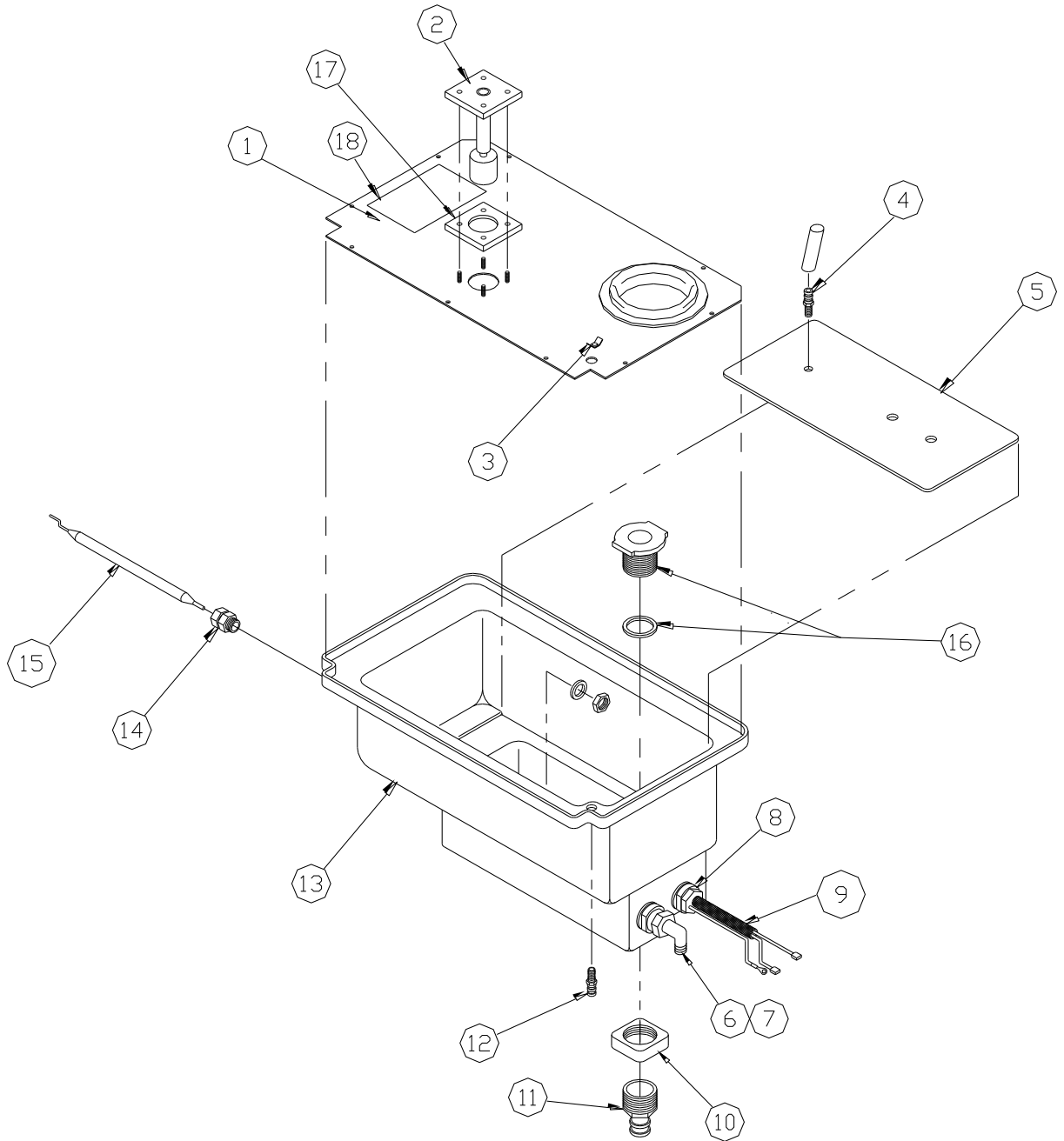


Figure 12. NORM-O-TEMP® Internal Exploded Reservoir Assembly

<u>Index #</u>	<u>I.D. #</u>	<u>Description</u>
1	06902	Reservoir Cover
2	91702	Low Water Switch Assembly
3	N/A	Grounding Terminal
4	50211	Plastic 1/4" Hose Barb
5	52371	Plastic Reservoir Divider
6	51014	Bulkhead Fitting, 3/8"
7	51060	Elbow, 1/2", Hose barb
8	51033	Bulkhead Fitting, 1/2"
9	91735	800 Watt Heater Assembly
10	51001	3/4" Tank Fitting
11	50315	Plastic 3/4" Hose Barb
12	50211	Plastic 1/4" Hose Barb
13	52377	Plastic Reservoir
14	09641	3/8 inch Compression Fitting
15	37025	Independent High Limit Safety Thermostat,
16	51001	3/4 inch Tank Fitting
17	51426	Gasket Float Switch
18	39951	Power Supply Board

Figure 13. Reservoir Assembly Parts List

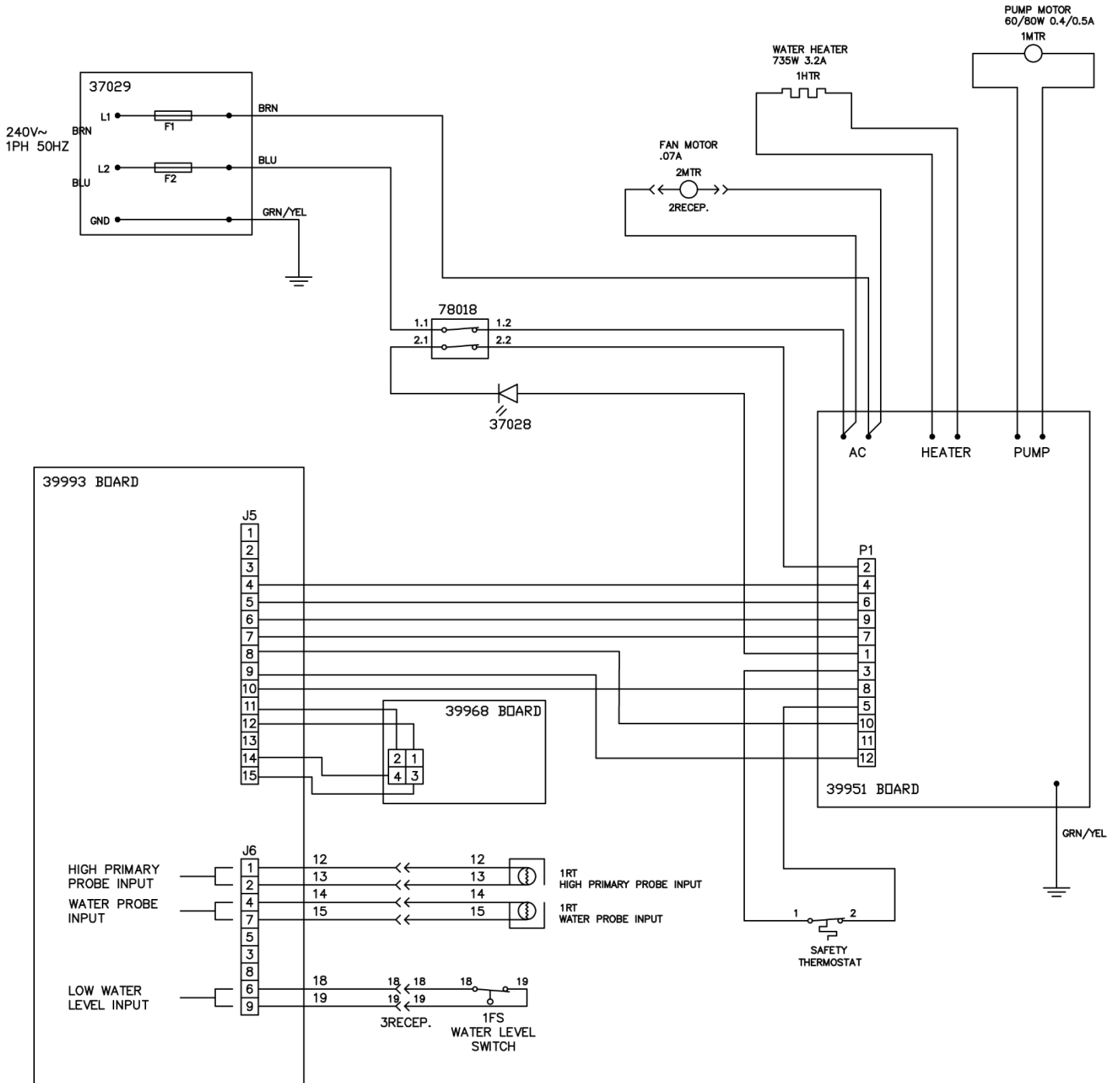


Figure 14. NORM-O-TEMP® Electrical Wiring Diagram

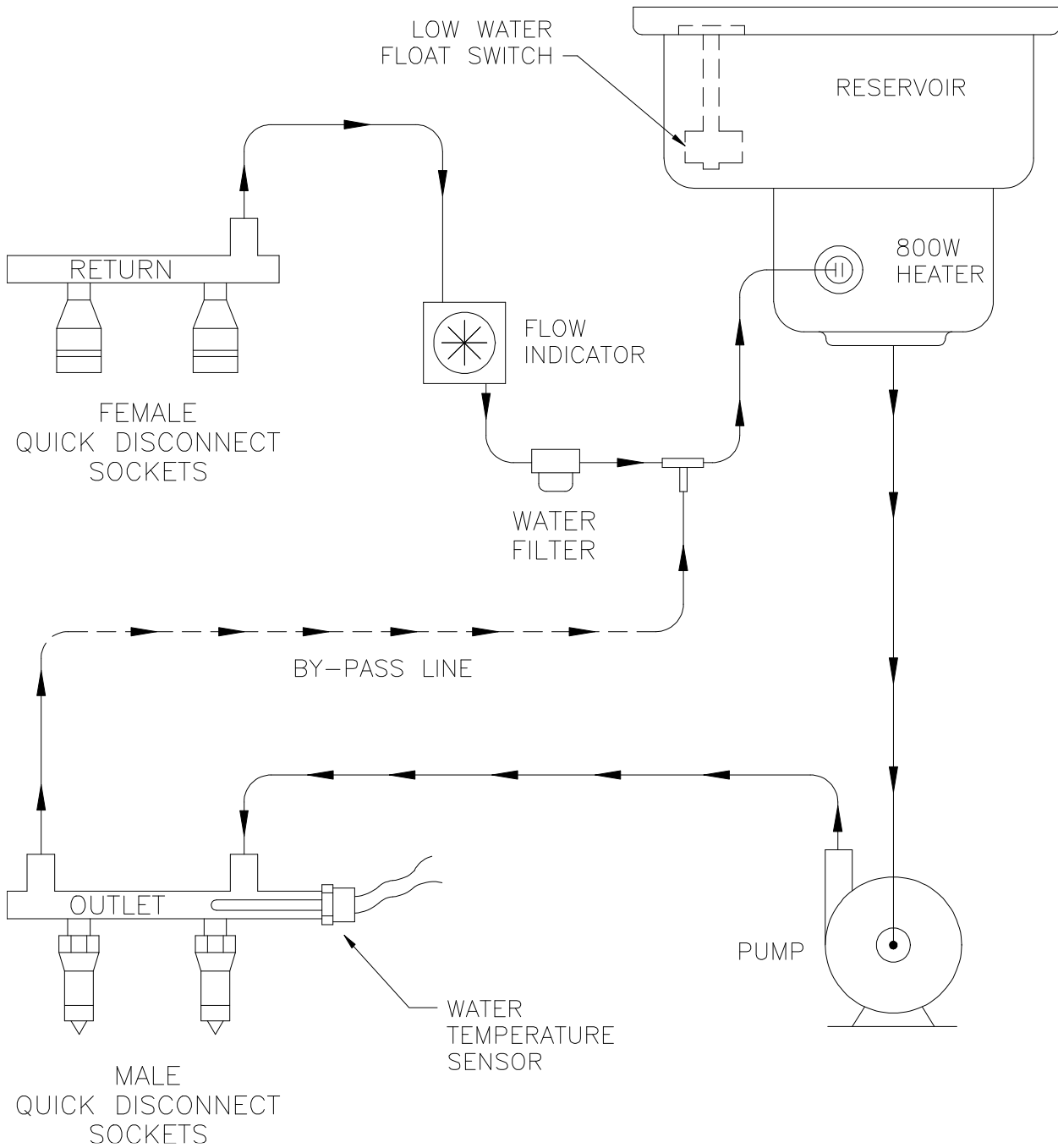


Figure 15. NORM-O-TEMP® Water Circulation Diagram

Accessories

Stands

118	Stand/IV Pole
119	Low Profile Stand

Blankets / Pads

MAXI-THERM Single-Patient Use Blankets/pads

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 Blanket/pad(s)

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

PLASTIPAD Reusable Molded Plastic Blanket/pad(s) (Polyurethane)

195N	Narrow Adult Size (20" x 60")
193CPC	Infant Size with CPC Connectors (12" x 18")

Gelli-Roll Reusable Blanket/pad(s)

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

Figure 16. NORM-O-TEMP® System Accessories

The following tables are presented in fulfillment of the requirements of IEC 60601-1-2


Guidance and manufacturer's declaration – electromagnetic emissions		
The NORM-O-TEMP®, Model 111W is intended for use in the electromagnetic environment specified below. The customer or the user of the NORM-O-TEMP®, Model 111W should assure that it is used in such an environment.		
Emissions tests	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The NORM-O-TEMP®, Model 111W uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The NORM-O-TEMP®, Model 111W is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
The NORM-O-TEMP®, Model 111W is intended for use in the electromagnetic environment specified below. The customer or the user of the NORM-O-TEMP®, Model 111W should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the NORM-O-TEMP®, Model 111W requires continued operation during power mains interruptions, it is recommended that the NORM-O-TEMP®, Model 111W be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note: U_T is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer’s declaration – electromagnetic immunity

The NORM-O-TEMP®, Model 111W is intended for use in the electromagnetic environment specified below. The customer or the user of the NORM-O-TEMP®, Model 111W should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	<p>Portable and mobile RF communications equipment should be used no closer to any part of the Norm-O-Temp, Model 111W, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = 1,2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 1,2\sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = 2,3\sqrt{P} \quad 800 \text{ MHz to } 2,5 \text{ GHz}$ <p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicated theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measure field strength in the location in which the NORM-O-TEMP®, Model 111W is used exceeds the applicable RF compliance level above, the NORM-O-TEMP®, Model 111W should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the NORM-O-TEMP®, Model 111W.

^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the NORM-O-TEMP®, Model 111W			
The NORM-O-TEMP®, Model 111W is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the NORM-O-TEMP®, Model 111W can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the NORM-O-TEMP®, Model 111W as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1,2\sqrt{P}$	80 MHz to 800 MHz $d = 1,2\sqrt{P}$	800 MHz to 2,5 GHz $d = 2,3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

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