

NORM-O-TEMP[®]

Operation Manual

Model 111W Hyperthermia System



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

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Manual 57127 Rev. W

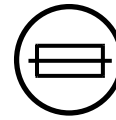
SYMBOLS



Caution: Read Operation Instructions and Manual Before Operating



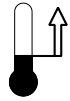
Temperature Set



Fuse



Water Temperature



Increasing Temperature



Silence Alarm



Temp. Set Point Indicator



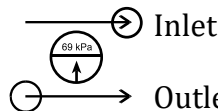
Decreasing Temperature



Fill to Strainer



Water Flow Indicator



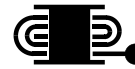
Heat



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



Disconnect Power Before Servicing



Power Cord Holder



On / Off



AC Voltage



Danger; Risk of Electric Shock



Type BF Equipment



Separate collection for electrical and electronic equipment



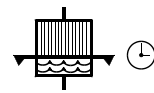
Protective Earth (Ground)



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. **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.
- **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.
- Do not use the NORM-O-TEMP® system in the presence of flammable anesthetics. **Risk of explosion can result.**
- Power interruption will cause the NORM-O-TEMP® unit 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 located in the Operation/Technical Manual to resume operation. **Failure to resume therapy could result in serious injury or death.**
- 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® unit 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® unit to patient use after repairs, the FIRST TIME SET-UP/SYSTEM TEST ROUTINE in the Operation/Technical Manual 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® unit 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"> Means to maintain contact between the patient and the blanket during therapy may be required and should not block the fluid pathways of the blanket or connecting hose. Failure to do so may result in inadequate treatment.
<ul style="list-style-type: none"> Blanket punctures can result in an increased risk of infection or electrical shock. Inspect all blankets for mechanical damage before use. Do not use in proximity to sharp objects.
<ul style="list-style-type: none"> Use of materials of good thermal conductivity, such as water, gel, and similar substances, with the NORM-O-TEMP® system not switched ON may decrease the temperature of the patient. The area between the patient and the blanket should be kept dry to avoid injury to patient.
<ul style="list-style-type: none"> Use only hospital grade plug or electric shock may result.

CAUTION	
•	Federal law restricts this device to sale by or on the order of a licensed healthcare professional.
•	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® system 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) practices should be followed during replacement of any electronic board.
•	To Discharge the NORM-O-TEMP® system, 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 (U.S)	1-800-989-7373
12011 Mosteller Road	Fax	1-513-772-9119
Cincinnati, OH 45241	(U.S.) 24hr Clinical Support	1-513-460-2038

EU Authorized Representative:

EC REP

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

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. Reference the Operation/Technical manual for service instructions.

NORM-O-TEMP® System Operating Instructions “Quick Start” Guide

Read Operation Manual before using this device

First Time Use Cleaning:

Refer to Section 4-2 for cleaning instructions.

Initial Operation:

1. Fill reservoir with sterile water or water that has been passed through a filter less than or equal to 0.22 microns
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. Allow gravity to drain the water back into the unit from the blanket/pad.

Alarm Conditions:

- If an alarm sounds, check indicator lights or display for problem and take corrective action.
- Alarm may be silenced temporarily for five minute 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, 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. All personnel who operate or service the unit should be familiar with all parts of this manual.

Physical characteristics are described in Section 1-3.

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 nursing 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.

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 the Operation/Technical Manual.
- 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 a 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.

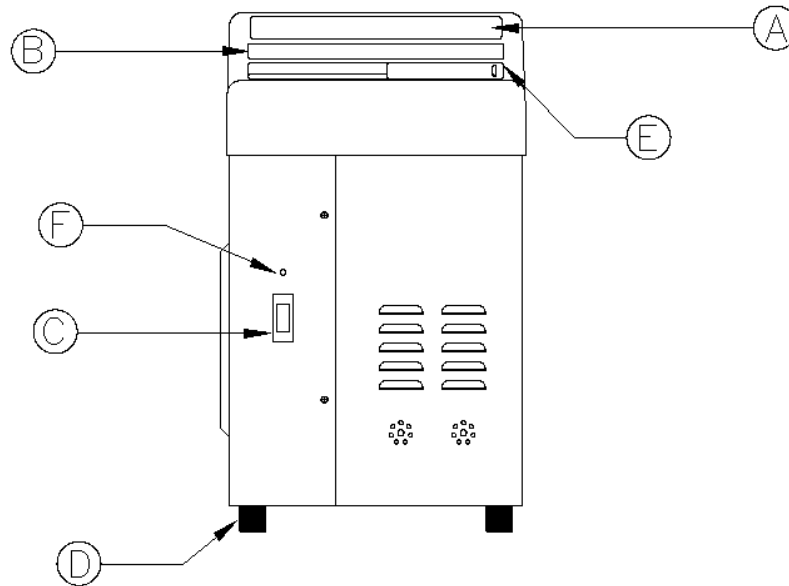


Figure 1. NORM-O-TEMP® unit, Front View

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.

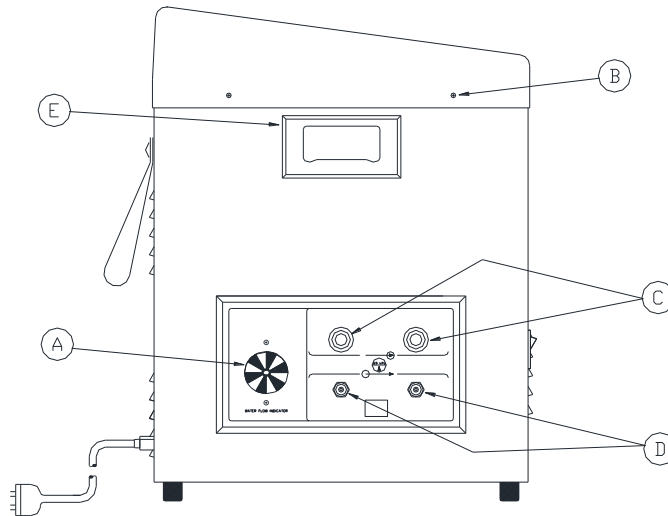


Figure 2. NORM-O-TEMP® unit, Left Side View

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 2-0.
- F. Ground Lug

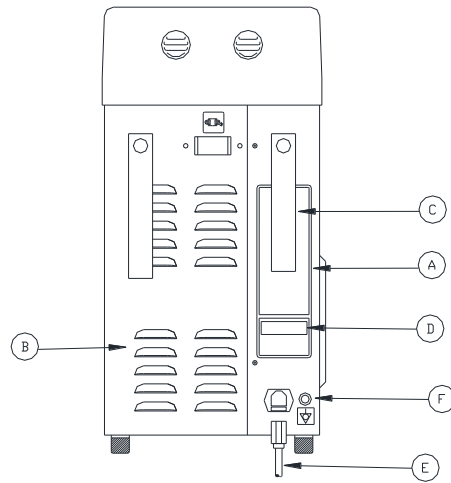


Figure 3. NORM-O-TEMP® unit, Rear View

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.

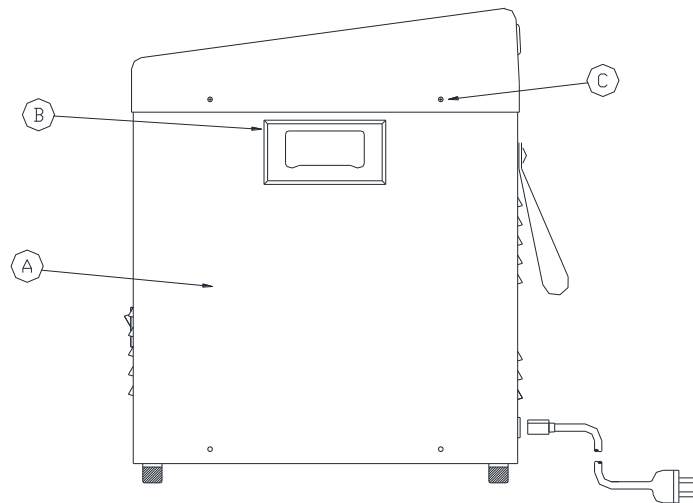


Figure 4. NORM-O-TEMP® unit, Right Side View

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 $46^{\circ}\text{C} \pm 0.6^{\circ}\text{C}$. 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.
- 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
- J. Fill Spout

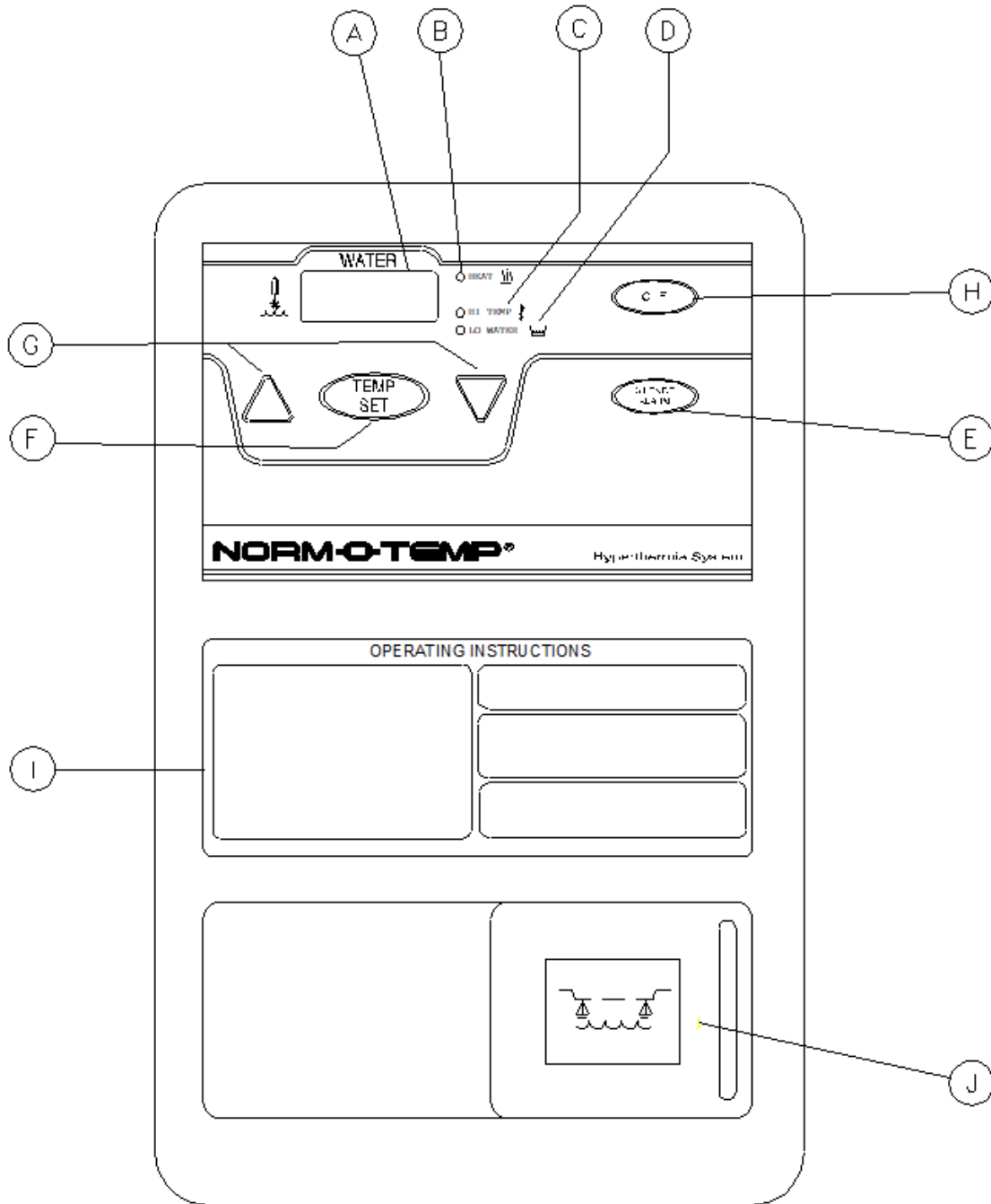


Figure 5. NORM-O-TEMP® unit, Model 111W Top View.

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 the Operation/Technical Manual.

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

Section 2. Specifications and Certifications

Specifications for the NORM-O-TEMP® unit 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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<p style="text-align: center;"><u>Electrical System</u></p> <p>Electrical Characteristics: 230V, 50Hz, 4.8 Amps 240V, 50Hz, 4.6 Amps</p> <p>Heater Power: 800 watts</p> <p>Time to Heat: 23°C ± 2°C to 37°C in approximately 7 minutes at ambient temperature.</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 style="text-align: center;"><u>Safety System</u></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 style="text-align: center;"><u>Environmental Conditions</u> (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 style="text-align: center;"><u>Warranty</u></p> <p>1 year parts. Parts and labor if returned to factory. Additional Warranty Available</p>
<p>UL Electrical Classification Equipment is Class I. Equipment is Type BF.</p> <div style="display: flex; justify-content: center; align-items: center; gap: 20px;">  <div style="border: 1px solid black; padding: 5px;">IP22</div> </div>	
<p>CERTIFICATIONS</p> <div style="display: flex; justify-content: space-between; align-items: center;"> <div style="text-align: center;">  </div> <div> <p>Medical Electrical Equipment In Accordance With: UL 60601-1 2nd Ed. IEC 60601-1-2 3rd Ed. IEC 60601-1-6 3rd Ed. ASTM F-2196-2</p> </div> <div style="text-align: center;">  </div> </div>	

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

2-0. 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 the beginning of the manual for a complete list of warnings and cautions related to the NORM-O-TEMP® system.*

2-1. Patient Preparation and Bedside Care

Effective use of the NORM-O-TEMP® hyperthermia 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.

2-2. 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 any time, 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.

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 4-1.
- 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 the pump and turn off heater. In addition, the HI TEMP LED flashes and the audible 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 the pump and the heater. In addition, the HI TEMP LED illuminates and the audible 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 3. Operating the NORM-O-TEMP® System

3-0. 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.

3-1. 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 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.

- 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-hypo thermia 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 hyper-hypo thermia blanket/pad.
- O. If a top hyper-hypo thermia blanket/pad is to be used, cover with a dry sheet
- P. Connect the blanket/pad 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.
- Q. If no top hyper-hypo thermia 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 2-1.

NOTE: *If at any time, 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.*

3-2. 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® system 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.

3-3. 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 the Operation/Technical Manual.

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 4. General Maintenance of the NORM-O-TEMP® System

4-0. Introduction

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. See the Operation/Technical Manual for maintenance procedures that should be performed quarterly. Dispose of the NORM-O-TEMP® unit per hospital protocol.

4-1. Replenishing the Reservoir / Fixing a Low Water Alarm

- A. Check that the drain hose is disconnected.
- 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.

4-2. Maintenance of the NORM-O-TEMP® unit Exterior – Cleaning Instructions

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 nursing personnel or by other trained persons.

The following actions are considered maintenance:

1. Inspecting, cleaning, and disinfecting the exterior
2. Replacing hoses
3. Cleaning hoses, blankets
4. 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

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 are cleaned quarterly as well.

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	<p>$d = 1,2\sqrt{P}$ 80 MHz to 800 MHz</p> <p>$d = 2,3\sqrt{P}$ 800 MHz to 2,5 GHz</p> <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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