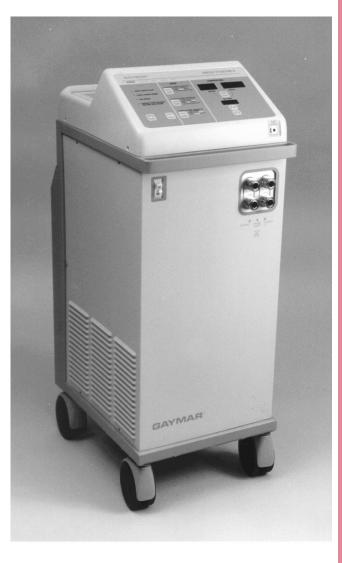
Medi-Therm[™] II Hyper/Hypothermia Machine MTA5900 Series

Manual Mode Automatic Mode Monitor Mode





LISTED 303L



STANDARD [NORME] C22.2 No. 125 RISK CLASS [CATEGORIE DE RISQUES] NO. 2G



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Important

U. S. Federal law restricts this device to sale by or on the order of a physician.

Read and understand this Medi-Therm II Operating Manual and all Safety Precautions (see section 1.0, page 1 and section 8.0, pp. 14-15) prior to using the Medi-Therm II Hyper/Hypothermia Machine.

Receiving Inspection

Refer to the Medi-Therm II Service Manual for Receiving Inspection and Check-out Procedures.

If you have any questions, contact Gaymar's Technical Service Department for assistance.

Telephone:

Toll free	800 828-734
Direct	(716) 662-2551

Fax:

Toll free	I 800 993-7890
Direct	(716) 662-0748

1.0 Safety Precautions

Read and understand this operating manual and all precautions listed below prior to using the Medi-Therm II Hyper/Hypothermia Machine.

A DANGER

Do not use the Medi-Therm II machine in the presence of flammable anesthetics. **Risk of explosion can result.**

▲ WARNING

- If the patient's temperature is not responding or does not reach the prescribed temperature in the prescribed time or deviates from the prescribed temperature range, notify the attending physician promptly. Failure to notify the physician promptly may result in serious injury or death.
- Power interruption will cause the Medi-Therm II machine to go into a standby mode, resulting in no therapy to the patient. Follow instructions for desired mode to resume operation. Failure to resume therapy could result in serious injury or death.
- When performing the *PROBE CHECK* (p. 18, 10.1.2, item 4), use a protective sheath on the probe. Failure to use a sheath could result in cross-contamination.
- A physician's order is required for setting blanket temperature and for continued use of equipment. At least every 20 minutes or as directed by a physician, check patient's temperature and skin condition of areas in contact with blanket; also, check blanket water temperature. Pediatric, temperature-sensitive, and operating room patients should be checked more frequently.
 Failure to monitor patient may result in skin damage or inappropriate patient temperature.
- Avoid placing additional heat sources between the patient and blanket. **Skin damage may result.**
- Prevent excessive and/or prolonged tissue pressure and shearing forces, especially over boney prominences. **Skin damage may result.**

A WARNING

- Keep the area between the patient and the blanket dry. **Excessive moisture may result in skin damage.**
- Do not tip machine over without first draining the water out and unplugging the power cord.
 Damage to the machine or electrical shock can result.
- Repairs should be performed by qualified personnel such as certified biomedical electronics technicians or certified clinical engineers familiar with repair practices for servicing medical devices, and in accordance with the *Medi-Therm II Service Manual*. Do not attempt repairs to Gaymar medical equipment unless you possess these skills.
 Damage to the machine or malfunction may otherwise result.

A CAUTION

- Fill with distilled water only. Failure to use distilled water may result in poor machine performance. Do not use alcohol. Alcohol may accelerate blanket deterioration. Do not operate without water, since damage to internal components may result. Do not overfill. Overfilling may result in overflow because the water in the blanket drains back into the machine when the machine is turned off.
- Place a dry absorbent sheet between the patient and the blanket when using all-vinyl blankets.
 Moisture may accumulate which may result in skin damage.

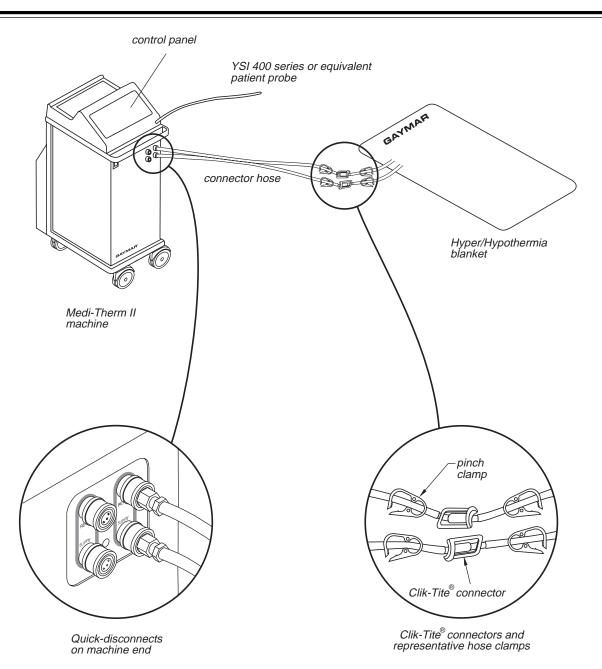


Figure 1—Medi-Therm II Hyper/Hypothermia System

2.0 Description

This manual describes the operation of the Medi-Therm II Hyper/Hypothermia machine.

The Medi-Therm II Hyper/Hypothermia machine provides a means of regulating patient temperature by supplying temperature-controlled water through a connector hose to a Gaymar Hyper/Hypothermia blanket. The companion blanket provides the interface for heating or cooling the patient. A patient probe senses patient temperature. The Medi-Therm II machine, Hyper/Hypothermia blanket, connector hose, and patient probe comprise the Medi-Therm II system (fig. 1).

Please read and understand the precautions on page I and the following operating instructions before attempting to use the Medi-Therm II system. In addition, we recommend you request in-service training from your Gaymar representative.

3.0 Features

Please familiarize yourself with the location and purpose of the features (fig. 2) before reading the start-up procedures or attempting to operate the Medi-Therm II Machine.

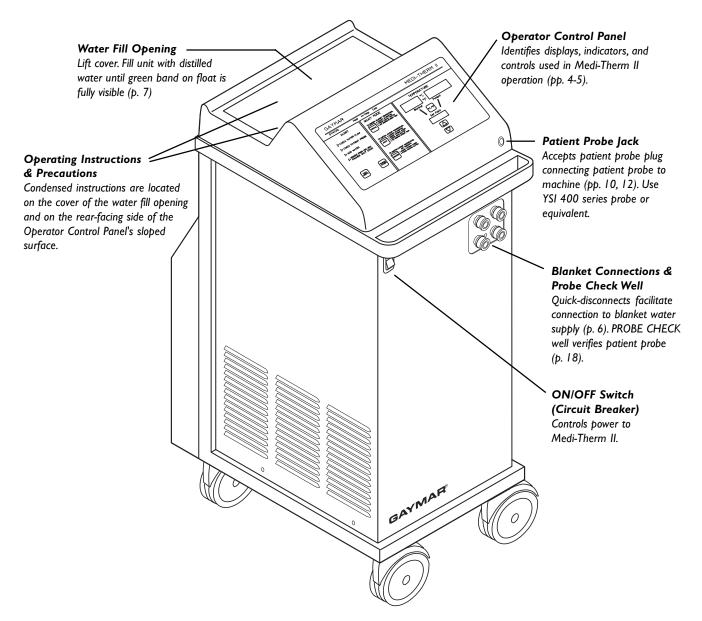


Figure 2—Medi-Therm II features

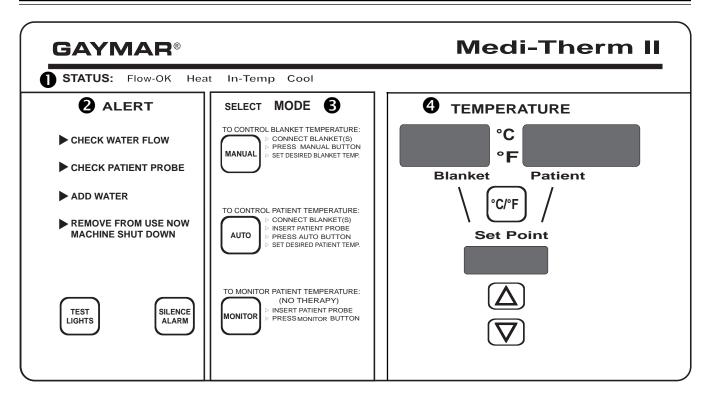


Figure 3-Medi-Therm II Control Panel

4.0 Operator Control Panel

The control panel is divided into sections according to function and use. The principal panel sections are identified in figure 3.

STATUS SECTION

STATUS displays light to indicate both the machine's flow status and how the blanket water temperature is being controlled to reach the desired temperature setting. STATUS displays function in both MANUAL and AUTO modes.

FLOW-OK indicates blanket water is flowing adequately.

HEAT indicates blanket water is being heated. The maximum blanket temperature is:

- MTA5900 41°C (105.8°F)
- MTA5901 41°C (105.8°F)
- MTA5942 42°C (107.6°F)

IN-TEMP indicates the Medi-Therm II is controlling temperature at the desired setting.

COOL indicates blanket water is being cooled. Minimum blanket temperature is $4^{\circ}C$ (39.2°F).

2 ALERT SECTION

ALERT indicators light when some form of operator action is required. In addition to the visual indicator, an audible alarm may sound. ALERT controls allow the Medi-Therm II operator to test panel lights or to silence the audible alarm.

CHECK WATER FLOW indicates the flow of water to the blanket has been restricted.

CHECK PATIENT PROBE indicates the patient probe is sensing an abnormal patient temperature (below 32°C [89.6°F] or above 45°C [113°F]). It may indicate the patient probe has become dislodged, an incorrect probe is being used, or a probe has become defective. An audible alarm accompanies this alert.

ADD WATER indicates the water reservoir is filled to less than the recommended level.

REMOVE FROM USE NOW / MACHINE

SHUTDOWN indicates the Medi-Therm II has shut down due to blanket water temperature exceeding either the high or the low limit. An audible alarm accompanies this alert. **Remove the Medi-Therm II machine from use immediately.** **TEST LIGHTS** confirms that all indicator lights and digital displays are working, and that the audible alarm is functioning. The displays flash and the audible alarm sounds as long as the *TEST LIGHTS* button is pressed.

SILENCE ALARM temporarily silences the audible alarm. The alarm will reactivate in approximately 5 minutes if the condition persists.

NOTE: The SILENCE ALARM button will **not** function if the REMOVE FROM USE NOW / MACHINE SHUTDOWN indicator is lit.

B MODE SECTION

The SELECT indicator lights when a choice of operating modes is required. MODE buttons select the desired operating mode. Patient therapy is provided in either MANUAL or AUTO mode. A third mode, MONITOR, may be used to monitor patient temperature without providing therapy. After the mode button is pressed, the indicator at the top of the mode button lights.

MANUAL selects the manual mode of operation. In *MANUAL* mode, the operator must observe patient temperature and adjust the blanket water set point temperature to obtain the desired results.

AUTO selects the automatic mode of operation. In AUTOMATIC mode, the operator sets the desired temperature and the patient temperature is automatically regulated to the operator specified set point.

MONITOR selects the monitor mode of operation. In *MONITOR* mode, the operator may monitor patient temperature without providing therapy.

4 TEMPERATURE SECTION

TEMPERATURE displays identify BLANKET, PATIENT, and SET POINT temperatures. Temperature may be set and displayed in either degrees Celsius (°C) or Fahrenheit (°F). *

BLANKET indicates the actual temperature of the water being delivered to the blanket. This display is illuminated when MODE is set to either MANUAL or AUTO.

PATIENT indicates actual patient temperature as sensed by the probe connected to the patient probe jack. This display is illuminated when MODE is set to MANUAL, AUTO, or MONITOR and a patient probe is plugged into the PATIENT PROBE jack.

SET POINT indicates the desired SET POINT temperature. When operating in MANUAL mode, pressing the SET POINT button (" ∇ " or " Δ ") sets the desired BLANKET water temperature. When in AUTO mode, pressing the SET POINT button sets the desired patient temperature.

°C/°F displays the temperature in either degrees Celsius (°C) or Fahrenheit (°F). Pressing the °C/°F button will display the corresponding indicator.*

* Some models do not have the $^{\circ}C/^{\circ}F$ feature.

Medi-Therm II

5.0 Start-up Procedure

For your convenience, condensed versions of the following instructions have been permanently mounted on the cover of the water fill opening and on the rearfacing side of the Operator Control Panel's sloped surface.

Perform the following start-up procedure each time the Medi-Therm II system is placed in operation:

5.1 Close Pinch Clamps

Pinch clamps are provided on both the connector and blanket hoses to prevent water spillage when blankets are changed (fig. 4).

Close the pinch clamps on the connector hose and Hyper/Hypothermia blanket.

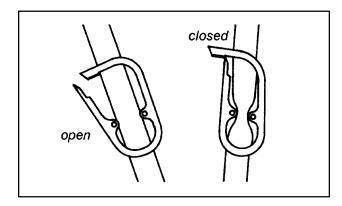


Figure 4—Pinch Clamps

5.2 Attach Blanket

Attach the Hyper/Hypothermia blanket to the Medi-Therm II machine (fig. 1):

Connect a Gaymar Model DBK9 connector hose to a. the Medi-Therm II machine. The hose is ten feet long. It has quick-disconnect (metal) fittings for the Medi-Therm II machine end and Clik-Tite® (plastic) connectors for the blanket end.

To connect the hose, attach one quick-disconnect fitting to the RETURN machine connection (top) and one to the SUPPLY (bottom). See figure 5. To insure a tight connection, push the retaining collar toward the cabinet and insert the quick-disconnect fitting firmly. While holding the fitting, allow the retaining

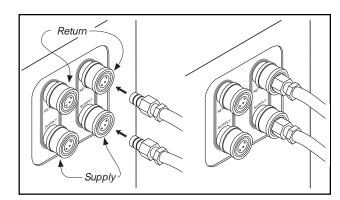


Figure 5—Quick-disconnects

collar to snap back into position. Check to make sure the fitting is fully engaged by tugging firmly on the hose fitting.

b. Attach the two Clik-Tite connectors (fig. 6) on the connector hose to the blanket. Insert the male fitting into the female. When fittings are fully seated, snap the locking ring into place to assure a positive lock.

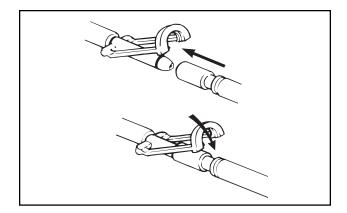


Figure 6—Clik-Tite Connector

5.3 Open All Pinch Clamps

Open all pinch clamps on the connector hose and the Hyper/Hypothermia blanket.

Failure to open the pinch clamps will prevent water flow and will trigger the CHECK WATER FLOW alert.

5.4 Check Water Level

Check to make sure water is at the proper level by raising the cover on the water fill opening. Fill with distilled water until the green band on the float is fully visible (fig. 7).

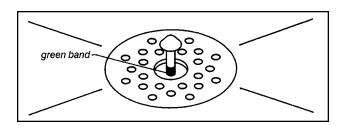


Figure 7—Float, showing proper water level

▲ CAUTION

- Add distilled water only. Failure to use distilled water may result in poor machine performance.
- **Do not use alcohol**, which may accelerate blanket deterioration.
- **Do not operate without water**, since damage to internal components may result.
- **Do not overfill.** Overfilling may result in overflow because the water in the blanket drains back into the machine when the machine is turned off.

5.5 Connect Power/Turn Machine On

If the machine is not already plugged in, insert the power cord plug into a properly grounded AC receptacle at this time. Press the ON/OFF Switch to the ON position.

When first turned on, the Medi-Therm II enters its standby mode:

- the ON/OFF switch will light;
- the machine will beep once;
- the SELECT heading will light;
- the BLANKET, PATIENT, and SET POINT temperature displays will show dashes; and
- the "°C" or "°F" indicator will light, depending on the scale last selected. *
- NOTE: If the ADD WATER indicator lights, add distilled water until the green band on the float is visible.

5.6 Perform Indicator Light Test

Since machine indicators are essential to proper machine operation, you should test the indicator lights each time the machine is placed in operation. Perform this test by pressing and holding the TEST LIGHTS button.

While holding the TEST LIGHTS button down, verify the following occurs:

- the right and left halves of the display panel light alternately;
- the four status legends (FLOW-OK, HEAT, IN-TEMP, and COOL) light;
- the ALERT legend and its four (triangular) indicators light;
- the three mode legends and SELECT heading light;
- the three temperature displays (BLANKET, PATIENT, and SET POINT) indicate 888, 888.8, and 888.8, respectively;
- the two temperature control legends ("°C" and "°F") * and the two lines connecting SET POINT to both the BLANKET and PATIENT display light;
- the audible alarm sounds.

If any indicator does not light, or the alarm does not sound, **remove the machine from use**.

This completes the start-up procedures for the Medi-Therm II machine. Please proceed to sections 7.0 through 7.3 for the operating instructions for MANUAL, AUTO and MONITOR modes.

6.0 Shutdown Procedure

When therapy is completed, turn off the Medi-Therm II machine. Close pinch clamps before disconnecting the blanket.

 * Some models do not have the $^\circ\text{C}/^\circ\text{F}$ feature.

7.0 Modes of Operation

Read and understand the contents of these Operating Instructions and associated precautions before using the Medi-Therm II machine. Any application of the Hyper/ Hypothermia System must be under the direction of the attending physician.

▲ WARNING

 If the patient's temperature is not responding or does not reach the prescribed temperature in the prescribed time or deviates from the prescribed temperature range, notify the attending physician promptly.

Failure to notify the physician promptly may result in serious injury or death.

• Power interruption will cause the Medi-Therm II machine to go into a standby mode (see item 5.5, p. 7), resulting in no therapy to the patient. Follow instructions for desired mode to resume operation.

Failure to resume therapy could result in serious injury or death.

The Medi-Therm II machine is designed to operate in three (3) modes:

- MANUAL (blanket temperature control),
- AUTO (automatic patient temperature control), and
- MONITOR (patient temperature monitoring).

Some applications may require a second blanket in order to achieve additional or more rapid heating or cooling. For these situations, a second blanket may be connected to the machine. The rate of patient heating or cooling may also be increased by positioning half- and full-size blankets so that greater body surface is in contact with the blankets.

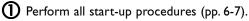
NOTE: When connecting a second blanket to the Medi-Therm II machine, check the water level (see *Start-up Procedure*, pp. 6-7) **prior** to connecting the additional blanket.

7.1 Manual Mode (To Control Patient Temperature)

When operating in the MANUAL mode, the Medi-Therm II machine regulates the BLANKET water temperature to the selected SET POINT. A temperature sensor within the machine monitors water temperature, and the machine heats or cools the blanket water as required to bring it to the SET POINT temperature.

In MANUAL mode, the operator must observe the patient's temperature and manually adjust the blanket temperature to obtain the desired results.

To operate in MANUAL mode:



Press the MANUAL mode button. The upper window on the MANUAL button will light.

The BLANKET display will indicate blanket water temperature. The SET POINT display will indicate the default temperature (32°C [89.6°F]) at startup, until selecting the SET POINT temperature in step 4 below.

- If desired, change the temperature scale by pressing the "°C/°F" button. *
- Adjust the SET POINT display to the prescribed blanket temperature setting by pressing the " ∇ " or " Δ " button to decrease or increase the SET POINT.

The STATUS display will indicate HEAT or COOL while the machine is heating or cooling the blanket water. When the blanket temperature stabilizes (within $1^{\circ}C$ [1.8°F] of the SET POINT temperature), the IN-TEMP indicator will light indicating that the desired blanket water temperature is being maintained.

NOTE: When the Medi-Therm II machine is turned on, the machine set point defaults to 32°C (89.6°F) when MANUAL mode is selected, or 37°C (98.6°F) when AUTO mode is selected.

> Once a SET POINT temperature for a mode has been selected, it is retained for that mode until the SET POINT temperature is changed or the machine has been turned off. The SET POINT temperature in one mode does not affect the SET POINT temperature in another mode.

 \ast Some models do not have the °C/°F feature.

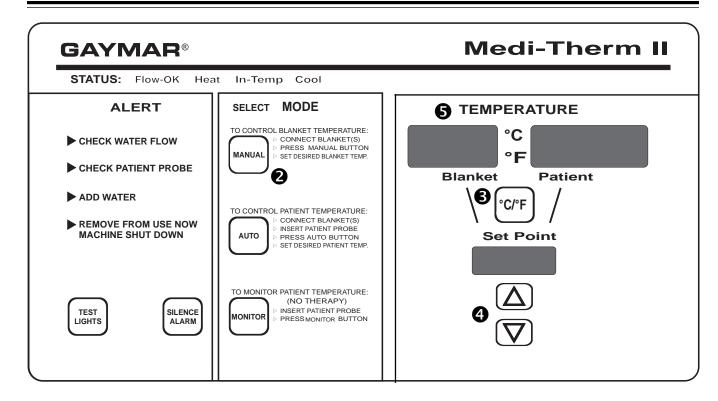


Figure 8—Manual Mode

20 minutes or as dir

At least every 20 minutes, or as directed by a physician, check the patient's temperature and skin condition of areas in contact with blanket; also check *BLANKET WATER* temperature display.

6

WARNING

Failure to monitor patient may result in skin damage or inappropriate patient temperature.

NOTE: While operating in the *MANUAL* mode, the patient probe may be used to monitor the patient's temperature.

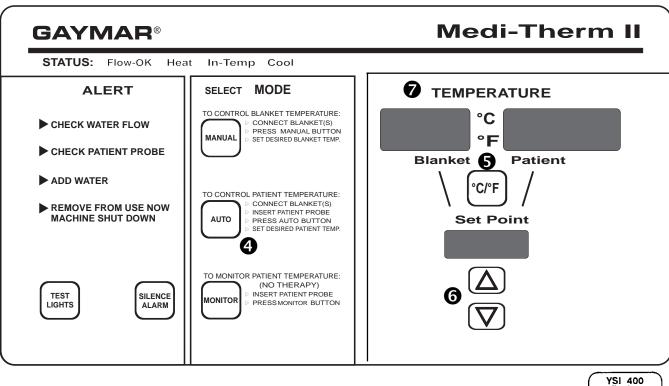
To use this Medi-Therm II feature, insert sensing end of patient probe into patient and tape

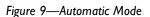
securely to prevent accidental dislodgment. Insert plug end of patient probe into PATIENT PROBE jack. Make sure probe plug is fully seated. The MANUAL mode switch must be pressed.

Use YSI 400 Series Probes or equivalent. If in doubt that the correct probe is being used and is operating properly, perform a *PROBE CHECK* test (p. 18, 10.1.2, item 4).

Patient temperature will be indicated on the *PATIENT* temperature display.

If the patient probe senses an abnormal patient temperature (below 32°C [89.6°F] or above 45°C [113°F]), the CHECK PATIENT PROBE alert will light and an audible alarm will sound. This condition may indicate the patient probe has become dislodged, an incorrect probe is being used, or the probe has become defective (see Alerts, pp. 18-19).







7.2 Automatic Mode (To Control Patient Temperature)

When operating in the AUTO mode, the Medi-Therm II automatically regulates the patient's temperature to the selected SET POINT. The machine constantly compares actual patient temperature with the SET POINT value, and automatically adjusts the BLANKET water temperature so that the desired patient temperature is achieved.

To operate in AUTO mode:

- () Perform all start-up procedures (pp. 6-7).
- (2) Insert sensing end of patient probe into patient and tape securely to prevent accidental dislodgment.

B Insert plug end of patient probe into PATIENT PROBE jack.

NOTE: Make sure probe plug is fully seated. Use YSI 400 series probes or equivalent. If in doubt that the correct probe is being used and is operating properly, perform a PROBE CHECK test (p. 18, 10.1.2, item 4).



4 Press the AUTO mode button. The upper window on the AUTO button will light.

NOTE: To prevent accidental triggering of the CHECK PATIENT PROBE alert, place probe in patient and wait five (5) minutes before pressing AUTO mode button.

The BLANKET display will indicate blanket water temperature. The PATIENT display will indicate patient temperature. The SET POINT temperature will indicate the default temperature (37°C [98.6°F]) at start-up, until selecting the SET POINT temperature in step 6 (p. 11).

5 If desired, change the temperature scale by pressing the "°C/°F" button. *

* Some models do not have the °C/°F feature.

7

- 6 Adjust the SET POINT display to the prescribed patient temperature setting by pressing the " ∇ " or " Δ " button to decrease or increase the SET POINT.
 - NOTE: When the Medi-Therm II machine is turned on, the machine set point defaults to 32°C (89.6°F) when MANUAL mode is selected or 37°C (98.6°F) when AUTO mode is selected.

Once a SET POINT temperature for a mode has been selected, it is retained for that mode until the SET POINT temperature is changed or the machine has been turned off. The SET POINT temperature in one mode does not affect the SET POINT temperature in another mode.

▲ WARNING

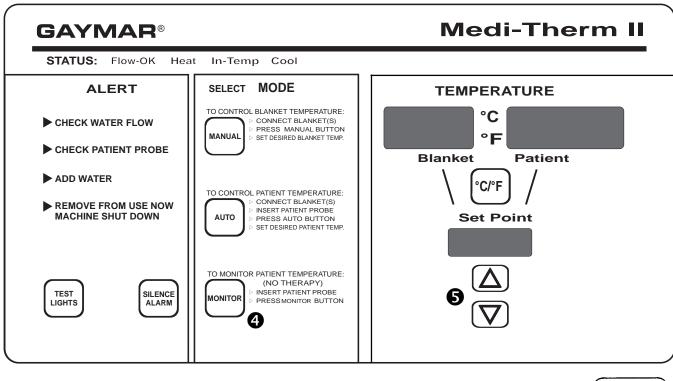
• At least every 20 minutes, or as directed by a physician, check the patient's temperature and skin condition of areas in contact with blanket; also check BLANKET WATER temperature display.

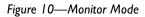
Failure to monitor patient may result in skin damage or inappropriate patient temperature.

 If the patient probe senses an abnormal patient temperature (below 32°C [89.6°F] or above 45°C [113°F]), therapy will stop, the CHECK PATIENT PROBE alert will light and an audible alarm will sound.

This condition may indicate the patient probe has become dislodged, an incorrect probe is being used, or the probe has become defective (see *Alerts*, pp. 18-19).

NOTE: The PATIENT temperature display will flash when the patient's temperature is more than 1°C (1.8°F) from the SET POINT temperature. Such flashing occurs **only** in the AUTO mode.







7.3 Monitor Mode (Patient Temperature Monitoring,

No Therapy)

Press MONITOR mode when no patient temperature therapy is required, but monitoring of patient temperature is desired.

To operate in MONITOR mode:

- Perform steps 5.4, 5.5, and 5.6 of the Start-up Procedure (pp. 6-7).
- (2) Insert sensing end of patient probe into patient and tape securely to prevent accidental dislodgment.
- B Insert plug end of patient probe into the PATIENT PROBE jack.

Make sure probe plug is fully seated. Use YSI 400 Series Probes or equivalent.

If in doubt that the correct probe is being used and is operating properly, perform a PROBE CHECK test (p. 18, 10.1.2, item 4).

4 Press the *MONITOR* mode button. The upper window on the MONITOR button will light. The patient's temperature will be displayed.



5 If desired, change the temperature scale by pressing the "°C/°F" button. *

NOTE: If the patient probe senses an abnormal patient temperature (below 32°C [89.6°F] or above 45°C [113°F]), the CHECK PATIENT PROBE alert will light and sound an audible alarm.

> This condition may indicate the patient probe has become dislodged, an incorrect probe is being used, or a probe has become defective (see Alerts, рр. 18-19).

REMEMBER ... in MONITOR mode, **no therapy** is provided.

* Some models do not have the °C/°F feature.

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8.0 Patient Safety

Use the Medi-Therm II Hyper/Hypothermia machine only under the direction of a physician.

Review the following precautions and procedures prior to each application:

A DANGER

Do not use the Medi-Therm II machine in the presence of flammable anesthetics.

Risk of explosion can result.

A WARNING

 If the patient's temperature is not responding or does not reach the prescribed temperature in the prescribed time or deviates from the prescribed temperature range, notify the attending physician promptly.

Failure to notify the physician promptly may result in serious injury or death.

• Power interruption will cause the Medi-Therm II machine to go into a standby mode, resulting in no therapy to the patient. Follow instructions for desired mode to resume operation.

Failure to resume therapy could result in serious injury or death.

• The Medi-Therm II machine is provided with a means of checking rectal/esophageal temperature probes. When performing the *PROBE CHECK* (p. 18, 10.1.2, item 4), use a disposable protective sheath on the probe.

Failure to use sheath could result in cross-contamination.

(continued next column)

A WARNING

• A physician's order is required for setting blanket temperature and for continued use of equipment. At least every 20 minutes, or as directed by a physician, check patient's temperature and skin condition of areas in contact with blanket; also, check blanket water temperature. Pediatric, temperature-sensitive and operating room patients should be checked more frequently.

Failure to monitor patient may result in skin damage or inappropriate patient temperature.

PEDIATRICS - The temperatures of infants and children are more responsive to surface heating and cooling than adults. The smaller the patient, the more pronounced the effect because of their higher ratio of skin contact area to body mass.

TEMPERATURE-SENSITIVE PATIENTS -Patients with impaired peripheral blood circulation caused by vascular diseases and patients who are incapacitated may be more sensitive to temperature changes than patients with more normal circulation.

OPERATING ROOM PATIENTS - Patients with poor circulation associated with inadequate heart function, reduction in blood volume, and constriction of peripheral blood vessels may deviate from the normal response to the external application of heat and cold.

• Avoid placing additional heat sources between the patient and blanket.

Skin damage can result.

Heat applied by the blanket can result in a rise in skin temperature at the areas of contact. The additional heat rise due to electrosurgical currents flowing to the dispersive electrode could be sufficient to cause tissue injury. Each thermal effect by itself may be completely safe, but the additive effect may be injurious.¹ Keep additional heat sources from between the patient and the blanket.

(continued next page)

A WARNING

• Prevent excessive and/or prolonged tissue pressure and shearing forces, especially over boney prominences.

Skin damage may result.

Localized skin injury due to tissue compressed between boney prominences and fluid filled channels has occurred during prolonged cardiovascular procedures at blanket temperatures well below the scientifically established epidermal burn injury threshold.²

Local ischemia can follow the application of pressures exceeding capillary pressure resulting in tissue necrosis. This local effect may be enhanced by generalized impairment of the circulation, local shearing forces and increased metabolic demand because of temperature elevation. Pathological changes may begin in two (2) hours.

• Keep the area between the patient and the blanket dry.

Excessive moisture may result in skin damage.

The application of heating or cooling may affect the toxicity of solutions. Prep solutions have been reported to injure the skin when allowed to remain between patients and water circulating heating blankets during prolonged procedures.³

▲ CAUTION

• Place a dry absorbent sheet between the patient and the blanket when using all-vinyl blankets.

Moisture may accumulate which may result in skin damage.

A dry absorbent sheet placed between the patient and the Hyper/Hypothermia Blanket will provide a sanitary barrier and absorb perspiration. It will also promote more uniform distribution of heat. Vinyl blankets with nonwoven fabric surfaces do not require an absorbent sheet when using the nonwoven side.

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9.0 Care of Medi-Therm II

As with any precision equipment, proper care and maintenance will insure proper performance and reliability. The following routine maintenance procedures will help insure dependable Medi-Therm II operation.

9.1 Machine Care

A WARNING

Do not tip machine over without first draining the water out and unplugging the power cord.

Damage to the machine or electrical shock can result.

▲ CAUTION

- Add distilled water only.
- Failure to use distilled water may result in poor machine performance.
- **Do not** use alcohol. Alcohol may accelerate blanket deterioration. Alcohol is flammable.
- **Do not** operate without water, since damage to internal components may result.
- **Do not** overfill. Overfilling may result in overflow because the water in the blanket drains back into the machine when the machine is turned off.
- When filling an empty Medi-Therm II machine, add a small amount of germicidal or sanitizer solution to the water (MTA33 liquid, or equivalent). Carefully follow manufacturer's recommended concentration to prevent algae growth within the Medi-Therm II system and Hyper/Hypothermia blanket.

Do not use too much concentrate, since it will result in "foaming," which can reduce the blanket efficiency and may damage the circulating pump.

• **Do not** use bleach. Bleach will damage the heating element, which could result in excessive leakage.

NOTE:

- The Medi-Therm II control panel and top surfaces can be cleaned with a soft cloth lightly dampened with isopropyl alcohol.
- Clean up any accidental spills immediately—use a cloth lightly dampened with isopropyl alcohol.
- You may check for clarity of fluid by viewing water flowing through clear vinyl blanket.

9.2 Blanket Care

- Allow the blanket to remain connected to the Medi-Therm II machine for about 10 minutes after the machine has been turned off. This will allow most of the water to drain back into the machine.
- Standard blankets should be cleaned with a damp cloth and mild detergent. If blankets must be sterilized, use any cold sterilization means, except alcohol. Exposure to harsh chemicals will cause blankets to lose flexibility and reduce their resistance to cracking.
- When storing standard blankets, they should be rolled loosely. (Do not allow to freeze.) Single-patient use blankets should be discarded after use.
- Standard blankets can often be repaired using a vinyl patch kit. Do not return blankets to factory for repair.

9.3 Probe Care

- Do not autoclave. If probe must be sterilized, use any cold sterilization means except alcohol, which may accelerate probe deterioration. Always wipe dry.
- Reusable probes may be cleaned with a damp cloth and mild detergent. Always wipe dry.
 Exposure to harsh chemicals will cause probe to lose flexibility and resistance to cracking.
- Disposable probes should be discarded after use.

9.4 Probe Check Well Care

The PROBE CHECK WELL should be cleaned with a small tubular brush and detergent, and then wiped with a commercial disinfectant.

▲ DANGER

When performing the PROBE CHECK, use a protective sheath on the probe. (Becton-Dickinson catalog 3700 oral sheath or equivalent.

Failure to use a sheath could result in cross-contamination.

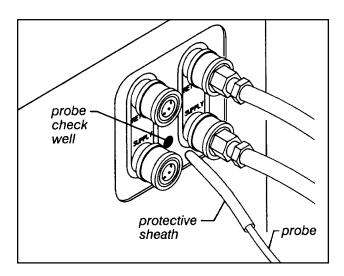


Figure 11—Probe Check Well

9.5 Quick Disconnects

The quick-disconnects joining the connector hose to the machine may become difficult to engage. This problem can be eliminated by applying a silicone base or light machine oil to the outside of the male connector prior to engagement.

9.6 Draining Machine

It is not necessary to drain the Medi-Therm II machine after each use. However, periodic draining is recommended at least once a month.

To lower the water level, close both pinch clamps on the connector hose. Place the end with both Clik-Tite connectors into a sink or pail. Open the pinch clamp. Press the ON/OFF switch to ON and press MANUAL mode button. The machine will pump the water reservoir empty. Press ON/OFF button to OFF when CHECK WATER FLOW lights. After the water is pumped out, do not leave the machine on or it may overheat.

Preventive maintenance and service procedures are described in the *Medi-Therm II Service Manual*. These procedures should be performed by qualified personnel such as certified biomedical electronics technicians or certified clinical engineers.

10.0 Alerts/ Troubleshooting

Most Medi-Therm II operating problems are minor and can be corrected by the operator. The following are alerts and troubleshooting details.

A WARNING

Repairs should be performed by qualified personnel such as certified biomedical electronics technicians or certified clinical engineers familiar with repair practices for servicing medical devices, in accordance with the *Medi-Therm II Service Manual*. **Do not** attempt repairs to the Medi-Therm II machine unless you possess these skills.

Damage to the machine, malfunction, or electrical shock may otherwise result.

10.1 Alerts

The Medi-Therm II machine has both visual and audible alert indicators to help you identify machine or operator caused problems. An explanation of these signals and their probable causes follow. Perform corrective action in the sequence listed.

10.1.1 Check Water Flow

Circulation of water through the blanket has been restricted. Air bubbles in the blanket may remain stationary although water is flowing; a few bubbles do not adversely affect operation of the blanket.

To locate and correct the source of low flow:

- Check that hoses are fully inserted and seated into one RETURN (top) and one SUPPLY (bottom) connector on the machine. (See Start-up Procedure, p. 6.)
- 2. Check that all pinch clamps are fully open.
- Check that hoses are not kinked or pinched off. Make sure blanket is flat and not creased. If a blanket is used with patient in sitting position, flow may be pinched off.
- 4. Confirm that water supply is at proper level.
- Turn off machine. Close all pinch clamps. Disconnect blanket from connector hose. Direct connector hoses into water fill opening, start machine, and select MANUAL or AUTO mode. Open connector pinch clamps. If there is still no flow, turn machine off and remove from use.

10.1.2 Check Patient Probe

Indicates that the patient probe is sensing below $32^{\circ}C$ (89.6°F) or above $45^{\circ}C$ (113°F), and is not a normal patient temperature.

A WARNING

If CHECK PATIENT PROBE light comes on, therapy will stop (in AUTO mode only), status lights will go out, and no additional heating or cooling will occur until the problem is corrected.

- 1. CHECK PATIENT PROBE audible alarm can be silenced for five minutes while diagnosing problem by pressing SILENCE ALARM.
- CHECK PATIENT PROBE alert may sound if machine is placed in MANUAL, AUTO, or MONITOR mode before patient probe has been inserted in patient, since probe will be sensing room temperature. Place probe in patient and wait five (5) minutes before pressing MANUAL, AUTO, or MONITOR mode button.
- 3. Check probe to make sure it has not become dislodged from patient. Reinsert and tape securely if required. Wait five (5) minutes before pressing AUTO mode button.
- 4. Perform **PROBE CHECK:**
 - a. Insert probe into protective sheath and then into PROBE CHECK WELL on front of machine base (fig. 11).

A WARNING

When performing the PROBE CHECK, use a protective sheath on the probe.

Failure to use a sheath could result in cross-contamination.

b. Operate machine in MANUAL mode with a blanket connected. Adjust SET POINT temperature to between 33°C (91.4°F) and 37°C (98.6°F). Wait until machine temperature stabilizes (IN-TEMP lights and patient temperature display stabilizes). Blanket and patient temperature displays should read within 2°C (3.6°F) of each

other. If not, patient probe may be defective or incorrect probe is being used.

Use only YSI 400 Series probes or equivalent.

c. If probe appears defective, try another probe and repeat *PROBE CHECK*. If a new, correct probe does not meet this test, remove machine from use and notify your medical equipment repair department.

10.1.3 Add Water

Check to make sure water is at the proper level by raising the cover on the water fill opening. If green band on float is not visible, fill with distilled water until the green band is visible (fig. 7). If green band on float is visible, do not add water—remove machine from use and notify your medical equipment repair department.

▲ CAUTION

- Add distilled water only. Failure to use distilled water may result in poor machine performance.
- **Do not** use alcohol. Alcohol may accelerate blanket deterioration.
- **Do not** operate without water. Damage to internal components may result.
- **Do not** overfill. Overfilling may result in overflow because the water in the blanket drains back into the machine when the machine is turned off.

10.1.4 Remove From Use Now Machine Shutdown

This alert indicates that the machine has shut down due to the blanket water temperature exceeding the high or low limit, or if a system error is detected. **Remove machine from use immediately.** Notify your medical equipment repair department.

10.2 Troubleshooting

10.2.1 Blanket Will Not Heat

- Check that water is circulating through the blanket. If there is no circulation, the CHECK WATER FLOW alert should light. If CHECK WATER FLOW is lit, refer to Alerts section (pp. 18-19) for corrective measures. Do not fold blankets.
- Check that the temperature control is operating by pressing the MANUAL mode button and then adjusting the SET POINT temperature to at least 2°C (3.6°F) above the indicated blanket temperature. This should cause the HEAT indicator to light.

10.2.2 Blanket Will Not Cool

- Check to see if water is circulating through the blanket. If there is no circulation to the blanket, the CHECK WATER FLOW alert should light. If CHECK WATER FLOW is lit, refer to Alerts section (pp. 18-19) for corrective measures. Do not fold blankets.
- 2. Check that rear and side air vents are not blocked. Inlet and exhaust grills should be kept clear and clean to allow air to circulate freely.
- Check that the temperature control is operating by changing the SET POINT temperature to at least 2°C (3.6°F) below the indicated blanket temperature. This should cause the COOL indicator to light.

10.2.3 Machine Will Not Turn On

- I. Make sure the power cord is plugged in.
- 2. Reset the ON/OFF switch (circuit breaker) by turning it first off, then on.
- 3. If the machine still does not turn on, remove machine from service and notify your medical equipment repair department.

10.2.4 On/Off Switch Is Turned On, But Control Panel Is Dark And No Operating Sound Is Coming From Machine

Remove machine from use and notify your medical equipment repair department.

11.0 Blankets/Accessories

Adult and pediatric size blankets are available in all vinyl or vinyl with nonwoven fabric surfaces.

SINGLE PATIENT USE BLANKETS, PLASTIC WITH NONWOVEN FABRIC

- DHP810 O.R. Table and General Use
- DHP812 Pediatric General Use
- DHP813 Adult General Use

SINGLE PATIENT USE BLANKETS, ALL VINYL

DHP901	Adult General Use
DHP902	Pediatric General Use
DHP903	Adult General Use (Narrow)

SINGLE PATIENT USE BLANKETS, ALL VINYL WITH NONWOVEN FABRIC

DHP911	Adult General Use
DHP912	Pediatric General Use

REUSABLE BLANKETS, HEAVY DUTY VINYL

HP7020 Pediatric General Use

All blankets require reusable DBK9 connector hoses.

ACCESSORIES

DBK9	10 foot Connector Hose
HBX8	10 foot Hose Extension
PATIOI	Adult Reusable Probe (YSI 400 series)
PAT102	Pediatric Reusable Probe (YSI 400 series)
DP400	Disposable Probe, Adult and Pediatric (YSI 400 series)
ADP10	Reusable Probe Adaptor
MTA33	Germicide/Algaecide

12.0 Customer Training

In-service training is recommended and can be arranged through your Gaymar Representative. Comprehensive repair and maintenance training is also available through Gaymar Technical Services (for telephone numbers, see back cover).

13.0 Warranty

The Medi-Therm II Hyper/Hypothermia machine is warranted free of defects in material and workmanship for a period of two (2) years under the terms and conditions of the Gaymar warranty in place at the time of purchase. The compressor portion of the machine carries a five (5) year prorated warranty. Contact Gaymar Technical Service if you have questions about warranty or repair.

www.gaymar.com P/N 10464-vvv 11/30



GAYMAR INDUSTRIES, INC.

10 Centre Drive Orchard Park, NY 14127-2295

Phone: 1 800 828-7341 (716) 662-2551

FAX: 1 800 993-7890 (716) 662-0748