

Medi-Temp II™

FW400 Blood/Fluid Warmer

FW401 Blood/Fluid Warmer

REF FW403 Blood/Fluid Warmer

Réchauffeur de sang/liquide REF FW403

Riscaldatore per sangue/fluidi REF FW403

Recalentador de sangre y fluidos REF FW403

Aquecedor de Sangue/Líquidos REF FW403

REF FW403 Blut-/Flüssigkeitswärmer

REF FW403 Bloed-/vloeistofverwarmer

REF FW403 Varmeaggregat til blod/væske

REF FW403 Värmeaggregat för blod/vätska

REF FW403 Veren/nesteenlämmitin

REF FW403 Blod-/væskevarmer

Σύστημα Θέρμανσης Αίματος/Υγρών REF FW403

FRANÇAIS

ITALIANO

ESPAÑOL

PORTUGUÊS

DEUTSCH

NEDERLANDS

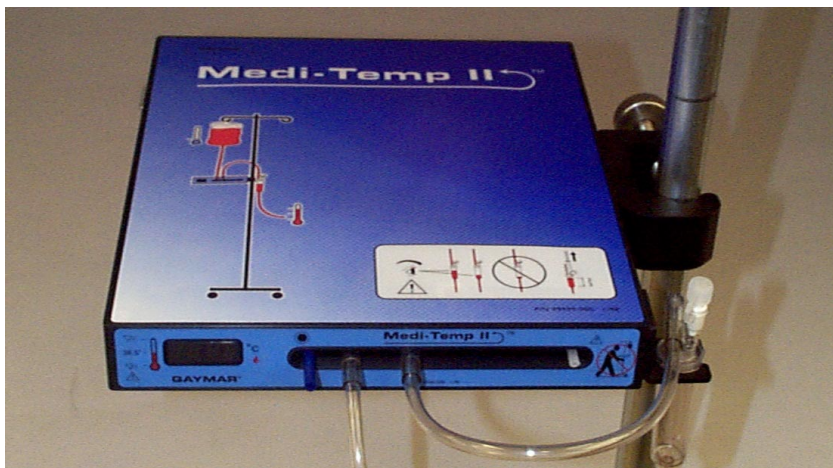
DANSK

SVENSKA

SUOMI

NORSK

ΕΛΛΗΝΙΚΑ



Operator's Manual

Manuel d'utilisation

Manuale per l'operatore

Manual del operador

Manual do Utilizador

Bedienungshandbuch

Bedieningshandboek

Operatørhåndbog

Operatörshandbok

Käyttäjän KäsiKirja

Brukerhåndbok

Εγχειρίδιο Χρήσης

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Before you begin. . .



Important

Before using the Medi-Temp II FW400/FW401/REF FW403 (FW400 Series) Blood/Fluid Warmer, please read and understand this *Operator's Manual* and the *SAFETY PRECAUTIONS* prior to each application.

If you have any questions, please contact your local dealer for assistance.

Warranty

The Medi-Temp II FW400 Series Blood/Fluid Warmer is warranted free of defects in material and workmanship for a period of one (1) year.

The Disposable Warming Sets are warranted free of defects in material and workmanship for a single application.

A copy of the warranty is available upon request. Gaymar disclaims all implied warranties including, but not limited to, the implied warranties of merchantability and of fitness for a particular purpose.

Operator's Manual

FW400 Series Blood/Fluid Warmer

1.0 Indications for Use

This device is intended to aid in the prevention of inadvertent hypothermia during administration of blood, blood products, and other fluids.



1.1 Safety Precautions

DANGER



Risk of electric shock. Refer servicing to qualified medical service personnel.

WARNING

- All air must be removed from the fluid lines prior to connection to the patient.
- Monitor the fluid lines to insure they are air free. Never administer fluids if there are air bubbles in the line between the bubble trap and the patient connector.
- Monitor the fluid level in the bubble trap frequently. Bubbles released during heating are captured in the trap. To refill the trap, insert a sterile syringe into the valve and draw air out until the trap is two-thirds (2/3) full. Do not allow the bubble trap to go below one-quarter (1/4) full. See figure 5, page 6.
- The bubble trap must be mounted and kept in a vertical position at all times.

Failure to follow the above warnings could result in the introduction of air to the patient. Introduction of air to the patient could result in death or serious injury.

WARNING

- Repairs should be performed only by qualified medical service personnel in accordance with this product's service manual. **Otherwise, damage to the Blood/Fluid Warmer and improper therapy may result.**

CAUTION

- U.S. Federal law restricts this device to sale by or on the order of a physician.
- Do not immerse in cleaning and/or sterilization solution. Do not submerge or soak unit; it is fluid-resistant, not fluid-proof.
- For grounding reliability of the Blood/Fluid Warmer, plug only into a properly grounded outlet.
- Do not attempt to transport the Blood/Fluid Warmer while mounted to an IV pole. It could tip over. Remove the Blood/Fluid Warmer for transport.

2.0 Product Description

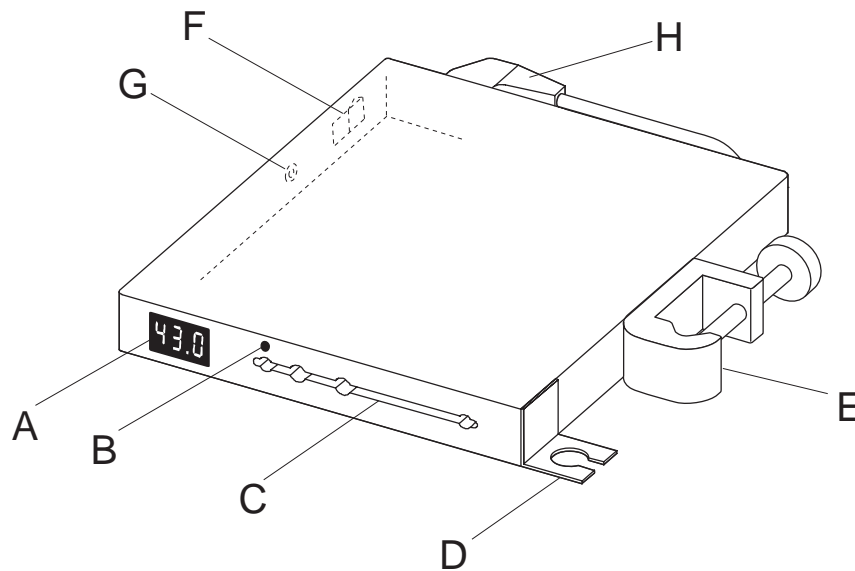
The Medi-Temp II FW400 Series Blood/Fluid Warmer is a simple, dry heat device designed for safe and rapid in-line warming of blood, blood products, and other fluids through the utilization of disposable Blood/Fluid Warming Sets.

The Warmer does not provide fluid flow rate control. Blood, blood products, and other fluids at temperatures 10°C and below will be warmed to temperatures between 36°C and 43°C at flow rates of 10 to 300 ml/min. Room temperature fluids (20°C) can be warmed at flow rates up to 500 ml/min. The disposable Blood/Fluid Warming Sets are available in Standard, Standard with Extensions, Pediatric, and High Flow models.

2.1 Warmer (see figure 1)

The Medi-Temp II FW400 Series Blood/Fluid Warmer is a sealed, fluid-resistant device. A lighted on/off circuit breaker is located on the side panel. An LED temperature display is located on the front panel. Fluid temperature is indicated in degrees Celsius on the display. Also located on the front of the unit is a slot for insertion of the Blood/Fluid Warming Set's flexible cassette. On the side of the unit is a holder for the bubble trap.

The Blood/Fluid Warmer can be placed in an X-Ray cassette slot within an operating room table or on horizontal surfaces. An integral pole clamp also allows the unit to be pole mounted.



A	LED Temperature Display	E	Pole Clamp
B	Blue Guide Rail Location Indicator	F	Lighted On/Off Circuit Breaker
C	Disposable Flexible Warming Cassette Slot	G	Test Switch Access Screw - Refer to Gaymar Medi-Temp II FW400 Series Blood/Fluid Warmer Service Manual
D	Bubble Trap Holder	H	Detachable Power Cord

Figure 1—Medi-Temp II FW400 Series Blood/Fluid Warmer

Operator's Manual

FW400 Series Blood/Fluid Warmer

2.2 Disposable Warming Sets (see figure 2)

The Medi-Temp II FW400 Series Blood/Fluid Warmer is designed to be used with Gaymar D25000 Series Blood/Fluid Warming Sets only. The following Blood/Fluid Warming Sets are available for use at this time. Check with your local dealer for more details.

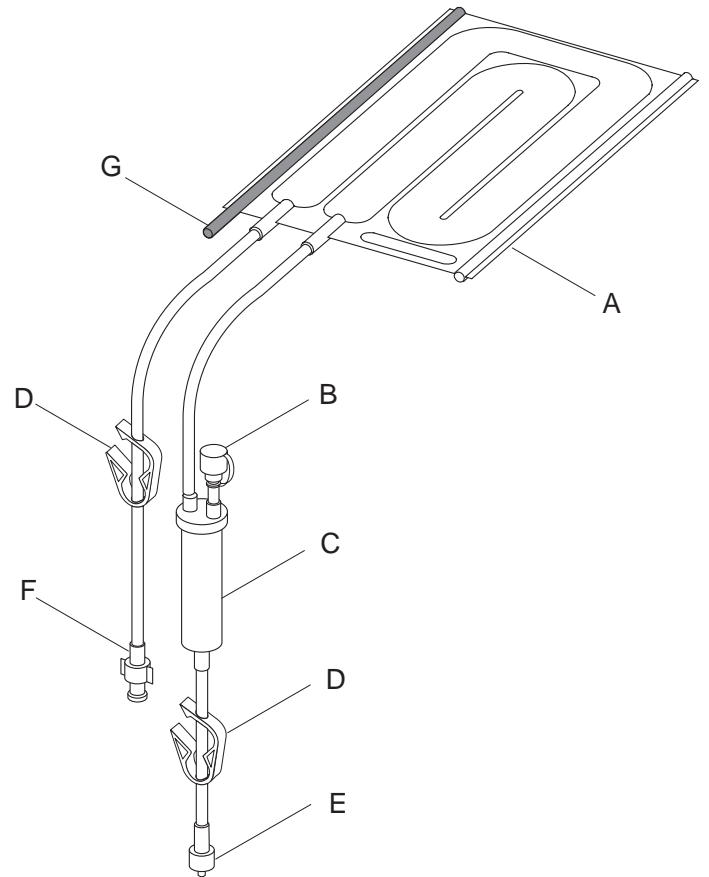
Each Warming Set consists of a flexible cassette (for insertion into the warmer) and a bubble trap with a manual air eliminator. They are designed for use below 300 mm Hg pressure with hospital standard intravenous (IV) administration sets and venipuncture sets utilizing luer type connectors. Each Warming Set also has input and output pinch clamps. See figure 2.

The Standard Warming Set is designed for use at 300 ml/min or lower flow rates. The Standard Warming Set with Extensions provides the user with added patient lead length. The priming volume of the Standard Warming Set is 39 ml. The priming volume of the Standard Warming Set with Extensions is 48 ml.

The Pediatric Warming Set has a lower priming volume of 30 ml. Its patient connection lead utilizes thicker walled tubing to provide added insulation at the lower pediatric warming flow rates.

The High Flow Warming Set uses leads having a larger inner diameter. This reduces restriction during circumstances requiring rapid infusion. The priming volume of the High Flow Warming Set is 79 ml.

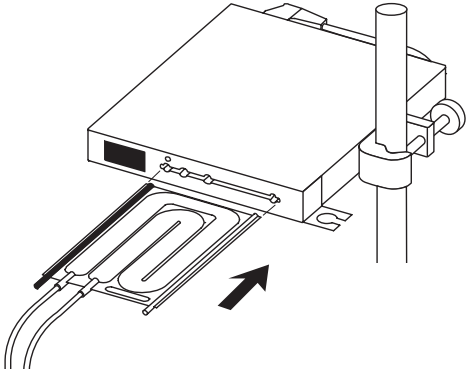
Description	Catalog No.
Standard	D25340CE
Standard with Extensions	D25310CE
Standard with Extensions (60")	D25315CE
Pediatric	D25320CE
High Flow	D25330CE



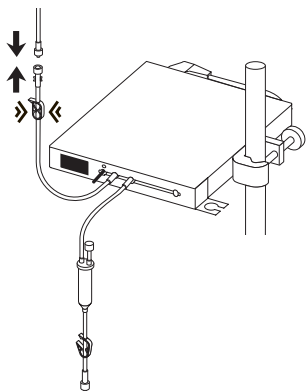
A	Flexible Cassette	E	Male Luer (to Patient)
B	Manual Air Eliminator (Relief Valve)	F	Female Luer (to Blood/Fluid Source)
C	Bubble Trap	G	Blue Guide Rail
D	Clamp		

Figure 2—Medi-Temp II FW400 Series Blood/Fluid Warmer—Standard Warming Set

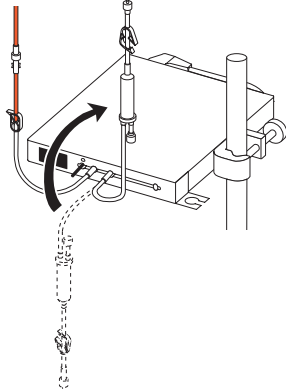
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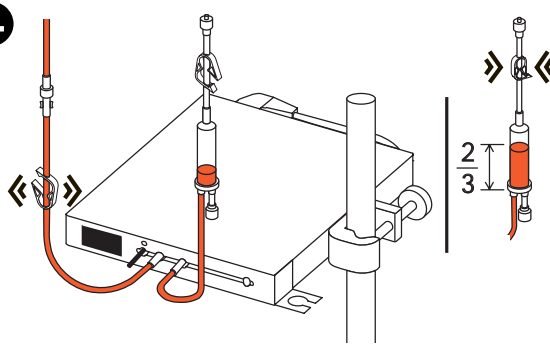
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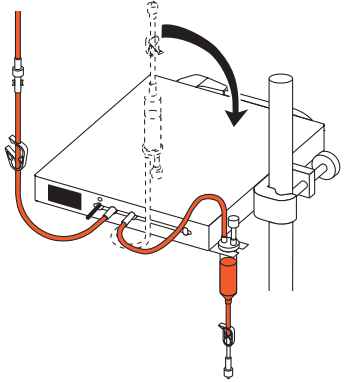
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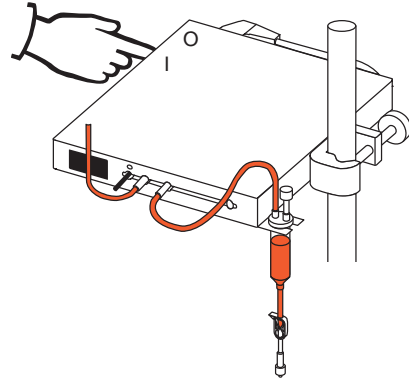
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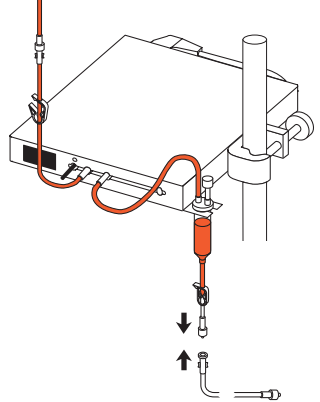
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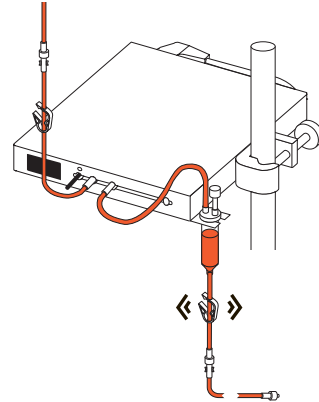



Figure 3—Instructions for Use—Setup



3.0 Instructions for Use—Setup

Select a site for placement of the Warmer. If the Warmer is attached to a pole, ensure the pole clamp is securely tightened.

CAUTION	
	Do not attempt to transport the Warmer while mounted to an IV pole. It could tip over. Remove the Warmer for transport.

Plug the power cord into a properly grounded electrical outlet.

NOTE: Do not turn unit on without first inserting a Warming Set. Doing so may activate the Over Temperature Safety Thermostats. Also, do not prime the Warming Set prior to inserting it into the Warmer.

Follow the instructions below (see corresponding illustrations numbered 1 through 8 on page 4).

NOTE: Warming Sets are designed for use below 300 mm Hg.

- 1 Remove the Warming Set from its sterile packaging.

WARNING
Do not use the contents of the package if any part of the contents is damaged, distorted or contaminated. Contents are sterile and non-pyrogenic in unopened, undamaged package.

NOTE: The flexible cassette is designed so it can be inserted into the Warmer in only one orientation (see figure 1, page 2). The blue guide rail on the cassette lines up with the blue guide rail indicator on the front of the Warmer.

Grasp each rail (see figure 4 below) with the blue guide rail in the left hand.

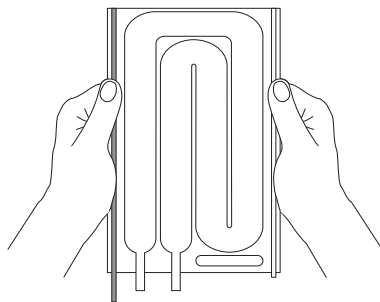


Figure 4—Grasp and stretch flexible cassette

Stretch the flexible cassette slightly and insert the front end into the front of the Warmer, aligning the rails to each edge of the slotted opening.

Move hands to the rail protrusions and continue to insert the cassette until the clear guide rail is flush with the front of the unit. (The blue guide rail will protrude slightly for easy removal.)

- 2 Close Warming Set input clamp. Remove the protector from the female luer of the Warming Set and connect it to the male luer on the IV administration set.

Remove the protector from the male luer of the Warming Set. To minimize temperature drop and priming volume, remove unnecessary lead extensions at this time.

- 3 Invert the bubble trap.
- 4 Open Warming Set input clamp. Allow fluid to prime the Set.

When the bubble trap fills to approximately two-thirds (2/3) full, close output clamp.

- 5 Re-invert the bubble trap and mount it in the bubble trap holder so it is in a vertical position.

WARNING
The bubble trap must be mounted and kept in the vertical position at all times. Failure to do so could result in the introduction of air to the patient. The introduction of air to the patient could result in death or serious injury.

- 6 Turn the on/off circuit breaker on. The Warmer will perform a two-second self-check before turning on the display.

- 7 If required, connect an extension for patient connection.

- 8 Purge air from remaining length of tubing by opening output clamp and allowing fluid to flow.

WARNING
Air must be removed from the fluid lines prior to connection to the patient. Failure to do so could result in the introduction of air to the patient. The introduction of air to the patient could result in death or serious injury.

3.1 During Use

WARNING

- Monitor the fluid lines to insure they are air free. Never administer fluids if there are air bubbles in the line between the bubble trap and the patient connector.
- Monitor the fluid level in the bubble trap frequently. Bubbles released during heating are captured in the trap. Do not allow the bubble trap to go below one-quarter (1/4) full. Air can be removed from the bubble trap by inserting a sterile syringe into the Manual Air Eliminator (see figure 2, page 3) and withdrawing air until the trap is two-thirds (2/3) full. See figure 5 below.

Failure to follow the above warnings could result in the introduction of air to the patient. Introduction of air to the patient could result in death or serious injury.

3.2 Warming Set Removal

The flexible cassette of the Warming Set cannot be removed from the Warmer when there is fluid within it.

1. Drain the Warming Set of fluid.
2. Remove bubble trap from holder.
3. Pull blue guide rail to remove flexible cassette from Warmer.
4. Dispose of Warming Set per hospital protocol.

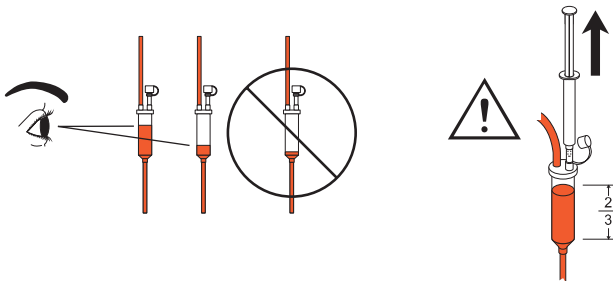


Figure 5—Monitoring Fluid Level

During normal operation the Warmer will indicate approximately 43.0°C on its display.

If the audible alarm sounds during operation, the Warmer may not be heating. Refer to section 4.0.



4.0 Safety Systems

4.1 Electronic System Self Check

Each time the Warmer is turned on, it performs a self-check (about 2 seconds) before lighting the display. If a problem is detected, an error code will be displayed and the Warmer must be removed from use.

4.2 Temperature Control



The Medi-Temp II FW400 Series Blood/Fluid Warmer noninvasively senses fluid temperature on the surface of the Warming Cassette. At steady state, the Warmer indicates approximately 43.0°C on its display. Output fluid temperature will be 36°C–43°C for 10°C input fluid temperature. Fluid temperature is affected by fluid flow rate as shown in figure 6 below.

Room temperature fluid may be warmed at flow rates up to 500 ml/min.

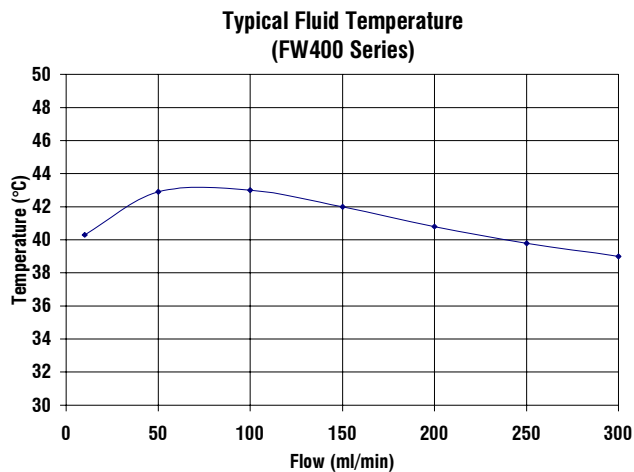


Figure 6 - Typical fluid temperature vs. flow values

4.3 Control Alarm—HI



If a fluid temperature over 45°C is sensed by the Warmer, it turns the heaters off and activates an audible alarm. The display will alternately indicate the word “HI” and the temperature.

The audible alarm may be silenced during this condition by turning the unit off then on again.

If the fluid temperature drops below 45°C, the unit will resume normal operation.

Refer to section 5.1, page 8.

4.4 Over Temperature Safety Thermostats



In the event of Warmer failure, there are two mechanical thermostats that will interrupt power to the heaters.

The first thermostat will turn off the heaters, activate the audible alarm and turn the display blank.

The second thermostat will interrupt power to the Warmer if the first one fails.

Cold fluid through the Warming Set can be used to reset the thermostats. The unit must be turned off, then back on to reset the alarm circuits.

Refer to section 5.1, page 8.

4.5 Control Alarm—LO



If the sensed fluid temperature drops below 34°C, the Warmer will activate an audible alarm, and the display will alternately indicate the word “LO” and the temperature.

Refer to section 5.1, page 8.

5.0 Troubleshooting and Maintenance

5.1 Troubleshooting and Servicing

Use the following checklist to identify and solve Warmer problems. If after following these guidelines, the problem persists, have unit serviced by a qualified medical service person in accordance with the *Medi-Temp II FW400 Series Blood/Fluid Warmer Service Manual* (contact your local dealer or Gaymar to obtain the *Service Manual*).

Situation	Solution
On/off circuit breaker is not lighted.	<ul style="list-style-type: none"> • Check if on/off circuit breaker is on. • Check if power cord is securely attached and plugged in. • Service required. Send unit for servicing.
Display indicates a flashing “hl”, and audible alarm is activated.	<p>OVER TEMPERATURE CONDITION</p> <ul style="list-style-type: none"> • An alarm may occur if the Warmer has been turned on prior to inserting a Warming Cassette. <ol style="list-style-type: none"> 1. Turn unit off. 2. Insert Warming Set and prime the Set. 3. Turn unit back on. • An alarm may occur if flow rate is stopped abruptly. <ol style="list-style-type: none"> 1. Silence the alarm by turning the on/off circuit breaker off then on again. 2. Restart flow of fluid to reduce sensor temperature. Proceed with use when the indicated sensor temperature is under 45°C. • If an alarm condition persists, remove from use. Send unit for servicing.
Display is off, on/off circuit breaker is lighted, and audible alarm is either on or off.	<p>OVER TEMPERATURE CONDITION</p> <ul style="list-style-type: none"> • Backup thermostats were activated. <ol style="list-style-type: none"> 1. Reduce flow rate. 2. Turn power off. 3. Run cold fluid through the Warming Set to reset the thermostat (with power off). 4. Turn power on. • If condition reoccurs, remove Warmer from use and send for servicing. If condition doesn't reoccur, it may have occurred due to excessively high flow rate with very cold fluid.
Display indicates a flashing “LO”, and audible alarm is activated.	<p>LOWER TEMPERATURE CONDITION</p> <ul style="list-style-type: none"> • An alarm may occur if a very high flow of cold fluid is present. The alarm should last no more than 20 seconds. • If alarm is continuous, heater circuit may be inoperative. Remove from use. Send unit for servicing.
Display indicates “ER2”.	Temperature sensor has failed. Remove from use. Send unit for servicing.

Operator's Manual

FW400 Series Blood/Fluid Warmer

5.2 Cleaning

CAUTION
Do not immerse Warmer in cleaning and/or sterilization solution. Do not submerge or soak unit; it is fluid-resistant, not fluid-proof.

Perform the following care and cleaning between patient use or per hospital protocol:

Unplug unit prior to cleaning.

To clean the external surfaces of the Warmer, use a nonabrasive cleaning solution (such as warm soapy water) and a clean cloth.

To clean the inside of the Warmer, flush the cassette slot with cleaning solution over a sink. (The slot is open at the

bottom to facilitate cleaning.) Use the thin brush supplied with the Warmer to clean the inside of slot. Rinse slot with warm water.


Wipe Warmer dry with a clean, dry cloth.

Apply a disinfectant such as 10% chlorinated bleach solution (chlorinated bleach with 5.25% sodium hypochlorite) to the external surfaces of the Warmer and allow to dry.

5.3 Function Check

A function check should be performed every three (3) months or as per hospital protocol by qualified medical service personnel in accordance with the *Medi-Temp II FW400 Series Blood/Fluid Warmer Service Manual* (contact your local dealer or Gaymar to obtain the *Service Manual*).

6.0 Technical Specifications

	FW400	FW401	FW403
Voltage	~120 V	~100 V	~220 V – 240 V
Current	9 A	11 A	4.5 A
Capacity	1200 W		
Frequency	50/60 Hz		50 Hz
Ambient Temperature	15.6°C–29.4°C (60°F–85°F)		
Power Cord	Detachable, 15 feet long. Use only UL listed type SJT, 16 AWG 3-conductor cord with molded on grounding type hospital grade attachment plug.		Detachable, 4.6 meters long. Use only an international (harmonized) 3-wire cord using cordage approved to HD-21 conductor size 1.00 mm ² (H05VVF3G1.00).
Classification	Class 1 grounded, splash-proof equipment not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.		
	 IPX4		
Weight	4.5 kg (10 pounds)		
Size	35 mm x 235 mm x 275 mm (1 3/8" x 9 1/4" x 10 3/4")		