KIMBERLY-CLARK*
Patient Warming System

M1000 Control Unit
Operator's Manual: U.S.

Kimberly-Clark

*Trusted Clinical Solutions**

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Preface

This Operator's Manual provides a detailed discussion of the KIMBERLY-CLARK* Patient Warming System M1000 Control Unit, its components, and relevant accessories. The Patient Warming System provides a safe and effective way of modifying patient temperature, providing precise temperature control using a novel approach.

The Patient Warming System M1000 Control Unit is equipped with numerous safety features, such as temperature and system alarms and alerts, and programming of maximum or minimum water temperatures. Reading and understanding this Operator's Manual will help to guide the user to providing the maximum performance of the Patient Warming System in a safe manner.

CAUTION: This product is to be used by or under the supervision of trained, qualified medical personnel.

Customer Information and Technical Support

Kimberly-Clark hours of operation are 8 am to 5 pm Eastern Standard Time. For service please call your sales representative or 1-800-KC-HELPS. Educational materials, such as training programmes for in-house staff, operator manuals, quick reference guides, and a bibliography of relevant materials are available to all Kimberly-Clark customers through your Kimberly-Clark sales representative.

Prior to using the KIMBERLY-CLARK* Patient Warming System M1000, a Kimberly-Clark representative will provide on-site in-services to ensure adequate training has occurred. Additional requests for technical support, information or orders may be placed by mail, fax, or by calling Kimberly-Clark customer service.

Model No.	**KIMBERLY-CLARK* Patient Warming System M1000**
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1.1 Introduction

The KIMBERLY-CLARK* Patient Warming System has been designed to monitor and control patient temperature. The indications for use of the device include any condition where patient temperature control within the range covering mild hypothermia to normothermia is required. The system consists of M1000 Control Unit, Fluid Delivery Line, Thermal Pads and other associated accessories. Using a novel direct heat conduction approach, the Patient Warming System aids in the elimination of unplanned hypothermia.

Unplanned hypothermia may occur for a variety of reasons, including exposure to cold environments, brain injury, or complex surgical procedures. During surgery, a patient typically experiences mild hypothermia due to the effect of general anaesthesia on the body's thermoregulatory system and prolonged exposure of internal organs. Mild hypothermia in the medical or surgical patient has been proven to prolong the time to extubation, contribute to coagulopathies, increase the chance of infection, and increase cardiac demand as a result of shivering.[1]

The use of the Patient Warming System is designed to be an effective means of counteracting this drop in patient temperature by applying heat to the patient through a set of patented thermally conductive foam pads.

1.2 Symbols and Standards

The KIMBERLY-CLARK* Patient Warming System meets the electrical safety requirements of IEC 60601 and UL 2601, the relevant safety standard for electrical medical devices. The control unit has also been tested to meet both the electromagnetic interference and susceptibility requirements of IEC 60601-1, and is compatible with other equipment that also currently conforms to that standard. There is no known failure mode in the Patient Warming System M1000 Control Unit associated with electromagnetic interference from other devices.

The Patient Warming System M1000 Control Unit bears the following symbols affixed to the system. (see Table 1)

[1]Schwab S. Schwart S. Spranger M, et al. Moderate Hypothermia in the Treatment of Patients with Severe Middle Cerebral Artery Infarction. *Stroke* 1998;29 (12): 2461-6

1.2 Symbols and Standards (continued)

Table 1

	For the safe and effective use of this device, the operator must consult the accompanying documents prior to use.
	This symbol adjacent to the patient connections means that the thermal probe connection is a "Defibrillator-Proof, Type BF Applied Part," per standard IEC 60601-1 and affords the degree of patient protection defined in that standard for this type of applied part.
	The Entela Monogram means that the control unit has been Certified for Safety by Entela, Inc. against standard IEC 60601 and UL 2601.
	Identifies the equipotential terminal on the equipment, which is intended to be connected with the equipotential terminal(s) on one or more other types of equipment in close proximity, in order to bring all pieces of equipment to the same potential for safety purposes.
	Indicates high temperature part or component.
	Indicates that only sterile or distilled water should be used when filling the Patient Warming System M1000 Control Unit.
	Identifies Patient Temperature 1, the primary patient temperature probe input.
	Identifies Patient Temperature 2, the secondary patient temperature probe input.
	Identifies the drain port.
	Identifies the heater fuse.
	Identifies the storage relative humidity range.
	Indicates electrical hazard.
	Indicates Earth Ground.
	Indicates sharp object.
 2005-01	Manufactured Date

1.3 Environmental Conditions

The KIMBERLY-CLARK* Patient Warming System M1000 Control Unit should be stored and used within the following specific operating conditions:

AMBIENT TEMPERATURE RANGE:

Operating Temperatures: 10ºC to 27ºC (50º to 80ºF)
Storage Temperatures: -30ºC to 50ºC (-20º to -120ºF)

NOTE: At higher room operating temperatures, the cooling capability is compromised and the ability to cool a patient may be compromised. Therefore, the unit's cooling capacity is de-rated at an ambient temperature above 27ºC (80ºF).

AMBIENT HUMIDITY RANGE:

Operating: 5% to 70% relative humidity, non-condensing
Storage: 5% to 95% relative humidity, non-condensing

1.4 Indications for Use

The Patient Warming System is intended for monitoring and controlling patient temperature. The indications for use of the device include any condition where patient temperature control within a range covering mild hypothermia to normothermia is required.

1.5 Contraindications for Use

There are no known contraindications for the use of a thermoregulatory system. The KIMBERLY-CLARK* Thermal Pads should not be placed on skin that is ulcerated, burned, is poorly perfused or non-perfused, or has the appearance of rash. While there are no known allergies to the hydrogel materials used in this product, caution should be exercised with any patient who has a history of skin allergies or sensitivities.

CAUTION: This product is to be used by or under the supervision of trained, qualified medical personnel.

1.6 General Warnings

- Do not use the KIMBERLY-CLARK* Control Unit in the presence of flammable agents because an explosion and/or fire may result.
- Kimberly-Clark will not be responsible for patient safety or equipment performance if the procedure to operate, maintain, modify or service the Control Unit is other than those specified by Kimberly-Clark. Anyone performing the procedures must be appropriately trained and qualified.
- There is a risk of electrical shock and hazardous moving parts. Refer servicing to qualified personnel.
- Power cable has a hospital grade plug. Grounding reliability can only be achieved when connected to an equivalent receptacle marked "hospital use" or "hospital grade."
- When using the Patient Warming System, note that any other thermal conductive systems, such as water blankets and water gels, in use while warming or cooling with the Patient Warming System may alter or interfere with patient temperature control.

1.7 Cautions

- This product is to be used by or under the supervision of trained, qualified medical personnel.
- The operator is responsible for determining the appropriateness of user-settable parameters.
- The KIMBERLY-CLARK*Patient Warming System M1000 Control Unit must be used only with the KIMBERLY-CLARK* Thermal Pads.
- The Thermal Pads are non-sterile. If used in a sterile environment, pads should be placed according to the physician's request, prior to the sterile preparation or sterile draping. Thermal Pads should not be placed in a sterile field.
- The Control Unit will control and monitor core temperature using an indwelling temperature probe attached to the system – Kimberly-Clark recommends the use of a second site to verify core temperature while controlling and monitoring patient temperature.
- It is the sole responsibility of the clinician operator to monitor patient temperature when in Manual Mode and to adjust the water temperature target appropriately.
- Federal law (USA) restricts this device to sale by or on the order of a physician.
- The Control Unit will not control the patient's temperature in Manual Mode (Water Temperature Control). Ensure that the selected target water temperature is appropriate for the patient's temperature. Since patient temperature is not controlled in Manual Mode, patient temperature should be monitored at regular intervals during prolonged warm water or cold water treatment to minimise over-warming or over-cooling the patient.
- Any device connected to the RS232 data port must comply with the applicable standards for that device.
- Patient temperature will not be controlled and alarms are disabled in Stop Mode Patient temperature may increase or decrease with the KIMBERLY-CLARK* Patient Warming System M1000 Control Unit in Stop Mode.
- Do not place Thermal Pads over an electrosurgical grounding pad. The combination of heat sources may result in skin injury.
- The Thermal Pads must be changed after 24 hours of use. If thermal treatment is to continue, a new set of pads should replace the old pads.
- Do not allow circulating water to contaminate the sterile field if pad lines are disconnected. The circulating water is non-sterile.
- The pads are non-sterile for single patient use. Do not reprocess or sterilize.
- Do not puncture the pads with sharp objects. Punctures will result in air entering the fluid pathway and may reduce performance.

1.7 Cautions (continued)

- Use only distilled or sterile water The use of other fluids may damage the Patient Warming System M1000 Control Unit.
- Skin injury may occur as a cumulative result of pressure, time and temperature. Do not place a bean bag or other firm positioning devices under the pads. Do not place positioning devices under the pad manifolds or patient lines.
- Due to underlying medical or physiological conditions, some patients are more susceptible to skin damage from pressure and heat or cold. Patients at risk include those with poor tissue perfusion or poor skin integrity due to diabetes, peripheral vascular disease, poor nutritional status, steroid use or high dose vasopressor therapy.
- If accessible, examine the patient's skin under the pads often, especially those at higher risk of skin injury.
- If warranted, use pressure relieving or pressure reducing devices under the patient to protect from skin injury.
- Do not allow antibacterial agents to pool underneath the pads. Excess antibacterial agents can absorb into the pad adhesive and cause chemical burns and loss of pad adhesion.
- Carefully remove pads from the patient's skin at the completion of use.
- Carefully observe the system for air leaks in the system before and during use. If the pads fail to prime or a significant continuous air leak is observed in the pad return line, check connections. If needed, replace the leaking pad. Leakage may result in lower flow rates and potentially decrease the performance of the system.
- The top of the controller must be placed at a level15 cm to 90 cm (6 in. to 36 in.) below the patient to ensure proper fluid flow.
- Users should not use cleaning or decontamination methods different from those recommended by the manufacturer without first checking with the manufacturer that the proposed methods will not damage the equipment.
- It is advisable not to cancel the alarm or alert until the situation is resolved. If an alarm is cancelled and the condition has not been cleared, the alarm will recur. If an alert is cancelled and the alert condition has not been cleared, the alert will not recur unless the Stop Mode is activated.

2.1 KIMBERLY-CLARK* Patient Warming System M1000 Description

Figure 1

When in use, the display module can be separated from the control module and placed in a convenient position. The display module can also be attached to the handle for easy visibility.

The KIMBERLY-CLARK* Patient Warming System M1000 Control Unit is a CLASS I (Type BF, IPX0 and Mode of Operation - Continuous) portable device per classification scheme of IEC 60601 (UL 2601).

The Patient Warming System is a thermoregulatory device that monitors and controls patient temperature within a range of 33°C to 37°C (91.4ºF to 98.6ºF). The control unit pulls temperature-controlled water ranging between ambient temperature to 42°C (68ºF to 107.6ºF) through the Thermal Pads at approximately one liter per minute per pad. This results in heat exchange from the water to the patient. The system functions in either Automatic Mode or Manual Mode. In Automatic Mode, a patient temperature probe is connected to the Patient Warming System M1000 Control Unit and provides feedback to an internal control algorithm. This control algorithm then modifies the water temperature (thus pad temperature) to reach a pre-set patient temperature target determined by the clinician. In Manual Mode, the feedback control algorithm is not activated. The operator adjusts the temperature of the water delivered to the pads to achieve the appropriate patient temperature.

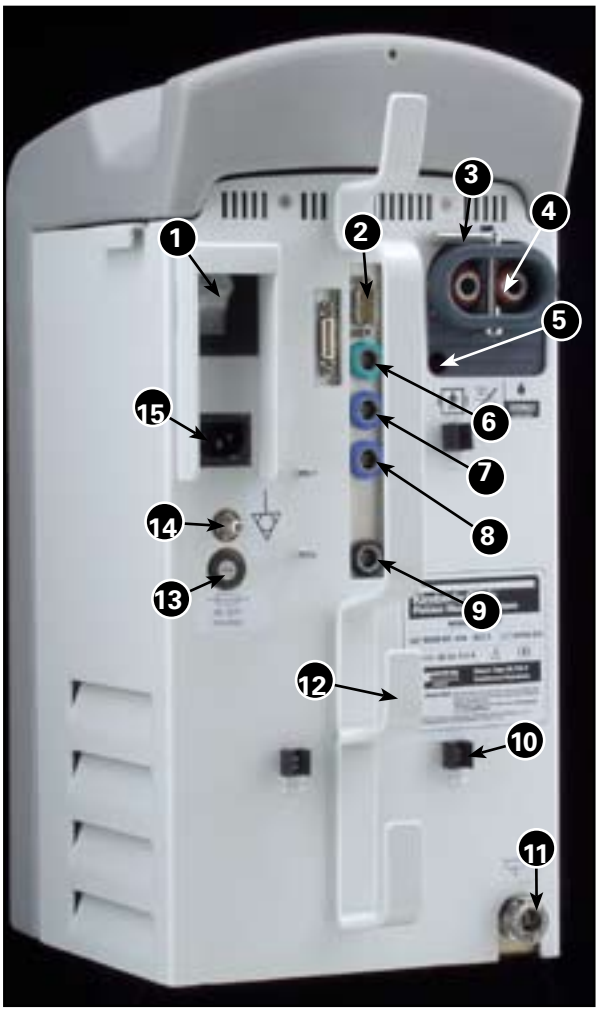
The KIMBERLY-CLARK* Patient Warming System M1000 Control Unit must be used only with the KIMBERLY-CLARK* Thermal Pads. The pads are thin, conformable, and anatomically shaped to cover areas of the patient's skin. They come in non-sterile kits in sizes to cover a broad range of patients, fit both males and females, and are for single patient use only. Each pad has an inlet and an outlet connection that attaches to a fluid delivery line. The pads allow water to flow within an internal pathway across its surface to provide even, efficient heat transfer between the skin and water. The pads adhere to the patient by the use of a skin compatible hydrogel adhesive which maintains its adhesion level over extended periods. The biocompatible hydrogel material consists of approximately 50% water and is a good thermal conductor. The pads can be removed and replaced on the patient's skin if repositioning is needed. The back of each pad is insulated to minimise heat loss to the environment and condensation when cooling. The Thermal Pads contain no natural rubber latex.

The Patient Warming System M1000 Control Unit (Figure 1) can be placed in various locations while being controlled from a remote display panel. The Control Unit is mounted on a four-wheel independent locking action cart with an adjustable height stand.

2.2 System Diagram of the Controller

Below is a diagram (Figure 2) of the KIMBERLY-CLARK* Patient Warming System M1000 Control Unit showing the connection ports for the associated accessories. The Fluid Delivery Line, Primary and Secondary Patient Temperature Cables, Temperature Output Cable, Remote Display Cable, and the Power Cable are all connected to the rear of the control unit. The lengths of these accessories are found in Table 2.

Figure 2



1	Power Switch
2	RS232 Data Port
3	Latch Handle
4	Fluid Delivery Line Port (Manifold)
5	Fill Port
6	Reserved for future use
7	Patient Temperature 1 Input
8	Patient Temperature 2 Input
9	Patient Temperature Output (Echo)
10	Fill Tube Clip
11	Drain
12	Power Cable Storage
13	Heater Fuse
14	Equipotential Terminal
15	Power Cable Connection

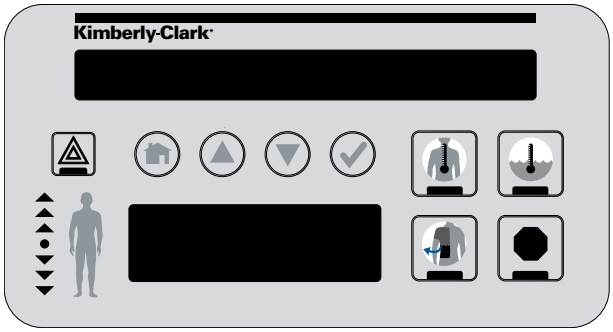
Table 2

Accessories	Metres	Feet
Remote Display Cable (standard)	1.1 metres	42 feet
Remote Display Cable (optional)	4.6 metres	15 feet
Power Cable	4.6 metres	15 feet
Water Supply Lines	3.0 metres	10 feet
Temperature Input Cables	3.0 metres	10 feet
Temperature Output Cable (pigtail)	13 centimetres	5 inches
Fill Tube	0.6 metres	24 inches

2.3 KIMBERLY-CLARK* Patient Warming System M1000 Control Unit User Interfaces

The Patient Warming System M1000 Control Unit can be operated from remote locations by attaching the User Interface (Figure 3) to an IV pole or other suitable holder. The User Interface is connected to the Patient Warming System M1000 by a 1.1 metre (42 inch) cable. A 4.6 metre (15 foot) cable is also available.

Figure 3



2.4 Modes of Operation

There are four principle modes of operation. These can be accessed by pressing any of the four keys on the lower right side of the display: Automatic, Manual, Purge, and Stop. Each key represents a unique function of the KIMBERLY-CLARK* Patient Warming System M1000 Control Unit.

AUTOMATIC MODE:

The Automatic Mode monitors and controls the patient's temperature to a set target temperature. Water will be cooled or warmed as needed and pulled through the Thermal Pads to achieve the pre-set patient target temperature. Patient temperature can be controlled and monitored between 33°C and 37°C (91.4ºF and 98.6ºF).

NOTE: The system will not go into Automatic Mode unless a patient's temperature probe is inserted into a patient and attached to the control unit.

CAUTION: The Control Unit will control and monitor core temperature using an indwelling temperature probe attached to the system. Kimberly-Clark recommends the use of a second site to verify core temperature while controlling and monitoring temperature.

MANUAL MODE:

The Manual Mode is functional with or without a patient temperature probe placed. Water temperature is established and managed by the operator. Patient temperature is not controlled in Manual mode. The operator must monitor patient temperature when Manual Mode is active. Water temperature can be modified during the Manual Mode Operation.

NOTE: Manual Mode can be used prior to placement of a temperature probe or transition to Automatic Mode.

2.4 Modes of Operation (continued)

PURGE MODE:

The Purge Key removes water from the Thermal Pads. Water flows from the Thermal Pads back to the reservoir prior to disconnection, which minimizes leakage and reduces the amount of water remaining in the pads.

NOTE: Pads should be emptied prior to a Fill Cycle. Failure to empty pads before filling may result in inadequate emptying of the pads, or overfilling the device.

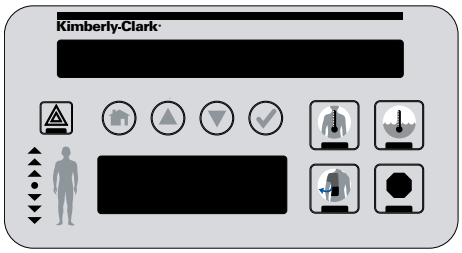
STOP MODE:

The Stop Key halts all modes of operation. During power up and alarm states, the system defaults to a Stop Mode. While in Stop Mode, all of the customisable machine settings can be adjusted.

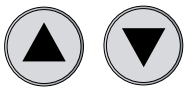
CAUTION: Patient temperature will not be controlled in Stop Mode. Patient temperature may increase or decrease with the Patient Warming System M1000 in Stop Mode. Alarms are not enabled in the Stop Mode.

2.5 Custom Menu Keys

The KIMBERLY-CLARK* Patient Warming System M1000 Control Unit control settings can be adjusted through a series of menu options displayed on the LCD screen at the top of the user interface.



The Menu Control Keys are used to scroll through the various menu options and adjust settings.



DOWN OR UP ARROW

When in Stop Mode, these keys allow the operator to review custom menu options and display screens. The arrows are also used for adjusting settings for the custom options. During Manual Mode, these arrows provide access to the Water Target Temperature Modification Screen.

ENTER KEY

The Enter Key is used to accept modifications or enter changes to a custom parameter.

HOME KEY

Pressing the Home Key returns the screen to the Main Menu when in any custom display screen. This key does not accept modifications or changes.

ALARM KEY

The Alarm Key is illuminated when situations arise that may pose a safety issue for the patient or if the system is not performing to its proper specification. To silence or acknowledge an alarm or alert, press the Alarm Key.

2.6 Patient Temperature Trend Indicator

The Patient Temperature Trend Indicator reflects the change in the patient's temperature over the previous five minutes. Flashing Up arrows indicate patient temperature is increasing. Flashing Down arrows indicate patient temperature is decreasing.

- Center circle no change or less than 0.25ºC (0.45ºF) change per hour
- One arrow (up or down) – 0.25ºC to 0.5C (0.45ºF to 0.96ºF) change per hour
- Two arrows (up or down) – 0.5ºC to 0.75ºC (0.96ºF to 1.35ºF) change per hour
- Three arrows (up or down) – 0.75ºC to 2.0ºC (1.35ºF to 3.6ºF) change per hour
- Three arrows flashing simultaneously – > 2.0ºC (> 3.6ºF) change per hour

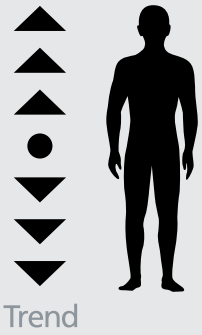


Figure 4 Patient Temperature Trend Indicator

2.7 Patient Temperature Display

The Patient Temperature Display indicates temperature from Patient Temperature 1 in degrees Centigrade (C) or degress Fahrenheit (F). The display units can be changed in the custom parameter menu found under Setup when in Stop Mode. The temperature range that can be displayed is between 10°C and 42°C (50ºF to 108ºF).

2.8 Fluid Delivery Lines

Water flows from the KIMBERLY-CLARK* Patient Warming System M1000 Control Unit to the thermal pads through the Fluid Delivery Line that connects to the back of the control unit. The Fluid Delivery Line is reusable and should only be replaced if defective (see Section 5.2 Troubleshooting). The Fluid Delivery Line comes in two configurations accepting either 2 pads (Part # 00834-04) or 4 pads (Part # 00834-05).

2.9 Patient Temperature Probes

To run the Patient Warming System M1000 Control Unit in Automatic Mode, an indwelling temperature probe must be placed into the patient and connected to the control unit. The control unit comes with an adapter cable to connect to the patient temperature probe. This temperature probe cable adapter is inserted in the Patient Temperature 1 Input port in the rear of the machine (Figure 2). Two types of adapter cables are available: one for 2-pin connections (Nellcor/SIMS) and one for a single jack connector (Bard).

The control unit only works with Yellow Springs Instrument 400 Series (YSI 400) thermistor compatible patient temperature probes. These probes include nasopharyngeal, esophageal, tympanic, rectal, or bladder probes. Refer to the temperature probes' Manufacturer's Instructions for Use for the specific indications and placement of these probes.

A second patient temperature probe, identified as Patient Temperature 2, may be connected to the Patient Warming System M1000 Control Unit to provide patient temperature monitoring from a second patient site. The adapter is similar to Patient Temperature 1 and is inserted into the appropriately labelled connector directly below the Patient Temperature 1 port.

NOTE: Patient temperature is not controlled from the secondary patient temperature probe. The secondary patient temperature probe is a backup patient temperature monitor for increased patient safety in those instances when patient temperature is not constantly monitored by the clinician. The secondary probe will alarm and shut down the control unit if the primary probe is dislodged or fails.

2.10 Patient Temperature Output (Echo)

The Patient Warming System M1000 will output Patient Temperature 1 (the primary patient temperature) input reading to a YSI 400 compatible hospital monitor using the Patient Temperature Output (Echo). An adapter for use with various temperature probe cables (similar to the patient temperature adapter cables) included with the installation kit, can be inserted into the Patient Temperature Output (Echo) port in the rear of the machine. The temperature displayed on the Patient Warming System M1000 Control Unit and monitor represents the same temperature but may not be identical due to calibration differences between the control unit and the monitor.

3.1 Operating Instructions

The KIMBERLY-CLARK* Patient Warming System offers an easy efficient way of managing patient temperature. The sophisticated control algorithm works to modify patient temperature precisely and accurately. It is essential that the clinician review the patient's medical history, inspect the skin integrity, and determine the adequacy of tissue perfusion prior to treating with the Patient Warming System. The clinician can then adjust the specific parameters prior to cooling or warming the patient.

3.2 Start Up

To begin using the Patient Warming System M1000 Control Unit, press the ON/OFF Switch to the ON position. The system will go through a brief self-diagnostic system check and check the water level in the reservoir. When finished, the display will read "Kimberly-Clark Patient Warming System." This is the Main Menu or "Home" Screen.

When the Patient Warming System M1000 Control Unit is turned to the ON position, a power up test for the independent safety alarm is automatically run. The audio alarm will sound and the alarm indicator will illuminate during setup. The operator must verify that both are operational before operating the system. For additional information on alarms, see Appendices B and C.

WARNING: Do not use the Patient Warming System M1000 in the presence of flammable agents because an explosion and/or fire may result.

WARNING: Power cable has a hospital grade plug. Cable grounding reliability can only be achieved when connected to an equivalent receptacle marked "hospital use" or "hospital grade."

3.3 Filling the KIMBERLY-CLARK* Patient Warming System M1000

The water level is displayed at a variety of times: when the system is powered on; after completion of a fill; after the pads are emptied or purged; and, when accessing the Fill Screen from the custom menu. The levels displayed are as follow:

Water Level	Action
Full	Do not add water
3/4 Full	Add approximately 0.5 liters
1/2 Full	Add approximately 1.0 liters
Water Level Low	Add approximately 1.5 liters
Water Level Empty	Add approximately 2.0 liters
Initial Installation & refill after cleaning	Use approximately 3 liters

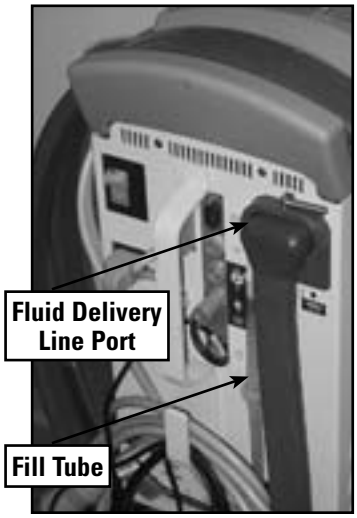
Table 3

The KIMBERLY-CLARK* Patient Warming System M1000 Control Unit can be operated at any level except when reading Water Level Empty.

CAUTION: Use only distilled or sterile water. The use of other fluids may damage the Patient Warming System M1000.

NOTE: If Alarm 4 or 5 is activated when the unit is turned on, silence the alarm by pressing the flashing alarm button. Perform the following procedure to fill the unit before operating. Additionally, if Alert 3 (Low Fluid Level) sounds, Kimberly-Clark recommends filling the unit as well.

3.3 Filling the KIMBERLY-CLARK* Patient Warming System M1000 (continued)



To fill the KIMBERLY-CLARK* Patient Warming System M1000, take the following steps:

1. Obtain approximately 2.0 liters of distilled or sterile water.
2. Locate the Fill Tube on the back of the controller and to the lower left of the Fluid Delivery Line (see Appendix E Parts Table for part number for reordering). *NOTE: Fluid Delivery Line Port (Figure 2) must have either a fluid delivery line without pads or manifold plug attached in order to properly fill the tank.*
3. Press the Home Key. Then press the down arrow until the fill screen appears: "Water Level Empty. Enter to Fill." Press Enter to proceed.
4. The display screen will read: "Place the Fill Tube in the container of water. Press Enter to fill." Place the end of the fill tube in the container of water.
5. Press Enter again and the Patient Warming System M1000 will automatically fill until the reservoir is full. The fill tube may have to be held in the container to ensure adequate suction.
6. The screen will read "Fill Complete." Press Enter and remove the Fill Tube from the container. Keep the fill tube connected to the Control Unit.
7. Press Home to return to Main Menu.

NOTE: Pads must not be connected to the fluid delivery line while filling the unit.

The filling cycle can be terminated at any point during the filling process by pressing Stop. If the filling cycle is stopped prior to completion, the reservoir will have a volume less than full and may require more frequent filling. The number of procedures that can be conducted prior to filling depends on the number of pads used and the amount of water remaining in the pads after a Purge cycle is completed.

To avoid overfilling, do not fill the KIMBERLY-CLARK* Patient Warming System M1000 Control Unit unless pads have been emptied by pressing the Purge Key. If the reservoir is filled prior to emptying the pads, the reservoir may be full and may not allow a full Purge to occur. An incomplete Purge may result in excess water remaining in the pads.

In the event of a power failure or shutdown of the system, the reservoir may read EMPTY if the pads are filled with water. Press Purge to refill the reservoir and then resume treatment.

3.4 Placement of the KIMBERLY-CLARK* Patient Warming System M1000 Control Unit

The control unit has been designed to take up a minimal amount of space and to be easily moved to an appropriate location in the Operating Suite. To ensure proper operation, the top of the unit should be located 15 cm to 90 cm (6 in. to 36 in.) below the patient to ensure proper flow. Maintaining the reservoir lower than the patient also minimises accidental leakage in the event of puncture or disconnection of the fluid delivery lines.

CAUTION: The top of the controller must be placed at a level 15 cm to 90 cm below the patient to ensure proper flow.

3.5 Setting Custom Parameters

The Patient Warming System M1000 Control Unit is shipped with default settings (see Tables 4-6 below), which may be modified as needed. Settings can be changed for individual patients or procedures, or permanently changed to create new default settings.

Prior to using the Patient Warming System on a patient, it is important to verify that all parameters are appropriately set for the particular patient or procedure, including maximum water temperature in Automatic Mode.

Table 4 indicates the parameters, the default settings, the available ranges of settings, and incremental changes. When pressing the Down arrow, the parameters that are displayed are shown in order of their appearance.

Table 4

Parameter–Default	Explanation	Range	Resolution
Patient Target XX°C Automatic Mode/ (Default-37°C) (98.6°F)	Set desired target patient temperature in Automatic Mode.	33°C-37°C (91.4°F to 98.6°F)	0.1°C (0.1°F) increments
Water Target XX°C Manual Mode/ (Default-37°C) (98.6°F)	Set desired water temperature in Manual Mode.	20°C-42°C (68°F to 105.8°F)	1.0°C (1.0°F) increments
Water Level	Shows the level of the water in the reservoir at any given time. This reading is updated during purge, fill cycle & power on.	Empty to Full	Empty, Low, Full
Maximum Water XX°C Automatic Mode (Default-42°C) (107.6°F)	Set the maximum water temperature the system will use to control patient temperature in Automatic Mode.	32°C-42°C (89.6°F to 107.6°F)	1.0°C (1.0°F) increments
Minimum Water XX°C Automatic Mode (Default-4°C) (39.3°F)	Set the minimum water temperature the system will use to control patient temperature in Automatic Mode.	20°C-32°C (68°F to 89.6°F)	1.0°C (1.0°F) increments

Setup provides a second tier of user-defined options that pertain to equipment settings that may require less frequent changes. (See Tables 5 and 6)

Table 5

Parameter–Default	Explanation	Range	Incremental Changes
Patient High Alert XX°C Automatic Mode (Default 42°C) (107.6°F)	Defines the temperature limit at which the system should issue an alert if the patient temperature exceeds that limit.	10.1°C- 42.0°C (50.1°F to 107.6°F)	0.1°C (0.1°F)
Patient Low Alert XX°C Automatic Mode (Default 10°C) (50°F)	Defines the temperature limit at which the system should issue an alert if the patient temperature falls below that limit.	10.0°C- 41.9°C (50°F to 107.5°F)	0.1°C (0.1°F)

3.5 Setting Custom Parameters (continued)

Table 6

Parameter–Default	Explanation	Options
Patient Temperature 2(Default-Disabled)	Allows user to enable the system for a second patient temperature probe if a probe is connected to the control module from a secondary site on the patient. The second site is for monitoring, not controlling patient temperature.	Enabled Disabled
Control Strategy (Default: Surgical)	Determines the response of the internal algorithm to anaesthetised patients.	Surgical Reserved
Temperature Mode (Default -°C)	Select temperature units of measure. *NOTE: All custom settings should be verified if changing between °C and °F.*	°C (Centigrade) °F (Fahrenheit)
Language (Default-English)		English
Data Output Interval (Default-1 minute)	Data outlet intervals 2000 systems house a 250 power speed when sending real time system information through the RS232 port for data collection.	Off, Between 5 and 60 seconds: 5 second increments; Between 1 and 10 minutes: 1 minute increments
Reset Calibration Alert Timer	Alert will notify user at defined intervals to contact Kimberly-Clark or authorised biomedical engineer to verify system calibration and operation.	Do not reset until calibration is completed.
Save Current Settings as Defaults	Press Enter to save all current settings as defaults.	Press Return to Main Menu Key to return to the main screen.

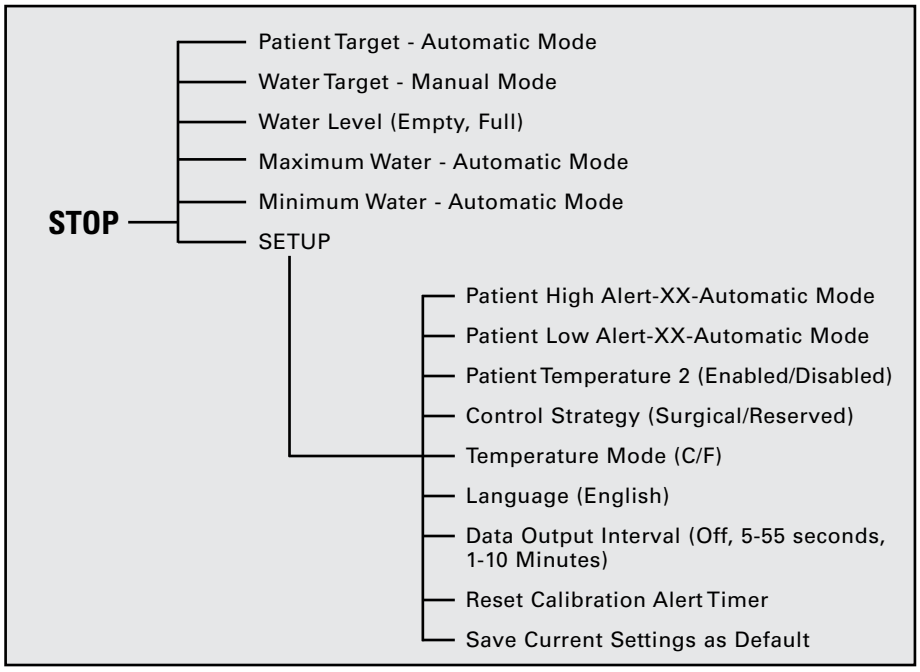
CAUTION: The operator is responsible to determine the appropriateness of custom parameters for each patient.

With the Stop Key lit, press the Down or Up Arrow to access the custom settings menu to verify or modify default parameters. To modify a setting, scroll to the appropriate parameter shown on the display screen. Press the Enter Key. The setting will flash indicating that the setting can be changed. Using the Down or Up Arrows, change the setting. Press Enter to accept the new setting. (See Figure 5 for an overview of the settings.)

NOTE: When the system is powered off, all changes will revert to the default unless the new settings have been established as new defaults.

3.5 Setting Custom Parametres (continued)

Figure 5



3.6 Pre-warming the KIMBERLY-CLARK* Patient Warming System M1000

Pre-warming of the Patient Warming System can be accomplished prior to connecting the pads to facilitate efficient operating theatre setup. To pre-warm the control unit, turn the power on by pressing the On/Off switch to the "On" position. The control unit then performs the startup self-diagnostic check and will eventually show the Main Menu or "Home" Screen. Press the "Manual" Key to begin warming the water in the unit.

The control unit will then begin heating the water to the previously saved default water target temperature. To change this temperature, press the Down Arrow Key once until the screen reads "Water Target Temperature XX, Press Enter to Change." Press "Enter" and adjust the temperature using the Up and Down Arrow Keys.

From room temperature (20ºC/68ºF) the control unit will warm the water to the target temperature in approximately 5 to 10 minutes.

CAUTION: The surface of the heating device should be checked for mechanical damage prior to use.

3.7 Connecting the Thermal Pad to the Fluid Delivery Lines

To connect the Patient Warming System Thermal Pads to the control unit and pre-warm them prior to surgery, begin by placing the correct size and configuration pads (see Section 3.8 below), liner side up on the surgical table. Connect the translucent pad lines to the fluid delivery line by inserting the blue connector into the blue labelled receptacle on the manifold. Similarly, insert the white connectors into the white labelled receptable immediately adjacent. This can be done without stopping the machine if it is already in Manual Mode.

CAUTION: Carefully observe the system for air leaks in the system before and during use. If the pads fail to prime or if large air bubbles are observed in the pad return line, indicating the presence of a significant continuous air leak, check connections. If this does not correct the problem refer to Section 5.2: (Troubleshooting) for more information. Leakage may result in lower flow rates and potentially decrease the performance of the system.

If the machine is in Stop Mode, press the "Manual" Key to begin warming. Press the Down Arrow Key once to go to the Water Target Temperature set point screen. Press Enter to allow adjustment of the target using the Up/Down Arrow Keys. When the desired water target temperature is highlighted, press enter to accept.

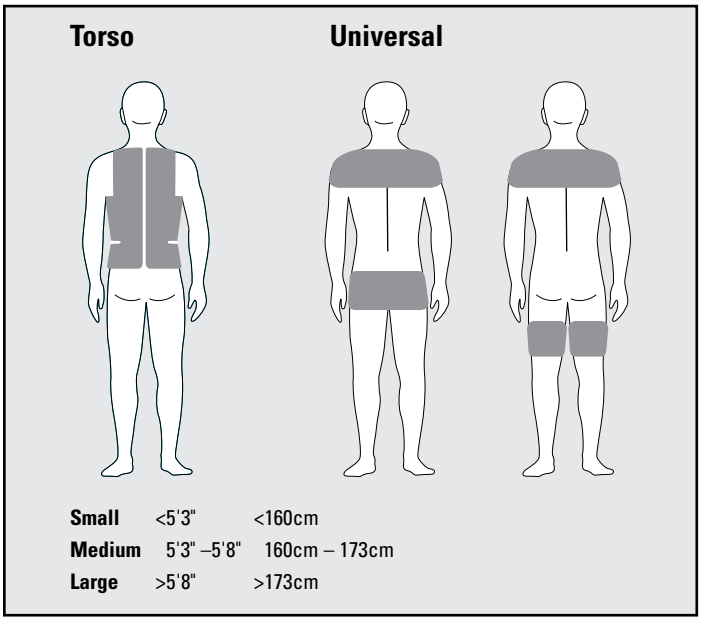
The pads will be at temperature in approximately 5 minutes.

NOTE: The temperature at the surface of the pad is approximately 1°C less than the water temperature under normal circumstances.

3.8 Thermal Pad Selection

PAD SELECTION

- Each patient should be individually assessed to determine that pads are sized appropriately.

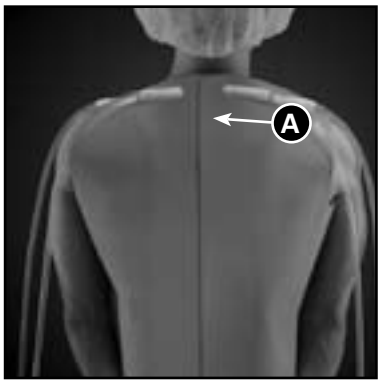


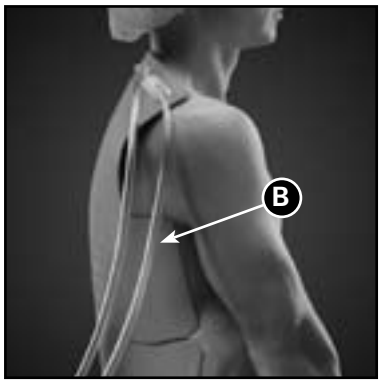
3.9 Thermal Pad Placement

VERTICAL OR SHOULDER REFERENCE

- If patient is sitting upright, place tip of pad 5 cm (2") below C7.

  If lying down, place top of pad 2.5 cm (1") below C7. (Reference A.)





MID-AXILLA OR HORIZONTAL REFERENCE

- The side of the pad should be mid-axilla. (Reference B.)
- Depending on patient back width, the pads may overlap across the spine. This is normal and acceptable.

PAD SKIN CONTACT

After the patient has been transferred to the surgical table and prior to draping, pads can be placed on the patient using one of the following methods outlined on the next page. Place the pads on healthy skin only. Remove any creams or lotions from patient's skin before pad application. Remove the release liner from each pad and apply to the appropriate area. The pads may be overlapped or folded adhesive to adhesive. The pads may be removed and reapplied as necessary. The pad surface must be contacting the skin for optimal efficiency.

3.9 Thermal Pad Placement
(continued)

APPLICATION METHODS - TORSO PADS

1. With the patient sitting on the operating theatre table, overlap the inside seam of the pads so the width of the pads between the flap insert is approximately as wide as the patient's back.
2. Pads can be placed by log rolling the patient.
3. Roll the patient to one side.
4. Remove the release liner on a pad.

5. Start pad placement by placing the second flap mid-axilla and smoothing the pad down the patient's back and towards the spine.
6. Repeat on the other side.
7. Ensure that manifolds are placed free and clear of pressure areas, such as the scapula.
8. Adhere pad flaps to the side of the patient.

NOTE: Make sure to reposition the upper flap after arm tuck

APPLICATION METHODS - UNIVERSAL PADS

1. Select any area of intact skin that will be away from the incision
2. Pads may be placed horizontally, vertically, or around limbs; shaving of hair is not required
3. Simply peel off the white liner and apply gel pad to skin

3.10 Treating a Patient in Automatic Mode

For off-pump cardiac artery bypass procedure and other general surgeries, Kimberly-Clark advises the use of the Automatic Mode of treatment. In this mode, the KIMBERLY-CLARK* Patient Warming System M1000 Control Unit uses the feedback from an indwelling patient temperature probe to adjust the water temperature of the system. This allows the patient temperature to be controlled with minimal overshoot of the desired target.

- Prior to using the Automatic Mode, check the machine settings to assure proper operation for the specific patient and procedure. Adjust these settings as necessary using the procedure outlined in Section 3.5 Setting Custom Parameters.

- Patient Target XX°C -Automatic Mode: Determines the temperature set point for the patient. This set point can be adjusted in 0.1°C (0.1°F) increments between the temperature range of 33°C to 37°C (91.4°F to 98.6°F).
- Maximum Water XX°C -Automatic Mode: Limits the highest temperature of the water that will flow through the pads. Maximum water temperature is 41°C (105.8°F). This can be lowered for patients with fragile skin or other medical conditions.
- Minimum Water XX°C -Automatic Mode: Limits the lowest temperature of the water that will flow through the pads. The minimum water temperature is 20°C (68°F). This can be increased for patients with fragile skin or other medical conditions.

CAUTION: Check that the patient temperature probe is accurately placed and is functioning prior to initiating the treatment.

For procedures that will use this Automatic Mode of operation, set up is the same as described above:

- Pre-warm the Thermal Pads to a safe temperature for the specific patient being treated. (Kimberly-Clark recommends pre-warming to a water target temperature of 41°C (105.8°F). If this is uncomfortable for the patient, adjust the water target temperature down to 38°C (100.4°F) prior to intubation.)
- Insert a YSI 400 compatible temperature probe and connect the temperature probe to the Patient Temperature 1 adaptor cable attached to the back of the control unit.
- Press the Automatic Mode Key In Automatic Mode, water temperature will automatically increase or decrease to achieve the target temperature.
- Adjust the patient target temperature by pressing the Down Arrow to reveal the patient target temperature set point screen. Press Enter and Up/Down Arrows to adjust. Press Enter again to accept changes.

3.10 Treating a Patient in Automatic Mode (continued)

While in Automatic Mode, the KIMBERLY-CLARK* Patient Warming System M1000 Control Unit incorporates a control algorithm that responds to patient temperature and patient temperature trends. The temperature of the water flowing through the pads is automatically adjusted to transfer enough energy to reach a pre-determined patient target temperature. When warming, water temperature will increase to the maximum water temperature set for the patient or procedure. Water temperature may decrease before reaching its target to avoid overshooting patient target temperature. When cooling, water temperature will decrease to the minimum water temperature set for the patient or procedure. Water temperature may actually rise before reaching the target to avoid overshooting patient target temperature.

NOTE: Heat transfer efficiency depends on the number of pads used or surface coverage, the rate of heat lost or generated, the time available to reach the target, and the temperature of the water used during the procedure.

CAUTION: The Patient Warming System M1000 will control and monitor core temperature based on the temperature probe attached to the system Patient Temperature 1 (primary patient temperature) input port. Kimberly-Clark recommends measuring patient temperature from a second site to verify core temperature while controlling and monitoring patient temperature with the Patient Warming System M1000.

CAUTION: Manual Mode should only be used when a patient's temperature and condition are continuously monitored.

Note: A second patient temperature probe may be enabled and connected to the secondary patient temperature input port on the rear of the control module and utilised to monitor patient temperature from second site. The system does not control patient temperature from the secondary patient temperature input. The operator can display the secondary patient temperature probe reading by pushing the Up Arrow when in Automatic, Manual or Stop Mode.

3.11 Treating a Patient in Manual Mode

For on-pump cardiac artery bypass graft surgeries and other surgeries where the clinician prefers direct control of the amount of heat provided to the patient, the KIMBERLY-CLARK* Patient Warming System M1000 Control Unit may be run in Manual Mode.

When operating the Patient Warming System M1000 Control Unit in Manual Mode, it is important to remember that patient temperature is not being controlled by the control unit. It is the responsibility of the clinician or operator to monitor patient temperature and adjust the water target temperature appropriately during Manual Mode operation.

3.11 Treating a Patient in Manual Mode (continued)

To treat a patient during on-pump procedure, first determine the temperature management strategy:

Warm the patient prior to CPB
Set the water temperature to enhance warming

OR

Patient allowed to drift
Set water target temperature to avoid rapid warming

OR

Normothermic throughout case
Set water target temperature to enhance warming

CAUTION: It is the sole responsibility of the clinician or operator to monitor patient temperature during Manual Mode and to adjust the temperature of the water flowing through the pads accordingly.

CAUTION: Since temperature is not controlled in Manual Mode, patient temperature should be noted at regular intervals during prolonged warm water or cold water treatment to prevent over-warming or over-cooling the patient.

CAUTION: Manual Mode should only be used when a patient's temperature and condition are continuously monitored.

To begin treatment, pre-warm the pads as described above for Automatic Operation. Kimberly-Clark recommends using a set point of 38ºC to pre-warm the pads, and during initial pad placement for on-pump procedures.

Once the pads have been placed on the patient, adjust the water target temperature as described below to accomplish the specific control strategy appropriate for the patient and procedure in question.

TO ADJUST WATER TARGET TEMPERATURE:

- Press the Up or Down Arrow to reach the Water Target screen. Message displays: Water Target XXºC. Press Enter to Change.
- Press the Enter Key
- Numbers will flash on screen indicating that change can be made.
- Press Down or Up Arrow until desired temperature is displayed.
- Press Enter Key again to accept. Return to Main Menu by pressing Up or Down Arrow.

3.12 Completing a Procedure

After achieving your overall treatment goal or when terminating a procedure, the pads should be purged prior to removing:

- Press the Stop Key
- Press the Purge Key The control unit will begin removing water from the pads. This process will take approximately 2 minutes.
- The Purge Cycle will stop automatically when completed and display the water level remaining in the reservoir. There will be a small amount of water remaining in the pads.
- Disconnect the Thermal Pad from the Fluid Delivery Lines by pressing the metal disengage tab on the connectors. Disconnect the patient probe from the Patient Temperature 1 probe adapter cable attached to the rear of the control unit.
- Carefully remove the Thermal Pads from the patient. (If the patient is going to be reconnected, pads can remain in place.)
- Turn the On/Off Switch to the Off position.

Discard the pads according to hospital protocol for disposing of contaminated material.

Note: If power is lost while the power switch is in the On position, the KIMBERLY-CLARK Patient Warming System M1000 Control Unit will issue an audible warning until the switch is turned off. This alerts the user that treatment has been accidentally stopped.*

CAUTION: Carefully remove pads from the patient's skin at the completion of use. Aggressive removal of the pad or edge tape adhesive from the patient's skin may result in skin tears. Adhesive tape is included on certain pad designs.

CAUTION: Do not allow residual water to contaminate the sterile field when patient lines are disconnected.

3.13 Interrupting Treatment for Patient Transport or Relocation

It is sometimes necessary to move a patient or continue warming treatment post surgery. To minimise water spillage, follow the protocol below before moving a patient:

- Press the Purge Key The control unit will begin removing water from the pads. This process will take approximately 2 minutes.
- The Purge Cycle will stop automatically when completed and display the water level remaining in the reservoir.
- Disconnect the Thermal Pad from the Fluid Delivery Lines by pressing the metal disengage tab on the connectors. Disconnect the patient probe from the Patient Temperature 1 probe adapter cable attached to the rear of the control unit.
- The patient may then be moved with pads in place.
- To restart temperature management regimen, reconnect the pad lines and temperature probe, then select appropriate mode to initiate cooling or warming.

Note: If the device is turned off, the settings will return to the default settings when restarted unless new settings were saved as default settings.

3.14 Collecting Data from the RS232 Port

The KIMBERLY-CLARK* Patient Warming System M1000 Control Unit has an RS232 data communication port (refer to Figure below for port location). Data can be downloaded real time as the events are happening while the system is ON. Data cannot be stored or retrieved once an event has occurred. Refer to Appendix F for details on the data communication protocol.

CAUTION: Any device connected to the RS232 data port must comply with the applicable IEC electrical safety standards for that device.

4.1 Maintenance and Service Information

The KIMBERLY-CLARK* Patient Warming System M1000 Control Unit should be inspected periodically for any problems, such as bent or broken switches, frayed or extremely twisted power cables, and loose or missing hardware. Discontinue using any equipment displaying one or more of the above conditions until the problem is corrected and it has been verified that the device is operating correctly.

Kimberly-Clark offers a one-year warranty on parts and labour, provided the system has been used according to its intended use. Kimberly-Clark accepts responsibility for the safety, reliability, and performance of this equipment only if:

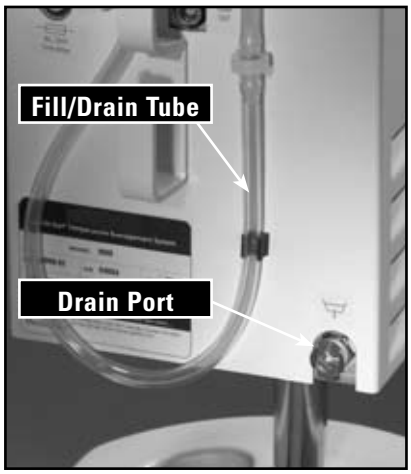
1. operational procedures and repairs are performed by appropriately qualified persons;
2. the electrical installation of the relevant room complies with all applicable local electrical codes; and,
3. the equipment is used in accordance with the published instructions for use.

Preventative Maintenance

The Patient Warming System M1000 internal reservoir should be cleaned every 3 months. See Section 4.3 on the next page.

The Patient Warming System M1000 internal fluid filters should be inspected every six weeks or whenever flow is lower than expected for the given Thermal Pad configuration. See Section 5.2 Troubleshooting.

4.2 Draining the KIMBERLY-CLARK* Patient Warming System M1000



For the purpose of routine maintenance or shipping the Patient Warming System M1000 Control Unit you will need to drain the unit of circulating water. To accomplish this, you will need to use the Patient Warming System M1000 Fill/Drain line which is attached to the control unit. Additional lines can be obtained by contacting Kimberly-Clark Service (see Appendix E Parts List for part number).

To drain the unit, turn off the power and unplug the power cable. Remove the fill line from the fill port and attach the connector to the drain port on the lower right corner of the unit. Place the distal end of the line into a suitable container. The device will passively drain all tubing, reservoirs and pump within the system. A small amount of water will remain in the unit.

NOTE: Collect and dispose of all waste in accordance with local and national laws. Neutralise with a chemical reducing agent such as sodium metabisulfate.

4.3 Cleaning the KIMBERLY-CLARK* Patient Warming System M1000

ROUTINE CLEANING OF EXTERNAL SURFACES

Clean all surfaces of the Patient Warming System M1000 Equipment after each use and after any spills. Cleaning should include the exterior of the main case assembly and the power cables. Use a soft cloth and mild detergent or disinfectant according to hospital protocol. The display screen can be wiped with a clean, lint-free, moist cloth.

NOTE: To prevent possible discolouration, do not use any iodine-based solutions, such as betadine® solution, on any part of the machine.

CLEANING THE FLUID DELIVERY LINES AND TEMPERATURE CABLES

Fluid Delivery Lines and Temperature Cables should be cleaned with an EPA approved disinfectant.

CLEANING OF INTERNAL RESERVOIR

Kimberly-Clark recommends cleaning the water reservoir and circuit at least once every 3 months with the KIMBERLY-CLARK* Patient Warming System M1000 Cleaning Solution. This cleaning solution is supplied in the cleaning kit (Part #00838-01), which can be purchased from Kimberly-Clark.

- Completely drain the unit using the Drain Procedure described in section 4.2.
- Replace Filter using procedure below
- Obtain a liter of cleaning solution from cleaning kit (Part # 00838-01). Refill the unit using the liter of cleaning solution, and two liters of sterile/distilled water.
- Place a recirc line on the fluid delivery line. Run the control unit in Manual at 30ºC for approximately 10 minutes.
- The M1000 control unit is now ready for normal operation.

4.4 Cleaning / Replacing Fluid Delivery Line Filter

Approximately every 6 weeks the filter condition should be checked to minimise disruptions to fluid flow through the system.

To remove the filter, begin by removing the fluid delivery line from the rear of the control unit by moving the lever on the top of the port on the rear of the unit from right to left.

- Remove the fluid delivery line by gently rocking back and forth while pulling away from the control unit.
- To access the filter, take an 8mm hex wrench and unscrew the metal cap on the left-hand side of the port.
- Gently remove the filter from control unit.
- Check the filter and clean or replace as necessary
- To replace the filter in the control unit, gently insert the filter into the metal cap
- Using the 8mm hex wrench, slowly tighten the cap in the port until the cap is snug, being careful not to damage the filter.
- Re-attach the fluid delivery line by placing it firmly on the port, and secure it by moving the silver lever from left to right.

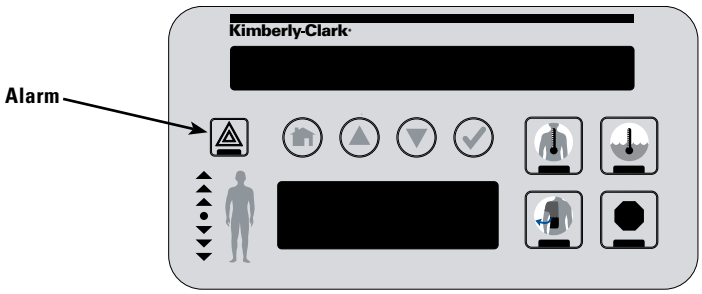
5.1 Alarms and Alerts

The KIMBERLY-CLARK* Patient Warming System M1000 Control Unit has safety features to warn the user of certain conditions that may interfere with patient safety, system performance, or patient outcome. There are two types of warning conditions in the Patient Warming System M1000 Control Unit - Alarms and Alerts. A list of the Alarms and Alerts is located in Appendix B.

ALARMS:

When an Alarm condition occurs, there is a chance that a potentially unsafe condition has occurred or can occur with respect to the equipment, the patient, or an improperly functioning system. An Alarm is denoted by an audio signal that lasts for 0.5 seconds, illumination of the Alarm Key on the Remote Display Screen User Interface, and a message on the Display Screen. An Alarm will repeat itself every 10 seconds until cleared. If the alarm condition is not addressed and the problem persists, the Alarm will recur.

While there are multiple alarms and safety features in the Patient Warming System M1000 Control Unit, there are four main safety alarms that are non-changeable:



- High Patient Temperature Alarm - In Automatic Mode, an alarm condition will occur when the patient temperature reaches 38°C, the water temperature is greater than patient temperature and the system is unable to cool the water.
- Low Patient Temperature Alarm - In Automatic Mode, an alarm condition will occur when the patient temperature reaches 32°C, the water temperature is lower than patient temperature and the system is unable to heat the water.
- High Water Temperature Alarm - An alarm will occur if the water temperature rises above 42.5°C for 10 seconds.
- Low Water Temperature Alarm - An alarm will occur if the water temperature drops below 3.5°C.

In each of these conditions, the system will switch to Stop Mode until the condition is rectified.

5.1 Alarms and Alerts (continued)

If an alarm condition occurs that prevents proper use of the machine or proper treatment of the patient, the system will not allow the operator to continue a treatment. This type of alarm is known as Non-Recoverable. If this situation occurs, turn the machine off and contact Kimberly-Clark. Alarms that are classified as Recoverable may temporarily stop the machine until the operator takes action to correct the cause of the alarm.

Confirmation of Independent Safety Alarm

When the KIMBERLY-CLARK* Patient Warming System M1000 Control Unit is turned to the ON position, a power up test for the independent safety alarm is automatically run. The test simulates a "water over-temperature fault" on both the primary and secondary sensors. Both the primary and secondary control systems must respond to the fault as verified by the opposing system. If both control systems don't respond, either Alarm 80 (Outlet Water over-temperature test-fail Control) or Alarm 81 (Outlet Water over-temperature test fail - Monitor) will be activated. Should either an Alarm 80 or 81 appear on the display screen, notify Kimberly-Clark that this has occurred. These alarms are unrecoverable errors and need to be checked by Kimberly-Clark personnel. For additional information on alarms, see Appendices B and C.

Alerts

Alerts are intended to inform the user about patient and equipment status without interrupting the procedure. Alerts are denoted by an audio signal that lasts 0.5 seconds. The Alarm Key will illuminate and a message will appear on the display screen. When an Alert condition occurs, the system continues to function in its current mode. An Alert will repeat itself every 2 minutes until cleared. Once cleared, the Alert will not be repeated unless the alert condition reappears.

NOTE: It is advisable not to cancel the alarm or alert until the situation is resolved. If an alarm is cancelled and the condition has not been cleared, the alarm will recur. If an alert is cancelled and the alert condition has not been cleared, the alert will not recur unless the Stop Mode is activated and unit is restarted.

5.2 Troubleshooting

Flow Rate

Many factors contribute to reaching a target temperature, including the patient's temperature, the size of the patient, the surface area covered, and the water flow rate through the pads.

Initially, when the Fluid Delivery Lines are connected to the Patient Pad Lines, water will be pulled through the pads displacing the entrained air. This is reflected in the lower right hand corner as "Flow Priming." After one minute the system will automatically calculate flow and display the flow rate in L/min (liters per minute). To ensure that water is flowing adequately through the pads, verify that all patient lines are connected properly and are not kinked. After two minutes of flow, verify that a flow rate is present on the screen.

Once all the pads are primed (approximately 10 minutes), assure the flow rate displayed on the control panel is appropriate for the number of pads connected (see Table 7).

Number of Pads **Flow Rate in liters per minute**

Number of Pads	Flow
2	>1.5
3	>2.0
4	>2.5

Table 7

The system will track the initial highest flow rate. If flow drops by 50%, the system will alert you to check the lines to ensure water is flowing to the patient.

The following is a list of suggestions for some commonly occurring conditions. If there are any questions, please contact Kimberly-Clark Service.

ISSUE:
Water flow rate suddenly decreases

ACTION:

- Check to ensure lines are patent and not compressed or kinked. Check that connections between Patient Pad Lines and Fluid Delivery Line are secure.
- If a significant amount of air is present in the line and connections are secure, the pad or Patient Pad Line may have been damaged. Disconnect the damaged pad and replace if possible. If not, disconnect the pads and allow the patient to be warmed with the remaining pad(s).

5.2 Troubleshooting
(continued)

ISSUE:
When warming, patient temperature is not increasing and trend indicator is either decreasing or remaining stable despite prolonged warming

ACTION:

- Check the water temperature on the display screen. If the temperature of the water circulating through the pads is not at or near the maximum water temperature, check the following parameters:
  - Check the flow rate to ensure adequate flow has continued since the beginning of the treatment.
  - Ensure that no other warming devices or water blankets are in use with the KIMBERLY-CLARK* Patient Warming System M1000 Control Unit concurrently.
  - Is the system set to Automatic or Manual Mode? If operating in Manual Mode and the patient's skin integrity and tissue perfusion are acceptable, adjust the water target temperature to a higher set point.
    CAUTION: Do not set the water temperature to 42ºC for greater than 4 hours.
  - If operating in Automatic Mode press Stop, then using the Up and Down Arrows, scroll to the Maximum Water Target Screen and ensure that the temperature is set to the highest possible setting for the patient and procedure.

ISSUE:
When warming in Automatic Mode, water temperature begins to decrease prior to reaching the target

ACTION:
As the patient's temperature increases, the control algorithm will decrease the water temperature to bring the patient to target with minimal overshoot. This is a normal function. Water temperature will increase or decrease to maintain the target.

ISSUE:
Patient Temperature on the display screen changes significantly within seconds

ACTION:

- Check the connection between the patient temperature probe and the temperature cable attached to the KIMBERLY-CLARK* Patient Warming System M1000.
- Ensure that the connection between the temperature probe and cable is kept thoroughly dry. If wet, replace the cable.
- If a Foley catheter temperature probe is in use, make certain it is not leaning against the Pads or Patient Lines. Foley probes may read low when urine flows retrograde past the sensor.

5.2 Troubleshooting
(continued)

- Check location and security of the temperature probe. In some cases, rectal probes may be displaced in incontinent patients. Nasopharyngeal probes may slip into the mouth and read room temperature.
- If the temperature changes cannot be corrected, replace the temperature probe

ISSUE:
Patient Temperature is not displayed on the screen

ACTION:
- Ensure that the connection between the temperature probe and the cable is secure.
- Ensure that the cable connection to the back of the Patient Warming System M1000 Control Unit is secure.
- If the temperature cable is wet, replace with a new cable.

NOTE: If temperature is out of range three dashes (---) will appear on the screen.

ISSUE:
Flow rate is below expected values for the number of pads being used after unit has been run for at least 30 minutes:

<1.5 liters per minute for 2 pads

<2.2 liters per minute for 3 pads

ACTION:
- Check filter. Replace if clogged.
- Check to see if any lines are kinked.
- Check for air bubbles in Pad Line. If air is present, then check Pad Line connection to Fluid Delivery Line. If air bubbles appear to come from pad, replace pad. If bubbles appear to come from Fluid Delivery Line, then change Fluid Delivery Line.

For additional information contact your Kimberly-Clark sales representative or Kimberly-Clark customer service at 1-800-KC-HELPS.

Appendix A — Installation & Test Procedure

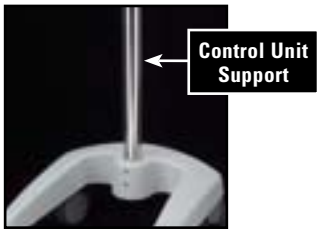


Figure 1

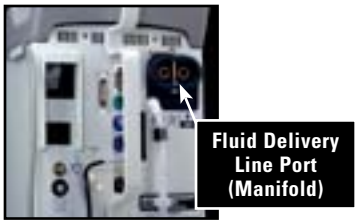


Figure 2

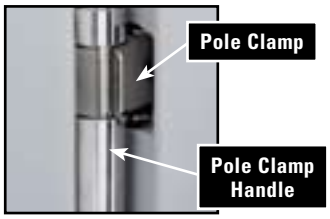


Figure 3

Tools Needed: 1/8" Hex Wrench

1. Unpack both boxes associated with the KIMBERLY-CLARK* Patient Warming System M1000: the Control Unit (Part # 01000-01) and the Installation Kit (Part # 00839-01).
2. Insert the Steel Pole into the moulded base of the cart. Align the depressions in the pole with the screws in the base of the cart and tighten these screws with a 1/8" Hex Wrench. (Figure 1) Adjust the top pole such that the hook at the top points away from the base.
3. Ensure all four wheels of the cart won't move by pressing down on the latch on the wheel. This will aid in attaching the control unit to the cart.
4. Remove the control unit from the plastic bag and wipe down any condensation on the exterior of the unit.
5. Remove the plugs from the Manifold on the back of the unit, and the foam plug from the vent hole. (Figure 2)
6. Open the pole clamp on the control unit by turning the handle on the side of the unit counterclockwise. (Figure 3)
7 Carefully lift the control unit such that the clamp fits just on top of the support ledge on the pole. Tighten down the pole clamp by turning the pole clamp handle clockwise until just snug. (Figure 4) Raise top pole and rotate so curve is extended over control unit.
8. Remove the fill tube (Part # 00809-02) from its bag and attach it to the fill tube port located just below the Fluid Delivery Line connection. (Figure 5)
9. Remove the User Interface Cable [Part # 00832-01(42 in.) or Remote Display Cable Part # 00832-02 (15 ft.)] from its bag and attach it to the UI Cable Port on the back of the control unit.

   NOTE: It is important that the thumbscrews on the connector be tightened securely to assure a good connection. (Figures 6 & 7)

10. Locate a butterfly nut and a cable clamp in the strain relief kit (Part # 00832-99) Place the UI Cable in the cable clamp (clamp should be just snug on the cable). Leaving approximately 3 in.(7.5 cm) of cable from the clamp to the connector, place the clamp on the top metal screw stud located next to the power outlet. Secure the clamp with the butterfly nut provided.

Appendix A — Installation & Test Procedure
(continued)

Figure 4

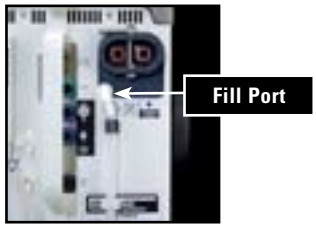


Figure 5

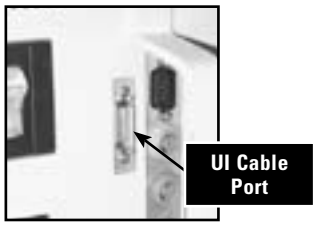


Figure 6

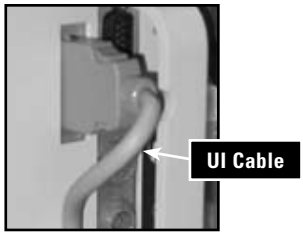


Figure 7

Figure 8

11. Remove the User Interface (Part # 00831-02) from its box. The clamp on the bottom of the User Interface must be rotated 90 degrees before securing it to the pole *(Figure 8 to Figure 9)*. Secure the User Interface to the cart pole.
12. Connect the free end of the User Interface Cable to the plug at the base of the User Interface and tighten the thumbscrews securely. Coil and secure cable and place it on the holder just below the top of the tank.
13. Remove the power cable (Part # 00833-01) from its bag and attach it to the power outlet on the back of the CU (Figure 10). Coil and secure the cable and place it on the lower holder on the back of the CU.
14. Remove the Fluid Delivery Line (Part # 00834-05) from its bag and attach it to the back of the unit at the manifold. Insert the connector in the manifold (may require jiggling the connector to seat it properly) then secure the connector by moving the latch on the top of the manifold from right to left. (Figure 11).
15. Remove the Patient Temperature Probe adapter (Part # 00835-02) from its bag and attach the blue and grey connector to the Patient Temp 1 Port on the back of the unit. Patient Temp 2 Port is not used except for special situations where dual patient temperature measurement is required. (Figure 13)
16. Using the remaining butterfly nut and clamp, find the strain relief kit and connect the port 2 cable to the second threaded bolt next to the power cable. (Figure 12)
17. Remove the Patient Temperature Output Cable [Part # 00835-52(Nellcor)] from its bag and attach the black and grey connector to the Temp Out Port on the back of the unit. (Figure 13)

Initial Test

1. Turn the unit on by pressing the On/Off switch located above the power cable. The unit will go through a self-check signaled by a single alarm. When the self-check is complete, the unit will then check fluid level and an Alarm 4 (low water level) will sound. Silence the alarm by pressing the Alarm indicator button. The unit will then display the Main Menu.
2. Locate the container of cleaning solution from the cleaning kit (Part # 00838-01). Obtain an additional 2 liters of distilled or sterile water.
3. On the User Interface, press the Down Arrow until the screen appears below. Press Enter. The screen will then read, "Place the Fill Tube in the container of water. Press Enter to fill." Press Enter again.

   Press the Down Arrow Key once until the screen reads, "Water Target temperature XX, Press Enter to change." Press Enter.
4. Then take the end of the fill tube and place it in the cleaning solution. The machine will aspirate the entire solution from the container. When the vial is empty, transfer the fill tube to the 2 liters of distilled or sterile water obtained. The unit will then aspirate the remaining fluid.

Appendix A — Installation & Test Procedure
(continued)

Figure 9

Figure 10

Figure 11

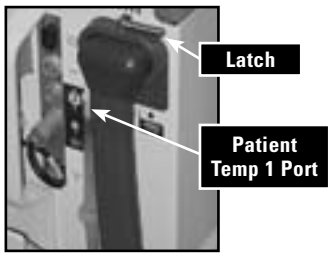


Figure 12

Figure 13

5. When the machine is full, the pump will stop and the screen will read, "Fill Complete." Press Enter at this point.
6. Gently shake and tap the Fill Tube to remove residual water from the line and secure the line to the back of the unit using the pre-attached clamps.
7. Attach the recirculating line (Part # 00809-04) to the end of the fluid deliver line.
8. Press the Manual Key on the User Interface.
9. The target temperature will begin blinking. Using the arrow keys, adjust the temperature up or down to 41°C (105.8ºF). Press Enter when complete.
10. Allow the machine to run for approximately 5 minutes. Verify that the flow rate displayed is at least 3 L/min and that the temperature is climbing. The water temperature should reach 41°C (105.8ºF) within 10 minutes. Some overshoot (approximately 0.5°C) is normal, while the unit will eventually settle at the target temperature +/- 0.1°C/F.
11. Change the water temperature set point to 30°C (86ºF) by pressing the Down Arrow Key again until the screen reads, "Water Temp Target XX, press Enter to change." Adjust as before, and press Enter when complete.Verify that the cooling fan comes on and that the water temperature begins to cool. The unit should reach 30°C (86ºF) within 15 to 20 minutes.
12. Once the unit has reached 30°C (86ºF), purge the system by pressing the Purge Key . Verify that the water is removed from the recirculating line.
13. Turn off the KIMBERLY-CLARK* Patient Warming System M1000 Control Unit and remove the recirculating line.
14. The unit is now ready for use.

Appendix B — Alarms/Alerts: Descriptions and Specifications

ALARM CONDITION:

When an Alarm condition occurs, there is a chance that a potentially unsafe condition has occurred, or could occur with respect to the equipment, the patient, or an improperly functioning system.

ALERT CONDITION:

Alerts are intended to inform the user about patient and equipment status, without interrupting the procedure.

The following chart represents all potential alarms or alerts that might occur, a description of the condition, the status of the system during the alarm or alert, and potential corrective action items. If the operator cannot troubleshoot the condition, note the alarm or alert number and phone Kimberly-Clark Service.

CAUTION: It is advisable not to cancel the alarm or alert until the situation is resolved. If an alarm is cancelled and the condition has not been cleared, the alarm will recur. If an alert is cancelled and the alert condition has not been cleared, the alert will not recur unless the Stop Mode is activated or the KIMBERLY-CLARK* Patient Warming System M1000 has been turned to the OFF position.

SPECIFICATIONS:
ALARMS AND ALERTS

Parameter	Specification
Water Temperature High Alarm 10 seconds	>42.5ºC (108.5ºF) for 10 seconds
Water Temperature Low Alarm	>42.5ºC(108.5ºF) for 10 seconds
System Patient Temperature High Alarm	38.0ºC (100.4ºF)
System Patient Temperature Low Alarm	32.0ºC (89.6ºF)
Adjustable Patient Temperature High Alert	10.1ºC to 42.0ºC (50ºF to 107.5ºF)
Adjustable Patient Temperature Low Alert Patient Probe Fault Alarm Water Flow Alert	10.0ºC to 41.9ºC (50ºF to 107.5ºF) Short or Open 50% of case maximum
System Water Temperature High Alarm	43.0ºC (109.4ºF/111.2ºF)
System Patient Temperature Low Alarm	3.0ºC (37.4ºF)
Resivor Level Alert then Alarm	Low then Empty
System Self-Test Alarm	At power up

Appendix C — Alarm/Alert Table

Alarm/ Alert	Message Displayed	Alarm/Alert Description	System Status	Action
01	Low fluid pressure in lines. Check connections. Alert	Patient Line is open to air, leaking or has significant air in line.	Current Mode continues. Audio alarm half-second tone every 2 minutes. Alarm/Alert indicator flashing	• Check all connections. • Check for air leak in pads or patient lines. • Check connections between patient lines and fluid delivery line. • Check connection of fluid delivery line to the system. • Check Fluid Delivery Line filter and ensure it is not clogged (see section 4.4 of manual) • Make certain all fittings are secure. • Listen to hear if pump is running. If not, contact Kimberly-Clark Service. • If situation is corrected, cancel alert.
02	Low water flow to pads. Check lines, connections and pads. Alert	Flow to the pads is decreased by >50% of the maximum flow detected during the case or since the last low flow alert, or the flow is < 0.3 liters per minute (300 ml/minute).	Current Mode continues. Audio alarm half-second tone every 2 minutes. Alarm/Alert indicator flashing.	• Check all connections. • Check for air leak in pads or patient lines. • Check connections between patient lines and fluid delivery line. • Check connection of fluid delivery lines to the system. • Make certain all fittings are secure. • Check to make sure that lines are not kinked or blocked. • Check Fluid Delivery Line filter and ensure it is not clogged (see section 4.4 of manual) • Listen to hear if pump is running. If not, contact Kimberly-Clark Service. • If situation is corrected, cancel alert.
03	Water reservoir level low. Alert	Reservoir fluid level almost empty. There is only enough water left in the reservoir to run one procedure.	Alert occurs after Purge is complete, at start up, or after a fill cycle. Audio alarm half-second tone every 2 minutes. Alarm/ Alert indicator flashing.	• If connected to pads, purge pads. • Fill Reservoir.
04	Water reservoir level empty. Fill reservoir or purge pads. Alarm	Reservoir level is empty or below the minimum to run the system.	Remains in Stop Mode. Audio alarm half-second tone every 10 seconds. Alarm indicator flashing.	• If connected to pads, purge pads. • Fill Reservoir.
05	Water reservoir level empty. Fill reservoir. Alarm	After pads are purged, reservoir is empty or below minimum required to run the system.	Changes to Stop Mode. Audio alarm half-second tone every 10 seconds. Alarm indicator flashing.	• If connected to pads, purge pads. • Fill Reservoir.

Appendix C — Alarm/Alert Table

Alarm/ Alert	Message Displayed	Alarm/Alert Description	System Status	Action
06	Water reservoir level empty. Fill reservoir. Alarm	Reservoir is empty.	Changes to Stop Mode. Audio alarm half-second tone every 10 seconds. Alarm/ Alert indicator flashing.	• If connected to pads, purge pads. • Fill Reservoir.
07	Purge not complete. Pads may contain extra water. Alarm	A significant amount of water was still being returned from the pads at the end of the purge cycle.	Remains in Stop Mode (at end of purge). Audio alarm half-second tone every 2 minutes. Alarm indicator flashing.	• Pads may contain a significant amount of water. • Use caution when removing pads from machine to avoid spilling water. • Machine may have been overfilled. Check level. • May indicate a machine malfunction, contact Clinical/Biomedical Engineering or Kimberly-Clark Service if problem persists and the reservoir is not overfilled.
08	System warming and Patient Temperature 1 high. Alarm	Patient Temperature 1 reading is above 38°C (100.4°F), water temperature is above 38°C (100.4°F) and system is unable to cool in Automatic Mode.	Changes to Stop Mode. Audio alarm half-second tone every 2 minutes. Alarm indicator flashing.	• Verify patient temperature from another source. • Press Automatic Mode and observe water temperature to see if it has started to cool. • Check that the vents on the sides of the machine are not blocked. • If water temperature does not decrease, turn system off and allow to system to cool. • Restart Automatic Mode. • If water temperature does not fall in response to patient temperature, shut system off and call Kimberly-Clark Service.
09	Patient Temperature 1 above user-defined limit. Alert	Patient Temperature 1 reading is equal to or greater than the user-defined value established in the custom settings menu	Current Mode continues. Audio alarm half-second tone every 2 minutes. Alarm/ Alert indicator flashing.	• Check patient temperature. • Cancel alert. • If system stopped, alert will re-appear. • Adjust Patient High Temperature Alert in the custom menu, if desired.
10	System cooling and Patient Temperature 1 low. Alarm	Patient Temperature 1 reading is below 32°C (89.6°F), water temperature is below 32°C (89.6°F) and the system is unable to heat in Automatic Mode	Changes to Stop Mode. Audio alarm half-second tone every 10 seconds. Alarm/Alert indicator flashing.	• Operate the system in manual mode with a set point above room temperature. • When set point temperature has been reached, press Automatic Mode and observe water temperature to see if it has started to warm. • Verify patient temperature from another source. • Turn system off. • Restart Automatic Mode. • If water temperature does not rise in response to patient temperature, shut system off and call Kimberly-Clark Service.
11	Patient Temperature 1 below user-defined limit Alert	Patient Temperature 1 reading is equal or less than the user-defined value established in the custom settings menu.	Current Mode continues. Audio alarm half-second tone every 2 minutes. Alarm/ Alert indicator flashing.	• Check patient temperature. • Cancel alert. • If system stopped, alert will re-appear. • Adjust Patient Low Temperature Alert in the custom menu, if desired.

Appendix C — Alarm/Alert Table

Alarm/ Alert	Message Displayed	Alarm/Alert Description	System Status	Action
12	Patient and water temperature high. Check water temperature. Alert	Patient Temperature 1 reading is above 38°C (100.4°F), water temperature is above 38°C (100.4°F) and the system is unable to cool in Manual Mode.	Current Mode continues. Audio alarm half-second tone every 2 minutes. Alarm/Alert indicator flashing.	• Check that the vents on the sides of the machine are not blocked. • Reduce Water Target Temperature.
13	Patient and water temperature low. Check water temperature. Alert	Patient Temperature 1 reading is below 32°C (89.6°F), water temperature is below 32°C (89.6°F) and the system is unable to heat in Manual Mode.	Changes to Stop Mode. Audio alarm half-second tone every 2 minutes. Alarm/Alert indicator flashing	• Increase Water Target Temperature.
14	Patient Temperature 1 probe disconnected or out of range. Alarm	Patient Temperature 1 reading is outside the lower limits of the display range in Automatic Mode.	Changes to Stop Mode. Audio alarm half-second tone every 10 seconds. Alarm/Alert indicator flashing.	• Check that patient temperature probe is properly placed and has not been dislodged. • Check connection of patient temperature probe and cable connection. If wet, replace cable. Check temperature cable at back of machine. • Test the input with a cable and probe proven good on another Patient Warming System. If the new cable performs correctly, replace the original cable.
15	Unable to obtain stable patient temperature for Automatic control. Alarm	Patient temperature discontinuity. Significant change in patient temperature reading for more than 10 minutes.	Changes to Stop Mode. Audio alarm half-second tone every 10 seconds. Alarm/ Alert indicator flashing.	• Check that patient temperature probe is properly placed and has not been dislodged. • Check connection of patient temperature probe and cable connection. If wet, replace cable. Check temperature cable at back of machine. • Test the input with a cable and probe proven good on another Patient Warming System. If the new cable performs correctly, replace the original cable.
16	Temperature probe 1 malfunction. Replace temperature probe or cable. Alarm	Patient Temperature 1 reading is outside the high limit of the display range in Automatic Mode.	Changes to Stop Mode. Audio alarm half-second tone every 10 seconds. Alarm/Alert indicator flashing.	• Check that patient temperature probe is properly placed and has not been dislodged. • Check connection of patient temperature probe and cable connection. If wet, replace cable. Check temperature cable at back of machine. • Test the input with a cable and probe proven good on another Patient Warming System. If the new cable performs correctly, replace the original cable.

Appendix C — Alarm/Alert Table

Alarm/ Alert	Message Displayed	Alarm/Alert Description	System Status	Action
17	Patient Temperature 1 calibration error. Restart system. Alarm	In Automatic Mode, internal temperature calibration from Patient Temperature 1 probe input is not functioning.	Changes to Stop Mode. Audio alarm half-second tone every 10 seconds. Alarm/ Alert indicator flashing.	• Check that patient temperature probe is properly placed and has not been dislodged. • Contact Clinical/Biomedical Engineering or Kimberly-Clark Service to verify calibration. • System may be run in Manual Mode, but patient temperature will be displayed as three dashes (---).
18	Patient Temperature 1 calibration error. Restart system. Alarm	In Manual Mode, internal temperature calibration from the Patient Temperature 1 probe input is not functioning.	Current Mode continues. Audio alarm half-second tone every 2 minutes. Alarm/Alert indicator flashing.	• Check that patient temperature probe is properly placed and has not been dislodged. • Contact Clinical/Biomedical Engineering or Kimberly-Clark Service to verify calibration. • System may be run in Manual Mode, but patient temperature will be displayed as three dashes (---).
19	Patient Temperature 1 calibration error. Restart system. Alarm	In Automatic Mode, internal temperature calibration from Patient Temperature 1 probe input is not functioning.	Changes to Stop Mode. Audio alarm half-second tone every 10 seconds. Alarm/Alert indicator flashing.	• Check that patient temperature probe is properly placed and has not been dislodged. • Contact Clinical/Biomedical Engineering or Kimberly-Clark Service to verify calibration. • System may be run in Manual Mode, but patient temperature will be displayed as three dashes (---).
20	System is cooling and Patient Temperature 2 low. Alert	Patient Temperature 2 reading is below 32°C (89.6°F), water temperature is below 32°C (89.6°F) and the system is unable to heat in Manual Mode.	Current Mode continues. Audio alarm half-second tone every 2 minutes. Alarm/Alert indicator flashing.	• Increase Water Target Temperature.
21	Patient Temperature 1 calibration error. Restart system. Alarm	Patient Temperature 2 reading is above 38°C (100.4°F), water temperature is above 38°C (100.4°F) and system is unable to cool in Automatic Mode.	Changes to Stop Mode. Audio alarm half-second tone every 10 seconds. Alarm/Alert indicator flashing.	• Verify patient temperature from another source. • Press Automatic Mode and observe water temperature to see if it has started to cool. • Check that the vents on the sides of the machine are not blocked. • If water temperature does not decrease, turn system off and allow to system to cool. • Restart Automatic Mode.
22	Patient Temperature 2 above user-defined limit. Alert	Patient Temperature 2 reading isequal to or greater than the user-defined value established in the custom settings menu.	Current Mode continues. Audio alarm half-second tone every 2 minutes. Alarm/Alert indicator flashing.	• Check patient temperature. • Cancel alert. • If system stopped, alert will re-appear. • Adjust Patient High Temperature. • Alert in the custom menu if desired.

Appendix C — Alarm/Alert Table

Alarm/ Alert	Message Displayed	Alarm/Alert Description	System Status	Action
23	Patient Temperature 2 low. Check patient temperature. Alarm	Patient Temperature 2 reading is below 32°C (89.6°F), water temperature is below 32°C (89.6°F) and the system is unable to heat in Automatic Mode.	Changes to Stop Mode. Audio alarm half-second tone every 10 seconds. Alarm/Alert indicator flashing.	• Press Automatic Mode and observe water temperature to see if it has started to warm. • Verify patient temperature from another source. • Turn system off. • Restart Automatic Mode. • If water temperature does not rise in response to patient temperature, shut system off and call Kimberly-Clark Service.
24	Patient Temperature 2 below user-defined limit. Alert	Patient Temperature 2 reading is equal to or greater than the user-defined value established in the custom settings menu.	Current Mode continues. Audio alarm half-second tone every 2 minutes. Alarm/Alert indicator flashing.	• Increase Water Target Temperature.
25	System is warming and Patient Temperature 2 high. Alert	Patient Temperature 2 reading is above 38°C (100.4°F) and water temperature is above 38°C (100.4°F) and the system is unable to cool in Manual Mode	Current Mode continues. Audio alarm half-second tone every 2 minutes. Alarm/Alert indicator flashing.	• Check that the vents on the sides of the machine are not blocked. • Reduce Water Target Temperature.
26	System is cooling and Patient Temperature 2 low. Alert	Patient Temperature 2 reading is below 32°C (89.6°F), water temperature is below 32°C (89.6°F) and the system is unable to heat in Manual Mode	Current Mode continues. Audio alarm half-second tone every 2 minutes. Alarm/Alert indicator flashing.	• Increase Water Target Temperature.
27	Patient Temperature 2 probe disconnected or out of range. Alarm	Patient Temperature 2 reading is outside the lower limits of the display range in Automatic Mode.	Changes to Stop Mode. Audio alarm half-second tone every 10 seconds. Alarm/Alert indicator flashing.	• Check that patient temperature probe is properly placed and has not been dislodged. • Check connection of patient temperature probe and cable connection. If wet, replace cable. Check temperature cable at back of machine. • Test the input with a cable and probe proven good on another Patient Warming System. If the new cable performs correctly, replace the original cable.

Appendix C — Alarm/Alert Table

Alarm/ Alert	Message Displayed	Alarm/Alert Description	System Status	Action
28	Temperature probe 2 malfunction. Replace temperature probe or cable.	Patient Temperature 2 reading is outside the lower limits of the display range in Automatic Mode.	Changes to Stop Mode. Audio alarm half-second tone every 10 seconds. Alarm/ Alert indicator flashing.	• Check that patient temperature probe is properly placed and has not been dislodged. • Check connection of patient temperature probe and cable connection. If wet, replace cable. Check temperature cable at back of machine. • Test the input with a cable and probe proven good on another Patient Warming System. • If the new cable performs correctly, replace the original cable.
29	Patient Temperature 2 calibration error. Restart system. Alarm	In Automatic Mode, internal temperature calibration from the Patient Temperature 2 probe input is not functioning.	Changes to Stop Mode. Audio alarm half-second tone every 10 seconds. Alarm/Alert indicator flashing.	• Check that patient temperature probe is properly placed and has not been dislodged. • Contact Clinical/Biomedical Engineering or Kimberly-Clark Service to verify calibration. • System may be run in Manual Mode, but patient temperature will be displayed as three dashes (---).
30	Temperature probe 2 malfunction. Replace temperature probe or cable.	In Manual Mode, internal temperature calibration from the Patient Temperature 2 probe input is not functioning.	Current Mode continues. Audio alarm half-second tone every 2 minutes. Alarm/Alert indicator flashing.	• Check that patient temperature probe is properly placed and has not been dislodged. • Contact Clinical/Biomedical Engineering or Kimberly-Clark Service to verify calibration. • System may be run in Manual Mode, but patient temperature will be displayed as three dashes (---).
31	Patient Temperature 2 calibration error. Restart system. Alarm	In Automatic Mode, internal temperature calibration from the Patient Temperature 2 probe input is not functioning.	Changes to Stop Mode. Audio alarm half-second tone every 10 seconds. Alarm/Alert indicator flashing.	• Check that patient temperature probe is properly placed and has not been dislodged. • Contact Clinical/Biomedical Engineering or Kimberly-Clark Service to verify calibration. • System may be run in Manual Mode, but patient temperature will be displayed as three dashes (---).
32	Patient Temperature 2 calibration error. Restart system. Alarm	In Manual Mode, internal temperature calibration from the Patient Temperature 2 probe input is not functioning.	Current Mode continues. Audio alarm half-second tone every 2 minutes. Alarm/Alert indicator flashing.	• Check that patient temperature probe is properly placed and has not been dislodged. • Contact Clinical/Biomedical Engineering or Kimberly-Clark Service to verify calibration. • System may be run in Manual Mode, but patient temperature will be displayed as three dashes (---).
33	Water temperature high. Allow system to cool. Alarm	Water temperature is above 44°C (111.2°F).	Changes to Stop Mode. Audio alarm half-second tone every 10 seconds. Alarm/Alert indicator flashing.	• This alarm may be caused by transient conditions such as a momentary occlusion, air bolus, hot restart, or no-load condition. • Check flow rate. Low flow rate or fluctuating flow rates may cause overheating the water. • Wait until water cools. • Restart Automatic Mode or Manual Mode. • If problem persists, contact Kimberly-Clark Service.

Appendix C — Alarm/Alert Table

Alarm/ Alert	Message Displayed	Alarm/Alert Description	System Status	Action
34	Water temperature high. Allow system to cool. Alarm	Water temperature is above 42.5°C (108.5°F).	Changes to Stop Mode. Audio alarm half-second tone every 10 seconds. Alarm/Alert indicator flashing.	• This alarm may be caused by transient conditions such as a momentary occlusion, air bolus, hot restart, or no-load condition. • Check flow rate. Low flow rate or fluctuating flow rates may cause overheating of the water. • Wait until water cools. Restart Automatic Mode or Manual Mode. • If problem persists, contact Kimberly-Clark Service.
35	Water temperature low. Allow system to warm. Alarm	Water temperature is below 3.5°C (38.3°F).	Changes to Stop Mode. Audio alarm half-second tone every 10 seconds. Alarm/Alert indicator flashing.	• This alarm may be caused by transient conditions such as a momentary occlusion, air bolus, hot restart, or no-load condition. • Wait until water warms. Restart Automatic Mode or Manual Mode. • If problem persists, contact Kimberly-Clark Service.
36	Water temperature above safety level. Allow system to cool. Alarm	Water temperature is below 44°C (111.2°F).	Changes to Stop Mode. Audio alarm half-second tone every 10 seconds. Alarm/Alert indicator flashing.	• This alarm may be caused by transient conditions such as a momentary occlusion, air bolus, hot restart, or no-load condition. • Check flow rate. Low flow rate or fluctuating flow rates may cause overheating of the water. • Wait until water cools. Restart Automatic Mode or Manual Mode. • If problem persists, contact Kimberly-Clark Service.
37	Water temperature below safety level. Allow system to warm. Alarm	Water temperature is below 3.5°C (38.3°F).	Changes to Stop Mode. Audio alarm half-second tone every 10 seconds. Alarm/Alert indicator flashing.	• This alarm may be caused by transient conditions such as a momentary occlusion, air bolus, hot restart, or no-load condition. • Wait until water warms. Restart Automatic Mode or Manual Mode. • System can be run in Manual Mode, but Water Target Temperature should be increased. • If problem persists, contact Kimberly-Clark Service.
38	Water temperature below safety level. Allow system to warm. Alarm	Water temperature is below 3°C (37.4°F).	Changes to Stop Mode. Audio alarm half-second tone every 10 seconds. Alarm/Alert indicator flashing.	• This alarm may be caused by transient conditions such as a momentary occlusion, air bolus, hot restart, or no-load condition. • Wait until water warms. Restart Automatic Mode or Manual Mode. • System can be run in Manual Mode, but Water Target Temperature should be increased. • If problem persists, contact Kimberly-Clark Service.
40	System unable to maintain stable water temperature. Alarm	Alarm In Manual Mode, system is unable to control water within 1.0°C/F of set point after 25 minutes in current mode or at the time of last change in Water Target Temperature.	Changes to Stop Mode. Audio alarm half-second tone every 10 seconds. Alarm/Alert indicator flashing.	• Contact Kimberly-Clark Service.

Appendix C — Alarm/Alert Table

Alarm/ Alert	Message Displayed	Alarm/Alert Description	System Status	Action
41	Low bypass flow. Heating not available. Alert	Insufficient internal flow during priming or bypass mode.	Current Mode continues. Audio alarm half-second tone every 2 minutes. Alarm/Alert indicator flashing	• Contact Kimberly-Clark Service to determine cause of low bypass flow.
43	User settings not saved. System default settings restored. Alarm	Saved customer user profile settings are invalid.	Current Mode continues. Audio alarm half-second tone every 2 minutes. Alarm/Alert indicator flashing.	• Check all custom user settings and temperature alerts before restarting procedure. Save all values. • Contact Kimberly-Clark Service if problem persists.
46	User Interface Disconnect. Alarm	User Interface not detected by control system.	Changes to Stop Mode. Audio alarm half-second tone every 10 seconds. Alarm/Alert indicator flashing.	• Check user interface cable connections on the user interface module and KIMBERLY-CLARK* Patient Warming System M1000 Control Unit. • If the error persists, replace the User Interface Cable and power up. • If problem continues, replace User Interface. • Contact Kimberly-Clark Service.
47	User Interface Disconnect. Alert	User Interface not detected by control system.	Current Mode continues. Audio alarm half-second tone every 2 minutes. Alarm/Alert indicator flashing.	• Check user interface cable connections on the user interface module and KIMBERLY-CLARK* Patient Warming System M1000 Control Unit. • If the error persists, replace the User Interface Cable and power up. • If problem continues, replace User Interface. • Contact Kimberly-Clark Service.
48	Patient Temperature Output invalid. Alarm.	Alarm In Manual Mode, system is unable to control water within 1.0°C/F of set point after 25 minutes in current mode or at the time of last change in Water Target Temperature.	Changes to Stop Mode. Audio alarm half second tone every 10 seconds. Alarm/Alert indicator flashing.	• Contact Kimberly-Clark Service.
49	Patient Temperature Out system error. Alarm	Calculated Patient Temperature Output (Echo) is ±0.1°C/F from measured Patient Temperature 1 (primary patient temperature).	Changes to Stop Mode. Audio alarm half-second tone every 10 seconds. Alarm/Alert indicator flashing.	• Contact Kimberly-Clark Service.

Appendix C — Alarm/Alert Table

Alarm/ Alert	Message Displayed	Alarm/Alert Description	System Status	Action
50	Patient Temperature 1 erratic. Check temperature probe. Alert	Patient temperature discontinuity. Significant change in patient temperature reading for more than 8 minutes.	Current Mode Continues. Audio alarm half-second tone every 2 minutes. Alarm/Alert indicator flashing.	• Check that patient temperature probe is properly placed and has not been dislodged.
51	Patient Temperature 1 below control range. Check temperature probe. Alert	Patient temperature less than 33°C (91.4°F) when Automatic Mode entered.	Current Mode continues. Audio alarm half-second tone every 2 minutes. Alarm/Alert indicator flashing	• Verify accuracy of reading. • Make sure the probe is properly placed and has not been dislodged. • Verify patient temperature is below 34° C via independent temperature measurement. • If patient temperature is low, warm in Manual Mode until patient temperature is above 33° C. • If outside measurement is >34° C, then check connection of patient temperature probe and cable connection. If wet, replace cable. • Test the input with a cable and probe proven good on another Patient Warming System. If the new cable performs correctly, replace the original cable.
52	Non-recoverable system fault. Refer to Operator's Manual. Alarm	System error that cannot be managed without speaking to Kimberly-Clark.	Changes to Stop Mode. Audio alarm half-second tone every 10 seconds. Alarm/Alert indicator flashing.	• Power off. • Contact Clinical/Biomedical Engineering or Kimberly-Clark Service.
61	Parameter Memory invalid. (Control) Alarm	Control Processor parameter memory fault.	Changes to Stop Mode. Audio alarm half-second tone every 10 seconds. Alarm/Alert indicator flashing.	• Contact Kimberly-Clark Service.
62	Parameter Memory invalid. (Monitor) Alarm	Monitor Processor parameter memory fault.	Changes to Stop Mode. Audio alarm half-second tone every 10 seconds. Alarm/Alert indicator flashing.	• Contact Kimberly-Clark Service.
64	Safety Intervention Mechanism Power Up Test #1 Fault. Alarm	Unable to enable pump power. (Control)	Changes to Stop Mode. Audio alarm half-second tone every 10 seconds. Alarm/Alert indicator flashing.	• Contact Kimberly-Clark Service.

Appendix C — Alarm/Alert Table

Alarm/ Alert	Message Displayed	Alarm/Alert Description	System Status	Action
65	Safety Intervention Mechanism Power Up Test #2 Fault. Alarm	Unable to enable pump power. (Monitor)	Changes to Stop Mode. Audio alarm half-second tone every 10 seconds. Alarm/Alert indicator flashing.	• Contact Kimberly-Clark Service.
66	Safety Intervention Mechanism Power Up Test #3 Fault. Alarm	Unable to disable pump power. (Control)	Changes to Stop Mode. Audio alarm half-second tone every 10 seconds. Alarm/Alert indicator flashing.	• Contact Kimberly-Clark Service.
67	Safety Intervention Mechanism Power Up Test #4 Fault. Alarm	Unable to disable pump power. (Monitor)	Changes to Stop Mode. Audio alarm half-second tone every 10 seconds. Alarm/Alert indicator flashing.	• Contact Kimberly-Clark Service.
68	LCD Write Fault. Alarm	LCD display communication fault.	Changes to Stop Mode. Audio alarm half-second tone every 10 seconds. Alarm/Alert indicator flashing.	• Check user interface cable connections on the user interface module and KIMBERLY-CLARK* Patient Warming System M1000 Control Unit. • If the error persists, replace the User Interface Cable and power up. • If problem continues, replace User Interface. • Contact Kimberly-Clark Service.
69	SPI Queue Overrun. Alarm	Interprocessor communication fault.	Changes to Stop Mode. Audio alarm half-second tone every 10 seconds. Alarm/Alert indicator flashing.	• Contact Kimberly-Clark Service.
70	AC Line Sync Fault. Alarm	Mains signal is missing or inconsistent.	Changes to Stop Mode. Audio alarm half-second tone every 10 seconds. Alarm/Alert indicator flashing.	• Contact Kimberly-Clark Service.
71	Primary Outlet Water Temperature Sensor Open. Alarm	T2 Thermistor signal out of range - high resistance.	Changes to Stop Mode. Audio alarm half-second tone every 10 seconds. Alarm/Alert indicator flashing.	• Contact Kimberly-Clark Service.

Appendix C — Alarm/Alert Table

Alarm/ Alert	Message Displayed	Alarm/Alert Description	System Status	Action
72	Primary Outlet Water Temperature Sensor Shorted. Alarm	T2 Thermistor signal out of range - low resistance.	Changes to Stop Mode. Audio alarm half-second tone every 10 seconds. Alarm/Alert indicator flashing.	• Contact Kimberly-Clark Service.
73	Secondary Outlet Water Temperature Sensor Open. Alarm	T1 Thermistor signal out of range - high resistance.	Changes to Stop Mode. Audio alarm half-second tone every 10 seconds. Alarm/Alert indicator flashing.	• Contact Kimberly-Clark Service.
74	Secondary Outlet Water Temperature Sensor Shorted. Alarm	T1 Thermistor signal out of range - low resistance.	Changes to Stop Mode. Audio alarm half-second tone every 10 seconds. Alarm/Alert indicator flashing.	• Contact Kimberly-Clark Service.
75	Inlet Water Temperature Sensor Open. Alarm	T3 Thermistor signal out of range - high resistance.	Changes to Stop Mode. Audio alarm half-second tone every 10 seconds. Alarm/Alert indicator flashing.	• Contact Kimberly-Clark Service.
76	Inlet Water Temperature Sensor Shorted. Alarm	T3 Thermistor signal out of range - low resistance.	Changes to Stop Mode. Audio alarm half-second tone every 10 seconds. Alarm/Alert indicator flashing.	• Contact Kimberly-Clark Service.
79	Outlet Water Temperature Sensor	T1 and T2 differ by more than 1.0 degree C		• Sensor disagreement can occur when unit is heated from a starting temperature of less than 20 °C. If this is the case, pre-heat the unit to 25 °C & then continue to use per normal operating instructions. • Contact Kimberly-Clark Service.
80	Outlet Water Temperature Overtemperature Test Failure (Control) Alarm	The Control Processor has failed to detect a simulated water temperature fault.		• Contact Kimberly-Clark Service.
81	Outlet Water Temperature Overtemperature Test Failure (Monitor) Alarm	The Monitor Processor has failed to detect a simulated water temperature fault.		• Contact Kimberly-Clark Service.

Appendix C — Alarm/Alert Table

Alarm/ Alert	Message Displayed	Alarm/Alert Description	System Status	Action
82	A/D Acquisition Fault. Alarm	A/D converter fault.		• Contact Kimberly-Clark Service.
83	Interprocessor communication failure (Monitor) Alarm	The Monitor Processor does not communicate.		• Contact Kimberly-Clark Service.
84	Interprocessor communication failure (Control) Alarm	The Control Processor does not communicate.		• Contact Kimberly-Clark Service.
85	Machine Type Fault. Alarm	Unit has very little or no cleaning solution in the reservoir.		• Turn unit off, drain unit, fill unit using cleaning kit (part #00838-01). See cleaning kit instructions for details. • Contact Kimberly-Clark Service.
86	Power Supply Fault. Alarm	Power supply voltage out of range.		• Contact Kimberly-Clark Service.
97	Processor Fault. Alarm	Processor Fault.		• Contact Kimberly-Clark Service.
98.X	Unexpected interrupt. Alarm	Processor fault.		• Contact Kimberly-Clark Service.
99	Processor Fault. Alarm	Processor Fault.		• Contact Kimberly-Clark Service.

Appendix D — Specification Table

General Parametre	Specification
Control Modes	Automatic, Manual, Purge, Stop
Heater Capability	750 W
Circulating Fluid	Distilled or Sterile Water
Reservoir Capacity	3 liters for initial set up
Water flow rate (total)	0.5 - 8.0 liter/min
Patient Probe Type	YSI 400 Series compatible
Number of Patient Probes	2 (Patient Probe 1, the primary probe which controls temperature; Patient Temperature 2, the secondary probe which monitors only)
Patient Temperature	10°C to 42°C (50ºF to 107.6ºF)
Display Range	0.1°C/ºF
Resolution	
Patient Temperature	±0.2°C/°F (32°C to 38°C) (89.6ºF to 100.4ºF)
Measurement Accuracy	±0.4°C (lower boundary to 32°C/89.6ºF) ±0.4°C (38°C/100.4ºF to upper boundary) (includes 0.1°C/ºF external probe)
Patient Temperature Control Range - Automatic Mode	33°C to 37°C (91.4ºF to 98.6ºF) In 0.1°C/ºF increments
Water Temperature Display Range Resolution	3°C to 45°C (37.4ºF to 113ºF) 1°C/ºF
Water Temperature Control Range - Manual Mode	20°C to 42°C (68ºF to 107.6ºF) In 0.1°C/F increments
Maximum Water Temperature (Automatic Mode)	32°C to 42°C (89.6ºF to 107.6ºF) In 1°C/F increments
Minimum Water Temperature (Automatic Mode)	20°C to 32°C (68ºF to 90ºF) In 1°C/F increments
Mains Input†	115VAC, 60 Hz, 8 A (nominal)
Current Leakage	< 300uA
Circuit Breaker	12 A Amp (115V)

†Mains supply voltage fluctuations are not to exceed ±10% of nominal supply voltage.

Appendix D — Specification Table (continued)

DIMENSIONS TABLE

Parameter	Specification
Maximum relative humidity (operating)	70%
Maximum relative humidity range (storage)	5-95%
Temperature range (operating)	10°C to 27°C (50ºF to 80ºF)
Temperature range (storage)	-30°C to 50°C (-20ºF to 120ºF)
Height of unit (handle down)	17.3" (43.9cm)
Length of unit 9.8" (25.9cm)	Width of unit 8.3" (21.1cm)
Weight of unit filled	37.4 lbs (17kg)

Appendix E — Product List

Part	Part Number
Patient Temperature Cable, Nellcor®	00835-02
Patient Temperature Cable, Bard®	00835-03
Temperature Output Cable, Nellcor®	00835-52
Temperature Output Cable, Bard®	00835-53
Power Cord, North America	00833-00
Remote Display Cable, 1.1 meter (42 inches)	00832-01
Remote Display Cable, 4.6 meter (15 feet)	00832-02
Fluid Delivery Line, Single	00834-04
Fluid Delivery Line, Y	00834-05
Fill Drain Tube	00809-02
Strain Relief Kit	00832-99
Recirculation Line	00809-04
Cart, M1000	00830-01
Cleaning Kit	00838-01
Install Kit, North America	00839-01
M1000 Control Unit	01000-01

Appendix F — Data Output

To collect data from the KIMBERLY-CLARK* Patient Warming System M1000 Control Unit use the RS232 Port on the rear of the device. Portable PDAs (personal data assistants) or computers can be connected to the Patient Warming System M1000 Control Unit to download data. The data stream can be received on a conventional PC by using Hyperterminal or other data collection programs using the following communication protocol. Data can be collected as often as every 5 seconds to every 10 minutes. To establish the desired interval, press the Stop Key. Scroll through the custom menu pressing the Up or Down Arrows until the Setup screen is displayed. Press Enter and continue to scroll through the options until Data Output Interval Screen is displayed. Press Enter and adjust the desired setting using the Up or Down Arrows. Press Enter to set the new value.

Data Output Parametres

Protocol: RS-232 Port Configuration
9600 Baud, 8 Data Bits, No Parity, 1 Stop Bit, No Handshake

Wiring: DB-9 connector

Pin No.	Function
Pin 2	Receive In
Pin 3	Transmit Out
Pin 4	5 Earth

The RS-232 connector wiring is configured for connection to a Palm PDA. Connection directly to a PC may require a "Null Modem" adapter.

Data Format:

The data output stream is a series of ASCII characters. A "$" is sent as the first item of a new data sequence. Each data item within the sequence is separated by a comma (ASCII 44). The data sequence is terminated with a carriage return character (ASCII 13) followed by a new line character (ASCII 10). The time since power up of each data sequence can be calculated from the Serial Sequence Number and Communications Output Interval.

Example: $,13,36.5,36.4,34.5,2,0,14.3,14.4,16.5,4.6,14.2,0,60,0,2.3,5,-7.1,0,45,165,1,0,0

Sequence No. Description Values 1 Sequence Start Indicator $ (ASCII 36)

Appendix F — Data Output (continued)

PARAMETRE SEQUENCE:

Sequence Number	Description	Values
1	Sequence Start Indicator	$(ASCII 36)
2	Serial Sequence Number	1,2,3,4,5..., Initialised at power up.
3	Patient Temperature 1	°C, 0 if probe not connected
4	Patient Temperature 2	°C, 0 if probe not connected
5	Patient Target Temperature	°C Regardless of current mode
6	Operating Mode	0 = Initialization, 1 = Stop, 2 = Automatic, 3 = Manual, 4 = Purge, 5 = Fill
7	Diagnostic Mode	0 = Normal Mode, 1 = Diagnostic Mode
8	Outlet Water Temperature Monitor	°C
9	Outlet Water Temperature	°C
10	Inlet Water Temperature	°C
11	Chiller Temperature	°C
12	Water Outlet Target Temperature	°C
13	Temperature Display Mode	0 = °C, 1
14	Communications Output Interval	Seconds
15	Current Alarm Number	See Alarm/Alert list for corresponding numbers
16	Flow Rate Liter/minute	
17	Reservoir Level Last Measured	5 or 4 = Full, 3= 3/4, 2 = 1/2, 1 = Low, 0 = Empty
18	Inlet Pressure	Pounds per square inch
19	Heater Power	0-32 where 32 = 100%
20	Mixing Pump Power	0-255 where 255 = 100%
21	Flow Pump Power	0-255 where 255 = 100%
22	Control Parametre Mode	0 = Surgical
23	Reserved Data	
24	Reserved Data	

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Healthcare-Associated Infection Solutions

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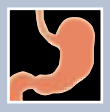

Digestive Health

Pain Management

Commitment to Excellence

If, for any reason, our products do not meet your expectations, please let us know your comments or suggestions for improvement. Your input will result in a concerted effort on our part to meet your requirements. Our goal is to provide quality products that completely meet your needs time after time.

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