## 16n1®

# THE 1-LITER BAG WARMING SYSTEM<sup>™</sup> OPERATORS MANUAL



## Medical Solutions, Inc.

3901 Centerview Drive, Suite L, Chantilly, VA 20151 (800) 435-7600 Phone • (703) 834-0039 Fax • <u>www.warmiv.com</u>

## TABLE OF CONTENTS

| 1.0   | Intended Use1  |
|-------|--|
| 2.0   | System Description1  |
| 2.1   | Important Labels and Directions1                             |
| 3.0   | General Operating Instructions2                              |
| 3.1   | Cleaning Instructions  |
| 4.0   | Specifications and Operating Information5                    |
| 4.1   | Specifications   |
| 4.2   | Ambient Operating Conditions                                 |
| 4.3   | Electrical Requirements                                      |
| 5.0   | Set-up Instructions  |
| 5.1   | The Documentor <sup>®</sup> Resetting Instructions7          |
| 5.1.1 | Changing The Documentor <sup>®</sup> Date7                   |
| 5.1.2 | Changing The Documentor <sup>®</sup> Time                    |
| 5.2   | Code Lock Instructions                                       |
| 5.2.1 | Changing the Code Lock Sub-Master Code9                      |
| 5.2.2 | Setting the Code Lock User Code9                             |
| 5.2.2 | .1 To Set Or Change the User Code Using the Sub-Master Code9 |
| 5.2.2 | .2 To Change the User Code Using the Current User Code:10    |
| 6.0   | Troubleshooting11  |
| 6.1   | Failure to Warm11  |
| _     | 5695.B   |

| 6.2                                    | Excessive Fluids In 16N1 <sup>®</sup>                               | 12 |  |  |  |
|--|---|----|--|--|--|
| 6.3                                    | "Reload" Displayed with Fluid Bag In Compartment                    | 12 |  |  |  |
| 6.4                                    | Time and Temperature Displayed for Compartment With No Bag Inserted | 12 |  |  |  |
| 6.5                                    | Set Point Can Not Be Changed  | 12 |  |  |  |
| 6.6                                    | Code Lock Does Not Work Correctly                                   | 12 |  |  |  |
| 6.7                                    | "Tripped" Error Code  | 12 |  |  |  |
| 6.8                                    | "Fault" Error Code  | 12 |  |  |  |
| 7.0                                    | Preventative Maintenance Plan                                       | 13 |  |  |  |
| 7.1                                    | Temperature Verification Procedures                                 | 13 |  |  |  |
| Appendix A: Electrical Schematics14    |   |    |  |  |  |
| Appendix B: Fuse Installation18        |   |    |  |  |  |
| Appendix C: Removing Service Panel 19  |   |    |  |  |  |
| Appendix D: Software License Agreement |   |    |  |  |  |
| Appendix E: Limited Warranty           |   |    |  |  |  |
| Арр                                    | Appendix F: In-Service Sign-In Sheet                                |    |  |  |  |

## TABLE OF FIGURES

| Figure 1 - Control Panel Display        | 2  |
|---|----|
| Figure 2 - Code Lock                    | 3  |
| Figure 3 - Master Power Switch Location | 6  |
| Figure 4 - Controller Schematic         | 14 |
| Figure 5 - Heating Tray Schematic       | 15 |
| Figure 6 - Fuse Locations               | 18 |
| Figure 7 - Service Panel                | 19 |

## 16N1<sup>®</sup> The 1-Liter Bag Warming System<sup>™</sup>

Please read and understand the Operators Manual before using the 16N1<sup>®</sup> 1-Liter Bag Warming System<sup>TM</sup>.

#### 1.0 INTENDED USE

The 16N1<sup>®</sup> is designed to store, rapidly warm, and maintain the temperature of fluid bags prior to their use.

It is suggested that each facility should contact the fluid manufacturer to obtain the manufacturer's specifications for maximum warming time and temperature for warming fluid.

#### 2.0 SYSTEM DESCRIPTION

The 16N1<sup>®</sup> holds sixteen (16) one liter fluid bags and is a warming system, which is mounted on a wheeled base. A temperature controller is used to regulate the heating of each fluid bag. The temperature controller has a large display (Control Panel Display. See Figure 1) to show:

- o Desired temperature (identified as the "Set Point" temperature)
- Current time and date
- o Actual fluid temperature of each bag
- o Length of time each bag has been in the 16N1<sup>®</sup>.

The Documentor<sup>®</sup> is designed to assist in the compliance with Joint Commission<sup>®</sup> standard MM 2.20 and the fluid bag manufacturer's specifications for maximum warming time and temperature.

#### 2.1 Important Labels and Directions

The following important labels and directions are found on the 16N1<sup>®</sup>. NOTE: Directions for replacing fuses can be found in Appendix B.

- o Rating/Model/Serial Number label.
- o Warning: Replace Fuse as Marked: 250V 0.5 Amp.
- o Warning: Replace Fuse as Marked: 250V 1.5 Amp.
- o Warning: Replace Fuse as Marked: 250V 15.0 Amp.
- Caution: Electrical shock hazard. Do not remove protective panel. Refer servicing to qualified personnel.
- o Danger: Risk of explosion if used in the presence of flammable anesthetics.
- Warming: Unit not intended for blood or blood products.
- o Ground Reliability Unit must be plugged into a Hospital Grade Receptacle.
- Use Receptacle for The Documentor<sup>®</sup> only.

#### 3.0 GENERAL OPERATING INSTRUCTIONS

- 1. Ensure the 16N1<sup>®</sup> is powered on. The 16N1<sup>®</sup> can be left on indefinitely without harm to the system.
- 2. The Control Panel Display (see Figure 1) provides critical information for the operation of the 16N1<sup>®</sup> including:
  - a) Current Date and Time. This information is preset by Medical Solutions, Inc. and can be changed during the set up of the 16N1<sup>®</sup>. Instructions for changing the date and time can be found in Section 5.0, "Set-Up Instructions".
  - b) Current Set Point Temperature. The Set Point identifies the desired temperature of the fluid bag. This is preset by Medical Solutions, Inc., and can be changed by following the instructions found in Section 5.0, "Set-Up Instructions".



Figure 1 - Control Panel Display

NOTE: Temperatures and times indicated in Figure 1 are examples only. Actual time to reach temperature may vary depending on factors such as the starting temperature of the fluid bag.

- c) Heating Compartment Information. Each of the sixteen (16) heating compartments has corresponding information presented on the Control Panel Display including:
  - Current Bag Temperature and Time-In identifies the actual temperature of the fluid bag and the amount of time the bag has been in the heating compartment. The Time-In indicator displays hours or days, depending on the length of time the fluid bag has been in the heating compartment. Please check with your bag manufacturer for specific recommendations for maximum temperature and length of storage time.
  - Reload identifies that no bag is in the heating compartment.
  - Pre-warming identifies that the fluid bag has been recently placed in the heating compartment. There is a seven (7) minute pre-warming cycle, after which the actual temperature and time-in will be displayed.
- 3. To open the 16N1<sup>®</sup>, enter the Sub-Master Code or User Code (See "Set Up Instructions" for changing the Sub-Master Code and the User Code) on the Code Lock on the door of the 16N1<sup>®</sup>. The factory preset Sub-Master Code is 8-7-6-5-4-3-2-1 and the User Code is 2-2-4-4. When this code is entered, the blue indicator light on the Code Lock will light identifying that the correct Sub-Master or User Code has been entered. Turn the handle clockwise and open the door (See Figure 2).
  - NOTE: The red indicator light will illuminate if an incorrect User Code has been entered. Entering three (3) incorrect codes in succession will cause the lock to shut down for 10 seconds.



Figure 2 - Code Lock

- 4. Use The Documentor<sup>®</sup>, located on the top of the 16N1<sup>®</sup>, to label fluid bags. Do not remove the outer packaging, if outer packaging is provided by the bag manufacturer, when placing the fluid bag in the 16N1<sup>®</sup>. The Documentor<sup>®</sup> can create labels with a future date (See Section 5.0, "Set Up Instructions" for adjusting the clock date) that follow manufacturer's recommendations or hospital guidelines for the maximum length of time a bag is to be warmed. To create labels using The Documentor<sup>®</sup>:
  - a) Hold the label sheet face up;
  - b) Line up the arrow on The Documentor<sup>®</sup> under the words "Remove Fluid By" on the label;
  - c) Push the label sheet towards the arrow until The Documentor<sup>®</sup> is activated and
  - d) Place a label on each fluid bag for documentation and compliance purposes.
  - o NOTE: The Documentor<sup>®</sup> automatically adjusts for Daylight Savings Time.
- 5. Place the labeled bags into the 16N1<sup>®</sup>, one bag per compartment. As the bags are placed into the 16N1<sup>®</sup>, the Control Panel Display will change from "Reload" to "Pre-Warming". After a seven (7) minute Pre-Warming cycle, the actual temperature of the fluid in the bag and length of time the bags have been warming will be displayed. (See Figure 1).
  - NOTE: For optimal performance, the 16N1<sup>®</sup> should initially be loaded with bags in sequential order (starting with Compartment 1 and continuing in order through Compartment 16). Fluid bags should be placed with ports up and facing towards the door. Thereafter, bags should be removed from and replaced in the 16N1<sup>®</sup> in sequential order. In the event you are unclear which Compartment is next in sequence, refer to the Display to see which bag has been warming the longest. Fluid bags with the longest warming times should be removed first.
  - NOTE: Fluid bags should not be removed until the time and temperature are displayed.
  - NOTE: Fluid bags previously heated should not be placed into the 16N1<sup>®</sup>.
- 6. Close the door and turn the handle on the Code Lock left to an upright position.
- 7. When the fluid temperature of the bag has reached the Set Point temperature, the fluid bag can be removed by unlocking the 16N1<sup>®</sup> door by entering the User Code, and turning the Lock right to the Unlocked position.
  - NOTE: Heater plates are hot and contact should be avoided.

If the fluid temperature in the bag is 2°F over the Set Point temperature, the Control Panel Display for that heating compartment will read "OVERTEMP". An audible and visual alarm will activate until the bag is removed from the 16N1<sup>®</sup>, or the fluid temperature of the bag drops to within 2°F of the Set Point.

#### 3.1 Cleaning Instructions

- 1. Turn the 16N1<sup>®</sup> off at the Control Panel Power Switch and the Master Power Switch (See Figure 3) and unplug the 16N1<sup>®</sup> from the receptacle.
- 2. Wipe down the exterior of the 16N1<sup>®</sup> with a damp cloth using a general hospital cleaner (example: Isopropyl Alcohol) as needed, following the cleaner manufacturer's instructions.

3. In the event that excessive fluids enter the 16N1<sup>®</sup>, disconnect power to the 16N1<sup>®</sup> and refer to qualified service personnel (See Section 6.2).

### 4.0 SPECIFICATIONS AND OPERATING INFORMATION

#### 4.1 Specifications

| Classification                       | Class 1   |
|--------------------------------------|---|
| Dimensions                           | With base: 47.5" tall x 28.5" wide x 23"deep<br>Without base: 41" tall x 21.5" wide x 15.5"deep |
| Weight                               | With base: 97 lbs<br>Without base: 77 lbs   |
| Capacity                             | Sixteen (16) 1-liter fluid bags   |
| Mounting                             | Wheeled cabinet   |
| Construction                         | Aluminum, powder coat finish  |
| Operating Temperature                | Room temperature to 104°F (10°C to 40°C)  |
| Factory Preset Operating Temperature | 104°F (40°C)  |
| Certification                        | MET Laboratory – E112230  |

#### 4.2 Ambient Operating Conditions

| Storage Temperature                           | -22°F to 176°F (-30°C to 80°C)      |
|---|-------------------------------------|
| Humidity Conditions                           | 0 to 90% up to 104°F non-condensing |
| Ambient Operating Temperature                 | 14°F to 131°F (-10°C to 55°C)       |
| Atmospheric Pressure During<br>Transportation | Minimum of 16.288 in. Hg.           |

#### 4.3 Electrical Requirements

| Power Requirements         | 16N1 <sup>®</sup> and Documentor <sup>®</sup> : 110/120 VAC, 60 HZ |  |  |
|----------------------------|--|--|--|
| Fused                      | 16N1 <sup>®</sup> : 2 each 15 Amp                                  |  |  |
|                            | Documentor : 2 each 0.5 Amp  |  |  |
| Amperage Consumed          | 13.875 Amps  |  |  |
| Heater Wattage             | 16 at 100 watts each   |  |  |
| Thermal Cutout Temperature | Fluid temperature at 2°F (1°C) over Set Point temperature          |  |  |

#### 5.0 SET-UP INSTRUCTIONS

- 1. Remove the 16N1<sup>®</sup> from the shipping box.
- 2. Check before operating to ensure that all of the packaging material and manuals are removed from the unit. Visually inspect the 16N1<sup>®</sup> for any signs of damage.
- 3. Locate The Documentor's<sup>®</sup> shipping box and remove The Documentor<sup>®</sup> from the shipping box. Attach The Documentor<sup>®</sup> to the 16N1<sup>®</sup> following the instructions below.
  - a) Remove the four (4) screws in the top of the 16N1<sup>®</sup>. Align the four (4) holes in the Time/Clock Mounting Bracket and secure using the four (4) screws.
  - b) Remove the three (3) screws in the back of The Documentor<sup>®</sup>. Attach The Documentor<sup>®</sup> to the Mounting Bracket using these three (3) screws.
  - c) Plug The Documentor<sup>®</sup> into the Hospital Grade Receptacle located on the side of the 16N1<sup>®</sup>.
- 4. Locate the Master Power Switch on the back of the 16N1<sup>®</sup> near the bottom of the panel. Confirm that the Master Power Switch is turned off. Plug the power cord into an approved outlet. Turn on the Master Power Switch.





- 5. On the front of the 16N1<sup>®</sup> is the Control Panel. Press and hold the Power Button for one second (See Figure 1).
  - NOTE: During the start-up process, the Control Panel Display will first display a "Welcome" screen and then displays a "Software Licensing" screen.
  - NOTE: The start-up process completes with the Control Panel Display showing a grid pattern resembling the heater compartment (See Figure 1). The display will show "RELOAD" for each compartment.
- 6. Confirm that the correct time/date is indicated on the Display. Due to shipping to different time zones, this might need to be adjusted. To adjust Time/Date use the following instructions:
  - a) Press the "Time/Date" button for three (3) seconds.
  - b) In the top left corner of the Display the date indicator will begin to flash. Use the "Up" and "Down" buttons to adjust to the correct date.
  - c) Press the "Time/Date" button to move to the month indicator. Use the "Up" and "Down" buttons to adjust to the correct month.
  - d) Press the "Time/Date" button to move to the year indicator. Use the "Up" and "Down" buttons to adjust to the correct year.
  - e) Press the "Time/Date" button to move to the hour indicator. Use the "Up" and "Down" buttons to adjust to the correct hour.
  - f) Press the "Time/Date" button to move to the minute indicator. Use the "Up" and "Down" buttons to adjust to the correct minute.
  - g) Press the "Time/Date" button to move to the on/off indicator. Use the "Up" and "Down" buttons to adjust to select on or off.
  - h) Press the "Time/Date" button to return to the Temperature Control Screen.
- 7. To adjust the Set Point temperature, use the "Up" or "Down" buttons. Each press of the buttons will move the Set Point temperature up or down 1°F on the Display.
- 8. The 16N1<sup>®</sup> is factory pre-set to operate in degrees Fahrenheit (°F). To change the system to operate in degrees Celsius (°C), contact Medical Solutions, Inc. at 800-435-7600.
- 9. The Display will show "RELOAD" for each compartment.
- 10. The 16N1<sup>®</sup> can be left on indefinitely without harm to the unit.

#### 5.1 The Documentor<sup>®</sup> Resetting Instructions

#### 5.1.1 Changing The Documentor<sup>®</sup> Date

- 1. Plug The Documentor<sup>®</sup> into a hospital grade receptacle.
- 2. Press and hold the blue RESET button located on the bottom of The Documentor<sup>®</sup>.
- 3. While holding down the RESET button, press and hold the right button on the front panel.

- 4. While holding the right button, release the RESET button.
- 5. When "Prog" appears in the display, release the right button. "Prog" then finishes.
- 6. Tap the right button again. The display will show "0000" and the 1<sup>st</sup> digit will flash.
- 7. Tap the  $\triangleleft$  left button until the number "8" appears.
- 8. Tap the  $\bullet$  right button twice so the 3<sup>rd</sup> "0" is flashing.
- 9. Tap the  $\blacktriangleleft$  left button until the number "8" appears in the 3<sup>rd</sup> position.
- 10. Tap the right button.
- 11. Tap the  $\blacktriangleleft$  left button until the number "8" appears in the 4<sup>th</sup> position.
- 12. When the display reads "8088" tap the right button.
- 13. When the display flashes all four digits tap the right button.
- 14. The display will flash "P1 (date)".
- 15. Tap the right button and the small digits on the left, representing the year, will flash.
- 16. Tap the  $\blacktriangleleft$  left button until the desired number appears.
- 17. Tap the right button. The digits representing the month should flash.
- 18. Tap the  $\blacktriangleleft$  left button until the desired number appears.
- 19. Tap the right button. The digits representing the day should flash.
- 20. Tap the  $\blacktriangleleft$  left button until the desired number appears.
- 21. Tap the right button.
- 22. When the desired date is set, tap the right button until the display flashes "P1 (date)".
- 23. Tap the blue RESET button to return to the standard display.

#### 5.1.2 Changing The Documentor<sup>®</sup> Time

- 1. Follow steps 1-13 in Section 5.1.1 above.
- 2. Tap the  $\blacktriangleleft$  left button.
- 3. The display will flash "P2 Cloc".
- 4. Tap the right button.
- 5. The hour format will flash (12 or 24). If necessary, tap the ◀ left button until 24 flashes.
- 6. Tap the right button.
- 7. The hour digits will flash. Tap the ◀ left button until the desired setting is achieved. (the hour must be set in military time 3:05pm = 15:05)
- 8. Tap the right button.
- 9. The minutes digits will flash. Tap the  $\blacktriangleleft$  left button until the desired setting is achieved.
- 10. Tap the right button twice.

- 11. The display will flash "P2 Cloc".
- 12. Press and release the blue RESET button.

#### 5.2 Code Lock Instructions

To Unlock the Code Lock, enter the Sub-Master Code (Preset to 8-7-6-5-4-3-2-1) or User Code (Preset to 2-2-4-4) and turn the Code Lock handle clockwise to the open position (see Figure 2).

• NOTE: Entering three incorrect codes will cause the lock to shutdown for 10 seconds. The red indicator light on the Code Lock will illuminate if an incorrect code is entered. A correct code is indicated by the illumination of the blue light on the Code Lock.

The Code Lock is powered by two (2) AAA 1.5v batteries and should provide well in excess of 15,000 openings of 4 seconds each. If the batteries are low in power, the Red LED will flash 3 times before the Blue LED flashes to signal acceptance of the code. If this occurs or the batteries fail, contact Medical Solutions, Inc. at 800-435-7600.

#### 5.2.1 Changing the Code Lock Sub-Master Code

- NOTE: To program the Code Lock, the lock must be in the open position with the # button visible and the door to the 16N1<sup>®</sup> should be open.
- 1. Press the red "#" button located under the Code Lock handle (see Figure 2).
- 2. Enter the current Sub-Master Code.
- 3. Enter 0-6 and verify a 1 second blue LED flash.
- 4. Enter a new eight (8) digit Sub-Master Code and verify a 1 second blue LED flash.
- 5. Enter the new Sub-Master Code again and verify two 1 second blue LED flashes.

Example: #, 8-7-6-5-4-3-2-1•, 0-6•, 1-2-3-4-5-6-7-8•, 1-2-3-4-5-6-7-8••

Result: A new Sub-Master Code, 1-2-3-4-5-6-7-8, is activated and the prior Sub-Master Code is deleted.

#### 5.2.2 Changing the Code Lock User Code

• NOTE: To program the Code Lock, the lock must be in the open position with the # button visible and the door to the 16N1<sup>®</sup> should be open.

#### 5.2.2.1 To Change the User Code Using the Sub-Master Code

- 1. Press the red "#" button located under the Code Lock handle (see Figure 2).
- 2. Enter the current Sub-Master Code and verify a 1 second blue LED flash.
- 3. Enter 0-7 and verify a 1 second blue LED flash.
- 4. Enter the new four (4) digits User Code and verify two 1 second blue LED flashes.

Example: #, 8-7-6-5-4-3-2-1•, 0-7•, 1-3-1-3••.

Result: The Code Lock User Code is set to 1-3-1-3.

#### 5.2.2.2 To Change the User Code Using the Current User Code:

- 1. Press the red "#" button located under the Code Lock handle.
- 2. Enter the current User Code and verify a 1 second blue LED flash.
- 3. Enter the new User Code and verify a 1 second blue LED flash.
- 4. Enter the new User Code again and verify two 1 second blue LED flashes.

Example: #, 2-2-4-4•, 1-3-5-7•, 1-3-5-7••

Result: The new User Code is 1-3-5-7.

#### 6.0 TROUBLESHOOTING

The following provides basic troubleshooting techniques for qualified personnel.

#### 6.1 Failure to Warm

If the 16N1<sup>®</sup> fails to warm, check the following:

- 1. Is the Control Panel Display on?
  - a) YES: Proceed to #2.
  - b) NO:
    - Check to see that the 16N1<sup>®</sup> is plugged in and the Master Power Switch is turned on. (See Figure 3).
    - Press and hold the Power Button on the Control Panel (See Figure 1) for one (1) second.
    - If the screen does not turn on, have trained service personnel check the fuses in accordance with the instruction in Appendix B.
    - If changing the fuses does not resolve the issue, contact Medical Solutions, Inc. at 800-435-7600.
    - o If screen is powered on, proceed to #2.
- 2. Place a fluid bag into the compartment to be tested and wait 10 minutes.
- 3. Does the fluid temperature and time appear on the Control Panel Display for the heating compartment containing the fluid bag?
  - a) YES: Proceed to #4.
  - b) NO:
    - o If the Control Panel Display shows "RELOAD" see Section 6.3.
    - If the Control Panel Display fails to indicate the fluid temperature and time, discontinue use of that compartment and contact Medical Solutions, Inc. at 800-435-7600.
- 4. Is the Set Point temperature greater than the fluid temperature?
  - a) YES: Proceed to #5.
  - b) NO: the Set Point temperature must be greater than the actual fluid temperature for the compartment to heat.
- 5. Does the Time-In indicator show 999 days?
  - a) YES:
    - o If 999 days is accurate, replace the fluid bag.
    - If 999 days is displayed in error, proceed to #6.
  - b) NO: Proceed to #6.

6. If the compartment still fails to heat, discontinue use of that compartment and contact Medical Solution, Inc. at 800-435-7600.

#### 6.2 Excessive Fluids In 16N1<sup>®</sup>

In the event excessive fluids enter the 16N1<sup>®</sup>:

- 1. Disconnect power to the 16N1<sup>®</sup>.
- 2. Remove the service panel (See Appendix C).
- 3. Remove any liquid and then dry components.
- 4. Perform normal hospital electrical safety checks.

#### 6.3 "Reload" Displayed with Fluid Bag In Compartment

Verify that the fluid bag is properly positioned in the heating compartment. The switch at the back of the heating compartment must be depressed by the fluid bag. If the bag is positioned properly, but the Control Panel Display continues to indicate "RELOAD", contact Medical Solutions, Inc. at 800-435-7600.

#### 6.4 Time and Temperature Displayed for Compartment With No Bag Inserted

The switch at the back of the heating compartment is caught in the depressed position. A fluid bag should be inserted into the heating compartment affected. Please note that there will be a discrepancy for the actual time heating for that fluid bag, which will be reflected in the displayed "Time-In" indicator. The remaining heating compartments in the 16N1<sup>®</sup> can continue to be used. Contact Medical Solutions, Inc. at 800-435-7600.

#### 6.5 Set Point Can Not Be Changed

If the Set Point can not be changed (can not be decreased from 104°F or raised/decreased from any other temperature) power the 16N1<sup>®</sup> off and then power back on. If the Set Point can still not be reset, contact Medical Solutions, Inc. at 800-435-7600.

#### 6.6 Code Lock Does Not Work Correctly

The Code Lock will shutdown if three (3) incorrect codes are entered consecutively. Wait 10 seconds and enter the correct User or Sub-Master Code. For any other issues, including instructions on how to change the batteries, contact Medical Solutions, Inc. at 800-435-7600.

#### 6.7 "Tripped" Error Code

If the 16N1<sup>®</sup> displays the error code "TRIPPED" in the Control Panel Display, remove the bag and discontinue use of that compartment. Contact Medical Solutions, Inc. at 800-435-7600.

#### 6.8 "Fault" Error Code

If the 16N1<sup>®</sup> displays the error code "FAULT" in the Control Panel Display, discontinue use of the 16N1<sup>®</sup> and contact Medical Solutions, Inc. at 800-435-7600.

#### 7.0 PREVENTATIVE MAINTENANCE PLAN

The 16N1<sup>®</sup> requires minimal preventative maintenance. The 16N1<sup>®</sup> temperature controller should be verified at least once every five years via the procedure below.

#### 7.1 Temperature Verification Procedures

The following items are required to accurately measure the bag temperature for verification of the temperature controller:

- o Fluke 51II Digital Thermometer
- 6" Long 0.093" diameter Type T Needle Thermocouple, with the Thermocouple calibrated to the thermometer.
- 1. Power the  $16N1^{\text{®}}$  on.
- 2. Adjust the Set Point temperature to 104°F.
- 3. Load the 16N1<sup>®</sup> with sixteen (16) 1-Liter fluid bags.
- 4. Allow the 16N1<sup>®</sup> to operate for a minimum of two (2) hours before verifying the temperatures.
- 5. Select the fluid bag in heating compartment 1.
- 6. With the outer wrap still on the fluid bag (if applicable), pierce the bag through the needle injection port on the bag with an 18ga needle to make it easier to insert the Thermocouple.
- 7. Insert the Thermocouple through the pierced needle injection port.
- 8. Feed the Thermocouple wire out of the 16N1<sup>®</sup> to the Fluke Thermometer.
- 9. Document the temperature readouts on the Control Panel Display and the Fluke Thermometer.
- 10. Compare the temperatures on the Control Panel Display to the temperature reading on the Fluke Thermometer for each fluid bag evaluated. The temperature on the Control Panel Display has been verified if the two (2) temperature readings are within 2°F of each other. If the temperatures are not within 2°F of each other, contact Medical Solutions, Inc. at 800-435-7600.
- 11. Repeat steps 6-10 for heating compartments 2 through 16.

## APPENDIX A: ELECTRICAL SCHEMATICS



Figure 4 - Controller Schematic



Figure 5 - Heating Tray Schematic







Figure 6 - Fuse Locations

## APPENDIX C: REMOVING SERVICE PANEL



Figure 7 - Service Panel

## APPENDIX D: SOFTWARE LICENSE

## AGREEMENT

The following software license agreement is packaged with each 16N1<sup>®</sup>.

The 16N1<sup>®</sup> is preloaded with a software program necessary to operate the unit (the "Software"). The Software is proprietary to and owned by MSI, and MSI holds the copyright to the Software. Use of the 16N1<sup>®</sup> implies acceptance of the terms of the Software License Agreement packaged with the unit.

ALL USERS SHOULD CAREFULLY READ THE TERMS AND CONDITIONS OF THE SOFTWARE LICENSE AGREEMENT BEFORE USING THE 16N1<sup>®</sup>. USING THE 16N1<sup>®</sup> IMPLIES ACCEPTANCE OF THE TERMS AND CONDITIONS OF THE LICENSE AGREEMENT. IF YOU DO NOT AGREE TO THEM, YOU SHOULD PROMPTLY RETURN THE 16N1<sup>®</sup> UNUSED AND IN ITS ORIGINAL PACKAGING TO MSI, AND YOUR MONEY WILL BE REFUNDED.

### APPENDIX E: LIMITED WARRANTY

For one year from the date of shipment to the Buyer (the "Warranty Period"), Medical Solutions, Inc. ("MSI") warrants that the Equipment provided to the Buyer shall be free from defects in workmanship and materials. In the event of a breach of this warranty during the Warranty Period, MSI shall, at its option, repair or replace the Equipment. Buyer's remedies are limited to such repair or replacement.

MSI DISCLAIMS ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING THE WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT SHALL MSI BE LIABLE FOR DIRECT, INDIRECT, PUNITIVE, ECONOMIC, CONSEQUENTIAL OR OTHER DAMAGES, INCLUDING BUT NOT LIMITED TO LOST PROFITS. To enable MSI to administer the Warranty properly, Buyer shall (1) register the Warranty using the form provided below within thirty days of receipt of Equipment, and (2) promptly notify MSI of any claim hereunder. As a condition to the Warranty, Buyer shall use and maintain the Equipment according to the provisions of the Operators Manual.

#### IMPORTANT: THIS IS YOUR 16N1® WARRANTY REGISTRATION

Please register your Warranty by filling out this page and sending it to Medical Solutions, Inc. within thirty (30) days of purchase.

| Hospital Name:               |                    |        |           |
|------------------------------|--------------------|--------|-----------|
| Mailing Address              | Street<br>Address: |        |           |
|                              | City:              | State: | Zip Code: |
| Contact Name:                |                    |        |           |
| Date Purchased:              |                    |        |           |
| Serial Number:               |                    |        |           |
| Department Purchased<br>For: |                    |        |           |

#### COPY THIS PAGE AND MAIL OR FAX TO:

Medical Solutions, Inc. ATTN: Warranty Supervisor 3901 Centerview Drive, Suite L Chantilly, VA 20151

FAX NUMBER: 703-834-0039

## APPENDIX F: IN-SERVICE SIGN-IN SHEET

In-Service Sign-In Sheet

Date:

Hospital:

| Name | Title | Department | Contact Number | E-mail Address |
|------|-------|------------|----------------|----------------|
|      |       |            |                |                |
|      |       |            |                |                |
|      |       |            |                |                |
|      |       |            |                |                |
|      |       |            |                |                |
|      |       |            |                |                |
|      |       |            |                |                |
|      |       |            |                |                |
|      |       |            |                |                |

| Name | Title | Department | Contact Number | E-mail Address |
|------|-------|------------|----------------|----------------|
|      |       |            |                |                |
|      |       |            |                |                |
|      |       |            |                |                |
|      |       |            |                |                |
|      |       |            |                |                |
|      |       |            |                |                |
|      |       |            |                |                |
|      |       |            |                |                |
|      |       |            |                |                |
|      |       |            |                |                |
|      |       |            |                |                |
|      |       |            |                |                |