Fluid Management System
FluidSmart® Operation Manual

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FluidSmart® Fluid Management System

Part Numbers: P2000, W2100

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Every effort has been made to ensure that the information in this manual is accurate and details provided are correct at the time of printing. The company reserves the right to modify the equipment shown.

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The products described are covered by one or more Patents or Patents Pending.

Federal law (U.S.A.) restricts this device to sale by, or on the order of, a physician or properly licensed practitioner.

Pictures are for reference only.

Specifications are subject to change without notice.
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Section 1 – About this Manual

The instructions within this Operation Manual contain important information for safe use of the product. Read the entire Operation Manual, including Warnings and Cautions, before using the product.

Failure to properly follow warnings, cautions, and instructions could result in death or serious injury to the patient.

This Operation Manual describes the setup and use of the system including the suction canister ring and optional secondary display.

This Operation Manual is intended for use by individuals trained in the healthcare and biomedical professions.

⚠️ WARNING
Read the entire Operation Manual before using the product. Failure to properly follow warnings, cautions, and instructions could result in death or serious injury to the patient.
Section 2 – Description

The Thermedx® FluidSmart® is intended for irrigation, distention, fluid warming, and fluid volume/deficit measurements in endoscopic procedures within gynecology, urology, and orthopedic disciplines. Fluids commonly used include 0.9% saline, lactated ringer’s solution, 5% mannitol, 1.5% glycine, and sterile water.

The main unit is mounted on a rolling stand which houses the technology used to warm the fluids and the peristaltic pump used to pressurize the fluids. A touch-screen operated processor provides closed loop controls for fluid warming and pumping. The processor monitors temperature and pressure sensors to adjust warming power and pump speed as required. Load cells attached to the fluid bag hooks and suction canister ring allow the processor to monitor fluid levels pumped to and suctioned from the surgical site.

Disposable Tubing Sets
Several versions of the disposable tubing sets are available. The LL0002 is an inflow tubing set used for endoscopic procedures with maximum fluid pressures up to 150 mmHg. The LL0004 is an inflow and outflow tubing set used for endoscopic procedures with maximum pressures up to 150 mmHg. The LL0006 is an inflow tubing set used for endoscopic procedures with maximum fluid pressures up to 300 mmHg. The tubing sets terminate in a luer lock fitting for use with existing hospital equipment, typically an endoscope. Each tubing set includes spikes for the fluid bags, tubing clamps, a cartridge for fluid warming, and a luer lock for connection to the surgical instrument or to a tube that connects to the surgical instrument. The luer lock features a pressure relief valve operating in a range specific to that model of tubing set.
The touch-screen menu (example shown below) provides users with step by step instructions on setup (see Section 7 for more details).

The Run screen provides real time values for Temperature (Temp.), Pressure, Deficit (if enabled), Volume and Flow. Set-point values can be changed simply by pressing the adjustment buttons.

Note - Displayed values represent readings at the device. They may not represent in-cavity conditions.
Section 3 – Indications for Use

The Thermedx® FluidSmart® is intended for irrigation and fluid warming in laparoscopic procedures and irrigation, distention, fluid warming, and fluid volume/deficit measurements in endoscopic procedures within gynecology, urology, and orthopedic disciplines.

CONTRAINDICATIONS

General Usage:

Not for use with blood products including platelets, cryo-precipitates, or granulocyte suspensions.

Use of this device for distention is contraindicated whenever endoscopy is contraindicated. See the Operation Manual of your endoscope for absolute and relative contraindications.

Knee, Shoulder and Small Joint Distention:

The use of this device is contraindicated for use in patients with:

- Ankylosis
- Inflammation or bacterial contamination
Section 4 – Principle of Operation

- The FluidSmart® uses a peristaltic pump to pressurize fluids from fluid bags hanging on either side of the unit.
- Fluid is conducted through a warming mechanism that uses infrared lamps to warm the irrigation fluids on demand to a specified set temperature, generally approximating body temperature. The warming mechanism may be enabled during approved procedures.
- Flow rates are calculated by counting pump rotations and tracking changes in the weight of fluid bags via load cells associated with the fluid bag hooks.
- IR (infrared) temperature sensors are used to measure the fluid temperature in a non-contact method. Three sensors are used in the warming mechanism (beginning, middle, and end of fluid path). Two additional temperature monitors are used downstream of the warming mechanism as a safety measure independent of software.
- Using the flow rate, inlet temperature, and desired set-point temperature, the IR lamp power is calculated. The warming process is adjusted as needed based on feedback from temperature sensors.
- Temperature measurements displayed by the system are readings of fluid temperature at the exit of the warming mechanism. These readings do not account for temperature losses as fluid passes through the disposable tubing.
- Fluid volume instilled (inflow) and fluid deficit are determined on the basis of weight using load cells in the fluid bag hooks and suction canister ring.
- Fluid pressure is monitored via pressure transducers. Redundant sensors are used for safe operation. Pressure measurements displayed by the system are readings at the system and may not reflect the pressure at the surgical site.
- The system operates via pressure control. The system will attempt to maintain the specified pressure (i.e. 100mmHg). Pump speed will increase or decrease accordingly.
- On the basis of the selected clinical discipline and procedure the system will enable procedure specific pressure, flow, warming, and/or deficit monitoring alarm values.
  - The default values are user adjustable within specified safety limits. Not all features are available for all procedures.
Section 5 – Important Safety Information

The safe and effective use of surgical equipment is dependent, to a large degree, upon factors solely under the control of the operator. There is no substitute for a properly trained and vigilant operating room staff. It is important that the operating instructions supplied with this or any other surgical equipment be read, understood, and followed.

⚠️ WARNING

General Usage:

-Read and follow all instructions, labeling, and accompanying documents supplied with this medical device. Failure to follow instructions, including all warnings and cautions, could lead to misuse of the device or device malfunction. Death or serious injury may occur to the patient or user if these warnings are not followed.

-Do not use the FluidSmart® in high-energy fields such as: MRI, X-RAY, portable and mobile RF communications equipment, and other such devices. The FluidSmart® may act as a projectile in a strong magnetic field, cause image artifacts, or not function as intended.

-Do not operate the FluidSmart® in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide. The risk of explosion exists if the FluidSmart® is operated in a potentially explosive environment.

-Exposed conductors on the power cord can cause an electrocution hazard. Remove device from service if the power cord has exposed wires.

-The power cord is to be used for mains disconnection.

-Use only with a dedicated, properly grounded, 120 volt, 20 amp receptacle for P2000 model or 240 volt, 10 amp receptacle for W2100 model. Risk of electric shock exists if the equipment is not connected to a properly grounded receptacle.

-The tubing must be properly placed in the Bubble Detector. Failure to do so may result in failure of the device to operate properly.

-While the warming cartridge contains two bubble traps, the following are recommended to further reduce the potential risk of an air embolism:
  - Remove and purge all air from fluid lines and instrument before using. Failure to do so can result in infusion of air into the surgical site.
  - Ensure the tubing sets are fully primed with fluid prior to use, and that the respective suction and irrigation lines are correctly attached.
  - Do not reuse partially full fluid bags. Fluid bags that have been partially drained, un-spiked, and reinstalled may contain air, which if used can increase the risk of introducing air into the surgical site. Use only new fluid bags from which the air has been removed.
  - Ensure correct patient positioning.
  - Proper surveillance through the use of standard monitoring devices, such as transesophageal echocardiography (TEE), precordial Doppler ultrasound, end-tidal CO2 monitoring, pulse oximetry, or other appropriate methods, is suggested as a possible additional precaution, if deemed necessary by the physician for higher risk procedures.

-The FluidSmart® is for use only with Thermedx® supplied or approved parts, accessories, and disposable sets. The device may not function as intended with the use of unapproved parts, accessories, or disposable sets.
- Do not remove cartridge from unit during operation. If removed and re-installed, unit may fail to read actual fluid pressure accurately.
- Inspect disposable packaging for damage before use. Discard disposables with damage or punctured packaging.
- The luer lock connector features an integrated pressure relief valve. Relief valve operating pressure is specific to the model of tube set. Use the correct model tube set for the procedure for patient safety. The correct tube set is identified on the procedure selection screen.
- Fluid deficit monitoring operates on the basis of weight. Movement, disruption, improper setup, or user error may contribute to false readings. If the user suspects the reported reading is not accurate a visual estimate of fluid instilled and collected should be made in accordance with facility operating procedures.

General Distention

- For liquid distention, strict fluid intake and output surveillance should be maintained. If a low viscosity liquid distention medium is used, intrauterine instillation exceeding 2000 ml should be followed with great care due to the possibility of fluid overload. See your Operation Manual of your endoscope for specific indications for use.
- In all situations, it is most appropriate to select the lowest fluid pressure which will provide adequate distention and visualization.
- Ensure the correct type of distention fluid is being used for the procedure and/or accessories used, and that the fluid manufacturer’s instructions for use are followed.
- Be sure to strictly monitor, evaluate, and manage fluid deficit and/or absorption levels as appropriate for the selected procedure to prevent potential complications (e.g., fluid overload, etc.).
  - Observe the patient for electrolyte imbalances (e.g., hyponatremia, hypervolemia, etc.) and symptoms of other fluid complications particular to the procedure being performed (e.g., fluid intravasation, fluid extravasation, etc.).

Hysteroscopic Distention

- The risk of fluid absorption is dependent on pre-requisite factors that include surgically opening blood vessels, type of resection technique, fluid pressure level, duration of hysteroscopy, and type of distention fluid.
- In addition to monitoring fluid deficit levels and/or absorption, ensure no uterine perforation occurs through use of the instrument or otherwise.
  - In the event a perforation occurs terminate the procedure since fluid may otherwise be lost in the peritoneal cavity.
- Intrauterine pressure should be maintained as low as possible so as to allow adequate distention and minimize the forces potentially driving fluid, room air, and/or gas into the patient’s circulatory system.
- The risk of bleeding is dependent on pre-requisite factors that include laceration or injury to blood vessels.
- Complications of distention may include the following:
  - Hyponatremia: Intravasation of some distension fluids may lead to fluid overload and, consequently hyponatremia, with its attending sequelae. This can be affected by the distending pressure, flow rate, and duration of hysteroscopic procedure. It is critical to closely monitor the input and outflow of the distending liquid.
o Pulmonary Edema
o Idiosyncratic Reaction (Intravascular coagulopathy, allergic reaction, including anaphylaxis)

o Rupture of a fallopian tube secondary to tubal obstruction
o Cerebral Edema

o Hypothermia: The use of room temperature distention fluids may contribute to intraoperative hypothermia, which may consequentially increase the risk of acidemia and cardiac arrhythmias, decrease myocardial contractility and interfere with coagulation.

o Tubal Spasms: The use of room temperature distention fluids may contribute to the risk of tubal spasms, which may consequentially prevent placement of the tubal plugs.

o Uterine Pain: The use of room temperature distention fluid may contribute to uterine pain in diagnostic hysteroscopy procedures.

o For additional guidance, see the 2013 AAGL Practice Report: Practice Guidelines for the Management of Hysteroscopic Distending Media, and AORN Recommended Practices for Minimally Invasive Surgery.

**Bladder Distention**

o Monitor symptoms and signs of TUR Syndrome, including monitoring fluid deficit levels, and identify factors that may increase its risk.

o Increase in fluid irrigation flow rate may accelerate the normal 20 cc/min absorption intravenously by the venous sinuses and may produce dilutional hyponatremia (TUR syndrome of water overload).

**Shoulder, Knee, and Small Joint Distention**

o Monitor and assess patient for signs and symptoms of potential arthroscopic complications associated with fluid distention media for the particular procedure which may include fluid extravasation, neuropaxia, compartment syndrome, vascular injuries, and tachycardia, together with airway compromise, pneumothorax, and tissue tearing particular to shoulder arthroscopy.

o There is a risk of extra-articular edemas in patients with pathologically changed articular capsules and for procedures involving an opening of the capsule (e.g., lateral release).

o Site swellings are complications which have been observed and described in the literature in cases where roller pumps are used in arthroscopy. This build-up of fluid can lead to post-operative swellings and pathological changes in patients. It is therefore of the utmost importance that the surgeon monitors both the FluidSmart® and the patient closely during the procedure.

o The use of overly warmed fluids above 43°C may increase the risk of thermal injury, and/or damage to articular cartilage.

o The use of room temperature arthroscopy irrigation fluids may contribute to intraoperative hypothermia and/or articular cartilage damage.

o The use of room temperature irrigation fluid for arthroscopy may contribute to intraoperative hypothermia, which may increase blood loss, and/or contribute to articular cartilage damage.

⚠️ CAUTION

Part Number - 00824 Revision K, DCO 2017-0074
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Physical injury to the patient, user, and/or an adverse effect on the device or its performance may occur if these cautions are not followed:

General
- Do not use the FluidSmart® if equipment or disposable tubing set malfunction is evident.
- To reduce the risk of cross contamination, do not reuse disposable tubing sets. Disposable tubing sets are for single use only.
- Do not use electrolytic irrigation fluids (0.9% sodium chloride and lactated ringer’s) with monopolar electrocautery probes.
- Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.

General Distention
- Pressure values shown on the touch-screen and secondary display are system pressures, not surgical cavity pressures. For procedures where monitoring of cavity pressure is required, it is recommended to use a secondary system of pressure monitoring.

Bladder Distention
- If used for hydro-distention of the bladder be sure the patient has been properly evaluated and correctly diagnosed with Interstitial Cystitis using the NIH Consensus Criteria.
Section 6 – Assembly and Setup Instructions

This device must be assembled and tested by authorized Thermedx® personnel, an authorized distributor of Thermedx®, or a qualified person prior to placing the device into service. The following steps describe how to assemble and perform preliminary setup of the product.

Read through the instructions completely prior to setting up the device.

Components Checklist:

- Wheeled base with storage basket
- Support pole with threaded fasteners
- Main unit with power cord
- Canister ring with hanger pin
- Alignment tool/Allen wrench
- Secondary display (Optional accessory)

Assemble support pole and canister ring using hanger pin. Tighten (1) locking screw with alignment tool.

Insert support pole into wheeled base. Position support pole so cord of canister ring is opposite locking caster on wheeled base. Tighten (2) locking screws with alignment tool.
Insert alignment tool into top hole of support pole.

Install main unit onto support pole, ensuring front of main unit is in line with locking caster of wheeled base. The main unit is seated on the support pole when the pins protruding from the base align with the holes in the bottom of the main unit. Attach with (4) threaded fasteners and lock washers. The preferred lifting method is one hand on the top handle, and one under the recess on the back of the unit.

Plug in canister ring and secondary display (optional) to ports in lower rear of main unit. Install power cord.
The canister ring has an adjustable slide feature that will accommodate canisters of 4.75 to 6.25 inches (120-160mm) in diameter. Loosen thumb screw on bottom of ring and slide to adjust. Tighten knob again when in desired position.

Insert secondary display (optional) into rear of main unit, until end of tube is flush with lower mount. Tighten (4) mounting screws with alignment tool.

Perform electrical safety tests as required per institutional procedure. These include but are not limited to: leakage current, high-pot, and ground bond test.

⚠️ **WARNING**

Grounding reliability can only be achieved when the power cord is connected to a properly grounded receptacle. Risk of electric shock exists if the equipment is not connected to a properly grounded receptacle and can result in death or serious injury to the patient or user.

The Electrical Safety Check must be performed by qualified personnel authorized by the institution to perform such testing. The Electrical Safety Check must be performed and documented at least once per year, or according to institutional policy. The degree of protection against electric shock: Type BF Applied Part.
If a P2000 model, Power On the fluid management system by plugging the unit into a dedicated 120 volt 20 amp outlet and turning the power switch in the rear lower right corner to the On position.

If a W2100 model, Power On the fluid management system by plugging the unit into a dedicated 240 Volt 10 amp outlet and turning the power switch in the rear lower right corner to the On position.

The product will power on and display a splash screen. A startup screen showing the facility information will appear while the software loads.

The system will prompt the user for a facility name and address if one is not entered. Enter information by touching an empty field and using the on screen keyboard to fill it in. Dismiss the keyboard with the yellow down button, then press Save when finished. The facility information will be included on procedure summary tickets, as well as displayed on the startup screen.

The date, time, and sound level can be adjusted in the settings screen, accessible with the Gear Icon.
Date and time can be adjusted using the appropriate increment buttons. Alarm and bag chime sound level can be adjusted by selecting the Adjustment Icon. Save changes to exit, or press the back button to cancel changes. The Edit button allows the facility information to be edited.
Section 7 – Operating Instructions

The FluidSmart® touch-screen provides step-by-step setup instructions. Arrows allow the user to move forward and back through the steps. Experienced users not needing step-by-step instructions may select Skip Instructions.

Insert cartridge into slot as shown. Push until seated.
Press Step-by-step instructions to proceed.

Open pump. Place tube in opening. Close pump.
When complete press Right Arrow to proceed.

When complete press Right Arrow to proceed.

Prepare fluid bags (1-5 liters). Close clamps, spike bags, hang bags. (1 per hook).
When complete press Right Arrow to proceed.
Place 4 canisters (if monitoring deficit) and connect as shown. (if necessary, toggle from multiple canister to single canister setup using selection button at bottom of screen)

When complete press Right Arrow to proceed to Procedure Selection.

Select:
1. Discipline
2. Tube-set/Procedure
3. Confirm selection

Once Choices are confirmed press the Right Arrow.

Follow on-screen instructions and select Press here to start prime.

Do not remove cartridge from unit during operation. If removed and re-installed, unit may fail to read actual fluid pressure accurately.

Cartridge is filling.
Prime is complete. Attach distal tubing and open clamps. **Press forward button** to proceed to Run screen.

On the Run screen:
- Press **RUN** to start fluid flow
- Use the +/- buttons to adjust set-points.
- Use **toggle** buttons to enable or disable features.
- Press the **gear icon** to access additional settings (see below).

Pump will start, stop, reverse, and change speed as required to maintain selected pressure.

Press **STOP** to stop the pump. Pressing **STOP** does not stop deficit measurement.

The flow icon indicates pump is running.

When procedure is over press **END procedure**. Doing so will freeze the deficit measurement and display a summary of the system performance.
User may **Print** one or more copies of the summary, then **Power off** or proceed to a **New procedure**.

---

**Print Summary**
User may **Print** a summary of the procedure.

---

**Thermedx**
Fluid Management System
SN: 20100005
SW: 20.4-7298fa37

P2000 TEST
31200 SOLON RD
SOLON OH 44139
4405420883

Date: 28-Dec-2016
Start time: 14:58

Procedure  ACL Reconstruction
Tubing Set  Luer Lock
Heating disabled
Average temp.  19.5°C
Average pressure:  29 mmHg
Fluid pumped (input)  230 ml
Fluid returned (output)  230 ml
Fluid deficit:  0 ml
End Time: 15:20

If the printer runs out of paper, replace the paper.
### Bag Changes

Fluid Bags may be replaced as needed. **No button press required.**

- A. Close clamp on empty bag, open clamp on full bag & remove empty bag from hook
- B. Remove spike from bag
- C. Spike new bag
- D. Hang new bag and open clamp when fluid is needed

Note: For best accuracy minimize bouncing on hooks.

### Canister Changes

Suspend fluid collection by disconnecting or clamping suction source. *Failure to do so will result in error in the displayed deficit volumes.* Note: Fluid inflow may continue.

Select **Change suction cans.**

Remove, add, or replace canisters, tissue collection accessories, or additional suction lines as needed. Re-connect vacuum and/or suction lines. **Do Not** resume suction yet. Allow movement or vibration of canister ring caused by changing canisters and/or reconnecting vacuum and/or suction lines to dissipate.
Press the **Close** button to save new canister weights and leave the screen.

Once back to the Run screen: reconnect/unclamp vacuum and/or suction source to resume fluid collection.

Note: If pumping continued during the change, fluid will have accumulated in drape or cavity. Initially this will appear as **Deficit** and may cause an alarm. Continue suctioning and deficit volume will decrease as fluid returns to canisters.

### MISCELLANEOUS

#### Low Bags
When a bag’s volume drops below 30%, the bag indicator background turns red. When volume drops below 20%, a tone sounds. User should prepare more bags to continue past remaining volume. If bags run dry a “Fluid not Flowing” message will display, and the unit will continue to pump in an attempt to maintain pressure.

At the end of a procedure, if the pressure is too high, relieve the fluid pressure within cartridge/tubing set by unclamping distal tubing and draining. Notification will extinguish once pressure is reduced.

#### HELP MENU

To facilitate cartridge and tubing set removal, please reduce pressure.
Help Menu

Selecting the **Question mark** icon brings up the help menu. Users may select a topic, or press the **Close** button to return to the run screen.

### Main Help Menu

<table>
<thead>
<tr>
<th>No or Low Flow</th>
<th>Deficit Too High</th>
</tr>
</thead>
<tbody>
<tr>
<td>能源不足</td>
<td>多余缺陷</td>
</tr>
</tbody>
</table>

### No or Low Flow

1. Confirm RUN button is pressed.
2. Check for empty fluid bags. Confirm clamps are open, and look for kinks or twists.
3. Check to make sure instrument inflow and outflow valves are open.
4. Check for occluded scope.
5. If flow is present but low, increase pressure setting.

### Deficit Too High

1. Check for fluid on the floor: suction as much as possible into canisters.
2. Note fluids suctioned during canister change are not counted in deficit calculation. Suspend suction while changing canisters.
3. Once a canister change has occurred, allow time for fluid collected in buttocks drape while suction was suspended to be returned to canisters.
4. Deficit will read high if weight is removed from the canister ring after pressing (RUN) without using the canister change button.
Tissue Removal System

Suction Set-up – single canister

Suction Set-up – multiple canister

No Heat
**Deficit Too Low**

1. Make sure no extraneous weight (fluid bags, tubing sets) is placed on canister ring after pressing [RUN].
2. Calculations will be affected and deficit will be low if:
   a) Bladder is evacuated after pressing [RUN].
   b) Weight is added after pressing [RUN] without pressing [Change Suction Can] button.
   c) Inflow line is emptied at the end of procedure.

**Interactive Run Screen**

**Change Fluid Type**

1. Press [STOP], remove bag(s), spike and hang new bag(s).
2. Print a snapshot of current ‘volume’ and ‘deficit’ (use button on advanced settings screen or at the bottom of this screen).
3. Press [RUN], allow 150 - 200mL to flow into drape, back into canisters, and continue the procedure.
4. Subtract the recorded ‘volume’ and ‘deficit’ values at the end of the procedure to determine values for second fluid.
5. Note: Starting a new procedure will result in an error in measurements. There is no need to change canisters.
   - Print a summary of current volume and deficit (if applicable).

**Ureteroscopy Only**

1. Clamp inflow tubing.
2. Remove cystoscope.
3. Remove ‘General Urology’ pressure relief valve and ureter adapter tubing if applicable.
4. Attach ‘Ureteroscopy Only’ pressure relief valve and ureter adapter tubing if applicable.
5. Attach cystoscope.
6. Un-clamp inflow tubing.
7. Increase fluid pressure as needed.

Warning: If returning to cystoscope, remove ‘Ureteroscopy Only’ pressure relief valve and ureter adapter tubing if applicable, re-connect ‘General Urology’ pressure relief valve and ureter adapter of applicable to the cystoscope, and lower fluid pressure.

**ADDITIONAL SETTINGS**
**Perforation Alarm** (optionally enabled)

The perforation alarm can be enabled when using deficit monitoring; it is **off** by default.

If enabled the alarm will sound when the **rate** of deficit rise is faster than the value selected (Default of 200ml/min up to flow rate limit for the selected procedure).

Note: False positives can occur during periods of high flow, such as when filling cavities, or when removing the scope from a cavity without closing inflow valve.

**Print Summary**

User may **Print** a summary of pertinent case information such as current volume and deficit.

**Volume/Deficit snapshot**

- Fluid pumped (input) 30 ml
- Fluid returned (output) 30 ml
- Fluid deficit: 0 ml

Procedure ongoing...

**Alarm and bag chime sound level**

Alarm and bag chime sound level can be adjusted by selecting the **Adjustment Icon**
# ALARM, ERROR AND WARNING MESSAGES

Where "call for support" is indicated, please call your distributor or Thermedx® at 888-542-9276. For customers outside the US, please call your distributor or Thermedx® at 011.1.440.542.0883.

## ALARM MESSAGES

Temperature, pressure, flow rate, and deficit values exceeding limits may be accompanied by an audible alarm.

Users may **Mute** audio from low level "set-point" alarms. These alarms may also be bypassed by touching the notification on screen. Bypassing allows the user to continue the procedure unless an upper "safety" limit is reached.

<table>
<thead>
<tr>
<th>Temperature has exceeded set-point by 3 degrees C. This can be caused by abrupt changes in flow rates. User may press to continue operation. System will not warm until temperature has dropped below limit.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temperature has exceeded 46 degrees C. Wait for fluid to cool, system will then continue operation.</td>
</tr>
<tr>
<td>Temperature has exceeded 46 degrees C, and secondary temperature protection means have engaged. Replace tube set and reboot system to continue.</td>
</tr>
<tr>
<td>Pressure has exceeded set-point by 10% or 12mm/Hg (whichever is greater). This can be caused by abrupt changes in flow rates. User may bypass alarm, system will continue to attempt to control pressure to the set-point.</td>
</tr>
<tr>
<td>Pressure has exceeded the maximum allowed (varies by procedure). Fluid pressure must drop to continue. The pump will reverse and attempt to lower pressure.</td>
</tr>
<tr>
<td>Flow rate has exceeded set-point by 10%</td>
</tr>
<tr>
<td>Flow rate has exceeded maximum allowed (varies by procedure).</td>
</tr>
<tr>
<td>Deficit has exceeded user selected set-point. User may press to bypass, collect fluids to lower deficit, or raise set-point.</td>
</tr>
<tr>
<td>Deficit has exceeded maximum limit. This varies by procedure. Collect fluids to lower deficit or end case.</td>
</tr>
</tbody>
</table>
Rate of Deficit increase has exceeded perforation alarm limit. Slow deficit increase or disable alarm.

<table>
<thead>
<tr>
<th>ERROR MESSAGES</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>A Message Center</strong> displays any Errors and provides the user with instructions.</td>
</tr>
<tr>
<td>In the example to the right indicates there is no fluid detected by the bubble detector. Fluid warming will be disabled.</td>
</tr>
<tr>
<td>Connect canister ring. If connected and message persists call for support.</td>
</tr>
<tr>
<td>Indicates no volume change detected while pump is running. If problem persists, call for support.</td>
</tr>
<tr>
<td>Open door detected, close door to resume, <strong>DO NOT REMOVE CARTRIDGE</strong>. Do not remove cartridge from unit during operation. If removed and re-installed, unit may fail to read actual fluid pressure accurately.</td>
</tr>
<tr>
<td>A new cartridge must be installed in device. If a procedure has been started, use the end procedure button to return to setup screens, then press error message to dismiss. Proceed through screens to re-prime new cartridge.</td>
</tr>
<tr>
<td>Stop vibrations. If problem persists, call for support.</td>
</tr>
<tr>
<td>No disposable cartridge detected. Insert cartridge until click is felt. If cartridge inserted and message persists, call for support.</td>
</tr>
<tr>
<td>Remove, discard, and replace tube set. Suction clean out port on back of unit. If the problem persists, call for support.</td>
</tr>
<tr>
<td>Ensure tubing is fully inserted into bubble detector. Check for bubbles in bubble detector. If problem persists, call for support.</td>
</tr>
<tr>
<td>Device requires re-calibration. Call for support.</td>
</tr>
</tbody>
</table>

**Perforation alarm:** deficit rate exceeds alarm limit, increase limit or disable alarm. Press here to dismiss.
**ERROR MESSAGES**

Power down the unit using the power switch. Allow the unit to cool if needed and reboot. If the problem persists, call for support.

<table>
<thead>
<tr>
<th>Error Message</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>I/O bus error. Reboot system, call service if condition repeats.</td>
<td></td>
</tr>
<tr>
<td>Heater control error. Reboot system, call service if condition repeats.</td>
<td></td>
</tr>
<tr>
<td>Heater fan error. Reboot system, call service if condition repeats.</td>
<td></td>
</tr>
<tr>
<td>Pump subsystem error. Reboot system, call service if condition repeats.</td>
<td></td>
</tr>
<tr>
<td>System fan error. Reboot system, call service if condition repeats.</td>
<td></td>
</tr>
<tr>
<td>Software error. Reboot system, call service if condition repeats.</td>
<td></td>
</tr>
<tr>
<td>Sensor error. Reboot system, call service if condition repeats.</td>
<td></td>
</tr>
<tr>
<td>Chassis over-temperature. Check vents at bottom and back for blockage.</td>
<td></td>
</tr>
</tbody>
</table>

**WARNING MESSAGES**

For Ureteroscopy, there is a persistent message indicating pressure set-point is elevated, normally above 75mm Hg. A proper relief valve will be required in these circumstances. See Help Menu for specific instructions.

<table>
<thead>
<tr>
<th>Warning Message</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Warning: high fluid pressure. Attach Ureteroscopy only valve. For other functions, lower pressure and re-attach General Urology valve.</td>
<td></td>
</tr>
<tr>
<td>Warning: higher pressures may affect patient safety. Press here to confirm increasing pressure set-point.</td>
<td></td>
</tr>
<tr>
<td>Warning: high fluid deficit may affect patient safety. Press here to confirm increasing deficit set-point.</td>
<td></td>
</tr>
<tr>
<td>During some procedures, the pressure can be increased to potentially unsafe levels. Press the notification to confirm fluid pressure set-point increase during specific procedures.</td>
<td></td>
</tr>
<tr>
<td>High fluid deficit may affect patient safety. Press the notification to confirm deficit set-point increase during specific procedures.</td>
<td></td>
</tr>
</tbody>
</table>
Section 8 – Maintenance

Only Thermedx® authorized or trained personnel should perform routine maintenance and repairs to the product. Routine maintenance includes calibrations.

- Clean the surface of the system after every use. Use only mild detergents, water, and a soft cloth.
- To disinfect external surfaces, use a 10% bleach/distilled water solution or a quaternary ammonium disinfectant.
- The FluidSmart® should be visually inspected for damage before each use. If there is apparent damage, for example from a fall or rough handling, the unit should be inspected and approved by qualified personnel before returning to service.
- Thermedx® recommends the unit be calibrated annually. The customer is responsible for coordinating calibration with your distributor or Thermedx®.
Section 9 – Limited Product Warranty

Pursuant to Thermedx®’s Terms & Conditions of Sale in Section 13, Thermedx® will provide the Customer with the following express limited warranty on the respective Products (the “Limited Product Warranty”);

(*End User subject to Distributor’s Limited Product Warranty, if Products supplied by Distributor)

A. Scope of Limited Product Warranty: Thermedx® warrants the FluidSmart® to be free from defects in materials and workmanship under normal use and service, for a period of twelve (12) months from the date of shipment to the End-User(s). Thermedx® warrants the Thermedx® Disposables to be free from defects in materials and workmanship under normal use and service until the expiration date set forth on the label of the Disposables.

B. Limitations of Limited Product Warranty: Thermedx®’s sole responsibility, and the exclusive remedy for Customer under the Limited Product Warranty, will be to repair or replace, at Thermedx®’s option as determined in its sole and absolute discretion, any defective component(s) or Product(s) and pay transportation expenses for such replacement. Any replacement or repaired Product(s) will be covered only for the remainder of the original Limited Product Warranty period. In the event no defect is discovered by Thermedx® upon receipt of any returned Product(s), the Product will be returned to Customer at Customer’s expense and Customer will, if requested by Thermedx®, reimburse Thermedx® for the transportation charges, labor and associated charges incurred in testing the allegedly defective Product.

EXCEPT FOR THIS LIMITED PRODUCT WARRANTY, THERMEDX® MAKES NO OTHER WARRANTIES, EITHER EXPRESS OR IMPLIED, REGARDING THE PRODUCTS COVERED HEREBY INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTIES OF MERCHANTABILITY, OR FITNESS FOR A PARTICULAR PURPOSE, ALL OF WHICH ARE HEREBY DISCLAIMED BY THERMEDX®. NO EMPLOYEE, AGENT OR REPRESENTATIVE OF THERMEDX® IS AUTHORIZED TO MAKE ANY REPRESENTATION OR WARRANTY ON BEHALF OF THERMEDX® EXCEPT FOR THERMEDX®’S PRESIDENT OR EXECUTIVE VICE-PRESIDENT IN WRITING. THERMEDX® WILL NOT BE LIABLE TO ANY CUSTOMER (INCLUDING NEGLIGENCE AND STRICT LIABILITY), FOR ANY LOSS, COSTS, EXPENSES OR DAMAGES OF CUSTOMER OR OTHER PARTIES, AND/OR FOR ANY DIRECT, SPECIAL, INDIRECT, INCIDENTAL, PUNITIVE, EXEMPLARY OR CONSEQUENTIAL DAMAGES OR EXPENSES WHATSOEVER, INCLUDING BUT NOT LIMITED TO, ANY DELAYS, DOWNTIME, LOSS OF USE OF THE PRODUCT(S), AND/OR LOSS OF REVENUES, PROFITS, OR INCOME, WHETHER BASED IN CONTRACT, WARRANTY, TORT, INCLUDING WITHOUT LIMITATION, STRICT LIABILITY, NEGLIGENCE, OR ANY OTHER LEGAL OR EQUITABLE THEORY. THERMEDX®’S TOTAL LIABILITY FOR ANY CLAIM OR ACTION WILL NOT EXCEED THE PURCHASE PRICE OF THE PRODUCTS OUT OF WHICH SUCH CLAIM OR ACTION AROSE.

NOTWITHSTANDING ANYTHING TO THE CONTRARY HEREIN, THERMEDX® WILL HAVE NO LIABILITY WHATSOEVER TO CUSTOMER OR ANY OF ITS PATIENTS, FOR ANY CUSTOMER OR THIRD PARTY PRODUCTS OR ACCESSORIES ATTACHED TO THERMEDX®’S PRODUCTS, OR FOR ANY INJURY DIRECTLY OR INDIRECTLY RESULTING FROM A PRE-EXISTING CONDITION OF CUSTOMER’S PATIENT(S).

C. Exclusions of Limited Product Warranty: Thermedx®’s Limited Product Warranty on the Product(s) will NOT apply if Thermedx® determines in its sole and absolute discretion that any of the following have occurred: (i) The Product(s) is not used or maintained in accordance with Thermedx®’s Device Operation Manual, written instructions, and/or labeling; (ii) Any unauthorized modifications, repairs, service, alterations or other work have been performed on such Product(s), other than work performed with Thermedx®’s written authorization and according to its approved procedures;
(iii) The alleged defect is a result of abuse, misuse, neglect, improper maintenance, accident or the negligence of any party other than Thermedx®; (iv) The alleged defect results in whole or in part from the use of components, accessories, parts or supplies not furnished by Thermedx®; or (v) more than thirty (30) days has passed since the End-User Customer first learned of the defect.
## Section 10 – Troubleshooting Guide

This device contains no user serviceable parts. All service must be performed by an authorized representative of Thermedx®.

<table>
<thead>
<tr>
<th>DESCRIPTION:</th>
<th>USER SUGGESTIONS / SOLUTIONS:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Device does not turn on</strong></td>
<td>WHERE “CALL FOR SUPPORT” IS INDICATED, PLEASE CALL YOUR DISTRIBUTOR OR THERMEDX® AT 888-542-9276. FOR CUSTOMERS OUTSIDE THE US, PLEASE CALL YOUR DISTRIBUTOR OR THERMEDX® AT 011.1.440.542.0883.</td>
</tr>
<tr>
<td></td>
<td>• Check that the Device is fully plugged into the wall, and the power cord is fully plugged into the unit.</td>
</tr>
<tr>
<td></td>
<td>• Check that Device's power switch is on.</td>
</tr>
<tr>
<td></td>
<td>• Check wall outlet power.</td>
</tr>
<tr>
<td></td>
<td>• If problem persists call for support.</td>
</tr>
<tr>
<td><strong>Device alarms on start up</strong></td>
<td>• Follow on screen instructions for any error messages displayed. See the errors and alarms section of this manual for further information.</td>
</tr>
<tr>
<td></td>
<td>• Ensure that the disposable (if one is fitted) is not pressurized. Disconnect from any surgical instruments and unclamp outflow to relieve pressure.</td>
</tr>
<tr>
<td></td>
<td>• Ensure the disposable (if one is fitted) is not over-heated from a previous use. Allow time to cool.</td>
</tr>
<tr>
<td></td>
<td>• Reboot device.</td>
</tr>
<tr>
<td></td>
<td>• If problem persists call for support.</td>
</tr>
<tr>
<td><strong>No or low flow, poor visualization</strong></td>
<td>• Confirm the RUN button has been pressed to begin fluid flow.</td>
</tr>
<tr>
<td></td>
<td>• Check for empty fluid bags, confirm clamps are open, and look for kinks and twists in bags and tubing.</td>
</tr>
<tr>
<td></td>
<td>• Check to make sure inflow and outflow valves are open.</td>
</tr>
<tr>
<td></td>
<td>• Check for occluded scope.</td>
</tr>
<tr>
<td></td>
<td>• If flow is present but low, increase pressure setting.</td>
</tr>
<tr>
<td></td>
<td>• If problem persists call for support.</td>
</tr>
<tr>
<td><strong>Hysteroscopic tissue removal system troubleshooting</strong></td>
<td>• To increase distention, increase pressure or reduce suction by adjusting regulator. If no regulator is available, open an extra port on a suction canister to reduce suction.</td>
</tr>
<tr>
<td></td>
<td>• To increase suction: turn up vacuum regulator or reduce the number of suction lines.</td>
</tr>
<tr>
<td></td>
<td>• If suction is inadequate, go back to system setup screens and view suction canister setup instructions.</td>
</tr>
<tr>
<td><strong>Device has burning smell</strong></td>
<td>• Remove Cartridge, check for debris. Do not reuse cartridge.</td>
</tr>
<tr>
<td></td>
<td>• Confirm Fluid Bag(s) are not empty. Replace as necessary.</td>
</tr>
<tr>
<td></td>
<td>• Confirm the vents on the bottom and rear of the unit are not blocked.</td>
</tr>
<tr>
<td></td>
<td>• If problem persists call for support.</td>
</tr>
<tr>
<td><strong>Device is making noise</strong></td>
<td>• A faint whistling noise is normal while priming due to air venting out of the cartridge.</td>
</tr>
<tr>
<td></td>
<td>• Repetitive “sucking” noise from the pump is due to lack of fluid. Check fluid levels and clamps.</td>
</tr>
<tr>
<td></td>
<td>• Faint “ticking” noises from the fans or pump are indicative of normal operation.</td>
</tr>
<tr>
<td></td>
<td>• If problem persists call for support.</td>
</tr>
<tr>
<td><strong>Device is not warming fluid</strong></td>
<td>• Confirm Warming is enabled. Go to the settings screen to enable warming.</td>
</tr>
<tr>
<td></td>
<td>• Allow fluid to flow. Warming is enabled only when fluid is flowing.</td>
</tr>
<tr>
<td></td>
<td>• If the no fluid icon is displayed, ensure tubing is fully seated in the bubble detector and bubble free.</td>
</tr>
<tr>
<td></td>
<td>• Ensure no error messages are displayed in the message center on the bottom of the screen.</td>
</tr>
<tr>
<td></td>
<td>• If problem persists call for support.</td>
</tr>
</tbody>
</table>
### User Suggestions / Solutions:

Where “Call for Support” is indicated, please call your distributor or Thermedx® at 888-542-9276. For customers outside the US, please call your distributor or Thermedx® at 011.1.440.542.0883.

<table>
<thead>
<tr>
<th>Description</th>
<th>Solution</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Device operating above temperature set-point</td>
<td>• Do not use pre-warmed fluid bags; instead use bags at room temperature.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Ensure the on screen bag volume indicators seem approximately correct, and there is no extraneous vibration or disruption of the bags. Remove and re-hang fluid bag to reset bag indicator.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• If problem persists call for support.</td>
<td></td>
</tr>
<tr>
<td>Over temperature alarm continues during device use</td>
<td>• Check that outlet vents on back of device are clear and not blocked.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Check that intake vents underneath the devices are clear and not blocked.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Allow time for device to cool.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• If problem persists call for support.</td>
<td></td>
</tr>
<tr>
<td>Deficit appears too high</td>
<td>• Visually estimate the deficit using fluid bag and canister graduations to determine if the reported value is inaccurate.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Check for fluid on the floor. Suction as much as possible into canisters</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Note: Fluids suctioned during canister change are not counted in deficit calculation.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Once a canister change has occurred allow time for fluid collected in the underbody drape while suction was suspended to be returned to canisters.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Ensure the Change Suction Cans button is used and the on-screen instructions are followed when changing canisters.</td>
<td></td>
</tr>
<tr>
<td>Deficit appears too low</td>
<td>• Visually estimate the deficit using fluid bag and canister graduations to determine if the reported value is inaccurate.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Make sure no extraneous weight (fluid bags, tubing sets) is placed on canister ring after pressing Run.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Calculations will be affected and deficit will be low if:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>a. Bladder is evacuated after pressing Run</td>
<td></td>
</tr>
<tr>
<td></td>
<td>b. A canister is added after pressing Run without using the Change Suction Cans button</td>
<td></td>
</tr>
<tr>
<td></td>
<td>c. Inflow line is emptied at the end of the procedure</td>
<td></td>
</tr>
<tr>
<td>Pressure is erratic or not read</td>
<td>• Replace Disposable Tubing Set and follow on-screen set up procedures.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Do not remove cartridge from unit during operation. If removed and re-installed, unit may fail to read actual fluid pressure accurately.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• If problem persists call for support.</td>
<td></td>
</tr>
<tr>
<td>Printer will not print</td>
<td>• Confirm the status LED on the printer is green and continuously illuminated.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Confirm there is paper in the printer. The green status LED on the printer will blink if the printer is out of paper, and an error message will appear on the summary screen if the printer is out of paper.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Confirm the paper is oriented correctly. Pull the lever on the door to open, and route the paper so the “tail” extends from the bottom of the roll, not the top.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• If problem persists call for support.</td>
<td></td>
</tr>
<tr>
<td>Secondary display does not function</td>
<td>• Check connector pins to be sure they are not bent.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Reinsert connection of Secondary Display into rear of Device.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• If problem persists call for support.</td>
<td></td>
</tr>
<tr>
<td>Suction canister will not fit in holder</td>
<td>• Reach underneath canister ring and loosen knob by turning counter clockwise, adjust arm to be tight against Suction Canister, and tighten knob by turning clockwise.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• If problem persists call for support.</td>
<td></td>
</tr>
<tr>
<td>Touch-screen fluid bag volume indicator is incorrect</td>
<td>• Ensure Fluid Bags are hanging freely.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Ensure there is only one bag of fluid hanging on each hook.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• If problem persists call for support.</td>
<td></td>
</tr>
<tr>
<td>Touch-screen total fluid volume readout is incorrect</td>
<td>• Ensure Fluid Bags are hanging freely.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Ensure there is only one bag of fluid hanging on each hook.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• If problem persists call for support.</td>
<td></td>
</tr>
</tbody>
</table>

Part Number - 00824 Revision K, DCO 2017-0074
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<table>
<thead>
<tr>
<th>DESCRIPTION:</th>
<th>USER SUGGESTIONS / SOLUTIONS:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Relief valve is leaking on disposable tubing set</td>
<td>WHERE “CALL FOR SUPPORT” IS INDICATED, PLEASE CALL YOUR DISTRIBUTOR OR THERMEDX® AT 888-542-9276. FOR CUSTOMERS OUTSIDE THE US, PLEASE CALL YOUR DISTRIBUTOR OR THERMEDX® AT 011.1.440.542.0883.</td>
</tr>
</tbody>
</table>

- Ensure relief valve is properly installed into valve body. Press relief valve back into position. If relief valve is absent, replace Disposable Tubing Set.
- Ensure proper valve is chosen: i.e. procedure pressure setting elevated in Ureteroscopy and “General Urology” valve is installed.
Section 11 – Specifications

Mechanical dimensions:
Height (on stand)  55 inches
Width:  26 inches (660mm)
Depth:  26 inches (660mm)
Weight:  95 pounds
Operation:  15.5°C to 25.5°C, 30 to 75% relative humidity
Transportation:  -40°C to 70°C, 25 to 95% relative humidity, and pressure within 50 to 106 kPa.
Storage:  0°C to 40°C, 25 to 95% relative humidity, and pressure within 50 to 106 kPa.

Temperature set-point: user selectable 37- 40°C
Tolerance: between initial fluid temperature and set-point +3°C
Over temperature protection: 46°C +3/-0°C

Irrigation bag capacity: 1-5 liters per hook (1 bag per hook).
Suction canister capacity: 3 liters maximum per canister. Up to four (4) suction canisters can be accommodated.
Fluid measurement accuracy: +/- 250ml or +/- 10% of fluid pumped (whichever is greater).

This device is not manufactured using natural rubber latex components.

P2000: Electrical 120VAC, 60 Hz, 16A, (requires dedicated 20A outlet)
W2100: Electrical 240VAC, 50/60 Hz, 8A (requires dedicated 10A outlet)

Electrical Type, Protection Against Electrical Shock Class I Equipment, Type BF Applied Part
Mode of Operation Continuous
Type of Current Alternating
Ingress Protection Rating IPX1

MEDICAL EQUIPMENT WITH RESPECT TO ELECTRIC SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH UL 60601-1, IEC/EN 60601-1, CAN/CSA C22.2 No. 601.1
47LG (P2000 only)
Section 12 – Part Numbers

**Base Unit**
P2000 - Fluid Management System with deficit monitoring
W2100 - Fluid Management System with deficit monitoring, 240V (international model)

**Disposable Tubing Sets**
LL0002 – Luer Lock Set Single Lumen
LL0004 – Tubing Set – Single Lumen Inflow with Dual Outflow
LL0006 – Urology Set
## Section 13 – Symbols

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>IPX1</td>
<td>Protected Against Dripping Water</td>
<td>Attention, see instructions for use</td>
</tr>
<tr>
<td>REF</td>
<td>Catalog Number</td>
<td>Type BF Applied Part</td>
</tr>
<tr>
<td>SN</td>
<td>Serial Number</td>
<td>Sterilized using ethylene oxide</td>
</tr>
<tr>
<td>LOT</td>
<td>LOT/Batch Code</td>
<td>Do not use if package is damaged.</td>
</tr>
<tr>
<td></td>
<td>Date of Manufacture</td>
<td>Temperature limitation</td>
</tr>
<tr>
<td></td>
<td>Manufacturer</td>
<td>Use by</td>
</tr>
<tr>
<td></td>
<td>Protective Earth [Ground]</td>
<td>Humidity Limits</td>
</tr>
<tr>
<td></td>
<td>Fragile</td>
<td>Keep Dry</td>
</tr>
<tr>
<td></td>
<td>Do Not Reuse</td>
<td></td>
</tr>
</tbody>
</table>