TO: All Regional Food and Drug Directors  
Attn: Regional Milk Specialists

FROM: Milk and Milk Products Branch (HFS 316)

SUBJECT: MicroDairy Designs LLC Vat Pasteurization Combination Recording/Indicating Thermometer System, Model Therm 2

In accordance with M-I-00-2, Milk and Milk Product Equipment-A Guideline for Evaluating Construction, FDA’s Central Region Milk Specialists and CFSAN’s Milk and Milk Products Branch have specifically evaluated the MicroDairy Designs LLC Vat Pasteurization Combination Recording/Indicating Thermometer System, Model Therm 2 and have validated and confirmed the technical information submitted by MicroDairy Designs LLC and the review findings of the Atlantic Midwest Dairy Equipment Review Committee (AMDERC).

The MicroDairy Designs LLC Vat Pasteurization Combination Recording/Indicating Thermometer System, Model Therm 2 has been reviewed and found to comply with the applicable provisions of Item 16p.(A)-Batch Pasteurization of the Grade “A” Pasteurized Milk Ordinance (PMO) when used on a batch (vat) pasteurizer to monitor the milk or milk product and airspace temperatures for recording on a circular chart. In addition, the package provides an independent all electronic reference temperature for both the milk product and airspace thermometers, eliminating the requirement for the use of mercury-in-glass thermometers.

Compliance with the PMO is based upon the installation and operation in conformance with the manufacturer’s specifications as cited in the MicroDairy Designs LLC Vat Pasteurization Combination Recording/Indicating Thermometer System, Model Therm 2 manual, dated March 25, 2015.

The technical information that was submitted and reviewed addressing the MicroDairy Designs LLC Vat Pasteurization Combination Recording/Indicating Thermometer System, Model Therm 2 constitutes the AMDERC’s Engineering Design and Technical Construction File (EDTCF). The material in the EDTCF is the property of the manufacturer and may be provided at their discretion.
For additional information regarding this equipment, including an electronic copy of the MicroDairy Designs LLC Vat Pasteurization Combination Recording/Indicating Thermometer System, Model Therm 2 manual, dated March 25, 2015, please contact:

MicroDairy Designs LLC  
13339 Smithsburg Pike  
Smithsburg, MD 21783  

Attn: Frank Kipe  
Phone: 301-824-3689  
Email: frank@microdairydesigns.com

FDA’s review and acceptance of the MicroDairy Designs LLC Vat Pasteurization Combination Recording/Indicating Thermometer System, Model Therm 2 does not constitute FDA or Regulatory Agency endorsement or approval. Any representation on a label or in printed literature citing or indicating as “FDA Approved” would be considered as false and misleading.

An electronic version of this memorandum is available for distribution to Regional Milk Specialists, Milk Regulatory Agencies and Milk Sanitation Rating Officers in your region. The electronic version should be widely distributed to representatives of the dairy industry and other interested parties and will also be available on the FDA Web Site at http://www.fda.gov at a later date.

If you would like an electronic version of this document prior to it being available on the FDA Web Site, please e-mail your request to Robert.Hennes@fda.hhs.gov.

Donald R. Goldsmith  
FDA Regional Dairy Specialist  
Central Region

Robert Hennes, RS, MPH  
CAPT U.S. Public Health Service  
Milk and Milk Products Branch

Attachments:

Programming the Chart Recorder for Pasteurization  
Installing the Regulatory Seals
PROGRAMMING THE CHART RECORDER FOR PASTEURIZATION

<table>
<thead>
<tr>
<th>Key Stroke</th>
<th>Response</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Load 12 Hour 80-180 Degree Chart</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Set Start Time to Current Time</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Move Mode Switch to Program</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DOWN Arrow</td>
<td>PEN1</td>
<td><em>Notes</em></td>
</tr>
<tr>
<td>DOWN Arrow</td>
<td>INPS</td>
<td><em>Notes</em></td>
</tr>
<tr>
<td>Scroll Key 11</td>
<td></td>
<td>Means RTD Sensor with Degrees F Scale</td>
</tr>
<tr>
<td>Scroll Key ICOR</td>
<td></td>
<td>Means Input Correction to adjust Thermometer</td>
</tr>
<tr>
<td>Scroll Key 0.0</td>
<td></td>
<td>Always keep this setting to match Inspectors Thermometer</td>
</tr>
<tr>
<td>Scroll Key AL</td>
<td></td>
<td>Means Alarm Type</td>
</tr>
<tr>
<td>Scroll Key HI</td>
<td></td>
<td>This allows the Chart Recorder plug to operate a device</td>
</tr>
<tr>
<td>Scroll Key DISP</td>
<td></td>
<td>Will Display the Pen 1 Temp on the Chart Recorder</td>
</tr>
<tr>
<td>Scroll Key ON</td>
<td></td>
<td>Standard Setting is ON</td>
</tr>
<tr>
<td>Scroll Key DPOS</td>
<td></td>
<td>Means Decimal Position</td>
</tr>
<tr>
<td>Scroll Key 1</td>
<td></td>
<td>Standard Setting is 1 Decimal Point</td>
</tr>
<tr>
<td>Scroll Key CHUP</td>
<td></td>
<td>Means Upper Chart Limit</td>
</tr>
<tr>
<td>Scroll Key 100.0</td>
<td></td>
<td>This is the setting for the Bulk Tank Chart</td>
</tr>
<tr>
<td>UP or DOWN Arrow</td>
<td>180.0</td>
<td>180.0 = Upper Limit of Pasteurization Chart</td>
</tr>
<tr>
<td>Scroll Key CHLO</td>
<td></td>
<td>Means Lower Chart Limit</td>
</tr>
<tr>
<td>Scroll Key 0.0</td>
<td></td>
<td>This is the setting for the Bulk Tank Chart</td>
</tr>
<tr>
<td>UP or DOWN Arrow</td>
<td>80.0</td>
<td>80.0 = Lower Limit of Pasteurization Chart</td>
</tr>
<tr>
<td>Scroll Key HYST</td>
<td></td>
<td>Mean Hysteresis - Alarm On-Off Differential setting</td>
</tr>
<tr>
<td>Scroll Key 2.0</td>
<td></td>
<td>Standard setting is 2 degrees differential</td>
</tr>
<tr>
<td>Scroll Key DFF</td>
<td></td>
<td>Display Filter Factor</td>
</tr>
<tr>
<td>Scroll Key 1</td>
<td></td>
<td>Standard Setting is 1</td>
</tr>
<tr>
<td>Scroll Key ALC</td>
<td></td>
<td>Alarm Changes Allowed?</td>
</tr>
<tr>
<td>Scroll Key ON</td>
<td></td>
<td>Standard Setting is ON</td>
</tr>
<tr>
<td>Scroll Key INPS</td>
<td></td>
<td>You are now back to the beginning of the PROG options</td>
</tr>
<tr>
<td><strong>OPTIONAL</strong></td>
<td></td>
<td>The following steps are for Pen 2 confirmation only</td>
</tr>
<tr>
<td>Scroll Key PEN2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DOWN Arrow</td>
<td>INPS</td>
<td></td>
</tr>
<tr>
<td>Scroll Key 11</td>
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</tr>
</tbody>
</table>
Scroll Key HI This allows the Chart Recorder plug to operate a device
Scroll Key DISP Will Display the Pen 1 Temp on the Chart Recorder
Scroll Key ON Standard Setting is ON
Scroll Key DPOS Means Decimal Position
Scroll Key 1 Standard Setting is 1 Decimal Point
Scroll Key CHUP Means Upper Chart Limit
Scroll Key 100.0 or 180.0 These are the settings for the 2 charts used
UP or DOWN Arrow Select 180.0 180.0 = Upper Limit of Pasteurization Chart
Scroll Key CHLO Means Lower Chart Limit
Scroll Key 0.0 or 80.0 These are the settings for the 2 charts used
UP or DOWN Arrow Select 80.0 80.0 = Lower Limit of Pasteurization Chart
Scroll Key HYST Mean Hysteresis - Alarm On-Off Differential setting
Scroll Key 2.0 Standard setting is 2 degrees differential
Scroll Key DFF Display Filter Factor
Scroll Key 1 Standard Setting is 1
Scroll Key ALC Alarm Changes Allowed?
Scroll Key ON Standard Setting is ON
Scroll Key INPS You are now back to the beginning of the PROG option
UP Arrow PEN2
Scroll Key CHAR Means Chart Section
DOWN Arrow CHSP Means Chart Speed
Scroll Key 7DAY This is the setting for the Bulk Tank Chart
UP or DOWN Arrow Select 12HR 12HR = Chart Speed for Pasteurization Chart
Scroll Key CHSP
UP Arrow CHAR
UP Arrow PROG You are Now Done Programming the Chart Recorder for Pasteurization Change Mode Switch to RUN
Scroll Key (twice) Alarm 1/1 Blinks Last Alarm Setting will be displayed
UP or DOWN Arrow Select 135.0 Optionally this will turn on a device attached to the Chart Recorder plug when the probe temp reaches 135 degrees
Scroll Key Returns to run mode Remove Boots from pens
Installing the Regulatory Seals

Sealing Chart Recorder Program/Run Switch

Open the door to the Chart Recorder. Locate the Program/Run Switch. Remove the Wire Lockable Screws. Place the Cover over the Program/Run Switch and align with the threaded holes on the Chart Recorder. Insert the Wire Lockable Screws. Install the Regulatory Seal.
Sealing Indicating Thermometer Wiring Access Points and Programming Cover

Figure 1

Figure 2

Figure 3

Figure 4
The system is shipped with an internally mounted Cover Bracket (Fig.1) that blocks access to the Sensor Wiring Screw Terminals on the Indicating Thermometer Displays. This Cover Bracket is locked in position by an external screw located between the Indicating Thermometer Displays (Fig.2). Install the Programming Cover (Fig.3) over the indicating thermometer displays. This blocks unauthorized access to the Cover Bracket that is protecting the Wiring Screw Terminals. It also blocks access to the Programming Buttons on the Indicating Thermometer Displays. Insert the two Wire Lockable Screws (Fig.4). Install the regulatory seal (Fig.5).
Sealing Chart Recorder Wiring Access Door

Open the door to the Chart Recorder. Locate the Wire Lockable Screws. Install the Regulatory Seal