

5100 Paint Branch Parkway
College Park, MD 20740-3835

M-b-376

April 20, 2015

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

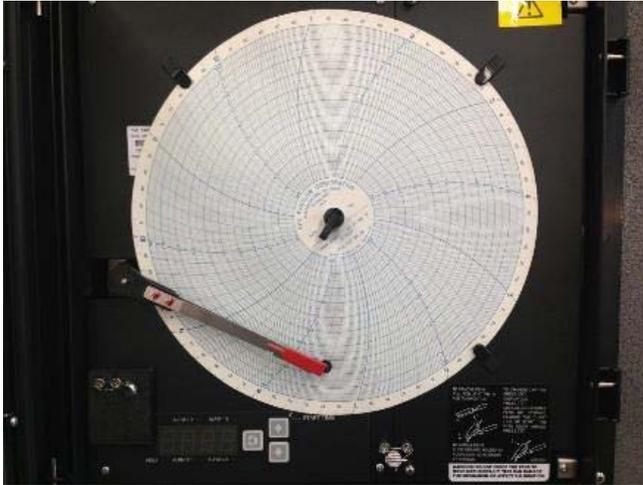
PROGRAMMING THE CHART RECORDER FOR PASTEURIZATION

<u>Key Stroke</u>	<u>Response</u>	<u>Notes</u>
		Load 12 Hour 80-180 Degree Chart Set Start Time to Current Time Move Mode Switch to Program
DOWN Arrow	PEN1	
DOWN Arrow	INPS	
Scroll Key	11	Means RTD Sensor with Degrees F Scale
Scroll Key	ICOR	Means Input Correction to adjust Thermometer
Scroll Key	0.0	Always keep this setting to match Inspectors Thermometer
Scroll Key	AL	Means Alarm Type
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	This is the setting for the Bulk Tank Chart
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	This is the setting for the Bulk Tank Chart
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 options
UP Arrow	PEN1	
**OPTIONAL	The following steps are for Pen 2 confirmation only	
Scroll Key	PEN2	
DOWN Arrow	INPS	
Scroll Key	11	Means RTD Sensor with Degrees F Scale
Scroll Key	ICOR	Means Input Correction to adjust Thermometer
Scroll Key	0.0	Always keep this setting to match Inspectors Thermometer
Scroll Key	AL	Means Alarm Type

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	DFE	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

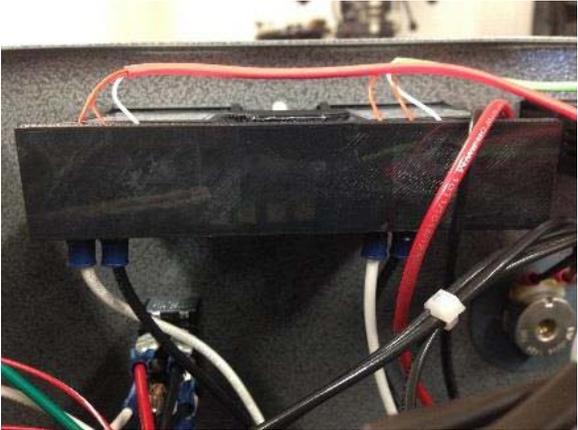


Figure 1



Figure 2

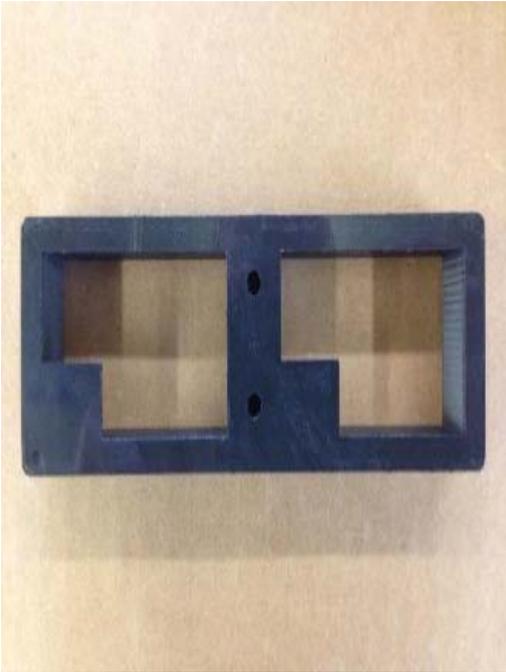


Figure 3



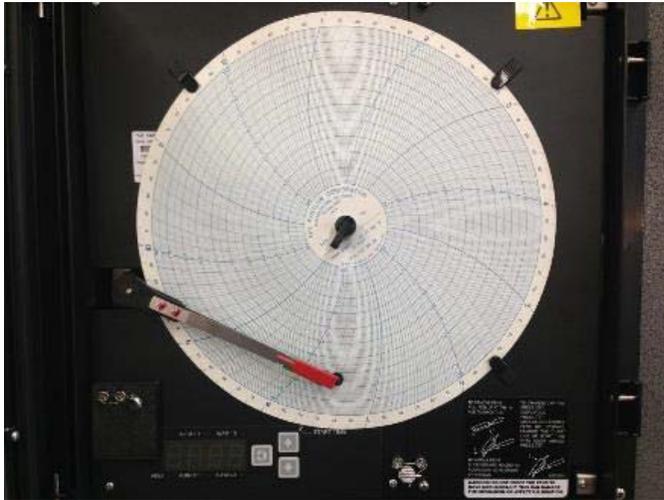
Figure 4



Figure 5

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