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M-b-332
Supplement 2

November 21, 2006

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

FROM: Milk Safety Branch (HFS-626)

SUBJECT: Anderson AV 9900 Microprocessor Based Safety Thermal Limit
                Recorder/Safety Flow Limit Recorder (STLR/SFLR) Field Setup
                Guide Revision 3.0.

This memorandum is a supplement to M-b-332 (Anderson AV 9900 Microprocessor Based Safety Thermal Limit Recorder (STLR)), issued August 16, 1999 and M-b-332, Supplement 1, (Anderson AV 9900 Microprocessor Based Safety Thermal Limit Recorder (STLR)), issued July 22, 2005.

A limited number of Anderson AV 9900 Microprocessor Based STLR/SFLR units currently in use have programming that is not in compliance with Provision 3 of M-b-332, Supplement 1. Provision 3 states: "The flow rate value and the event marker traces are pre-printed on circular charts, which are pre-printed with a set of concentric lines spaced at .04 inches apart. The flow rate range is programmed with the configuration values at a range of 0 to 100% and to a time span of 12 hours in 15 minutes divisions. The flow rate must be displayed in the inner 40% of the chart to prevent the overlapping of flow rate and pasteurization temperature traces." The units were purchased and installed as STLR/SFLRs before July 2005, and functionally, with respect to hardware, these units are identical.

Anderson Instrument has recommended the following programming changes and upgrades to bring these existing STLR/SFLR units into compliance with M-b-332 Supplement 1.

1. **Chart Programming**

In order to meet the requirements of M-b-332, Supplement 1 in relationship to magnetic flow meter based timing systems (MBTS), the chart must be reprogrammed in such a fashion that any action of the flow pen trace would not interfere with the recording of the temperature trace during normal processing.

This requirement is accomplished by limiting the FLOW recording pen to the first 40 rings of the total 100 rings that appear on the printed chart.

Note: Refer to Page 11 of the Field Setup Guide Revision 3.0, 5.2 Meter Based Timing Function-Chart Verification for the Proper Programming of the FLOW Recording Pen, which is provided on page 3 of this memorandum.

2. **Light Emitting Diode (LED) Programming**

In order to properly perform the required testing the MBTS functions as cited in Appendix I of the PMO, two (2) of the on-board AV 9900 LED indicators must be reprogrammed. Once set, the LEDs indicate the switching of the mechanical relays used for the "Loss of Signal" and "High Flow" alarms.

Note: Refer to Page 19 of the Field Setup Guide Revision 3.0, 5.7.1 LED Indicators and "Loss of Signal Alarm" and "High Flow Alarm" for the reprogramming of these LED's, which is provided on page 5 of this memorandum.

For additional information regarding this equipment, please contact:

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FDA's review and acceptance of this piece of equipment does not constitute FDA endorsement or approval. Any representation on a label or in printed literature citing or indicating as "FDA Approved" is false and misleading.

An electronic version of this memorandum is available for distribution to Regional Milk Specialists, State Milk Regulatory Agencies and State 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.

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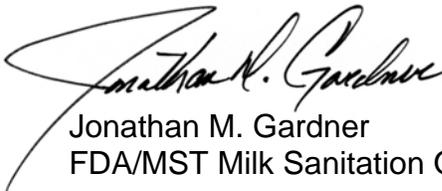
Jonathan M. Gardner
FDA/MST Milk Sanitation Officer

Attachments:
Applicable Sections of Model AV 9900 Pasteurization Recorder/Controller Field Setup Guide Revision 3.0

(STOP)   Prior to completing tests, a check should be made to verify that the chart is properly programmed to show the FLOW portion on the first 40 units of the chart. This configuration is REQUIRED. Procedure is as follows:

1. Unit MUST be in PROGRAM mode – see Section 3.2

2. Press the ⊖ key until the display shows:

SELECT	<->
CONFIGURATION	

3. Press the ⇩ key.

4. Press the ⊖ key until the display shows:

CONFIGURE	<->
RECORDING PENS	

5. Press the ⇩ key.

6. Press the ⊖ key until the display shows:

RECORDING FUNCTION
SFLR INPUT/EVENT

7. Press ENTER key once.

8. Press the ⊖ key until the display shows:

SFLR INP ZONE LOW	
DIVISION	X

9. Verify that DIVISION "0" is programmed.

10. Use the MOD key along with ⇧⇩ keys to make a change if necessary.

11. Press the ⊖ key until the display shows:

SFLR INP ZONE HIGH	
DIVISION	X

12. Verify that DIVISION "40" is programmed.

13. Use the MOD key along with ⇧⇩ keys to make a change if necessary.

14. Press the ⊖ key until the display shows:

SFLR INP ZONE LOW	
VALUE	X

15. Verify that VALUE "0" is programmed.

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16. Use the ⌷MOD⌷ key along with ⌷⇧⌷⌷⇩⌷ keys to make a change if necessary.

17. Press the ⌷⌷ key until the display shows:

> **SFLR INP ZONE HIGH**
> **VALUE   X**

18. Verify that VALUE equivalent to the full scale output of the Flow Meter is programmed.

19. An example would be a meter that outputs 4.00 mA at 0 GPM flowrate, and 20.00 mA at 464 GPM flowrate. The proper value to be entered into the ZONE HIGH VALUE would be 464. This value may be obtained from the individual that commissioned the flow meter.

20. Use the ⌷MOD⌷ key along with ⌷⇧⌷⌷⇩⌷ keys to make a change if necessary.

21. Press the ⌷RESET⌷ key to return to the main display.
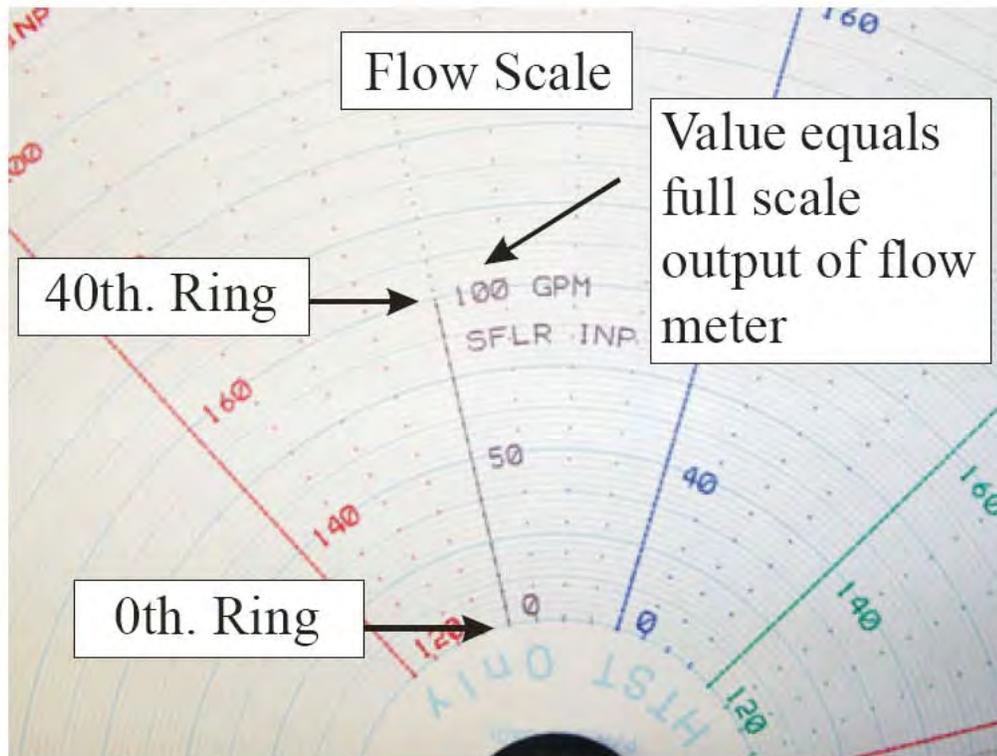
5.7. Test 11 – Continuous Flow Holding Tubes – Holding Time

PMO test 11 covers methods used to determine hold time of various system configurations. For AV-9900 systems integrating the Safety Flow Limit Record function (Meter Based Timing), additional details have been provided to assist in completing the required testing.

5.7.1. LED Indicators for "Loss of Signal" and "High Flow" Alarms

For AV-9900 systems integrating the SFLR function, mechanical relays have been interfaced with the Flow Diversion Device control unit. As the AV-9900 even pen printing is not "real time" print, LED indicators have been provided to give instantaneous feedback as to the position of the Loss of Signal and High Flow alarm and associated relay position. They are located above the main user display, and are set as follows:

LED Number 1 – Tied to Loss of Signal (Low Flow) alarm / relay point

LED Number 2 – Tied to High Flow alarm / relay point

Prior to completing tests in this section, proper programming of the LED's will need to be verified. Complete procedure is as follows:

1. AV-9900 will need to be in PROGRAM mode – see Section 3.2 of this publication.

2. Press the ⊟ key until display shows:

```
SELECT                    <->
CONFIGURATION
```

3. Press the ⇩ key once.

4. Press the ⊟ key until display shows:

```
CONFIGURE                 <->
LEDS
```

5. Press the ⇩ key once.

6. Press the ⊟ key until display shows:

```
LED 1 ACTUATOR            <->
SFLR ALARM 1
```

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7. If display does not show "SFLR ALARM 1," setting is incorrect. Use the [MOD] and [⇧][⇩] arrow keys to make necessary changes; [ENTER] key to accept change

8. Press the [⏎] key until display shows:

```
LED 2 ACTUATOR        <->
SFLR ALARM 2
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9. If display does not show "SFLR ALARM 2," setting is incorrect. Use the [MOD] and [⇧][⇩] arrow keys to make necessary changes; [ENTER] key to accept change

10. When done making changes, press the [RESET] key to return to the main display.

As indicated, the LED's are tied directly to the action of the Loss of Signal and High Flow alarms and relays. The following illustration shows proper operation of the flow alarms:
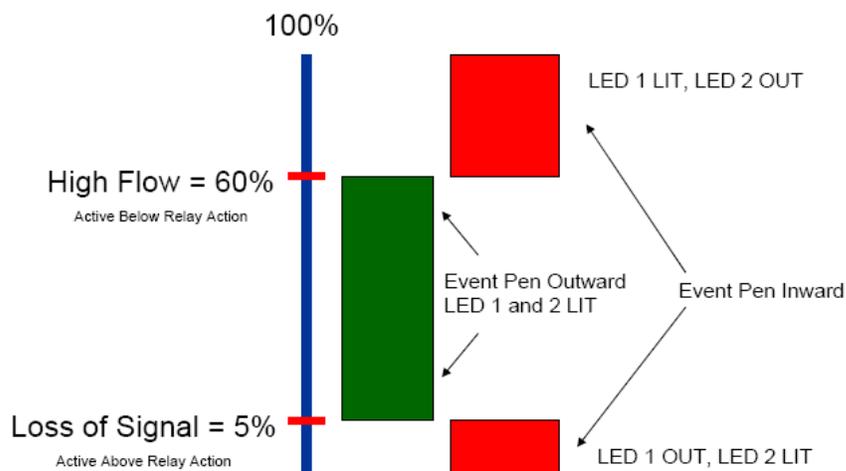
♪ Percentages shown for illustration purposes only. Actual field units may be programmed in %, or actual units.

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