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College Park, MD 20740-3835

M-b-364

August 5, 2010

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

FROM: Dairy and Egg Branch/Milk Safety Team (HFS-316)

SUBJECT: Anderson AJ-300 Series VAT Pasteurization Combination Electronic Control Package

In accordance with M-I-00-2, *Milk and Milk Product Equipment-A Guide for Evaluating Construction*, FDA's Northeast Region Milk Specialists and CFSAN's Dairy and Egg Branch/Milk Safety Team have specifically evaluated the Anderson AJ-300 Series VAT Pasteurization Combination Electronic Control Package and have validated and confirmed the technical information submitted by Anderson Instruments Company, Inc. and the review findings of the Northeast Region Dairy Equipment Review Committee (NERDERC).

The Anderson AJ-300 Series VAT Pasteurization Combination Electronic Control Package has been reviewed and found to comply with the applicable provisions of the *Grade "A" Pasteurized Milk Ordinance* (PMO) when used on a VAT Pasteurizer to monitor the product and airspace temperatures for recording on a circular chart. In addition, the package provides an independent all electronic reference temperature for both the 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 and includes the following criteria:

1. Reference material for evaluating conformance of a system can be found within the manufacturer's document entitled:

"VAT Pasteurization Combination Electronic Control Package Field Setup Guide, Revision 5.1 - 6/21/2010 - Document Number 1162"

- Refer to Section 3.1 for the Recorder.
- Refer to Section 3.3 for the Product and Airspace Probes.

- Refer to Section 5 for the System Wiring.
2. This memorandum applies to a “COMPLETE” system consisting of the following:
 - Dual pen AJ-300 series circular chart recorder (Models may vary).
 - Model CT8V sensor for product recording and reference indication.
 - Model CT8V sensor for airspace recording and reference indication.
 3. For systems utilizing components in any other form than cited above, final approval shall be at the discretion of the State Regulatory Agency whose jurisdiction resides over the individual customer location.

Key Public Health Items:

1. Once testing is completed, a regulatory tamper evident seal shall be placed on the following:
 - Recorder - Chart plate as per Section 3.2. of the Field Setup Guide.
 - Product Sensor - Model CT8V sensor as per Section 3.4. of the Field Setup Guide
 - Airspace Sensor - Model CT8V sensor as per Section 3.4. of the Field Setup Guide
2. To test, confirm and/or program the AJ-300 Series Recorder, a security shunt located behind the chart plate must be positioned in the ‘Program’ mode. In addition, key program menus that affect public health controls are not accessible in “Run” mode. To enable or disable, refer to Section 4 of the Field Setup Guide for detailed procedures.
3. When installed, the system will comply with all applicable controls and test requirements outlined in Section 16p-Pasteurization, Appendix H-Pasteurization Equipment and Procedures and Other Equipment and Appendix I-Pasteurization Equipment and Controls – Tests of the PMO, as well as specific procedures regarding the completion of Appendix I Tests of the PMO detailed in Section 6 of the “VAT Pasteurization Combination Electronic Control Package Field Setup Guide, Revision 5.1 – 6/21/10 – Document 1162”.

The technical information that was submitted and reviewed addressing the Anderson AJ-300 Series VAT Pasteurization Combination Electronic Control Package constitutes the NERDERC'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.

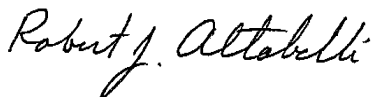
For additional information regarding this equipment, including an electronic copy of the "VAT Pasteurization Combination Electronic Control Package Field Setup Guide, Revision 5.1 – 6/21/10 – Document 1162", please contact:

Anderson Instrument Co, Inc.
156 Auriesville Road
Fultonville, NY 12072
Attn: Gary Ratajczak
Phone: (518)922-5315 ext 577
FAX: (518)922-8997
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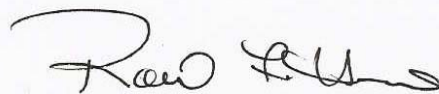
FDA's review and acceptance of the Anderson AJ-300 Series VAT Pasteurization Combination Electronic Control Package does not constitute FDA or State Regulatory Agency endorsement or approval. Any representation on a label or in printed literature citing or indicating as "FDA Approved" would be considered as false and misleading.

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

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.



Robert Altobelli
FDA Regional Dairy Specialist



CAPT Robert Hennes
FDA/DEB Milk Sanitation Officer

Attachments: EDTCF Packet Overview and Contents
Photos of the Recorder, Sensors and Internal Pucks

NERDERC Engineering Design and Technical Construction File (EDTCF)

Packet Overview and Contents

1. Packet Overview and Contents
2. Overview Drawing
3. Detail Drawings and Test Results
4. 3-A Supporting Materials
5. 3-A Symbol Copy
6. Verification of Compliance to PMO Standards
7. Instruction Manual
8. Serial Manufacturing Conformity
9. Engineering Reports
10. Laboratory Reports
11. Description and Documentation of Materials Used
12. Wiring Diagrams
13. Materials and Procedures to Verify Compliance
14. Additional Supporting Documentation
15. Verification of How Safeguards are Met
16. Alternate Testing Procedures



Anderson AJ-3000 Series VAT Pasteurizer Recorder



Anderson AJ-3000 Series VAT Pasteurizer Recorder



Anderson AJ-3000 Series VAT Pasteurizer Sensors



Anderson AJ-3000 Series VAT Pasteurizer Sensors



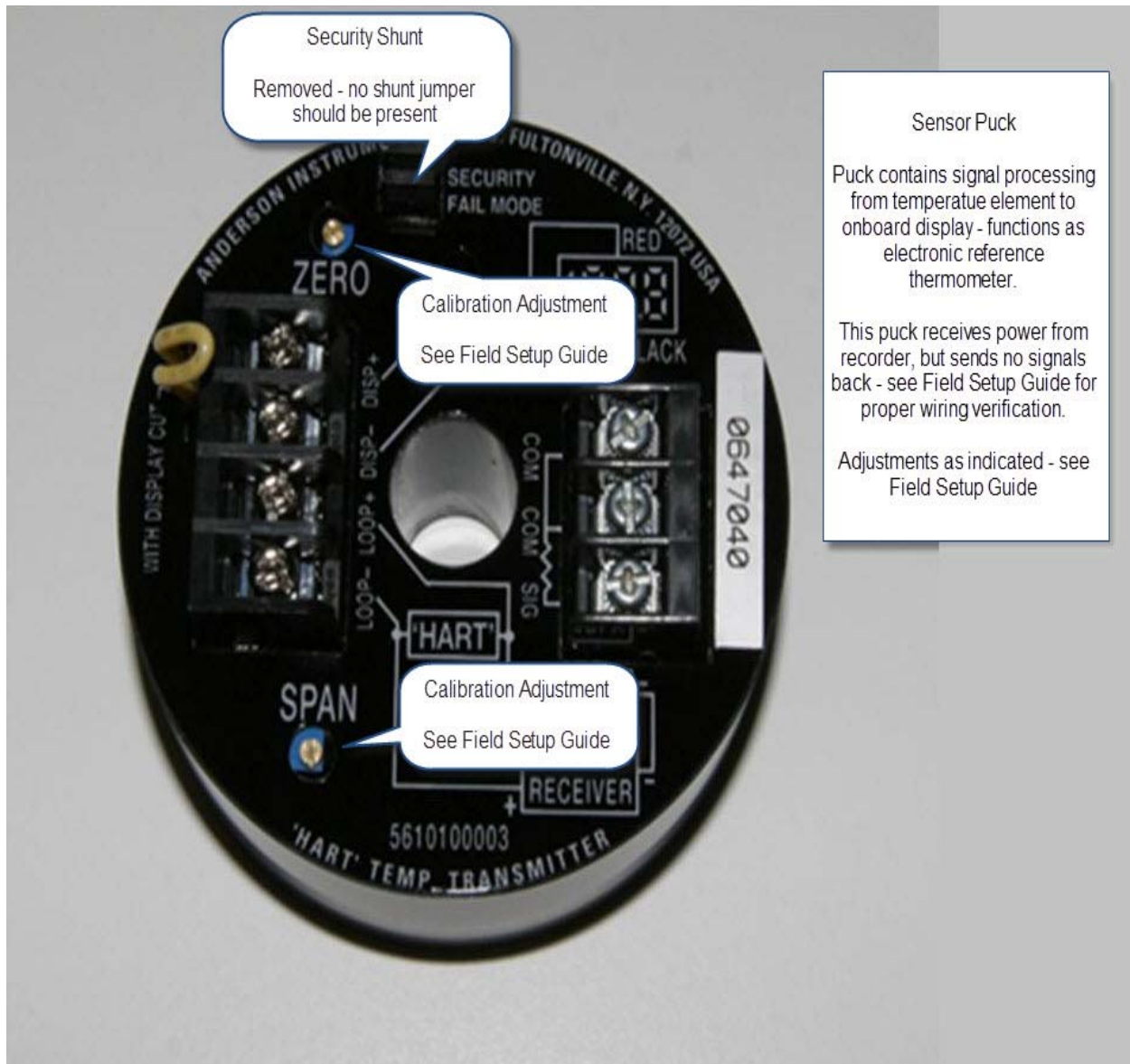
Sensor Puck

Pass through for temperature signal from sensor to recorder.
Bottom puck located within sensor housing. One each for Airspace as well as Product Sensors.

No user adjustments

Internal RTD Wiring Puck

(This is a pass through for the temperature signal from the sensor to the recorder.)



Internal Transmitter Puck

(This puck is the processed signal from the sensor to the onboard display. This puck **MUST** be the model as indicated as it contains the error checking and diagnostics for the digital referenced thermometer.)

NOTE: Verifying the Matrix number of the sensor as described in the VAT Pasteurization Combination Electronic Control Package Field Setup Guide, Revision 5.1 - 6/21/2010 - Document Number 1162 ensures that these pucks shown on pages 9 and 10 have been correctly supplied.