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M-b-350
Supplement 2

October 31, 2008

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

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

SUBJECT: Rosemount 8721 Sanitary Flowmeter And The 8712E Or 8732E Transmitters

This memorandum is a supplement to M-b-350 (Rosemount 8721 Sanitary Flowmeter and 8712C or 8732D Transmitters), issued August 18, 2005 and M-b-350 (Supplement 1) (Rosemount 8721 Sanitary Flowmeter and 8712D or 8732C Transmitters), issued October 5, 2005. This Supplement is referencing model designation 8712E as a direct replacement of the 8712D transmitter and model designation 8732E as a direct replacement of the 8732C transmitter.

The 8732E model designation upgrades the electrical components to the same level as the 8712D transmitter. The 8732E transmitter has a diagnostics that enables the transmitter to verify the operation of the flow meter. This software enabling this diagnostic was also added to the 8712D transmitter, which was released as the 8712E model designation transmitter.

In accordance with M-I-00-2, *Milk and Milk Product Equipment-A Guide for Evaluating Construction*, FDA's Atlantic Midwest Dairy Equipment Review Committee (AMDERC) and CFSAN's Dairy and Egg Branch/Milk Safety Team have evaluated and validated the technical information submitted by AMDERC.

When constructed, installed, operated and maintained as outlined in the instructions of the manufacturer's manual 00809-0100-4664, Revision AA, issued September 2008 and 00809-0100-4664 BA, issued May 2008, the Rosemount 8721 Sanitary Flowmeter and 8712E and 8732E Transmitter have been found to comply with the *Grade "A" Pasteurized Milk Ordinance (PMO)*.

The technical information that was reviewed addressing the Rosemount 8721 Sanitary Flowmeter along with the 8732E and 8712E Transmitters 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 shown at their discretion.

For additional information regarding this equipment, please contact:

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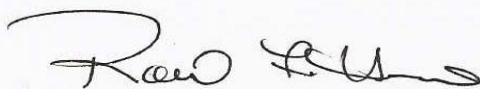
FDA's review and acceptance of this piece of equipment does not constitute FDA endorsement or approval. Any representation on a label or in printed literature citing or indicating as "FDA Approved" is false and misleading.

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.cfsan.fda.gov> at a later date.

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



Donald R Goldsmith
FDA Regional Dairy Specialist



CAPT Robert Hennes
FDA/MST Milk Sanitation Officer

Attachments:

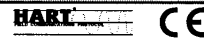
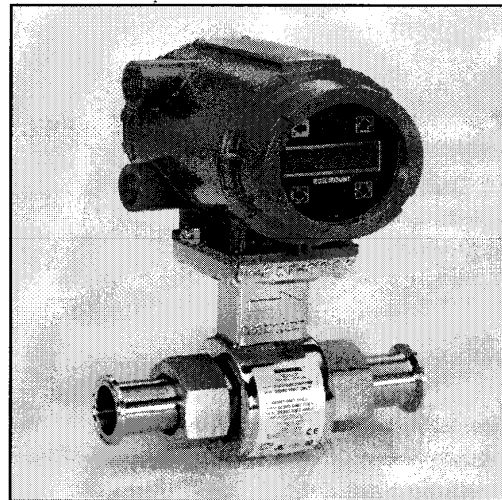
Technical Note 00840-0100-4901, Revision AA, October 2008 (Pages 1, 5 and 6)

Rosemount 8721 Sanitary Flowmeter in Pasteurization Applications

Pasteurization Applications

The Rosemount 8721 Magnetic Flowmeter meets or exceeds the requirements of a magnetic flowmeter for use as a component in a Meter Based Timing System in Grade "A" milk plants as outlined in the Pasteurized Milk Ordinance (PMO). This is documented in the provisions of the review letter, M-b 350. The Rosemount 8721 was designed specifically for use in sanitary applications, with materials, fit, and finish that meet application and CIP/SIP requirements.

- Rosemount 8721 conforms to 3-A Sanitary Standards and is authorized to display the 3-A Symbol; Authorization #1222
- Rosemount 8721 is European Hygienic Equipment Design Group (EHEDG) Type EL certified; Certificate #C03-5229



The Rosemount 8721 Flowmeter provides an accurate and repeatable signal that indicates the rate of flow of the fluid through the pasteurization loop. This signal is used by the pasteurization control device or system to determine if the product holding time meets the legal holding time requirement for the pasteurization process being used. If it does not, the flow must be diverted by the system to the unpasteurized milk return.

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Process Management

Rosemount 8721

Lock Out and Sealing

Once the operation of the Meter Based Timing System has been tested and confirmed, the flow meter configuration can be locked to prevent configuration changes, and the transmitter sealed with tamper evident regulatory seals. Each Rosemount flow transmitter has a transmitter security switch located on the main transmitter circuit board that when set to the **ON** position prevents any changes to the configuration. The operator can still view parameters, but cannot make any changes.

Once the inspector has confirmed proper operation, the following steps should be used to lock out and seal the flow meter:

1. Open the Transmitter cover and locate the Transmitter Security switch on the main transmitter board. (see Figure 1, Figure 2, and Figure 3 for location of the Transmitter Security Switch.)

NOTE

8732E transmitter board: The transmitter Security Switch is located near the right side of the board labeled *Security*.

8712D and 8712E transmitter board: The transmitter Security Switch is located near the middle of the board and is labeled *Security*.

8732C transmitter board: The transmitter Security Switch is located near the top of the board and is labeled *WP*.

2. Set the hardware switch to the **ON** position, enabling the transmitter security.
3. Close the covers tightly and seal with tamper evident seals. (Tamperproof Kits can be used to simplify sealing the flow meter.)

FIGURE 1. Rosemount 8732E Electronics Board and Hardware Switches

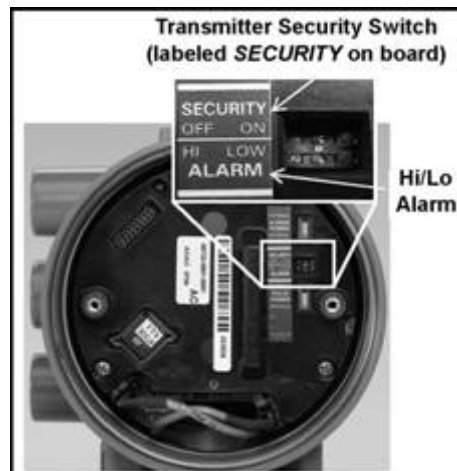


FIGURE 2. Rosemount 8712D and 8712E Electronics Board and Hardware Switches

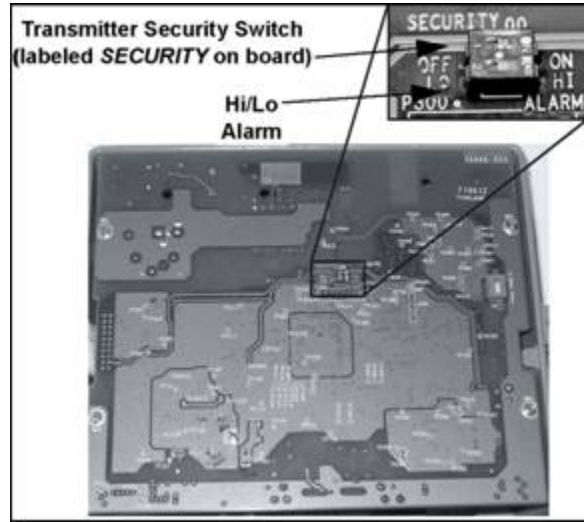
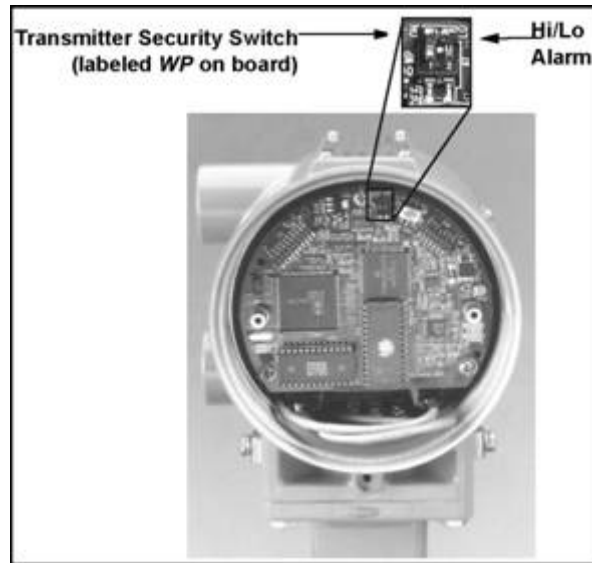


FIGURE 3. Rosemount 8732C Electronics Board and Hardware Switches



Rosemount 8721

Tamperproof Kits

For MBTS applications, the flow meter must be sealed by the Regulatory Agency. Tamperproof Kits, shown below, can be used to seal the flow meters, and are sold separately.

FIGURE 4. Rosemount 8721 with remote junction box (used with remote transmitter)

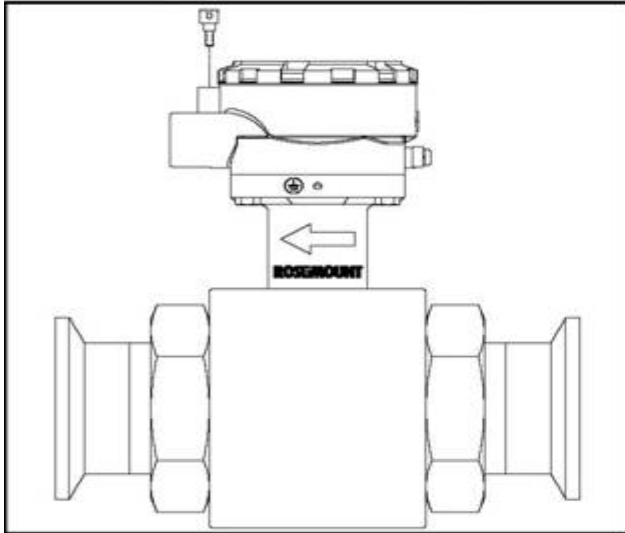


FIGURE 5. Rosemount 8732C or 8732E transmitter integrally mounted to the 8721 flow tube.

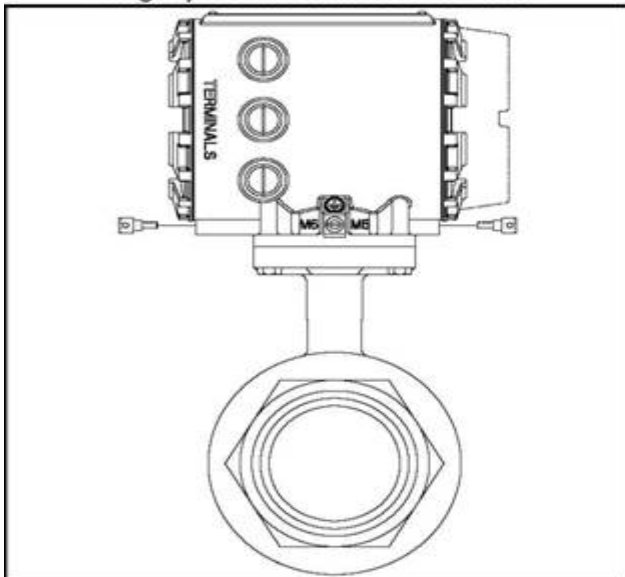
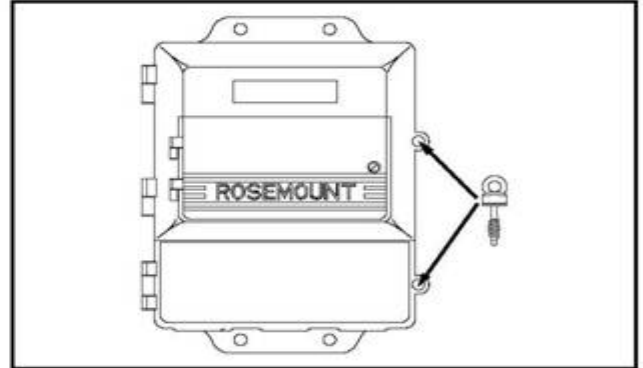


FIGURE 6. Rosemount 8712D



08721-0549-0001 8732E Integral Tamperproof Kit

Contains 2 tamperproof fasteners; one each for 8732E electronics cover and 8732E terminal cover.

08721-0548-0001 8712D Remote Tamperproof Kit

Contains 2 tamperproof fasteners; one each for 8712D electronics cover, 8712D terminal cover.

08721-0547-0001 8732C Integral Tamperproof Kit

Contains 2 tamperproof fasteners; one each for 8732C electronics cover and 8732C terminal cover.

This kit can be used as a tamperproof fastener for the flowtube remote junction box.