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College Park, MD 20740-3835

M-b-352

November 30, 2006

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

FROM: Milk Safety Branch (HFS-626)

SUBJECT: ABB FXE 4000 Model DE21-PMO With Remote E4-PMO Signal Converter And Model DE23-PMO With Integral E4-PMO Signal Converter

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 Safety Team have evaluated this piece of equipment and have validated the technical information reviewed and submitted by the Atlantic-Midwest Dairy Equipment Review Committee (AMDERC) addressing the ABB FXE 4000 Model DE21-PMO with Remote E4-PMO Signal Converter and Model DE23-PMO with Integral E4-PMO Signal Converter. When constructed, installed and operated as described in this memorandum, the ABB Model DE21-PMO with Remote E4-PMO Signal Converter and Model DE23-PMO with Integral E4-PMO Signal Converter have been found to meet the applicable provisions of the *Grade "A" Pasteurized Milk Ordinance* (PMO) when used as a magnetic flow meter based timing system for HTST pasteurizers.

Compliance with the PMO is based upon construction, installation and operation as described in the Manufacturer's Instruction Manual, Supplement Magnetic Flow-meters FXE4000 Series PMO Application DE21-PMO and DE23-PMO, PN25118_0, Published July 2006; the Data Sheet Electromagnetic Flow-meter FXE4000 (COPA-XE/MAG-XE) D184SO44U02, Rev. 03, Published 05.04; and Operating Instruction D184B105U02 Electromagnetic Flow-meter FXE4000 (COPA-XE/MAG-XE) with Pulse DC Magnetic Field Excitation, Published April 2004, Rev. 02., as well as the following provisions:

1. All PMO installations must comply with the Manufacturer's Instruction Manual, Supplement Magnetic Flow-meters FXE4000 Series PMO Application DE21-PMO and DE23-PMO, PN25118_0, Published July 2006.
2. The ABB FXE 4000 Model DE21-PMO with Remote E4-PMO Signal Converter and Model DE23-PMO with Integral E4-PMO Signal Converter shall

be installed in compliance with Appendix H. Pasteurization Equipment and Procedures, Magnetic Flow Meter Based Timing Systems for HTST Pasteurizers of the PMO.

3. Upon installation the configured values will be documented by the manufacturer and maintained so that the operator and/or Regulatory Agency can verify these values. The Regulatory Agency should maintain a copy for their files. After the configuration values have been verified, the lockout switch must be placed into the closed position and the cover of the converter is replaced. Access to the electromagnetic flow-meter converter shall be restricted by the application of a regulatory seal. This electromagnetic flow-meter is equipped with a magnetic stick for ease of operator operation; however, once the configuration values have been verified and the lockout switch has been moved to the closed position the magnetic stick can not be used to alter any configuration values.

4. When installed, the magnetic flow-meter sensor and converter shall comply with all applicable test requirements in Appendix I. Pasteurization Equipment and Controls -Tests of the PMO.

For information regarding this equipment, please contact:

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Product Manager
ABB Inc.
125 East County Line Road
Warminster, PA 18974
Phone: (978) 582-9229
Fax: (215) 674-6394

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 "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 CFSAN 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 CFSAN Web Site, please e-mail your request to Robert.Hennes@fda.hhs.gov.



Donald R. Goldsmith
FDA Regional Dairy Specialist



Jonathan M. Gardner
FDA/MSB Milk Sanitation Officer

FXE4000 Sanitary Magmeter

Model

DE21-PMO
with remote E4-PMO Signal Converter



FXE4000 Sanitary Magmeter

Model

DE23-PMO
with integral E4-PMO Signal Converter



4) System Parameter Verification for DE21-PMO with remote E4-PMO signal converter and DE23-PMO with integral signal converter

E4-PMO Remote Signal Converter



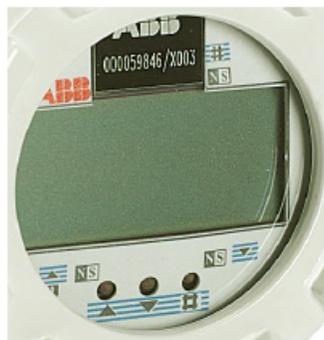
E4-PMO Signal Converter Display



DE23-PMO Integral Signal Converter



DE23-PMO Signal Converter Display



5) User Lockout Switch for PMO applications.

The User Lockout function is a switch located behind the sealed cover, with the switch in the closed position the user is prohibited from changing any parameter that affects the accuracy of the flow meter (Parameters may be viewed but not changed). For PMO applications the switch is set to the CLOSED position at the factory. If prior to putting the meter into operation any parameters need to be changed the switch will need to be placed into the OPEN position. The switch must be placed back into the CLOSED position before the meter cover is sealed and put back into operation.

With the Front Cover Removed, the approximate location of the switch is as shown.



To Enable System Programming of parameters via the magnetic stick or keypad – PLACE SWITCH INTO THE OPEN POSITION

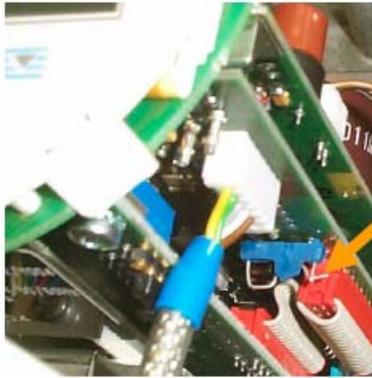


Lockout Switch in OPEN position.

ALLOWS changes to the parameters via the following.

1. Magnetic Stick Operation
2. Keypad Configuration

To Disable System Programming of parameters via the magnetic stick or keypad -
PLACE SWITCH INTO THE CLOSED POSITION



Lockout Switch in CLOSED position.

ALLOWS ONLY REVIEW of PARAMETERS via the following.

1. Magnetic Stick Operation
2. Keypad Configuration

POSITION for PMO prior to Sealing Cover.

=== WITH LOCKOUT SWITCH IN CLOSED POSITION ===

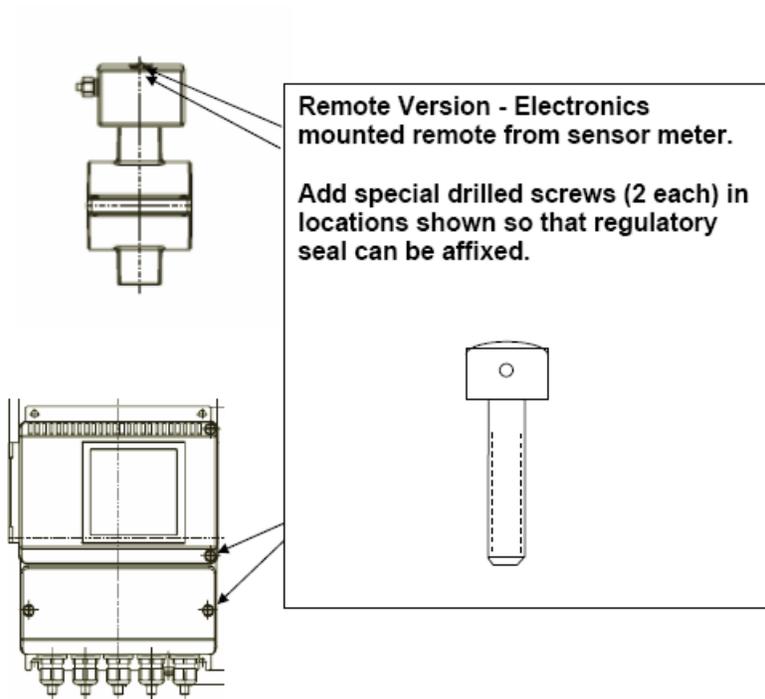
Attempting to change any parameter will display the following message.

*******ERROR*******
Prot.cust.trans

6) Flow Meter Sealing Instructions

DE21-PMO with remote E4-PMO signal converter

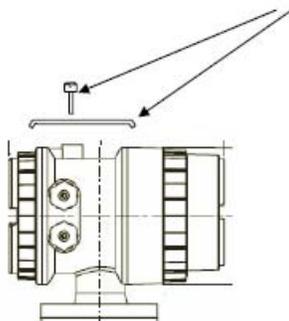
Proper sealing of the DE21-PMO and E4-PMO is shown below. Two special screws are included with each so that the regulatory seal can be affixed.



Note: The remote sensor housing and transmitter covers must be sealed by the Regulatory Agency.

DE23-PMO with integral E4-PMO signal converter

Proper sealing of the DE23-PMO with integral E4-PMO signal converter is shown below. A special clamp and screw is included with the flow meter so that the regulatory seal can be affixed.



Integral Version – Electronics mounted directly to sensor meter.

Add Tamper Proof Clamp directly to housing with special drilled screw so that regulatory seal can be affixed.

Note: Both covers of the integral housing must be sealed by the Regulatory Agency.

