HHS:PHS:FDA:CFSAN:OC:DCP:MSB

5100 Paint Branch Parkway
College Park, MD 20740-3835

M-b-345

March 30, 2004

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

FROM: Milk Safety Branch (HFS-626)

SUBJECT: Endress and Hauser PROline Promag 50/53 H Electromagnetic Flow Measuring System

The Endress and Hauser PROline Promag 50/53 H Electromagnetic Flow Measuring System has been reviewed and found to comply with the applicable provisions of the *Grade "A" Pasteurized Milk Ordinance* (PMO) when used as a flow-measuring system.

Compliance with the PMO is based upon construction, installation and operation as described in the Manufacturer's Manuals PROline Promag 50 Electromagnetic Flow Measuring System (#50097085 and #50097092) and PROline Promag 53 Electromagnetic Flow Measuring System (#50097083 and #50097092) and the following provisions:

1. The Endress and Hauser PROline Promag 50/53 H Electromagnetic Flowmeter shall be installed in compliance with Appendix H. PASTEURIZATION EQUIPMENT AND PROCEDURES, MAGNETIC FLOW METER BASED TIMING SYSTEMS FOR HTST PASTEURIZERS, including the criteria for COMPONENTS and PLACEMENT OF COMPONENTS of the PMO.

2. The Endress and Hauser PROline Promag 50/53 H Electromagnetic Flowmeter shall be tested in accordance with the supplemental set-up instruction for Endress and Hauser sanitary flow meter series PROline Promag 50 H and 53 H for use in HTST or Aseptic Processing Systems according to the PMO. Upon installation, the configuration 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 transmitter cover shall be reattached. Access to the electromagnetic flowmeter transmitter shall be restricted by the application of a regulatory seal.

3. When installed, the magnetic flowmeter sensor and transmitter shall comply with all applicable test requirements in Appendix I. 11.2A-2E MAGNETIC FLOW METER BASED TIMING SYSTEMS CONTINUOUS FLOW-HOLDING TIME of the PMO. Access to the electromagnetic flowmeter senor shall be restricted by the application of a regulatory seal.

The technical information that was reviewed constitutes the Endress and Hauser PROline Promag 50/53 H Electromagnetic Flow Measuring System Engineering Design and Technical Construction File (EDTCF).

For additional information regarding this equipment please contact:

Ola Wesstrom
Industry Mgr. Food & Beverage
Endress & Hauser USA
Phone: (317)-535-2134
Fax: (317)-535-1498
E-mail: ola.wesstrom@us.endress.com

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

Copies of this memorandum are enclosed for distribution to Regional Milk Specialists, State Milk Regulatory Agencies and State Milk Sanitation Rating Officers in your region. This memorandum 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.

/ss/

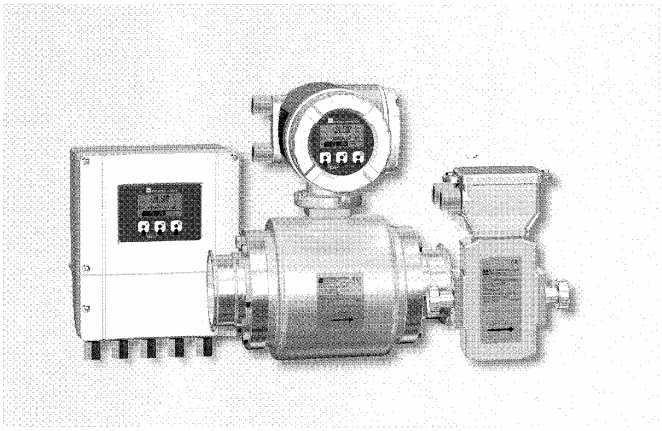
Jonathan M. Gardner
FDA/MSB Milk Sanitation Officer

Attachments:
Equipment Literature
Quick Field Reference
Regulatory Sealing Diagram

Technical
Information
TI 048D/24/ae

Electromagnetic Flow Measuring System *promag 50/53 H*

Flow measurement in food, beverage, pharmaceutical, or process applications



Features and benefits
- Nominal diameters 1/12" to 4"
- PFA for cleaning temperatures up to +300°F
- Guaranteed product quality - suitable for CIP/SIP cleaning and piggable
- Stainless steel housing for high sanitary safety
- 3-A authorized and EHEDG-tested
- Robust field housing, NEMA 4X (IP 67)
- NEMA 4X (IP 67) wall-mount housing for straight-forward installation of the remote version
- High measuring accuracy for improved process control:
  - Promag 50: ± 0.5% (option: ± 0.2%)
  - Promag 53: ± 0.2%
- Promag 53 with Touch Control
- Expandable software packages:
  - for batching applications
  - for electrode cleaning
  - for extended diagnosis and enhanced operational dependability
- Quick setup menus for straight-forward commissioning in the field
- Interfaces for integration into all major process-control systems:
  - HART® interface as standard
  - Promag 50: PROFIBUS-PA
  - Promag 53: PROFIBUS-PA/-DP, FOUNDATION fieldbus
- Explosion proof approval for installation in Division 1 (FM, CSA, ATEX, etc.)

Application

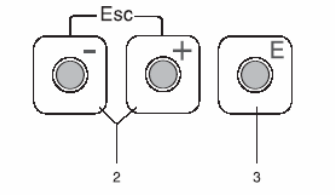
All fluids with a minimum conductivity of ≥ 5 µS/cm can be measured:
- beverages, e.g. fruit juice, beer, wine
- milk products, fruit mixtures
- salt solutions
- acids and caustic solutions, etc.

A minimum conductivity of ≥ 20 µS/cm is required for measuring demineralized water.

PROline *Evolution in flow*

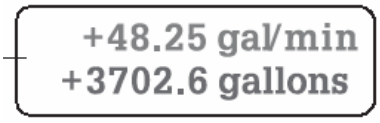
Endress+Hauser
The Power of Know How

Basic operation of Promag 50H (internal pushbuttons) and 53H (touch control)



Push buttons (2)
– Enter numerical values, select parameters
– Select different function groups within the function matrix
– Press and hold down +/- keys for longer than 3 seconds - Return directly to HOME position
Enter push button (3)
–Entry into the function matrix
– Save the numerical values you input or settings you change

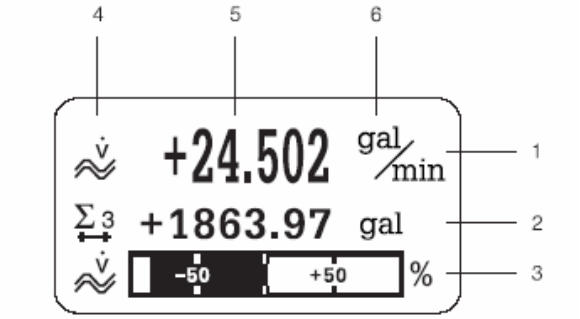
Promag 50 H - Quick review of measured value and set maximum flowrate



The backlit, two-line liquid-crystal display shows measured values, dialog texts, error messages and information messages. The display as it appears when normal measuring is in progress is known as the HOME position (operating mode).
Upper display line: Shows primary measured values, e.g. volume flow in [gal/min] or in [%].
Lower display line: Shows supplementary measured variables and status variables, e.g. totalizer reading in [gallons], bar graph, measuring point designation

- To see current flow rate make sure display is in “Home position” – press and hold +/- buttons simultaneously for >3 seconds
- To view set maximum flow rate press “E” once and then scroll using “+” to “Current Output” then scroll using “E” to “Value 20mA”

Promag 53H - Quick review of measured value and set maximum flowrate



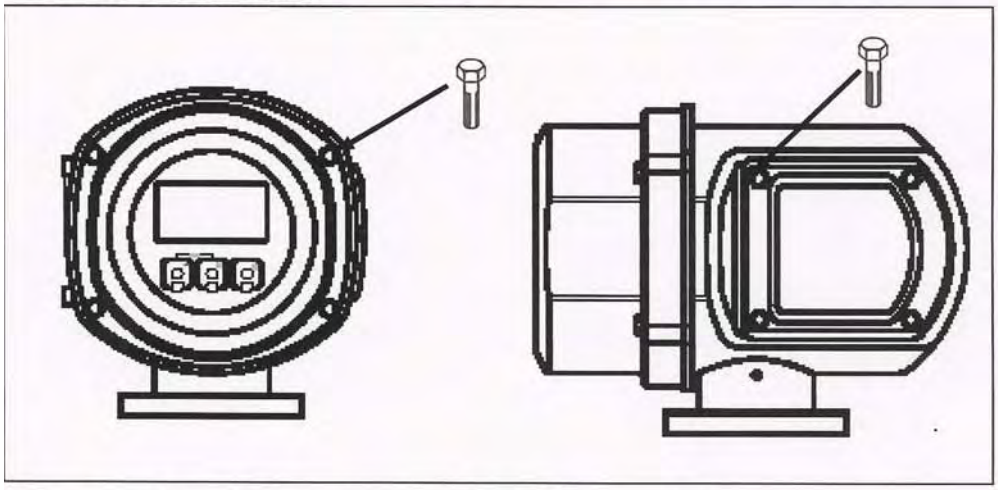
The display as it appears when normal measuring is in progress is known as the HOME position (operating mode).
1 Main line shows primary measured values, e.g. volume flow in [gal/min, l/s].
2 Supplementary line shows supplementary measured variables, e.g. totalizer No. 3 in [gallons / m3]
3 Information line shows additional information on the measured variables, e.g. bar graph of the limit value reached by the volume flow.

- To see current flow rate make sure display is in “Home position” Press and hold +/- buttons simultaneously for >3 seconds
- To view the set maximum flow rate Press “E” once and then scroll using “+” to “Outputs”. Press “E” once “Current output 1” press “E” once "configuration” scroll using “E” to “Value 20mA”

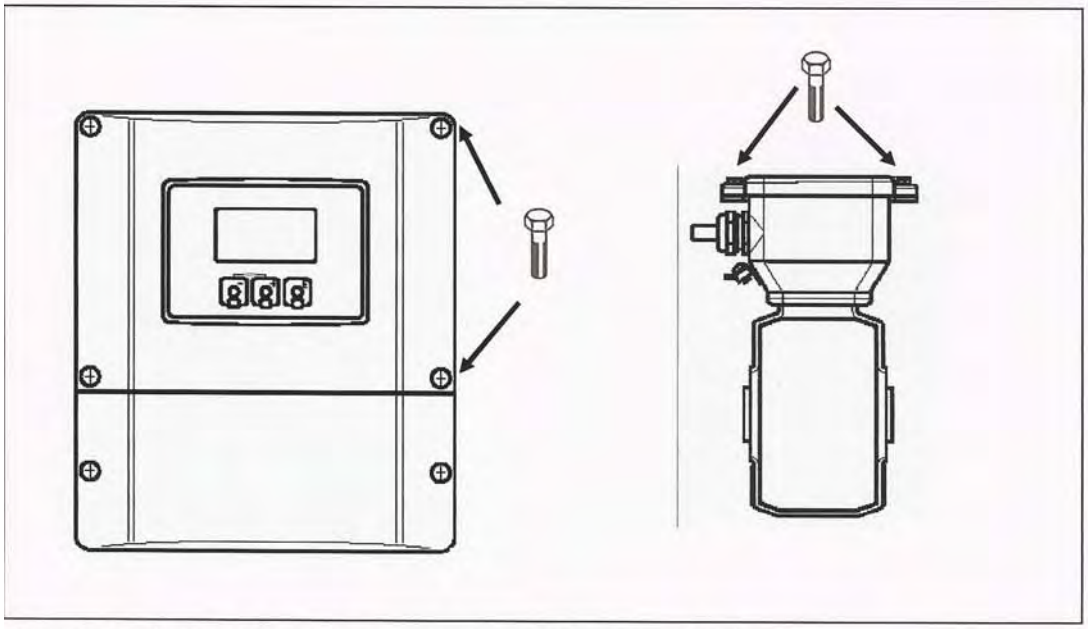
Endress+Hauser
People for Process Automation

Appendix C - Magflow Meter Sealing instructions

Note: Special screws with drilled holes from screw kit P/N 84601050 should be installed in the locations indicated below, so that regulatory seals can be affixed to prevent access to the flow meters programming.



Compact version with electronics mounted directly to sensor body



Remote version with electronics mounted remotely from sensor body

Page 4/10

Note: The Transmitter Cover and Sensor Body must be sealed by the Regulatory Agency.