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College Park, MD 20740-3835

M-b-381

October 31, 2018

TO: Director, Office of State Cooperative Programs
Attn: All Staff, Division of Milk Safety

FROM: Milk and Milk Products Branch (HFS - 316)

SUBJECT: Endress+Hauser Promag H 500 Series Electromagnetic Flowmeter
Sizes 0.5", 1", 1 1/2", 2", 2 1/2", 3", 4" and 6".

In accordance with M-I-00-2, *Milk and Milk Product Equipment-A Guide for Evaluating Construction*, FDA's Milk Specialists and CFSAN's Milk and Milk Products Branch along with Atlantic Midwest Dairy Equipment Review Committee (AMDERC), have specifically evaluated the Endress+Hauser Promag H 500 Series Electromagnetic Flowmeter, Sizes 0.5", 1", 1 1/2", 2", 2 1/2", 3", 4" and 6" and have validated and confirmed the technical information submitted by Endress+Hauser and the review of findings by the Atlantic Midwest Dairy Equipment Review Committee (AMDERC).

When constructed, installed, operated and maintained as outlined in the instructions of the manufacturer's manual and the Supplement attached: Endress+Hauser Proline Promag H 500 Series Electromagnetic Flowmeter, BA01398D/06/EN/02.17 71376049 Valid as of version 01.01. zz (Device firmware) Supplement for Pasteurized Milk Ordinance Application, has been found to meet the applicable provisions of Item 16p-Pasteurization and Aseptic Processing of the *Grade "A" Pasteurized Milk Ordinance* (PMO).

The technical information that was submitted and reviewed addressing the Endress+Hauser Promag H 500 Series Electromagnetic Flowmeter Sizes 0.5", 1", 1 1/2", 2", 2 1/2", 3", 4" and 6" 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, and to request a copy of the manufacturer's referenced manual please contact:

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FDA's review and acceptance of the Endress+Hauser Promag H 500 Series Electromagnetic Flowmeter Sizes 0.5", 1", 1 1/2", 2", 2 1/2", 3", 4" and 6" 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 FDA Milk Specialists, Milk Regulatory/Rating Agencies and 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 monica.metz@fda.hhs.gov.



Donald R. Goldsmith
Milk Specialist



Chief
Milk and Milk Products Branch

Attachments:

BA01398D/06/EN/02.17
71376049
Valid as of version
01.01.xx (Device firmware)

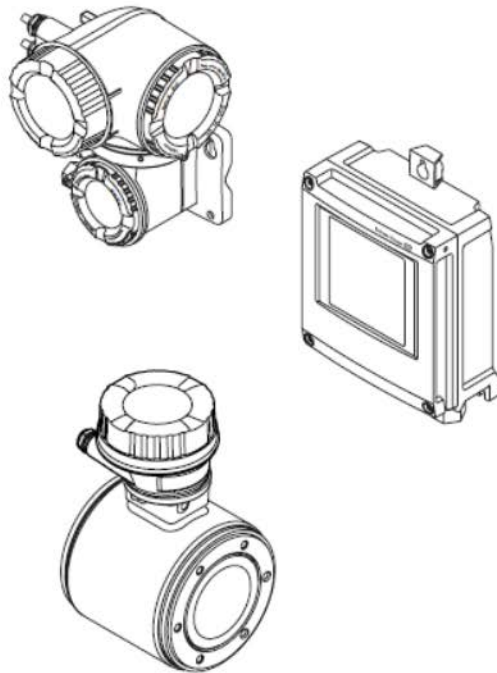
Products

Solutions

Service

Operating Instructions Proline Promag H 500 HART

Electromagnetic flowmeter



Endress+Hauser 
People for Process Automation

Promag H500 Supplemental Setup instructions for Endress + Hauser sanitary magnetic flowmeter series Promag H500 for use in HTST or Aseptic processing systems.
All applicable parts of PMO (2017 revision) appendix H and I apply.

Model Number and Option Inclusion List for PMO applications:

5H5Bxx- 010 015 020 030 040 050 060 070 075 080

5 = Promag Magnetic Flowmeter

H= Hygienic Sensor

5= 500 series electronic

B = Generation index (b,c...)

xx = sizes 2 through 150mm or 1/12th through 6". See set-up table for flow ranges per meter diameter

010 = Non-Hazardous Area Classification or Class 1 Division 2 Area Classification

015 = Self-Switching VAC/VDC Power Supply or Fixed Input value

020 = Output Code Option **B = 4-20mA, HART + Pulse/Frequency/ Switch Output or Selectable Fieldbus ***

***021= If Channel 1 output selected as Digital, Channel 2 Analog/ Configurable I/O required for Legal Output**

030 = With or Without Display. * Local Display includes local keypad/ buttons and must be covered prior to seal

040 = Transmitter housing material. All allowed with unique security seal kit

050 = Electrical Connection. Conduit entry or M12 Cord set

060 = Process connection Seal. Aseptic Shape Only allowed. (e.g. Aseptic EPDM FDA Listed material)

070 = Process Connection. (e.g. Tri-clamp®)

075= Electrode material and shape. (e.g. Stainless Steel 1.4435/ 316L electropolished measuring sensors)

080 = Flowmeter volumetric laboratory calibration. (e.g. 0.2% or 0.5%)

480 = Device Model 1.

Additional Options Allowed for PMO Applications:

500: Display Language. (e.g. English, Spanish, French, etc.)

520: Sensor Options for internal potting, inclusion of temperature sensor, and IP69 wash down construction

540: Heartbeat Verification and Monitoring, OPC-UA, Extended HistoRom on board recording memory (May be used at set-up or as output condition only after seal is applied)

580: Material certificates and additional factory certificates and test protocols. (e.g. hydrostatic test)

590: Additional Approval Markings applied to the device: 3A, EHEDG, CRN

850: Firmware Version generation in case of documented requirement for in-place device

895: Marking/ Tagging / RFID identification to customer specific request at manufacturer

Notes: Model Number Code Excludes WLAN (Wireless LAN remote accessibility)

In order to meet FDA “PMO” requirements for magnetic flow meter based timing systems for HTST pasteurizers, the meter programming and configuration function must be disabled before regulatory seals are affixed. The procedures below must be followed in order to program the device parameters using the web browser, disable the possibility of reprogramming, and seal the device properly. Secondly, the procedure demonstrates an alternate initial programming with use of local HMI (Human Machine Interface) with optical key pad entry.

Endress + Hauser, model Promag H 500 ...

Web Browser Device Configuration Interface: The web browser is used in order to configure the device so that the parameter values are specific to HTST pasteurizer applications. (See appendices F and D or Promag 500 operating instructions manual for details.)

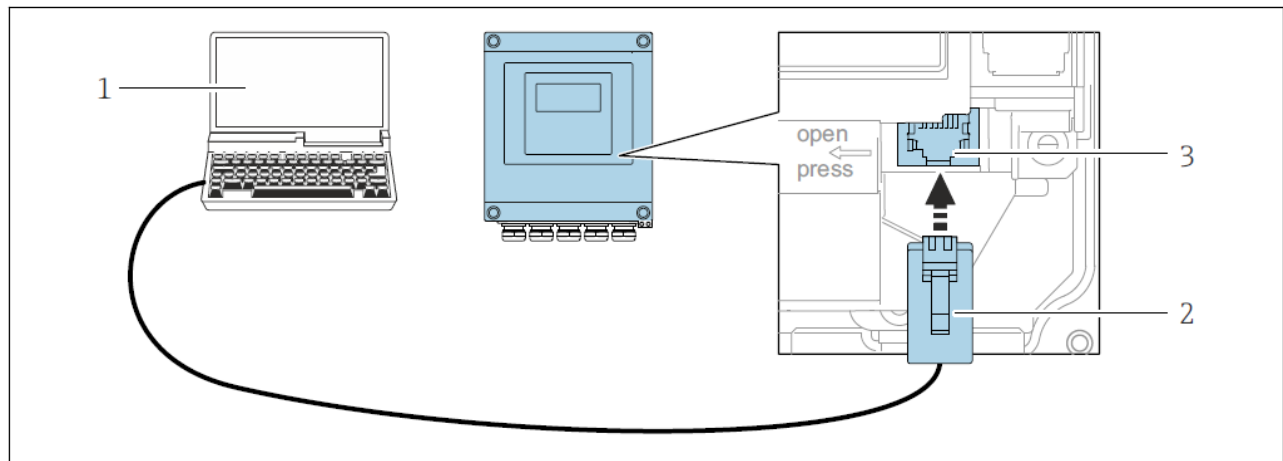
Disabling Configuration interfaces: When using a Promag 500 device, configuration functionality of the flow meter must be turned off using “Write Protection.” This can be done using a dip switch after removing the device cover. After enabling write protection, configuration will be disabled from editing by HART protocol, service interface (CDI connection,) and the web browser. (See appendix F or Promag 500 operating instructions manual for details.)

Regulatory Seals: It is necessary to install seals on the flow meter housing covers to prevent unauthorized access to the flow meter. Special enclosure screws are available, which accommodate a wire and leaded seals. (See appendix F for details.)

Appendix A Promag H 500 – Web Browser Connecting to the Web Browser:

Configuring the Internet Protocol of the Computer:

1. Switch on the measuring device and connect to the computer via the Ethernet cable.



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2. If a 2nd network card is not used: all the applications on the notebook should be closed, or all the applications that require the Internet or network, such as e-mail, SAP applications, Internet or Windows Explorer, i.e. close all open Internet browsers.
3. Configure the properties of the Internet protocol (TCP/IP) as defined in the table below.

IP address	192.168.1.XXX; for XXX all numerical values except: 0, 212 and 255 → e.g. 192.168.1.213
Subnet mask	255.255.255.0
Default gateway	192.168.1.212 or leave cells empty

Table 1: Configuring Internet Protocol of Computer

Starting the Web Browser:

1. Start any Web browser on the computer.
2. If the IP address of the measuring device is known, enter the defined device address in the address line of the Web browser. If it is unknown, set DIP switch No. 10 to ON, restart the device and enter the standard IP address: 192.168.1.212
3. The following page should appear:

The screenshot shows a web browser interface for a device. At the top, there is a header area with a logo for 'EH Endress+Hauser' on the right and a 'Device tag' field in the center. A grey box labeled '2' points to a grey square on the left. A vertical line labeled '1' points to the 'Device tag' field. Below the header, there is a 'Webserv.language' dropdown menu set to 'English'. A prominent 'Ent. access code' field contains four dots, with an 'OK' button to its right. At the bottom, there is an 'Access stat.tool' dropdown menu set to 'Maintenance'.

4. Enter access code “0000” and press “Enter.”

Changing Parameters:

1. Click the “Menu” tab on the top of the screen. This will take you into the menu structure where all programmable parameters can be changed. See the figure 1.1.1.3 below for what this page will look like.

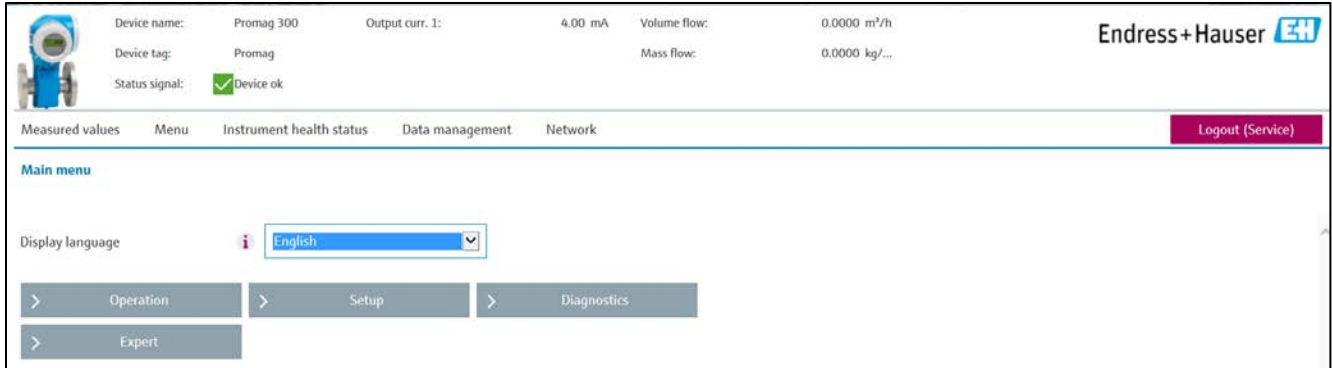
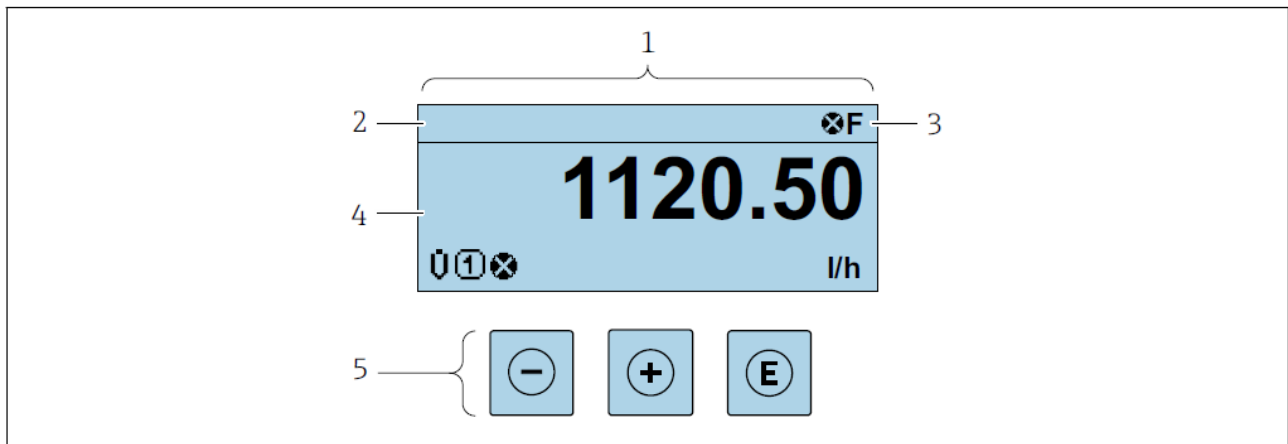


Figure 3: Web Browser Menu Screenshot

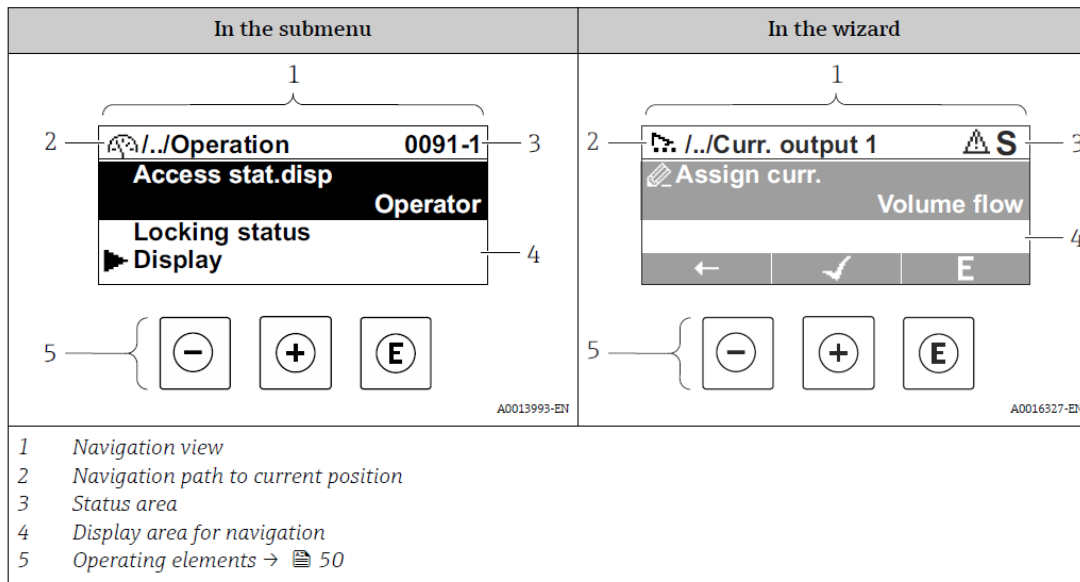
2. See appendix B (1.1.1.4) for default configuration values. NOTE: When inputting values, you will need to press “Enter” or “Apply” to store the new entry.
3. When finished programming the device, simply disconnect the Ethernet cable.

Local Operation via Optical Key Pad



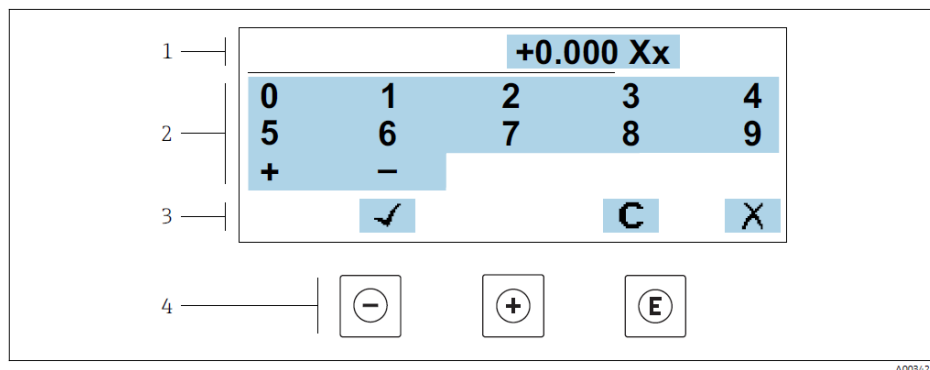
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- 1 Operational display
- 2 Device tag → 75
- 3 Status area
- 4 Display area for measured values (4-line)
- 5 Operating elements → 50



Using the operating elements in the editing view

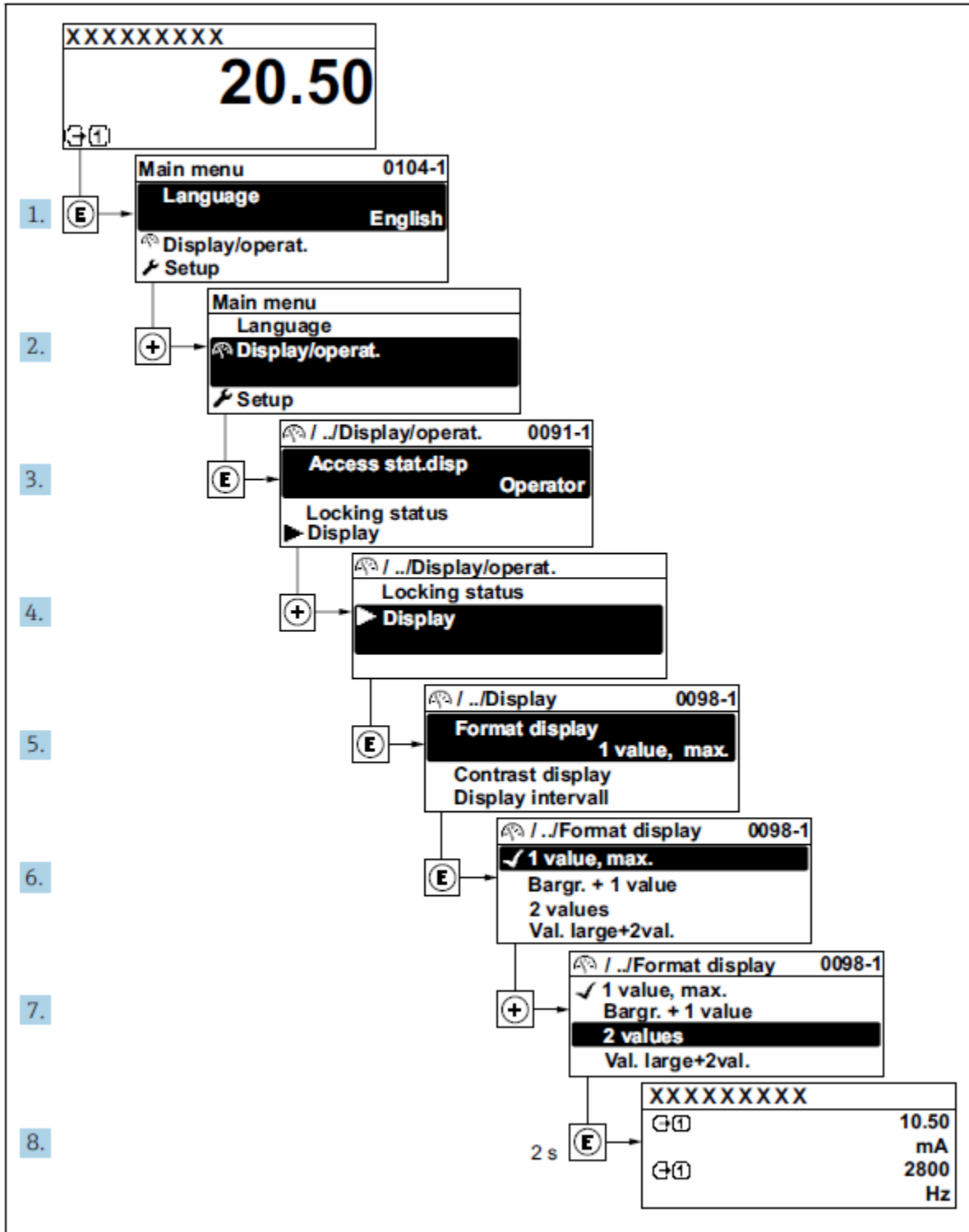
Operating key(s)	Meaning
	Minus key Move the entry position to the left.
	Plus key Move the entry position to the right.
	Enter key <ul style="list-style-type: none"> Press the key briefly: confirm your selection. Press the key for 2 s: confirm the entry.
	Escape key combination (press keys simultaneously) Close the editing view without accepting the changes.



22 For entering values in parameters (e.g. limit values)

- 1 Entry display area
2 Input screen
3 Confirm, delete or reject entry
4 Operating elements

Example: Setting the number of displayed measured values to "2 values"



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Appendix B – Configuration Values

Key Parameters for verification of Flow meter settings

Applicable to Endress+Hauser electromagnetic flow meter **Promag H 500**

Programming location	Function description	Required setting	Application specific (set during initial start-up)	Notes
Diagnostics, Device Info	Serial number	Sensor serial #		Device Specific
Diagnostics, Device Info	Firmware version	x.xx.xx		Device Specific Revision
Set Up/ System units	Unit volumetric flow	gal/min		Gal/min
System units	Unit volume	gal		Gal
Diagnostics	Current simulation	Off		off
Set Up/ Current Output 1 or 2*	Assign current output	Volume flow		Volume flow
Current Output 1 or 2*	Current Span	4-20mA		4-20mA
Current Output 1 or 2*	Value at 4mA flow	Set during start-up to application specific value	Example: 0gpm	Size dependent
Current Output 1 or 2*	Value at 20mA (Flow full scale)	Set during start-up to application specific value	Example: 75gpm for 2” sensor	Size Dependent
Output Condition	Damping output 1	1	Same as damping constant	0s
Current Output 1 or 2*	Failure mode	Min. Current	Drives current to 4mA in case of failure	Min. Current
Process parameters	Flow Damping	6	Same as system damping	6
Set Up/ Advanced SetUp/ Sensor Adjustment	Installation Direction	Forward Flow	Forward flow direction only	In Direction of Arrow (on flow tube label)

Setup	Low Flow cut-off	Factory default On "Volume flow"	Use factory default values(based on meter size) 1-1/2" = 0.75gpm 2" = 1.25gpm 2-1/2" = 2.0gpm 3" = 2.5gpm 4" = 4.0gpm
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Table 2: HTST Configuration Values

Notes: Flow Damping value = 6. 1 measuring period = 16.7ms x 6 = 1 second maximum allowable damping to flowmeter system.

CIP Standard Filter is allowable during normal operation and does not bias measurement value underflowing process conditions. CIP standard filter is activated at a rapid change in conductivity values e.g. milk >water>cleaning agent and supports measurement tracking under cleaning process.

(Activation allowable via: Main Menu: Expert: Sensor: Process Parameters: Filter Options)

Device specific software and Firmware Revision Management -The device manufacturer delivers new instruments with controlled firmware. The firmware can be monitored and managed in the manufacturers equipment record. Only manufacturer information that states a required corrective action to change firmware should be considered as the control decision for device behavior of a previously placed-in-service instrument.

Current Output 1 or 2*

Condition 1:

If device is ordered with 4-20mA HART as Channel 1, no additional fieldbus (e.g. Ethernet I/P or other) is available on the device transmitter and therefore Current Output 1 is the legal output and all HART communication is disabled when the write protection DIP switch is in the ON position.

Condition 2:

If the device is ordered with Channel 1 Fieldbus version (e.g. Ethernet I/P or other) then channel two is required as the legal output. This can be ordered as a fixed 4-20mA output or as a Configurable I/O channel and subsequently programmed to behave as a 4-20mA output.

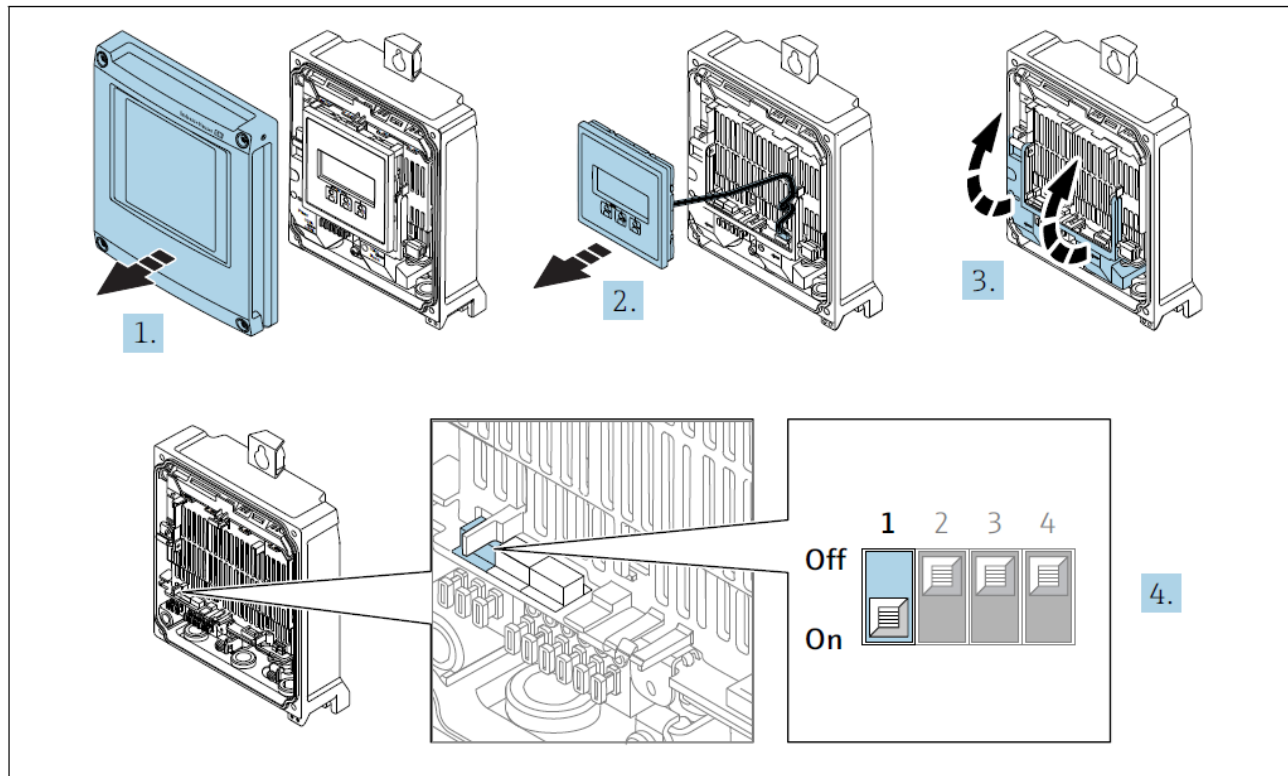
Condition 1 model # 5H3Bxx-xx x BA x xxxxxxxxxxxxxx

Condition 2 model # 5H3Bxx-xx x(GA,MA,NA,RA, or SA) B or D code required
xxxxxxxxxxxxxx

Appendix C – Write Protection via Write Protection Switch

To Enable Write Protection:

1. First, loosen the securing clamp or fixing screw of the housing cover.
2. Depending on the housing version, unscrew or open the housing cover and disconnect the local display from the main electronics module where necessary.

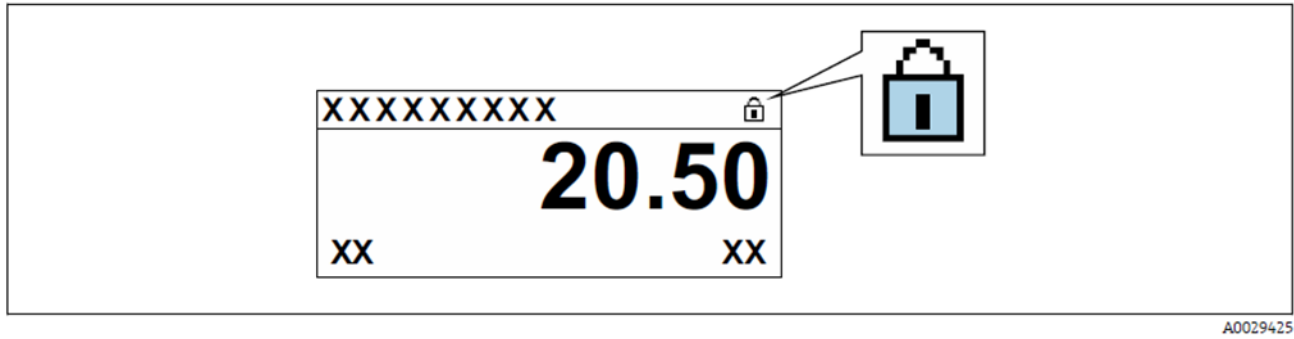


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3. Setting the write protection switch on the main electronics module to the ON position enables the hardware write protection. Setting the write protection switch on the main electronics module to the OFF position (factory setting) disables the hardware write protection.

The write protection must be in “ON” position prior to sealing the meter

- If hardware write protection is enabled, the Locking status parameter displays the Hardware locked option; if disabled, the Locking status parameter does not display any option



Appendix D – Regulatory Sealing Instructions

Note: The lower right corner of the Promag H500 wall mount transmitter housing has a loop system to allow for security seal to be applied. This is to prevent access to the flow meters programming. When display with optical configuration keys are used, the keys must be covered with foil or non-transparent tape (example electrical tape) Fig 7. Being a remote configuration, the sensor side must also be sealed. Use the screw kit and install screws with holes for regulatory sealing wire.

***Note – Remote Sensor junction box must be sealed to ensure the proper sensor and transmitter connection are made and to prevent tamper once placed in service. See fig 8**



Figure 8: Special Screw Insertion Diagram for Regulatory Seals

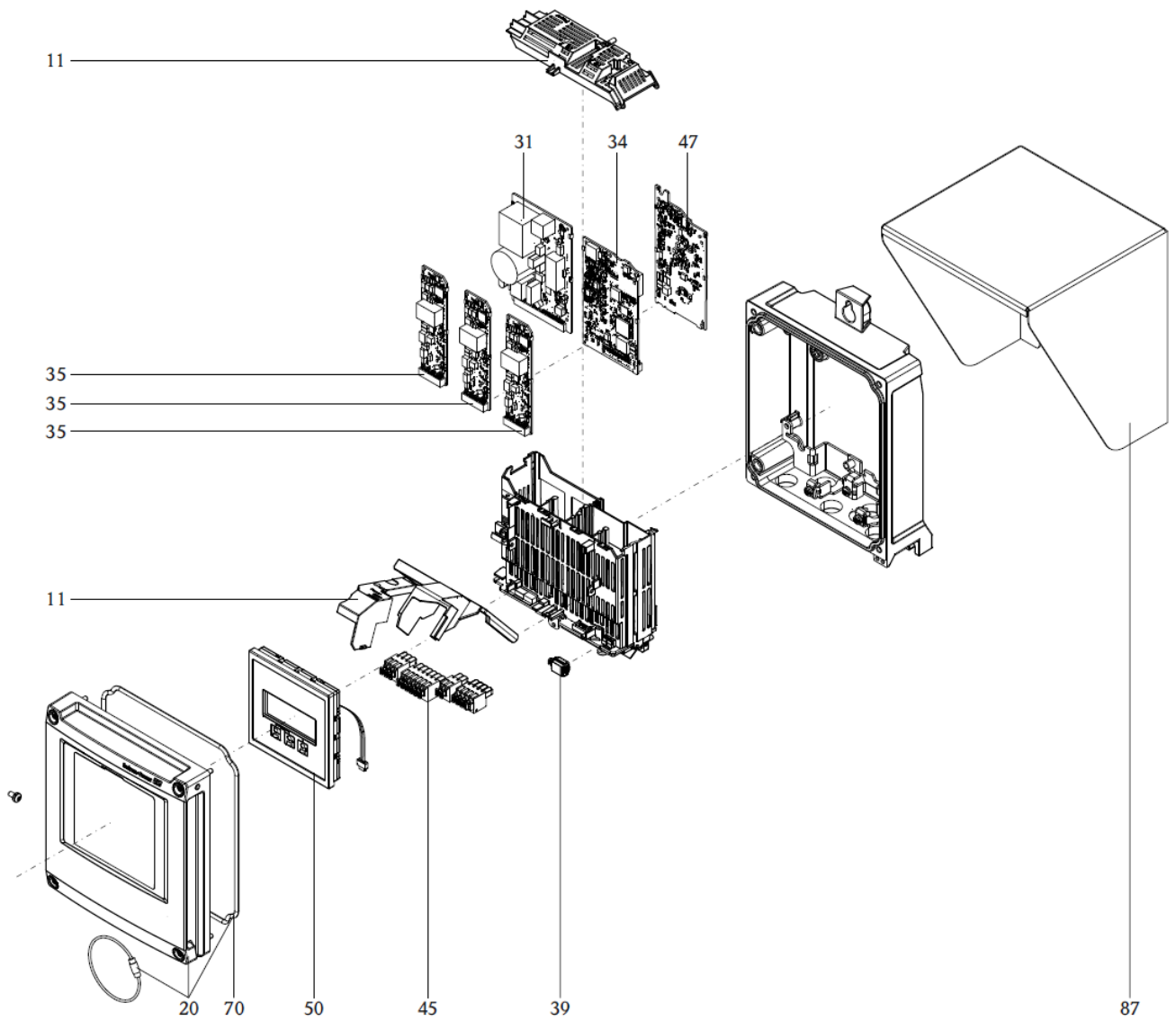


Figure 6: Special Screw Insertion Diagram for Regulatory Seals

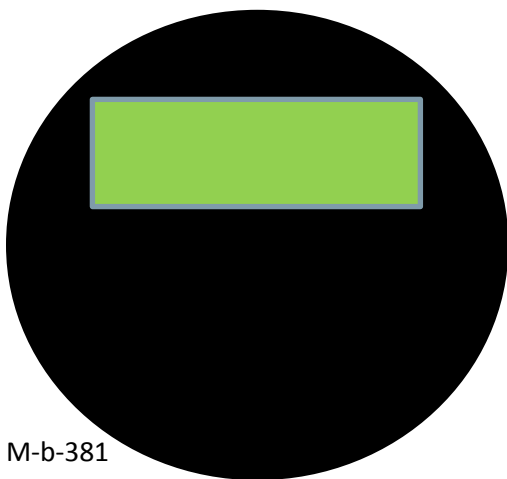


Fig 7.
 Prior to sealing a device and placing into PMO service, the display key pad must be covered with the provided foil.