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M-b-365 Supplement 1

June 1, 2018

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

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

SUBJECT: KROHNE, Inc. IFC 300F, OPTIFLUX 6000 / 6300C Magnetic Flow Meter,
Sizes 0.5", 1", 1.5", 2", 2.5", 3" and 4"

This memorandum is a supplement to M-b-365 (KROHNE, Inc. IFC 300F, OPTIFLUX 6000/6300C Magnetic Flow Meter, Sizes 0.5", 1", 1.5", 2", 2.5", 3" and 4") which was issued December 3, 2010. This Supplement is to address the concern that certain IFC configuration parameters were accessible when using the Infra-Red keys on the IFC 300 signal converter display, when the Jumper was installed in the locked position. In order to assure that the configuration parameters were inaccessible, a non-transparent tape was affixed to the glass window of the IFC 300 display cover. The non-transparent tape eliminates the potential of the configuration parameters being changed by the Infra-Red keys. A Pasteurized Milk Ordinance (PMO) check list is included in this Supplement for use during installation.

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 have specifically evaluated the KROHNE, Inc. IFC 300F, OPTIFLUX 6000 / 6300C Magnetic Flow Meter, Sizes 0.5", 1", 1.5", 2", 2.5", 3" and 4" and have validated and confirmed the technical information submitted by KROHNE, Inc. and the review findings of the Atlantic Midwest Dairy Equipment Review Committee (AMDERC).

When constructed, installed, operated and maintained as outlined in the instructions of the manufacturer's manual: IFC 300 Handbook, Signal Converter for Electromagnetic Flow Meters, Electronic Revision ER 3.3.xx [SW REV 3.3.x] Reference Number: © KROHNE 08/2010 - 4000069803 - MA IFC 300 R04 en and IFC 300 Handbook Supplement for Pasteurized Milk Ordinance Application, IFC 300F, OPTIFLUX 6000 / 6300C, Document Number 8.80240.01.00 -- Version Number 2.0 -- Printed 2-April, 2018, and the non-transparent tape is affixed to the glass window of the IFC 300 display cover as described above, the KROHNE, Inc. IFC 300F, OPTIFLUX 6000/6300C Magnetic Flow Meter, Sizes 0.5", 1", 1.5", 2", 2.5", 3" and 4" have 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 KROHNE, Inc.

IFC 300F, OPTIFLUX 6000, or OPTIFLUX 6300C Magnetic Flow Meter, Sizes 0.5", 1", 1.5", 2", 2.5", 3" and 4" 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. (NOTE: Just reformatted from original)

For additional information regarding this equipment, and to request a copy of the manufacturer's referenced manual, IFC 3-Handbook, please contact:

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FDA's review and acceptance of the KROHNE, Inc. IFC 300F, OPTIFLUX 6000, or OPTIFLUX 6300C Magnetic Flow Meter, Sizes 0.5", 1", 1.5", 2", 2.5", 3" and 4" 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:

Purpose of Document:

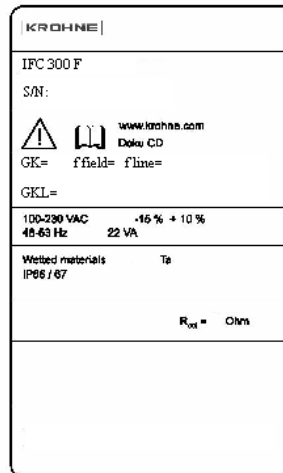
This supplement's purpose is to aid in the installation, programming and testing of KROHNE's IFC 300F, OPTIFLUX 6000, or OPTIFLUX 6300C Magnetic Flow Meter in Meter Based Timing Systems Application as described in Appendix H of the Pasteurized Milk Ordinance, 2015 Revision. Our IFC 300F signal converter can be connected remotely to OPTIFLUX 6000 flow meter sensor. Our OPTIFLUX 6300C Magnetic Flow Meter (C = Compact version) consist of the same IFC 300F signal converter that is directly mounted to the same OPTIFLUX 6000 flow meter sensor. IFC 300F / OPTIFLUX 6300C Magnetic Flow Meter for Meter Based Timing Systems Application must be installed, programmed and tested to be in compliance with the PMO.

Identification tags and model numbers for these meter components that can be used for PMO applications and can be found under the following Name plate information:

OPTIFLUX 6300C (compact version)



IFC 300F (Field remote version)



OPTIFLUX 6000 F (remote flow meter sensor)



Note: Relevant nameplate data for PMO include Model, GK / GKL values, and Size of flow meter sensor (DN15 / 0.5 inch through DN100 / 4 inches nominal diameter acceptable).

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PMO CHECKLIST

This information was taken from the function table on pages 83 to 112 of the KROHNE IFC 300 Handbook, Signal Converter of Electromagnetic Flowmeter. The following values are the public health control program parameters that should be programmed into the IFC 300F Magnetic Flow Meter signal converter for Meter Based Timing Systems Application as described in Appendix H of the Pasteurized Milk Ordinance. State regulatory is to check that these values are present to ensure that the meter is programmed for MBTS applications

A4 analog outputs

Program number	Function	Settings / description	PMO parameters
A4.1	Measurement	1)Measurement selection: volume flow/mass flow/diagnosis value/flow speed/coil temperature/conductivity	Volume flow
A4.2	unit	Selection of the unit from a list, depending on the measurement.	gpm
A4.3	range	1) Setting for main current output (range: 0...100%) Setting: 0...x.xx (format and unit, depending on measurement, see A4.1 and A4.2 above)	see nameplate
A4.4	low flow cutoff	1) Setting for main current output (sets output value to "0") Setting: x.xxx ± x.xxx% (range: 0.0...20%) (1st value = switching point / 2nd value = hysteresis), condition: 2nd value ≤ 1st value	3% with adjustable dead-band
A4.5	time constant	1) Setting for main current output (applicable to all flow measurements) Setting: xxx.x s (range: 000.1...100 s)	000.1 s

A7 process input

Program number	Function	Settings / description	PMO parameters
A7.3	size	Select from size table; range: DN2.5...3000 mm / 1/10...120"	see nameplate and C1.1.3, C1.1.4 and C1.1.5
A7.4	GK	Depending on the selection in Fct. A7.4 / A7.5, the Fct. C1.1.0, 5 or 6 appears. Set value acc. to nameplate; range: 0.5...12 (20)	see nameplate and C1.1.3, C1.1.4 and C1.1.5
A7.5	GKL	Depending on the selection in Fct. A7.4 / A7.5, the Fct. C1.1.0, 5 or 6 appears. Set value acc. to nameplate; range: 0.5...12 (20)	see nameplate and C1.1.3, C1.1.4 and C1.1.5
A7.10	field frequency	Setting as on measuring sensor nameplate = line frequency x value (from the following list): 1/6 or 1/2	1/6 or 1/2
A7.11	flow direction	Define polarity of flow direction. normal = forward direction forwards (according to the arrow on the measuring sensor) or backwards (in the opposite direction to the arrow) neg. = reverse flow	normal

C1 process input

C1.1 calibration

Program number	Function	Settings / description	PMO parameters
C1.1.2	size	Select from size table; range: DN2.5...3000 mm / 1/10...120"	see nameplate
C1.1.3	GK selection	Select the field current and the active GKx values; select GK value (see nameplate of the measuring sensor). Select: GK & GKL (both values possible / linearity test) / GK (250 mApp) (only GK values possible) / GKL (125 mApp) (only GKL values possible) / GKH (250 mApp) (only GKH values possible)	GK / GKL (GKH is not applicable)
C1.1.4	GK	Depending on the selection in Fct. C1.1.3, Fct. C1.1.4, 5 or 6 appears. Set value acc. to nameplate; range: 0.5...12 (20)	see nameplate
C1.1.5	GKL	Depending on the selection in Fct. C1.1.3, Fct. C1.1.4, 5 or 6 appears. Set value acc. to nameplate; range: 0.5...12 (20)	see nameplate

C1.2 filter

Program number	Function	Settings / description	PMO parameters
C1.2.2	flow direction	Define polarity of flow direction. normal = forward direction forwards (according to the arrow on the measuring sensor) or backwards (in the opposite direction) negative = reverse flow	normal
C1.2.3	time constant	For all flow measurements and outputs. xxx.x s; range: 0.0...100 s	1 sec or less
C1.2.4	pulse filter	Suppresses noise due to solids, air/gas bubbles and sudden changes in pH. Select: off (without pulse filter) / on (with pulse filter)	Off

Program number	Function	Settings / description	PMO parameters
C1.2.7	noise filter	Suppresses noise at low conductivity, high solids content, air and gas bubbles, and chemically in homogeneous media. Select: off (without noise filter) / on (with noise filter)	Off
C1.2.10	low flow cutoff	Sets output value of all outputs to "0": (1st value = switching point / 2nd value = hysteresis), condition: 2nd value \leq 1st value	feet / second

C1.3 self-test

Program number	Function	Settings / description	PMO parameters
C1.3.1	empty pipe detect	cond. + empty pipe [F] (conductivity measurement and empty pipe indication, error category [F] application); Flow indication "= 0" when pipe empty	cond.+ empty pipe [F]

C2.1 hardware

Program number	Function	Settings / description	PMO parameters
C2.1.1	terminal A	Select: off (switched off) / current output / frequency output / pulse output / status output / limit switch / control input / current input	current output

C2.A current output X

Program number	Function	Settings / description	PMO parameters
C2.A.1	range 0%...100%	xx.x ...xx.x mA; range: 0.00...20 mA (condition: 0 mA ≤ 1st value ≤ 2nd value ≤ 20 mA)	4-20 mA
C2.A.2	extended range	xx.x ...xx.x mA; range: 03.5...21.5 mA (condition: 0 mA ≤ 1st value ≤ 2nd value ≤ 21.5 mA)	3.5mA... 21.5mA
C2.A.3	error current	xx.x mA; range: 3...22 mA (condition: outside of extended range)	21.5 mA
C2.A.4	error condition	Select: error in device (error category [F]) / application error (error category [F]) / out of specification (error category [S])	Error Device
C2.A.5	measurement	Select: volume flow / mass flow / diagnosis value / flow speed / coil temperature / conductivity	volume
C2.A.6	range	0...xx.xx __ __ (format and unit depend on the measured variable, see above)	see nameplate
C2.A.7	polarity	Select: both polarities (plus and minus values are displayed) / positive polarity (display for negative values = 0) / negative polarity (display for positive values = 0) / absolute value (use for the output)	positive polarity
C2.A.8	limitation	Limitation before applying the time constant. ±xxx ...±xxx%; range: -150...+150%	-120%.. +120%
C2.A.9	low flow cutoff	Sets output value to "0" : x.xxx ±x.xxx%; range: 0.0...20%	3% with adjustable dead-band
C2.A.10	time constant	Range: 000.1...100 s	.1 s
C2.A.11	special function	Automatic range; select: off (switched off)	Off

C5.2 display

Program number	Function	Settings / description	PMO parameters
C5.2.1	language	Language selection depends on the device version.	English
C5.2.2	contrast	Adjust display contrast for extreme temperatures. Setting: -9...0...+9	0

C5.3 and C5.4. 1. measurement page and 2. measurement page

Program number	Function	Settings / description	PMO parameters
C5.3.1	function display	Select: one line / two lines / three lines	one line
C5. 3.2	measurement 1.line	Specify measurement for 1st line: Select: volume flow / mass flow / diagnosis value / flow speed / coil temperature / conductivity	volume flow
C5. 3.3	range	0...100% of the measurement set in Fct. C5. x.2	see nameplate
		0...xx.xx _ _ _ (format and unit depend on the measurement)	
C5. 3.4	limitation	Limitation before applying the time constant.: xxx%; range: -120...+120%	-120%... +120%
C5. 3.5	low flow cutoff	Sets output to "0": x.xxx ± x.xxx %; range: 0.0...20%	3% with adjust. dead-band
C5. 3.6	time constant	Range: 0.1...100 s	0.1 s
C5. 3.7	format 1.line	Specify decimal places: Select: automatic (adaptation carried out automatically) / X(=none) ...X.XXXXXXXXXX (max. 8 digits)	automatic

C5.7 units

Program number	Function	Settings / description	PMO parameters
C5.7.1	volume flow	m ³ /h; m ³ /min; m ³ /s; l/h; l/min; l/s (1 = litres); ft ³ /h; ft ³ /min; ft ³ /s; gal/h; gal/min; gal/s; free unit (set factor and text in the next two functions, sequence see below)	gal / min

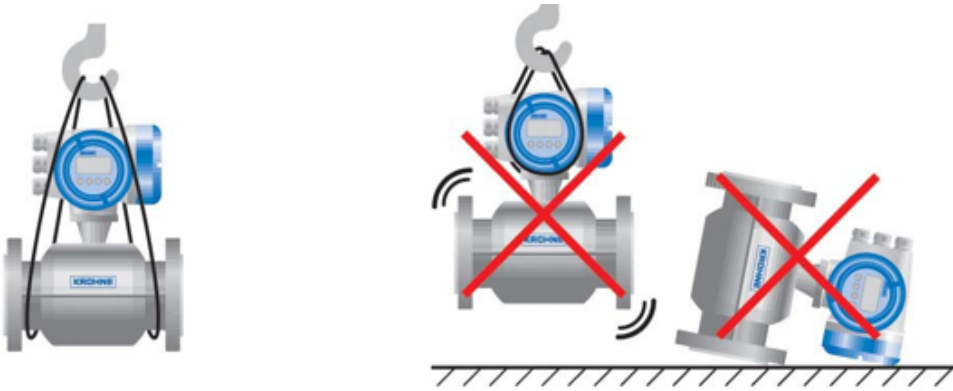
C5.8 HART

Program number	Function	Settings / description	PMO parameters
C5.8.1	HART	Switch HART® communication on/off: Select: HART on (HART® activated) current = 4...20 mA / HART off (HART® not activated) current = 0...20 mA	off

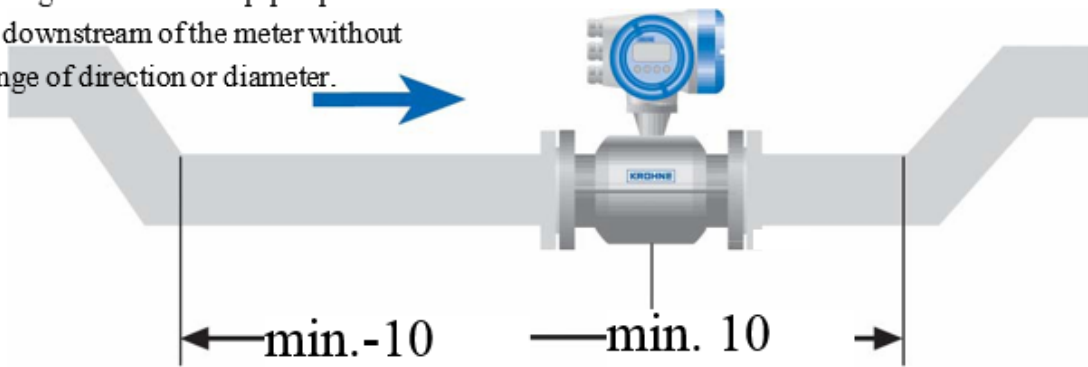
C5.9 quick setup

Program number	Function	Settings / description	PMO parameters
C5.9	quick setup	Activate quick access in quick setup menu: active with jumper in place Select: yes (switched on) / no (switched off)	on

Handling and installation instructions



Installation directions including provisions for 10 pipe diameters of straight unobstructed pipe upstream and downstream of the meter without change of direction or diameter.



Important Installation Notes:

Flowmeter must always be completely full at all times.

Installing the meter in a vertical pipe or in an incline will help assure that the pipe remains full. The flow meter shall not be installed in an upside-down position.

Horizontal mounting is acceptable when other precautions are taken to assure that both electrodes are in contact with the product. The flow meter shall not be mounted on a high horizontal line which may only be partially full and thereby trap air.

Installation for PMO milk pasteurization shall comply with applicable State and local regulation and the Pasteurization Milk Ordinance.

This KROHNE flow meter or transmitter cannot be used with any other manufacturer's flow meter or transmitter for Pasteurization Milk Ordinance configuration.

PMO Sealing Instructions for:

OPTIFLUX 6300 C Magnetic Inductive Flow Meter and IFC 300 F Signal Converter

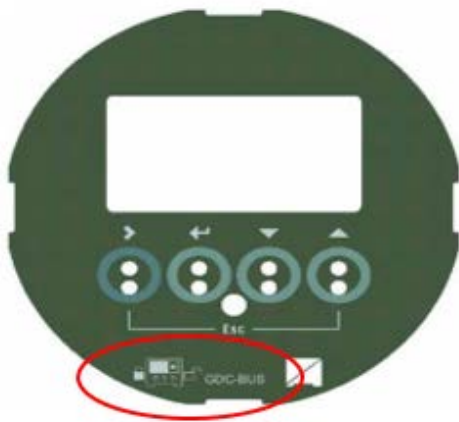
Directions for Sealing Instructions, Seal Locations and Programming Lock Out for **OPTIFLUX 6300 C Magnetic Inductive Flow Meter and IFC 300 F Signal Converter**

When Pasteurized Milk Ordinance versions of OPTIFLUX 6300 C and IFC 300 are to be used for a meter based timing system (MBTS), the device has to be protected against misuse. Following provisions have to be made:

- a) Disable all capabilities to change settings without opening the housing
- b) Provide means for a regulatory seal after the enclosure is closed.

Important to know is that although the IFC300 Parameter Sealing Lock is activated, the various menus and settings can be seen but NOT changed!

The IFC 300 C can be programmed by using the optical sensors. For Pasteurized Milk Ordinance applications, the IFC 300 has an “IFC300 Parameter Sealing Lock” to protect the change of sensitive settings. The IFC300 Parameter Sealing Lock is activated by setting a jumper on the display board, then locking display and terminal cover with locking screw + wire-lead crimped. See detail below in the red circle.





IFC300 Parameter Sealing Lock DISABLED (see above photo)



IFC300 Parameter Sealing Lock ENABLED (see 2 pins covered by protruding Tab in above photo)



IFC 300 signal converter PMO parameters are secured by a locking mechanism, once they are programmed. This lock includes an eye hole tab that is welded to the display cover and a second eye hole tab that is welded to the housing below the tab for the cover. Wire is then fed through these two eye holes then lead is crimped with a stamp by the PMO inspector. See photo above.



IFC 300 has a glass window cover with a foil Tape attached to the inside of the glass. This is used to prevent menu parameter changes by use of 4 infra-red keys after wire seal has been applied. The words VOID IF REMOVED are printed on it to inform the user that it cannot be reused if removed. The word VOID will be left on the glass and repeated across this Tape material if removed. If Tape has been removed, then request new Tape from KROHNE, Inc. and notify the regulatory agency. Testing may be required due to removal of a seal.

Directions for performing PMO required tests if parameters are modified

Field testing will be completed at any point within the stated flow range for the meter system. Test results must be found satisfactory and tests will be completed following methods described in the PMO Appendix I. Tests completed will be 11.2A, 11.2B, 11.2C, 11.2D, 11.2E, 11.2F, and Test 15.