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M-b-354

January 28, 2008

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

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

SUBJECT: Sudmo D 365it Double-Seat Mixproof Valve With The Vent Cavity
Cleaning Option, Sizes 1.5", 2", 2.5", 3", 4" And 6"

In accordance with M-I-00-2, *Milk and Milk Product Equipment-A Guideline for Evaluating Construction*, FDA's Pacific Region Dairy Products Team (DPT) and CFSAN's Dairy and Egg Branch/Milk Safety Team have specifically evaluated the valve vent cavity cleaning function of the Sudmo D 365it Double-Seat Mixproof Valve with the Vent Cavity Cleaning Option, Sizes 1.5", 2", 2.5", 3", 4" and 6" and validated and confirmed the technical information reviewed and submitted by the Pacific Region Dairy Equipment Review Committee (PRDERC).

The design of the Sudmo D 365it Double-Seat Mixproof Valve with the Vent Cavity Cleaning Option, Sizes 1.5", 2", 2.5", 3", 4" and 6" provides the capability for the cleaning of the valve vent cavity and one (1) valve seat via seat lifting under normal operating conditions of 0.1 bar (1.45 psig) through ten (10) bar (145 psig), while milk or milk products are present in the opposite valve housing. In addition, the design of the Sudmo D 365it Double-Seat Mixproof Valve with the Vent Cavity Cleaning Option, Sizes 1.5", 2", 2.5", 3", 4" and 6" prevents direct impingement of liquids on the opposite valve seat gasket during seat lifting and provides for the pressure in the critical seat area of the valve vent cavity to be atmospheric or less at all times.

When constructed, installed and operated as described in this memorandum, the Sudmo D 365it Double-Seat Mixproof Valve with the Vent Cavity Cleaning Option, Sizes 1.5", 2", 2.5", 3", 4" and 6" has been found to meet the applicable provisions of the *Grade "A" Pasteurized Milk Ordinance (PMO)*. Compliance with the PMO is based upon construction, installation and operation as described in the Manufacturer's Operating Instruction Manual, dated 01/16/2008, as well as the following provisions:

1. The Sudmo D 365it Double-Seat Mixproof Valve with the Vent Cavity Cleaning Option, Sizes 1.5", 2", 2.5", 3", 4" and 6" shall be installed in compliance with Item 15p. Protection from Contamination, Administrative Procedures 15p.(B) of the PMO, as applicable, when the valve vent cavity cleaning option is utilized. During a seat-lift operation, the position of the seat opposite to the seat being lifted shall be monitored by a proximity switch that is interlocked with the cleaning pump or source of the Clean-in-Place (CIP) cleaning solution pressure such that if this opposite seat is determined to be other than fully closed, the cleaning pump or source of CIP cleaning solution pressure will be immediately de-energized.
2. When installed, the Sudmo D 365it Double-Seat Mixproof Valve with the Vent Cavity Cleaning Option, Sizes 1.5", 2", 2.5", 3", 4" and 6" shall have an Automated Fail-Safe Control System and this Control System shall comply with applicable provisions of Appendix H. Pasteurization Equipment and Procedures, Section V. Criteria for the Evaluation of Computerized Systems for Grade "A" Public Health Controls of the PMO.
3. The valve vent cleaning cycle (seat-lift) shall be limited to a maximum of five (5) second intervals as referenced on page 9 of the Manufacturer's Operating Instruction Manual, dated 01/16/2008.
4. The standard installation position of the valve shall be in the upright vertical position. Care must be taken to assure that the valve housing, the piping system and the leakage outlet system can drain properly.
5. Sudmo D 365it Double Seat Mixproof Valve with the Vent Cavity Cleaning Option, Sizes 1.5", 2", 2.5", 3", 4" and 6" may be used to separate milk and milk products from tanks or circuits containing cleaning and/or sanitizing solutions. These valves cannot be used to separate raw products (dairy, non-dairy or water) from pasteurized milk or milk products.

For information regarding this equipment, please contact:

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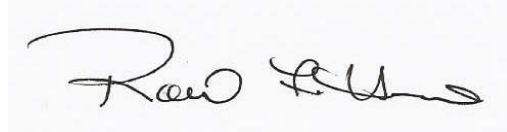
FDA's review and acceptance of the option for the cleaning of the valve vent cavity for this piece of equipment does not constitute FDA endorsement or approval. Any representation on a label or in printed literature citing or indicating as "FDA Approved" is false and misleading.

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 CFSAN 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@fda.hhs.gov.



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FDA Regional Dairy Specialist



CAPT Robert F. Hennes, RS, MPH
Milk Sanitation Officer

BAA D 365it

Double seat valve
Type D 365it

DN 1 1/2" – 6"



Amendment	Date	Name	Amendment	Date	Name	Amendment	Date	Name	Amendment	Date	Name
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prepared 16.01.2008 Graf
checked 16.01.2008 Neuhauser

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SEAT TESTING PROCEDURE – D365it

January 16, 2008

General

The Sudmo D365it valve requires two proximity switches. These proximity switches are critical for safe process operation as they relay to the control system the position of the valve upper and lower seat. Two proximity switches are located in the control top (one optional) and one is mounted externally on the valve in the lantern. The following procedure describes how to simulate valve / proximity switch failure and the resulting action the controls system will take. The failsafe position for the valve is block, block, and bleed through the drainage area.

Procedure:

1. S2 is the upper switch mounted in the control top, and used to indicate valve close / fail safe. It also indicates lower seat position and seat lift.
 - a. To simulate seat failure, valve non-closure, or proximity switch failure simply unplug the proximity switch from the circuit board.
 - b. This will force the control system to do the following:
 - i. Terminate any CIP function associated with the valve for which the proximity switch failure occurred (For example, the CIP supply pump or the source of the CIP solution pressure in the upper line will be deactivated if any valve in the associated valve group experiences a valve fault).
 - ii. Display a valve fault message for the faulted valve on the operator terminal. Note: The proximity switches should be monitored at all times for the required valve position based on the PLC requested state. Usually, all devices in the control system have hand-off-auto capability. If so, all mix-proof valve hand-off-auto functions are password protected at a supervisory level. There should never be a need to manually intervene with the mix-proof valves as all the automatic functions are simple transfers.
 - c. The following steps should be taken to ensure proximity switch location is correct:
 - i. Ensure the valve control air is off or remove the air supply from the middle and upper air connections L1 and L3.

- ii. Check that the prox is on. The correct setting is to start the prox on the top side of the target and using the fine adjustment screw, adjust the prox down until the LED comes on and turn two additional complete revolutions.
- 2. S1 is the lower switch mounted in the control top, and used to indicate valve open. If the valve does not open properly or if the open proximity switch fails, this does not designate a safety issue.
 - a. To simulate valve non-open, or proximity switch failure simply unplug the proximity switch from the circuit board.
 - b. This will force the control system to display a valve fault message for the faulted valve on the operator terminal.
 - c. The following steps should be taken to ensure proximity switch location is correct:
 - i. Ensure the valve control air is applied to the middle air connection only.
 - ii. Check that the prox is on. The correct setting is to start the prox on the top side of the target and using the fine adjustment screw, adjust the prox down until the LED comes on and turn two additional complete revolutions.
- 3. The external lantern mounted proximity switch, S3, is only used on the PMO style valves and indicates valve close / fail safe. It also indicates upper seat position and seat lift.
 - a. To simulate seat failure, valve non-closure, or proximity switch failure simply disconnect the proximity switch connector.
 - b. This will force the control system to do the following:
 - i. Terminate any CIP function associated with the valve for which the proximity switch failure occurred (For example, the CIP supply pump or the source of the CIP solution pressure in the upper line will be deactivated if any valve in the associated valve group experiences a valve fault).
 - ii. Display a valve fault message for the faulted valve on the operator terminal. Note: The proximity switches should be monitored at all times for the required valve position based on the PLC requested state. Usually, all devices in the control system have hand-off-auto capability. If so, all mix-proof valve hand-off-auto functions are password protected at a supervisory level. There should never be a need to manually

intervene with the mix-proof valves as all the automatic functions are simple transfers.

- c. The following steps should be taken to ensure proximity switch location is correct:
 - i. Ensure the valve control air is off or remove the air supply from the middle and lower air connections L1 and L2.
 - ii. Check that the prox is on. The correct setting is to screw the prox into the lantern until it contacts the upper stem target. The prox should then be turned back out two complete revolutions and the locking nut tightened.

	Upper Prox In Ctop S2	Lower Prox In Ctop S1	External Prox S3
Valve closed (No Air)	X	O	X
Valve open L1 (Solenoid 1)	O	X	O
Lift upper disc L2 (Solenoid 3)	X	O	O
Lift lower disc L3 (Solenoid 2)	O	O	X

Red optional

X enabled

O disabled

EXAMPLE OF AUTOMATED FAIL SAFE CONTROL SYSTEM – D365it

January 16, 2008

General

The example below describes how the control system shall interlock while product is transferred in Process line 1 (purple) and process line 3 is being cleaned (green).

In order to have feedback for the upper and lower seat, the PMO mix proof is equipped with (1) proximity switches in the control top and (1) external proximity switch in the lantern area. The chart below gives the logic including the optional feedback for valve open.

	Upper Prox In Ctop S2	Lower Prox In Ctop S1	External Prox S3
Valve closed (No Air)	X	O	X
Valve open L1 (Solenoid 1)	O	X	O
Lift upper disc L2 (Solenoid 3)	X	O	O
Lift lower disc L3 (Solenoid 2)	O	O	X

Red optional

X enabled

O dissabled

CIP of Process 3 line (Green). This is the upper line of valves A & B.

1) The following must be verified before the CIP source can be activated.

- a) Lower seat prox S2 for valve A must be on.
 - b) Lower seat prox S2 for valve B must be on.
- 2) If at any time the lower seat proxes for A & B are lost, the CIP source must be stopped.

Product transfer in Process 1 line (Purple). This is the lower line of valves A & C.

- 1) The following must be verified before the Product source can be activated.
 - a) Upper seat prox S3 for valve A must be on.
 - b) Upper seat prox S3 for valve C must be on.
- 2) If at any time the upper seat proxes for A & C are lost, the CIP source must be stopped.

