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M-b-357

October 29, 2008

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

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

SUBJECT: Waukesha Cherry-Burrell W75CP PMO Double Seat Mix Proof Valve With The Vent Cavity Cleaning Option, Sizes 1.5", 2.0", 2.5", 3.0", 4.0" And 6.0"

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 Dairy and Egg Branch/Milk Safety Team have specifically evaluated the valve vent cavity cleaning function of the Waukesha Cherry-Burrell W75CP PMO Double Seat Mix Proof Valve with the Vent Cavity Cleaning Option, Sizes 1.5", 2.0", 2.5", 3.0", 4.0" and 6.0" and validated the technical information reviewed and submitted by the Atlantic-Midwest Dairy Equipment Review Committee (AMDERC).

The design of the Waukesha Cherry-Burrell W75CP PMO Double Seat Mix Proof Valve with the Vent Cavity Cleaning Option, Sizes 1.5", 2.0", 2.5", 3.0", 4.0" and 6.0" 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 Waukesha Cherry-Burrell W75CP PMO Double Seat Mix Proof Valve with the Vent Cavity Cleaning Option, Sizes 1.5", 2.0", 2.5", 3.0", 4.0" and 6.0" prevents 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, operated and maintained as described in this memorandum, the Waukesha Cherry-Burrell W75CP PMO Double Seat Mix Proof Valve with the Vent Cavity Cleaning Option, Sizes 1.5", 2.0", 2.5", 3.0", 4.0" and 6.0" 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, operation and maintenance as described in the Manufacturer's Operating and Maintenance Manual, Mix Proof Valves (in O.D.

Tubing Sizes), W75CP PMO Mix Proof, Revision Date: September 2008, Publication 95-03094, as well as the following provisions:

1. The Waukesha Cherry-Burrell W75CP PMO Double Seat Mix Proof Valve with the Vent Cavity Cleaning Option, Sizes 1.5", 2.0", 2.5", 3.0", 4.0" and 6.0" shall be installed in compliance with Item 15p. Protection from Contamination, Administrative Procedure 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 Waukesha Cherry-Burrell W75CP PMO Double Seat Mix Proof Valve with the Vent Cavity Cleaning Option, Sizes 1.5", 2.0", 2.5", 3.0", 4.0" and 6.0" 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 ten (10) second intervals as referenced.
4. The standard installation position of the valve shall be upright and in no case more than fifteen degrees (15°) to the vertical. Care must be taken to assure that the valve housing, the piping system and the leakage outlet system can drain properly.

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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Attachments: Front Cover and Inside Front Cover of Manual Publication 95-03094,
Revision Date September 2008
Test Procedures
Test Procedures for Confirmation of Control System Seat Lifting
Interlock During Operation

Manual publication 95-03094, Revision Date: September 2008 can be identified as follows:

Front Cover:



**Operation and Maintenance Manual
Mix Proof Valves
(in O.D. Tubing Sizes)
W75CP PMO Mix Proof**



Read and understand this manual
prior to installing, operating or servicing this equipment.

Inside Front Cover:



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Revision Date: September 2008

Publication: 95-03094

TEST PROCEDURES

(Page 13 of the Operation and Maintenance Manual, dated September 2008)

Stem Gauge

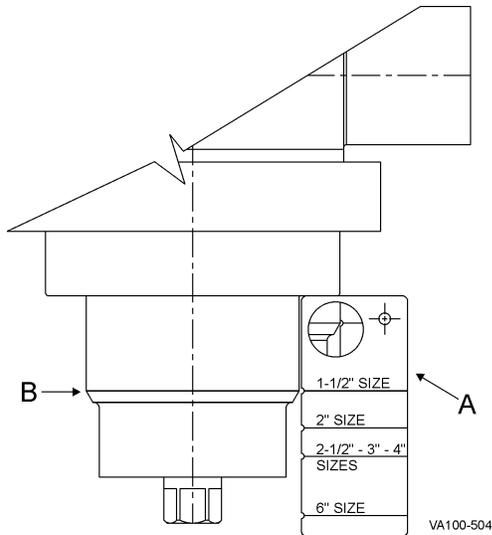


Figure 9 - Test Gauge and Stem Alignment

Confirm the proper location of the lower valve stem. Place a test gauge (Figure 9, item A) as shown on the lower shoulder of the stem. The shoulder should line up with the gauge.

Corrective Action: Check the stem assembly, ensuring that the lower stem is fully turned in.

Confirm the yoke area proximity switch location for detection of upper stem movement within 1/16". Insert a test gauge sideways between the detection cap and the switch with the valve in the closed position.

The proximity switch (Figure 10, item C) should contact the gauge (item D) without compressing the detection cap (item E).

Corrective Action: Check the stem assembly, ensuring that the lower stem is fully turned in.

Confirm the yoke area proximity switch location for detection of upper stem movement within 1/16". Insert a test gauge sideways between the detection cap and the switch with the valve in the closed position.

The proximity switch (Figure 10, item C) should contact the gauge (item D) without compressing the detection cap (item E).

Corrective Action: Loosen the proximity switch bolt and adjust the position.

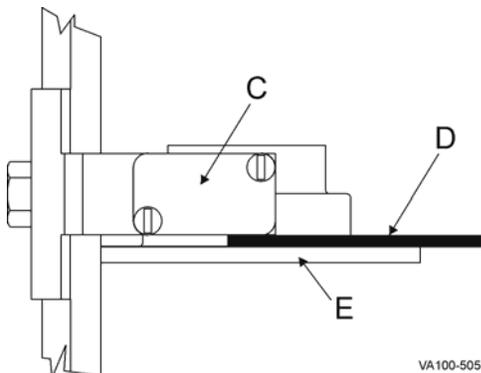


Figure 10 - Proximity Switch Location

Positive Fail-Safe Detection Test

Perform a test to verify the fully closed fail-safe position. Both the upper and lower valve plugs are position-detectable via proximity switches. Set the valve plug feedback proximity switches for the fully opened and fully closed positions of the valve. See Figure 4 on page 10 (Refer to page 7 of this M-I) for port and corresponding chambers. (See Figure 9 and Figure 10 on page 4 of this M-I to confirm the stem and switch positions using a stem gauge.)

Decommission the system, drain the lines and lock out the pumps.

1. With the valve fully closed, confirm that the proximity switches conform to Table 2 (Refer to page 8 of this M-I.). Verify the switch status on the PLC control system.
2. Pressurize chamber 1 to open the valve. Confirm that the proximity switches conform to Table 2.
3. Vent chamber 1 to close the valve.
4. Activate the upper seat lift either through the control system or manually by supplying air to the air port in chamber 2.
5. When the upper seat lifts, confirm that the proximity switches conform to Table 2. Verify the switch status on the PLC control system.
6. Vent the air in chamber 2 to deactivate the seat lift.
7. Activate the lower seat push either through the control system or manually by supplying air to chamber 3 on the valve actuator.
8. When the lower seat is pushed, confirm that the proximity switches conform to Table 2. Verify the switch status on the PLC control system.
9. Vent the air in chamber 3 to deactivate the seat lift.
10. Disconnect the air from the valve actuator, placing the valve in the fail-safe position. Verify that the proximity switches register that the valve is fully closed.

Corrective Action

If the Double Seat Mix Proof valve fails to respond as indicated above, immediately check the valve assembly and wiring to locate and correct the cause.

- Check the proximity switch adjustment.
- Check for the correct assembly and adjustment of the valve.

TEST PROCEDURES FOR CONFIRMATION OF CONTROL SYSTEM SEAT LIFTING INTERLOCK DURING OPERATION

(Page 14 of the Operation and Maintenance Manual, dated September 2008)

The purpose of this test is for regulatory inspectors to check and confirm that proper controls interlocking of the W75CP PMO valve is in place during active CIP operation.

This test is to be performed during active CIP of either the upper or lower housing of the valve. The inspector will manually force open the protected seat lift to confirm proper interlocking.

Procedure

1. Select a W75CP test valve for the interlock test. Confirm proper valve assembly and switch status prior to testing. (Refer to "Positive Fail-Safe Detection Test" on page 5 of this M-I.)
2. Choose upper body cleaning or lower body cleaning.

WARNING: *Confirm that the product is not present in the valve prior to start and through the duration of this test.*

3. Energize CIP for the selected body. Confirm that CIP pressure is present in the selected body.
4. Energize the seat lift of the protected seat:
 - Cleaning through the upper body: energize solenoid for lower seat lift.
 - Cleaning through the lower body: energize solenoid for upper seat lift.

If the control system interlocking is correct, the CIP supply pump or source will be de-activated.

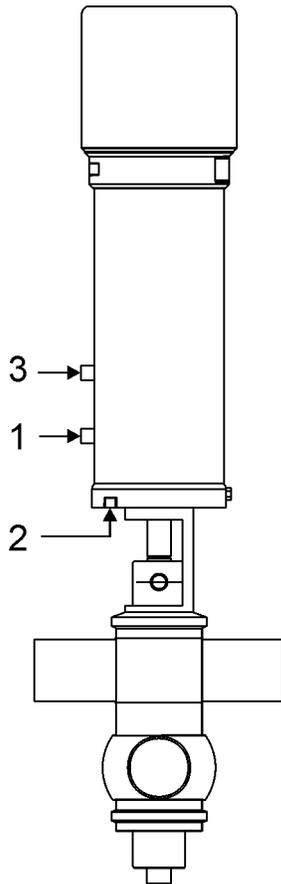
5. De-energize the seat lift of the protected seat.

Corrective Action

If the control system does not de-activate the cleaning solution pressure, shut down the control system and evaluate and revise the control interlocking.

Test procedures are also available on pages 13-14 of the manual publication 95-03094, Revision Date: September 2008.

Solenoid Valve Port Connections



VA100-093C

Figure 4 – Solenoid Valve Port Connections

Up to three air supplies, controlled by solenoid valves, supply air to the valve actuator (Figure 4).

The air supply must be 72 to 100 psi (4.9 to 6.9 bar).

ON = Solenoid energized (OPEN).

OFF = Solenoid de-energized (CLOSED). LED is off.

Solenoids are normally closed.

Air connections are 1/8" NPT.

* Seat lifting requires (2) two additional air supplies.

For specific air-routing and solenoid porting, please refer to control module publications 95-03077 (3-Piece) or 95-03083 (2-piece).

Table 1: Solenoid/Valve Position

Condition	Solenoid		
	3	1	2
Closed	OFF	OFF	OFF
Open	OFF	ON	OFF
Upper Seat Cleaning	OFF	OFF	ON
Lower Seat Cleaning	ON	OFF	OFF

Automatic Fail-Safe System

Table 2: Valve Stem Detection Conditions

Condition	Upper Switch (NO)	Lower Switch (NC)	Yoke Switch (NC)
Switch Symbol			
Valve Closed	0	1	1
Valve Open	1	0	0
Valve Closed with Upper Seat Lift	0	1	0
Valve Closed with Lower Seat Lift	0	0	1

1 = Energized; LED is lit 0 = de-energized; LED is off

Upper Switch - Sends an input signal when the valve is properly open.

Lower Switch - Sends an input signal when the valve is properly closed.

Yoke Switch - Sends an input signal when the upper seat is properly closed.

The valve seats are part of an automatic fail-safe system preventing contamination of the product with cleaning or sanitizing solutions. Automatic fail-safe systems are unique to each particular installation. Typically, both blocking valve seats are properly seated in the blocked position before the mechanical cleaning system can be activated for the cleaning circuit containing the valve arrangement. W75CP PMO valves are spring-to-closed fail-safe into the blocked position. Waukesha Cherry-Burrell does not offer control systems, only the PMO double seat valve.