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College Park, MD 20740-3835

M-b-347  
Supplement 1

September 21, 2011

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

FROM: Dairy and Egg Branch (HFS-316)

SUBJECT: Sudmo BAA S400FDV-IT Select Flow Diversion Valve, Equipped with Proximity Switches, Sizes DN 1", 1.5", 2.0", 2.5", 3.0", And 4"

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 Sudmo BAA S400FDV-IT Select Flow Diversion Valve, Equipped with Proximity Switches, Sizes DN 1", 1.5", 2.0", 2.5", 3.0", and 4" and have validated and confirmed the technical information submitted by Sudmo North America, Inc.

The Sudmo Flow Diversion Device consists of two (2) Sudmo non-slamming compression-type divert valves (Type BAA S400) clamped together to form an assembly. The assembly is used to enable the "Divert Flow", "Leak Detect" or "Forward Flow" positions. M-b-347 (Supplement 1) addresses the use of Sudmo BAA S400FDV-IT with an IntelliTop 2.0 Control Head that contains a proximity switch as the position detection device instead of a micro-switch as reviewed and referenced in M-b-347 (Sudmo BAA S400 Flow Diversion Device, Model 2000, DN 1"- 4" Inch). Adjustment procedures for the automatic setting of the proximity switch are outlined in the Manufacturer's Operating Instructions BAA S400FDV-IT Select, Flow Diversion Valve, DN 1"-4", Issue 5/13/2011/Version 2.01.

When constructed, installed, operated and maintained as described in this memorandum, the Sudmo BAA S400FDV-IT Select Flow Diversion Valve, Equipped with Proximity Switches, Sizes DN 1", 1.5", 2.0", 2.5", 3.0", and 4" has been found to meet the applicable provisions of Item 16p-Pasteurization and Aseptic Processing 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 Instruction BAA S400FDV-IT Select Flow Diversion Valve, DN 1"-4", Issue 5/13/2011/Version 2.01 and the IntelliTop 2.0 Control Head Operating Instructions, Issue 2010-2011, as well as the following provisions:

1. The control system utilized with the FDD shall comply with Appendix H. of the PMO and shall be found acceptable to the State Regulatory Agency.
2. The installation shall comply with all applicable tests cited in Appendix I. of the PMO.
3. Appendix I., Test 5.4, Device Assembly, of the PMO, shall be conducted in accordance with the testing procedures cited in the Operations and Instructions Manual, provided by the manufacturer. The manufacturer shall provide a spacer (0.059 inches/1.5mm wide) to facilitate conducting this test in the required manner.
4. Upon proper installation and the determination of compliance through appropriate PMO testing, regulatory seals shall be applied through the handle of the manual air shut-off valves and around the valve body. The seal shall be sufficiently tight to assure that the manual shut-off valve cannot be closed without breaking the seal.

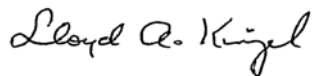
For information regarding this equipment, and to request copies of the documents listed, please contact:

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FDA's review and acceptance of this flow diversion device 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" 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 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 Robert.Hennes@fda.hhs.gov.



Lloyd Kinzel  
FDA Regional Dairy Specialist



CAPT Robert Hennes, RS, MPH  
MST Senior Milk Sanitation Officer

Attachments: Cover Page-Manufacturer's Operating Instructions BAA S400FDV-IT Select Flow Diversion Valve, DN 1"-4" (5/13/2011/Version 2.01)  
Setting the Position Measuring System, Page 30, Manufacturer's Operating Instructions BAA S400FDV-IT Select Flow Diversion Valve, DN 1"-4" (5/13/2011/Version 2.01)  
Cover Page-IntelliTop 2.0 Control Head Operating Instructions-FDD (Issue 2010-2011)

# BAA S400FDV-IT Select

Version 2.01

## Flow diversion valve DN 1" – 4"

Profile seal – PEEK seal, process control head IntelliTop® 2.0



| Revision | Date | Name | Revision | Date | Name | Revision | Date | Name | Revision | Date | Name |
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created on/by 13.05.2011 Graf H.  
reviewed on/by 13.05.2011 Feldmeier T.

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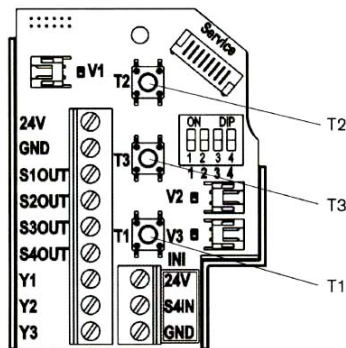
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## 12. Setting the Position Measuring System (Teach-In)

### 12.1. Adjustment procedure

- ⇒ Open the housing observing the notes contained in chapter.
- ⇒ Supply electrical power so that the position measuring system and the LED display can function.
- ⇒ Position the process valve at the lower switching position.
- ⇒ Depress the lower Teach-In button (T1) for approx. 1.5 seconds:  
The LED corresponding to this position will flash quickly three times during the teaching phase. Once this position has been stored, the corresponding LED will remain continuously lit until the position of the piston is changed.
- ⇒ Afterwards, position the process valve at the upper switching position to be recorded.
- ⇒ Depress the upper Teach-In button (T2) for approx. 1.5 seconds:  
The LED corresponding to this position will flash quickly three times during the teaching phase. Once this position has been stored, the corresponding LED will remain continuously lit until the position of the piston is changed.
- ⇒ If necessary, return control head and system to normal state (switching position, power supply).
- ⇒ Close the housing observing the notes contained in chapter



Future information see operating instructions BA IntelliTop 2.0 capture 15



Anyone who has been designated by the purchaser to install, start up, operate and maintain the process control head IntelliTop® 2.0 must have read and understood the complete operating instructions BA IntelliTop 2.0 (especially all stipulated safety instructions).



## IntelliTop 2.0

Control Head



Operating instructions