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

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

SUBJECT: Teat Preparation Protocol BouMatic Robotics MR-S1 and MR-D1 Milking Robots

ITEM 13r. MILKING – FLANKS, UDDERS AND TEATS

The Teat Preparation Protocol for BouMatic Robotics MR-S1 and MR-D1 Milking Robots has been submitted and evaluated by FDA’s Central Region Milk Specialists and CFSAN’s Milk and Milk Products Branch/Milk Safety Team and has been determined to be in compliance with Item 13r - Milking-Flanks, Udders and Teats of Section 7- Standards for Grade “A” Raw Milk for Pasteurization, Ultra-Pasteurization or Aseptic Processing and Item 13r - Milking- Flanks, Udders and Teats of Appendix Q - Operation of Automatic Milking Installations for the Production of Grade “A” Raw Milk for Pasteurization. Item 13r within Appendix Q of the PMO states:

“AMI manufacturers shall submit data to FDA to show that the teat prepping system employed in their system is equivalent to Item 13r., Administrative Procedures #4: “Teats shall be treated with a sanitizing solution just prior to the time of milking and shall be dry before milking.” Each installer shall provide the producer and the Regulatory Agency with a copy of this approval, including a detailed description of the approved procedure. Each producer shall keep a copy on file at the farm.”

Compliance with Item 13r of the PMO was based upon the following guidance, provided by BouMatic Robotics, LLC (May 12, 2016) for the Teat Preparation Protocol:

**NOTE:** While this protocol is specified for use with the BouMatic Robotics MR-S1 and MR-D1 Milking Robots, its acceptance will remain in effect with future versions (models) of this equipment as long as this accepted Teat Preparation Protocol can be applied as written. If the Protocol has not been changed, the manufacturer shall provide this accepted protocol with future versions (models) of their automated milking installations.
Teat Preparation Protocol for BouMatic Robotics MR-S1 & MR-D1 Milking Robots

May 12th, 2016
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1   Teat Preparation Equipment

1.1 Teat Preparation Summary

The BouMatic Robotics MR-S1 & MR-D1 Milking Robots are equipped with a “teat preparation cup”. When a cow enters into the milking robot, it is identified by a tag she wears around her neck. This identification is linked to a specific teat map that is loaded in the system. The robotic arm grips the teat preparation cup from the home position and begins to locate the first teat using the teat map. 3D and 2D cameras, which make up the vision system, aid the robotic arm in making finite adjustments. When the desired teat has been positively located, the robotic arm moves the teat preparation cup so that it is placed around the teat for cleaning, sanitizing and drying. The robotic arm will hold the teat preparation cup in place while the teat preparation procedure takes place. When the procedure is complete, the robotic arm will move the teat preparation cup to the next teat. This process is repeated for each of the remaining teats. When finished, the teat preparation cup returns to its home position where it is sanitized before prepping the next cow.

1.2 Teat Preparation Cup

The preparation cup consists of a stainless steel shell, teat cup liner, and a ring assembly. The ring transfers water, chemical, and clean compressed air around the teat.

Table 1 - Cross-section of the Teat Preparation Cup

<table>
<thead>
<tr>
<th>Item No</th>
<th>Part Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>8591892 or D381993</td>
<td>Liner, Teat Preparation Cup</td>
</tr>
<tr>
<td>2</td>
<td>061400110A</td>
<td>Shell, Teat Preparation</td>
</tr>
<tr>
<td>3</td>
<td>070101331</td>
<td>Ring, (Water, Air, Chemical)</td>
</tr>
</tbody>
</table>

Figure 1 - Cross-section of the Teat Preparation Cup
2 Teat Preparation Procedure

1. The cow enters the milking box and is identified via RFID tag.
2. The software determines whether milking should take place or not.
3. If the cow is to be milked, the robotic arm removes the teat preparation cup from the home position.
4. The vision system locates the bottom of the first teat.
5. The robotic arm raises the teat preparation cup around the teat. When the teat bottom enters the cup, vacuum is applied and the preparation procedure begins. **(See Table 2 for sequence timing)**.
6. The pulsator is turned on to pre-strip milk from the teat. Pulsation and vacuum are used to stimulate and fore-strip the teat. Waste water and fore-strip milk are collected in the preparation waste vessel. During this period of time, the pulsator is operating at 60 pulses per minute, with a ratio of 60/40%. The pulsation rate and ratio are not critical, but are factory set, and cannot be changed.
7. The teat is cleaned and sanitized for a minimum of 2 seconds. **(Step 1) OxyPre-RBT (1.0% Hydrogen Peroxide 0.5% Lactic acid Blend) is the teat sanitizer recommended for use in this process**.
8. Vacuum and compressed oil-free filtered air dries the teat via the teat preparation cup for a minimum of 3 seconds. **(Step 2)**
9. Vacuum continues to dry the teat for a minimum of 8 seconds. **(Step 3)**.
10. At the end of the sequence shown in Table 2, the vacuum and pulsator are turned off and the preparation cup is removed from the teat.
11. The teat preparation cup is moved to the next teat and the teat preparation steps are repeated for the remaining teats.
12. After the teats have been prepared, the teat preparation cup returns to its home station inside the technical area.
13. The teats have been cleaned, sanitized, dried, and is ready to be milked.
Table 2 - Teat cleaning sanitizing and drying procedure

<table>
<thead>
<tr>
<th>Step</th>
<th>Descriptions</th>
<th>Sec.</th>
<th>Vacuum to Prep cup</th>
<th>Filtered Air to Prep Cup</th>
<th>Water with Chemical to Prep Cup</th>
<th>Prep Cup Pulsation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Clean &amp; Sanitize Teat</td>
<td>2</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Air blow to Dry Teat</td>
<td>3</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Vacuum to Dry Teat</td>
<td>8</td>
<td>X</td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>END</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Default settings shown. Times outlined in section 2.1 may be extended as needed but may not be reduced

3. Preparation Cup Sanitizing

1. Between cows, the contents of the preparation waste vessel (waste water, Teat Cleaner/Sanitizer and fore-striped milk) are dumped down the drain. Table 3 shows the details of this procedure.
2. The teat preparation cup and waste preparation vessel are cleaned and sanitized during the main CIP process which happens three times daily. The teat preparation cup is rinsed with cold water and sanitized between each cow. (#2 in Table 3)

Table 3 - Preparation Cup Sanitizing

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
<th>Sec.</th>
<th>Vacuum to Prep cup</th>
<th>Waste Vessel Drain</th>
<th>Cold Water to prep cup</th>
<th>Filtered Air to Teat Cup</th>
<th>Sanitizing Sol. to Prep cup</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Waste Vessel Drain</td>
<td>3</td>
<td>417</td>
<td>444</td>
<td>451</td>
<td>453</td>
<td>454</td>
</tr>
<tr>
<td>2</td>
<td>Rinse Prep cup</td>
<td>3</td>
<td>X</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Vacuum/Drain Prep cup</td>
<td>2</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Air Blow Prep Cup†</td>
<td>3</td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Sanitize</td>
<td>3</td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Air Blow Prep Cup†</td>
<td>1</td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Vacuum/Drain Prep cup</td>
<td>6</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Air blow / Dry Prep Cup†</td>
<td>4</td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Drain</td>
<td>5</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>END</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

† Oil free filtered air under pressure at 2 bar.
4 Verification

4.1 Teat Sanitizer Solution Verification

1. Valve function can be verified by putting the robot in SERVICE mode and dropping the prep cup jetter and actuating pumping on the process viewer by navigating to “Service” “Commands” “Cleanings” and then pressing the “Preparation Program” button.
2. A minimum of 10 ml of Teat sanitizing solution per teat is delivered
3. To capture Teat dip solution for measurement, a bag may be placed over the prep cup and captured contents directed into a graduated cylinder.

Figure 2 - Teat Sanitizer solution system

4.2 Teat Cleaning and Drying Verification

1. Cleaning cycles from Table 2 may be verified using the Inspector Software program or by visual inspection.
2. Proper drying may be verified by observing the teats after removal of the preparation cup but before application of the teat cups.
3. The air pressure may be verified on the gauge shown in Figure 3.
4. Valve actuation times can be verified by viewing the parameters on the touch screen in the process viewer, Figure 10.
4.3 Preparation Cup Sanitizing Verification

1. Valve function can be verified by observing the discharge of waste from the teat preparation waste vessel.

2. Valve actuation times can be verified by viewing the parameters on the touch screen in the process viewer, Figure 10.

3. Valve function can be verified by going to the touch screen, putting the robot in manual mode, and selecting the valve you would like to verify on the Process viewer. Selecting the valve will toggle it on and off. The corresponding solenoid valve indicator light will be “on” when the valve is actuated.
4.4 Valve actuation

Disable the hydraulic system when entering the mechanical room. This can be done by opening the mechanical room door. If the button is blinking, the hydraulic system is disabled and the arm will not move – Refer to Figure 4.

Other safety information can be found in section 2.3 of the User Manual.

To force valves or pumps manually, place the robot Milkbox State in SERVICE mode, by pressing the service selection on the panel PC. The panel PC is to the right of the door to the mechanical room for the MR- D1(double box) robots and to the left of the door on the MR-S1(single box) robots.

To put a milking box into service, on the touchscreen double tap the desired Milkbox Box id to put into service.
A Commands screen will appear and select the Service button.

![Milkbox Commands](image)

Figure 6- Milkbox Commands

Navigating to the Process Viewer is through the service mode from the BRI application by double pressing on the “Service” area – refer to Figure 7.

![BRI application, service mode](image)

Figure 7, BRI application, service mode

From the Service Menu, touch the “User” icon Figure 8 and enter 196426 to enable the process viewer button.

![User icon](image)

Figure 8, User icon
Press the Process viewer button Figure 9.

![Process Viewer Button](image1.png)

**Figure 9, Process Viewer button**

The Process Viewer screen will appear. Below is an example of the MR-S1 Process viewer screen Figure 10.

![Process Viewer MR-S1](image2.png)

**Figure 10, Process viewer MR-S1**

Individual valves may be manually forced from the panel PC touch screen via the process viewer. Activation for all I/O is indicated by color. **Red** indicates a deactivated state (default). **Green** indicates an active state.

To change the state of a valve or pump, press the associated icon on the Panel PC screen. The valve/pump will engage/disengage and the color of the icon in the process viewer will change state from red to green or vice versa Figure 11.

![Process Viewer Valve States](image3.png)

**Figure 11, Process Viewer valve states**
Observing the physical valve state indication via the Process viewer or Inspector™ program while activating a valve will prove the relationship between valve and state indicator in software. Several valve-to-indicator correlations may be “proven” in this way, allowing for confirmation of the information coming from the process viewer and Inspector™ software.

Proper selection and sequencing of valves can allow observable water, air or vacuum to flow, proving valve actuation.

5 Serial Number Location

Table 5 - Serial Number

<table>
<thead>
<tr>
<th>Model &amp; Name</th>
<th>Example Serial No.</th>
<th>Location of Serial Plate</th>
</tr>
</thead>
<tbody>
<tr>
<td>MR-S1</td>
<td>MRS1NLD110007</td>
<td>Door jamb technical area</td>
</tr>
<tr>
<td>MR-D1</td>
<td>MRD1NLD110007</td>
<td>Door jamb technical area</td>
</tr>
</tbody>
</table>

![Serial Number Location](image)

Figure 12, Serial Number location
An electronic version of this memorandum is available for distribution to Regional Milk Specialist, 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 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.

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