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

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

SUBJECT: Teat Preparation Protocol GEA In-liner Teat Preparation Stall Unit 7820-3001-000, 7820-3003-000, 7820-3004-000 And 7820-5003-000

ITEM 13r. MILKING – FLANKS, UDDERS AND TEATS

The Teat Preparation Protocol for GEA In-liner Teat Preparation Stall Unit 7820-3001-000, 7820-3003-000, 7820-3004-000 and 7820-5003-000 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 GEA-NA (GEA North America) (June 14, 2016) for the Teat Preparation Protocol:

NOTE: While this protocol is specified for use with the GEA In-liner Teat Preparation Stall Unit 7820-3001-000, 7820-3003-000, 7820-3004-000, and 7820-5003-000, 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.
GEA In-liner Teat Preparation

Stall unit
7820-3001-000
7820-3003-000
7820-3004-000
7820-5003-000
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1) **Summary**

The teat cleaning process takes place within the milking teat cups. Initially, all fluids are routed to a waste line. All teats are located, by the camera if automatic attachment, or by eye, if manual attachment, and then the cups are attached to the teats. A double block and bleed valve arrangement isolates the milk during the teat preparation process. Teat cleaning and sanitizer solution (hereafter referred to as “teat prep solution”) is introduced onto the entire teat surface through a passage within the head of the milking liner. Clean oil-free filtered air is used to disperse teat prep solution over entire teat and purge any excess. The teats prepping supply lines are completely isolated through a double block and bleed arrangement of valves. Vented air continues to be admitted to dry the teat. Initial milk flow is used to rinse teat prep solution and foremilk from the system, then valves isolating the teat cups from the milk system are switched and milk is allowed to flow to the milk line. If a block-bleed-block valve fails at any time, the process is halted and the teat cups are detached. All prepping, drying and switching from prep milk to milk are done on an individual teat basis, and may happen at different times.

2) **Teat Preparation Procedure**

a) **Switchover to the prep process.**
   Valves to and from the teat cup begin in a configuration to divert all flow to a waste line. Once the valves are switched to this position, the teats are located and the cups are attached.

b) **Teat prep solution dispensing**
   Teat Prep solution is dispensed to deliver cleansing and sanitizer solution into the delivery hose at a setting of 60 to 300 milliseconds. This length of time is dependent upon how long it takes to dispense 5–10 ml of teat prep solution. Approved teat prep solutions are Oxycide® 5 AMS and Oxycide® AMS.

c) **Teat cleaning**
   Teat cleaning is accomplished by flowing liquids past the teat while pulsation is operating. Air flows to push the teat prep solution to the teat, distribute it onto the teat, aid in the removal of dirt, remove excess teat prep solution, and dry the teat. The liquid solution flows into the head of the liner and is directed all around the teat by geometry inside the liner head. Pulsation continues throughout the entire process to enhance movement of solution onto all teat surfaces, to aid in loosening and removal of dirt from the teat and to strip fore-milk. **Acceptable liners are part numbers 7802-3025-029, 7801-3025-501, 7801-2725-110.**
d) **Teat sanitation.**
   Teat sanitization time occurs from the moment prep solution arrives to the teat until valves switch to milking mode.

e) **Teat Drying**
   Teat drying is accomplished by using both low pressure air and atmospheric air. Low pressure air is used to remove excess prep solution from teat and continues to blow for a minimum of 8 seconds. Then atmospheric air is drawn in for a minimum of 2 seconds to continue drying teat until switching to milk mode is possible, which is after prep solution purge. **This length of time is referred to as Pre-dip air pressure and is a minimum of 8000 milliseconds or 8 seconds.**

f) **Prep solution purge from milk lines**
   To purge the milk hoses of prep solution and foremilk, a small amount of foremilk is used to clean the teat prep solution and solids from the milk line.

g) **Switchover to milking**
   Various block-bleed valve arrangements on a teat-by-teat basis are switched to allow milk to flow to the milk receiver rather than the bad milk receiver.
3) Verification

a) Model Identification

Legend:
- HU = supplier (e.g. Hubl, BR for Brökelmann)
- 08 = manufacturing week of the year
- 15 = year
- /15 = unique ongoing number

Acceptable part numbers are as follows:

- 7820-3001-000 Stall Unit, Hydro-formed, RH
- 7820-3003-000 Stall Unit, Welded, RH
- 7820-3004-000 Stall Unit, Welded, RH
- 7820-5003-000 Stall Unit, Welded, LH

Figure 1. Model Identification
b) **Software version**  
Software version can be identified by the screen below. PCU package version should be 1.1.192 or higher.

![Figure 2. Software Version](image)

**c) Approved prep solutions**  
Look for solution to verify it is the correct solution for use as stated in Teat Prep Protocol.
d) **Critical components**

**Liners**

Acceptable liners are part numbers 7802-3025-029, 7801-3025-501, 7801-2725-110. They are embossed as shown below.

![Figure 3. Liners](image-url)
Regulators (dip supply and dip chase) and filter, located in the supply unit, near the box.

Figure 4. Regulators (dip supply and dip chase) and filter, located in the supply unit, near the box.
Prep Safety Valves

Figure 5. Prep Safety Valves

Air filter
7750-0038-753
or
7750-0121-815
(Not Shown)

Prep safety valve
7820-3320-330

Area Shown

Air filter
7750-0038-753
or
7750-0121-815
(Not Shown)

Prep safety valve
7750-0125-962
Figure 5 (continued). Prep Safety Valves

**Area Shown**

Air filter
7750-0038-753
or
7750-0121-815
(Not Shown)

Prep safety valve
7820-3320-330

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**Figure 6. Dip Pump**

**Area Shown**

Dip Pump
7750-0122-171
e) **Process observation**

After attachment, and before milking begins, observe the clear silicone milk hose attached to the bottom of the liner. You will be able to observe a yellow fluid moving through the hose prior to milking beginning.

During the prep process, remove the cup from the teat and examine the teat. It should be dry. This can be accomplished by removing the teat cup when the color on the milking information screen turns from light green to green (see Appendix A).

The method is by pressing the yellow button on the control panel for three seconds. This will completely detach the cluster from the teats.

f) **Drying time observation**

Drying time is confirmed by viewing parameter 100/100/009 (predip air pressure time) on the computer in the utility room (HMPC). This parameter should be set to .8000 (Milliseconds).
After a cow enters the stall, the IPC screen at the stall looks something like this.

Figure 7. Milking Information Screen

Select the magnifying glass, as shown in figure 9 circled in red, to get the screen below.
Figure 8. Milking Information Screen

The circles on this screen correspond to the teat cups. They will change color, depending upon what stage the milking process is in. Below is a legend of what the colors mean.
<table>
<thead>
<tr>
<th>Teat State</th>
<th>Color:</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>IDLE</td>
<td>Light Grey</td>
<td>This quarter is not attached.</td>
</tr>
<tr>
<td>Attaching/cleaning</td>
<td>Light Blue</td>
<td>This quarter is being milked into the waste line. It is either being attached to the teat, or actively priming or air purging after the pre-dipping has happened. The Dip safety valves may be open at this time if the cleaning or prepping is ongoing. The transition from this state to pre milk closes the pre dip safety valves and protects the milk line with a block bleed configuration.</td>
</tr>
<tr>
<td>Pre milk</td>
<td>Light Green</td>
<td>This quarter is being milked to the waste line. It is awaiting the proper conditions of milk before transitioning to the milk line.</td>
</tr>
<tr>
<td>Milking</td>
<td>Green</td>
<td>This quarter is milking to the milk line, for the bulk tank.</td>
</tr>
<tr>
<td>ERROR</td>
<td>Red</td>
<td>This quarter is in error, and is shut off from milking.</td>
</tr>
<tr>
<td>Separation</td>
<td>Orange</td>
<td>This quarter is being milked to the waste line.</td>
</tr>
</tbody>
</table>

Figure 9. Milking Screen Legend
Appendix B
Method for validation of prep solution delivery and air for drying teat after cleaning and sanitation

1. Always wear safety glasses when performing this validation.
2. With the Monobox system, disable the box before beginning. The box can be disabled by selecting the button (blue arrow) below. This can be done while a cow is being milked.

![Milking Screen](image)

Figure 10. Milking Screen

3. Wait until the milking is completed, and the cow has exited, or if a cow is not in the stall, proceed to the next step.
4. Disconnect the prep solution and drying air delivery hose at the union underneath the arm (shown below), and add a 2 foot length of 6mm hose to the union. Place the hose in a graduated cylinder with a capacity of 50 ml. A supply kit will be available on farm for the inspectors to use.
5. Place stall in manual mode by pressing the green button on the control panel.
6. The light will start blinking yellow, and the cluster will move out of its home position.
7. After the vacuum starts, plug each cup as shown. A supply kit available will be available on farm for the inspectors to use.
8. Point the top of the graduated cylinder away from your face. Dip will be discharged, along with air to push the dip through the hose. Another pulse of air will ensue, which is the teat drying air. **This length of time is referred to Pre-dip air pressure and is a minimum of 8000 milliseconds or 8 seconds.**

9. Once the drying air is finished, set aside the graduated cylinder and allow the dip to settle. Point the hose away from you in a safe direction.

10. Push the yellow button on the control panel for 3 seconds to cancel milking. Once the vacuum has been shut off from the claw, quickly remove the plugs from the teat cups, before the claw is retracted to the home position.

11. Observe the amount of dip collected. This amount must be between 5 and 10 ml.

12. Remove 2 foot section of hose and reinsert hose from teat cup back into the union.
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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