TO:    Director, Office of State Cooperative Programs  
Attn:    All Staff, Division of Milk Safety  
FROM:   Milk and Milk Products Branch (HFS-316)  
SUBJECT:   Pre-Milking Teat Preparation 2006 and 2007 DeLaval VMS™ 

ITEM 13r. MILKING - FLANKS, UDDERS AND TEATS

The DeLaval VMS™ Teat Preparation Protocol has been submitted and evaluated by CFSAN’s Milk and Milk Products Branch/Milk Safety Team (MMPB/MST) and 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, Aseptic Processing and Packaging or Retort Processed after Packaging 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, Ultra-Pasteurization, Aseptic Processing and Packaging or Retort Processed after Packaging of the PMO. 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 milking system is equivalent to Item 13r., ADMINISTRATIVE PROCEDURES #4 of this Ordinance: “Teats shall be treated with a sanitizing solution just prior to the time of milking and shall be dry before milking.” Each AMI installer shall provide the dairy producer and the Regulatory Agency with a copy of this FDA acceptance, including a detailed description of the accepted equivalent procedure. Each dairy producer shall keep a copy of the accepted teat prep protocol along with the appropriate AMI manufacturer’s teat prep protocol verification procedures on file at the dairy farm.”

Compliance with Item 13r of the PMO was based upon the following guidance, provided by DeLaval, (2006 VMS™-945672-U.S.A. and 2007 VMS™-945720-U.S.A., issued February 22, 2007) for the Teat Cleaning Protocol:

NOTE: While this protocol is specified for use with the 2006 VMS™ and 2007 VMS™, 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.

Please note that upon the issuance of this M-I-07-5 (Supplement 3), M-I-07-5 (Supplement 2), issued July 31, 2017, will be classified as “INACTIVE”.

With this Supplement, Opti Blue™ 1% dodecyl benzenesulfonic acid is identified as an additional acceptable teat sanitizing product.

An electronic version of this memorandum is available for distribution to Regional Milk Specialists, 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 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 monica.metz@fda.hhs.gov.

Monica Metz  
Branch Chief  
Milk and Milk Products Branch
VMS TEAT PREPARATION PROTOCOL

Name Subject
Pre-Milking Teat Preparation VMS™ U.S.A.

Ref. No.
945672-U.S.A.

Version
4

Replacing
3

Product Name: 2006 VMS™ U.S.A.

Issued by
Russ Kolstad

Depart
SCNA

Date
February 22, 2007

Page No.
1

Approved by
Epke Bosma

Depart
VMS™

Date
March 16, 2007

No. of pages
13

Versions / Features of this release:
NEW: Hydraulic Milking Arm, First Release
STANDARD: C-200 CIP Controller, detached wall-mounted solution vat and control assembly

Additional Identifying Information:
Serial Numbers: U.S. 1887 and lower
Location: media supply cabinet wall, behind cover, eye level, adjacent to power supply box

Name Subject
Pre-Milking Teat Preparation VMS™ U.S.A.

Ref. No.
945720-U.S.A.

Version
4

Replacing
3

Product Name: 2007 VMS™

Issued by
Russ Kolstad

Depart
SCNA

Date
February 22, 2007

Page No.
1

Approved by
Epke Bosma

Depart
VMS™

Date
March 16, 2007

No. of pages
13

Versions / Features of this release:
NEW: CIP Controller and Solution Vat Integrated into VMS™ Milk Station, New Release
STANDARD: Hydraulic Milking Arm

Additional Identifying Information:
Serial Numbers: U.S. 1888 + (beginning s/n)
Location: media supply cabinet wall, behind door, eye level, adjacent to power supply box
2 Summary

The DeLaval VMS™ Milk Station uses a single separate “Teat Cleaner” cup to wash the teats individually prior to milking. Per PMO procedure, teats shall be treated with a germicidal solution prior to the time of milking. A pressurized spray nozzle can optionally pre-spray a germicidal teat dip product onto the teats in sequence, prior to positioning the Teat Cleaner cup over the teat(s) for washing sequentially each teat “trained” in memory as lactating. In the United States, the VMS™ Milk Station shall have a mixing system to incorporate a teat wash product with germicidal properties into the potable water delivered to this Teat Cleaner cup for teat preparation.
3  Teat Preparation Procedure

DeLaval VMS™ Milk Station uses a multi-purpose robotic arm with an integrated spraying nozzle, as well as a robotic gripper to apply a specifically designed Teat Cleaner cup which is connected to a cleaning control system, delivering the following teat preparation steps:

1. **OPTIONAL** Pre-Spray: a germicidal teat dip product can be sprayed on all the teats in sequence, after cow identification and cow pre-positioning functions deliver motion guidance to the robotic arm.

2. **STANDARD** Cleaning Process: begins with the robotic arm gripping the Teat Cleaner cup from its storage location outside the cow milking stall where it hangs upside-down, and moving the Teat Cleaner cup to placement over the first teat.

3. The teat cleaning process operates with pulses of a warm solution of potable water and a teat wash product with germicidal properties (IodoZyme™ 3% iodine, or UdderDyne™ 1.75% iodine, or Clean™ 1.75% iodine, or Tri-Fender™ 1% iodine, or Teat Cleaner NI01™ lactic acid / formic acid, or Hex-O-Prep™ 0.5% chlorhexidine gluconate, or Opti Blue™ 1% dodecyl benzenesulfonic acid), alternating with air pulses, and with this method the air pressure helps to distribute the cleaning solution and increases its impingement for washing teat skin. Pulses inside the Teat Cleaner cup are directed by nozzle orifices, spiraling from the top periphery downward and off the teat. The cleaning solution, together with any residuals, is swept by airflow to be collected into a vacuum recovery waste-water tank.

4. Air pulses with increasing vacuum is applied in the Teat Cleaner cup to fore-strip.

5. The arm is lowered slowly to remove the Teat Cleaner cup and dry the teat by airflow from the top attachment periphery downwards towards the vacuum outlet, removing remaining droplets to the waste-water tank, and drying the teat surfaces.

6. When completed, the teat cleaning process removes pre-sprayed teat dip if applied, together with soils, and leaves the teats washed with a germicidal solution, fore-stripped, dried, and stimulated, ready to be milked.

7. The Teat Cleaner cup is applied to the other teats in sequence and the washing, fore-stripping, and drying process is repeated for each teat “trained” in memory as lactating.

8. Cleaning solution residue from the teats, any pre-spray sanitizer if exists, and fore-stripped milk is collected in a waste-water tank mounted in the VMS™ Milk Station. This tank is separate from the milking system, and is emptied to a drain at the end of the completed teat preparation procedure.

9. The Teat Cleaner cup is retracted and stored upside down to drain outside the cow positioning stall, forward of the milking teat cup storage unit, farthest from the rear of the milking stall.
10. The Teat Cleaner cup is rinsed after the cow is released and covered for protection when the VMS™ Milk Station flushes the milking teat cups and spray cleans the cow platform. The CIP cover protects the rinsed Teat Cleaner cup from potential sources of contamination.

11. The entire Teat Cleaner and waste-water tank system is “Cleaned-In-Place” in the same fashion as the milking equipment of the VMS™ Milk Station, with a separated circulation.

12. Shielding for urine and fecal discharge is integrated into the mechanical positioning unit behind the cow which incorporates a diversion pan that is pressed against the cow, above rear udder attachment, and directs urine and/or feces rearward, outside the cow positioning stall and shielded from beneath the udder.

4 Technical Specifications

General Overview

The teat preparation is performed with a single separate Teat Cleaner cup that is connected to a waste-water receiving tank. The Teat Cleaner and its chemical injection system are separated during milking from the milking equipment of the VMS™ Milk Station. The waste from the teat washing process, together with the fore-milk, is collected into the waste-water tank, and this fluid is released to drain after the teat preparation procedure for a cow is completed.

4.1 Optional Pre-Milking Teat Dip Spray Application

The optional application of a germicidal teat dip spray is activated by trained representatives or dairy farm operators. The VMS™ Milk Station multi-purpose arm can pre-spray the teats, before the teat cleaning process, in several application patterns (pattern data table below). Programming configures the arm motion. The acceptance region for quantities delivered are valid for DeLaval teat dip spray products specified for the VMS™ Milk Station. The quantity stated is total for one spraying application to the teats.

DeLaval uses a globally recognized method (EN 1656) to measure the germicidal effect of a teat dip against mastitis causing pathogens in-vitro. A formulation is considered an efficacious teat dip under the EN1656 standard when it is able to achieve a 5 log reduction (99.999% kill) of *E. coli*, *S. uberis*, and *S. aureus* within 5 minutes of exposure at a temperature of 30°C in the presence of milk at a concentration of 1% v/v. In order to further mimic application conditions, and better predict mastitis prevention with our teat dips, DeLaval's internal standard is stricter by reducing contact time in EN1656 teat dip testing to 60 sec for post-milking teat disinfectants and 30 sec for pre-milking teat disinfectants.
<table>
<thead>
<tr>
<th>Pattern name</th>
<th>Shape</th>
<th>Quantity Delivered</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>W</td>
<td>0.41 - 0.44 Oz (12-13 ml)</td>
</tr>
<tr>
<td>Economic</td>
<td>U</td>
<td>0.31 - 0.34 Oz (9-10 ml)</td>
</tr>
</tbody>
</table>

4.2 Teat Cleaner Cup Attachment to Teat

During attachment, vacuum is applied to the Teat Cleaner cup which is controlled in position by the arm. The airflow is limited at 28 – 35 SCFM (800-1000 l/min). Airflow rate is limited, either by variable vacuum pump capacity or by an airflow limiting valve.

4.3 Teat Cleaner with Germicidal Properties

The Teat Cleaner solution shall have germicidal properties. DeLaval uses a globally recognized method (EN 1656) to measure the germicidal properties of the Teat Cleaner solution. A Teat Cleaner formulation is considered to have germicidal properties when it is able to achieve a 5 log reduction (99.999% kill) of \textit{E. coli}, \textit{K. pneumoniae}, \textit{S. uberis}, and \textit{S. aureus} within 30 seconds of exposure at a temperature of 30°C in the presence of 3g/L of Bovine Serum Albumin. This is a DeLaval internal standard based on EN1656 methodology.
4.4 Teat Cleaner Cup Method

The Teat Cleaner cup device and method has a teat receiving top opening mouthpiece with a resilient rubber or plastic collar which gives a substantially air-tight sealing contact with the udder when the teat is fully inserted into the Cleaner cup. The cup is connected to a vacuum supply at its bottom draining outlet. The circular inner wall of the Cleaner cup is rigid, and is a larger diameter than almost all cow’s teats. Vacuum applied causes the teat to expand in this chamber, which cracks and loosens any dried-on matter on the teat. Cleaning solution is supplied as a pulsating flow, and with sequenced injecting of air into this flow for accelerating the cleaning fluid ejected from the inner wall nozzle orifices to high speed for cleaning impingement force. The rows of directional orifices in the chamber wall direct this flow to impact tangentially on the teat. The resulting impact of this fluid flow on the circular inner wall of the Cleaner cup produces vortices which clean the teat due to its turbulent motion. This Teat Cleaner cup device and method makes it effective to wash expanded teat skin for removing dried-on matter, and easy for sweeping residuals out from the space between the chamber inner wall and the teat, and downward to the draining outlet during the cleaning process.

After cleaning the teat, dried air is blown into the Cleaner cup to forcefully purge out fluid and residues within. In this step the vacuum ‘under-pressure’ within the Cleaner cup increases, sufficient to overcome the muscle pressure holding closed the milk canal which leads from the teat milk cavity to the teat end orifice. This causes the milk canal to open and the pre-milk contained in the teat milk cavity to flow out.

Final drying is achieved by the robotic arm lowering the Teat Cleaner cup. Air flowing down and off the teat is greatly increased by the opening of the cup collar sealing contact with the udder. The robotic arm movement controls the shutoff of the vacuum supply. When the cup has moved down to the coordinates of the teat end, the vacuum is stopped and the Teat Cleaner cup releases the teat.
4.5 Teat Cleaner Cycle Options

There are different programs: Extra Light; Light; Medium; Heavy; and Double. A Double teat cleaning procedure means that the selected program for a cow is done twice (the cup will attach to all trained teats in sequence, then repeat the sequence again). Per VMS™ Milk Station, its default program can be set to Light, Medium, or Heavy. Then per cow, their individual program can be set to choose any one of the options, including Extra Light, or Double (for cows that tend to be dirty).

<table>
<thead>
<tr>
<th>Program Name</th>
<th>Teat Cleaning</th>
<th>Fore-Stripping</th>
<th>Drying</th>
<th>Total Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Extra-Light per cow parameter</td>
<td>2.7s</td>
<td>1s</td>
<td>3.3s</td>
<td>7s</td>
</tr>
<tr>
<td>Light per station parameter</td>
<td>5.8s</td>
<td>1s</td>
<td>3.3s</td>
<td>10.1s</td>
</tr>
<tr>
<td>Medium per station parameter</td>
<td>7.8s</td>
<td>1s</td>
<td>3.3s</td>
<td>12.1s</td>
</tr>
<tr>
<td>Heavy per station parameter</td>
<td>9.8s</td>
<td>1s</td>
<td>3.3s</td>
<td>14.1s</td>
</tr>
<tr>
<td>Double per cow parameter</td>
<td>The Teat Cleaner cup will attach to all teats twice. Both passes operate a full program cycle, including fore- stripping and drying</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Limits and thresholds for the cleaning media action have been established for the VMS™ Milk Station, and studies have been documented which validate the effectiveness. Vacuum level is evaluated for the Teat Cleaner cup during the teat cleaning process by measuring the vacuum level in the VMS™ Milk Station supply piping, which is higher but proportionate. An alarm is generated when the vacuum level is too low. Airflow rates are limited, either by variable vacuum pump capacity or by an airflow limiting valve.

<table>
<thead>
<tr>
<th>Supply</th>
<th>Pressure/Vacuum</th>
<th>Flow Rate</th>
<th>Quantity</th>
<th>Chemical</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cleaning Solution: chemical injection into warm potable water supply</td>
<td>29 – 58 PSI (2 – 4 bar)</td>
<td>&gt;2.1 SCFM (&gt;60 l/min)</td>
<td>~14 Oz / teat (~0.4 l/teat)* maximum</td>
<td>IodoZyme™ .27%  UdderDyne™ .46% Clean™ .46% Tri-Fender™ .8% Teat Cleaner NI01™ .6% Hex-O-Prep™ .3% Opti Blue™ 1%</td>
</tr>
<tr>
<td>Compressed Air</td>
<td>29 – 73 PSIG (2-5 bar)</td>
<td>&gt;2.1 SCFM (&gt;60 l/min)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vacuum During Cleaning</td>
<td>4.5 – 9 inches HG (15-30 kPa)</td>
<td>21 - 25 SCFM (600-700 l/min)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
4.5.1 Teat Cleaner Adjustment and Verification

To check and/or adjust the washing water delivery, a water pressure regulator and gauge is provided on the tempered water supply line beside the waste-water tank, beneath the milk receiver in the VMS™ Milk Station. **Standard water setting is 36 PSI** (2.5 bar). Water system supply capacity will affect delivery volume, and adjusting the pressure regulator can accommodate for this effect, therefore this setting is variable.

**Washing Water Pressure and Temperature Adjustment**

**Figure 1**

![Teat Cleaner Adjustment Diagram]

**Air Pressure Adjustment**

To check and/or adjust the washing air pressure, an air pressure regulator and gauge is provided in the 'Upper Beam' cabinet. **Standard air setting is 43.5 PSIG** (3 bar). Air pulse injections accelerate water in the solution delivery tubes for washing effect, but can be set too high for cow comfort.

**Figure 2**

Location of air distribution manifold with final filter, regulators, and gauges.
4.6 Fore-Stripping

Air pressure pulses with increasing vacuum is applied to the Teat Cleaner cup for one second to purge and dry the supply tubes and nozzles, and fore-strip the teat. The vacuum can vary somewhat (as measured inside the Teat Cleaner cup) depending on shape of the teat. The fore-milk will be collected in the waste-water tank together with the washing residuals. This cycle does not require measurement of vacuum level.

<table>
<thead>
<tr>
<th>Supply</th>
<th>Vacuum Level</th>
<th>Flow Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vacuum During</td>
<td>6 – 9 inches of Hg (20-30 kPa)</td>
<td>21 – 25 SCFM (600-700 l/min)</td>
</tr>
<tr>
<td>Fore-Stripping</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

4.7 Drying/Cleaner Cup Removal

Vacuum is applied in the Teat Cleaner cup for drying the teats. During this cycle, the robotic arm moves very slowly downwards, to remove the Teat Cleaner cup. Incremental airflow from Teat Cleaner cup mouthpiece withdrawal is added to that from Cleaner cup atmosphere vents. The typical vacuum decay in the Teat Cleaner cup is the result of increasing airflow which is drying the teat.

<table>
<thead>
<tr>
<th>Supply</th>
<th>Pressure</th>
<th>Flow Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vacuum During</td>
<td>Decline from fore-stripping, 6 – 9 inches Hg, to</td>
<td>From fore-stripping</td>
</tr>
<tr>
<td>Drying</td>
<td>atmosphere (0 PSIG) due to increasing airflow</td>
<td>level, increasing to</td>
</tr>
<tr>
<td></td>
<td></td>
<td>28 – 35 SCFM (800-1000 l/min)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

4.8 Result

The teat preparation procedure leaves the teats washed with a germicidal solution, fore-stripped, dried, and stimulated, ready to be milked.
4.9 Sequence

Washes each teat ‘trained’ in memory as lactating.

4.10 Waste-Water and Fore-Milk Discard

Cleaning solution, residue from the teats, any pre-spray sanitizer product if exists, and fore-stripped milk are collected in the waste-water tank mounted on the VMS™ Milk Station. This tank is emptied to a drain at the end of the teat preparation procedure. The capacity of the tank is 2.64 gallons (10 L), which is much larger than necessary for the fluid volume, this is to provide a vacuum reserve volume during drying, together with a centrifugal airflow design for separation of water from airflow to protect against dirty water from entering the vacuum supply line.

4.11 Teat Cleaner Cup Flushing

The Teat Cleaner cup is rinsed between each cow when retracted, and hangs upside down, away from the rear of the stall, and is protected from splash by its CIP cover. This process allows for the drainage of the rinse water, as well as the protection of the rinsed Teat Cleaner cup from contamination.

4.12 Cleaning-In-Place

During the “Cleaning-In-Place” (CIP) of the VMS™ Milk Station, the entire Teat Cleaner system is cleaned and sanitized in the same fashion as the milking equipment of the VMS™ Milk Station in separated circulation. To protect the cow’s teats from residue of aggressive chemicals which may be used in CIP, the Teat Cleaner cup purges with a short potable water rinse when the VMS™ Milk Station cleaning is completed.

5 Verification

The sequential pulse injections creating the washing spiral action, and the suction removal, can be easily observed by looking into the Teat Cleaner cup during test operation. The individual valve function can also be verified for evaluating each valve’s performance, as well as validating the inclusion of chemical into washing water for compliance with Item 13r. Administrative Procedure #4, that teats shall be treated with a sanitizing solution just prior to the time of milking. The following describes various means of verification for Teat Cleaner operation.

5.1 Visual Verification of Teat Cleaning Sequence

During normal operation of the VMS, using a stopwatch, start timing from the moment the Teat Cleaner cup is raised to engulf a teat, which begins the vacuum and pulsing of cleaning solution and air pressure. Be alerted for the impending stop of timing when the cup begins to be lowered. Stop timing at the moment the cup is pulled free from the teat. The per teat time measured will be either the ‘default’ setting of the Milk Station, or the ‘override’ setting
of the individual cow, as shown in table 3.3. The dairyman can assist viewing and determining which setting is operating for Milk Station(s) or for individual cow(s). A duration of 7 to 14 seconds indicates a valid cleaning sequence has occurred.

5.2 Test Simulation of Teat Cleaner Cup Function

A Teat Cleaner 'test' for viewing can be made by navigating from main touch screen view (Prepare, Milk, Clean, Stall, Cow) by pressing “VMS™ Menu” button to open service and calibration functions. The following touch screen navigation guide can be used to observe cleaning cycle simulation. NOTE: The short program cycle for simulation is “Extra Light”.

Figure 1 - Main touch screen 'tabs' view (Prepare, Milk, Clean, Stall, etc.)

Press “VMS™ MENU” to change touch screen view for service and calibration functions

Figure 2 - VMS™ Menu touch screen view

Press “Teat Cleaner” to change touch screen view for service control of Teat Cleaner functions
Figure 3 - Teat Cleaner touch screen view

Press the function buttons to operate the Cleaner cup. Press ‘Release Cleaner’ and pull the Cleaner cup from storage magazine. Press ‘Start Cleaner’ to observe the cleaning operation sequence. Press ‘Retract Cleaner’ when done to pull Cleaner cup back to storage.

5.3 Testing Valve Function

Digital ‘outputs’ can be individually energized such that each valve operation can be evaluated for performance. The “IO Test” button is intended for service technicians, and can be used for testing and verification purposes.

The following touch screen navigation guide can be used for control system testing.

Figure 4 - VMS™ Menu touch screen view

Press “IO Test” to change touch screen view for digital output test menu.
Figure 5 - IO Test touch screen view

As indicated by the “press” and “slide” symbols, pull the slider bar down and up to quickly find the desired functions in alphabetical order.

The individual valves for Teat Cleaner cup are ‘paired’ such that two vertical rows of spray orifices are connected within the cup to one (1) air valve and one (1) water/solution valve. Around the internal circumference of the Teat Cleaner cup there are two (2) such pairs of vertical spray cleaning orifice rows, each controlled sequentially to produce the circumferential spiral washing action due to the tangential porting of orifices. Each water and air valve, as well as the chemical input valve can be verified.

Figure 6 - TC Air Valves, 1 and 2 testing:

With the Cleaner cup released from storage position (figure 3), the air output(s) to test can be selected as indicated by #1 press the name, highlighting it as shown (name row becomes grayed). Next press the digital output ‘ON’ as indicated by #2 press of “I”.
Last press digital output “OFF” as indicated by #3 press of “O”. Repeat for verifying both air valves and viewing performance.
**Figure 7 - TC Water Valves, 1 and 2 testing:**

With the Cleaner cup released from storage position (figure 3), the water output(s) to test can be selected as indicated by #1 press the name, highlighting it as shown (name row becomes grayed). Next press the digital output ‘ON’ as indicated by #2 press of ‘I’.

Last press digital output “OFF” as indicated by #3 press of “O”. Repeat for verifying both water valves and viewing performance.

**Figure 8 - TCD chemical solution valve test:**

With the Cleaner cup released from storage position (figure 3), and with one (either) water output energized for solution flow to test, the TCD chemical supply can be selected as indicated by #1 press the name, highlighting it as shown (name row becomes grayed).

Next press the digital output ‘ON’ as indicated by #2 press of “I”.

Last press digital output “OFF” as indicated by #3 press of “O”.