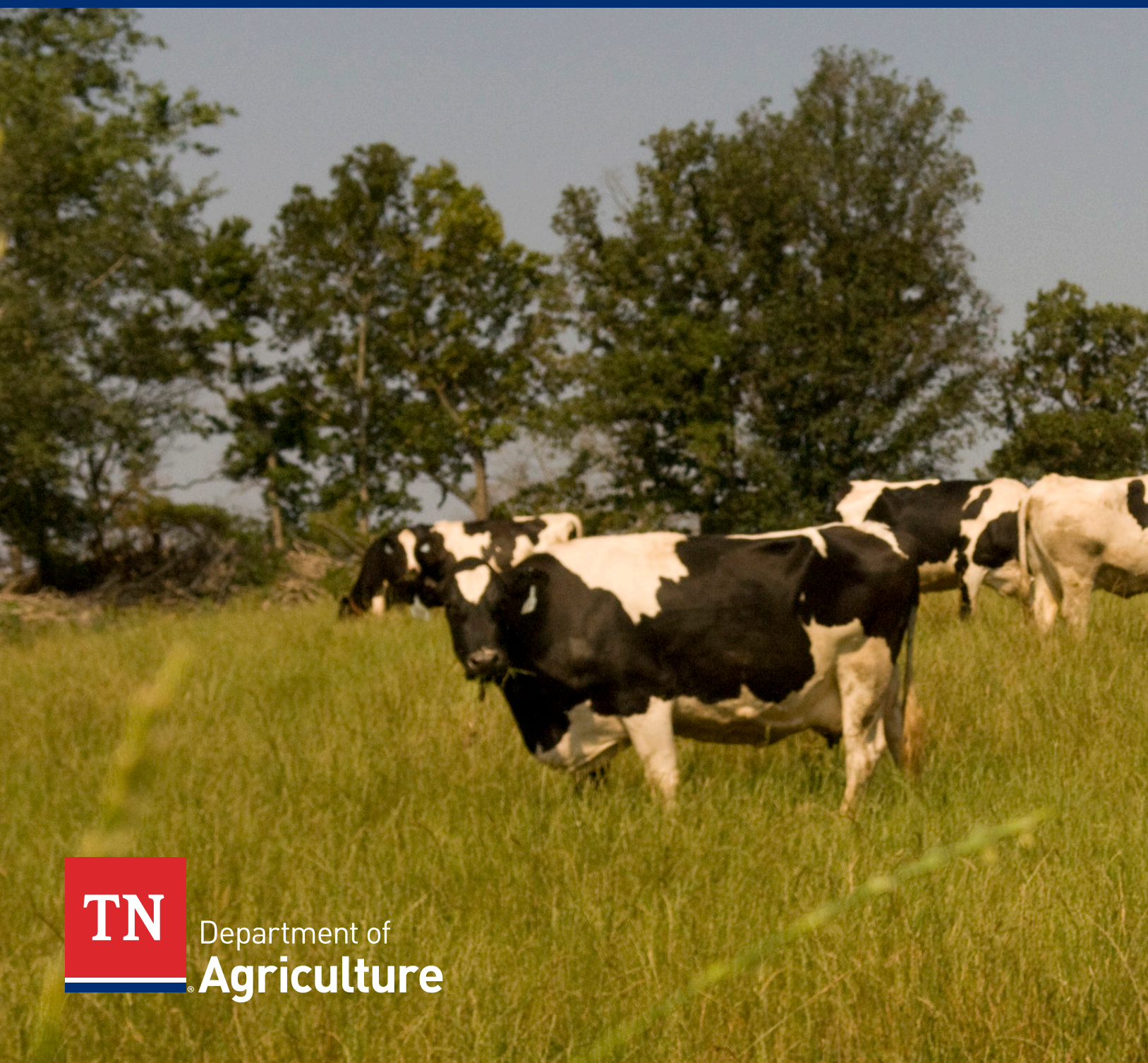
ROBOTICS at DAIRIES
IN TENNESSEE

Automatic Milking Installation and what it could mean for your Tennessee Dairy Farm



TN Department of Agriculture

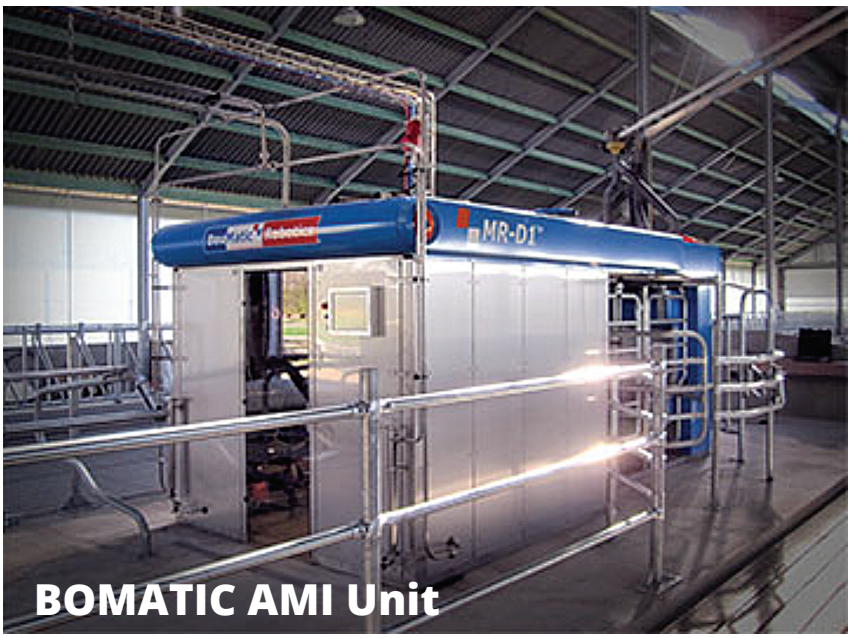
Automatic Milking Machine Installations

Over the last decade, Automatic Milking Installation (AMI units), or as many of us call them robot milking systems, have become a large part of the dairy industry in the United States. First seen in the Northeast and Midwest, AMI units are now marketed across the country and have become a more trusted and useful technological advancement. AMI units can confine the cow, feed the cow, clean teats, milk the cow multiple times each day, apply teat dip, and recognize and dump abnormal milk. Each manufacturer is working to complete designs that comply with the public health regulations outlined in the Pasteurized Milk Ordinance (PMO) on their units to accomplish these steps in an efficient and safe manner. The first step when considering an AMI for your farm is to reach out the Tennessee Department of Agriculture (TDA).

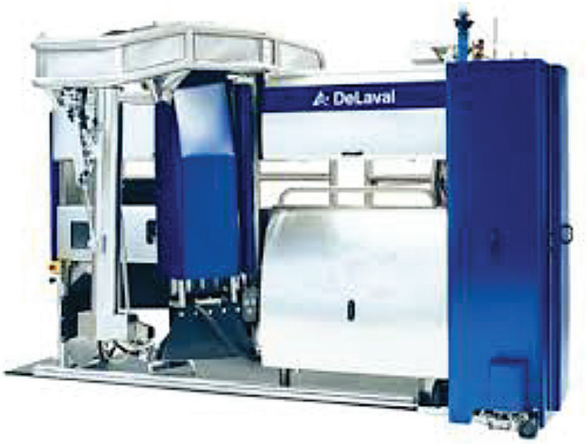
There have been and continue to be opportunities for improvement on the AMI units offered in the U.S. Five manufacturers have met with the Food and Drug Administration (FDA) to have their units evaluated. These meetings have led to a better understanding of the engineering and regulatory requirements of these units.

As you know, the dairy industry in the U.S. has three levels of inspection. Your local state inspector is the first level. In Tennessee, it is expected that our inspectors will conduct an inspection at your Tennessee dairy farm approximately every four months. The second level of inspection is the state rating officer (SRO). The SROs are required by regulation in the PMO to complete a state rating every two years. The third level is the federal check rating. These are completed every four years by FDA Milk Specialists.

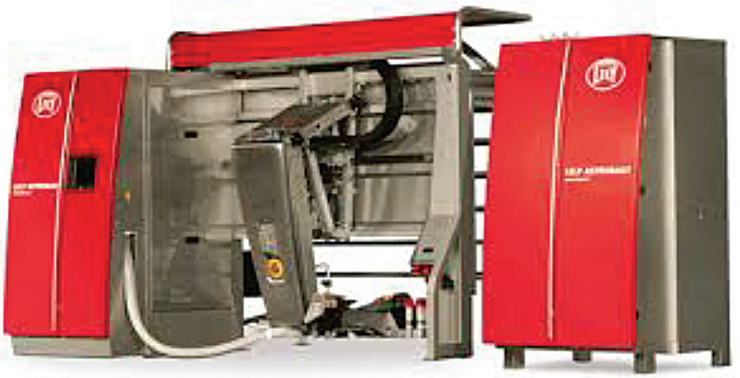
The following information is current and explains issues that have been areas of concern with AMI units. The manufacturers have been asked to address the areas of concern. Retro upgrades for those AMI units that are already in use will be required to be installed as they become available. It is very important to know that there is no such thing as being “grandfathered in.” You will also see ideas presented in the following materials to consider as you decide whether a “robot” is right for you and your Tennessee dairy farm. TDA Dairy Section will be here for guidance as AMI units become part of Tennessee’s dairy landscape.



BOMATIC AMI Unit



DELAVAL AMI Unit



LELY AMI Unit

GALAXY AMI Unit

GEA AMI Unit

Let's look at what regulatory agencies see as opportunities for improvement in these AMI units and **how your farm would be scored** during a Federal Check Rating

Robots and the FDA

The FDA has issued a number of documents called **Memoranda of Information**, **or MI**. These are issued to clarify requirements in the PMO and if the manufacturer has met those requirements. These **MI**s are included in this booklet and indicate:

The FDA has had valid questions on the ability of AMI units to accomplish a complete cleaning, fore-stripping and drying of teats prior to the milking process. Each AMI manufacturer has submitted what is called a "Teat Preparation Protocol" document.
The FDA has evaluated these documents. They have accepted each of them as explanations of how each manufacturer has designed a system that provides an adequate teat preparation prior to the milking process. The following eight pages are the **MI** documents issued by the FDA for AMI units manufactured by Lely, BouMatic, GEA, DeLaval and Galaxy.

- **M-I-07-7**: October 9, 2007-Teat Preparation Protocol **Lely** Astronaut A3-US 5.1003 And 5.1103 Robot Milking System.

- **M-I-16-8**: June 14, 2016- Teat Preparation Protocol **BouMatic** Robotics MR-S1 and MR-D1 Milking Robots.

- **M-I-16-12**: August 12, 2016- Teat Preparation Protocol **GEA** In-liner Teat Preparation Stall Unit 7820-3001-000, 7820-3003-000, 7820-3004-000 And 7820-5003-000.

- **M-I-07-5**: Supplement 2: July 31, 2017-Pre-milking Teat Preparation 2006 and 2007 **DeLaval** VMS.

- **M-I-12-10**: July 31, 2017- Teat Preparation Protocol Hokofarm Group B.V. **Galaxy** Astrea 20.20 USA Automatic Milking System.

HHS:PHS:FDA:CFSAN:OFS:DPDFS:DEB:MST

5100 Paint Branch Parkway
College Park, MD 20740-3835

M-I-07-7

October 9, 2007

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

FROM: Dairy and Egg Branch (HFS-316)

SUBJECT: Teat Preparation Protocol Lely Astronaut® A3-US 5.1003 And 5.1103 Robotic Milking System

ITEM 13r. MILKING - FLANKS, UDDERS AND TEATS

The Teat Preparation Protocol for the Lely Astronaut® A3-US 5.1003 AND 5.1103 Robotic Milking System has been submitted and evaluated by the Food and Drug Administration (FDA) 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 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 Lely, (2006-20 xx Astronaut® A3-US 5.1003 and 5.1103, serial number 0003050068 and up, version 4, issued September 8, 2007) for the Teat Preparation Protocol:

NOTE: While this protocol is specified for use with the Lely 2006-20xx Astronaut® A3-US 5.1003 and 5.1103 Robotic Milking System, 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.

HHS:PHS:FDA:CFSAN:OFS:DDEMP:MMPB

5100 Paint Branch Parkway
College Park, MD 20740-3835

M-I-16-8

June 14, 2016

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.

HHS:PHS:FDA:CFSAN:OFS:DDEMP:MMPB

5001 Campus Drive
College Park, MD 20740-3835

M-I-16-12

August 12, 2016

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.

HHS:PHS:FDA:CFSAN:OFS:DDEMP:MMPB

5001 Campus Drive
College Park, MD 20740-3835

M-I-07-5
Supplement 2

July 31, 2017

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 2), M-I-07-5 (Supplement 1), issued May 12, 2015, will be classified as "**INACTIVE**".

With this Supplement, Lactisan™ 3.5% Lactic acid is no longer identified as an acceptable teat sanitizing product. The following teat sanitizing products: Clean™ 1.75% iodine, Tri-Fender™ 1% iodine and Teat Cleaner NI01™ lactic acid/formic acid are identified as additional acceptable teat sanitizing products.

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 Robert.Hennes@fda.hhs.gov.

Randy Elsberry
Senior Milk Sanitation officer
Milk and Milk Products Branch

Robert Hennes, RS, MPH
CAPT U.S. Public Health Service
Milk and Milk Products Branch

HHS:PHS:FDA:CFSAN:OFS:DDEMP:MMPB

5001 Campus Drive
College Park, MD 20740-3835

M-I-12-10
Supplement 1

July 31, 2017

TO: Director, Office of State Cooperative Programs
Attn: All Staff, Division of Milk Safety

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

SUBJECT: Teat Preparation Protocol Hokofarm Group B.V. Galaxy Astrea 20.20 USA Automatic Milking System.

ITEM 13r. MILKING – FLANKS, UDDERS AND TEATS

The Teat Preparation Protocol for Hokofarm Group B.V. Galaxy Astrea 20.20 USA Automatic Milking System has been submitted and evaluated by CFSAN's Milk and Milk Products Branch/Milk Safety Team (MMPB/MST) and has been determined to be in compliance with Item 13r-Milking-Flanks, Udders and Teats, 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, 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 Indento Operations, Division of Hokofarm Group B.V. Galaxy Astrea 20.20 USA (April 25, 2017) for the Teat Preparation Protocol:

NOTE: While this protocol is specified for use with the Hokofarm Group B.V. Galaxy Astrea 20.20 USA Automatic Milking System, 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.

With this Supplement, the company's name "Insentec B.V." was changed to "Hokofarm Group B.V", which occurred several years ago, and the Galaxy Pre-Wash 502 pre-milking iodine sanitizer is being replaced with five (5) sanitizers that are identified in Section 2.1 (Cleaning of the teats). This Supplement provides updated screen shots for the current "Saturnus 20.20" management software that replaced the original "Saturnus" software and also provides a revised mechanical diagram for the preparation reservoir.

Please note that upon the issuance of this M-I-12-10 (Supplement 1), M-I-12-10, issued May 14, 2012, will be classified as "**INACTIVE**".

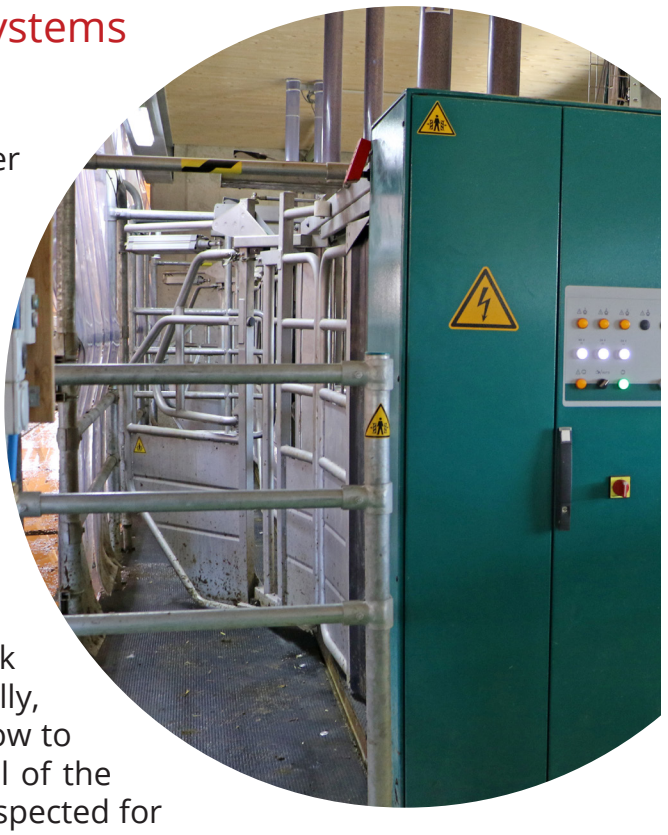
An electronic version of this memorandum is available for distribution to Regional Milk Specialist, Milk Regulatory/Rating Agencies and Milk Sanitation Rating Officers in your region. The electronic version should be widely distributed to representatives of the FDA Web Site at http://www.fda.gov at a 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.

Randy Elsberry
Senior Milk Sanitation Officer
Milk and Milk Products Branch

Robert Hennes, RS, MPH
CAPT, U.S. Public Health Service
Milk and Milk Products Branch

Now let's look at the computer systems that run these AMI units



The systems in these units control a number of features, and some of them are not designed in a way that allowed them to be easily checked or verified. The FDA and TDA feel there are three features on these units with potential for improvement to meet PMO requirements:

- **1r** in Appendix Q of the PMO- Each of these units has sensors in the path of the milk that may detect milk with the presence of blood, which is considered "abnormal milk." They have been designed to valve this abnormal milk out and route it to a dump tank. Specifically, the machine will not allow this milk to flow to the holding tank to be marketed. Not all of the units have a way for this system to be inspected for accurate function.
- **13r** in Appendix Q of the PMO- Computer programing also controls the teat preparation that we discussed previously. Although the **MI**s on teat prep protocol cover the design and accepted function of the equipment during teat preparation, this programming and its parameters are not easily verified on all units.
- **14r** in Appendix Q of the PMO- This section addresses the testing and verification of the storage, cleaning and protection from contamination of the teat cups prior to and after the milking procedure. The section also addresses opportunities to improve the separation of milk and any other fluids in lines, such as cleaning and sanitizing chemicals. The block-bleed-block valves, their sensors and their function have not all been designed in a way for them to be easily evaluated.

Now that we have discussed computer opportunities, let's look at the way the FDA has approached these Appendix Q items. As you might guess, they have addressed the items with an **MI** related to computer systems. The **MI** states that until further notice, computer system(s) verification requirements related to Appendix Q, Items **1r**, **13r** and **14r** will not be debited on Federal Check Ratings. TDA anticipates following this lead. As the manufacturers design these evaluation processes and they become available it will be expected that they <u>are installed and utilized</u>. The following page is the **MI** that addresses Computer Systems in AMI units.

M-I-17-3: April 20, 2017- AMI Computer System Guidance

HHS:PHS:FDA:CFSAN:OFS:DDEMP:MMPB

5001 Campus Drive
College Park, MD 20740-3835

M-I-17-3

April 20, 2017

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

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

SUBJECT: Guidance Related To The Requirements For Automatic Milking Installations (AMIs) Addressing Computer System(s) Verification and General Computer Functions Related to Pasteurized Milk Ordinance (PMO), Appendix Q, Items 1r, 13r and 14r.

Proposal 134 that was submitted and passed by the delegates at the 2015 National Conference on Interstate Milk Shipments (NCIMS) added wording to the Pasteurized Milk Ordinance (PMO), Appendix Q to clarify the requirements for the operation of automatic milking installations (AMIs) addressing computer system(s) verification and general computer functions related to Items 1r, 13r and 14r. This proposal also established an implementation date of one (1) year from the issuance of the 2015 version of the electronic PMO (March 15, 2017).

It is our understanding that at this time AMIs do not comply with computer system(s) verification requirements of PMO, Appendix Q, Item 1r, 13r and 14r. FDA has been and will continue to work with AMI manufacturers to bring their computer systems into compliance with PMO, Appendix Q. Until further notice, computer system(s) verification requirements related to Appendix Q, Item 1r, 13, and 14r will not be debited on federal check ratings.

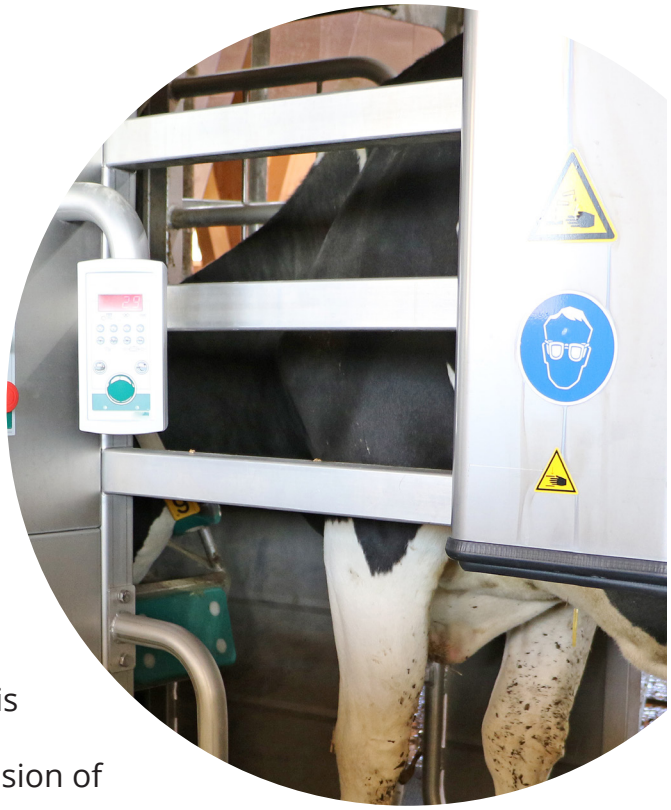
An electronic version of this memorandum is available for distribution to Regional Milk Specialists, Regulatory/Rating Agencies and Milk Sanitation Rating Officers in your region. The electronic version should be widely distributed to representatives of the dairy industry and other interested parties 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 randy.elsberry@fda.hhs.gov.

Randy Elsberry
Senior Milk Sanitation Officer
Milk and Milk Products Branch

The Federal Check Rating on AMI Units

and what it will mean at the State Rating and State inspection levels



The FDA has issued two additional **MI** documents that address AMI units. One was issued on April 21, 2014 and it is **M-I-14-8**. This **MI** explains that Appendix Q of the PMO specifically addresses the requirements of AMI units and regulations governing the design, installation and use of AMI units. In other words, it is the section in the PMO that will be referenced during AMI inspections. That **MI** is not included in this handout, as it is lengthy and is in the PMO as Appendix Q. It can be seen in the 2015 revision of the PMO.

Previously, federal and state inspectors were expected to debit up to **13** points on a federal check rating and a state rating if an AMI unit is present on a farm. Since the meetings have taken place between manufacturers of AMI Units and the FDA, there have been some changes. Farms that have AMI units can now only be debited up to **4** points related to design deficiencies. This change is at the federal and state level and is stated in **M-I-17-5**, which was issued on October 6, 2017 by the FDA. The following page is **M-I-17-5**, which addresses design deficiencies in AMI units. Tennessee inspectors and rating officers are not required to show issues with AMI units as "repeat" violations at this time.

This is a great deal of information on the balance between AMI units, the manufacturers of the units, the FDA, the PMO, **MI** documents and state inspectors. We feel that as improvements are made on the units and as regulatory agencies and manufacturers work together to solve issues with AMI units, these units could become a very important part of Tennessee's dairy industry. The TDA Dairy Section is committed to help if you move toward AMI units on your farms. The first step when considering an AMI for your farm is to reach out to the Tennessee Department of Agriculture.

Consumer and Industry Services Dairy Section
615-837-5536
Contact.Dairy@tn.gov

5001 Campus Drive
College Park, MD 20740-3835

M-I-17-5

October 6, 2017

TO: Director, Office of State Cooperative Programs
Attn: All Staff, Division of Milk Safety

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

SUBJECT: Guidance Related To The Check Ratings For Automatic Milking Installations (AMIs)

This M-I, effective immediately, is intended to provide guidance and clarification as to how AMIs are to be evaluated during federal check ratings until the implementation of the PMO to be published after the 2019 conference.

The following represents FDA's analysis on the design of each manufacturer's currently marketed unit based on FDA's interpretation of PMO requirements, as will be detailed in the forthcoming supplements to M-I-14-8.

Based on FDA's evaluations, the maximum debit any non-compliant AMI equipment will incur for design deficiencies will be a single debit, not to exceed 4 points. No repeat violation penalties will be assessed for any debits on federal check ratings of AMI equipment for design.

An electronic version of this memorandum is available for distribution to FDA Milk Specialists, Regulatory/Rating Agencies and Milk Sanitation Rating Officers. 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 & Milk Products Branch

Things to Consider if you decide a Robot Milking System is right for you and your Tennessee Dairy Farm

Communicate with TDA if you move to incorporate an AMI unit into your facility. Equipment design and install plans must be submitted to and approved by TDA. There are important aspects of the install that must be completed correctly, such as back flow prevention. As of 2017, the five manufacturers that the FDA has issued MI documents for are Lely, Galaxy, Boumatic, DeLaval and GEA.

- The maximum 4 points discussed in the previous section pertain to "robot" design related deficiencies ONLY. This does not limit other violations related to your farm.
- Research the available AMI units to decide which best fits you and your Tennessee dairy farm.
- Not all cows will work with an AMI unit. Some cows have personalities that will not function well with these units.Guide your genetics toward replacements that are "robot cows."
- Know your manufacturer and communicate your expectations and how their unit fills those expectations and needs.
- Communicate with TDA as you move to incorporate an AMI unit into your facility.
- Know your installer and service agent. Although there are items that the FDA has addressed with MI documents, the unit must be installed correctly or it could lead to further violations during an inspection.
- TDA inspectors will not be disassembling components of your AMI unit. It will be necessary for you or your service agent to be on site during inspections to assist with the inspection of these units. We understand this means scheduling inspections at the four month intervals, but it is important that TDA fully inspect all aspects of your AMI unit.
- Teat Prep Protocol documents on your units must be on farm and accessible by your inspector.
- As retrofit upgrades become available to address items that are now covered by MI documents, they will need to be installed and used. There is NO "grandfathering in." During your contract negotiations, find out who will cover the cost of the retro installations you or the manufacturer.

Finally, never forget that the installation of an AMI unit replaces only one person on your farm. That is the person who milks. It does not replace the animal care person, the person responsible for cleaning, the manager, the maintenance personnel or the person changing tank charts or weight tickets. These units are one of many tools available as you pursue a productive, profitable, efficient and modern milking facility.

NOTES


Tennessee Department of Agriculture, Authorization No. 325476, 200 copies, December, 2017. This public document was promulgated at a cost of $2.69 per copy.