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M-I-12-10

May 14, 2012

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

FROM: Dairy and Egg Branch (HFS-316)

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

ITEM 13r. MILKING – FLANKS, UDDERS AND TEATS

The Teat Preparation Protocol for Insentec B.V. Galaxy Astrea 20.20 USA Automatic Milking System has been submitted and evaluated by FDA's Central Region Milk Specialists and CFSAN's Dairy and Egg 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 Indento Operations, Division of Insentec B.V. Galaxy Astrea 20.20 USA (September 13, 2011) for the Teat Preparation Protocol:

NOTE: While this protocol is specified for use with the Insentec 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.

Teat Preparation Protocol for Insentec B.V.

Galaxy Astrea 20.20 USA Automatic Milking System

subject : Teat preparation protocol
model : Galaxy Astrea 20.20 USA
prepared by : Indento Operations – Division of Insentec B.V.
date : September 13, 2011
author : Wilt Feikema

Index

1. **Summary**
2. **Teat preparation procedure**
 - 2.1 Cleaning of the teats
 - 2.2 Fore-stripping
 - 2.3 Drying
 - 2.4 Sanitizing of the teat cleaning cup
3. **Post teat treatment**
4. **Technical specifications**
 - 4.1 Management software
 - 4.2 Attach tool
 - 4.3 Teat cleaning cup
 - 4.4 Preparation reservoir
 - 4.5 System overview
 - 4.6 Serial number location - Central Unit
 - 4.7 Serial number location - Milking Box

1. Summary

The industrial robot arm, used by the Insentec Galaxy Astrea 20.20 AMS, is equipped with a 'teat cleaning cup'. The system will clean every lactating teat according to the cow specific settings in the management software Saturnus. The positions of all teats are stored in the memory and they are used by the industrial robot arm to determine the start position of the teat scan. When the desired teat has been located by the vision system, the robot arm is moving upwards, so the teat cleaning cup is placed over the teat. The rinse/prepare cycle starts, which will be described thoroughly in chapter 2. When the teat cleaning has been performed for all teats and milking has been started the cleaning cup is cleaned and sanitized before the cleaning for the next cow starts.

2. Teat preparation procedure

The industrial robot arm has an integrated tool on which the teats are cleaned and the milk cups are connected to the cow's teats. This tool is called the 'attach tool'. (Figure 2) On this attach tool there is a cleaning cup connected which is cleaning/preparing the teats before milking. This cleaning cup has two relative positions to the arm. When the teats need to be prepared/cleaned the cleaning cup is moved upwards, otherwise it is downwards. The prep cup is a specially designed stainless steel shell (part number JH9167) with a specially designed teat liner with a stainless steel ring (part number DE0022) inserted through a hole in the mouthpiece of the liner (Figure 3 and 3A). In the top of the liner 200 ml to 300 ml of an iodine sanitizing solution is added during the cleaning cycle through a stainless steel teat preparation ring (Figure 3A) A pulsator is connected to the teat cup/teat liner so the prep cup liner will pre-milk the teat.

2.1 Cleaning of the teats

After the desired teat has been located by the vision system, the teat cleaning cup is moved over the teat. Vacuum is applied to the cleaning cup and the pulsator is also activated so the liner will be open around the teat. For 3 seconds a sanitizing solution is sprayed around the teat.(Refer to Figure 3 and 3A.) All the cows are treated in the same way. The time for spraying the sanitizing solution is adjustable and may be increased for all cows if the soil loads on the cow's teats increases and is operator dependent. A chemical pump is used to draw ready to use Galaxy Pre-Wash 502 pre-milking iodine sanitizer from the storage vessel and inject 200 ml to 300 ml into the teat cleaning cup. This is followed by a clear water rinse and an air blow dry.

2.2 Fore-stripping

After the cleaning phase, the teat is fore-stripped. This is accomplished by opening and closing the teat liner at a pulsation ratio of 50% on and 50% off with 60 pulses per minute. The teat liner is opened and closed in this manner 5 times. This is a system setting of the software, which can not be changed. This first milk is collected in a milk/waste water vessel, which is completely separated from the normal milking circuit, as it is a separated line. . The proper settings of the pulsation ratio are verified via the Teat Preparation Settings. These settings are stored on the Astrea 20.20 USA Settings Document located behind the main cover on the left side of the central unit. Checking the proper operation of the pulsator is included in the maintenance schedule.

2.3 Drying

When prepping is completed, the teat liner is opened again for 2.5 to 5 seconds to dry the teat. This setting is a system setting, which is not adjustable. This setting can be verified by performing a manual preparation. The proper procedure to follow for a manual preparation is found on the Astrea 20.20 USA Settings Document located behind the main cover on the left side of the central unit. The vacuum is still applied to the teat cup. Air is drawn through the air inlet; air is flowing from the top of the teat downwards. After this cycle the teat is dry. The vacuum will be stopped and the robot arm moves downwards so the teat cleaning cup will be removed from the teat. Now the system can

start cleaning/preparing the next teat or, when all teats have been prepared, the robot can start attaching the normal teat cups for milking. The fore-milk and waste water are emptied to drain.

2.4 Sanitizing of the teat cleaning cup

When all the teats have been prepared and all teat cups are attached and the cow is milking, the robot arm moves away from the cow. Now the teat cleaning cup will be sanitized. The robot arm places the teat cleaning cup into the cleaning station. Vacuum is applied to the teat cleaning cup. A cleaning can be started manually to verify the proper working of all the valves. The correct procedure for a manual cleaning is contained in the Test Procedure Document found on the Astrea 20.20 USA Settings Document located behind the main cover on the left side of the central unit. The waste water is collected in the milk/waste water vessel and dumped to drain afterwards. After this cycle the robot arm is ready to handle the next cow. The cleaning cup is also cleaned and sanitized during the normal CIP (Clean In Place) cycles of the entire system (2 or 3 times a day).

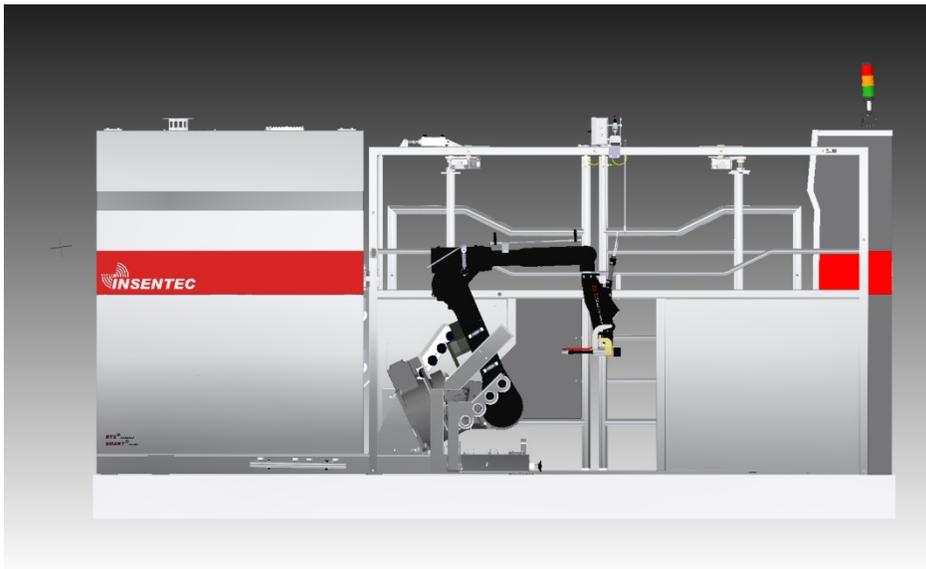


Figure 1 – Robotic Arm Home Position

Between each milking the cleaning cup is cleaned and placed in the clean area as shown in Figure 1.

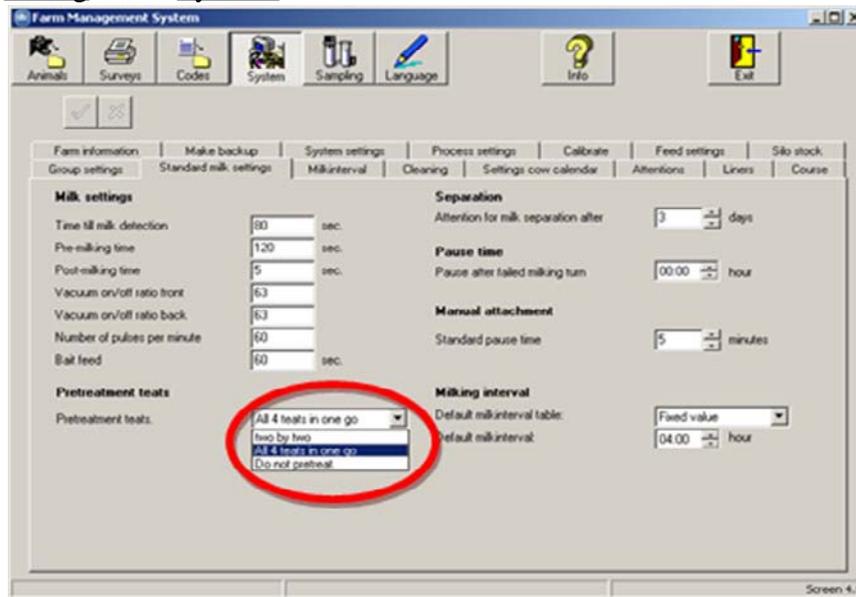
3. Post teat treatment

When milking is finished and all teat cups have been detached, the AMS system has the ability to spray post milking teat dip on the teats. For that purpose a spray nozzle comes up from the floor (between the rear legs) and is spraying, for a desired time, a post milking teat dip onto the cow's teats. The nozzle has a circular spray pattern. The spray pressure is 55 PSI. The amount of disinfectant used per cow can be adjusted from 0.34 oz to 0.50 oz.

4. Technical specifications

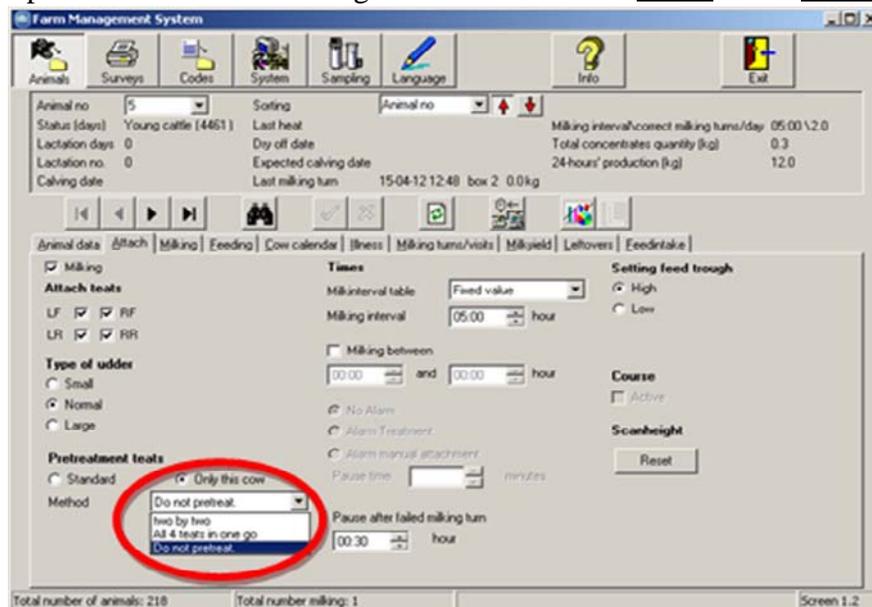
4.1 Management software

From the Saturnus20.20management software the following settings can be changed by the user concerning the pretreatment. The management software running on a farm can be verified by looking on the Saturnas management computer located in the farm office. Open the Saturnas program on the management PC. Go to the tab standard milk setting under System.



The preparation can also be changed on cow level.

Open Saturnas on the management PC. Go to tab attach under animals.



- All 4 in one go: the robot arm will perform a pretreatment cycle on all teats first before the teat cups are attached.

- Two by two: first the rear teats will be pretreated and then the teat cups will be attached to the rear teats. Then the front teats are pretreated and then the teat cups are attached.
- None: No pretreatment is performed, the robot arm starts attaching the teat cups immediately.

4.2 Attach tool

The attach tool is mounted on the robot arm. This tool is carrying the teat cleaning cup (4 – Figure 2). When the teat cleaning cup is not needed, it is moved in the position visible on Figure 2. When a teat prepare cycle needs to be done, the cleaning cup is moved upwards, between the two gripper arms (1-Figure 2). The teats are detected with the Galaxy Vision system. It consists of a laser (2-Figure 2) and a camera (3-Figure 2).

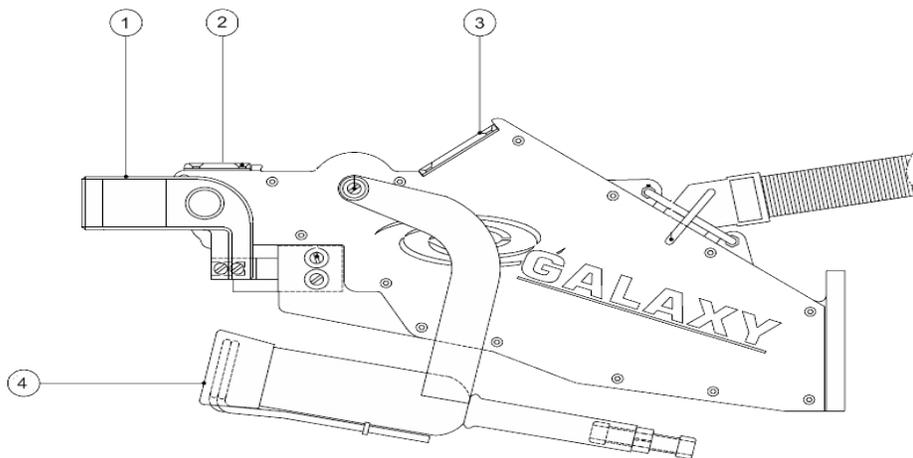


Figure 2 – Attach/Prep Tool

4.3 Teat cleaning cup

The teat cleaning cup consists of a stainless steel shell (part number JH9167) (2-Figure 3) with a teat liner (part number DE0022) (1-Figure 3). Both the stainless steel shell and the teat liner are specifically manufactured for this application. A sanitizing solution for cleaning of the teat is added under pressure through a stainless steel preparation ring (5-Figure 3). Proper operation of the prep procedure was described in section 2. Refer to Figure 3A for more detail. The milking/vacuum hose is connected to (4-Figure 3), the pulsation hose is connected to (3-Figure 3).

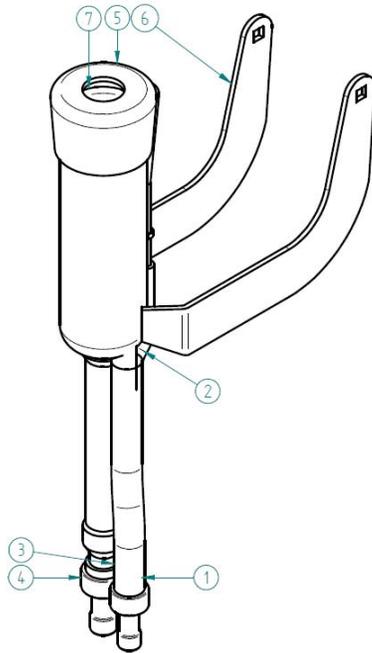


Figure 3 – Teat Preparation Cup

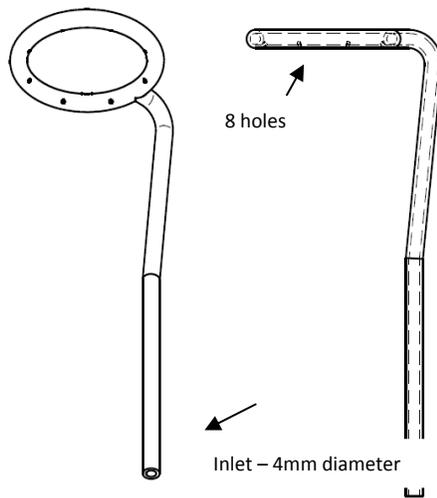


Figure 3A – Stainless Steel Preparation Ring

4.4 Preparation reservoir

Water and the foremilk of each teat preparation are collected in a waste water/milk reservoir (3-Figure 4). This part is completely separated from the normal milking circuit. After the cleaning/preparation of each teat the contents of the reservoir are dumped down the drain.

The first connection on top of the reservoir (1-Figure 4) leads to the vacuum shut off valve. Through this connection normal system milking vacuum of ± 12.5 inches of Hg is

applied to the reservoir. The second connection (2-Figure 4) is connected to the milk/vacuum hose that leads to the cleaning cup. When vacuum is applied to this circuit, the dump valve (4-Figure 4) will close automatically. The foremilk and cleaning water comes from the cleaning cup into the reservoir. When the cleaning of a teat is finished the vacuum shut off valve will close. This leads to a vacuum drop in the reservoir. As a result the dump valve (4-Figure 4) will open, so the milk and water residue flows away. At this moment the farmer has the ability to do a visual check on the foremilk and the amount of cleaning water. In this way the proper functioning of the system can be assured.

The system is cleaned and sanitized after each cow by sucking up hot water/steam (212° to 230°F) by the cleaning cup from the cleaning station. The water/steam flows through the cleaning cup and milk hose into the reservoir. When the vacuum valve is closed, the vacuum drops and the cleaning water is dumped into the drain.

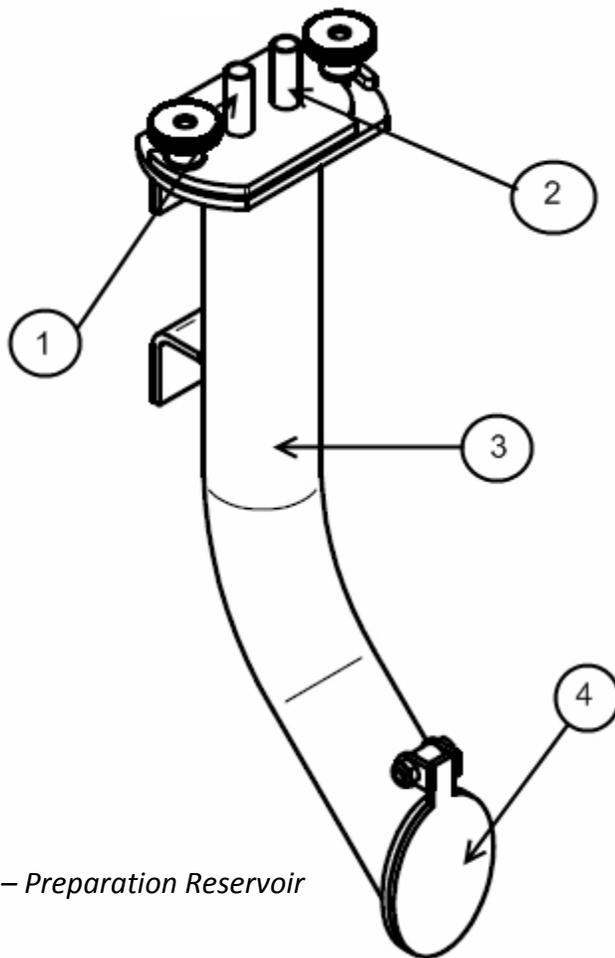


Figure 4 – Preparation Reservoir

4.5 System overview

See below for a system overview of the industrial robot arm with preparation system.

- (1) Water/milk reservoir
- (2) Cleaning cup
- (3) Attach tool
- (4) Cleaning station

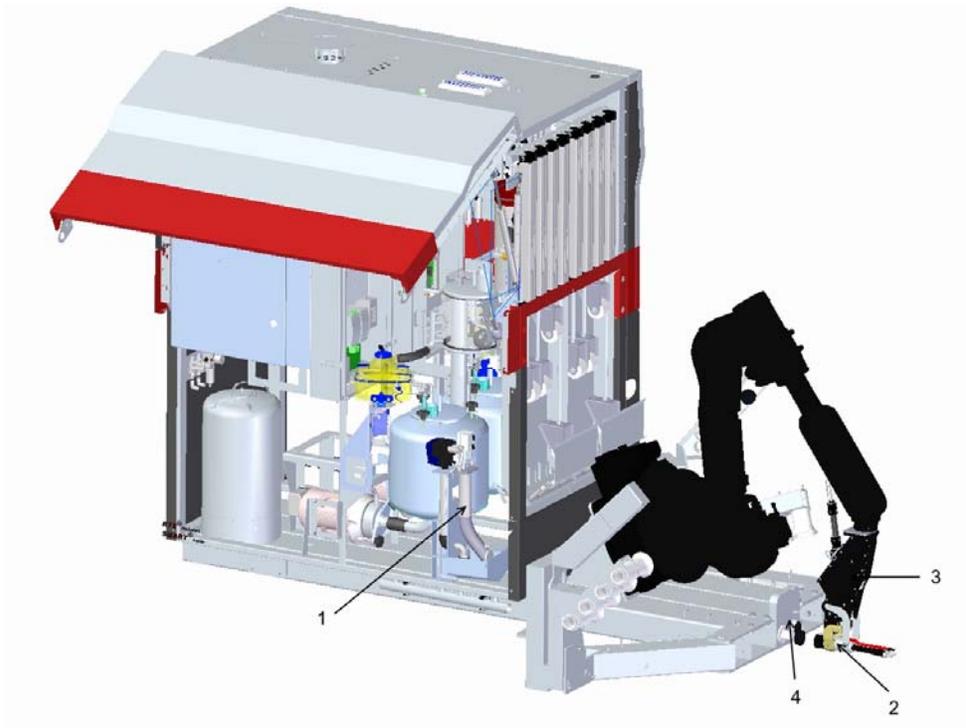


Figure 5 – Machine Unit With Robotic Attachment Arm

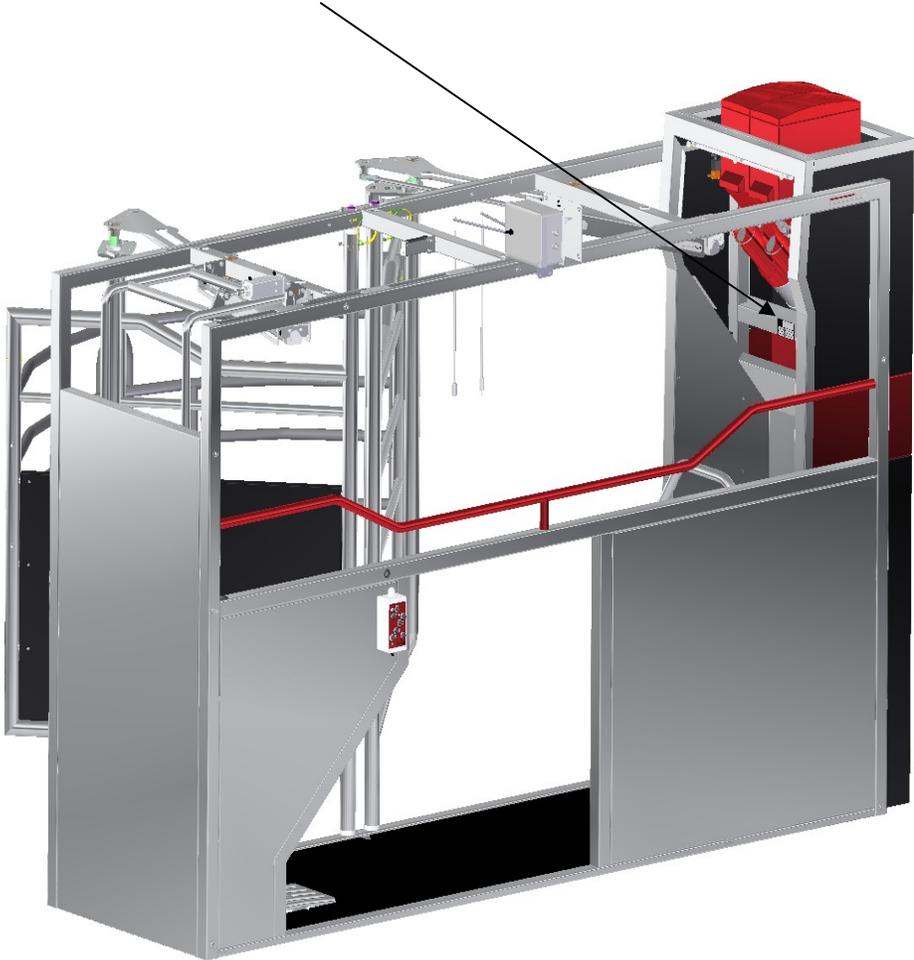
4.6 Serial number locations:

Model & Name	Serial NO.	Location Serial plate	Software
Astrea 20.20	<p>Central unit: 011001100 up to 019999999 *</p> <p>Milkbox left: 111001100 up to 119999999*</p> <p>Milkbox right 211001100up to 219999999*</p>	<p>In the central unit the serial plate is on the backside of the electronic cabinet.</p> <p>In the milkbox the serial plate is under the auger.</p>	<p>Milkbox Version: 110830C01 and up</p> <p>HJC II Version: 110829-002 and up</p> <p>Dairyroom Version: 110725 and up</p> <p>Motoman Version: 1.07.07.02 and up</p> <p>TRAC CPU Version: 1.34 and up</p>
<ul style="list-style-type: none"> • US models – Serial number ends with “US”. 			



Location of the serial plate in the central unit

4.7 Serial number location milking box:



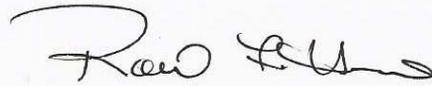
Location of the serial plate in the milkbox

An electronic version of this memorandum is available for distribution to Regional Milk Specialist, State Milk Regulatory Agencies and State 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.

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A handwritten signature in black ink, appearing to read "Robert Hennes", is centered within a light gray rectangular box.

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