COAG.1500.3.0 ROUTINE MAINTENANCE FOR THE SYSMEX CA-1500

PRINCIPLE
Maintenance is preformed to ensure optimal operating efficiency of the analyzer.

OWNERS
Manager, Regional Hematology Laboratory

REAGENTS
See Routine Operating Procedure for the Sysmex CA 1500

EQUIPMENT
A. Sysmex CA1500
B. Printer Paper
C. Alcohol Swab
D. Paper Towels
E. 70% Isopropal Alcohol

PROCEDURE
A. Maintenance Includes:
   1. Daily
      a. Check and replace Clinical Laboratory Reagent Water [CLRW] (carboy)
      b. Rinse and clean probes (sample and reagent)
      c. Empty waste container (if not direct drained)
      d. Turn power off/on
      e. Check Reagent Table
      f. Check and empty fluid from Pneumatic Trap Chamber
      g. Check pressure and vacuum levels
      h. Check temperatures
      i. Check and replenish supplies
      j. Check and replenish reagents
      k. Clean instrument surface.
   2. Weekly
      a. Disinfecting and cleaning waste container
      b. Priming hydraulic lines with rinse solution
   3. As Needed
      a. Replace chromogenic lamp
      b. Replace fuses
      c. Adjust pressures

B. Check Rinse Solution - replace as needed.
   If the rinse solution runs out during an analysis, an error message “Replenish Rinse fluid” will appear and the analysis will be interrupted. Replenish with rinse solution as described in the procedure below.

1. A "Being Interrupted" message will appear. Wait shortly until the interruption process is completed. When the system is ready for replenishing rinse fluid, a message will appear.

> **CAUTION**: Do not touch the float switch with your hand. If dust or foreign matter adheres to the float switch, the tank interior will get contaminated. If the interior gets contaminated, correct analysis results may not be obtained. If your hand or other object touches the float switch, wash off the float switch with rinse solution (or distilled water) and then attach it to the tank.

2. Turning the cap counterclockwise, open the cap and remove from carboy.
3. Attach the cap to a new carboy of CLRW.
4. Tighten the cap clockwise to close.
5. Make sure that the tubing is securely connected and is not kinked.
6. Press the [Resume] key. The analysis will continue.

C. Cleaning the Probes

Clean the sample probe and reagent probe at least every 24 hours.

> **WARNING:**
>
> - When cleaning probes, handle all instrument parts as biologically hazardous. Wear rubber gloves and wash your hands with disinfectant solution after cleaning.
> - When cleaning the probes, always start from the top to the bottom. If you worked from the bottom toward the top, the probe could pierce your finger or hand. The probe could also be bent.

1. From the Main Menu screen, press the [Rinse Probe] key. The Rinse Probe screen will appear.
2. Set CA CLEAN I in **both** the reagent holders A2 and E3.
3. Press the [Execute] key. Probe will start. It will take approximately 3 minutes to complete the cleaning.
4. Press the [Return] key.

5. Use an alcohol swab to clean outside of probes.

Note: Be careful to wipe straight and not bend the probe

D. Discarding the Used Reaction Tubes

The used reaction tubes are automatically thrown in the trash box. At completion of every 250 tests, or at least once every 24 hours, discard the used reaction tubes from the trash box and clean it with tap water.

> **WARNING:** When discarding used reaction tubes, handle all used tubes as biologically hazardous. Wear rubber gloves and wash your hands with disinfectant solution after discarding. Also, medical waste materials should be properly disposed of.

1. While power remains ON and instrument status is "Ready", pull up the trash box slightly and then draw it out from the left side panel. Although a message "Tube Trash has not been set" will appear, disregard this.
2. Discard the used reaction tube.
3. Clean the reaction tube trash box with tap water, and thoroughly wipe off moisture from the reaction tube trash box.
4. Restore the reaction tube trash box. After wiping off the moisture thoroughly, replace it. A message will appear asking if you wish to reset the number of used reaction tubes. If the tubes have been discarded, press the [OK] key. If you do not wish to discard or reset, press the [Cancel] key.

> **CAUTION:** If tubes are discarded after the power is turned OFF, press area (A) of the Consumable screen after the power is turned ON next time; then reset the number of used reaction tubes.

E. Discarding Waste Daily or as needed

> **WARNING:** When discarding waste, handle wasted as biologically hazardous. Wear rubber gloves and wash your hands with disinfectant solution after discarding. Also, medical waste and infected waste should be properly disposed of.

1. If the tank becomes full with waste during analysis, an alarm will sound and a confirmation screen will appear. Press the [OK] key and then wait shortly until the analysis is interrupted (analysis interrupting procedures will be activated). When the system becomes ready for wasted disposal, a message will appear.
2. Open the cap from the waste tank. Turn the cap counterclockwise and take out the float switch carefully avoiding splashes or drips.
3. Discard waste fluid and empty the waste tank.
4. Insert the float switch into the tank, and turn the cap clockwise.
5. Make sure that the tubing is securely connected and is not kinked.
6. Press the [Resume] key.

> **CAUTION:** When the tank has become full after dispensing all samples, the Analysis Start Confirmation screen will not appear and step (6) above is not required.

F. Removing Condensation from the Reagent Trays

Once every 24 hours, check to see if condensation has formed on the reagent keys. Remove any if found.

> **WARNING:**
>
> - Before cleaning the reagent trays, turn the power OFF and unplug the power cord. Failure to do so can result in electric shock.
> - When cleaning the reagent trays, handle all instrument parts as biologically hazardous. Wear rubber gloves and wash your hands with disinfectant solution after cleaning.

1. Turn OFF the power.
2. Open the light shield lid.
3. Pull out the reagent trays.
4. Using the paper towel, remove the condensation from the cooling unit.
5. Reinsert the reagent trays.
6. Close the light shield lid.

G. Check and Discard Trap Chamber Fluid

Daily, check the trap chamber fluid level and discard any fluid that has collected.

WARNING: When discarding the fluid trap chamber, handle the fluid as biologically hazardous. Wear rubber gloves and wash your hands with disinfectant solution after discarding.

CAUTION:

- If fluid collects every day, the hydraulic system may have failed. Contact your Sysmex service representative.
- Pay attention to the direction of the float in the chamber. Place it with its pointed end facing upward.

1. Turn OFF the power and wait approximately 30 seconds.
2. The trap chamber is located on the right side of the instrument. Turn the trap chamber clockwise and remove it.
3. Discard the collected fluid, and re-attach the trap chamber. Make sure that the float is inside and float direction is correct.

H. Check the Vacuum and the Pressures

1. From the "Main Menu" screen press [Special Menu] - the "Special Menu" screen will appear.
2. Press [Maintain] - the Maintenance sub menu will appear.
3. Press [Pressure Adjust.] - the "Pressure Adjustment" screen will appear.
4. Check the displayed vacuum and pressures. If the values displayed are within the range, press [Return] to return to the "Main Menu" screen; if not, proceed to the adjustment instructions.

Vacuum Setting >420 mm/Hg

The vacuum setting is not adjustable. If the vacuum is <420 mm/Hg, the following items should be checked.

a. Check the trap chamber for fluid and discard.
b. Check the vacuum line for loosened nipple or tubing.

Pressure settings:

2.2 Kg/cm^2 - 2.3 Kg/cm^2
1.0 Kg/cm^2 - 1/1 Kg/cm^2

The pressures from the built-in pneumatic unit are adjusted to 2.2 kg/cm^2. These pressures are constantly monitored by pressure sensors. If an abnormality is detected, an error message will appear. If any pressure related

error message is displayed, check the tubing connections for leaks. If nothing abnormal is found, adjust the pressure.

5. To adjust the pressure, turn the adjustment knob (located on the right side of the instrument) as you check the current pressure readings on the Pressure Adjustment screen.
6. Press the [Pressure Adjust.] key. The Pressure Adjustment screen will appear.
7. Adjusting the 2.2 kg/cm^2 Pressure
Loosen the fixing screw on the 2.2 kg/cm^2 adjustment knob by turning a screwdriver counterclockwise while the adjustment knob is held to prevent from rotating.

Adjust the pressure by turning the adjustment knob as you check the current value for the 2.2 kg/cm^2 pressure on the Pressure Adjustment screen. The pressure will rise as you turn the adjustment knob clockwise.

Target: 2.2 kg/cm^2 - 2.3 kg/cm^2

CAUTION: Always adjust the pressure so as to raise it to the specified level. If the pressure is too high, lower it to a value that is below the specified pressure; then slowly raise the pressure. Failure to do so can prevent correct pressure adjustment.

After adjustment, tighten the fixing screw while taking care not to allow the adjustment knob to rotate. When 2.2 kg/cm^2 pressure was adjusted, verify the 1.0 kg/cm^2 pressure and adjust if required.

8. Adjusting the 1.0 kg/cm^2 Pressure
Pull the 1.0 kg/cm^2 adjustment knob toward you to unlock. Adjust the pressure by turning the adjustment knob as you check the current value for the 1.0 kg/cm^2 pressure on the Pressure Adjustment screen. The pressure will rise as you turn the adjustment knob clockwise.

Target: 1.0 kg/cm^2 - 1.1 kg/cm^2

CAUTION: Always adjust the pressure so as to raise it to the specified level. If the pressure is too high, lower it to a value that is below the specified pressure; then slowly raise the pressure. Failure to do so can prevent correct pressure adjustment.

After the adjustment, prevent the adjustment knob from turning by pressing it in until it locks.

I. Check Temperatures Daily

1. All temperatures are displayed on the Main Menu screen in the upper right hand corner.
2. Target values for temperature are:

Cooler:	15.0C° +/- 2.0°
Reagent Probe:	37.0 C° +/- 1.0°
Detector 1:	37.0 C° +/- 0.5°
Detector 2:	37.0 C° +/- 0.5°

J. Replacing Sample Plates

If unused wells in the sample plate run out during an analysis, an error message “Sample Plate completely used. Replace Plate.” will appear and analysis will be interrupted.

1. A “Being Interrupted” message will appear. Wait for a few minutes until the interruption process is completed. When the system is ready for replacing plates, a message will appear.
2. Confirm that the “Lid” signal (status of cover opening) is green; then open the light shield lid.

CAUTION: If you remove a sample plate that is fresh (lit with green LED) or that is partly used (lit with red LED), a message window will appear instructing you to return the sample plate to its original position. Replace the original sample plate back into its original position.

3. Replace the sample plate(s).

Remove the sample plate that you are replacing, and set an unused, fresh sample plate in its place. Set the sample plate in the direction shown in the figure.

CAUTION: Use only unused sample plates. You cannot use a partially used plate because CA-1500 will not recognize the used wells.

NOTE: LED to the right side of each sample plate indicates one of the following (however, note that this signal will not be updated even if sample plates are manually replaced):

OFF:	Sample plate is not set
ON (green):	Sample plate has not been used at all
ON (red):	Sample plate is partially used
Flashing (red):	Sample plate has been completely

4. Close the shield lid.
5. Press the [Resume] key. The analysis will continue.

K. Replenishing Reaction Tubes

If the reaction tubes run short during analysis, the error message "Replenish Reaction Tubes" will be displayed. If you supply the instrument with reaction tubes while this message is displayed, the analysis will continue without interruption. If there are no more reaction tubes, the analysis will be interrupted and the message "No Reaction Tubes" will appear. Replenish the tubes; then press the [Resume] key. The analysis will continue.

1. To open the reaction tube hopper, press on the front part of the cover to pop it up; then open.
2. Replenish reaction tubes. The reaction tube hopper will hold up to 300 tubes.

CAUTION: Do not forcibly overfill the hopper. This will cause jamming.

3. Close the reaction tube hopper lid

L. Replenishing Reagents

If the reagent runs out during an analysis, an error message "Insufficient Reagent (Reagent Name)" will appear and the analysis will be interrupted. (This applies only when the Reagent Volume Alarm is set to "Stop All". For details, see *Chapter 11, Section 5.11: Alarm Settings*.)

1. A "Being Interrupted" message will appear. Wait shortly until the interruption process is completed. When the system is ready for replenishing reagent, a message will appear.

> **CAUTION:** For dispensed and incubated samples, parameters that have not had reagent added will have an "X" marked on the Main Menu screen. Register and re-analyze those parameters that are marked by an "X".

2. From the Main Menu screen, press the [Set Reagents] key. The Consumable screen will appear. For details on the contents of the Consumable screen.
3. Confirm that the "Lid" signal (status of cover opening) is green; then open the light shield lid.
4. Set the reagent into the reagent holder.

> **WARNING:** When handling materials derived from human plasma, handle all materials as biologically hazardous. Wear rubber gloves and wash your hands with disinfectant solution after handling such materials.

> **CAUTION:**
> - Set each reagent in its designated position. Failure to do so will cause incorrect analysis results. If a reagent is accidentally set in a wrong position and the analysis is performed, thoroughly clean the probe with rinse solution. For details on how to clean the probe, see *Section 3.1: Cleaning the Probes* in this chapter.
> - Take steps to prevent contaminants and dust from getting inside reagent bottles and rinse solution containers. If contaminated, correct analysis results may not be obtained.

5. If the Reagent Volume Alarm is set to "Reagent Volume", enter the present reagent volume. If you press the key for the reagent position, the numeric keys for reagent volume input will appear. Enter the reagent volume and press the [Enter] key. The reagent volume will be set.
6. Close the light shield lid.
7. Press the [Resume] key. Analysis will continue.

M. Cleaning the Instrument
Clean it once a week.

WARNING:
- Before cleaning the instrument, be sure to turn the power OFF and unplug the power cord. This is necessary to avoid the risk of electric shock.
- When cleaning the instrument, handle all instrument parts as biologically hazardous. Wear rubber gloves and wash your hands with disinfectant solution after cleaning.

1. Clean the instrument exterior.
   a. Turn OFF the power.
   b. Using a paper towel that has been moistened with water and a neutral detergent, wipe off the exterior; then wipe again with a soft, dry paper towel.
2. Clean the instrument interior.
   a. Open the light shield lid.
   b. Pull out the reagent trays.
   c. Using a paper towel that has been moistened with water and a neutral detergent, wipe over the interior; then wipe again with a soft, dry paper towel. Clean the removed reagent trays in the same way.
   d. Insert the reagent trays
   e. Close the light shield lid.

CAUTION: Never use any other cleaning solution than water and neutral detergent. Otherwise, the surface coating may be damaged.

N. Priming the Hydraulic Line with Rinse Solution
Weekly or whenever the instrument has been left without operation for a day or more regardless of its power ON or OFF, refill the hydraulic line with rinse solution.
1. Check that there is sufficient rinse solution in the rinse tank and waste tank is empty.
2. From the Main Menu screen, press the [Special Menu] key. The Special Menu will appear.
3. Press the [Maintain] key. The Maintenance sub menu will appear.
4. Press the [Rinse & Prepare] key. The Prime and Deprime Rinse Execution screen will appear.

5. Press the [Execute] key. Priming with rinse solution will start. While the priming is taking place, the time remaining will be displayed on the screen.
6. Press the [Return] key. The Maintenance sub menu will appear.

O. Clean and Disinfect the Liquid Waste Container (if not direct drained)

1. Open the liquid waste container by turning the cap counterclockwise - remove the float switch assembly and place on a clean towel.
2. Empty the liquid from the liquid wasted container completely.
3. Fill the liquid waste container with 100 ml of 70% isopropyl alcohol.
4. Replace the float switch and tighten the cap by turning clockwise.
5. Shake the rinse container vigorously. Let sit for 5 minutes shaking occasionally.
6. Remove the float switch and empty the alcohol from the liquid waste container.
7. Rinse the liquid waste container and the float switch with distilled water.
8. Replace the float switch and tighten the cap by turning clockwise.

Note: If float is stuck in up position: will give signal as full.

P. Replacing Fuses

If a fuse is blown, replace it as described in the procedure below.

WARNING: To avoid risk of electrical shock, disconnect the power cord before replacing the fuses.

1. Turn OFF the power and unplug the power cord.
2. Using a regular screwdriver, press the notch upward and pull out the fuse holder cap.
3. Replace the fuse and attach the fuse holder cap to the instrument.

Q. Replacing the lamp

The typical lamp service life is 2000 hours of illumination. (This lamp is continuously illuminated while the power is turn ON.) Replace the lamp if an error message “Replace Lamp Unit” is displayed. After replacing the lamp, calibrate it.

WARNING:

- Before replacing the lamp, turn the power OFF and unplug the power cord. Failure to do so can result in electric shock.
- Wait 30 minutes to allow lamp to cool.

1. Turn OFF the power and unplug the cord.

2. Loosen the thumb screw of the exterior lamp cover located on the right side of the instrument. Gently slide the cover toward the front side, pull it out, and remove it.
3. Loosen two thumb screws (2 turns will be enough), and remove the lamp cover.
4. Press the clamp of the connector and remove the connector.
5. Lamp could be still hot! Touch carefully. Holding down the lamp brace, remove the lamp from the lamp holder.
6. Install a new lamp in the reverse order of removal

> CAUTION: Do not touch inside and outside of the lamp reflector with your bare fingers. Lamp performance could be affected. If you transfer oil or protein from your fingers, the lamp may be damaged when the temperature rises.

7. After installing the lamp and replacing the covers, reconnect the power cord and turn ON the power switch.

   Note: A 30-minute "burn-in" is required before a lamp calibration is performed.

8. From the Main Menu screen, press the [Special Menu] key. The Special Menu will appear.
9. Press the [Maintain] key. The Maintenance sub menu will appear.
10. Press the [Calib. Lamp] key. The Lamp Calibration screen will appear.
11. Close the light shield lid, and press the [Execute] key. Lamp calibration will start and the Adjustment window will appear.
12. Press the [Return] key. The Maintenance sub menu will reappear.

WRITTEN BY (Pre-SharePoint): Diana Denton, MLT(ASCP)
IMPLEMENTATION DATE (Pre-SharePoint): September 2002