![Sysmex logo]

SYSMEX XE-5000™

Quick Guide

Start-Up

QC Analysis

Sample Processing

Sample Explorer/ Data Browser

Body Fluid Mode

HPC Mode

Reagent Replacement

QC Setup

Maintenance

If you need further assistance, please contact the Sysmex Technical Assistance Center:

Phone: **1-888-8SYSMEX (1-888-879-7639)**

Fax: **1-847-996-4499**

SYSMEX AMERICA, INC.
One Nelson C. White Pkwy.
Mundelein, IL 60060

Sysmex

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Power On Sequence

1. XE Information Processing Unit.
2. XE-5000 Main Unit.
3. GP Printer

Power On Information Processing Unit (IPU)

1. Turn on IPU power (power switch on monitor).
   Windows® system is automatically loaded.
2. When XE log-on displays, input your Lab's user name _____
   and password (if any). _____
   Press **[ENTER]** or **[OK]**.

Power button on IPU

Power On Main Unit and Log On

IPU must display XE-5000 program before powering Main Unit on.
1. Turn on Main Unit power (switch on right side).
2. Pneumatic Unit power is controlled by the Main Unit.
   Pneumatic Unit power switch should always remain on.
3. XE-5000 performs self-checks. If any checks fail, an error message
   displays. Refer to XE-5000 *Information for Use*, Troubleshooting Chapter.
4. Main Unit log-on displays after the Background is completed.
   • If needed, press **[NUM/ALPH]** to change from "NUM" to "ALP" or
   "alp" on XE Main Unit LCD panel.
   • Enter your Lab's user name _____ and password
   (if any). _____ by pressing specific keys until
   desired character is displayed.
   • Press **[ENTER]**.

IPU Log-on Dialog Box

CAUTION: *If you have to power the Main unit off and on, power off and wait
30 seconds before turning power back on.*

Background Checks

1. If no "Background Error" message is displayed, Background check is
   within acceptable limits.
2. If background counts are greater than the acceptable limits, a
   'Background Error' message is displayed.
3. Parameter(s) that exceed the Background limit are displayed and marked
   with a '+'on Main Unit.
4. Select 'RETRY' on Background error screen on Main Unit to perform
   another Background check.
5. To resolve a Background Error, refer to XE-5000 *Information for Use*,
   Troubleshooting Chapter.

Main Unit ON/Off Toggle

Reagent Volume Check

1. Click **[CONTROLLER]** in the IPU Menu Tab.
2. Double click on **[Remaining Reagent]** (bottle) icon to check for low
   volume reagents.
3. Do not replace the reagent until the Replace Reagent error occurs.
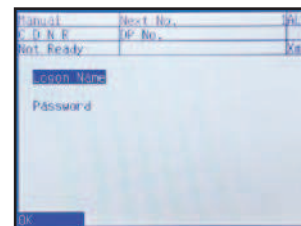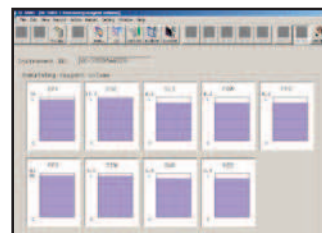   (Purple = full, white = empty)
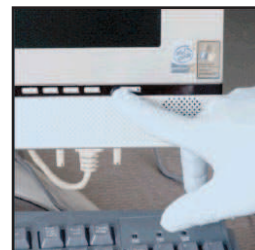
Main Unit Log-on Screen

Remaining Reagent Screen

SAMPLER (AUTO) MODE

'Control Entry Error' occurs if lot is not entered in QC files.
1. Warm controls to room temperature.
2. Pre-mix controls by gentle end-to-end inversion until suspended.
3. Place barcoded QC samples in rack, barcodes facing the front of the rack.
4. Verify XE Main Unit 'Ready' LED is on and 'Manual' is displayed on LCD
5. Place rack on the right rack pool of Sampler unit.
6. Press **[SAMPLER]** on Main Unit keypad.
7. Press **[Start]** on the function menu or press **[SAMPLER]** again.

MANUAL OPEN MODE

1. Warm controls to room temperature.
2. Pre-mix controls by end-to-end inversion until suspended.
3. Verify XE Main Unit is 'Ready' and 'Manual' is displayed.
4. On XE Main Unit Menu, press **[QC]** and **[EXEC. QC]**. If 'QC' is not displayed, press **[MORE]**.
5. Press **[↓]** to control to be analyzed (CRN/New, lot #, 'Manual', exp. date, level) and press **[SELECT]**. If lot is not listed, press **[↓]** to next screen.
6. Uncap and hold open control under aspiration pipette. Press **START SWITCH** on XE Main Unit.
7. Remove tube when 'Ready' LED stops blinking and 'beep-beep' sound is heard. Wipe top of control cap and reseal.

   Note: *No need to wipe tip of sample aspiration pipette*

8. When results display on XE Main Unit, press **[OK]** to plot, or press **[CANCEL]** to abort.
9. Press **[RETURN]** to exit from QC Mode on Main Unit.
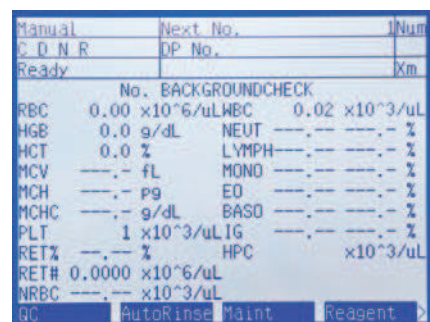
MANUAL CLOSED MODE

Alternate method for analyzing QC samples in closed mode without using barcodes: Tube MUST be placed in Tube Position 1.
1. Warm controls to room temperature. Pre-mix controls by gentle end-to-end inversion until suspended.
2. Verify 'Ready' LED is on and 'Manual' mode displays on Main Unit.
3. On XE Main Unit Menu, press **[QC]** and **[EXEC. QC]**. If 'QC' is not displayed, press **[MORE]**.
4. Press **[↓]** to control to be analyzed (CRN/New, lot #, 'Closed', exp. date, level) and press **[SELECT]**. If lot no. is not displayed, **[↓]** to next QC screen.
5. Place pre-mixed QC sample in Tube Position1 of rack. Place rack on right rack pool of sampler unit.
6. Press **START SWITCH** on XE Main Unit. Rack moves so first tube stops at the aspiration position. Cap Piercer picks up tube of blood and aspirates it.
7. When QC results display on XE Main Unit, press **[OK]** to accept QC, or **[CANCEL]** to abort. Accepted data transmits to IPU and is plotted on QC Chart.
8. Repeat steps 4-6 to analyze the other levels of control.
9. To exit from QC Mode on XE Main Unit, press **[RETURN]** on panel.
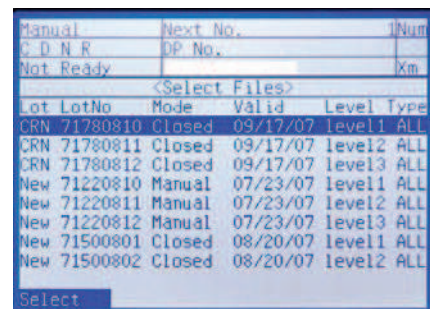10. Remove rack from Sampler Unit manually.
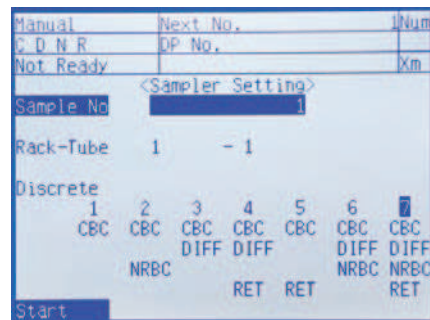
Sampler Screen

Main Unit Menu Screen
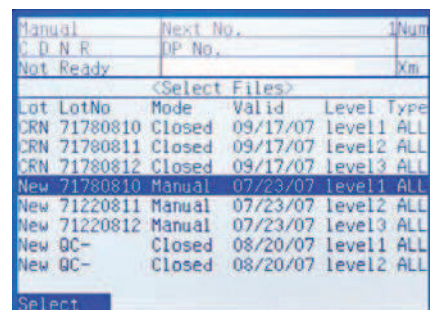
LCD Screen: Manual QC

LCD screen: Manual Closed Mode

QC Analysis

To View Radar Charts

Note: *Radar Charts for Current Lot only.*

1. On IPU, click on QC icon.
2. Click on **Radar** Tab.
3. Choose level and mode.
4. Control Data are displayed in green on Radar Chart.
5. If any parameter is outside of lower limit (inner red ring) or outside of upper limit (outer red ring), then go to **Control** tab to view actual data on L-J Charts.

To View e-CHECK L-J Charts

1. On IPU, click on QC icon and Control tab.
2. Choose Lot (Current, New, or Current + New), Level, and Mode.
3. QC chart for control is displayed.
4. To scroll down to view all QC parameters, click just above to page down arrow on vertical cursor bar on right side of QC Chart.
5. When viewing QC, look for data outside of limits (**X**). Ensure data is plotted and no data are missing (- - - -).

Auto Mode Error Messages L-J Limit Error

- QC Parameter > 1 x Limit %
- QC data plotted with **red X**, + or - next to data
- Press **[HELP]**, **[OK]** to clear error message

Manual Mode Error Messages

Check Control Chart Error

- QC Parameter > 1 x Limit %
- + or - in the Judge column
- Press **[OK]** to accept and plot data
- QC data plotted with **red X** on QC Chart if plotted.

Re-analyze Control Error

- QC Parameter > 3 x Limit %
- + or - in Judge column
- Press **[OK]** to accept and plot data or press **[Cancel]** to exit and QC data is not plotted.
- QC data plotted with **red X** on QC chart if plotted.

XM Limit Error

- XM plotted outside Limit %
- Investigate for systematic error or population shift
- Press **[HELP]**, **[OK]** to clear error message

Erasing QC Data

Note: *Delete function may require a special password.*

1. On IPU, click on QC icon. Choose Control (Current, New, or Current + New), Level, and Mode. QC chart is displayed.
2. Click on chart area. Set range of QC data to delete. Click on dark green line and drag line to last set of data to delete. Click **[Delete Data]**.
3. If undelete function is desired, click **[Undelete]**. This cancels the previous Delete command.
4. When exiting QC, a reminder displays that deleted data will be permanently lost. Click 'YES' to delete or 'No' to stop delete.
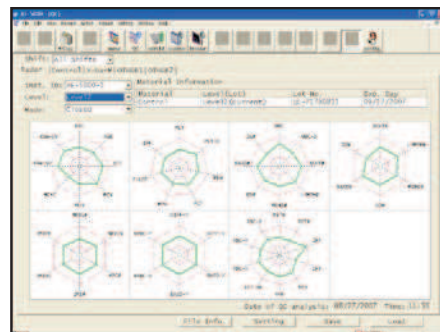

Radar Chart
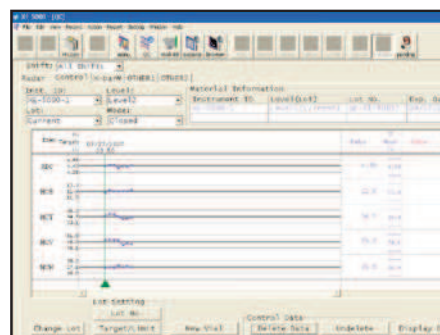
L-J (Levey-Jennings) Chart

Printing QC Report and Resending to LIS

1. On IPU, click on QC icon. Choose Control (Current, New, or Current + New), Level, and Mode. QC chart is displayed.
2. Click on chart area. Set range of QC data to print by clicking on dark green line and drag line to include all QC data or press **[Ctrl]** and **[A]** to select all.
3. **LP:** After selecting range, click **[Report]** and select **[Ledger(LP)]** to print QC data in line format.
4. **GP:** After selecting range, click **[Report]** and select **[Report(GP)]** to print QC Charts.
5. **HOST:** After selecting range, click **[Report]** and select **[Host(HC)]** to transmit QC data to Host (LIS) computer.
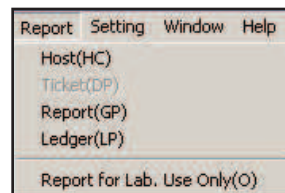

Report Menu

SAMPLER (AUTO) MODE with BARCODES

1. Verify XE Main Unit 'Ready' LED is on and 'Manual' is displayed on Main Unit.
2. Place barcoded sample(s) in sample rack(s) with barcodes facing front of rack.
3. Place rack on right side of Sampler Unit.
4. Press **[SAMPLER]** on the Main Unit keypad.
5. Select test to be performed for instruments that are not interfaced.
6. Press **[Start]** on the Main Unit menu or press **[SAMPLER]** again. Sample Number and Discrete test will be transmitted from LIS.

Note: *If XE is in sleep status, XE will automatically return to Ready when the Sampler Mode is started. Wait for Ready to appear on the screen.*
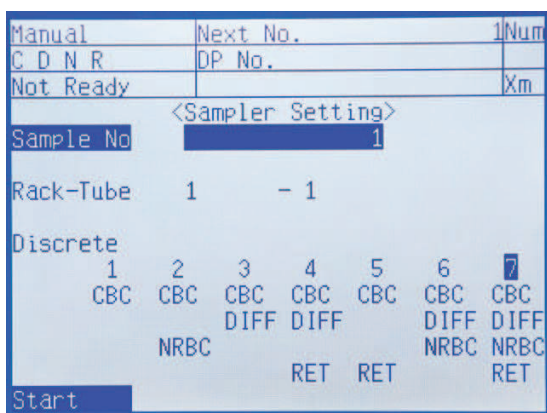
Sampler Screen

SAMPLER (AUTO) MODE without BARCODES
(Sequential numbering)

1. Set the ID Barcode reader to off on the IPU.
   • From the IPU Menu Window area, select 'Controller', 'Settings' and 'ID Reader'. Deselect the ID Reader to turn it off. Click **[APPLY]**.
   • From the Menu bar, click **[Settings]** and **[Analysis Ordering]**. Select 'Rack No./Tube Pos.'
2. Press **[SAMPLER]** on Main Unit and sampler setting screen appears.
3. Enter the first sample number (up to 15 alphanumeric characters) in the rack and the tube position. (ex. 101) Numbers are assigned sequentially thereafter.
4. Press **[↓]** to select **Discrete** test (1 to 7).
5. Place rack on Right Rack Pool and press **[START]** on the Function Menu, or press **[SAMPLER]** again.

INTERRUPT AUTO MODE FOR STAT

1. Press **[SAMPLER]** on Main Unit LED to interrupt Sampler Operation.
2. 'S-READY' appears at the upper left of Main Unit. Ready LED is on.
3. Analyze STAT using the Manual or Capillary Mode.
4. After STAT is completed, 'S-READY' appears at the upper left of the Main Unit screen. Press **[SAMPLER]** and XE resumes Sampler Mode Analysis.

XE-5000 MANUAL OPEN MODE

1. Verify XE green 'Ready' LED is on.
2. Press **[MANUAL]** on XE Main Unit LCD panel.
   • Enter Sample No. or Name. (13 characters). For Name, press 'Num' key 1, 2 or 3 times to display desired character (NUM, ALP, alp).
   • Press **[↓]** and **[1]** to select 'Manual Mode'.
   • Press **[↓]** to select **Discrete** test. Press number (1 to 7) to select desired test.
   • Press **[ENTER]**.
3. Mix sample prior to analysis. Uncap tube.
4. Hold uncapped tube under aspiration pipette. Press the **START SWITCH**.
5. Remove tube when 'Ready' LED stops blinking and 'beep-beep' sound is heard. No need to wipe pipette.
6. Results display after completion of analysis.
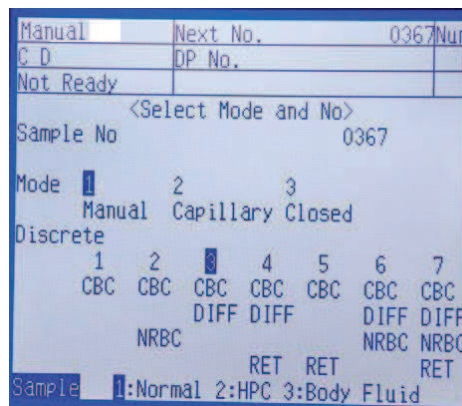
Manual Screen

Manual Aspiration/START SWITCH

SYSMEX XE-5000™

Quick Guide

XE-5000 Capillary Mode

Prepare 1:5 dilution. Minimum Volume 40µL blood and 160µL of CELLPACK (aspiration volume 130µL). Analyze within 30 minutes.

1. Verify XE green "Ready" LED is on.
2. Press **[MANUAL]** on XE Main Unit LCD panel.
   - Enter Sample No. or Name. (13 characters).
   - For Name, press 'Num' 1, 2 or 3 times to display desired character (NUM, ALP, alp).
   - Press **[↓]** and **[2]** to select "Capillary".
   - Press **[↓]** and select **Discrete** test 1 to 7.
   - Press **[ENTER]** on the panel.
3. Place well mixed 1:5 diluted sample under Manual Aspiration Pipette.
4. Press **[Start]** on XE Main Unit.
5. Remove tube when "Ready" LED stops blinking and "beep-beep" sound is heard. No need to wipe tip of sample aspiration pipette.
6. Results will display after completion of analysis. (Capillary results labeled with "C")
7. When all Capillary Mode samples are completed, return to Manual Mode. Press **[MANUAL]** on XE Main Unit LCD. Press **[↓]** and select "1 Manual Mode". Press **[ENTER]**.
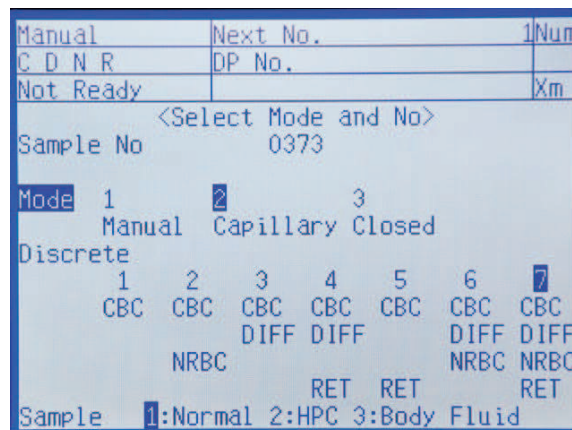
Capillary Screen

XE-5000 Manual Closed Mode

Blood analyzed using Cap Piercer (without mixing or reading barcode).

1. Verify 'Ready' LED is on.
2. To change XE Main Unit to Closed Mode, press **[MANUAL]** on Main Unit LCD panel.
   - Enter Sample No. or Name. (13 characters).
   - For Name, press 'Num' 1, 2 or 3 times to display desired character (NUM, ALP, alp).
   - Press **[↓]** and select "Closed".
   - Press **[↓]** and select **Discrete** test 1 to 7.
   - Press **[ENTER]**.
3. Mix sample (10 times inversion) and place tube in first tube position of rack.
4. Set rack on right end of analysis line on XE Sampler Unit.
5. Press **START SWITCH**. Sampler moves rack until tube is in front of CP aspiration hand.
6. Press **[Start]** on Main Unit. Cap Piercer picks up tube of blood and aspirates it. Results display after completion of analysis (Closed results labeled with P).
7. After measurement is completed, remove rack from the Analysis Line.
8. To change XE Main Unit back to Manual Mode, press **[MANUAL]** on XE LCD panel, **[↓]** to Discrete and select "1 Manual". Press **[RETURN]** to exit Manual Mode.
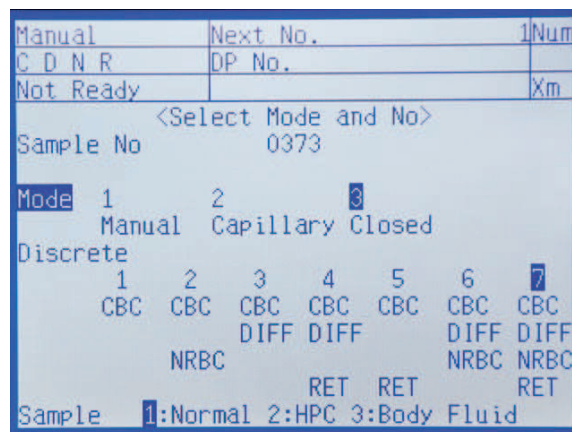
Manual Closed Screen

Finding A Sample

1. Click **[Sample Explorer]**. Verify "Last 20" icon is de-selected (top blue line displays "Filter All").
2. Click sample number at top of list.
3. From Tool Bar, click **[Edit]** and **[Find]**.
4. Find dialog box is displayed. Enter Sample number or Patient ID. (If you are using leading zeros, zeros have to be entered.) "*" or "?" can be used as a wildcard for following situations: ? Use in place of a single digit for an unknown number or letter. * Use for multiple unknown letters or numbers and placed at the end of a string.
6. Click **[NEXT]** to search below sample number in list or **[PREV]** to search above the sample number in list. The selected sample will display with cursor on it.

Edit Sample ID# or Patient ID#

1. Click **[Sample Explorer]** icon. Verify "Last 20" icon is de-selected (top blue line displays "Filter All"). Click sample number to be changed.
2. Click **[validate]** icon to un-validate sample. ("V" disappears in first column of Sample Information Tab).
4. Click **[property]** icon from Tool Bar. Sample Property box displays with selected Sample ID.
5. Click Sample ID or Patient ID to select number to edit. Delete old number and input new ID number.
6. Click **[OK]** and new sample information will be stored. Screen displays Stored Data with cursor on edited sample.
7. Click **[validate]** box and corrected ID number is reprinted to GP and retransmitted to HOST.

Reprint to Graphic Printer or Retransmit Data To Host

Note: *Un-validated data may not be reprinted or retransmitted.*

1. Click **[Sample Explorer]**.
2. Verify "Last 20" icon is de-selected (top blue line displays "Filter All"). Click on sample(s) by ID number to reprint or retransmit.
   - To select any single sample, click on sample ID.
   - To select multiple samples (not necessarily in order), press and hold **[Ctrl]** on keyboard and click each sample.
   - To highlight a block of samples, click on first sample to output. Then press and hold **[Shift]** and click on last sample to output.
3. To reprint to GP, click **[Report]** and **[Report(GP)]**.
4. To retransmit to LIS or HOST, click **[Report]** and **[Host (HC)]**.
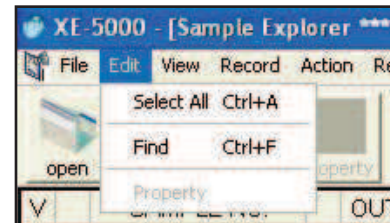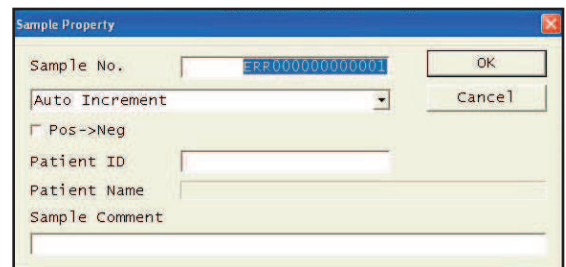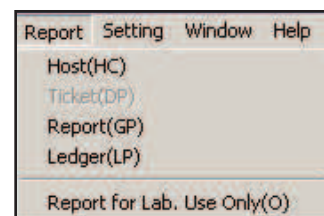

Edit Menu

FIND Dialog Box

property   **validate**

Property Screen

Report Menu

To Disconnect Host When LIS is Down

1. When the HOST is down, a pop-up error message displays on the IPU. HOST icon will be red on Status display line at bottom of IPU.
2. Click the IPU error box to close the message.
3. Go to the IPU Settings, **[HOST(HC)]** Setting.
4. Click the "Host(HC) Connect" to remove the check. This disconnects the IPU from the LIS .
5. Click **[OK]** to save the changes.
6. The red HOST(HC) icon disappears. The XE-5000 is ready to analyze without using Host/LIS orders.

Host HC ready Icon

Host(HC) connect

Host Tab On Browser

Select "Chartable GP Report" From Desktop

1. GP Customize is only available on XE pro software. Click "XE Pro" tab from IPU Main Menu.
2. Click "GP Customize" icon.
3. Select "Report" for Format type.
4. From the top grey menu line, click **[RECORD]** and **[RESTORE]**.
5. An "Open" dialog box displays with the message "A is not accessible". Click **[CANCEL]** to go to the Desktop.
6. Click the GP Customize folder. The desktop files are displayed. Select GP report format from list.
7. Click "Open" tab.
8. Click **[OK]** to restore.

Note: *When the HOST connection is resumed, restore your lab's original GP format.*

GP customize icon

To Re-connect the Host When LIS is Up

1. Go to the IPU Settings, HOST (HC) Setting.
2. Click the empty box next to "Host(HC) Connect" to reconnect IPU and Host.
3. Click **[OK]** to save the changes.
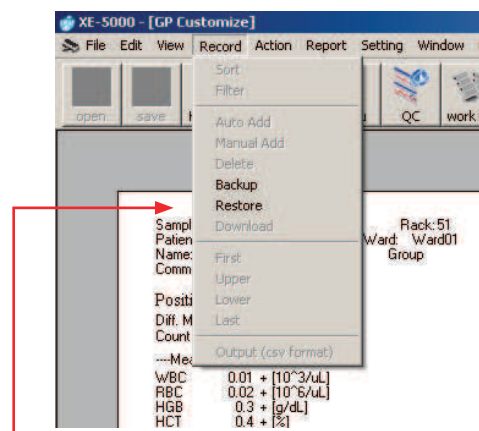4. The green HOST icon displays. The XE-5000 is now reconnected to the HOST.

Record menu

SYSMEX XE-5000™ | Body Fluid Mode
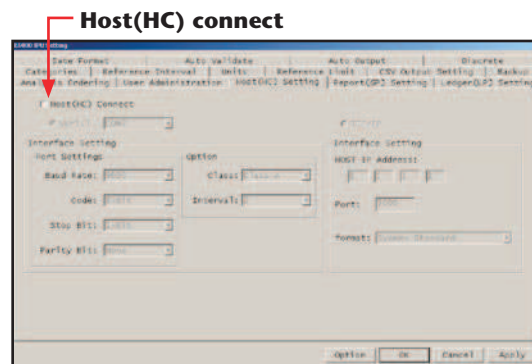
Summary of Body Fluid Analysis

The body fluid analysis mode of the XE-5000 uses the 4 DIFF scattergram and the RBC distribution obtained from a specialized analysis sequence to calculate and display the WBC counts, mononuclear cell (MN) / polymorphonuclear cell (PMN) count and percentages, and the RBC (RBC-BF) counts found in the body fluid.

Analysis Parameters

WBC-BF, RBC-BF, TC-BF #, MN#, MN%, PMN#, PMN%

## Sample Analysis In Body Fluid Analysis Mode

Body Fluid Mode must be selected to perform body fluid analysis.
1. Make sure that the instrument is in READY status. The READY LED should be lit.
2. Press the MANUAL key on the Main Unit panel keypad. The Manual Sample No. Setting screen will appear on the LCD.
3. Using the numeric keys, input the sample ID number or, read the bar-code using a hand held barcode reader (optional).
4. When analysis mode is not set in manual mode, press the ↑ key and change the set item to "Mode." Then using the → and ← keys, set the manual mode.
5. Use the ↑ key to change the setting parameter to Discrete, then use the → and ← keys to set CBC + DIFF unless any of the following is already selected:

   a. CBC+DIFF
   b. CBC+DIFF+RET
   c. CBC+DIFF+NRBC
   d. CBC+DIFF+NRBC+RET

Note: *Whichever of the above discrete settings is chosen, Discrete will change to CBC+DIFF when the ENTER key is pressed to confirm the input.*

6. Using the ↑ key to change the setting parameter to Sample, and then use the → and ← keys to set to Body Fluid.
7. After all the setting are completed, press the ENTER key to set sample NO.
8. When the ENTER key is pressed, a background check is run at the same time. Background check analysis is repeated three times for the background check. If the background value is judged to be within range the background check is completed.
   If the background value is not within the specified range, the message "Background Error" will be displayed on completion of the background check.
   In the case of a "Background Error," select "**B-Check**" on the LCD menu to perform automatic cleaning and repeat background.   If the value after the automatic cleaning is not lower than the acceptable background value, a "+" is displayed to the right of the value. To resolve background error, see the *Instructions for Use*.

Note: *The basic analysis procedure is the same as for Normal Mode, but for body fluid analysis it is necessary to reliably eliminate background influences.*
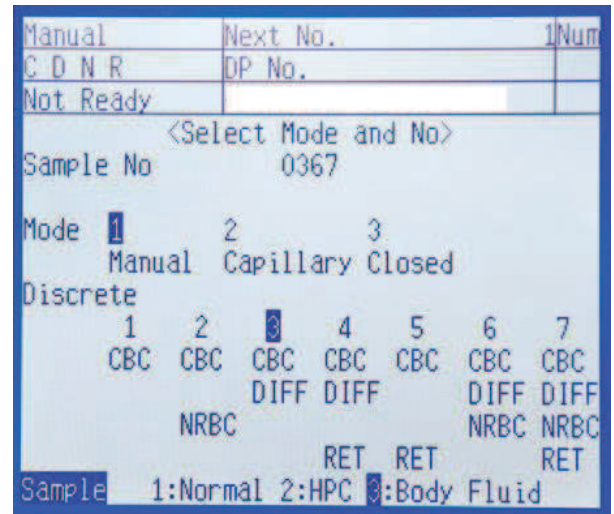
Body Fluid Order

9. If the results of the background check is such that the blank value is at or below the acceptable limit, the READY LED lights and the Main Unit enters body fluid analysis ready status.

10. Mix the contents of the test tube gently but thoroughly.

Note: *Excess mixing can break blood cells in the body fluid, making it impossible to obtain accurate results.*

11. Remove the cap carefully so as not to splatter the sample.

12. Set the test tube into the manual aspiration pipette, and then press the **START SWITCH**. Do not remove the test tube while the READY LED is blinking, sample is being aspirated.

13. After the READY LED turns off (and a short beep sounds two times), remove the test tube. Once analysis is completed, set Sample to Normal on the Sample No. setting screen to return to normal mode.

    CAUTION: *If either the analysis values from body fluid analysis (WBC-BF and/or RBC-BF) are high, there is the possibility of an influence on the analysis results for the next sample. If analysis results for WBC-BF and RBC-BF exceeds specifications, the "Execute Background Check" Error is displayed, asking the user to perform a background check before analyzing the next sample.*

14. The results of Body Fluid Mode are displayed on the menu screen of the Main Unit LCD screen. The results are also displayed on the sample explorer and the data browser screen Body Fluid Tab on the information processing unit (IPU)
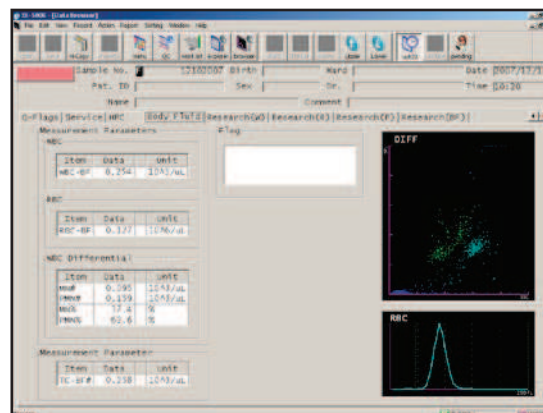
    Analysis samples analyzed in body fluid analysis mode are marked with an "F" mark to the left of the sample No. on the Main Unit LCD screen.

    "F" is displayed in the analysis mode display column of the sample explorer and data browser screens.

Explorer Screen "F" and Red "F"

Body Fluid Tab on Browser

Summary of HPC Analysis

The HPC (hematopoietic progenitor cell) analysis mode provides a rapid count of HPCs using peripheral blood and cord blood for screening purposes. The HPC count can help determine the optimal time for harvesting stem cells more quickly and at a lower cost.

The instrument must be set to HPC analysis mode in order to correctly analyze a sample for HPC#. HPC analysis can be performed on peripheral blood or umbilical cord blood.

CAUTION: *The clinician must take into consideration the full clinical picture to determine when to use the HPC results.*

Sample Analysis in HPC Analysis Mode

Samples for HPC testing should be analyzed immediately after drawing.
1. Make sure that the instrument is in READY status on the LCD screen on the Main Unit. The READY light should be lit.
2. Press the MANUAL key on the Main Unit panel keypad. The Manual Sample No. Setting screen will appear on the LCD.
3. Using the numeric keys, input the sample ID number or read the barcode using a hand held barcode reader (optional).
4. Set analysis mode to manual mode, by pressing the ↑ key to "Mode." Then using the → and ← keys, set to Manual Mode.
5. Use the ↑ key to move the cursor to Discrete. Then use the → and ← keys to select CBC + DIFF as Discrete test.
6. Use the ↑ key to change the setting parameter to Sample. Then use the → and ← keys to set to HPC.
7. After all the settings are completed, press the ENTER key to initiate analysis. When the ENTER key is pressed, a preparation sequence is executed.
8. Mix the contents of the test tube gently but thoroughly.
9. Remove the cap carefully so as not to splatter the sample. Set the test tube into the manual aspiration pipette, and then press the **START SWITCH**. Do not remove the test tube while the READY LED is blinking as the sample is being aspirated.
10. After the READY LED turns off (and a short beep sounds two times), remove the test tube. Once analysis is completed, set Sample to Normal on the Sample No. setting screen to return to normal mode.
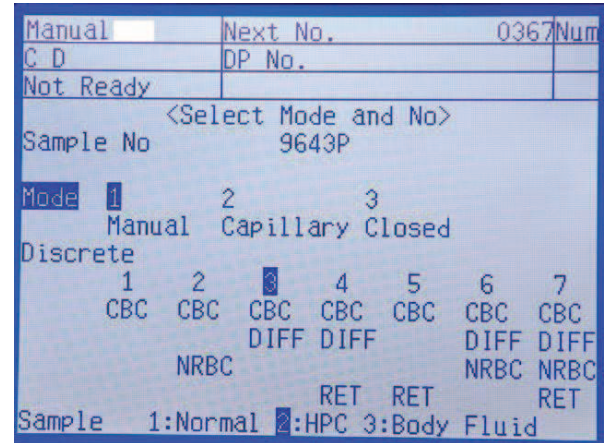
HPC Order

11. The results of HPC Mode are displayed on the Main Unit LCD screen. Samples analyzed in HPC Mode are marked with an "H" to the left of the Sample No. on the LCD screen.

The results are also displayed on IPU screens. On the Sample Explorer screen samples analyzed in HPC analysis mode are marked with an "H" to the left of the Sample No. Results are listed in the column to the right when the operator clicks on that sample.

On the Data Browser screen both the Graph and HPC tabs display HPC results. The sample mode is noted with an "H" to the left of the sample number.

Note: *In the HPC Analysis mode READY status is maintained for approximately 3 minutes after the last operation on the Main Unit. If no new operation is performed within approximately 3 minutes the preparation sequence will be executed again when the next operation is started.*

HPC Results on Explorer

HPC Results on Browser

1. When a reagent container is empty, an alarm sounds and error message displays. Press **[HELP]** on XE-Main Unit. Select **[OK]**.
2. Reagent Setting Screen is displayed with "Replace" next to reagent that needs replacing. Verify which reagent to change by matching reagent abbreviation to proper name of reagent. (See reagent label)
3. **Using hand held barcode reader**, scan long reagent barcode (EAN-128) on reagent box. Updated information is displayed (lot, exp. date, volume).

Note: *Use barcode on box for RED, SNR, and FFS. Do not use barcode label on bottle or foil dye pack.*

Caution: *NR(S) MUST be replaced each time the NR(L) cube is replaced. Empty NR(S) does not trigger message.*

If needed, manually input Reagent information:
  a. Press **[↑]** or **[↓]** to select reagent for manual entry.
  b. Press [MANUAL] on function menu. Manual Input is displayed.
  c. Press **[↑]** or **[↓]** and input information for new lot:
    • For Lot No.
      • Press **[NUM/ALP]** 1 time (ALP). Input 1st letter of Lot No.
      • Press **[NUM/ALP]** 2 times (Num). Input 4 digit Lot No.
      • **[↓]** to Exp. Date. Use "Num" key, input Month (nn).
        Press **[→]** to Day. Use 'Num" key (nn).
        Press **[→]** to Year. Use 'Num" key (nnnn).
      • **[↓]** to Exp. after Opened. Use "Num" and input open dating. Open dating is 60 days except SULFOYSER which is 90 days.
      • **[↓]** to package size. Input size from box.
  d. Press **[OK]** to exit Manual input display and return to Reagent Setting screen. Lot No., open Exp. Date, and package size is displayed.
4. Remove cap from new reagent container. Using clean technique, remove reagent tubing from empty container and insert into new container. Initial and date new reagent container.
5. Select **[EXECUTE]** from reagent replacement screen. The new reagent is primed.
6. Reagent replacement is documented on Reagent Log in XE Main Menu, Controller icon, Reagent Log icon. This Log may be printed by Report, Ledger (LP) Print. A Remaining Reagent Volume icon is also available.

Notes:

• *When changing NR(L) and RED, the diluent and dye must be changed at the same time. NR(S) does not trigger message.*

• *If STROMATOLYSER-NR or RET-SEARCH (II) reagents are empty and no replacement reagents are available, XE may still be analyzed using Open Manual Mode for CBC and DIFF orders only. Do not perform Auto Rinse or Shutdown.*

• *STROMATOLYSER-4DS (FFS) is replaced when the FFS reagent cycle counter reaches 2000. Do not replace this reagent unless "Replace FFS" Error message displays or counter will be incorrect.*
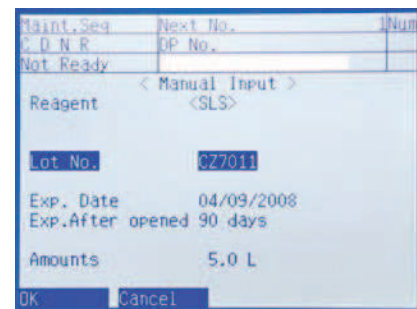
If replacing reagent foil packs, verify packs are properly seated in holders. For FFS reagent, both labels must face same direction.

Replace Container Message
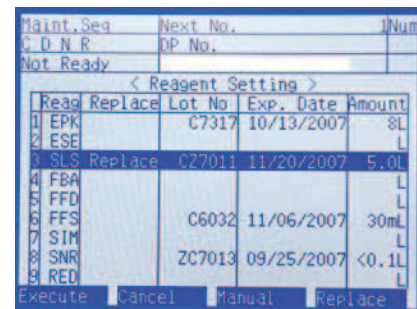
Reagent Scanned with Wand

Reagent Entered Manually

REAGENT	MESSAGE	VOLUME
CELLPACK™	EPK	20L
CELLSHEATH™	ESE	20L
STROMATOLYSER -4DL™	FFD	5.0L
STROMATOLYSER -4DS™	FFS	42mL
STROMATOLYSER -FB™	FBA	5L
STROMATOLYSER –NR(L)™	SNR	3.6L
STROMATOLYSER –NR(S)™	NA	42mL
STROMATOLYSER -IM™	SIM	10L
SULFOLYSER™	SLS	5.0L
RET-SEARCH (II) DILUENT™	RED	1.0L
RET-SEARCH (II) DYE™		
Open reagent stability is 60 days with the exception of SULFOLYSER which is 90 days.		

Input New Lot Number

1. Click **Control** tab. Select Level, Mode, and New lot.
2. Click **Lot No**. A box displays a window for lot information.
3. Input 8 digit lot number of new control. Click or tab to move cursor to expiration date. Input date in Year/Month/Day order.
4. Click **[OK]** to save new lot. Verify new lot information is correct.
5. Lot number and date may only be edited while in NEW file.

To Set Variable Target

(Used to establish lab's running mean for control)

1. Click QC icon. Choose **Control** tab. Select Level, Mode, and New lot. QC chart is displayed.
2. Click **[TARGET/LIMIT]**.
3. First parameter is highlighted. Click first parameter and drag cursor to include all QC parameters.
4. Click **[VARIABLE TARGET]** and **[OK]**.

To Autoset Target Values (setting mean value)

- Analyze New Lot at least 10 times before auto setting target values (preferably covering all shifts over 5 days).
- If desired, compare Current and New data before proceeding.

  1. Click QC icon. Choose **Control** tab. Select Level, Mode, and Lot. QC chart is displayed.
  2. If using XE pro software, set range of QC data for calculating targets. Click dark green line and drag line to left to include QC data or press **[CTRL]** and **[A]** to select all data.
  3. Observe right data column for Mean, SD, CV%.
  4. Click **[TARGET/LIMIT]**.
  5. First parameter is highlighted. Click top of list of parameters and drag cursor to include all QC parameters.
  6. Click **[AUTO SETTING]**. Auto setting window is displayed.
  7. Click **[TARGET]** and **[OK]**. Do not check limit. Observe target column. Target values should now be displayed.

Erasing QC Data (DELETE)

1. On IPU, click QC icon. Choose **Control** tab. Select Lot, Level, and Mode. QC chart is displayed.
2. Set range of QC data to delete. Click dark green line and drag line to last set of data to delete. Click **[DELETE DATA]**.
3. If undelete function is desired, click **[UNDELETE]**. This cancels the previous Delete command.

Note: *When exiting QC, a reminder displays that deleted data will be permanently lost. Press YES to delete.*

Level, Mode, Lot Boxes

Lot No screen

Variable Target button

Auto Set button
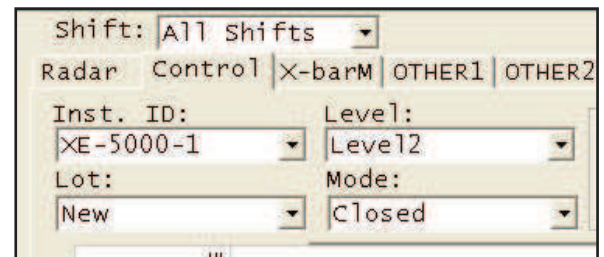
Printing QC Report and Resending to LIS

1. On IPU, click QC icon. Click **Control** tab and select Lot, Level, Mode. QC chart is displayed.
2. Click dark green line and drag line to include all QC data or press **[CTRL]** and **[A]** to select all.
3. After selecting range, click **[REPORT]**, **[LEDGER (LP)]** to print QC data in line format.
4. After selecting range, click **[REPORT]**, **[GP]** to print QC Charts.
5. After selecting range, click **[REPORT]**, **[HC]** to transmit QC data to Host/LIS computer.
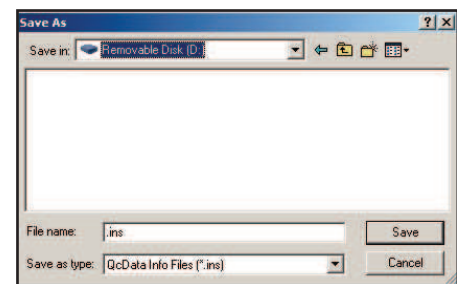

Report Menu

Save QAP Data Using Sysmex *Insight*™

- Sysmex *Insight* icon MUST be used for saving QC data for QAP.
- Review data and if desired, edit (delete) control data prior to submission. Ensure all QC data is plotted and no analysis error data is included (- - -) or (+ + +).
  1. Click **[SysmexInsight]** icon on Main Menu. Sysmex *Insight* screen is displayed.
  2. Click combo boxes to select QC chart:
     - **[MATERIAL]** to select Control.
     - **[LEVEL]** to select Level 1, Level 2, or Level 3.
     - **[ANALYSIS MODE]** to select Manual or Closed Mode.
     - **[LOT]** to select Lot (Current or New)
     - **[INSTRUMENT ID]** to select Main Unit.
     - Verify QC Data Info in right column.
  3. Insert Flash Drive into USB port on right side of IPU and click **[SAVE]**. The Save As dialog box opens.
  4. Check that the name for the Flash drive appears in the **Save As** box. If not, click the drop down arrow and select the Flash drive (Removable, Securegard, Data Traveler, or similar name) from the list
  5. Click the **Save** button.
  6. Repeat steps 2 – 5 for other levels or modes if applicable.
  7. With the Flash drive still inserted To verify QC data was downloaded to the Flash drive press and hold the Windows™ key (between Ctrl and Alt on keyboard) and press the "E" key once.
  8. Verify lot numbers and extension ending with "Lot No. ins".
  9. Remove Flash drive electronically by clicking on the .
  10. Click **[CLOSE]** to exit Sysmex *Insight* function.

Note: *Save each file separately. If saving both Closed and Manual Mode QC on the same device the operator should enter the letters "C" or "M" respectively as the first digit of file name. This prevents the second set of data from overwriting the first.*

Submit QAP Data To Sysmex

1. Go to www.sysmex.com. Click on Sysmex America Inc. "Go to *Insight*."
2. Log on: User name: Input first 4 digits *Insight* Customer No. Password: Input first 4 digits of *Insight* Customer No. and first 5 digits of institution Zip code. Press **[ENTER]**.
3. Your name and institution displays. Click Submit QC.
4. Click on type of data to be submitted: "Data Disk Uploaded"
5. Choose Analyzer and Shift by clicking **[↓]**. Insert floppy disk into drive (A-drive). Click "Browse". Using "Look in" box, select drive by clicking **[↓]**. Select 3 $^1/_2$ Floppy (A).
6. Click on One of three QC files. Click "Open". File displayed by Browse box. Click **[SUBMIT]**. Then click **[SUBMIT MORE FILES]** and repeat for other files.
7. Click **[REVIEW REPORT]** to view submitted data. Lot-to-Date report is displayed.
8. Click **[CLOSE]**. Click **[LOG OUT]**.

Insight Screen

Save As dialog box

"Safe Removal" Icon

Change Lot:

- Current Lot is deleted and New Lot moves to Current
- Print Current L-J Charts to GP and QC Data to LP and Submit QAP data to *Insight* before proceeding with Change Lot.
  1. On IPU, click QC icon. Select *e*-CHECK™. Select lot "Current", Level, Mode. QC chart is displayed.
  2. Click **[CHANGE LOT]**.
  3. A warning message is displayed "Save QC Data before changing lot?" about losing the Current Lot (which is replaced by New Lot). Insert a floppy disk into the floppy drive if saving QC data to a floppy disk. Click on "Yes". Save file box displays. Enter File Name using Lot # (Example: *e*-CHECK™ NNNN 0). Click "No" if you do not want to save QC to disk.
  5. Current QC Data is deleted and is replaced by the New Lot.

XE Pneumatic Unit:

Inspect Trap Chamber for Fluid
- Visually inspect Trap Chamber for fluid.
- If fluid is present, turn Pneumatic Unit off. Remove Trap   Chamber by turning clockwise. Discard fluid. Dry chamber and re-assemble trap on Pneumatic Unit. Do not over-tighten.
- Turn Pneumatic Unit On. Verify vacuum gauge is accurate.

XE Pressure and Vacuum Checks
- XE Main unit sensors monitor ranges for pressure and vacuum. If monitored ranges are exceeded (see Table), error messages are displayed. Press **[HELP]** and **[OK]** to display Sensor 1 screen. Then adjust to correct the error.
- Check pressure and vacuum on Pneumatic Unit before checking the Main Unit.
- Adjustment procedures listed below. Set using the adjust range (see Table).

### To Adjust XE Pneumatic Unit Pressure
- View XE Sensor 1 screen
- Loosen fixing screw using screwdriver
- Adjust 0.25 pressure using knob
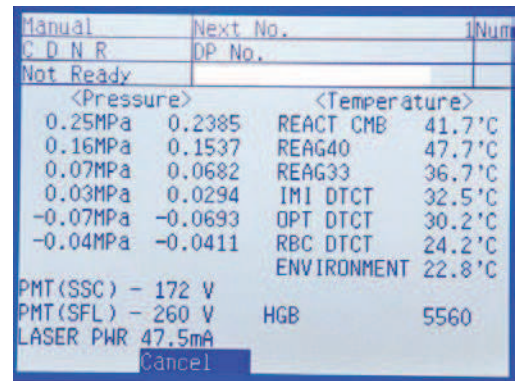
To Adjust XE Main Unit Pressure
- View Sensor 1 screen
- Pull knob to unlock
- Adjust regulator to range
- Push knob in to lock in place
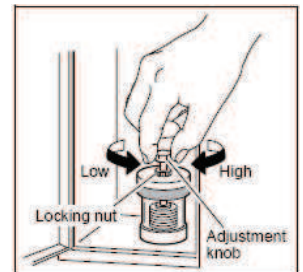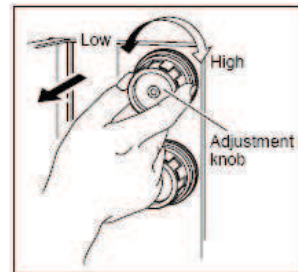
To Adjust XE Main Unit Vacuum
- View Sensor 1 screen
- Loosen lock nut on bellows unit
- Adjust using adjustment knob
- Retighten lock nut
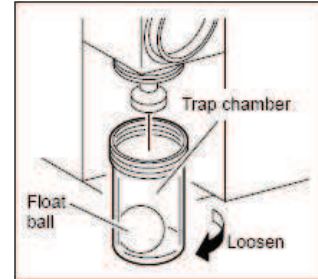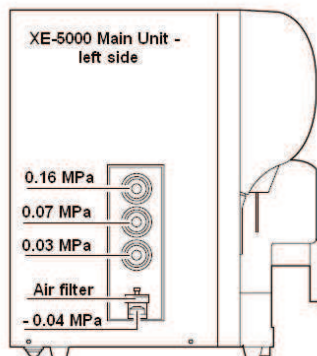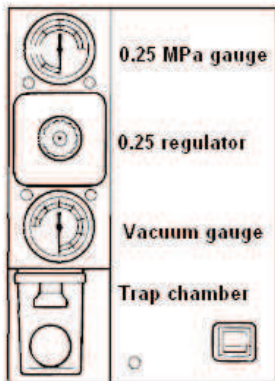
Vacuum Trap Chamber

Sensor 1 Screen

Pressure and Vacuum (In Order of Sensor 1 Screen)			
XE-5000	Adjust Range MPa	Monitored Static Range	Adjust Location
PU Pressure	0.24 to 0.26	2100 to 2900	PU Regulator
0.16 Pressure	0.159 to 0.161	1500 to 1700	XE Main Unit
0.07 Pressure	0.069 to 0.071	620 to 780	XE Main Unit
0.03 Pressure	0.029 to 0.031	270 to 330	XE Main Unit
PU Vacuum	must be ≥- 0.05	400 to 700	No PU Adjustment
- 0.04 Vacuum	- 0.039 to - 0.041	285 to 315	XE Main Unit

XE Daily Shutdown

Perform daily or when "Execute Shutdown" displays (every 500 samples) or perform instead of Rinse Flow Cell when "Execute Rinse Flow Cell" message displays (every 400 retics).

1. Press **[SHUTDOWN]** on Main Unit.
2. Hold 5mL of 5% NaClO filtered bleach (Clorox brand) up to manual pipette. Press **START SWITCH**. Bleach is aspirated.
3. When beeping stops and 'READY' LED turns off, remove tube of bleach.
4. After about 15 minutes, Main Unit displays "Please POWER Off."
5. To continue analysis, select "RESTART" on LCD screen. After auto-rinse and background check is completed, XE-5000 is "Ready".

Weekly: Power IPU off after performing Daily Shutdown

XE Power Off Order: 1) XE Main Unit 2) IPU

1. To power off XE, turn off Main Unit power switch.
2. To Power off IPU, click **[FILE]**, **[EXIT]** on screen. Click **[YES]** to exit XE-5000 program.
3. Click **[START]** at bottom of Windows desktop. Then click **[SHUTDOWN]**.
4. Click "Shutdown the Computer" and press **[ENTER]**.
5. The system displays: "Please wait while the system writes unsaved data to the disk".
6. When dialog box displays: "It is now safe to turn off your computer", turn IPU power off.

Every 30,000 Samples

- **Clean Sample Rotor Valve with 1:10 Bleach and DI water. Reset SRV Cycle Counter.**
  Convenient to clean Manual Rinse Cup and SRV Tray when SRV is cleaned.

- **Replace Piercer Needle and Reset PIAS Cycle Counter.**
  Convenient to clean Piercer Tray when Piercer is replaced.

- **Resetting Cycle Counters**
  1. On XE Main Unit press **[MORE]**, **[TEST]** and **[STATUS]** on the function menu. Select **[COUNTER]** from Status function menu screen.
  2. Use **[↓]** or **[↓]** arrows to select item to be reset. [toggles between SRV and PIAS (Piercer assembly)]
  3. Press **[OK]** on function menu to reset to zero. Press **[CANCEL]** to exit.
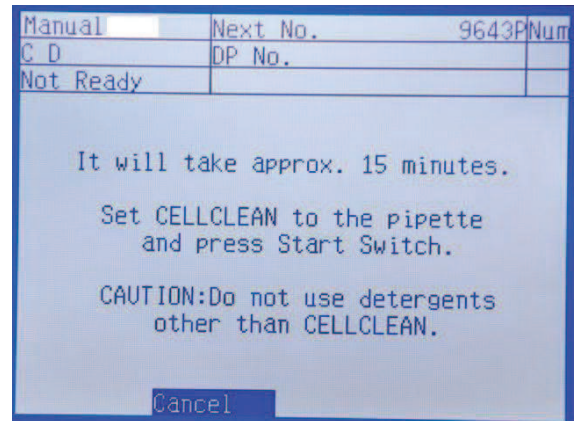
Shutdown Instructions

As-needed Maintenance:

Remove IMI or RBC clog

- Use HELP key if error occurs.
- Press Maintenance, **[3]** Clog removal on XE Main Unit.
- Clean IMI detector aperture if IMI Clog removal does not remove clog.
- Clean RBC detector aperture if RBC Clog removal does not remove clog.

Perform Rinse Flow cell

- Perform if "Execute Rinse Flow Cell" message displays (> 400 Retics per day).
- Perform if abnormal Scattergram pattern occurs.
- Perform if QC errors occur on flow cell parameters.
- Clean Flow Cell with 1mL of 5% Clorox bleach using Maintenance, **[4]** Rinse Flow Cell Procedure.
- When cleaning is completed, perform Maintenance, **[2]** Air Bubble Removal.

Remove Air Bubbles from flow cell if abnormal scattergram patterns occur. Also perform after executing Rinse flow cell (Maintenance, **[2]** Air Bubble Removal program).

Refer to Instructions for Use to Clean
- **Manual Rinse Cup**
- **SRV Tray**
- **Cap Piercer Tray**