



# Customer Bulletin:

## *Insight*<sup>TM</sup> Program Modification

**Attention:** Hematology Laboratory Director  
Analyzer Operators for Sysmex<sup>®</sup> XE-Series, XT-Series and SE-Series

### Introduction

The *Insight* Interlaboratory Quality Assessment Program provides a monthly report of analyzer performance. Each analyzer is compared to the peer group for on-average accuracy. To address participant concerns relating to SDI values for the Detector Control/Service Parameters, Sysmex has initiated a change in the program reports.

### Issue

Service parameter and reportable parameter data is currently submitted and analyzed with peer group statistics generated in the *Insight* report. Service parameters are a Sysmex service tool for monitoring stability of instrument components and should not be held to the same stringent QC rules that are followed for reportable parameters. If routine QC rules are applied to the service parameters, false positive QC rule violations will occur. These false positive rule violations cause the Sysmex user to spend time and effort troubleshooting and documenting QC violations that are not clinically significant. In an effort to provide a meaningful QC program focused on monitoring only required reportable parameters, Sysmex will change how service parameters are set on the instruments from utilizing QC rules to Manufacturer Defined Limits for XE-Series, XT-Series and SE-Series analyzers.

Service parameters will no longer be displayed on the assay sheet or on the resulting *Insight* Report beginning for the products and Lots listed below. The list of affected parameters can be found on the attached Manufacturer Defined Limits for the XE-Series, XT-Series and the SE-Series. The change will not impact reporting of the clinically significant reportable parameters presented on the *Insight* Report.

Product	Lot Number	Ship Date	Analyzer
e-CHECK	6360 / 6361	12/12/06	XE, XT
SE-CHECK	6360	12/26/06	SE-9500, SE-RAM

<input type="checkbox"/> Sysmex K-800	<input checked="" type="checkbox"/> Sysmex Alpha (R)	<input checked="" type="checkbox"/> Sysmex XE-Alpha
<input type="checkbox"/> Sysmex K-1000	<input checked="" type="checkbox"/> Sysmex Alpha II	<input checked="" type="checkbox"/> Sysmex XE-Alpha N
<input type="checkbox"/> Sysmex KX-21	<input type="checkbox"/> Sysmex SF-3000	<input checked="" type="checkbox"/> Sysmex HST-Series
<input type="checkbox"/> Sysmex KX-21N	<input checked="" type="checkbox"/> Sysmex XE-2100	<input checked="" type="checkbox"/> Sysmex HST-N Series
<input type="checkbox"/> Sysmex K-4500	<input checked="" type="checkbox"/> Sysmex XE-2100D	<input type="checkbox"/> Sysmex XS- Series
<input checked="" type="checkbox"/> Sysmex SE-Series	<input checked="" type="checkbox"/> Sysmex XE-2100L	<input type="checkbox"/> Sysmex pochH-100i
<input checked="" type="checkbox"/> Sysmex SE-Alpha	<input checked="" type="checkbox"/> Sysmex XT-2000i	
	<input checked="" type="checkbox"/> Sysmex XT-1800i	



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## Conclusion

This change will minimize false run rejection due to flagging of non-clinically significant parameters. Accuracy bias codes for the Detector Control/Service Parameters are only applicable for determining the need for or level of analyzer service adjustment and therefore, are not subject to standard QC monitoring rules.

The Manufacturer Defined Limits for Service Parameters are listed in the enclosed documents and should be entered into the analyzer's control files. Since these limits are defined as a variation from target values, they will not be changed lot to lot.

## Action Required

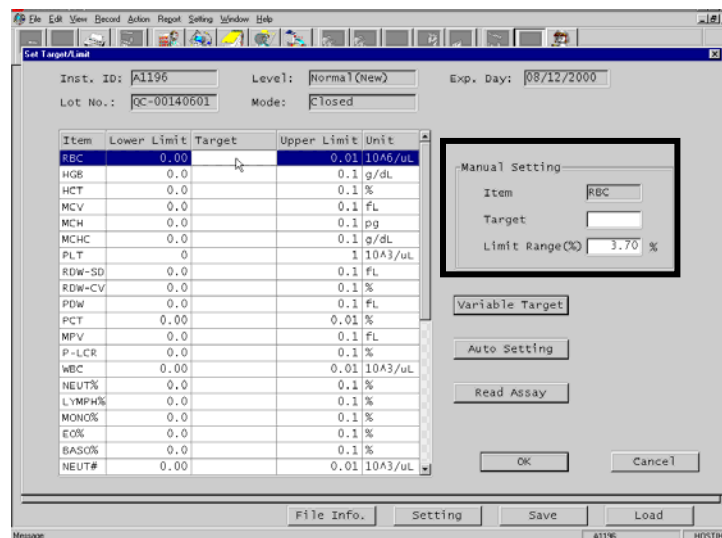
- Distribute this customer bulletin to appropriate staff.
- Add/change your QC procedures to state that the Service Parameters are for service use only and will not be included as part of your daily QC monitoring or peer review program.
- Use the appropriate Manufacturer Defined Service Parameter Limit Range% document to modify current limits.
- Instructions for entering the limits are attached and can also be found on the *Insight* page of the Sysmex website.

## Questions

For an immediate response to questions relating to this change, please contact *Insight* staff at 800-379-7639 extension 4563, or visit the FAQ's on the *Insight* page of the Sysmex web site. (<http://www.sysmex.com/usa/insight>)

## Instructions for XE-Series and XT-Series Input Limit Range% for DCP's/Service Parameters

1. Input the Limit Range% for the Detector Control/Service Parameters for a **New** lot using the values from the attached Limit% document. DCPs must be changed on a **New** lot that is already setup.
  - a. Click on the “QC” icon from the Menu window or Tool bar.
  - b. Click on the *e*-CHECK tab.
  - c. Click on the [▼] beside “Lot” and select “New”.
  - d. Click on the [▼] beside control Level 1.
  - e. Click on the [▼] beside Mode and choose “Closed”.
  - f. Click on the [Target/Limit] button.
  - g. Arrow down to find the DCPs listed on the attached DCP Limit% document. See example below.
  - h. Click on a DCP parameter. Highlighted parameter now appears in the Manual Setting box.
  - i. Highlight the value that appears in the Limit Range% box.
  - j. Enter the Limit % for chosen DCP/Service parameter from the attached DCP Limit% document. (Press ↓ twice on keyboard to go to next parameter).
  - k. Complete this process for all parameters listed on the DCP Limit Range% document.
  - l. Click **OK** to save all changes.
2. Repeat process for Level 2 and Level 3.
3. Repeat process for Manual Mode files for Level 1, Level 2 and Level 3.
4. The revised values will remain in the **New** lot files and will move to the **Current** files when **Change Lot** takes place.
5. This process only needs to be done once.




XE-Series and XT-Series  
Detector Control/Service Parameters  
Manufacturer Defined Limits

Using the instructions on Page 1, enter the Limit Range% values listed below in a **New** lot file for Level 1, Level 2 and Level 3 and for both Manual/Open and Closed Modes. These values will remain in the **New** lot files and will move to the **Current** lot files when **Change Lot** takes place. Once entered, these values should not be changed.

DCP's/Service Parameters	Limit Range%	XE-2100	XE-2100L	XE-2100D	XT-2000i	XT-1800i
DIFF-X	8	X	X	X	X	X
DIFF-Y	68	X	X	X	X	X
BASO-X	15	X	X	X	X	X
BASO-Y	21	X	X	X	X	X
IMI#	80	X	X			
IMIDC	20	X	X			
IMIRF	43	X	X			
NRBC-X	14	X	X			
NRBC-Y	14	X	X			
RBC-O	29	X			X	
HFR	217	X			X	
MFR	120	X			X	
LFR	56	X			X	
RBC-X	64	X			X	
RBC-Y	17	X			X	

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## SE-Series Instructions Input Limit Range% for DCPs/Service Parameters

1. Input the Limit Range% for the Detector Control/Service Parameters for each QC file in use.
2. Main Unit at Ready, press Home key to get to Main Screen.
  - a. Press **F5**: QC/CAL
  - b. Press **4**: QC Settings
  - c. Press **2**: Manual Settings/Enter
  - d. Highlight File/Press any Key
  - e. Press **4**: Edit
  - f. Arrow down to find the DCP's listed below
  - g. Enter new values for each DCP listed below
  - h. Escape
  - i. Set
3. This process needs to be completed for all QC lot files including Manual/Open Mode, Closed Mode, and Level 1, Level 2, and Level 3.

### SE-CHECK Detector Control/Service Parameters Manufacturer Defined Limits

Using the instructions above, enter the Limit Range% values listed below in the control files for Level 1, Level 2, and Level 3 and for both Manual/Open and Closed Modes. The DCP Limit Range Percents need to be input for all lot files and not changed.

DCP's	Limit Range% Level 1, Level 2, Level 3
IMI#	62
IMIDC	20
IMIRF	51
GRANDC	21
GRANRF	40
EO-MFV	15
BA-MFV	22



## *INSIGHT*<sup>™</sup> Program Modification Frequently Asked Questions (FAQ's)

1. Why are the DCP's/Service Parameters being eliminated?

DCPs are non-reportable parameters. Eliminating these parameters will help to minimize false run rejection due to flagging of non-clinically significant parameters.

2. Should I call service if any of my DCP's flag?

- Verify that the new percent limits are reset in the analyzer.
- If it's one level one time, continue to run analyzer.
- If multiple levels or reportable parameters are flagged, call the Technical Assistance Center.
- If reportable parameters are **not flagged** outside the acceptable ranges, patient results can continue to be reported.

3. How did Sysmex determine what the new DCP limits should be?

Based on manufacturer defined product specifications, new limits were set to eliminate erroneous false positive data.

4. Will my DCP results appear on the Insight Report?

No, the revised participant *Insight* Report will no longer compare the DCP's statistics to the group values.

5. How does this change affect my historical reports?

Reports previously generated and distributed to participants will remain unchanged. These historical reports are stored at Sysmex. Retrieval of previous lots from the website will not have the service parameters.

6. How do I change the Limit Percents?

- Instructions are attached to the customer bulletin.
- Instructions can also be found on the Insight page of the Sysmex website.

7. How long will it take to make the limit percent changes?

Approximately 30 minutes.

8. What are the DCPs?

The attached document lists the DCP's and the Percent File Limits for these parameters.

9. When should I start using the new limit percents for the DCP's?

- The DCP Limit Range Percents need to be input on a **New** Lot File.
- Be sure to input percents by dates shown on table below.

Product	Lot Number	Ship Date	Analyzer
e-CHECK	6360 / 6361	12/12/06	XE and XT
SE-CHECK	6360	12/26/06	SE-9500, SE-RAM

