

"Sysmex Network Communication System (SNCS) for coagulation"

September 13th, 2018



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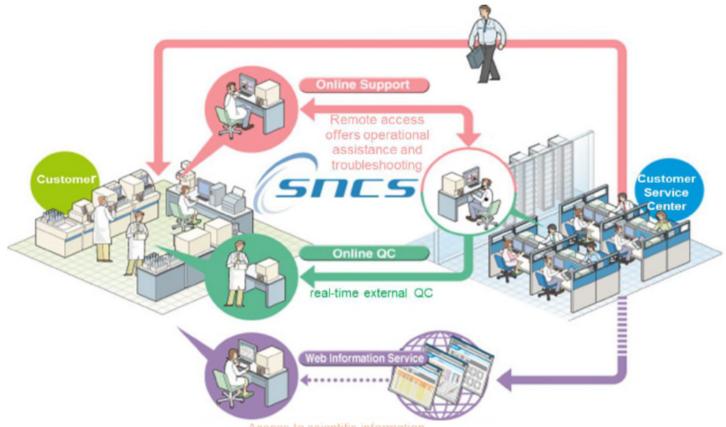


SNCS Features overview

What is SNCS?



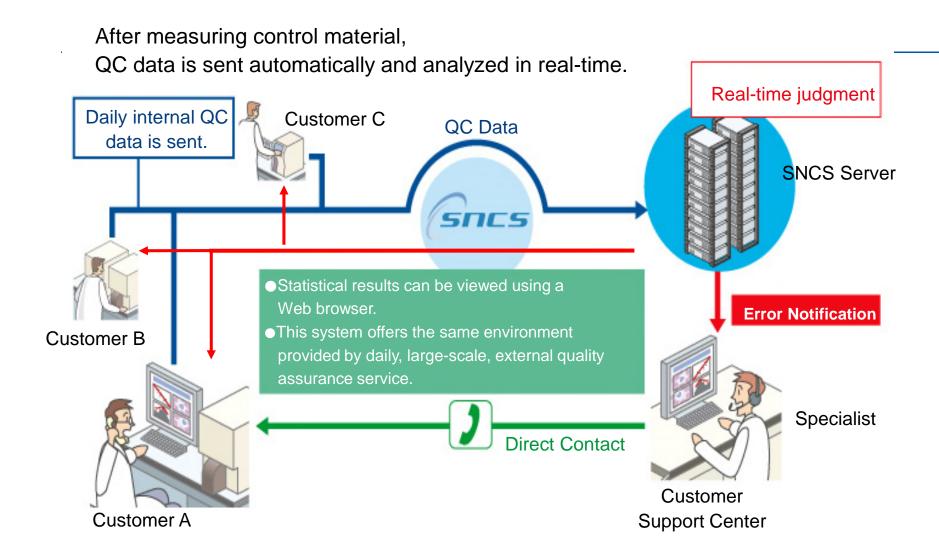
SNCS = Sysmex Network Communication System
Web-based quality assurance system that can provide real-time
EQA, Online QC and Online Support



Access to scientific information

Online QC



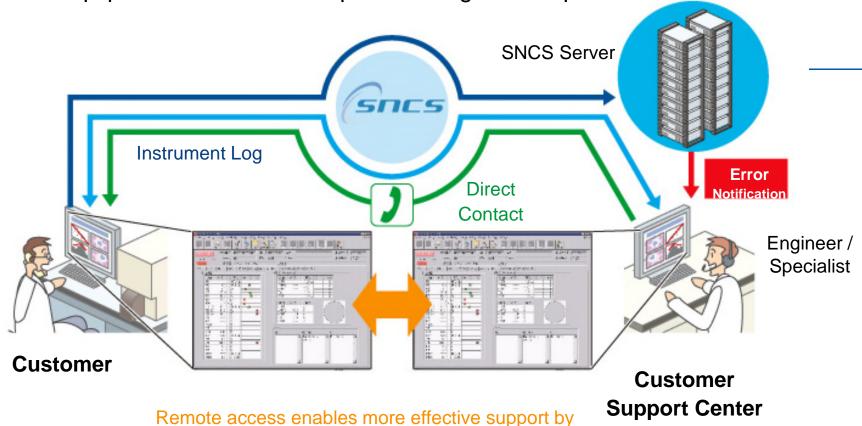




Online Support

Rapid service via online network!

Reduce equipment downtime and provide diagnosis of problems.

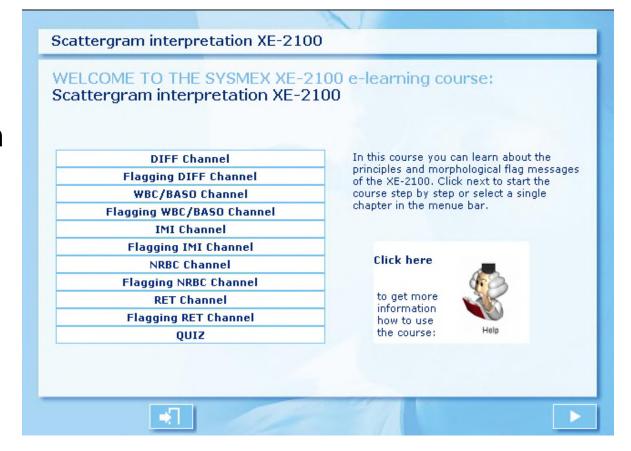


Remote access enables more effective support by sharing same instrument screen.



Scientific Web Information

- E-learning
- Case archive
- Technical Information
- FAQ section





How to Login

For Customer

The URL of login screen for customer is http://sncs-web.com/ap
In this site, SNCS system can be used in User/Group mode and Group Manager mode.





SNCS Online QC

External QC Online QC

- Periodical measurement of QC material
- Ensure accuracy of QC data by comparison with other analyzers

Integration of External & Internal QC

- Internal QC
- Daily measurement of control material
- Ensure precision of daily QC data by compare with assay limit & monitor the trend



Daily calculation of data gathered from instrument nation-wide

QC data from participants is automatically sent to Sysmex's Data Analysis Center, where the data is analyzed. The results can be viewed using Web browser.



QC data monitored in three monitoring methods

The quality control data from each participant is monitored in terms of accuracy, precision, and trend, in order to detect any problems.



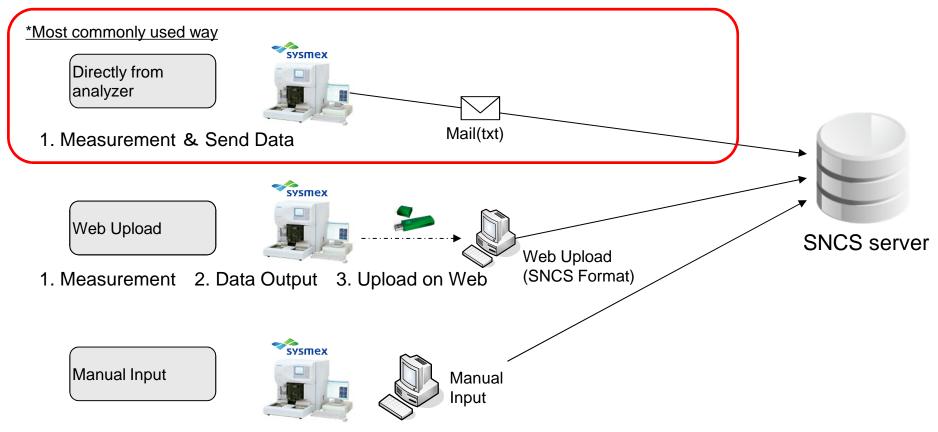
Follow-up participants

Abnormal data detected generated a email error notification to service organisation or customer for follow-up.

How to register QC data



Available Methods for Sysmex Analyzers



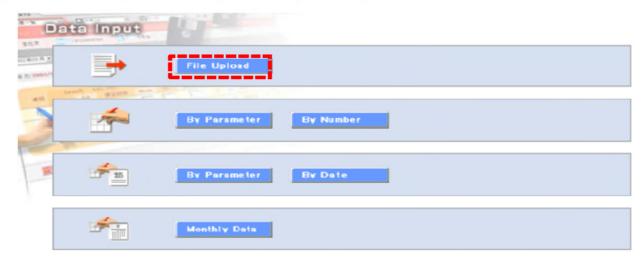
1. Measurement 2. Manual Input on Web

File Upload



The files within 3 days after measurement can be uploaded.

To upload files, select [File Upload].



Click "Browse" and select the file you want to upload.





Graphs & Charts

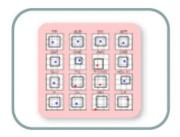
Five types of graphs are available in SNCS to analyze the QC data for accuracy, precision and trend. Daily and monthly QC reports can be downloaded in PDF format from the SNC Website when you perform backup of QC data.



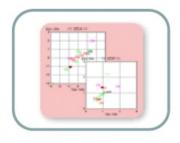
Time-Series



Perform Backup QC



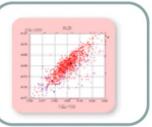
QAP Matrix



SDI/ Twin plot



SDI/Twin Plot (Group)



Scatter Plot

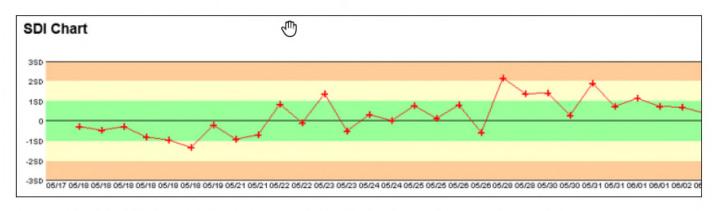




Time-Series Chart

The QC data can be viewed on Chart or Num. Table which are switchable.

Chart - Your data (intraday, daily and monthly) can be compared with peer group statistics graphically. Display chart type can be selected as ALL (SDI+PI+SDi), SDI, PI or SDi.



- Black line in the center of the chart represents the peer group mean
- Colored plot indicates your SDI
- Green color band indicates ±1SD, yellow ± 2SD and orange ±3SD
- Red "X" mark indicates data exceeded ±3SD





Time-series Chart

Num. Table – Your measurement results, your statistics, peer group statistics and judgment results (error flags) can be viewed in numerical values.

Date - Number	05-17-01	05-18-01	05-18-02	05-18-03	05-18-04
Time(HH:MM:SS)	15:49:07	07:10:35	12:30:42	12:37:10	13:29:51
Parameter Unit	RBC x10 ¹² /L				
Control Lot	#8127(L1)_OP	#8127(L1)_OP	#8127(L1)_OP	#8127(L1)_OP	#8127(L1)_OP
Your data	2.380	2.370	2.360	2.370	2.340
Group Mean	2.420	2.386	2.386	2.386	2.386
Your SDi					
Your SDI		-0.288	-0.461	-0.288	-0.808
Peer group Inter-SD	0.000	0.057	0.057	0.057	0.057
Your SD					
Peer group Total-SD	0.000	0.057	0.057	0.057	0.057





Time-series Chart

You can click on the Help button to display an explanation of the Num. Table.

Help	
Date - Number	Measurement day and number of measurement times
Time(HH:MM:SS)	Measurement time
Parameter Unit	Measurement parameter name unit
Control Lot	Control lot number
Your data	Measurement value
Group Mean	Mean value of the selected peer group at judgment
Your SDi	-
Your SDI	[Your data - Group Mean] / Inter SD*1
Peer group Inter-SD	Inter-SD of the selected peer group at judgment
Your SD	-
Peer group Total-SD	√ Inter-SD ² + Intra-SD ²
Group N	Number of participants of the selected peer group at judgment
Judge	Result of Error judgment

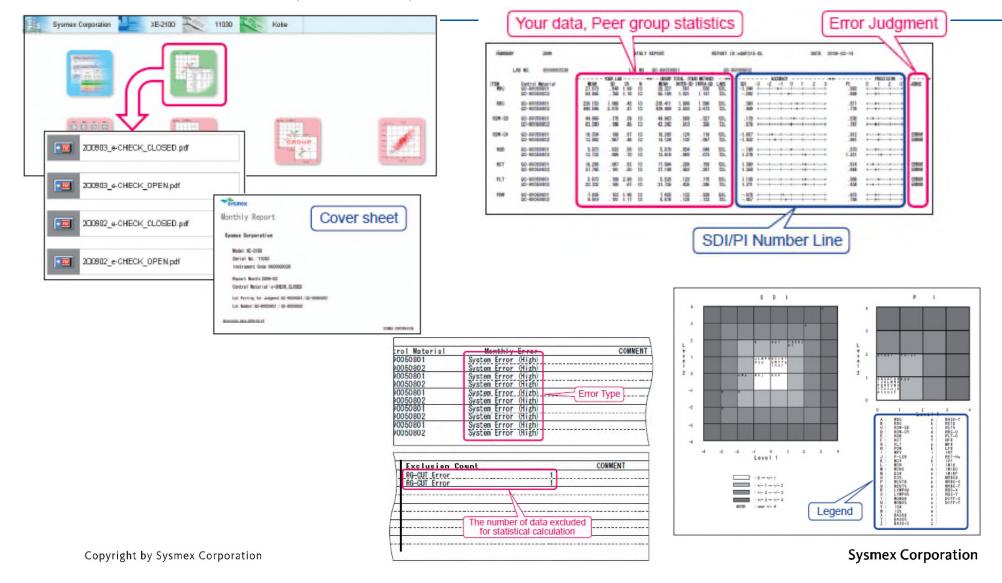
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Reports (PDF)



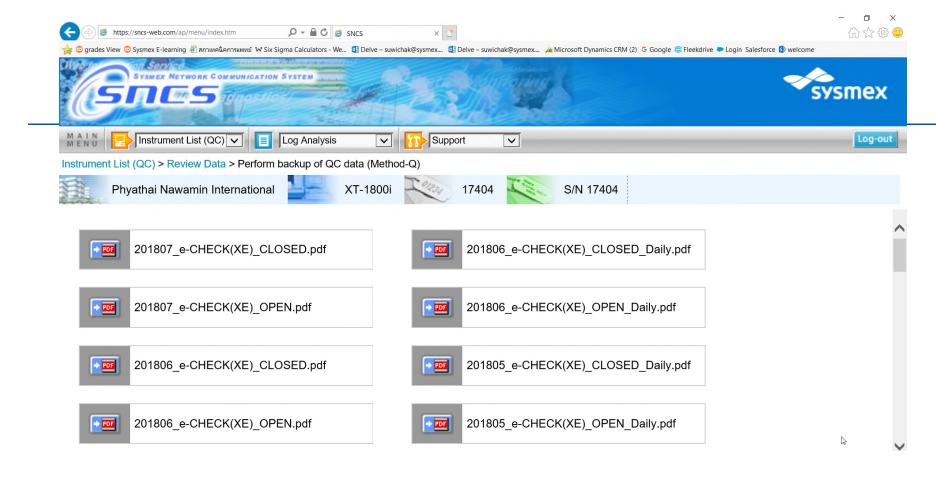
Monthly PDF report can be downloaded. In the PDF report, various statistical data, Error List, and SDI/PI Twin Plot are described.





Backup of QC data 12 Months Monthly, Daily summarize



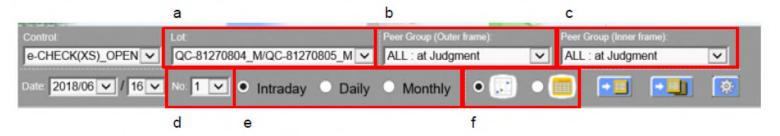






QAP Matrix

In QAP Matrix, QC data for all measurement data are displayed and can be compared with peer group mean (Total/ Group) at a glance. Below is the operation panel of QAP Matrix screen.



- Combination of lot number can be selected
- b. Peer group which will draw the outer frame (3SD) can be selected.
- Peer group which will draw the inner frame (2SD) can be selected.
- Number of times can be selected if intraday is selected.
- e. Data to be displayed and selectable period of measurement
- Graph or Num. table can be selected.

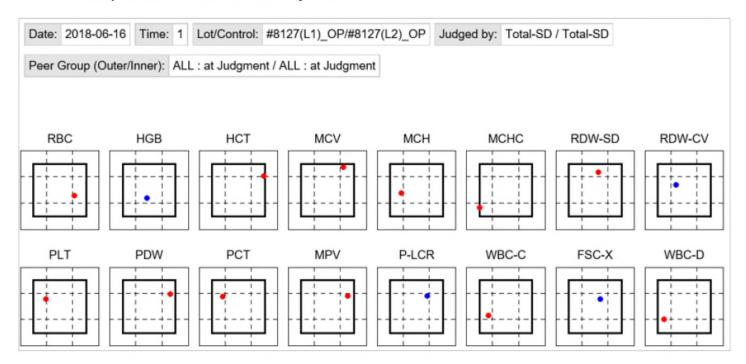




QAP Matrix

QAP Matrix consists of the following elements:

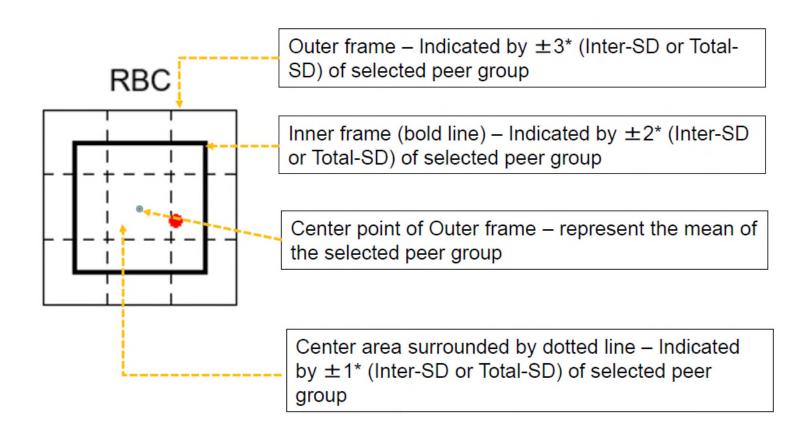
- Frames which are drawn based on judgment method of selected peer group (Inter-SD or Total-SD)
- A plot which indicates your SDI







QAP Matrix

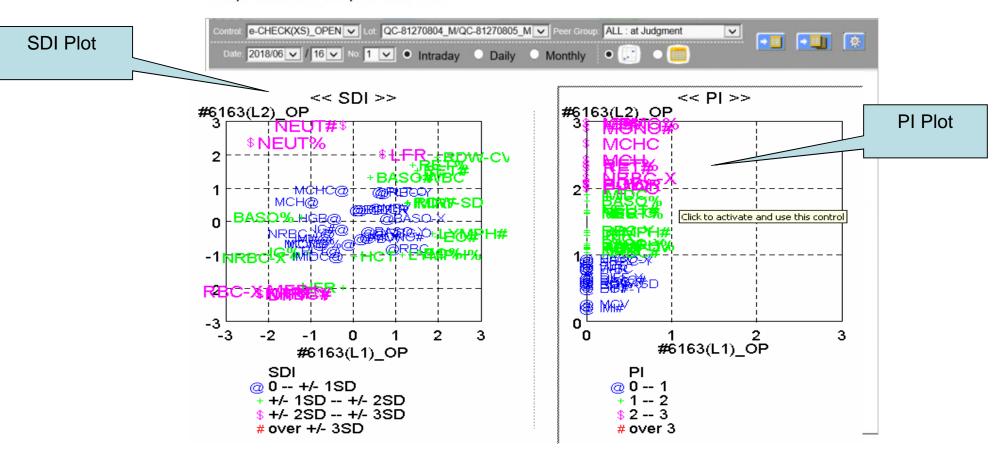






SDI/PI Twin plot

SDI and PI are calculated based on your data and peer group statistics. SDI and PI are plotted for all parameters.







SDI/PI Twin plot

In Num. Table display, the content differs whether selected peer group is <at Judgment> or not.

Peer Group <at Judgment>

	#9256(L1)_CL						#9256(L2)_CL						
Parameter	Mean	SD	SDI	PI	Ν	Judge	Mean	SD	SDI	PI	N	Judge	T_Judge
At Judge	Mean	SD	Inter-SD	Intra-SD	lab		Mean	SD	Inter-SD	Intra-SD	lab		
RBC	237.666	2.081	1.455	1.158	3	-	446.500	3.535	0.892	1.349	2	-	*
Group Mean	234.868	2.631	1.922	1.796	398		443.875	3.937	2.939	2.619	467		
HGB	6.000	0.000	1.142	0.000	3	-	12.400	0.000	1.152	0.000	2	-	*
Group Mean	5.936	0.073	0.055	0.048	398		12.298	0.118	0.088	0.078	467		

Peer Group not <at Judgment>

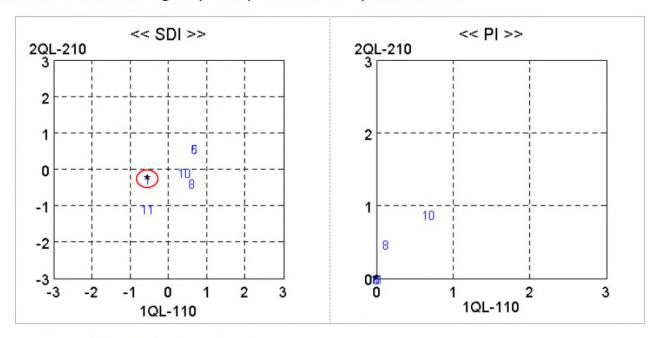
		#92	56(L1)_CL		#9256(L2)_CL					
Parameter	Mean	SD	SDI	PI	N	Mean	SD	SDI	PI	Ν
Your Cumulative Value	Mean	SD	Inter-SD	Intra-SD	N	Mean	SD	Inter-SD	Intra-SD	N
Latest Statistics	Mean	SD	Inter-SD	Intra-SD	lab	Mean	SD	Inter-SD	Intra-SD	lab
RBC	237.666	2.081	1.443	1.170	3	446.500	3.535	0.884	1.362	2
Your Cumulative Value	236.697	1.021			40	445.859	2.706			40
Latest Statistics	234.867	2.631	1.939	1.778	400	443.881	3.936	2.959	2.594	468





SDI/PI Twin Plot in Group

SDI and PI are calculated based on the peer group statistics in the selected group and your measurement results (raw data) or daily/monthly statistics. SDI and PI of instruments in the group are plotted for all parameters.



- Your instrument is plotted as "*" mark.
- Other instruments are plotted as the marks which have been set in "Plot Mark Settings". Only the Group Manager can change the setting.





SDI/PI Twin Plot in Group

In Num. Table display, the content differs whether the selected data is Intraday data or not.

Below is the Num. Table if Intraday data is selected.

			1QL-110			П		2QL-210		
Plot Mark		Your data	Time(HH:MM:SS)	No	SDI		Your data	Time(HH:MM:SS)	No	SDI
*		116.000	08:23:18	1	0.285		260.000	08:23:27	1	1.176
21		115.000	15:54:05	1	-0.326		251.000	15:54:09	1	-1.385
5		114.000	08:23:15	1	-0.938		251.000	08:23:24	1	-1.385
1		118.000	11:29:15	1	1.508		257.000	11:30:23	1	0.322
11		116.100	17:24:19	4	0.346		258.800	17:24:52	4	0.834
12		114.700	15:08:54	2	-0.510		250.400	15:09:20	2	-1.556
7		116.000	10:59:02	2	0.285		259.000	10:59:26	2	0.891
9		117.000	13:27:32	3	0.896		252.000	14:34:00	3	-1.101
		Mean	SD	N	INTER-SD		Mean	SD	N	INTER-SD
Latest Statistics (GROUP)	Ref.	115.886	1.463	22	1.067		255.681	3.268	22	2.503
		Mean	SD	N	INTER-SD		Mean	SD	N	INTER-SD
Latest Statistics (ALL)	Criteria	115.533	2.046	1695	1.634		255.868	4.272	1686	3.512

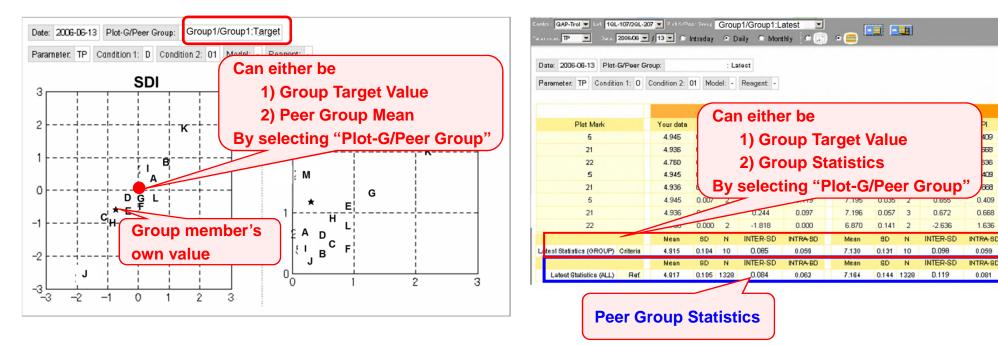
The group's latest statistics and the total latest statistics are displayed.





Features Group Members

1) Group Members can use "SDI/PI Twin Plot in Group" to review the results in comparison to other group members.



2) Group Members can check each other's data and error occurrence, when permission is given by the Group Manager.

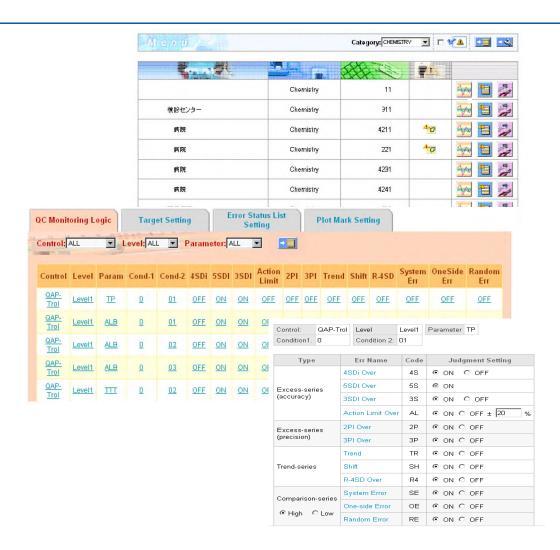




Features for Group Manger

 Group Manger can view the data of all analyzers registered to its group.

 Group Manager can customize the configuration for QC Monitoring, by turning the judgment setting ON/OFF.







Features for Group Manger

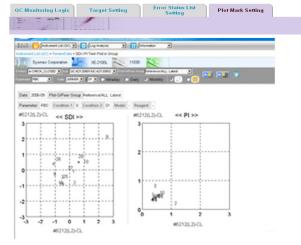
3) Group Manger can customize the Target Setting. Target values can be specified either by statistical value or specific target value.



4) Group Manager can customize the configuration of the Plot Marks for "SDI/PI Twin Plot

in Group."

Customer Name	Model	Nickname	Plot mark	Size	Color	Disp-Order
みさと便和クリニック	Chemistry	Pモジュール	21	3 🕶	Blue 💌	1
コシュ・ダイア1	Chemistry	MOD-D		5 🕶	Black	2
シュ・ダイア1	Chemistry	MOD-P	R	4 🕶	Red 💌	3
心立義同結合病院	Chemistry	MOD-P1	23	3 ~	Blue	4
公立種間經合病院	Chemistry	MOD-P2		5 💌	Black 💌	5
森和メデックス練富士	Chemistry	MOD-DP	22	3 🗸	Blue	6
大阪医療センター	Chemistry	P-Modular		5 🕶	Black M	7
大阪医療センター	Chemistry	M-PP	1	3 ~	Blue	8
大阪医療センター	Chemistry	M-PPE	2	3 🕶	Blue 💌	9
大阪南医療センター	Chemistry	2758401211		5 🕶	Black	10
大阪南医療センター	Chemistry	2758401221		5 🕶	Black 💌	11
大阪南医療センター	Chemistry	PPE	3	3 4	Blue	12
大阪南医療センター	Chemistry	PE	4	3 🕶	Blue	13



5) Group Manger can also configure whether or not to (1) receive error notification email, and (2) allow group members to view each other's data.

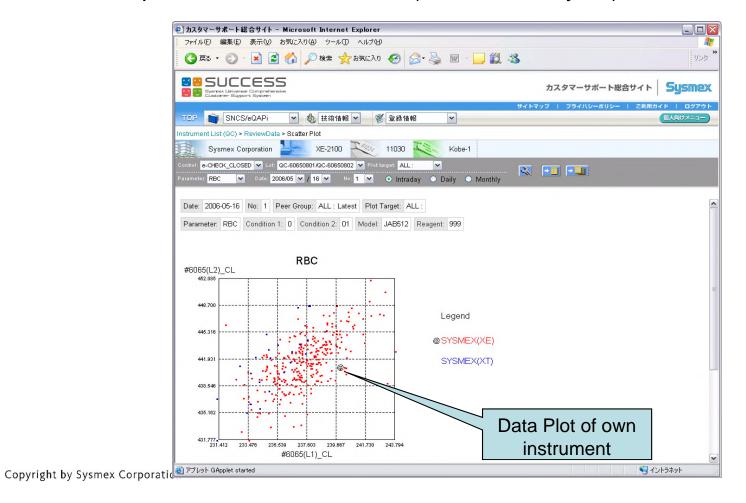
<u>Q</u>





Scatter Plot

Compares mean value of cumulative own instrument data with all instrument data for each parameter at condition 2 (model of analyzer).



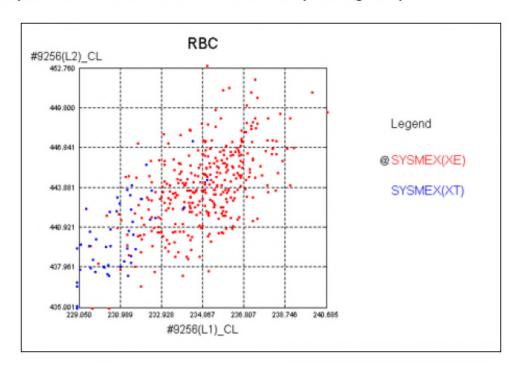




Scatter Plot

The cumulative mean of each instrument using the same combination of control lot are plotted in color for each Condition-2 per parameter.

Your measurement result (intraday data) or the mean value (daily/monthly data) is plotted as the "@" mark. The position of your data can be compared with the distribution of peer groups.



Error Judgment



Error Judgment in SNCS

There are 3 factors for the Error Judgment in SNCS:

- 1) Indexes of evaluation
 - > SDI
 - ➢ PI
- 2) 12 error types.
 - Excess-Series (Accuracy)
 - Excess-Series (Precision)
 - Trend Series
 - Comparison-Series
- 3) Timing of error Judgment
 - > Real-time Judgment
 - Judgment during processing

12 Error Types

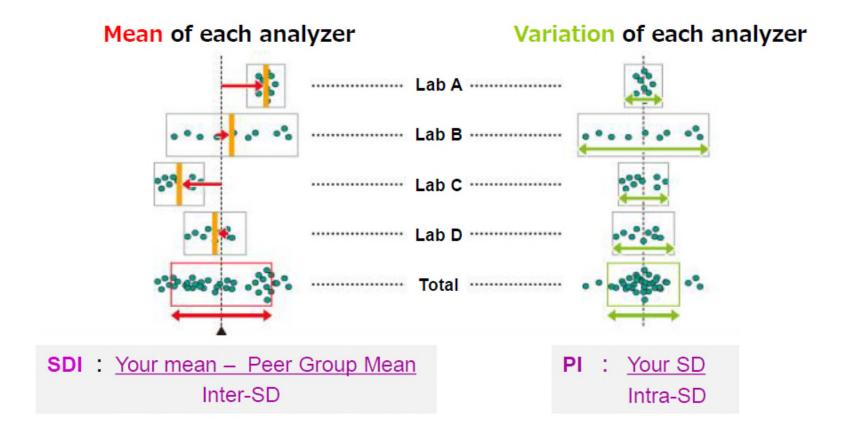


classification	contents	explanation
Excess-series	4SDi Over	Your data > mean +/- 4SD of own cumulative data
(accuracy)	5SDI Over	Your data > mean +/- 5xInter-SD of standard statistic data
	3SDI Over	Your data > mean +/- 3xInter-SD of standard statistic data
	Action Limit Over	Your data > mean of standard statistic data +/- permitted %
Excess-series	2PI Over	Your SD > 2xIntra-SD of standard statistic data
(precision)	3PI Over	Your SD > 3xIntra-SD of standard statistic data
Trend-series	Trend	Your data > mean +/- 2.7*Inter-SD of standard statistic data (continue 4 times, ascent or descent same direction)
	Shift	Your data > mean +/- 2.7*Inter-SD of standard statistic data (continue 10 times, same direction)
	R-4SDI Over	Your data – previous transmitted mean data > +/- 4xInter-SD of standard statistic data
Comparison-	System Error	SDI plot position of your data for 2 conc. is located at System error pos.
series (High mode	One-side Error	SDI plot position of your data for 2 conc. is located at One-side error position
(High mode, Low mode)	Random Error	SDI plot position of your data for 2 conc. is located at Random error position

Accuracy and Precision



In the SNCS system, individual QC data is evaluated for accuracy and precision. We use the SDI (Standard Deviation Index) to indicate accuracy, and PI (Precision Index) to indicate precision.



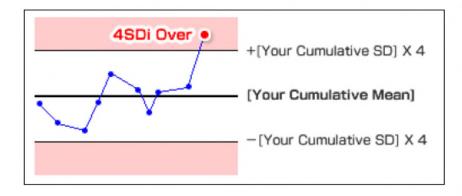


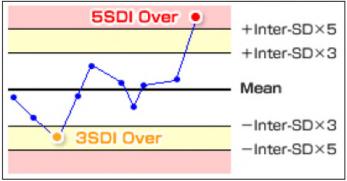
Excess-Series 1 (Accuracy)

Below table shows the type of QC errors generated and their definitions.

Error Judgment	QC error	Definition
Excess-series (accuracy)	4SDi Over	[Your data] exceeds the value of [Your Cumulative Mean] +/- ([Your Cumulative SD] x 4).
	5SDI Over	[Your data] exceeds the value of [Group Mean] +/- ([Peer Group Inter-SD or Total-SD] x 5).
	3SDI Over	[Your data] exceeds the value of [Group Mean] +/- ([Peer Group Inter-SD or Total-SD] x 3).
	Action Limit Over	[Your data] exceeds the value of [Group Mean] +/- [Action Limit %].

Example of graphs showing 4SDi Over and 5SDI Over errors.

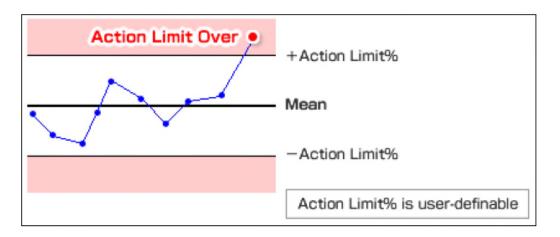






Excess-Series 1 (Accuracy)

Example of graph showing Action Limit Over error



Note:

 The data judged as 5SDI Over is not included in peer group statistics (total/group).

 4SDi is judged only when "your cumulative data" is [SD ≥ 0.01] and [CV ≥ 1] and [No. of days ≥ 60]

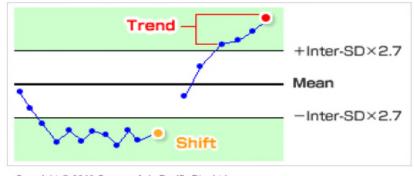


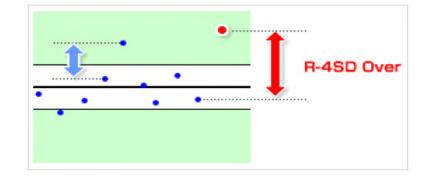
Excess-Series (Precision) & Trend

Below table shows the type of QC errors generated and their definitions.

Error Judgment	QC error	Definition
Excess-series	2PI Over	[Your SD] exceeds [Peer Group Intra-SD] x 2.
(precision)	3PI Over	[Your SD] exceeds [Peer Group Intra-SD] x 3.
Trend-series	Trend	[Your data] exceeds the value of [Group Mean] +/- ([Peer Group Inter-SD or Total-SD] x 2.7) for 4 times in a row in uptrend/downtrend.
	Shift	[Your data] exceeds the value of [Group Mean] +/- ([Peer Group Inter-SD or Total-SD] x 2.7) and is in the same position for 10 times in a row.
	R-4SDI Over	The difference between the previous [Your data] and the current [Your data] exceeds [Peer Group Inter-SD or Total -SD] x 4.

Example of graphs showing Trend and R-4SDI Over errors.





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Comparison-Series

Below table shows the type of QC errors generated and their definitions.

Error Judgment	QC error	Definition
Comparison- series (High mode, Low mode)	System Error	SDI plot position of [Your data] of 2 levels is located in system error. SE indicates High mode, and se indicates Low mode.
	One-side Error	SDI plot position of [Your data] of 2 levels is located in oneside error. OE indicates High mode, and oe indicates Low mode.
	Random Error	SDI plot position of [Your data] of 2 levels is located in random error. RE indicates High mode, and re indicates Low mode.

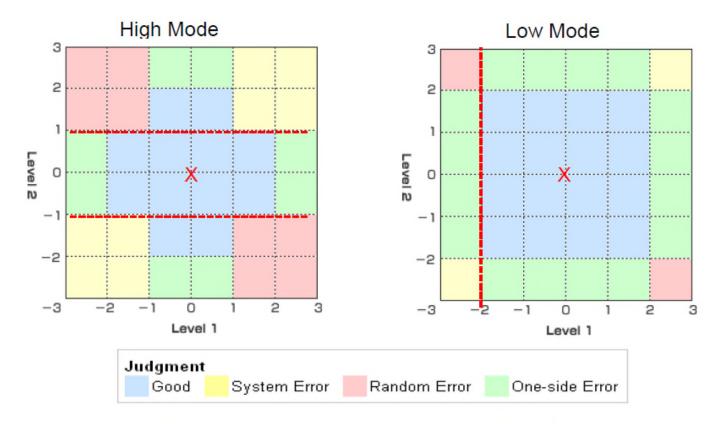
Lot pairing used for comparison-series judgment can set by customers. Customer can select the error detection mode as "High mode" or "Low mode" depending on their laboratory QC policy.

- "Low mode" generates an error when the control data exceeds ±2SD
- "High mode" is more stringent and generates an error when the control data exceeds ±1SD



Comparison-Series

- "Your data" is judged by its position in the matrix of the 2 control levels.
 - Center of the matrix marked with (x) represent the Group Mean of Level 1 & 2.
 - The grid line (----) represent Peer Group Inter-SD



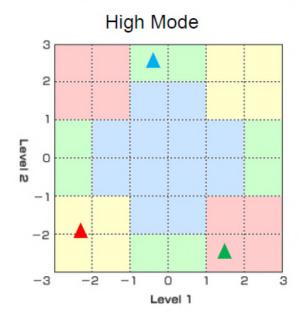


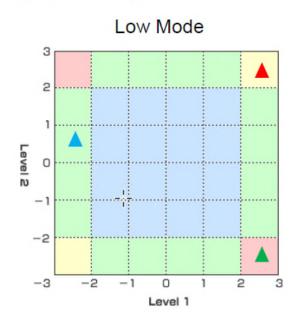
Comparison-Series

 A "System Error" flag is generated when the measurement results of both control levels shows the same trend.

▲ A "Random Error" flag is generated when the measurement results of both levels shows opposite trends; one is a high value and the other is low value.

▲ A "One-Side Error" flag is generated when one of the result is within ±1SD (high mode) and within ±2SD (low mode).







Error notification mail for QC error (method Q)

```
Dear customer.
This is an automatic error notification mail from SNCS service provided by Sysmex
Corporation.
Some suspected error(s) has been detected in the following instrument(s).
 Laboratory's Name: SYSMEX ASIA PACIFIC PTE LTD. SERVICE ORG
 Model: XE-2100
 Serial No: A2998
 Nickname: XE-AlphaN
 Instrument Code: 0000019866
-< Excess-Series/Trend-Series Error >-------
[Control: e-CHECK_CLOSED_3QC-61630803_S_Level3]
Error occurrence time: 11-JUL-2006 15:57
Parameter: BASO#_Unit: E3/uLi
Data type: Intraday
Measurement day: 11-JUL-2006, Number: 1, Time: 10:18
                       Measurement data: 14.730
 Your data
 Your cumulative data
                            Mean: 14,524 SD: 0.269 N: 5
                        Mean: 13.937 SD: 0.285 N: 47
 Statistics - ALL
                 Inter-SD: 0.225 Intra-SD: 0.176
                        3SDI Over
 Judgment
Please visit http://sncs-web.jp/global/, log-in SNCS-web, and check the
details of the detected error(s) for your instrument(s).
If you need further advices, please contact your Sysmex service representatives.
Sincerely.
SNCS Administrator
Sysmex Corporation
```

SNCS Web Information Service

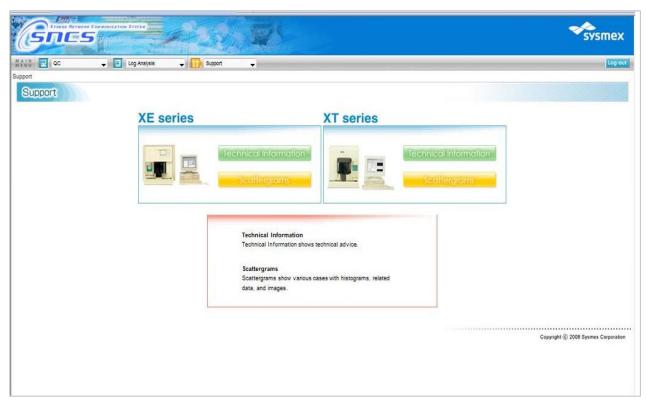


Web Information Service

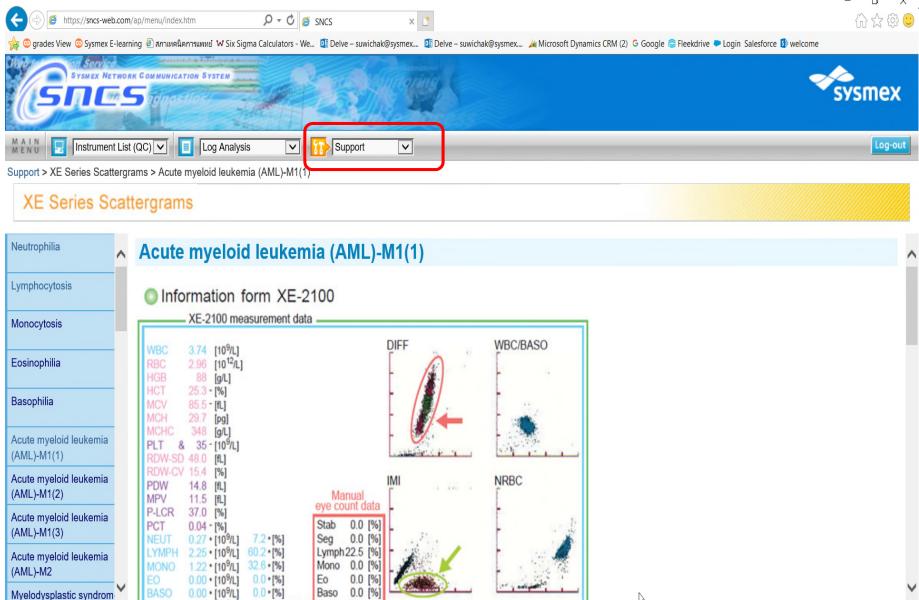
For AP customers, Web Information Service is provided on following URL:

http://sncs-web.com/ap/

The contents are managed by SAP, so adding the contents for Biochemistry customers can be considered in SAP.



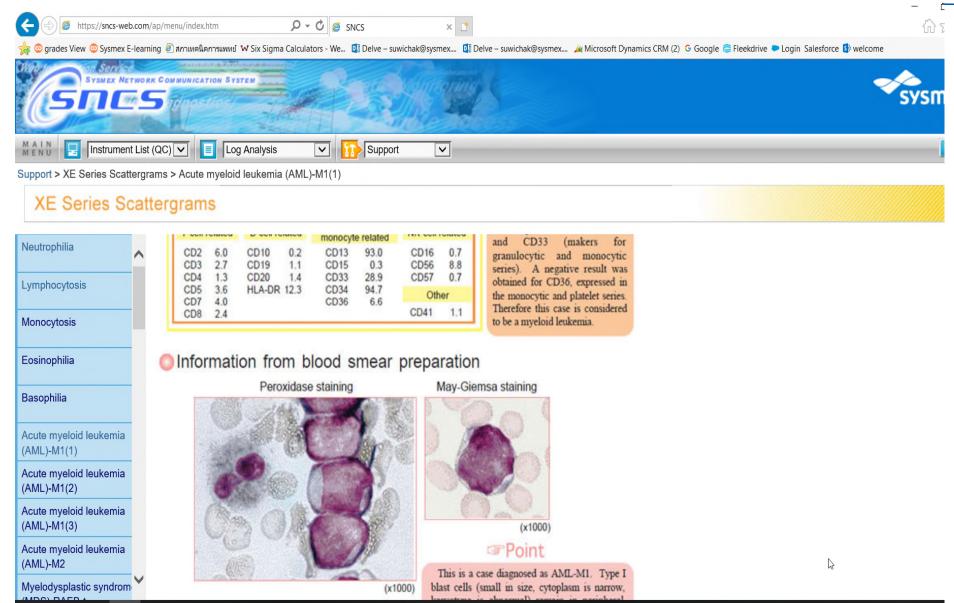




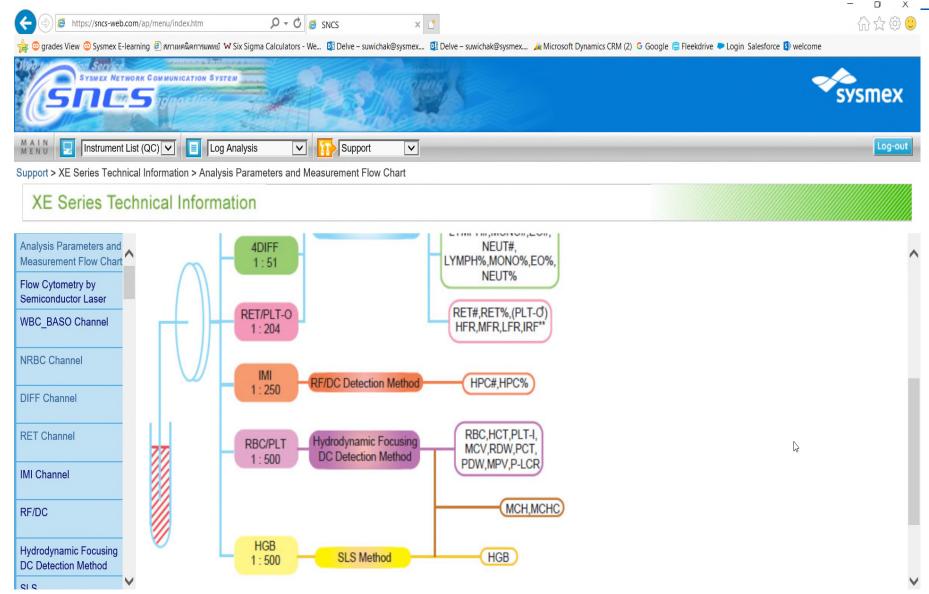
Copyright by Sysmex Corporation

Sysmex Corporation







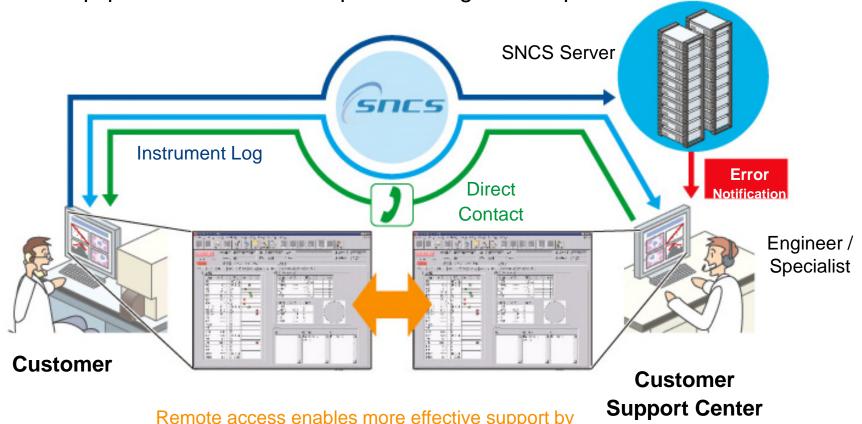


Online Support



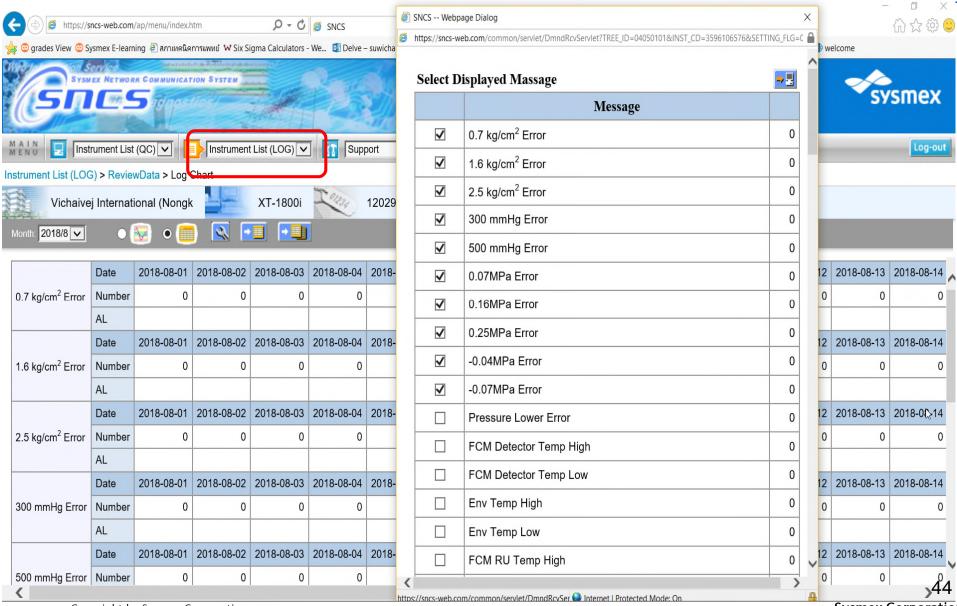
Rapid service via online network!

Reduce equipment downtime and provide diagnosis of problems.



Remote access enables more effective support by sharing same instrument screen.





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Lighting the way with diagnostics