

March 9, 2007

AU400® #257	AU640® #126
AU400® #128	AU2700® #193
AU640® #244	AU5400® #183

AU400®/AU400® Software Version 8.3

AU640®/AU640® Software Version 7.3

AU2700® Software Version 5.3

AU5400® Software Version 5.4

Dear Colleague:

Olympus America, Inc. is pleased to announce the release of new software versions for our AU400®/AU400®, AU640®/AU640®, AU2700® and AU5400® analyzers. These new software versions contain enhanced features to improve ease of use, performance, and flexibility of use.

An Olympus Field Service Engineer will be contacting you to schedule the installation of this software.

List of major changes you should be aware of:

Multi-point Calibration Slope Check Function, Inhibit Data from Printing in OD, Clot Detection, Reducing the “*” Flag, Improved Check for Substrate Depletion, Reagent Status - F6 Edit Improvements, Reagent Compartment Cover Opened, and other software corrections.

User Guide Changes for Multi-Point Calibration Slope Check Function:

Replace Pages D-105-D-108, AU400/AU400® User's Guide Vol.1.

Replace Pages D-105-D-108, AU640/AU640® User's Guide Vol.1.

Replace Pages D-117-D-122, AU2700 User's Guide Vol. 1.

Replace Pages D-113-D-116, AU5400 User's Guide Vol. 1.

Effective Date:

This function will become effective after the analyzer software is upgraded to the version listed above for your analyzer.

Action Items and Notes:

Please replace the existing pages of the associated manual pages with the enclosed ones according to your facility change control procedures. Conduct any associated training which may be required.

Olympus America Inc. appreciates your business and continued support. If you have any questions regarding this information, please contact our Technical Services Department at 800-223-0130.

Sincerely,

Frank S. Bartholf
Sr. Product Manager

Attachments: New Software Features and Corrections
Update pages for User's Guide

New Software Features:

- Multi-Point Calibration “Slope Check” Function:
 - Set the slope check option to “+” or “-” in [Parameters], [Calibration], [Calibration Specific] for all tests with multi-point calibrations. ***Refer to the chart on the following page.***
 - During a multi-point calibration (AA and 2AB – 7AB) the software checks to verify all OD values are increasing (+) or decreasing (-).
 - If the OD values do not all increase or decrease, an audible alarm “4060 Multi-Point-Cal. OD Slope Check Error” is generated. When this error is generated, a calibration factor is ***not*** generated, and the system uses the current factor to calculate data. If the system does not have a factor, the data does not print, and a “b” flag is generated.
 - The slope check is performed on all calibration formulas.
 - The slope check is not performed on one-point calibration type.

Caution:

Set all multi-point calibrations to “+” or “-” to avoid errors. Do not leave multi-point calibrations at “None”. “None” is the default setting.

	Order No.	Slope (+/-)		Order No.	Slope (+/-)
General Chemistry			Therapeutic Drug Monitoring (Olympus)		
Bicarbonate	OSR6x37	-	Acetaminophen tox	OSR7A229	+
Calcium Arsenazo	OSR6x76	+	Carbamazepine	OSR4F229	+
Calcium oCPC	OSR6x13	+	Digoxin	OSR4H229	+
Hemoglobin A1c	OSR6x92	+	Gentamicin	OSR4T229	+
Special Chemistry			N-Acetylprocainamide	OSR4N229	+
a1-Acid Glycoprotein	OSR6x62	+	Phenobarbital	OSR4D229	+
a1-Antitrypsin	OSR6x63	+	Phenytoin	OSR4A229	+
Apolipoprotein A1	OSR6x42	+	Procainamide	OSR4K229	+
Apolipoprotein B	OSR6x43	+	Quinidine	OSR4Q229	+
Antistreptolysin O	OSR 6x94	+	Salicylate tox	OSR7S229	+
B2-Microglobulin	OSR6x51	+	Theophylline	OSR4P229	+
C3 Complement	OSR6x59	+	Tobramycin	OSR4S229	+
C4 Complement	OSR6x60	+	Valproic Acid	OSR4G229	+
Ceruloplasmin	OSR6x64	+	Vancomycin	OSR4W229	+
C-Reactive Protein	OSR6x47	+	Amikacin	6X0x9	+
C-Reactive Protein	OSR6x99	+	Caffeine	6P4x9	+
Ferritin	OSR6x50	+	Disopyramide	6N3x9	+
Haptoglobin	OSR6x65	+	Ethosuximide	6Exx9	+
Immunoglobulin A	OSR6x44	+	Lidocaine	6M1x9	+
Immunoglobulin G	OSR6x45	+	Methotrexate	6L1x9	+
Immunoglobulin M	OSR6x46	+	Primidone	6C1x9	+
Microalbumin	OSR6x67	+	Drugs of Abuse (Emit II Plus) Semi Quantitative		
Prealbumin	OSR6x75	+	Amphetamine	OSR9C229	+
Rheumatoid Factor	OSR6x105	+	Barbiturate	OSR9D229	+
Transferrin	OSR6x52	+	Benzodiazepine	OSR9F229	+
Thyroid Tests			Cannabinoid	OSR9N229	+
Thyroxine	DRI – 0454	+	Cocaine	OSR9H229	+
T3 -Uptake	DRI – 0723	+	Ecstasy	OSR9X229	+
			Ethanol	OSR9K229	+
			LSD	9L019/9L119	+
			Methadone	OSR9E229	+
			Methaqualone	OSR9Q229	+
			Opiates	OSR9B229	+
			Oxycodone DRI	x00248/x00249	+
			PCP	OSR9J229	+
			Propoxyphene	OSR9G229	+

- Inhibit Data from Printing in OD:
 - When abnormal data is generated, it will print with a “space” and an error flag attached, instead of in OD. This avoids falsely reporting OD as a concentration result.
 - If there is no calibration factor, the test has a “b” flag.
 - If there is no calibration factor for the new lot number, the test has an “)” flag.
 - If the result is abnormal and calculation is not possible, the test has an “!” flag.
- Clot Detection Improvements: ***If a clot is detected:***
 - The sample probe dispenses the clot into the wash well.
 - The sample will not be repeated, even if a repeat requisition was generated based on programmed repeat run criteria.
 - All tests from the sample will be flagged with the “%”.
- Reducing “*” Flag:
 - An option to change the “Linearity Check” and “Reverse-reaction Check” in [System Maintenance], to reduce the chance of “*” flags on BUN and AST. Please contact Olympus Technical services for more information.
- Improved Check for Substrate Depletion:
 - New checks on the calculation of the reaction data have been added for improved detection of substrate depletion.
 - If the result is outside of dynamic range, a “space” with a flag prints, not the concentration and a flag. This will avoid reporting a result with an error flag attached.
 - To enable the improved data checks, set “No Lag Time” to Yes in [Parameters], [Specific Test Parameters]. Tests which should be set to “No Lag Time” Yes:

Test	Catalogue No.	No Lag Time
ALT	OSR6x07	Yes
AST	OSR6x09	Yes
Lipase	OSR6x30	Yes
LD	OSR6x27	Yes
Urea Nitrogen	OSR6x34	Yes

- If the reagent compartment cover is opened during a Measure mode, the analyzer goes to Stop mode immediately.
- Reagent Status enhancements to avoid errors:
 - When F6 Edit is selected, the reagent status becomes “Unchecked”.
 - When “Use Reagent ID” is selected, all other F6 Edit options are disabled.
 - When a position is changed between “Fixed and “Use Reagent ID”, the reagent position information is initialized (cleared).

Corrections (All Analyzers):

- Olympus Support Vision: Personal information does not transmit to the server.
- Data with a “b” flag displays in red in [System Status], [Data Display].
- In Auto Repeat with **barcode** analysis, the system checks the sample ID on the repeat run as well as the rack ID. A “4052 Illegal Repeat Sample ID” alarm is generated if the sample ID verification fails. The system assigns “NOP” and does not perform the repeat. The sample must be repeated manually (not in the Auto Repeat mode). The system continues with the next sample. ***This does not include the AU5400. It is impossible to read the sample ID on the repeat run because the repeat rack does not go past the sample ID reader.***
- In [Routine], [QC Monitor], [Day to Day Control] comments print correctly.

AU2700 Corrections:

- If a selectivity check is started when [System Status], [ISE Status], Result Select Tab is displayed, the data and results displays correctly (not 00/00/1980 Na: 0.0 and K: 0.0).
- When “3201 DI Water Short” occurs, the help screen shows the correct alarm help message.
- In [Auxiliary], [Reagent Consumption], F4 File correctly saves all sample kinds (serum, urine, and other) to a file.
- In [Maintenance], [Periodic Maintenance], F5 Execute can not be selected to update the W2 and Photocal procedures on the grid display.

Document Change Notification

AU400^e User's Guide

This document will be revised as additional information becomes available.

Document Revision Number	Software Version	Date	AU400 ^e User's Guide change description
58		May 15, 2006	Update #111: Please place the method sheet in the Routine Chemistries section. Replace the following: Methods Chapter Contents, Document Change Notification
59		June 16, 2006	Update #114: Please replace or add the attached pages in the appropriate chapters: Chapter C – Basic Operations C-31 – C-32 C-67 – C-68 C-97 – C-98 Chapter D – Software D-99 – D-100 D-125 – D-126 Chapter F – Maintenance F-3 – F-4 Chapter G – Error Flags G-21 – G-24 Chapter H – Troubleshooting H-13 – H-14 Document Change Notification: Pages DCN-5 – DCN-5
60		July 14, 2006	Update #116: Please place the method sheets in the Routine Chemistries, Urine Chemistries, and Specific Protein sections. Replace the following: Methods Chapter Contents, Document Change Notification.
61		August 16, 2006	Update #117: Please place the method sheet in the Urine Chemistries section. Replace the following: Methods Chapter Contents, Document Change Notification
62		November 1, 2006	Update #119 & 121: Please place the method sheets in the Routine Chemistries, Urine Chemistries, and Specific Protein. Replace the following: Methods Chapter Contents, Document Change Notification.
63		November 30, 2006	Update #123: Please replace or add the attached pages in the appropriate chapters: Chapter G: G-13 – G-14 Error Flags *, !, F, and G Document Change Notification: Pages DCN-5
64		January 16, 2007	Update #125: Please place the method sheets in the Routine Chemistries. Replace the following: Methods Chapter Contents, Document Change Notification.

Document Change Notification

AU400^e User's Guide

This document will be revised as additional information becomes available.

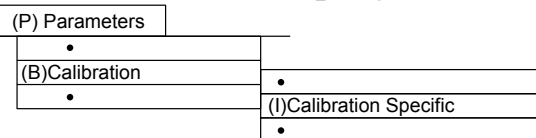
Document Revision Number	Software Version	Date	AU400 ^e User's Guide change description
65		March 2, 2007	Update #127: Please replace or add the attached pages in the appropriate chapters: Main Contents 1-6 Chapter C C-33-C-34 Chapter F F-1-F-2 F-37-F-38 F-61-F-62b Chapter I-27-I-28 Document Change Notification: Pages DCN-5 – DCN-6
66		March 2, 2007	Update #126: Please place the method sheets in the Special Chemistries section. Replace the following: Methods Chapter Contents, Document Change Notification.
67		March 9, 2007	Update #128: Please replace or add the attached pages in the appropriate chapters: AU400e Chapter D- Software D-105-D-108 Document Change Notification: Pages DCN-6 – DCN-7

Relationship of Cup Positions to Calibrator Numbers:

Refer to this chart to determine the specific yellow rack and cup number each calibrator will occupy.

Rack NO.	Cup Position	Calibrator NO.	Rack NO.	Cup Position	Calibrator NO.	Rack NO.	Cup Position	Calibrator NO.	Rack NO.	Cup Position	Calibrator NO.
0001	1	1	0006	1	51	0011	1	A1	0016	1	F1
	2	2		2	52		2	A2		2	F2
	3	3		3	53		3	A3		3	F3
	4	4		4	54		4	A4		4	F4
	5	5		5	55		5	A5		5	F5
	6	6		6	56		6	A6		6	F6
	7	7		7	57		7	A7		7	F7
	8	8		8	58		8	A8		8	F8
	9	9		9	59		9	A9		9	F9
	10	10		10	60		10	B0		10	G0
0002	1	11	0007	1	61	0012	1	B1	0017	1	G1
	2	12		2	62		2	B2		2	G2
	3	13		3	63		3	B3		3	G3
	4	14		4	64		4	B4		4	G4
	5	15		5	65		5	B5		5	G5
	6	16		6	66		6	B6		6	G6
	7	17		7	67		7	B7		7	G7
	8	18		8	68		8	B8		8	G8
	9	19		9	69		9	B9		9	G9
	10	20		10	70		10	C0		10	H0
0003	1	21	0008	1	71	0013	1	C1	0018	1	H1
	2	22		2	72		2	C2		2	H2
	3	23		3	73		3	C3		3	H3
	4	24		4	74		4	C4		4	H4
	5	25		5	75		5	C5		5	H5
	6	26		6	76		6	C6		6	H6
	7	27		7	77		7	C7		7	H7
	8	28		8	78		8	C8		8	H8
	9	29		9	79		9	C9		9	H9
	10	30		10	80		10	D0		10	I0
0004	1	31	0009	1	81	0014	1	D1	0019	1	I1
	2	32		2	82		2	D2		2	I2
	3	33		3	83		3	D3		3	I3
	4	34		4	84		4	D4		4	I4
	5	35		5	85		5	D5		5	I5
	6	36		6	86		6	D6		6	I6
	7	37		7	87		7	D7		7	I7
	8	38		8	88		8	D8		8	I8
	9	39		9	89		9	D9		9	I9
	10	40		10	90		10	E0		10	J0
0005	1	41	0010	1	91	0015	1	E1	0020	1	J1
	2	42		2	92		2	E2		2	J2
	3	43		3	93		3	E3		3	J3
	4	44		4	94		4	E4		4	J4
	5	45		5	95		5	E5		5	J5
	6	46		6	96		6	E6		6	J6
	7	47		7	97		7	E7		7	J7
	8	48		8	98		8	E8		8	J8
	9	49		9	99		9	E9		9	J9
	10	50		10	A0		10	F0		10	K0

3.6.2 Calibration Specific



Description

Use this screen to define the following for each test: calibration type, formula, calibration number, concentration, factor range, stability, and count. Calibration parameters are provided on the methodology sheets located in the User's Guide. Concentration is set using the calibrator package insert values.

See Also

For more information regarding calibration, refer to the Basic Operations Chapter.

Use This Software Screen to...

Set Individual Test Parameters

1. Select [Parameters], [Calibration], [Calibration Specific].
2. Use the pull-down menu or << >> buttons on screen to select a test name.
3. Select a sample type using the pull-down menu.
4. Press function key F4 (set). According to the messages displayed, set analysis parameters.

Use serum cal.: If this box is selected, the data is calculated in accordance with serum calibration during sample analysis. This box displays only if urine sample type is selected.

Cal. type: Select the calibration type for each analysis test from the pull-down menu.

Formula: Set a formula according to the calibration type using the pull-down menu.

Counts: Set the number of times to repeatedly perform calibration analysis and a reagent blank analysis. Enter a number between 1 and 4. Depending on the number, the following values will be used:

Set to 1: The OD value is used.

Set to 2: An average of two values.

Set to 3: An average of two close values.

Set to 4: An average of two values, excluding maximum and minimum values.

Process: Set the method to be used if an update of the calibration fails. Set to either "OD" or "CONC." To perform a concentration conversion using the existing factors, set to "CONC." Otherwise, set to "OD" if a concentration conversion is not initially performed. Save the measured OD value, and batch-perform the concentration conversion after performing the calibration again. This can be set only if the calibration type is set to ACAL (AB, AA, 2AB-7AB).

Cal No. : Enter the calibration number from 1 to 200 defined in the [Parameters], [Calibration Parameters], [Calibrator] menu.

Tip

A maximum of two digits can be entered to specify a calibrator number. If specifying a range between 1 and 99, enter the two numeric values as they are. If specifying a range between 100 and 200, enter the alphanumeric value corresponding to the chart on page D-105 of the User Guide.

Cal. No. of Calibrator specification point 1: This can be set only if the calibration type is set to 2MB - 7MB, AB, AA or 2AB-7MB.

Cal. No. of Calibrator specification point 2: This can be set only if the calibration type is set to 2MB - 7MB, AA or 2AB - 7AB.

Cal. No. of Calibrator specification point 3: This can be set only if the calibration type is set to 3MB - 7MB or 3AB - 7AB.

Cal. No. of Calibrator specification point 4: This can be set only if the calibration type is set to 4MB - 7MB or 4AB - 7AB.

Cal. No. of Calibrator specification point 5: This can be set only if the calibration type is set to 5MB - 7MB or 5AB - 7AB.

Cal. No. of Calibrator specification point 6: This can be set only when the calibration type is set to 6MB - 7MB or 6AB - 7AB.

Cal. No. of Calibrator specification point 7: This can be set only if the calibration type is set to 7MB or 7AB.

Lower limit of a factor range or absorbance range of each calibrator specification point: This can be set only if the calibration type is set to ACAL (AB, AA, 2AB-7AB). Set a factor range if the formula approximation is for a line. Set an absorbance range if the formula approximation is for a curve.

Upper limit of a factor range or absorbance range of each calibrator specification point: This can be set only if the calibration type is set to ACAL (AB, AA, 2AB-7AB).

1-point cal. point: This can be set only if the calibration type is set to 2AB - 7AB. Set a cal. no. up to the maximum point that is specified according to the calibration type. This sets which calibrator will be used for single point calibration.

Slope Check: Slope Check has three settings:

“None” - The default setting.

“+” - Positive slope check compares all increasing OD values to the next calibration point.

“-” - Negative slope check compares all decreasing OD values to the next calibration point.

If an error occurs the user will hear an audible alarm and a error message will be generated.

Processing the Slope Check

When the AU2700 performs a Multi-point calibration, it compares the OD values for the setting (“+” or “-”) selected. If the result of this comparison does not agree with the values selected, an audible alarm is generated and the error message displayed below is displayed where “nn” is the item number and “xxxx” is the test name that produced the error

4060 MULTI POINT-CAL. OD SLOPE CHECK ERROR (nn,xxxx)

If the slope check fails the result will print according to how the process is set in “Calibration Specific Parameters” (OD or CONC).

MB type Factor: This can be set only if the calibration type is set to MB.

Calibration Stability Period: Enter the number of days, between 1 and 999. To set this field to “No setting,” enter a space.

with CONC-0: If there is a standard solution with a concentration value of 0, calibration can be performed at concentration value 0 and at 2 other points. If calibration is made at 2 points, check the check box.

Advanced Calibration: Sets the advanced calibration execution condition (reagent lot number unit or reagent bottle number unit) for the test items being displayed. Select "Lot" or "Lot + Bottle" from the pull-down list. If the advanced calibration is not to be executed, select "None" from the pull-down list.

5. Press function key F2 (exit). Parameters set in this process will be saved.

Set an ISE Test

Set the individual test parameters of each ISE test (Na, K, Cl). Perform the following using a test number set between 97 and 99 in the [Calibration Specific] screen.

1. Select [Parameters], [Calibration], [Calibration Specific].
2. Select the "ISE" tab located in the upper left corner of the screen.
3. Use the pull-down menu or << >> buttons on screen to select a test name.
4. Select a sample type using the pull-down menu.
5. Press function key F4 (set). According to the messages displayed, set analysis parameters.
6. According to the messages displayed, set the analysis parameters. For cal. types, AB factors, and/or calibrator.

Cal. type: Set the calibration type for each analysis test to MCAL or ACAL. The default setting is MCAL. Counts: 1 to 4 for ACAL only. Factor A: slope or multiplier, B: offset or constant, cal. no., conc. factor range: for ACAL.

7. Press function key F2 (exit). *Parameters settings will be saved.*

Generate a Summary of Calibration Types

This system allows the operator to generate a maximum of 15 types of calibrations, depending on the analysis test. Five of the 15 major types of calibration plus 1-point recalibration will be described in the following: