

Much to look forward to in chemistry analyzers

Anne Ford

From the "Obvious Technological Statement of the Year" files: If you bought your cell phone in 1998, it's almost certainly time to get a new one. With all the sleek, streamlined models on the market that can do everything but shine your shoes, weighing yourself down with an old clunker just seems silly. The same may go for mid- and high-volume chemistry analyzers. "There are a lot of five- to 10-year-old chemistry systems in the field that are in need of replacement," says Gus Gardner, Clinical Data chief operating officer. "Many of them have DOS operating systems and are having obsolescence problems."

Fortunately, several new models have recently been or are about to be launched from a range of companies. They don't exactly offer text messaging or video-phone capabilities, but—as Denise Pastore, Bayer clinical chemistry marketing manager, points out—their benefits may sound even more exciting to laboratory technologists and technicians, who "simply put, want things to be smaller, faster, easier."

Abbott Laboratories' Keith Chaitoff, director of global marketing for chemistry, sums up the strength

of his company's new Architect c8000 analyzer in three words: "integration without compromise." He says that while the benefits of integrated systems have been apparent for a while—"reduced workstations in the face of labor shortages, improved workflow for faster turnaround time, reduced errors due to less sample handling, less blood drawn"—some integrated systems of the past required some laboratories to make "significant tradeoffs" because of carryover issues, limited menu, or turnaround times. The Architect c8000, when combined with the i2000 SR immunoassay analyzer, is known as the ci8200 and processes stat samples within 20 seconds because of the retest sample handler, which has no in- or out-queues.

Meanwhile, Clinical Data has just launched the Selectra XL mid- to high-volume chemistry analyzer, which performs up to 480 tests an hour. It features integrated four-parameter dry ISE, a reusable cuvette rotor, positive sample identification, and onboard reagent cooling. And, Gardner adds, "High-tech user features like touch-screen interfaces, flat-screen monitors, and wireless keyboards are all available for users who want them." After all, clean lines and sleek styling are just as attractive in a chemistry analyzer as they are in a cell phone.

As shoppers for any kind of technology know, the only thing more exciting than buying shiny new equipment is the prospect of buying even shinier, newer equipment in the future. In the works at Ortho-Clinical Diagnostics is the Vitros 5,1 FS chemistry system. It will feature several proprietary technologies, such as Intellicheck technology for advanced clot and bubble detection and MicroSensor technology for reagentless and fully automated sample interference monitoring. It will also, says worldwide product director Robert Geen, offer the new MicroTip technology, which "simplifies workflow in the lab by eliminating the water, plumbing, drains, fixed probes, and mixing assemblies characteristic of alternative technologies while doubling the available test menu at the same time."

Chemistry analyzer customers interested in combining their instruments with immunoassay systems can get an early look at Olympus America's AU3000i, scheduled for display at the AACC meeting this month. The AU3000i will be able to be used as a standalone immunoassay system or integrated with an Olympus AU-Connector lab automation workcell in combination with one or more AU chemistry systems. That kind of standardization of systems, says senior product manager Susan Watanabe, is "a relatively new lab strategy

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Chemistry analyzers (for mid-volume laboratories)

Chemistry analyzers

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for lowering operational costs." She adds, "With Olympus standardization, lab personnel can easily move from one AU model used as a primary chemistry analyzer to another AU model used for specialty testing or immunoassay."

New instruments on the horizon from other companies include Bayer's Advia 1200 chemistry system, to be introduced later this year, and Roche's Cobas 6000, which will be introduced in 2005. Already available from Roche are the Integrated Modular Analytics clinical chemistry and immunoassay systems, which, says marketing communications consultant Stacey Bogardus, "can be configured for mid- to high-volume labs."

Labs can look forward to a host of new assays as well. Beckman Coulter is focusing on expanding the menu of its Synchron LXi 725 clinical system, which already features more than 140 assays. "Already we've released a number of new chemistry assays this year, including homocysteine for cardiac as well as tests for key proteins like C3, C4 and haptoglobin," says David Heibel, director of product management marketing.

"Other assays we plan to release within the next few months include an improved HDLD assay, lithium, an improved benzodiazepine test, online hemoglobin A_{1c}, and an improved phosphorus assay." Dade Behring, too, is developing several new tests for its Dimension line of instruments, among them assays for NT-proBNP, microalbumin, N-acetyl procainamide, procainamide, tacrolimus, and cyclosporine. Bayer plans to add Li, TIBC, and wrCRP to its menu. And Abaxis will soon introduce a lipid panel that includes liver enzymes and an oncologist profile.

Awareness Technology offers economy to the 200-test-per-hour laboratory with its user-programmable ChemWell. "All new assays and systems require validation anyway," says Awareness president Mary Freeman, "so why not allow yourself the freedom to choose, optimize, and change your own test menu?" ChemWell can be used for biochemistry or for microwell EIA.

The appeal of all these instruments and assays, of course, lies not in the inherent charm of innovation, but in what they can offer laboratories that are struggling to keep up with increasing health care demands. "The needs of laboratorians in five, 10, or even 20 years are going to be far more intense," Heibel says. "They're going to need systems and processes that can accommodate increasing test volumes. They're going to want to deliver test results faster with greater accuracy. And, in the midst of all this, labs are going to have even less people to meet all the demand. Workstation consolidation and automation systems take away tedious manual steps and are a solution that's available today."

CAP TODAY's lineup of chemistry analyzers begins on this page. Vendors supplied the information listed. Readers interested in a particular analyzer should confirm that it has the stated features and capabilities. □

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Part 1 of 13	ABAXIS Ron Blasig ron.blasig@abaxis.com 3240 Whipple Road Union City, CA 94587 510-675-6505 www.abaxis.com
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Name of instrument/First year sold in U.S.	Piccolo/1995
List price	\$18,000
No. units in clinical use in U.S./Outside U.S.	500/300
Country where designed/Manufactured/Where reagents mftd.	U.S./U.S./U.S.
Operational type/Reagent type	discrete/self-contained single-use cartridges-packages-slides
Sample handling system/Model type	n/a/benchtop
Dimensions in inches (H x W x D)/Instrument footprint	9.5 x 6 x 11.5/1 sq. ft.
No. of tests for which analyzer has FDA-cleared applications	27
Tests clinically released in last 12 months	—
Tests cleared but not clinically released	—
Tests not available in U.S. but submitted for 510(k) clearance	—
Tests not available in U.S. but available in other countries	—
Research-use-only assays	—
Tests in development	lipid plus liver enzymes panel
User-defined methods implemented for what analytes	—
Methods supported/immunoassay methods	photometry/—
No. of direct ion selective electrode channels	—
No. of different measured assays onboard simultaneously	27
No. of different assays programmed, calibrated at once	27
No. of user-definable (open) channels/No. active simultaneously	n/a/27
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	14/14
Shortest/median onboard reagent stability/Refrigerated onboard	n/a/n/a
Multiple reagent configurations supported	yes
Reagent container placed directly on system for use	yes
Instrument has same capabilities when 3rd-party reagent used	n/a
Walkaway capacity in minutes/Specimens/Tests-assays	<13 min/1/14
System is liquid or dry	dry
Uses disposable cuvettes/Max. No. stored	uses reagent disks/n/a
Uses washable cuvettes/Replacement frequency	no
Minimum sample volume aspirated precisely at one time	n/a
Supplied with UPS (backup power)/Requires floor drain	no/—
Requires dedicated water system/Water consumption per hour	no/—
Noise generated in decibels	none
Dedicated pediatric sample cup/Dead volume	no
Primary tube sampling/Pierces caps on primary tubes	n/a/n/a
Sample bar-code reading capability	yes, by handheld scanner as tubes are loaded onto instrument
Reagent bar-code reading capability	yes
Bar code placement per NCCLS standard Auto2A	—
Onboard test auto inventory (determines volume in container)	no
Measures no. tests remaining/Short sample detection/Clot detection	no/yes/yes
Automatic detection of adequate reagent for aspir. & analysis	yes
Hemolysis/Turbidity detection-quantitation	yes/yes
Dilution of patient samples onboard/Automatic rerun capability	no/yes
Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results	no/no
Autocalibration or autocalibration alert	yes
Calibrants stored onboard/Multipoint calibration supported	n/a/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	—/—/—
Automatic shutdown/Startup programmable	no/no
Stat time to completion of all analytes, throughput per hr. for:	
• Sodium, potassium, chloride, TCO ₂	POC: <13 min, ~4 specimens
• Sodium, potassium, chloride, TCO ₂ , glucose, urea, creatinine	same as above for all analytes
• Album., bili. direct & total, AST, ALT, ALP	same as above for all analytes
Typical time delay from ordering stat test to aspir. of sample	n/a
How often QC required/Onboard SW capability to review QC	every 30 days/yes
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes
QC results transferred automatically to LIS	yes
Data mgmt. capability/Instrument vendor supplies LIS interface	no/no
Interfaces up and running in active user sites with	contact vendor
Bidirectional interface capability	no
Test results transmitted to LIS as soon as chem. time complete	yes
LIS interface operates simultaneously with running assays	yes
Uses LOINC to transmit orders & results	—
How labs get LOINC codes for reagent kits	—
Interface avail. (or will be) to automated specimen handling system	no
Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component	no/yes/yes
On-site time of svc. engineer/Onboard error codes for troubleshooting	Piccolo is compact and lightweight and can be returned to mfg. with replacement in 24 hrs
Mean time between failures/To repair failures	3 yr/—
Average time to complete maintenance by lab personnel	n/a
Onboard maintenance records/Maint. training demo module	no/—
Training provided with purchase/Advanced oper. training avail.	2 hr on site/no
Annual service contract cost (24 h/7 d)	\$1,200
Distinguishing features	portable/compact; small sample size; complete panel results in less than 13 minutes

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Survey editor: Raymond Aller, MD

Chemistry analyzers (for mid-volume laboratories)

Part 3 of 13	Awareness Technology Inc. Chris Schneider info@awaretech.com P.O. Box 1679 Palm City, FL 34991 772-283-6540 www.awaretech.com	Beckman Coulter Inc. 200 South Kraemer Blvd. P.O. Box 8000 Brea, CA 92822-8000 800-526-3821 www.beckmancoulter.com
See related comments, page 62		
Name of instrument/First year sold in U.S. List price No. units in clinical use in U.S./Outside U.S. Country where designed/Manufactured/Where reagents mftd. Operational type/Reagent type	ChemWell/1999 \$25,000 10/480 U.S./U.S./open system continuous random access/open reagent system	Synchron CX9 Pro/2001 \$220,600 900/500 U.S./U.S./U.S. & Ireland continuous random access/open reagent system
Sample handling system/Model type Dimensions in inches (H x W x D)/Instrument footprint	rack of 96 samples/benchttop 19 x 36 x 22 in/7 sq ft	sectors, centrifugable/floor standing 69 x 74 x 30 in/15.4 sq ft
No. of tests for which analyzer has FDA-cleared applications	22	>100
Tests clinically released in last 12 months	none	C3, C4, haptoglobin
Tests cleared but not clinically released	none	none
Tests not available in U.S. but submitted for 510(k) clearance Tests not available in U.S. but available in other countries Research-use-only assays Tests in development	18 EIA kits manuf. by BroCheck have been submitted open system open system none	none none none homocysteine, D-dimer, sirolimus, tacrolimus, Ip(a), tricyclics, semiquantitative DATs
User-defined methods implemented for what analytes	all colorimetric biochemistry & EIA that read between 340-700 nm	UIBC, cyclosporine
Methods supported/Immunoassay methods	photometry/microwell assays	photometry, potentiometry, turbidimetric/bidentate turbidimetric, direct turbidimetric, particle enhanced turbidimetric, enzyme immunoassay
No. of direct ion selective electrode channels No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels/No. active simultaneously No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set Shortest/median onboard reagent stability/Refrigerated onboard Multiple reagent configurations supported Reagent container placed directly on system for use Instrument has same capabilities when 3rd-party reagent used Walkaway capacity in minutes/Specimens/Tests-assays System is liquid or dry Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum sample volume aspirated precisely at one time Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption per hour Noise generated in decibels Dedicated pediatric sample cup/Dead volume Primary tube sampling/Pierces caps on primary tubes Sample bar-code reading capability	0 27 unlimited unlimited/27 27/reagent dependent reagent dependent/yes (15°C below ambient) yes reagent dependent yes not limited/96/not limited liquid yes (optional)/96 yes (optional)/weekly 2 µL no/no no/<1 L 60 no no/no yes, by handheld scanner as tubes are loaded onto instrument (2 or 5 interl., UPC, Codabar, codes 39 & 128)/autodiscrimination depends on handheld scanner models	5 (indirect) 33 59 102/33 33/25-2,500 168 hr/30 days/yes (2-8°C) yes yes yes 400/63/2,079 liquid no/n/a yes/permanent-2-yr warranty (80 stored on instrument) 3 µL yes/yes yes/7 L 70 yes/40 µL yes/no yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination
Reagent bar-code reading capability Bar code placement per NCCLS standard Auto2A	no no	yes yes
Onboard test auto inventory (determines volume in container) Measures no. tests remaining/Short sample detection/Clot detection Automatic detection of adequate reagent for aspir. & analysis Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable	yes yes/yes/no yes no/no yes/yes yes/no yes yes/yes user defined for all yes/yes	yes yes/yes/yes yes yes/yes yes/yes yes/yes yes no/yes 24 hr/up to 90 days/up to 60 days/14 days none required
Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TCO2 • Sodium, potassium, chloride, TCO2, glucose, urea, creatinine • Album., bili. direct & total, AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample How often QC required/Onboard SW capability to review QC Onboard real-time QC/Support multiple QC lot Nos. per analyte QC results transferred automatically to LIS	n/a n/a 5.5 min, 28 specimens 15 sec reagent dependent/yes yes/yes yes	52 sec, 75 specimens 52 sec, 75 specimens 10 min, 32 specimens 45 sec 24 hr/yes yes/yes yes
Data mgmt. capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with	onboard/yes (included in price) not known	onboard & optional add-on (SW mfr: Beckman Coulter DL2000)/yes (add'l cost) Cerner, Misys, Mediatech, Citation, MedLab, CHC, Siemens, McKesson, Labquest, CCA, VA-Mumps, all LISs yes (broadcast download & host query)
Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results How labs get LOINC codes for reagent kits	yes (broadcast download) yes yes no supplied by reagent manufacturer	yes yes yes no Web site, customer request
Interface avail. (or will be) to automated specimen handling system	no	yes (Power Processor)
Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component On-site time of svc. engineer/Onboard error codes for troubleshooting Mean time between failures/To repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/Maint. training demo module Training provided with purchase/Advanced oper. training avail. Annual service contract cost (24 h/7 d)	yes/yes/sometimes 48 hr/yes depends on user and varies/depends on problem and varies daily: <5 min; weekly: about 15 min; monthly: about 30 min or less no/no 2 days on site, 3 days at vendor offices/yes \$4,000	yes/no/no metro: same day, rural: same or next day/yes —/— daily: 5 min; weekly: 15 min; monthly: 25 min no/no 5 days at vendor offices/yes —
Distinguishing features	price; one instrument for EIA & biochemistry; completely open and user programmable; special discounts for biochemistry-only; calculates indices; very flexible formatting of reports	serum indices; centrifugable sectors; clot detection; design optimized for automation; continuous random access for samples, controls, reagents, and results; no-maintenance glucose oxygen sensor; no-wait autoloader; polychromatic correction; thermal ring and semi-permanent glass cuvettes; pulsed xenon lamp; advanced workflow and results mgmt.; liquid, ready-to-use reagents, calibrators, controls; DL2000 Workflow and Results Manager

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Chemistry analyzers (for mid-volume laboratories)

Part 4 of 13	Clinical Data slsmktg@clda.com 2 Thurber Blvd. Smithfield, RI 02917 800-345-2822 www.clda.com	Olympus America Inc. Susan M. Watanabe, PhD susan.watanabe@olympus.com Two Corporate Center Dr. Melville, NY 11747 800-223-0125 www.olympus.com
<i>See related comments, page 62</i>		
Name of instrument/First year sold in U.S.	Vitalab Selectra XL/2004	AU400/1998; AU400e/2002
List price	\$98,750	\$130,000
No. units in clinical use in U.S./Outside U.S.	0/—	500/1,700
Country where designed/Manufactured/Where reagents mftd.	Netherlands/Netherlands/U.S.	Japan/Japan/U.S. & Ireland
Operational type/Reagent type	random access/multi-use bottles	random access, discrete, continuous random access/open reagent system
Sample handling system/Model type	rotor/floor standing	rack & stat carousel/floor standing
Dimensions in inches (H x W x D)/Instrument footprint	45 x 46 x 30/12 sq ft	47.6 x 57.1 x 29.9/62.7 sq ft
No. of tests for which analyzer has FDA-cleared applications	31	122
Tests clinically released in last 12 months	ALT, alk phos., albumin, amylase, GOT, direct & total bilirubin, calcium, CO ₂ , chloride, cholesterol, CPK, creatinine, digoxin, direct HDL & LDL, GGT, glucose, total iron, LDH, magnesium, phenobarbital, phenytoin, phosphorus, potassium, total protein, sodium theophylline, triglycerides, BUN, uric acid	ceruloplasmin, urinary/CSF protein, cholinesterase, HbA1c
Tests cleared but not clinically released	—	—
Tests not available in U.S. but submitted for 510(k) clearance	—	—
Tests not available in U.S. but available in other countries	—	—
Research-use-only assays	—	none
Tests in development	hsCRP	lactate
User-defined methods implemented for what analytes	n/a	fructosamine, ammonia
Methods supported/Immunoassay methods	photometry, potentiometry (ISE)/immunoturbidimetric	photometry, potentiometry, calculated tests/homogeneous
No. of direct ion selective electrode channels	4	3
No. of different measured assays onboard simultaneously	40	up to 76
No. of different assays programmed, calibrated at once	40	99
No. of user-definable (open) channels/No. active simultaneously	5/40	95/—
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	70/700	76/100–1,333
Shortest/median onboard reagent stability/Refrigerated onboard	72 hr/7 days/yes (12°C below ambient)	120 hr/30 days/yes (4–12°C)
Multiple reagent configurations supported	—	yes
Reagent container placed directly on system for use	yes	yes
Instrument has same capabilities when 3rd-party reagent used	yes	yes
Walkaway capacity in minutes/Specimens/Tests-assays	240/80/2,400	varies/up to 102/varies
System is liquid or dry	liquid	liquid
Uses disposable cuvettes/Max. No. stored	no	no/n/a
Uses washable cuvettes/Replacement frequency	yes/every 10,000 reactions	yes/permanent
Minimum sample volume aspirated precisely at one time	1 µL	2 µL
Supplied with UPS (backup power)/Requires floor drain	yes/no	no (optional)/yes (no w/ optional water pump)
Requires dedicated water system/Water consumption per hour	no/0.8 L	yes/26 L per hr peak consumption
Noise generated in decibels	—	65
Dedicated pediatric sample cup/Dead volume	yes/20 µL	no/n/a
Primary tube sampling/Pierces caps on primary tubes	yes/no	yes/no
Sample bar-code reading capability	yes, as sample is being aspirated (2 of 5 interl., UPC, Codabar, codes 39 & 128)	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination
Reagent bar-code reading capability	no	yes
Bar code placement per NCCLS standard Auto2A	yes	yes
Onboard test auto inventory (determines volume in container)	yes	yes
Measures no. tests remaining/Short sample detection/Clot detection	yes/yes/yes	yes/yes/yes
Automatic detection of adequate reagent for aspir. & analysis	yes	yes
Hemolysis/Turbidity detection-quantitation	—/—	yes/yes
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/yes
Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results	yes/no	yes/yes
Autocalibration or autocalibration alert	yes	yes
Calibrants stored onboard/Multipoint calibration supported	no/yes	yes/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	4 hr/1–14 days/—/—	1 day/30 days/14 days/14–20 days
Automatic shutdown/Startup programmable	yes/yes	yes/yes
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO ₂	8 min, —	<5 min, 200 specimens
• Sodium, potassium, chloride, TCO ₂ , glucose, urea, creatinine	10 min, —	<5 min, 80 specimens
• Album., bili. direct & total, AST, ALT, ALP	10 min, —	<9 min, 67 specimens
Typical time delay from ordering stat test to aspir. of sample	6 min	<2 min
How often QC required/Onboard SW capability to review QC	shortest interval: 4 hr; longest: once a day/yes	per CLIA & laboratory's decision/yes
Onboard real-time QC/Support multiple QC lot Nos. per analyte	no/yes	yes/yes
QC results transferred automatically to LIS	yes	yes
Data mgmt. capability/Instrument vendor supplies LIS interface	optional add on/yes	onboard/no (optional)
Interfaces up and running in active user sites with	—	all common interfaces including Cerner, Antrim, CCA, Chemware, Dawning Technol., ADAC, Dynamic Healthcare, Antek, Siemens, McKesson (Data Innov.), CPSI, Mediatech, Misys, Citation
Bidirectional interface capability	yes	yes (broadcast download & host query)
Test results transmitted to LIS as soon as chem. time complete	yes	yes
LIS interface operates simultaneously with running assays	yes	yes
Uses LOINC to transmit orders & results	—	no
How labs get LOINC codes for reagent kits	—	—
Interface avail. (or will be) to automated specimen handling system	—	yes
Modem servicing available/Can diagnose own malfunctions/Determine malfunctioning component	no/yes/yes	yes/yes/yes
On-site time of svc. engineer/Onboard error codes for troubleshooting	within 24 hr/yes	<24 hr/yes
Mean time between failures/To repair failures	6 mo/4 hr	average 2 calls per yr/<24 hr
Average time to complete maintenance by lab personnel	daily: 10 min; weekly: 20 min; monthly: 60 min	daily: 3 min; weekly: 7 min; monthly: 45 min
Onboard maintenance records/Maint. training demo module	no/yes	yes (includes audit trail of who replaced parts)/yes
Training provided with purchase/Advanced oper. training avail.	3 days on site/yes	3–5 days on site, 5 days at vendor offices/yes
Annual service contract cost (24 h/7 d)	n/a	inquire
Distinguishing features	4 parameter dry ISE with CO ₂ ; reusable reaction cuvette rotor; onboard wash system	Olympus is a leader in standardization with its family of chemistry immuno systems, the AU400, AU400e, AU600, AU640, AU640e, AU2700, and AU5400; broad test menu of 122 methods delivers standardized results for improved patient management and streamlined operation; speed, reliability, advanced data management, and unprecedented onboard automation for one of the best walkaways in industry today

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Chemistry analyzers (for mid-volume laboratories)

Part 5 of 13	Roche Diagnostics Todd Atkinson, Product Manager 9115 Hague Rd., P.O. Box 50457 Indianapolis, IN 46250 800-428-5074 www. Roche.com	Roche Diagnostics Lisa Davis, Product Manager 9115 Hague Rd. Indianapolis, IN 46250 800-428-5074 ext. 3531 us.labsystems.roche.com
See related comments, page 62		
Name of instrument/First year sold in U.S. List price No. units in clinical use in U.S./Outside U.S. Country where designed/Manufactured/Where reagents mftd. Operational type/Reagent type	Cobas Integra 800/2001 (Integra introduced 1995) \$265,000 >500/>2,000 Switzerland/Switzerland/multiple countries random access, discrete, continuous random access/self-contained multi-use cartridges-packages-slides sample racks: RD 5-position rack/floor standing 47.3 x 74.8 x 35.4/—	Integrated Modular Analytics/2002 varies >50/>200 multiple countries/multiple countries/multiple countries continuous random access/self-contained, multi-use cartridges-pack-ages-slides 5-position rack/floor-standing varies with configuration/varies with configuration
Sample handling system/Model type Dimensions in inches (H x W x D)/Instrument footprint		
No. of tests for which analyzer has FDA-cleared applications Tests clinically released in last 12 months Tests cleared but not clinically released Tests not available in U.S. but submitted for 510(k) clearance Tests not available in U.S. but available in other countries	137 — — none LDH (P→L), ALP (DGKC)	>140 amikacin, quinidine, SHBG, C-peptide n/a n/a TG, anti-TG, urine cortisol, kappa, lambda, apoA, apoB, Lp(a), osteocalcin, P1NP n/a anti-HBc, anti-HBc IgM, anti-HBe, HBe-Ag, rubella IgG, rubella IgM, toxog IgG, toxo IgM, CA 19-9, CA 72-4, Lp PLA ₂ , vancomycin, lidocaine, cyclosporin yes, varies
Research-use-only assays Tests in development	— IgE, lipoprotein (a), kappa/lambda light chains, IMA	
User-defined methods implemented for what analytes	yes, varies	
Methods supported/Immunoassay methods	photometry, potentiometry, fluorescence polarization/ turbidimetric	photometry, potentiometry (ion selective electrode)/ electrochemiluminescence
No. of direct ion selective electrode channels No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels/No. active simultaneously No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set Shortest/median onboard reagent stability/Refrigerated onboard Multiple reagent configurations supported Reagent container placed directly on system for use Instrument has same capabilities when 3rd-party reagent used Walkaway capacity in minutes/Specimens/Tests-assays System is liquid or dry Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum sample volume aspirated precisely at one time Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption per hour Noise generated in decibels Dedicated pediatric sample cup/Dead volume Primary tube sampling/Pierces caps on primary tubes Sample bar-code reading capability	4 72 72 0/n/a 72/50-800 336 hr/84 days/yes (8°C) yes yes no 450/180/4,000 liquid yes/3,600 no/n/a 2 µL yes/yes no (direct connection, type I NCCLS)/5-7 L 58.5 yes/approx. 50-70 µL yes/no yes (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination	3 72->140 72->140 varies 72->140/100-3,000 72 hr/90 days/yes (2-12°C) yes yes limited 6 hr/300/varies liquid yes, 1,000 tests yes/monthly 2 µL yes/yes yes/50 L <62 yes/50 µL yes/no yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination yes yes
Reagent bar-code reading capability Bar code placement per NCCLS standard Auto2A	yes yes	yes yes
Onboard test auto inventory (determines volume in container) Measures no. tests remaining/Short sample detection/Clot detection Automatic detection of adequate reagent for aspir. & analysis Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable	yes yes/yes/yes yes yes/yes yes/yes yes/yes yes yes/yes 5 hr/once per lot/140 days/60 days yes/yes	yes yes/yes/yes yes yes/yes yes/yes yes no/yes 24 hr/varies from bottle change to lot change/bottle change/— yes/yes
Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TC02 • Sodium, potassium, chloride, TC02, glucose, urea, creatinine • Album., bili. direct & total, AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample How often QC required/Onboard SW capability to review QC Onboard real-time QC/Support multiple QC lot Nos. per analyte QC results transferred automatically to LIS	8.6 min, 118 specimens 8.6 min, 99 specimens 9.8, 118 specimens 1 min typically once per 24 hr/yes yes/yes yes	3.5 min, 300-600 specimens 5.5 min, 160-600 specimens 10 min, 133-600 specimens 50 sec 24 hr/yes yes/yes yes
Data mgmt. capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with	onboard/yes (add'l cost) Cerner, CHCS, Citation, Compton, CompuLab, DynaMedix, EDS, Fletcher Flora, McKesson (ALG, PathLabs, StarLabs), HMS, Intellilabs, Isys, LabDaq, Labforce, Labfusion, LabSoft, LCI, Meditech, Northern Soft, Orsys, Seacoast, Siemens, Soft Computer, Misys	onboard/no (add'l cost) all major LIS vendors
Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results How labs get LOINC codes for reagent kits	yes (broadcast download & host query) yes yes no —	yes (broadcast download & host query) yes yes no database
Interface avail. (or will be) to automated specimen handling system	no	yes (Roche Pre-Analytical Modular)
Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component On-site time of svc. engineer/Onboard error codes for troubleshooting Mean time between failures/To repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/Maint. training demo module	yes/yes/yes 8 hr or next business day/yes —/— daily: <1 min; weekly: <5 min; monthly: none yes (includes audit trail of who replaced parts)/yes (onscreen help with diagrams & maintenance wizard)	yes/yes/yes 8 hr/yes 260 days/3.5 hr daily: 5 min hands-on; weekly: 30 min; monthly: 15 min yes (includes audit trail of who replaced parts)/yes
Training provided with purchase/Advanced oper. training avail. Annual service contract cost (24 h/7 d)	1 day on site, 5 days at vendor offices/yes varies	5 days at vendor offices/yes varies
Distinguishing features	comprehensive test menu including hemoglobin A1c; reagent cassette requires no operator prep. or special handling (can go straight from refrigerator to system with no warmup time); 97 percent of reagents are liquid, ready to use, system automatically reconstitutes if necessary, system forecasts daily reagent requirements based on history; operator maintenance automatically scheduled by system, based on actual use, not by calendar schedule; (800 has clot detection, bubble detection, and can accommodate universal five-position Roche rack for modular systems and Elecsys IA analyzers)	high-throughput clinical chemistry and immunoassay system with single point of entry; single user interface; single host connection, providing productivity & efficiency gains; system offers flexibility to easily expand configuration on site; enhanced intelligent process management achieves optimized sample routing, seamless integration of stat samples into routine workflow, automatic rerun and repeat testing selectable by test and real-time reflex testing with Middleware Solutions

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Chemistry analyzers (for high-volume laboratories)

Part 6 of 13	Abbott Diagnostics Brian Michalski brian.michalski@abbott.com 100 Abbott Park Road Abbott Park, IL 60064 800-323-9100 www.abbott.com	Bayer HealthCare, Diagnostics Division Denise Pastore denise.pastore.b@bayer.com 511 Benedict Ave. Tarrytown, NY 10591 914-333-6162 labnews.com
<i>See related comments, page 62</i>		
Name of instrument/First year sold in U.S. List price No. units in clinical use in U.S./Outside U.S. Country where designed/Manufactured/Where reagents mftd. Operational type/Reagent type	Abbott Aeroset/1998 \$345,000 330/600+ Japan/Japan/U.S. continuous random access/open reagent system	ADVIA 1650/1999 \$279,000 180/805 Japan/Japan/Ireland batch, random access, discrete, continuous random access/open reagent system
Sample handling system/Model type Dimensions in inches (H x W x D)/Instrument footprint	rack, carousel/floor standing 42.7 x 74.4 x 44.1/22.7 sq ft	automated rack handler, sample carousel/floor standing 45 x 59 x 34/14 sq ft
No. of tests for which analyzer has FDA-cleared applications Tests clinically released in last 12 months	62 digoxin, valproic acid, CRP, RF, HbA1c, direct LDL, phenytoin	74 TIBC, C3, C4, haptoglobin
Tests cleared but not clinically released	microalbumin	salicylate, ethanol, acetaminophen
Tests not available in U.S. but submitted for 510(k) clearance Tests not available in U.S. but available in other countries	— A-1-AGP, ASP, β 2-microglobulin, digitoxin, ferritin, IgE, myoglobin, hsCRP, alpha amylase pancreatic, alpha HBDH, cholinesterase, CK-MB	none —
Research-use-only assays Tests in development	— ultra HDL, ammonia, ceruloplasmin, iron (UIBC), A-1 antitrypsin	none lithium
User-defined methods implemented for what analytes	ammonia, lithium	alcohol, C3, C4, salicylate, CK-MB, myoglobin, fructosamine, β 2-microglobulin, DAUs
Methods supported/Immunoassay methods No. of direct ion selective electrode channels No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels/No. active simultaneously No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set Shortest/median onboard reag. stability/Refrigerated onboard Multiple reag. configurations supported Reag. container placed directly on system for use Instrument has same capabilities when 3rd-party reag. used Walkaway capacity in minutes/Specimens/Tests-assays System is liquid or dry Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum sample volume aspirated precisely at one time Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption per hour Noise generated in decibels Dedicated pediatric sample cup/Dead volume Primary tube sampling/Pierces caps on primary tubes Sample bar-code reading capability	photometry, potentiometry/— 3 59 100 100/59 59/400 7 days/28 days/yes yes yes yes 60/231/50,000+ liquid no/n/a yes/minimum 1 yr guaranteed 2 μ L no/no yes/45 L — yes/50 μ L yes/no yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination	photometry, potentiometry, turbidimetrics/— 3 49 100 62/62 49/840 72 hr/28 days/yes yes yes yes 90-470/200/32,000 liquid no/n/a yes/4 mo (221 stored on instrument) 2 μ L yes/yes yes/25 L — yes/50 μ L yes/no yes (2 of 5 interl., Codabar [NW7], codes 39 & 128)/autodiscrimination
Reagent bar-code reading capability Bar code placement per NCCLS standard Auto2A	yes yes	yes yes
Onboard test auto inventory (determines volume in container) Measures no. tests remaining/Short sample detection/Clot detection Automatic detection of adequate reag. for aspir. & analysis Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable	yes yes/yes/no yes yes/yes yes/yes yes/yes yes yes/yes 8 hr/28 days/28 days/28 days yes/yes	yes yes/yes/yes yes yes/yes yes/yes yes/yes yes yes/yes daily/30 days/30 days/daily yes/yes
Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TC02 • Sodium, potassium, chloride, TC02, glucose, urea, creatinine • Album., bili. direct & total, AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample How often QC required/Onboard SW capability to review QC Onboard real-time QC/Support multiple QC lot Nos. per analyte QC results transferred automatically to LIS	10 min, 200+ specimens 10 min, 200+ specimens 10 min, 200+ specimens <15 sec shortest interval: 8 hr (ISE); longest: 24 hr/yes yes/yes yes	10 min, 150 samples, 600 tests 10 min, 150 samples, 1,050 tests 10 min, 200 samples, 1,200 tests 3 sec per CLIA and laboratory's decision/yes yes/yes yes
Data mgmt. capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with	no/yes (add'l cost) all major vendors	onboard/no Soft, Misys, Cerner, Meditech, Multidata, Seacoast, Triple G, CCA, Comp Service & Suppt Q, Fletcher Flora, HDS, PSA Consultants, Siemens
Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results How labs get LOINC codes for reagent kits	yes (broadcast download & host query) yes yes no —	yes (broadcast download & host query) yes yes yes e-mail, software
Interface avail. (or will be) to automated specimen handling system	in development	yes (all systems)
Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component On-site time of svc. engineer/Onboard error codes for troubleshooting Mean time between failures/To repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/Maint. training demo module Training provided with purchase/Advanced oper. training avail. Annual service contract cost (24 h/7 d)	no/no/no <24 hr/yes >2 mo/varies daily: 5 min; weekly: 10 min; monthly: 30 min no/no 5 days on site, 5 days at vendor offices/no \$23,700	yes/yes/yes 4-8 hr/yes —/4-8 hr daily: 10 min; weekly: 45 min; monthly: 1 hr yes/yes ongoing on site, 5 days at vendor offices/— \$23,000
Distinguishing features	workstation consolidation; high throughput; large capacity; reliable; flexible system, extended assay linearity, open channel test capability, integrated chip technology for ISE (minimum 45,000 tests per ICT module), auto repeat and auto dilution capability, low sample volume (2-35 μ L)	system will aspirate every three seconds and retain aliquot onboard; original sample is available to leave system; all testing performed with aliquot of sample remaining on ADVIA 1650; all reruns/repeats/dilutions automatically performed without operator intervention; microvolume technology allows up to 840 tests from a 70-mL test wedge of reagent; reflex testing available; 99 percent uptime guarantee

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Chemistry analyzers (for high-volume laboratories)

<p>Part 7 of 13</p> <p><i>See related comments, page 62</i></p>	<p>Bayer HealthCare, Diagnostics Division Denise Pastore denise.pastore.b@bayer.com 511 Benedict Ave. Tarrytown, NY 10591 914-333-6162 labnews.com</p>	<p>Beckman Coulter Inc. 200 South Kraemer Blvd. P.O. Box 8000 Brea, CA 92822-8000 800-526-3821 www.beckmancoulter.com</p>
<p>Name of instrument/First year sold in U.S. List price No. units in clinical use in U.S./Outside U.S. Country where designed/Manufactured/Where reagents mftd. Operational type/Reagent type</p>	<p>ADVIA 2400/2003 \$305,000 10/9 Japan/Japan/Ireland random access/self-contained single-use cartridges-packages-slides; open reagent system</p>	<p>Synchron LX20/1997 \$278,000 900/400 U.S./U.S./U.S. & Ireland continuous random access/open reagent system</p>
<p>Sample handling system/Model type Dimensions in inches (H x W x D)/Instrument footprint</p>	<p>carousel, rack handler option, automation option/floor standing 1,157 x 1,711 x 934 mm/—</p>	<p>racks, centrifugable/floor standing LX20 60 x 70 x 41/19.9 sq ft; LX4201 60 x 140 x 41/39.8 sq ft</p>
<p>No. of tests for which analyzer has FDA-cleared applications Tests clinically released in last 12 months</p>	<p>69 valproic acid, TIBC, C3, C4, RH, TDMs, pre-albumin, ASO, AAT</p>	<p>>100 C3, C4, haptoglobin</p>
<p>Tests cleared but not clinically released Tests not available in U.S. but submitted for 510(k) clearance Tests not available in U.S. but available in other countries Research-use-only assays Tests in development</p>	<p>none none none none salicylate, ethanol, lithium, acetaminophen</p>	<p>none none none none homocysteine, D-dimer, sirolimus, tacrolimus, Lp(a), tricyclic., semiquantitative DATs, lithium, HbA1c online, IMA UIBC, cyclosporine, homocysteine</p>
<p>User-defined methods implemented for what analytes</p>	<p>—</p>	<p>UIBC, cyclosporine, homocysteine</p>
<p>Methods supported/Immunoassay methods</p>	<p>photometry, potentiometry (ISE)/homogeneous turbidimetric</p>	<p>photometry, potentiometry, near infrared/bidentate turbidimetric, direct turbidimetric, particle enhanced turbidimetric, enzyme immunoassay</p>
<p>No. of direct ion selective electrode channels No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels/No. active simultaneously No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set Shortest/median onboard reag. stability/Refrigerated onboard Multiple reag. configurations supported Reag. container placed directly on system for use Instrument has same capabilities when 3rd-party reag. used Walkaway capacity in minutes/Specimens/Tests-assays System is liquid or dry Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum sample volume aspirated precisely at one time Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption per hour Noise generated in decibels Dedicated pediatric sample cup/Dead volume Primary tube sampling/Pierces caps on primary tubes Sample bar-code reading capability</p>	<p>3 46 colorimetric, 3 ISE 100 100/49 —/500 24 hr/14 day/yes (6–12°C) no yes yes 3.8 hr max./234/32,000 photometric, +90,000 ISE liquid no/340 yes/every 4 months 2 µL of diluted specimen yes/yes (or sink) yes/40 L <50 yes/~50 µL yes/no yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)</p>	<p>5 (indirect) 41 100 100/41 41/10,650 168 hr/30 days/yes (2–8°C) yes yes no 83/132/5,280 liquid no/n/a yes/semipermanent—2-yr warranty (250 stored on instrument) 3 µL yes/no yes/16 L 65 yes/40 µL (samples directly from pediatric bullet) yes/no yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination yes yes</p>
<p>Reagent bar-code reading capability Bar code placement per NCCLS standard Auto2A</p>	<p>yes yes</p>	<p>yes yes</p>
<p>Onboard test auto inventory (determines volume in container) Measures no. tests remaining/Short sample detection/Clot detection Automatic detection of adequate reag. for aspir. & analysis Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced/Increased to rerun out-of-linear- range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable</p>	<p>yes yes/yes/yes yes yes/yes yes/yes yes/— no yes/yes once per day/once per month/once per month/once per month yes/yes</p>	<p>yes yes/yes/yes yes yes/yes yes/yes yes/yes yes no/yes 24 hr/up to 90 days/up to 60 days/14 days none required</p>
<p>Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TCO2 • Sodium, potassium, chloride, TCO2, glucose, urea, creatinine • Album., bili. direct & total, AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample How often QC required/Onboard SW capability to review QC Onboard real-time QC/Support multiple QC lot Nos. per analyte QC results transferred automatically to LIS</p>	<p>11 min, 200 samples 11 min, 200 samples 11 min, 300 samples 30 sec shortest interval: 8 hr; longest: 24 hr/yes yes/yes yes</p>	<p>38 sec, 90 specimens 38 sec, 90 specimens 8 min, 90 specimens 16 sec 24 hr/yes yes/yes yes</p>
<p>Data mgmt. capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results How labs get LOINC codes for reagent kits</p>	<p>onboard/included in system price (TDC Technodata or Bayer CentralLink) Dawning, Paradox LIS, PerSé, Data Innovations, Misys, Soft, Cerner, Citation yes (broadcast download & host query) yes yes yes via software</p>	<p>onboard & optional add-on (Beckman Coulter DL2000)/yes (add'l cost) Cerner, Misys, Meditech, Citation, MedLab, CHC, Siemens, McKesson, Labquest, CCA, VA-Mumps, all LISs yes (broadcast download & host query) yes yes no Web site, customer request</p>
<p>Interface avail. (or will be) to automated specimen handling system</p>	<p>yes (with ADVIA WorkCell as of October 2003)</p>	<p>yes (Power Processor, total lab automation)</p>
<p>Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component On-site time of svc. engineer/Onboard error codes for troubleshooting Mean time between failures/To repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/Maint. training demo module Training provided with purchase/Advanced oper. training avail. Annual service contract cost (24 h/7 d)</p>	<p>yes/yes/yes varies by location, generally <4 hr/yes — daily: <5 min; weekly: 10 min; monthly: 20 min yes/yes varies according to need on site; 5 days at vendor offices/yes \$23,500</p>	<p>yes/yes/yes metro: same day, rural: same or next day/yes —/— daily: none; weekly: 5 min; monthly: 25 min no/no 5 days at vendor offices/yes —</p>
<p>Distinguishing features</p>	<p>system provides true workstation consolidation with more than 80 available chemistry and special chemistry methods and applications; also offers user-defined methods that equate to cost-effective consolidation; offers unrivaled walkaway capability with an onboard capacity of >450 specimens with the Universal Rack Handler option; 32,000 photometric tests and 90,000 ISE tests; sample saver technolo- gy allows automatic repeats, dilutions and reflex testing without operator intervention of having to return to the original specimen</p>	<p>serum indices; centrifugable racks; clot detection; no-wait autoloader/linear racks; multiple wavelength blanking; smart modules, fiber optics; advanced workflow and data management; thermal ring and semipermanent glass cuvettes; pulsed xenon lamp; electronic stat notification; review by exception; reflex testing; add-on test, DL2000 Workflow and Results Manager</p>

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Chemistry analyzers (for high-volume laboratories)

Part 8 of 13	Beckman Coulter Inc. 200 South Kraemer Blvd. P.O. Box 8000 Brea, CA 92822-8000 800-526-3821 www.beckmancoulter.com	Beckman Coulter Inc. Craig Hoechstetter 200 South Kraemer Blvd. P.O. Box 8000 Brea, CA 92822 800-526-3821 www.beckmancoulter.com
<i>See related comments, page 62</i>		
Name of instrument/First year sold in U.S.	Synchron LX20 Pro/2001	Synchron LXI725/2002
List price	\$343,000	—
No. units in clinical use in U.S./Outside U.S.	500/200	200/100
Country where designed/Manufactured/Where reagents mftd.	U.S./U.S./U.S. & Ireland	U.S./U.S./U.S.
Operational type/Reagent type	continuous random access/open reagent system	continuous random access/open reagent system
Sample handling system/Model type	racks, centrifugable/floor standing	racks, centrifugable/floor standing
Dimensions in inches (H x W x D)/Instrument footprint	60 x 70 x 41/19.9 sq ft	60 x 134.5 x 48/44.8 sq ft
No. of tests for which analyzer has FDA-cleared applications	>100	>135
Tests clinically released in last 12 months	C3, C4, haptoglobin	C3, C4, haptoglobin, Triage BNP, GI monitor (CA 19.9 antigen), BR monitor (CA 15.3 antigen)
Tests cleared but not clinically released	none	none
Tests not available in U.S. but submitted for 510(k) clearance	none	none
Tests not available in U.S. but available in other countries	none	none
Research-use-only assays	none	none
Tests in development	homocysteine, D-dimer, sirolimus, tacrolimus, Lp(a), tricyclic., semiquantitative DATs, lithium, HbA1c online, IMA	DHEAS, intact PTH, intrinsic factor, EPO, HbA1c online, IL6, IMA, lithium, dsDNA, D-dimer, TNF- α
User-defined methods implemented for what analytes	UIBC, cyclosporine, homocysteine	UIBC, homocysteine
Methods supported/Immunoassay methods	photometry, potentiometry, near infrared-bidentate turbidimetric, direct turbidimetric, particle enhanced turbidimetric/enzyme immunoassay, near infrared particle immunoassay	photometry, potentiometry (ISE), near infrared-bidentate turbidimetric, direct turbidimetric, particle enhanced turbidimetric/enzyme immunoassay, chemiluminescence
No. of direct ion selective electrode channels	5 (indirect)	5 (indirect)
No. of different measured assays onboard simultaneously	41	65
No. of different assays programmed, calibrated at once	100	124
No. of user-definable (open) channels/No. active simultaneously	100/41	100/100
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	41/10,650	65/11,850
Shortest/median onboard reagent stability/Refrigerated onboard	168 hr/30 days/yes (2–8°C)	168 hr/28 days/yes (2–10°C)
Multiple reagent configurations supported	yes	yes
Reagent container placed directly on system for use	yes	yes
Instrument has same capabilities when 3rd-party reagent used	no	no
Walkaway capacity in minutes/Specimens/Tests-assays	83/132/5,280	180/132/5,280
System is liquid or dry	liquid	liquid
Uses disposable cuvettes/Max. No. stored	no/n/a	yes/294 (immuno)
Uses washable cuvettes/Replacement frequency	yes/semipermanent—2-yr warranty (250 stored on instrument)	yes/2 yr (chemistry)
Minimum sample volume aspirated precisely at one time	3 μ L	3 μ L
Supplied with UPS (backup power)/Requires floor drain	yes/no	yes/yes
Requires dedicated water system/Water consumption per hour	yes/16 L	yes/16 L
Noise generated in decibels	65	n/a
Dedicated pediatric sample cup/Dead volume	yes/40 μ L	—
Primary tube sampling/Pierces caps on primary tubes	yes/yes	yes/yes
Sample bar-code reading capability	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination
Reagent bar-code reading capability	yes	yes
Bar code placement per NCCLS standard Auto2A	yes	yes
Onboard test auto inventory (determines volume in container)	yes	yes
Measures no. tests remaining/Short sample detection/Clot detection	yes/yes/yes	yes/yes/yes
Automatic detection of adequate reagent for aspir. & analysis	yes	yes
Hemolysis/Turbidity detection-quantitation	yes/yes	yes (chemistry)/yes (chemistry)
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/yes
Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results	yes/yes	yes (chemistry but not immuno)/yes (chemistry but not immuno)
Autocalibration or autocalibration alert	yes	yes (chemistry but not immuno)
Calibrants stored onboard/Multipoint calibration supported	no/yes	no/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	1 day/up to 90 days/up to 60 days/14 days	24 hr/up to 90 days/up to 60 days/14 days
Automatic shutdown/Startup programmable	none required	none required
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO ₂	38 sec, 90 specimens	38 sec, 90 specimens
• Sodium, potassium, chloride, TCO ₂ , glucose, urea, creatinine	38 sec, 90 specimens	38 sec, 90 specimens
• Album., bili. direct & total, AST, ALT, ALP	8 min, 90 specimens	8 min, 90 specimens
Typical time delay from ordering stat test to aspir. of sample	16 sec	36 sec
How often QC required/Onboard SW capability to review QC	24 hr/yes	shortest: 24 hr; longest: n/a/yes
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes
QC results transferred automatically to LIS	yes	yes
Data mgmt. capability/Instrument vendor supplies LIS interface	onboard & optional add-on (Beckman Coulter DL2000)/yes (add'l cost)	onboard & optional add-on (Beckman Coulter DL2000)/yes (add'l cost)
Interfaces up and running in active user sites with	Cerner, Misys, Meditech, Citation, MedLab, CHC, Siemens, McKesson, Labquest, CCA, VA-Mumps, all LISs	Cerner, Misys
Bidirectional interface capability	yes (broadcast download & host query)	yes (broadcast download & host query)
Test results transmitted to LIS as soon as chem. time complete	yes	yes
LIS interface operates simultaneously with running assays	yes	yes
Uses LOINC to transmit orders & results	no	yes
How labs get LOINC codes for reagent kits	Web site, customer request	customer request
Interface avail. (or will be) to automated specimen handling system	yes (Power Processor, total lab automation)	no
Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component	yes/yes/yes	yes/yes/yes
On-site time of svc. engineer/Onboard error codes for troubleshooting	metro: same day, rural: same or next day/yes	metro: same day, rural: same or next day/yes
Mean time between failures/To repair failures	—/—	n/a/n/a
Average time to complete maintenance by lab personnel	daily: none; weekly: 5 min; monthly: 25 min	daily: 15 min; weekly: 33.5 min; monthly: 25 min
Onboard maintenance records/Maint. training demo module	no/no	no/no
Training provided with purchase/Advanced oper. training avail.	5 days at vendor offices/yes	10 days at vendor offices/yes
Annual service contract cost (24 h/7 d)	—	n/a
Distinguishing features	serum indices; centrifugable racks; clot detection; no-wait autoloader/linear racks; multiple wavelength blanking; smart modules, fiber optics; advanced workflow & data management; thermal ring and semipermanent glass cuvettes; pulsed xenon lamp; electronic stat notification; review by exception; reflex testing; add-on test; closed-tube sampling, near infrared detection (for high-sensitivity CRP), DL2000 Workflow and Results Manager	workstation consolidation without compromise through single point of sample entry for both chemistry and immunoassay testing; closed-tube sampling; one of fastest stats for chemistry samples; dual scheduling and parallel processing of chemistry and immunoassay samples for optimum throughput; menu equivalence to Synchron and Access product lines

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Chemistry analyzers (for high-volume laboratories)

Part 9 of 13	Dade Behring Inc. P.O. Box 6101 Newark, DE 19714-6101 800-242-3233 www.dadebehring.com	Olympus America Inc. Susan M. Watanabe, PhD susan.watanabe@olympus.com Two Corporate Center Dr. Melville, NY 11747 800-223-0125 www.olympus.com
<i>See related comments, page 62</i>		
Name of instrument/First year sold in U.S.	Dimension RxL Integrated Chemistry System w/ Heterogeneous Module (HM)/1997; Dimension RxL Max Integrated Chemistry System/2003	AU640/1999; AU640e/2002
List price	—	\$185,000
No. units in clinical use in U.S./Outside U.S.	RxL: 2,500/—; RxL Max: >600/—	300/>1,000
Country where designed/Manufactured/Where reagents mftd.	U.S./U.S./U.S.	Japan/Japan/U.S. & Ireland
Operational type/Reagent type	batch, random access, continuous random access/self-contained multiuse cartridges-packages-slides	random access, discrete, continuous random access/open reagent system
Sample handling system/Model type	segmented sample wheel/floor standing	rack & stat carousel/floor standing
Dimensions in inches (H x W x D)/Instrument footprint	44 x 62.5 x 30.5/13.2 sq ft	50 x 74 x 32/68 sq ft
No. of tests for which analyzer has FDA-cleared applications	>90	122
Tests clinically released in last 12 months	—	ceruloplasmin, urinary/CSF protein, cholinesterase, HbA1c
Tests cleared but not clinically released	none	none
Tests not available in U.S. but submitted for 510(k) clearance	none	—
Tests not available in U.S. but available in other countries	none	—
Research-use-only assays	none	none
Tests in development	NT-proBNP, microalbumin, quinidine, triiodothyronine, tacrolimus	lactate
User-defined methods implemented for what analytes	none	fructosamine, ammonia
Methods supported/Immunoassay methods	photometry, potentiometry, Integrated Multisensor Technology (IMT)/heterogeneous EIA using HM, EMIT latex particle turbidimetric, latex turbidimetric	photometry, potentiometry, calculated tests/homogeneous
No. of direct ion selective electrode channels	4 (indirect)	3
No. of different measured assays onboard simultaneously	48/92 with optional inventory management system	up to 51
No. of different assays programmed, calibrated at once	190	99
No. of user-definable (open) channels/No. active simultaneously	10/10	95/—
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	44–88/max. 240	48 x 2/100–1,333
Shortest/median onboard reagent stability/Refrigerated onboard	72 hr/30 days/yes (2–8°C)	120 hr/30 days/yes (4–12°C)
Multiple reagent configurations supported	yes	yes
Reagent container placed directly on system for use	yes	yes
Instrument has same capabilities when 3rd-party reagent used	yes	yes
Walkaway capacity in minutes/Specimens/Tests-assays	can be hours	varies/up to 172/varies
System is liquid or dry	liquid, reconstitutes onboard	liquid
Uses disposable cuvettes/Max. No. stored	yes/12,000	no/n/a
Uses washable cuvettes/Replacement frequency	no/—	yes/permanent
Minimum sample volume aspirated precisely at one time	2 µL	2 µL
Supplied with UPS (backup power)/Requires floor drain	yes/no	no (optional)/yes (no w/ optional water pump)
Requires dedicated water system/Water consumption per hour	yes/3.2 L	yes/40 L per hr peak consumption
Noise generated in decibels	<70	65
Dedicated pediatric sample cup/Dead volume	yes/20 µL	no/n/a
Primary tube sampling/Pierces caps on primary tubes	yes, 5, 7, 10 mL/no	yes/no
Sample bar-code reading capability	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination
Reagent bar-code reading capability	yes	yes
Bar code placement per NCCLS standard Auto2A	yes	yes
Onboard test auto inventory (determines volume in container)	yes	yes
Measures no. tests remaining/Short sample detection/Clot detection	yes/yes/yes	yes/yes/yes
Automatic detection of adequate reagent for aspir. & analysis	yes	yes
Hemolysis/Turbidity detection-quantitation	yes/yes	yes/yes
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/yes
Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results	yes/yes	yes/yes
Autocalibration or autocalibration alert	yes	yes
Calibrants stored onboard/Multipoint calibration supported	yes/30–90 days	yes/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	every 2 hr-autocalibrate/—/60–90 days/30 days	1 day/30 days/14 days/14–20 days
Automatic shutdown/Startup programmable	no/no (2 min tech time, 5 min instrument time)	yes/yes
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TC02	50 sec, 288 tests	<4 min, 200 specimens
• Sodium, potassium, chloride, TC02, glucose, urea, creatinine	4.5 min, 500 tests	<5 min, 160 specimens
• Album., bili. direct & total, AST, ALT, ALP	10–11 min, 500 tests	9 min, 133 specimens
Typical time delay from ordering stat test to aspir. of sample	24 sec	1 min
How often QC required/Onboard SW capability to review QC	24 hr/yes	per CLIA & laboratory's decision/yes
Onboard real-time QC/Support multiple QC lot Nos. per analyte	no/yes	yes/yes
QC results transferred automatically to LIS	yes	yes
Data mgmt. capability/Instrument vendor supplies LIS interface	optional add-on (DBNet, Dade Behring)/yes (add'l cost)	onboard/no (optional)
Interfaces up and running in active user sites with	All major LIS vendors	all common interfaces including Cerner, Antrim, CCA, Chemware, Dawning Technol., ADAC, Dynamic Healthcare, Antek, Siemens, McKesson (Data Innov.), CPSI, Mediatech, Misys, Citation
Bidirectional interface capability	yes (broadcast download & host query)	yes (broadcast download & host query)
Test results transmitted to LIS as soon as chem. time complete	yes	yes
LIS interface operates simultaneously with running assays	yes	yes
Uses LOINC to transmit orders & results	no	no
How labs get LOINC codes for reagent kits	—	—
Interface avail. (or will be) to automated specimen handling system	yes	yes
Modem servicing available/Can diagnose own malfunctions/Determine malfunctioning component	yes/yes/yes	yes/yes/yes
On-site time of svc. engineer/Onboard error codes for troubleshooting	2–8 hr/yes	<24 hr/yes
Mean time between failures/To repair failures	—/—	average 2 calls per yr/<24 hr
Average time to complete maintenance by lab personnel	daily: 5 min; weekly: 10 min; monthly: 15 min	daily: 3 min; weekly: 27 min; monthly: 45 min
Onboard maintenance records/Maint. training demo module	yes/no	yes (includes audit trail of who replaced parts)/yes
Training provided with purchase/Advanced oper. training avail.	5 days on site, 4 days at vendor offices/yes	3–5 days on site, 5 days at vendor offices/yes
Annual service contract cost (24 h/7 d)	multiple types	inquire
Distinguishing features	integrates heterogeneous immunoassays onboard with other chemistries; allows single platform for over 95 percent of most requested tests; eliminates sample splitting between general tests and immunoassays	Olympus is a leader in standardization with its family of chemistry immuno systems, the AU400, AU400e, AU600, AU640, AU640e, AU2700, and AU5400; broad test menu of 122 methods delivers standardized results for improved patient management and streamlined operation; speed, reliability, advanced data management, and unprecedented onboard automation for one of the best walkaways in industry today

Tabulation does not represent an endorsement by the College of American Pathologists

Chemistry analyzers (for high-volume laboratories)

<p>Part 10 of 13</p> <p><i>See related comments, page 62</i></p>	<p>Olympus America Inc. Susan M. Watanabe, PhD susan.watanabe@olympus.com Two Corporate Center Dr. Melville, NY 11747 800-223-0125 www.olympus.com</p>	<p>Olympus America Inc. Hiro Sekiya hiro.sekiya@olympus.com Two Corporate Center Dr. Melville, NY 11747 800-223-0125 www.olympus.com</p>
<p>Name of instrument/First year sold in U.S. List price No. units in clinical use in U.S./Outside U.S. Country where designed/Manufactured/Where reagents mftd. Operational type/Reagent type</p>	<p>AU2700/2000 \$320,000 45/360 Japan/Japan/U.S. & Ireland random access, discrete, continuous random access/open reagent system</p>	<p>AU5421 with dual ISE/2001 \$465,000 100/130 Japan/Japan/U.S. & Ireland random access, discrete, continuous random access/open reagent system</p>
<p>Sample handling system/Model type Dimensions in inches (H x W x D)/Instrument footprint</p>	<p>rack & stat carousel/floor standing 50 x 79 x 45/92 sq ft</p>	<p>rack/floor standing 50 x 148 x 45/46.25 sq ft</p>
<p>No. of tests for which analyzer has FDA-cleared applications Tests clinically released in last 12 months Tests cleared but not clinically released</p>	<p>122 ceruloplasmin, urinary/CSF protein, cholinesterase, HbA1c none</p>	<p>122 ceruloplasmin, urinary/CSF protein, cholinesterase, HbA1c none</p>
<p>Tests not available in U.S. but submitted for 510(k) clearance</p>	<p>—</p>	<p>—</p>
<p>Tests not available in U.S. but available in other countries Research-use-only assays Tests in development</p>	<p>— none lactate</p>	<p>— none lactate</p>
<p>User-defined methods implemented for what analytes</p>	<p>fructosamine, ammonia</p>	<p>fructosamine, ammonia</p>
<p>Methods supported/Immunoassay methods No. of direct ion selective electrode channels No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels/No. active simultaneously No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set Shortest/median onboard reagent stability/Refrigerated onboard Multiple reagent configurations supported Reagent container placed directly on system for use Instrument has same capabilities when 3rd-party reagent used Walkaway capacity in minutes/Specimens/Tests-assays System is liquid or dry Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum sample volume aspirated precisely at one time Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption per hour Noise generated in decibels Dedicated pediatric sample cup/Dead volume Primary tube sampling/Pierces caps on primary tubes Sample bar-code reading capability</p>	<p>photometry, potentiometry, calculated tests/homogeneous 3 up to 51 99 95/— 48 x 2/100–4,000 120 hr/30 days/yes (4–12°C) yes yes yes varies/up to 322/varies liquid no/n/a yes/permanent 1 µL no (optional)/yes yes/65 L per hr peak consumption <65 no/n/a yes/no yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination</p>	<p>photometry, potentiometry, calculated tests/homogeneous 3 99 99 95/— 48 x 4/100–4,000 120 hr/30 days/yes (4–12°C) yes yes yes varies/up to 300/varies liquid no/n/a yes/permanent 1 µL no (optional)/yes yes/120 L <65 no/n/a yes/no yes, on sample transport, shortly before sample is aspirated (2 of 5 interl.)/autodiscrimination</p>
<p>Reagent bar-code reading capability Bar code placement per NCCLS standard Auto2A</p>	<p>yes yes</p>	<p>yes yes</p>
<p>Onboard test auto inventory (determines volume in container) Measures no. tests remaining/Short sample detection/Clot detection Automatic detection of adequate reagent for aspir. & analysis Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable</p>	<p>yes yes/yes/yes yes yes/yes yes/yes yes/yes yes yes/yes 1 day/30 days/14 days/14–20 days yes/yes</p>	<p>yes yes/yes/yes yes yes/yes yes/yes yes/yes yes yes/yes 1 day/30 days/14 days/14–20 days yes/yes</p>
<p>Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TCO2 • Sodium, potassium, chloride, TCO2, glucose, urea, creatinine • Album., bili. direct & total, AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample How often QC required/Onboard SW capability to review QC Onboard real-time QC/Support multiple QC lot Nos. per analyte QC results transferred automatically to LIS</p>	<p><4 min, 267 specimens <4 min, 267 specimens 9 min, 267 specimens 1 min per CLIA & laboratory's decision/yes yes/yes yes</p>	<p>—, max 600 —, max 600 —, max 533 — per CLIA & laboratory's decision/yes yes/yes yes</p>
<p>Data mgmt. capability/Instrument vendor supplies LIS interface</p>	<p>onboard/no (optional)</p>	<p>onboard/no (optional)</p>
<p>Interfaces up and running in active user sites with</p>	<p>all common interfaces including Cerner, Antrim, CCA, Chemware, Dawning Technol., ADAC, Dynamic Healthcare, Antek, Siemens, McKesson (Data Innov.), CPSI, Mediatech, Misys, Citation</p>	<p>all common interfaces including Cerner, Antrim, CCA, Chemware, Dawning Technol., ADAC, Dynamic Healthcare, Antek, Siemens, McKesson (Data Innov.), CPSI, Mediatech, Misys, Citation</p>
<p>Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results How labs get LOINC codes for reagent kits</p>	<p>yes (broadcast download & host query) yes yes no —</p>	<p>yes (broadcast download & host query) yes yes no —</p>
<p>Interface avail. (or will be) to automated specimen handling system</p>	<p>yes</p>	<p>yes</p>
<p>Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component On-site time of svc. engineer/Onboard error codes for troubleshooting Mean time between failures/To repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/Maint. training demo module Training provided with purchase/Advanced oper. training avail. Annual service contract cost (24 h/7 d)</p>	<p>yes/yes/yes <24 hr/yes TBD/TBD daily: 5 min; weekly: 30 min; monthly: 45 min yes (includes audit trail of who replaced parts)/yes 3–5 days on site, 5 days at vendor offices/yes inquire</p>	<p>yes/yes/yes <24 hr/yes TBD/TBD daily: 5 min; weekly: 30 min; monthly: 45 min yes (includes audit trail of who replaced parts)/yes 5 days at vendor offices/yes inquire</p>
<p>Distinguishing features</p>	<p>Olympus is a leader in standardization with its family of chemistry immuno systems—the AU400, AU400e, AU600, AU640, AU640e, AU2700, and AU5400; broad test menu of 122 methods delivers standardized results for improved patient management and streamlined operation; speed, reliability, advanced data management, and unprecedented onboard automation for one of the best walkaways in industry today</p>	<p>Olympus is a leader in standardization with its family of chemistry immuno systems—the AU400, AU400e, AU600, AU640, AU640e, AU2700, and AU5400; broad test menu of 122 methods delivers standardized results for improved patient management and streamlined operation; speed, reliability, advanced data management, and unprecedented onboard automation for one of the best walkaways in industry today</p>

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Chemistry analyzers (for high-volume laboratories)

Part 11 of 13	Olympus America Inc. Hiro Sekiya hiro.sekiya@olympus.com Two Corporate Center Dr. Melville, NY 11747 800-223-0125 www.olympus.com	Ortho-Clinical Diagnostics Donna Woodall 1001 U.S. Highway 202 Raritan, NJ 08869 800-828-6316 www.orthoclinical.com
<i>See related comments, page 62</i>		
Name of instrument/First year sold in U.S. List price No. units in clinical use in U.S./Outside U.S. Country where designed/Manufactured/Where reagents mftd. Operational type/Reagent type	AU5431 with dual ISE/2001 \$575,000 100/220 Japan/Japan/U.S. & Ireland random access, discrete, continuous random access/open reagent system	VITROS 950, VITROS 950AT/1995 950: \$196,000; 950 AT: \$250,000 >1,500/— U.S./—/— batch, random access, discrete, continuous random access/self-contained single-use cartridges-packages-slides
Sample handling system/Model type Dimensions in inches (H x W x D)/Instrument footprint	rack/floor standing 50 x 200 x 45/62.5 sq ft	sample trays/floor standing 55 x 68 x 38/26 sq ft
No. of tests for which analyzer has FDA-cleared applications Tests clinically released in last 12 months	122 ceruloplasmin, urinary/CSF protein, cholinesterase, HbA1c	69 none
Tests cleared but not clinically released Tests not available in U.S. but submitted for 510(k) clearance Tests not available in U.S. but available in other countries Research-use-only assays Tests in development User-defined methods implemented for what analytes	none — — none lactate fructosamine, ammonia	— — — — — —
Methods supported/Immunoassay methods No. of direct ion selective electrode channels No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels/No. active simultaneously No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set Shortest/median onboard reagent stability/Refrigerated onboard Multiple reagent configurations supported Reagent container placed directly on system for use Instrument has same capabilities when 3rd-party reagent used Walkaway capacity in minutes/Specimens/Tests-assays System is liquid or dry Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum sample volume aspirated precisely at one time Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption per hour Noise generated in decibels Dedicated pediatric sample cup/Dead volume Primary tube sampling/Pierces caps on primary tubes Sample bar-code reading capability	photometry, potentiometry, calculated tests/homogeneous 3 up to 147 99 95/— 48 x 6/100–4,000 120 hr/30 days/yes (4–12°C) yes yes yes varies/up to 300/varies liquid no/n/a yes/permanent 1 µL no (optional)/yes yes/180 L — no/n/a yes/no yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination	potentiometry, colorimetric-rate/— 3 75 75 n/a/n/a 75/60 7 days/14 days/n/a yes yes n/a —/40/900 per hr dry no/n/a no/n/a 6 µL no (optional)/no no/none — yes/30 µL yes/no yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination
Reagent bar-code reading capability Bar code placement per NCCLS standard Auto2A	yes yes	yes yes
Onboard test auto inventory (determines volume in container) Measures no. tests remaining/Short sample detection/Clot detection Automatic detection of adequate reagent for aspir. & analysis Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced/increased to rerun out-of-linear-range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable	yes yes/yes/yes yes yes/yes yes/yes yes/yes yes yes/yes 1 day/30 days/14 days/14–20 days yes/yes	yes yes/yes/yes yes not needed/not needed no/no no/no n/a no/yes 6 mo/6 mo/6 mo/n/a no/no
Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TC02 • Sodium, potassium, chloride, TC02, glucose, urea, creatinine • Album., bili. direct & total, AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample How often QC required/Onboard SW capability to review QC Onboard real-time QC/Support multiple QC lot Nos. per analyte QC results transferred automatically to LIS	—, max 600 —, max 600 —, max 800 — per CLIA & laboratory's decision/yes yes/yes yes	~6 min, 600 specimens ~6 min, ~700 specimens ~7 min, ~700 specimens 8 sec 24 hr/yes yes/yes yes
Data mgmt. capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with	onboard/no (optional) all common interfaces including Cerner, Antrim, CCA, Chemware, Dawning Technol., ADAC, Dynamic Healthcare, Antek, Siemens, McKesson (Data Innov.), CPSI, Mediatech, Misys, Citation	onboard/no (optional) all common interfaces
Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results How labs get LOINC codes for reagent kits	yes (broadcast download & host query) yes yes no —	yes (broadcast download) yes yes — —
Interface avail. (or will be) to automated specimen handling system	yes	yes (Lab-InterLink, Labotix, Coulter IDS, AutoLab)
Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component On-site time of svc. engineer/Onboard error codes for troubleshooting Mean time between failures/To repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/Maint. training demo module Training provided with purchase/Advanced oper. training avail. Annual service contract cost (24 h/7 d)	yes/yes/yes — <24 hr/yes TBD/TBD daily: 5 min; weekly: 30 min; monthly: 45 min yes (includes audit trail of who replaced parts)/yes 5 days at vendor offices/yes inquire	—/yes/yes — <4 hr/yes —/— daily: 2 min; weekly: 5 min; monthly: 15 min —/yes 3 days on site, 5 days at vendor offices/yes —
Distinguishing features	Olympus is a leader in standardization with its family of chemistry immuno systems—the AU400, AU400e, AU600, AU640, AU640e, AU2700, and AU5400; broad test menu of 122 methods delivers standardized results for improved patient management and streamlined operation; speed, reliability, advanced data management, and unprecedented onboard automation for one of the best walkaways in industry today	minimal interference from hemolysis, lipemia, bilirubin; smart metering; continuous process verification; minimal infectious waste; no plumbing, water, or drains; high reportable result efficiency

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Chemistry analyzers (for high-volume laboratories)

Part 12 of 13	Ortho-Clinical Diagnostics Donna Woodall 1001 U.S. Highway 202 Raritan, NJ 08869 800-828-6316 www.orthoclinical.com	Ortho-Clinical Diagnostics Melissa Heard 1001 U.S. Highway 202 Raritan, NJ 08869 908-218-8480 www.orthoclinical.com
<i>See related comments, page 62</i>		
Name of instrument/First year sold in U.S. List price No. units in clinical use in U.S./Outside U.S. Country where designed/Manufactured/Where reagents mftd. Operational type/Reagent type	VITROS 250, VITROS 250AT/1993 250 \$115,000; 250 AT \$130,000 >3,000/— U.S./—/— batch, random access, discrete, continuous random access/self-contained single-use cartridges-packages-slides	VITROS 5,1 FS Chemistry System/2004 \$305,000 0/0 U.S./U.S./— random access, discrete, continuous random access/self-contained single-use cartridges-packages-slides; open reagent system (post-launch)
Sample handling system/Model type Dimensions in inches (H x W x D)/Instrument footprint	rack/floor standing 47 x 45.5 x 28/8.8 sq ft	universal sample tray/floor standing 92.2 x 33.4 x 52.5/21.4 sq ft
No. of tests for which analyzer has FDA-cleared applications Tests clinically released in last 12 months Tests cleared but not clinically released	69 none —	70 none dHDL
Tests not available in U.S. but submitted for 510(k) clearance	—	none
Tests not available in U.S. but available in other countries Research-use-only assays Tests in development	— — —	none none —
User-defined methods implemented for what analytes	—	—
Methods supported/Immunoassay methods	potentiometry, colorimetric-rate/—	photometry, potentiometry (ion selective electrode), immuno-rate, turbidimetric, colorimetric/—
No. of direct ion selective electrode channels No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels/No. active simultaneously No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set Shortest/median onboard reagent stability/Refrigerated onboard Multiple reagent configurations supported Reagent container placed directly on system for use Instrument has same capabilities when 3rd-party reagent used Walkaway capacity in minutes/Specimens/Tests-assays System is liquid or dry Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum sample volume aspirated precisely at one time Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption per hour Noise generated in decibels Dedicated pediatric sample cup/Dead volume Primary tube sampling/Pierces caps on primary tubes Sample bar-code reading capability	3 60 60 n/a/n/a 60/60 7 days/14 days/n/a yes yes n/a —/40/200 per hr dry n/a/n/a n/a/n/a 6 µL no (optional)/no no/n/a — yes/30 µL yes/no yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination	3 125 400 10/10 125/up to 100 48 hrs/14 days/yes (temp: 10°C) yes yes yes varies/160/8,940 dry or liquid yes/348 no/— 2 µL no (optional)/no no/n/a — yes/30 µL yes/no yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination
Reagent bar-code reading capability Bar code placement per NCCLS standard Auto2A	yes yes	yes yes
Onboard test auto inventory (determines volume in container) Measures no. tests remaining/Short sample detection/Clot detection Automatic detection of adequate reagent for aspir. & analysis Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable	yes yes/yes/yes yes not needed/not needed yes/no no/no no no/yes 6 mo/6 mo/6 mo/n/a no/no	yes yes/yes/yes yes yes/yes yes/yes —/— no no/yes 6 mo/6 mo/6 mo/— no/no
Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TC02 • Sodium, potassium, chloride, TC02, glucose, urea, creatinine • Album., bili. direct & total, AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample How often QC required/Onboard SW capability to review QC Onboard real-time QC/Support multiple QC lot Nos. per analyte QC results transferred automatically to LIS	7 min, 230 specimens 7 min, 277 specimens 7 min, 250 specimens 12 sec 24 hr/yes yes/yes yes	— — — ~10 sec once per 24 hr/yes yes/yes yes
Data mgmt. capability/Instrument vendor supplies LIS interface	onboard/no (optional)	onboard/no (optional add-on)/no
Interfaces up and running in active user sites with	all common interfaces	—
Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results How labs get LOINC codes for reagent kits	yes (broadcast download) yes yes — —	yes (broadcast download & host query) yes yes no —
Interface avail. (or will be) to automated specimen handling system	yes (Lab-InterLink, Labotix, Coulter IDS, AutoLab)	yes (enGen, any open point in space systems)
Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component On-site time of svc. engineer/Onboard error codes for troubleshooting Mean time between failures/To repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/Maint. training demo module Training provided with purchase/Advanced oper. training avail. Annual service contract cost (24 h/7 d)	—/yes/yes —/yes/yes <4 hr/yes —/— daily: 2 min; weekly: 5 min; monthly: 15 min —/yes 3 days on site, 5 days at vendor offices/— —	yes/yes/yes —/yes/yes TBD/TBD daily: 9 min; weekly: 5 min; monthly: 31 min planned post-launch/yes varies on site, 5 days at vendor offices/yes varies
Distinguishing features	minimal interference from hemolysis, lipemia, bilirubin; smart metering; continuous process verification; minimal infectious waste; no plumbing, water, or drains; high reportable result efficiency	minimal interference from hemolysis, lipemia, bilirubin; smart metering; continuous process verification; minimal infectious waste; no plumbing, water drains, or fixed probes; high reportable result efficiency; e-connectivity interactive system management; V-DOCS; Microsensor Technology

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Chemistry analyzers (for high-volume laboratories)

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Part 13 of 13	Roche Diagnostics Ed Gilligan, Product Manager 9115 Hague Rd. Indianapolis, IN 46250 800-428-5074 ext. 4195 us.labsystems.roche.com
See related comments, page 62	
Name of instrument/First year sold in U.S. List price No. units in clinical use in U.S./Outside U.S. Country where designed/Manufactured/Where reagents mftd. Operational type/Reagent type	Modular/1998 varies >400/>3,000 multiple countries/multiple countries/multiple countries continuous random access/self-contained multiuse cartridges- packages-slides
Sample handling system/Model type Dimensions in inches (H x W x D)/Instrument footprint	5-position rack/floor standing varies per configuration/varies
No. of tests for which analyzer has FDA-cleared applications Tests clinically released in last 12 months	>100 amikacin; quinidine
Tests cleared but not clinically released	—
Tests not available in U.S. but submitted for 510(k) clearance	none
Tests not available in U.S. but available in other countries	apo A, apo B, Lpa, kappa, lambda
Research-use-only assays Tests in development	none lidocaine, cyclosporin, vancomycin
User-defined methods implemented for what analytes	yes, varies
Methods supported/Immunoassay methods	photometry, potentiometry/HbA1c
No. of direct ion selective electrode channels No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels/No. active simultaneously No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	3 47-100 47-100 varies 47-100/100-3,000
Shortest/median onboard reag. stability/Refrigerated onboard	72 hr/28 days/yes (2-12°C)
Multiple reag. configurations supported	yes
Reag. container placed directly on system for use	yes
Instrument has same capabilities when 3rd-party reag. used	no
Walkaway capacity in minutes/Specimens/Tests-assays	varies/300/varies
System is liquid or dry	liquid
Uses disposable cuvettes/Max. No. stored	no/n/a
Uses washable cuvettes/Replacement frequency	yes/monthly
Minimum sample volume aspirated precisely at one time	2 µL
Supplied with UPS (backup power)/Requires floor drain	yes/yes
Requires dedicated water system/Water consumption per hour	yes/varies (50 L/hr/mod)
Noise generated in decibels	<62
Dedicated pediatric sample cup/Dead volume	yes/50 µL
Primary tube sampling/Pierces caps on primary tubes	yes/no
Sample bar-code reading capability	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination
Reagent bar-code reading capability	yes
Bar code placement per NCCLS standard Auto2A	yes
Onboard test auto inventory (determines volume in container) Measures no. tests remaining/Short sample detection/Clot detection Automatic detection of adequate reag. for aspir. & analysis Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced/increased to rerun out-of-linear-range high/low results	yes yes/yes/no yes yes/yes yes/yes yes/yes
Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable	yes yes/yes 24 hr/varies/bottle change/lot change yes/yes
Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TC02 • Sodium, potassium, chloride, TC02, glucose, urea, creatinine • Album., bili. direct & total, AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample How often QC required/Onboard SW capability to review QC Onboard real-time QC/Support multiple QC lot Nos. per analyte QC results transferred automatically to LIS	3.5 min, 300-600 specimens 5.5 min, 160-600 specimens 10.5 min, 133-1,200 specimens <1 min 24 hr/yes yes/yes yes
Data mgmt. capability/Instrument vendor supplies LIS interface	onboard/no
Interfaces up and running in active user sites with	all major LIS vendors
Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results How labs get LOINC codes for reagent kits	yes (broadcast download & host query) no yes no database
Interface avail. (or will be) to automated specimen handling system	yes (Roche Pre-Analytical Modular)
Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component On-site time of svc. engineer/Onboard error codes for troubleshooting Mean time between failures/To repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/Maint. training demo module Training provided with purchase/Advanced oper. training avail. Annual service contract cost (24 h/7 d)	yes/yes/yes 8 hr/yes 260 days/3.5 hr daily: 5 min; weekly: 10 min; monthly: 15 min yes (includes audit trail of who replaced parts)/yes 5 days at vendor offices/yes varies
Distinguishing features	Roche Hitachi chemistry and automation proven reliability and more than 20 years of experience; capable of consolidating up to 100 different assays on one high-throughput analyzer; system can be connected directly to preanalytical automation; flexible, expandable to lab's changing needs; up to four modules per system

Tabulation does not represent an endorsement by the College of American Pathologists