Part 1 of 3	**ARKRAY** **Jane Nichols** nicholsj@arkrayusa.com **Edina, MN** **952-646-3224** arkrayusa.com/clinical-diagnostics	**ARKRAY** **Jane Nichols** nicholsj@arkrayusa.com **Edina, MN** **952-646-3231** www.arkrayusa.com	**Beckman Coulter** **Gabrielle Huff** gahuff@beckman.com **Brea, CA** www.beckmancoulter.com/urinalysis
Name of urinalysis instrument	AUTION ELEVEN AE-4022	AUTION MAX AX-4030	DxU Microscopy Series: DxU 850m Iris, DxU 840m Iris†
Type of instrument	urine chemistry	urine chemistry	microscopy/sediment
Instrument list price	—	—	—
First year instrument sold in U.S.	2017	2011	2003
No. of units installed in U.S./No. of units installed outside U.S.	— (also sold via Cardinal Health, Beckman Coulter, Medline Industries)	— (also sold via distribution partners)	>2,000/>4,000 globally for both systems combined (also sold via McKesson and Henry Schein in the U.S.)
Foreign countries where company markets instrument	worldwide	worldwide	worldwide
Country where instrument designed/manufactured	Japan/Japan	Japan/Japan	U.S./U.S.
Intended urine sample volume per day	—	>15	50–600+
Dimensions (HxWxD)/Weight fully loaded with reagents	6.5 × 8.3 × 12.9 in./7.9 lbs.	21 × 21 × 21 in./82 lbs.	22 × 21 × 24 in./100 lbs.
Power requirements	100–240 VAC (50–60 Hz)	100–240 VAC (50–60 Hz)	90–240 VAC (50–60 Hz)
Mean time between failure of instrument	600 days	364 days	—
Events that cause instrument to lock or stop analysis	user ID failure, result error	short sample, result error, sampling error	QC failure, short sample, barcode/sample ID misread, result error, sampling error, consumables replacement/expiration
Urine chemistry: *(Information in this box is specific to urine chemistry)*			
• Testing methodology: specific gravity/color/clarity	test strip/test strip/visual read, manual entry	refractometer/wavelength of absorbance within an analyzer well/turbidity within an analyzer well	—
• Urine chemistry tests available on instrument in the U.S.	bilirubin (0.5–14 mg/dL), hemoglobin (0.03–1.0 mg/dL), glucose (30–1,000 mg/dL), ketone (5–150 mg/dL), leukocyte esterase (25–500 leukocytes/µL), nitrite (0.08–0.5 mg/dL), pH (5–9), protein (10–1,000 mg/dL), specific gravity (1.005–1.030), urobilinogen (2–16 mg/dL)	bilirubin (0.5–10 mg/dL), hemoglobin (0.03–1.0 mg/dL), glucose (30–1,000 mg/dL), ketone (5–150 mg/dL), leukocyte esterase (0–500 leukocytes/µL), nitrite (0.08–0.5 mg/dL), pH (5–9), protein (10–600 mg/dL), specific gravity (1.000–1.050), urobilinogen (2–12 mg/dL)	—
• Color compensation pad included	yes	yes	—
• Flagging thresholds customizable	—	no	—
• Test strip configuration	loosely packed in bottles	loosely packed in bottles	—
• Calibration required after each test strip lot No. change	no	no	—
• Frequency of customer-performed calibration	—	—	—
• Form of calibration	—	—	—
• How results are displayed for urine chemistry	semiquantitative	semiquantitative	—
• Reporting format customizable	no	no	—
• No. of results that can be held in internal memory	520 (sample results and control results combined)	2,500 sample results/200 control results	—
• Specific gravity correction for protein/glucose	no (protein)/no (glucose)	yes (protein)/yes (glucose)	—
Microscopy/sediment: *(Information in this box is specific to microscopy/sediment)*			
• Microscopy/sediment technology	—	—	digital flow morphology using auto particle recognition software
• Microscopy/sediment analysis parameters	—	—	qualitative and quantitative: pathological casts, crystals, yeast-like cells, mucus, sperm, RBCs, WBCs, epithelial cells, bacteria, hyaline casts, WBC clumps
• Flagging thresholds customizable	—	—	yes
• Instrument eliminates amorphous crystal interference before sample analysis	—	—	no
• How results are displayed for microscopy/sediment	—	—	numeric values
• Reporting format customizable	—	—	yes
• No. of results that can be held in internal memory	—	—	10,000 sample results/200 control results
Reagent shelf life/storage temperature for unopened containers	2 years/1–30°C	2 years/1–30°C	varies based on reagent type
Reagent shelf life/storage temperature for opened containers	31 days/1–30°C	31 days/1–30°C	varies based on reagent type
Reagent barcode-reading capability	no	yes, for some tests	yes, for some tests
How often quality control samples are run	daily (can use other vendors' QC products)	daily (can use other vendors' QC products)	daily (cannot use other vendors' QC products)
Sample throughput per hour/Time to first result for chemistry	514/1 min.	225/1 min. cycle time	—
Sample throughput per hour/Time to first result for microscopy/sediment	—	—	DxU 840m: 70/—; DxU 850m: 101/<2 min.
Analyzer has stat mode	no	yes (minimum sample volume, 2 mL)	yes (minimum sample volume, 2 mL)
Sample dilutions required for urinalysis/body fluid analysis	no (urinalysis)/— (body fluid analysis)	no (urinalysis)/— (body fluid analysis)	no (urinalysis)/yes (body fluid analysis)
• Special sample handling required for body fluid analysis	—	—	yes (lyse reagent)
Minimum width of sample tube/Minimum length of sample tube	—	15.8 mm/105 mm	16 mm/100 mm
Conditions or substances that prevent a sample from being run	—	—	grossly visible turbidity
Means of sample ID entry	barcode scan, manual entry	barcode scan, manual entry	barcode scan, manual entry
Built-in liquid-level sensing for samples	no	yes	yes
Information that can be barcode scanned on instrument	operator identifier, specimen identifier	specimen identifier	specimen identifier, reagent lot No., reagent expiration
How LOINC codes for results are made available	—	e-mail query	manual transmission
Software includes reflex testing/cross-check functionality	no (reflex testing)/no (cross-check functionality)	no (reflex testing)/no (cross-check functionality)	yes (reflex testing)/yes (cross-check functionality)
Instrument automatically generates consolidated report*	no	no	yes
Instrument connections to transfer information	directly to LIS or via commercial middleware (Data Innovations)	directly to LIS or via commercial middleware (Data Innovations)	directly to LIS or EHR
Interface standards supported	ASTM 1394-91, ASTM 1381	ASTM 1394-91, ASTM 1381	ASTM with proprietary message layer
Bidirectional interface	no	yes (to other companies' LISs–Cerner, Epic, Meditech, Orchard, SCC Soft Computer, Sunquest [Clinisys])	yes (to other companies' LISs)
Test results can be transmitted to LIS as soon as tests completed	yes	yes	—
Connection to LIS to upload patient and QC results	direct serial connection or hospital network	direct serial connection or hospital network	—
Connection to EHR to upload patient and QC results	option not available	—	—
Information included in transmission from instrument to data-management software	device unique identifier, specimen ID, result, QC identifier	device unique identifier, specimen ID, result	device unique identifier, operator ID, patient ID, specimen ID, result, QC identifier
No. of days of training included with instrument purchase	0	1–2 days at customer site	1 day at customer site, 2.5 days at vendor office
Approximate scheduled maintenance time required	5 min. daily	<5 min. daily; <5 min. weekly; <10 min. monthly	—
• Maintenance records kept onboard instrument	no	no	yes
Provide list of client sites to potential customers on request	no (information is confidential)	yes (partial list of comparable sites)	yes (complete list with no restrictions regarding its use)
Clients restricted from sharing their experience with company or software	no	no	no
Distinguishing instrument features (supplied by company)	• standardized test strip technology across all ARKRAY platforms • clinically significant reporting ranges • small semi-automated footprint	• proven reliability with less than one unscheduled service event per year • abnormal color detection alerts operators to potential false-positive results • easy to use; strips easy to load; does not require calibration	• streamlines urinalysis workflow to achieve manual review rates of 4% • auto-classifies 12 urine particles based on size, shape, contrast, and texture to provide digital images for all samples • FDA-cleared body fluids module; linearity down to zero

**chemistry and microscopy results in one report*

Note: a dash in lieu of an answer means company did not answer question or question is not applicable

†formerly iQ200 series; answers in listing apply to both systems unless otherwise indicated

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Product guide editor: Raymond D. Aller, MD

URINALYSIS INSTRUMENTATION

Part 2 of 3	Beckman Coulter Gabrielle Huff gahuff@beckman.com Brea, CA www.beckmancoulter.com/urinalysis	Roche Diagnostics Claire Rhodes claire.rhodes@roche.com Indianapolis, IN 317-521-2000 www.roche.com
Name of urinalysis instrument	DxU Iris Workcell: DxU Iris 850, DxU Iris 840†	cobas u 411
Type of instrument	urine chemistry and microscopy/sediment combined	urine chemistry
Instrument list price	—	—
First year instrument sold in U.S.	2021	2006
No. of units installed in U.S./No. of units installed outside U.S.	>50/>70 globally for both systems combined (also sold via McKesson and Henry Schein in the U.S.)	>400/>2,300 globally
Foreign countries where company markets instrument	none	worldwide
Country where instrument designed/manufactured	U.S. and Japan/U.S. and Japan	Switzerland/Switzerland
Intended urine sample volume per day	50–600+	10–100
Dimensions (HxWxD)/Weight fully loaded with reagents	23 × 21 × 60 in./238 lbs.	10.24 × 16.73 × 13.34 in./~26 lbs.
Power requirements	90–240 VAC (50–60 Hz)	110 VAC
Mean time between failure of instrument	—	—
Events that cause instrument to lock or stop analysis	QC failure, short sample, barcode/sample ID misread, result error, sampling error, consumables replacement/expiration	—
Urine chemistry: *(Information in this box is specific to urine chemistry)*		
• Testing methodology: specific gravity/color/clarity	refractometer/wavelength of absorbance within an analyzer well/turbidity within an analyzer well	test strip/wavelength of absorbance within an analyzer well/—
• Urine chemistry tests available on instrument in the U.S.	bilirubin (0–>10 mg/dL), hemoglobin (0–>1 mg/dL), glucose (0–>1,000 mg/dL), ketone (0–>150 mg/dL), leukocyte esterase (0–500 leukocytes/µL), nitrite (–, 1+, 2+), pH (5–9), protein (0–>600 mg/dL), specific gravity (1.000–1.500), urobilinogen (0–≥12 mg/dL)	bilirubin (neg.–6 mg/dL), red blood cells (neg.–250 erythrocytes/µL), hemoglobin (neg.–250 erythrocytes/µL), glucose (normal–1,000 mg/dL), ketone (neg.–150 mg/dL), leukocyte esterase (neg.–500 leukocytes/µL), nitrite (positive/negative), pH (5–9), protein (neg.–500 mg/dL), specific gravity (1.000-1.030), urobilinogen (normal–12 mg/dL)
• Color compensation pad included	yes	yes
• Flagging thresholds customizable	no	no
• Test strip configuration	loosely packed in bottles	loosely packed in bottles
• Calibration required after each test strip lot No. change	no	no
• Frequency of customer-performed calibration	—	28 days
• Form of calibration	—	dry
• How results are displayed for urine chemistry	semiquantitative	semiquantitative
• Reporting format customizable	no	yes
• No. of results that can be held in internal memory	2,500 sample results/200 control results	1,000 sample results/300 control results
• Specific gravity correction for protein/glucose	yes (protein)/yes (glucose)	—
Microscopy/sediment: *(Information in this box is specific to microscopy/sediment)*		
• Microscopy/sediment technology	digital flow morphology using auto particle recognition software	—
• Microscopy/sediment analysis parameters	qualitative and quantitative: pathological casts, crystals, yeast-like cells, mucus, sperm, RBCs, WBCs, epithelial cells, bacteria, hyaline casts, WBC clumps	—
• Flagging thresholds customizable	yes	—
• Instrument eliminates amorphous crystal interference before sample analysis	no	—
• How results are displayed for microscopy/sediment	numeric values	—
• Reporting format customizable	yes	—
• No. of results that can be held in internal memory	10,000 sample results/200 control results	—
Reagent shelf life/storage temperature for unopened containers	varies based on reagent type	—/2–30°C
Reagent shelf life/storage temperature for opened containers	varies based on reagent type	—/2–30°C
Reagent barcode-reading capability	yes, for some tests	no
How often quality control samples are run	daily (cannot use other vendors' QC products)	— (can use other vendors' QC products)
Sample throughput per hour/Time to first result for chemistry	225/1 min.	600/1 min.
Sample throughput per hour/Time to first result for microscopy/sediment	DxU 840: 70/—; DxU 850: 101/<2 min.	—
Analyzer has stat mode	yes (minimum sample volume, 3 mL for microscopy/sediment)	no (minimum sample volume for sampler or track mode is minimum amount necessary to immerse pads)
Sample dilutions required for urinalysis/body fluid analysis	no (urinalysis)/yes (body fluid analysis)	no (urinalysis)/— (body fluid analysis)
• Special sample handling required for body fluid analysis	yes (lyse reagent)	—
Minimum width of sample tube/Minimum length of sample tube	16 mm/100 mm	—
Conditions or substances that prevent a sample from being run	grossly visible turbidity	preservatives
Means of sample ID entry	barcode scan, manual entry	barcode scan, bidirectional download from host, worklist download from host, manual entry
Built-in liquid-level sensing for samples	yes	—
Information that can be barcode scanned on instrument	specimen identifier, reagent lot No., reagent expiration	specimen identifier
How LOINC codes for results are made available	manual transmission	website, e-mail query
Software includes reflex testing/cross-check functionality	yes (reflex testing)/yes (cross-check functionality)	no (reflex testing)/no (cross-check functionality)
Instrument automatically generates consolidated report*	yes	no
Instrument connections to transfer information	directly to LIS or EHR	data-management system that connects to LIS or EHR, or data-management system that cannot further transmit data, or directly to LIS or EHR, or via commercial middleware (Data Innovations)
Interface standards supported	ASTM with proprietary message layer	ASTM 1394-91, ASTM 1238-95
Bidirectional interface	yes (to other companies' LISs)	yes (to other companies' LISs and EHRs)
Test results can be transmitted to LIS as soon as tests completed	—	yes
Connection to LIS to upload patient and QC results	—	direct serial connection
Connection to EHR to upload patient and QC results	—	—
Information included in transmission from instrument to data-management software	device unique identifier, operator ID, patient ID, specimen ID, result, QC identifier	specimen ID, result
No. of days of training included with instrument purchase	1 day at customer site, 2.5 days at vendor office	0
Approximate scheduled maintenance time required	—	5 min. daily; 10 min. monthly
• Maintenance records kept onboard instrument	yes	—
Provide list of client sites to potential customers on request	yes (complete list with no restrictions regarding its use)	no (information is confidential)
Clients restricted from sharing their experience with company or software	no	no
Distinguishing instrument features (supplied by company)	• streamlines urinalysis workflow to achieve manual review rates of 4% • auto-classifies 12 urine particles based on size, shape, contrast, texture to provide digital images for samples • FDA-cleared body fluids module; linearity down to zero	• fast, efficient processing of urine strips; analyzer ready to test every six seconds • Chemstrip 10UA strip has virtually no interference with ascorbic acid, minimizing false-negative glucose and hemoglobin results • flexible sample ID entry options let user choose barcode scan, download from host, or manual-entry options

**chemistry and microscopy results in one report*

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†formerly iQ Workcell; answers in listing apply to both systems unless otherwise indicated

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Part 3 of 3	**Sysmex America** **Jason Anderson** andersonja@sysmex.com **Lincolnshire, IL** **888-879-7639** www.sysmex.com/us	**Sysmex America** **Jason Anderson** andersonja@sysmex.com **Lincolnshire, IL** **888-879-7639** www.sysmex.com/us
Name of urinalysis instrument	Clinitek Novus Automated Urine Chemistry Analyzer	UN-Series Automated Urinalysis Solution (UN-2000, UN-3000, UN-9000)†
Type of instrument	urine chemistry	urine chemistry and microscopy/sediment combined
Instrument list price	$104,995	dependent on configuration
First year instrument sold in U.S.	2015	UN-2000: 2019; UN-3000 and UN-9000: 2020
No. of units installed in U.S./No. of units installed outside U.S.	>600/>57 (in Canada†)	>600 (all units combined)/—
Foreign countries where company markets instrument	Canada†	Canada
Country where instrument designed/manufactured	U.S. and United Kingdom/U.S. and United Kingdom	Japan/Japan
Intended urine sample volume per day	>50 tests	>80 tests
Dimensions (HxWxD)/Weight fully loaded with reagents	21 × 25 × 27 in./100 lbs.	varies by configuration/varies by configuration
Power requirements	100–240 VAC (48–62 Hz)	varies by configuration
Mean time between failure of instrument	120 days	90 days
Events that cause instrument to lock or stop analysis	user ID failure, sampling error, consumables replacement/expiration, calibration failure	user ID failure, consumables replacement/expiration
Urine chemistry: *(Information in this box is specific to urine chemistry)*		
• Testing methodology: specific gravity/color/clarity	refractometer/wavelength of absorbance in an analyzer well or test strip/turbidity within an analyzer well	refractometer/wavelength of absorbance in an analyzer well or test strip/turbidity within an analyzer well
• Urine chemistry tests available on instrument in the U.S.	bilirubin (0.5–2.7 mg/dL), red blood cells (trace level), hemoglobin (0.013–0.3 mg/dL), glucose (36–820 mg/dL), ketone (3.6–156 mg/dL), leukocyte esterase (6–91 cells/µL), nitrite (positive/negative), pH (5.3–8.7), protein (10.8–1,000 mg/dL), specific gravity (1.000–1.099), urobilinogen (0.24–6.24 mg/dL)	bilirubin (0.5–2.7 mg/dL), red blood cells (trace levels), hemoglobin (0.013–0.3 mg/dL), glucose (36–820 mg/dL), ketone (3.6–156 mg/dL), leukocyte esterase (6–91 cells/µL), nitrite (positive/negative), pH (5.3–8.7), protein (10.8–1,000 mg/dL), specific gravity (1.000–1.099), urobilinogen (0.24–6.24 mg/dL)
• Color compensation pad included	yes	yes
• Flagging thresholds customizable	yes	yes
• Test strip configuration	cartridge	cartridge
• Calibration required after each test strip lot No. change	yes	yes
• Frequency of customer-performed calibration	with every new lot No. of Novus cassette loaded or when same lot No. of Novus cassette has been loaded and calibration is greater than 24 hours old	with every new lot No. of Novus cassette loaded or when same lot No. of Novus cassette has been loaded and calibration is greater than 24 hours old
• Form of calibration	liquid	liquid
• How results are displayed for urine chemistry	semiquantitative	semiquantitative
• Reporting format customizable	yes	yes
• No. of results that can be held in internal memory	7,500 sample results/400 control results	100,000 sample results (in the urinalysis data manager)/400 QC analysis results
• Specific gravity correction for protein/glucose	no (protein)/no (glucose)	no (protein)/no (glucose)
Microscopy/sediment: *(Information in this box is specific to microscopy/sediment)*		
• Microscopy/sediment technology	—	flow cytometry with fluorescent stain, digital image capture on UN-3000 and UN-9000 configurations
• Microscopy/sediment analysis parameters	—	flagged and qualitative: pathological casts, crystals, yeast-like cells, mucus, sperm; quantitative: RBCs, WBCs, epithelial cells, bacteria, casts
• Flagging thresholds customizable	—	yes
• Instrument eliminates amorphous crystal interference before sample analysis	—	yes
• How results are displayed for microscopy/sediment	—	numeric values or scattergrams
• Reporting format customizable	—	yes
• No. of results that can be held in internal memory	—	100,000 sample results (in the urinalysis data manager)/2 concentrations × 3 lots (120 plots/lot) for control results
Reagent shelf life/storage temperature for unopened containers	365 days/15–30°C	varies based on reagent type
Reagent shelf life/storage temperature for opened containers	onboard stability of cassette, 14 days/15–30°C	varies based on reagent type
Reagent barcode-reading capability	yes, for all tests	yes, for all tests
How often quality control samples are run	follow government regulations or accreditation requirements (can use other vendors' QC products)	daily (cannot use other vendors' QC products)
Sample throughput per hour/Time to first result for chemistry	240/—	240/—
Sample throughput per hour/Time to first result for microscopy/sediment	—	varies by configuration/—
Analyzer has stat mode	yes (minimum sample volume, 2 mL)	yes (minimum sample volume, 2 mL for chemistry/1.6 mL for microscopy/sediment)
Sample dilutions required for urinalysis/body fluid analysis	no (urinalysis)/— (body fluid analysis)	no (urinalysis)/no (body fluid analysis)
• Special sample handling required for body fluid analysis	—	—
Minimum width of sample tube/Minimum length of sample tube	16 mm/100 mm	16 mm/100 mm
Conditions or substances that prevent a sample from being run	blood, mucus	blood, mucus, high fluorescence
Means of sample ID entry	barcode scan, worklist download from host, manual entry, RFID for authentic entry of cassette lot	barcode scan, manual entry, worklist download from host
Built-in liquid-level sensing for samples	yes	yes
Information that can be barcode scanned on instrument	operator identifier, specimen identifier, reagent lot No.	specimen identifier, reagent lot No.
How LOINC codes for results are made available	website, e-mail query	website, e-mail query
Software includes reflex testing/cross-check functionality	yes (reflex testing)/yes (cross-check functionality)	yes (reflex testing)/yes (cross-check functionality)
Instrument automatically generates consolidated report*	no	yes
Instrument connections to transfer information	data-management system that connects to LIS or EHR, or directly to LIS or EHR	data-management system that connects to LIS or EHR, or directly to LIS or EHR
Interface standards supported	ASTM 1394-91, ASTM 1381, HL7	ASTM 1394-91, ASTM 1381
Bidirectional interface	—	yes (to other companies' LISs and EHRs)
Test results can be transmitted to LIS as soon as tests completed	yes	yes
Connection to LIS to upload patient and QC results	direct serial connection or hospital network	hospital network
Connection to EHR to upload patient and QC results	direct serial connection	hospital network
Information included in transmission from instrument to data-management software	device unique identifier, operator ID, patient ID, specimen ID, result, QC identifier	device unique identifier, operator ID, patient ID, specimen ID, result, QC identifier
No. of days of training included with instrument purchase	½ day of virtual instructor-led training at customer site	2 days of virtual instructor-led training at customer site
Approximate scheduled maintenance time required	5–10 min. daily	20 min. daily; 10 min. weekly
• Maintenance records kept onboard instrument	no	yes
Provide list of client sites to potential customers on request	yes (partial list of comparable sites)	yes (partial list of comparable sites)
Clients restricted from sharing their experience with company or software	no	no
Distinguishing instrument features (supplied by company)	• reagent cassette format with RFID that provides complete traceability and 14-day onboard stability • digital color camera • sold as standalone system or configured for modular integration with Sysmex UN-2000, UN-3000, UN-9000	• combines urine chemistry, fluorescent flow cytometry, and digital image analysis for rapid urine screening • modular and scalable configurations • BeyondCare quality monitor for urinalysis provides a streamlined and automated QC experience
**chemistry and microscopy results in one report*	*†marketed in the U.S. and Canada by Sysmex; marketed in other countries by Siemens Healthineers*	*†modular systems: UN-2000, two modules; UN-3000, three modules; UN-9000, four or more modules*
Note: a dash in lieu of an answer means company did not answer question or question is not applicable		

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