Part 1 of 4

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	ARKRAY **Angie Howe** howea@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** **John Ebbs** jhebbs@beckman.com **Miami, FL** **352-647-0176** www.beckmancoulter.com
Name of urinalysis instrument	AUTION ELEVEN AE-4022	AUTION MAX AX-4030	iQ Workcell Series
Type of instrument	urine chemistry	urine chemistry	urine chemistry and microscopy/sediment combined
Instrument list price	—	—	—
First year instrument sold in U.S.	2017	2011	2018
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)	— (also sold via McKesson, Henry Schein)
Foreign countries where company markets instrument	worldwide	worldwide	worldwide
Country where instrument designed/manufactured	Japan/Japan	Japan/Japan	U.S. and Japan/U.S. and Japan
Intended urine sample volume per day	—	>15	70–600
Dimensions (HxWxD)/Weight fully loaded with reagents	6.5 × 8.3 × 12.9 in./7.9 lbs.	21 × 21 × 21 in./82 lbs.	22 × 48 × 26 in./200 lbs.
Power requirements	100–240 VAC (50–60 Hz)	100–240 VAC (50–60 Hz)	100–240 VAC
Mean time between failure of instrument	1,230 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	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)	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)
• Color compensation pad included	yes	yes	yes
• Flagging thresholds customizable	—	no	no
• Test strip configuration	loosely packed in bottles	loosely packed in bottles	loosely packed in bottles
• Calibration required after each test strip lot No. change	no	no	no
• Frequency of customer-performed calibration	—	—	—
• Form of calibration	—	—	—
• How results are displayed for urine chemistry	semiquantitative	semiquantitative	semiquantitative
• Reporting format customizable	no	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	2,500 sample results/200 control results
• Specific gravity correction for protein/glucose	no (protein)/no (glucose)	yes (protein)/yes (glucose)	yes (protein)/yes (glucose)
Microscopy/sediment: *(Information in this box is specific to microscopy/sediment)*			
• Microscopy/sediment technology	—	—	digital flow morphology (digital imaging)
• Microscopy/sediment analysis parameters	—	—	all of the following quantitative: pathological casts, crystals, yeast-like cells, mucus, sperm, RBCs, WBCs, epithelial cells, bacteria, hyaline casts, WBC clumps, yeast, squamous and nonsquamous epithelial cells, others
• 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	no	yes
How often quality control samples are run	daily (can use other vendors' QC products)	daily (can use other vendors' QC products)	daily
Sample throughput per hour/Time to first result for chemistry	514/1 min.	225/1 min. cycle time	up to 225/<1 min.
Sample throughput per hour/Time to first result for microscopy/sediment	—	—	up to 70 or 101, depending on model/<2 min.
Analyzer has stat mode	no	yes (minimum sample volume, 2 mL)	yes (minimum sample volume, 2 mL for chemistry/2 mL for sediment)
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	15.8 mm/105 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	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)	yes (to other companies' LISs and EHRs)
• Tests can be transmitted to LIS as soon as completed	yes	yes	—
Connection to LIS to upload patient and QC results	direct serial or hospital network	direct serial or hospital network	direct serial or hospital network
Connection to EHR to upload patient and QC results	option not available	—	direct serial or hospital network
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 with instrument purchase	0	1–2 days at customer site	1 day at customer site, 3 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	• advances urinalysis and body fluid testing through digital flow morphology using proprietary auto-particle-recognition software • increased productivity through improved workflow, reduced urine cultures, lower review rates, and review by exception • advanced technology allows for testing of body fluids and urine samples in a preservative tube

**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

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Product guide editors: Raymond D. Aller, MD, and Hal Weiner

URINALYSIS INSTRUMENTATION

Part 2 of 4 See **captodayonline.com/productguides** for an interactive version of guide	**Beckman Coulter** **John Ebbs** jhebbs@beckman.com **Miami, FL** **352-647-0176** www.beckmancoulter.com	**Roche Diagnostics** **Brittany Greiner** brittany.greiner@roche.com **Indianapolis, IN** **317-521-2000** roche.com	**Roche Diagnostics** **Brittany Greiner** brittany.greiner@roche.com **Indianapolis, IN** **317-521-2000** roche.com
Name of urinalysis instrument	iQ200 Series: SELECT, ELITE, SPRINT†	cobas u 411	cobas u 601
Type of instrument	microscopy/sediment	urine chemistry	urine chemistry
Instrument list price	—	$13,500	—
First year instrument sold in U.S.	2003	2006	2019
No. of units installed in U.S./No. of units installed outside U.S.	>2,000††/>4,000†† globally (also sold via McKesson, Henry Schein)	>400/>2,300 globally	—/1,200 globally
Foreign countries where company markets instrument	worldwide	worldwide	worldwide
Country where instrument designed/manufactured	U.S./U.S.	Switzerland/Switzerland	Hungary/Hungary
Intended urine sample volume per day	70–600	10–100	≥50
Dimensions (HxWxD)/Weight fully loaded with reagents	22 × 21 × 24 in./118 lbs.	10.24 × 16.73 × 13.34 in./~26 lbs.	25.35 × 42.48 × 20.94 in./207.5 lbs.
Power requirements	90–240 VAC, 200 watts maximum	110 VAC	100–125 VAC
Mean time between failure of instrument	—	—	160 days
Events that cause instrument to lock or stop analysis	QC failure, short sample, barcode/sample ID misread, result error, sampling error, consumables replacement/expiration	—	opening front cover
Urine chemistry: *(Information in this box is specific to urine chemistry)*			
• Testing methodology: specific gravity/color/clarity	—	test strip/wavelength of absorbance within an analyzer well/—	refractometer/test strip/turbidity within an analyzer well
• Urine chemistry tests available on instrument in the U.S.	—	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)	bilirubin (neg.–6 mg/dL), red blood cells (intact RBCs up to 50 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	yes
• Test strip configuration	—	loosely packed in bottles	cartridge
• Calibration required after each test strip lot No. change	—	no	no
• Frequency of customer-performed calibration	—	28 days	28 days
• Form of calibration	—	dry	dry
• How results are displayed for urine chemistry	—	semiquantitative	semiquantitative
• Reporting format customizable	—	yes	yes
• No. of results that can be held in internal memory	—	1,000 sample results/300 control results	10,000 sample results/300 control results
• Specific gravity correction for protein/glucose	—	—	—
Microscopy/sediment: *(Information in this box is specific to microscopy/sediment)*			
• Microscopy/sediment technology	digital flow morphology (digital imaging)	—	—
• Microscopy/sediment analysis parameters	all of the following quantitative: pathological casts, crystals, yeast-like cells, mucus, sperm, RBCs, WBCs, epithelial cells, bacteria, hyaline casts, WBC clumps, yeast, squamous and nonsquamous epithelial cells, others	—	—
• 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	—/2–30°C
Reagent shelf life/storage temperature for opened containers	varies based on reagent type	—/2–30°C	—/2–30°C
Reagent barcode-reading capability	yes	no	yes
How often quality control samples are run	daily	— (can use other vendors' QC products)	— (can use other vendors' QC products)
Sample throughput per hour/Time to first result for chemistry	—	600/1 min.	240/1 min.
Sample throughput per hour/Time to first result for microscopy/sediment	up to 40, 70, 101, depending on model/<2 min.	—	—
Analyzer has stat mode	yes (minimum sample volume, 2 mL)	no (minimum sample volume for sampler or track mode is minimum amount necessary to immerse pads)	yes (minimum sample volume, 1.5 mL)
Sample dilutions required for urinalysis/body fluid analysis	no (urinalysis)/yes (body fluid analysis)	no (urinalysis)/— (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	—	13 mm/65 mm
Conditions or substances that prevent a sample from being run	grossly visible turbidity	preservatives	preservatives
Means of sample ID entry	barcode scan, manual entry	barcode scan, bidirectional download from host, worklist download from host, manual entry	barcode scan, manual entry, worklist download from host, bidirectional download from host
Built-in liquid-level sensing for samples	yes	—	yes
Information that can be barcode scanned on instrument	specimen identifier, reagent lot No., reagent expiration	specimen identifier	specimen identifier, reagent lot No.
How LOINC codes for results are made available	manual transmission	website, e-mail query	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)	— (reflex testing)/yes (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)	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, Infinity)
Interface standards supported	ASTM with proprietary message layer	ASTM 1394-91, ASTM 1238-95	ASTM 1394-91, ASTM 1381
Bidirectional interface	yes (to other companies' LISs)	yes (to other companies' LISs and EHRs)	yes (to other companies' LISs and EHRs)
• Tests can be transmitted to LIS as soon as completed	—	yes	yes
Connection to LIS to upload patient and QC results	direct serial or hospital network	direct serial	hospital network
Connection to EHR to upload patient and QC results	direct serial or hospital network	—	hospital network
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	device unique identifier, operator ID, patient ID, specimen ID, result
No. of days of training 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	10 min. daily; 10 min. weekly; 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)	no (information is confidential)
Clients restricted from sharing their experience with company or software	no	no	no
Distinguishing instrument features (supplied by company)	• digital flow morphology using auto-particle-recognition software • increased productivity through improved workflow, reduced urine cultures, lower review rates, more • advanced technology allows for testing of body fluids and urine samples in a preservative tube	• 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	• cobas u pack strips have virtually no interference with ascorbic acid, minimizing false-negative glucose and hemoglobin results • innovative photometer with improved reflectance technology differentiates lysed and intact erythrocytes • 19-in. HD touchscreen monitor with an intuitive user interface and convenient QC management

**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

†answers in listing apply to all three systems unless otherwise indicated; ††combined total for iQ200 series

All information is supplied by the companies listed. The tabulation does not represent an endorsement by the CAP.

URINALYSIS INSTRUMENTATION

Part 3 of 4 See **captodayonline.com/productguides** for an interactive version of guide	**Siemens Healthineers** **Maya Daaboul** maya.daaboul@siemens-healthineers.com **Norwood, MA** **781-269-3000**/www.siemens-healthineers.com/en-us/urinalysis	**Siemens Healthineers** **Maya Daaboul** maya.daaboul@siemens-healthineers.com **Norwood, MA** **781-269-3000**/www.siemens-healthineers.com/en-us/urinalysis	**Sysmex America** **Jason Anderson** andersonja@sysmex.com **Lincolnshire, IL** **888-879-7639** www.sysmex.com
Name of urinalysis instrument	CLINITEK AUWi PRO Automated Urine Workstation†	CLINITEK Novus Automated Urine Chemistry Analzyer	UF-5000 Fully Automated Urine Particle Analyzer
Type of instrument	urine chemistry and microscopy/sediment combined	urine chemistry	microscopy/sediment
Instrument list price	—	—	$95,000
First year instrument sold in U.S.	2015	2015	2019
No. of units installed in U.S./No. of units installed outside U.S.	— (also sold via Cardinal Health, Fisher, Medline, McKesson)	— (also sold via Cardinal Health, Fisher, Medline, McKesson)	3/>1,000 globally
Foreign countries where company markets instrument	worldwide	worldwide	worldwide
Country where instrument designed/manufactured	U.S./England	U.S./England	Japan/Japan
Intended urine sample volume per day	50–500	50–1,000	40–75 microscopic analyses
Dimensions (HxWxD)/Weight fully loaded with reagents	27 × 63 × 35 in./~425 lbs.	21 × 25 × 27 in./~100 lbs.	35 × 26 × 36 in./232 lbs. (main unit)
Power requirements	100–240 VAC (50–60 Hz)	100–240 VAC (48–62 Hz)	100–240 VAC; 15 amps; 600 VA or less (main unit)
Mean time between failure of instrument	—	—	—
Events that cause instrument to lock or stop analysis	user ID failure, QC failure, short sample, barcode/sample ID misread, result error, sampling error, consumables replacement/expiration, calibration failure, other events	user ID failure, QC failure, short sample, barcode/sample ID misread, result error, sampling error, consumables replacement/expiration, calibration failure, other events	user ID 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/test strip/turbidity within an analyzer well	refractometer/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 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)†	—
• 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 Novus cassette change or every 24 hours when multiple same-lot Novus cassettes are used within 24 hours	with every Novus cassette change or every 24 hours when multiple same-lot Novus cassettes are used within 24 hours	—
• Form of calibration	liquid and dry	liquid and dry	—
• 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	7,500 sample results/400 control 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	—	flow cytometry with fluorescent stain
• Microscopy/sediment analysis parameters	flagged: pathological casts, crystals, small round cells, yeast-like cells, mucus, sperm; quantitative: RBCs, WBCs, epithelial cells, bacteria, hyaline casts	—	flagged: pathological casts, crystals, yeast-like cells, mucus, sperm; quantitative: RBCs, WBCs, epithelial cells, bacteria, total casts
• Flagging thresholds customizable	yes	—	yes
• Instrument eliminates amorphous crystal interference before sample analysis	yes	—	yes
• How results are displayed for microscopy/sediment	numeric values, scattergrams	—	numeric values, scattergrams
• Reporting format customizable	yes	—	yes
• No. of results that can be held in internal memory	up to 2 years worth (sample results)/up to 2 years worth (control results)	—	1,000 (sample results, including scattergrams)/2 concentrations × 3 lots, or 120 plots/lot (control results)
Reagent shelf life/storage temperature for unopened containers	365 days/15–30°C	365 days/15–30°C	varies based on reagent type
Reagent shelf life/storage temperature for opened containers	180 days; onboard stability of cassette, 14 days/15–30°C	onboard stability of cassette, 14 days/—	varies based on reagent type
Reagent barcode-reading capability	yes	yes	yes
How often quality control samples are run	daily (can use other vendors' QC products)	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/~2 min.	240/—	—
Sample throughput per hour/Time to first result for microscopy/sediment	80 at 100% sediment/~4 min.	—	up to 105/<1 min.
Analyzer has stat mode	yes (min. sample volume, 2 mL chemistry/1 mL sediment)	yes (minimum sample volume, 2 mL)	yes (minimum sample volume, 1.6 mL)
Sample dilutions required for urinalysis/body fluid analysis	no (urinalysis)/— (body fluid analysis)	no (urinalysis)/— (body fluid analysis)	no (urinalysis)/— (body fluid analysis)
• Special sample handling required for body fluid analysis	—	—	—
Minimum width of sample tube/Minimum length of sample tube	16 mm/95 mm	16 mm/95 mm	12 mm/95 mm
Conditions or substances that prevent a sample from being run	mucus, high fluorescence, grossly bloody samples, others	mucus, high fluorescence, grossly bloody samples	blood, mucus, high fluorescence, visible turbidity
Means of sample ID entry	barcode scan, worklist download from host, manual entry	barcode scan, worklist download from host, manual entry, RFID tag on cassette for automatic entry of lot and expiration	barcode scan, worklist download from host, manual entry
Built-in liquid-level sensing for samples	yes	yes	yes
Information that can be barcode scanned on instrument	specimen identifier, reagent lot No., more	operator identifier, specimen identifier, reagent lot No.	specimen identifier, reagent lot No.
How LOINC codes for results are made available	website, e-mail query, communications from Siemens	website, e-mail query, communications from Siemens	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)	yes (reflex testing)/— (cross-check functionality)
Instrument automatically generates consolidated report*	yes	—	—
Instrument connections to transfer information	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 (WAM)	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 (WAM)	data-management system that connects to LIS or EHR, or directly to LIS or EHR
Interface standards supported	ASTM 1394-91, HL7	ASTM 1394-91, ASTM 1381, HL7	ASTM 1381, ASTM 1894-97
Bidirectional interface	yes (to other companies' LISs and EHRs)	yes (to other companies' LISs and EHRs)	yes (to other companies' LISs and EHRs)
• Tests can be transmitted to LIS as soon as completed	yes	yes	yes
Connection to LIS to upload patient and QC results	direct serial or hospital network	direct serial or hospital network	hospital network
Connection to EHR to upload patient and QC results	direct serial or hospital network	direct serial or hospital network	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	device unique identifier, patient ID, specimen ID, result
No. of days of training with instrument purchase	1–3 days at customer site, 4 days at vendor office	1–2 days at customer site, 3 days at vendor office	based on configuration–virtual instructor-led training†
Approximate scheduled maintenance time required	10 min.: per shift, daily, weekly, monthly	5–10 min.: per shift, daily, weekly, monthly	20 min. daily; 10 min. weekly
• Maintenance records kept onboard instrument	no	no	yes
Provide list of client sites to potential customers on request	yes (partial list of comparable sites)	yes (partial list of comparable sites)	yes (partial list of comparable sites)
Clients restricted from sharing their experience with company or software	no	no	no
Distinguishing instrument features (supplied by company)	• can upgrade CLINITEK Atlas to CLINITEK Novus and have CLINITEK solution for dry pad chemistry • no sample pretreatment or on-screen review required • fluorescent flow cell technology with dedicated channels for bacteria and sediment to drive clinical outcomes	• digital color camera for improved accuracy of result measurement, including detection of intact RBCs • reagent cassette format with RFID that provides complete traceability and 14 days onboard stability • utilizes same dry pad reagent chemistry as CLINITEK family of analyzers—that is, Multistix 10SG	• fluorescent flow cytometry methodology offers accuracy, precision, efficiency, and standardization • highly modular and scalable system offering flexibility to add additional modules to meet increasing workload demands • BeyondCare quality monitor for urinalysis provides a streamlined and automated QC experience

**chemistry and microscopy results in one report*

†comprises CLINITEK Novus and Sysmex UF-1000i

††system does not report numeric values for most tests; it reports negative, trace, small, moderate, large, etc.

†system does not report numeric values for most tests; it reports negative, trace, small, moderate, large, etc.

†no limit on No. of times customer can sign up

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

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Sysmex America
Jason Anderson andersonja@sysmex.com
Lincolnshire, IL
888-879-7639 www.sysmex.com

Name of urinalysis instrument	UN-2000 Automated Urinalysis System
Type of instrument	microscopy/sediment
Instrument list price	—
First year instrument sold in U.S.	2019
No. of units installed in U.S./No. of units installed outside U.S.	3/~275 globally
Foreign countries where company markets instrument	worldwide
Country where instrument designed/manufactured	Japan/Japan
Intended urine sample volume per day	50–150 microscopic analyses
Dimensions (HxWxD)/Weight fully loaded with reagents	35 × 52 × 36 in./428 lbs. (main unit)
Power requirements	varies by configuration
Mean time between failure of instrument	—
Events that cause instrument to lock or stop analysis	user ID failure, short sample, barcode/sample ID misread, consumables replacement/expiration
Urine chemistry: *(Information in this box is specific to urine chemistry)*	
• Testing methodology: specific gravity/color/clarity	—
• Urine chemistry tests available on instrument in the U.S.	—
• Color compensation pad included	—
• Flagging thresholds customizable	—
• Test strip configuration	—
• Calibration required after each test strip lot No. change	—
• Frequency of customer-performed calibration	—
• Form of calibration	—
• How results are displayed for urine chemistry	—
• Reporting format customizable	—
• No. of results that can be held in internal memory	—
• Specific gravity correction for protein/glucose	—
Microscopy/sediment: *(Information in this box is specific to microscopy/sediment)*	
• Microscopy/sediment technology	flow cytometry with fluorescent stain and digital image analysis
• Microscopy/sediment analysis parameters	flagged and qualitative: pathological casts, crystals, yeast-like cells, mucus, sperm; qualitative: small round cells; quantitative: RBCs, WBCs, epithelial cells, bacteria, total casts; qualitative and quantitative: hyaline casts
• Flagging thresholds customizable	yes
• Instrument eliminates amorphous crystal interference before sample analysis	yes
• How results are displayed for microscopy/sediment	numeric values, scattergrams
• Reporting format customizable	yes
• No. of results that can be held in internal memory	400 (sample results, including captured image and extracted particle image information)/3 files per analyzer, or 120 plots per file (control results)
Reagent shelf life/storage temperature for unopened containers	varies based on reagent type
Reagent shelf life/storage temperature for opened containers	varies based on reagent type
Reagent barcode-reading capability	yes
How often quality control samples are run	daily (cannot use other vendors' QC products)
Sample throughput per hour/Time to first result for chemistry	—
Sample throughput per hour/Time to first result for microscopy/sediment	varies by configuration/<1 min.
Analyzer has stat mode	yes (minimum sample volume, 2.1 mL)
Sample dilutions required for urinalysis/body fluid analysis	no (urinalysis)/— (body fluid analysis)
• Special sample handling required for body fluid analysis	—
Minimum width of sample tube/Minimum length of sample tube	12 mm/95 mm
Conditions or substances that prevent a sample from being run	blood, mucus, high fluorescence, visible turbidity
Means of sample ID entry	barcode scan, 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.
How LOINC codes for results are made available	website, e-mail query
Software includes reflex testing/cross-check functionality	yes (reflex testing)/— (cross-check functionality)
Instrument automatically generates consolidated report*	—
Instrument connections to transfer information	data-management system that connects to LIS or EHR, or directly to LIS or EHR
Interface standards supported	ASTM 1381, ASTM 1894-97
Bidirectional interface	yes (to other companies' LISs and EHRs)
• Tests can be transmitted to LIS as soon as completed	yes
Connection to LIS to upload patient and QC results	hospital network
Connection to EHR to upload patient and QC results	hospital network
Information included in transmission from instrument to data-management software	device unique identifier, patient ID, specimen ID, result
No. of days of training with instrument purchase	based on configuration–virtual instructor-led training†
Approximate scheduled maintenance time required	20 min. daily; 10 min. weekly
• Maintenance records kept onboard instrument	yes
Provide list of client sites to potential customers on request	yes (partial list of comparable sites)
Clients restricted from sharing their experience with company or software	no
Distinguishing instrument features (supplied by company)	• powerful combination of fluorescent flow cytometry and digital image analysis allows for rapid screening of UA samples • highly modular and scalable system offering flexibility to add additional modules to meet increasing workload demands • BeyondCare quality monitor for urinalysis provides a streamlined and automated QC experience

**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

†no limit on No. of times customer can sign up

All information is supplied by the companies listed. The tabulation does not represent an endorsement by the CAP.