

Chemistry Analyzer – AU480



Pakistan

Yasir Aziz



AU480 a member of the AU Family





Beckman Coulter Biomedical K.K Mishima, Japan









The first one



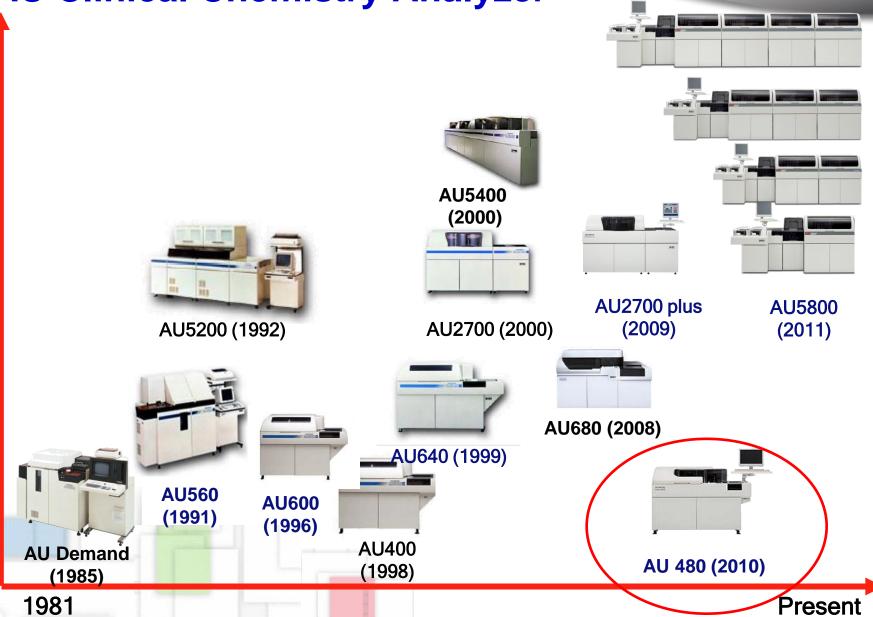
AU550 (1985)



Olympus Diagnostics (Japan) made the first analyzer in 1980's and achieved perfection after series of Improvement based on Customer Feedback.

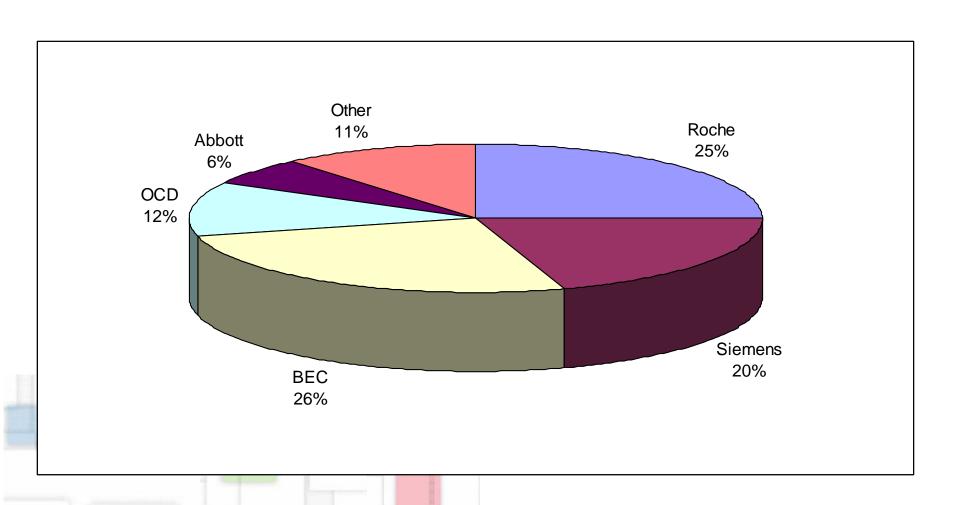
Today Beckman Coulter offers the new version of the Chemistry Analyzers that give precise, accurate, fast and reliable results...





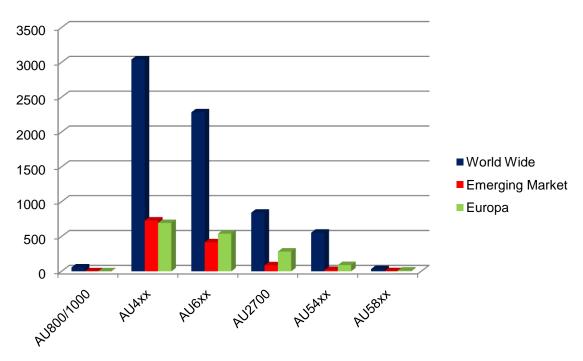


Market Segmentation - Clinical Chemistry WW (2009)





Installed Base September 2011



WW 6815 EM 1256 Europe 1620

1256 Systems older then 5 years are not included



Flexible Throughput

Scalable and unmatched throughput to meet all testing needs





AU680 Up to 800 / 1200 tests/hr / with ISE Mid-High Hospital Lab



AU5811/AU5812 Up to 2000 tests/hr 2900 /3800 with ISE Hospital Core Lab



Flexible Throughput

Scalable and unmatched throughput to meet all testing needs



AU5821/5822
Up to 4000 tests/hr
4900 / 5800 with ISE
Hospital Core / High Throughput
Labs



AU5831/5832
Up to 6000 tests/hr
6900 / 7800 with ISE
High and Ultra-high Throughput
Labs



AU5841/5842
Up to 8000 tests/hr
8900 / 9800 with ISE
Ultra-high Throughput Labs



Flexible Throughput

	Pipetting Cycle	Probes/ Photometric System	Photometric Throughput
AU480	9 sec / 1 test	1	400 tests/hr
AU680	4.5 sec / 1 test	1	800 tests/hr
AU5810	3.6 sec / 2 tests	2	2000 tests/hr
AU5820	3.6 sec / 4 tests	4	4000 test/hr
AU5830	3.6 sec / 6 tests	6	6000 test/hr
AU5840	3.6 sec / 8 tests	8	8000 test/hr



Beckman Coulter Ireland Inc Lismeehan, O'Callaghan's Mills Co. Clare

Lot-Size: 200 to 20.000 I 35 to 40 Lots/Week









Quality Systems

- FDA Quality System Requirement,
- IVDD
- Japanese Pharmaceutical Affairs Law (J Pal)
- ISO 13485
- ISO 14001 (environment)





AU Reagents are:

- Checked for Cross Contamination
- Ensure the quality of results due several checks i.e.
 - ✓ Dynamic range / Linearity
 - ✓ Reagent OD limit (Reagent contamination)
 - ✓ Min and Max OD check for Fixed and Rate methods
 - ✓ Calibration Factor range check
 - ✓ DataCeckParameters (Prozone Effect)
- Barcoded to avoid reagent missmatch
- LIH checked (test specific flagged by the AU systems)



- Same reagents are used for all AU platforms providing the same results
 - Most are ready to use
 - ➤ Bar-coded
 - Concentrated format
 - ➤ Tests from 50 to 5000 test per bottle, appropriated size for each analyzer
 - Broad Menu (over 125 assays)
- All analyzers can use15 mL, 30 mL, and 60 mL bottles.
 - > 120 mL on AU680
 - Maximize on board stability
 - ➤ Long self life of the lots

120mL & 180mL validation ongoing for AU5800





AU Reagents are:

- Highly concentrated (small packages)
- Available in different kit sizes
- Have a long shelf life
- Have a long onboard stability
- Most are ready to use (liquid stable)
- High quality



- AU Reagents are one or two shot reagents
- Reagents can be placed on the system without barcode (UDR / 3rd party reagents)
- Reagent load on the fly Can load and unload reagents without stopping the anaylzer



General Chemistry	Hepatic ****	Lipids	Inflammatory	TDMs	Drugs of Abuse
Albumin	Albumin	Apo A1	Alpha-1-Acidglycoprotein	Carbamazepine	Drugs of Abuse Amphetamines
ALP	ALP	Аро В	Alpha-1-Antitrypsin	Digitoxin	Barbiturate
ALT	ALT	Cholesterol	C3	Digoxin	Benzodiazepine
AST	AST	HDL Cholesterol	C4	Gentamicin	Cocaine
Amylase	GGT	LDL Cholesterol	Ceruloplasmin	Phenobarbital	Ectasy
Calcium Arsenazo	IgG	Triglycerides	C-Reactive Protein	Phenytoin	Cannabinoid 20 ng (THC)
Calcium oCPC	IgA		Haptoglobin	Theophylline	Cannabinoid 50 ng (THC)
Chloride	IgM	Diabetes		Valproic Acid	EDDP
CO2, Bicarbonate	Prealbumin	Direct HDL Cholesterol	Nutritional Assessment		Methadone
СК	Direct Bilirubin	Direct LDL Cholesterol	Albumin	Toxicology	Opiates 300 ng
Creatinine	Total Bilirubin	Glucose	Prealbumin	Acetaminophen (Paracetamol)	
Enzy. Creatinine	Total Protein	HbA1c	Ferritin		
Direct Bilirubin		Microalbumin		Tumor Markers]
GGT	Renal	Triglycerides	Autoimmune	Beta-2 Microglobulin	J
Glucose	Albumin	Urinary/CSF Protein	Anti-Streptolysin O		
Hydroxybutyrate Dehydrogenase	Beta-2 Microglobulin		C-Reactive Protein	Specialty	
LD	Calcium Arsenazo	Cardiac	High-sensitivity CRP	Cholinesterase	
Lipase	Calcium oCPC	СК	Rheumatoid Factor (RF)	Lactate	
Magnesium	Creatinine	CK-MB Activity		p-Amylase*	
Phosphorus	Enzy. Creatinine	Digoxin	Anemia		-
Potassium	Glucose	Myoglobin	Ferritin		
Sodium	Phosphorus	High-sensitivity CRP	Haptoglobin	N°	
Total Protein	Potassium		Iron		
Urea	Sodium	Esoterics	Transferrin	MSE	
Uric Acid	Total Protein	D-Dimer	UIBC		O BEOMAN
Urinary/CSF Protein	Urea	* User Defined Reagent	-	Section of the sectio	81 A10 DSR6194 - T

- Same reagents are used for all AU platforms providing
- Variable Kit size for optimal on board capacity

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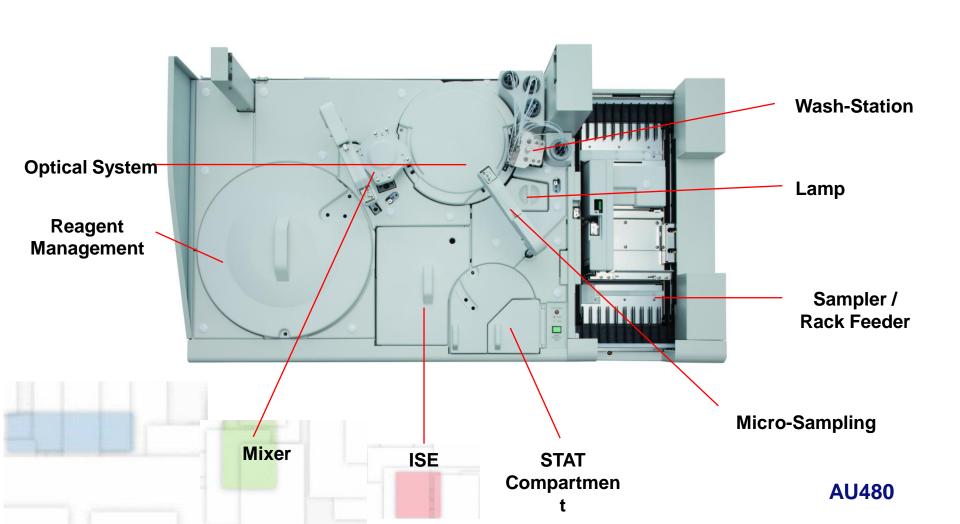
AU480

- AU 480 Features
- AU 480 ISE
- AU 480 Software
- AU 480 Maintenance





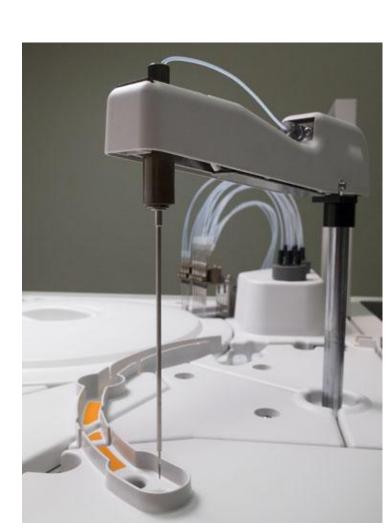






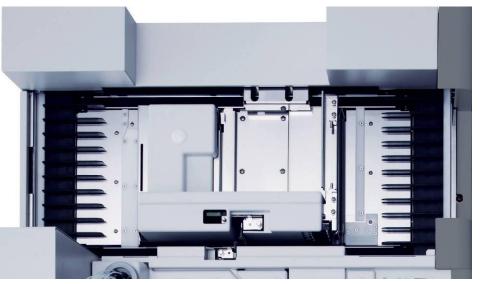
Sample Probe

- **≻Sample Clot Detection**
 - ✓ Attempts to clear and continues to sample
- > Level Detection
 - ✓ Verifies sample and reagent availability
- **≻Crash Detection**
- **≻Micro Sampling**
 - ✓ Small sample volumes (1.0 µl)
 - Ideal for pediatric, veterinary samples
- ➤ Sample Probe Cleaner on STAT table
- **Easy Access**
 - ✓ Easy to Replace, no tools required





Sample Loading



Continuous Loading

- Auto Repeat / Dilution
- Initial Capacity
 - ✓ More than 100 samples with continuous loading
- Flexible Racks
 - √ 10 position racks
 - ✓ Variety of tube sizes and tube heights can be loaded into the same rack

Barcode Capability

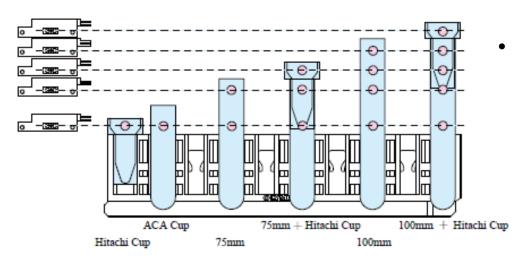
Mixed barcode types and digit lengths can be processed simultaneously





Sample Racks

Improved Cup-detection



Five different LED's for Cup detection

- ✓ Usage of "Nested cups"
- ✓ Special Down stroke for each LED

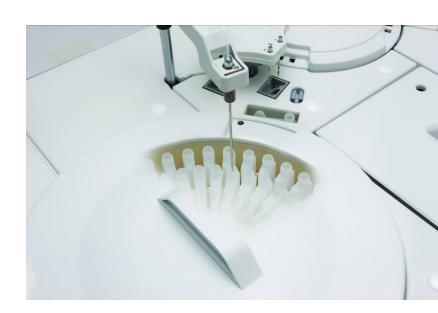
 customer specific adjustments –
 less dead volume.





Reagent Compartment

- > 76 Reagent positions
- Reagent compartments are refrigerated (4 12°C)
- Barcode identification and liquid level detection provides: shots per bottle, Lot and bottle number, expiring date
- One dilution bottle (for sample pre dilution) in front of the reagent compartment

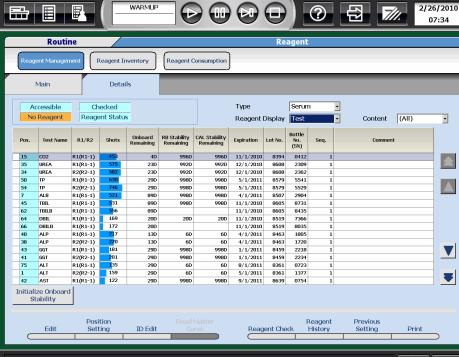




Reagent Management - Display



Complete reagent inventory on one view





STAT Sample

Improved Turnaround Time

- ✓ 22 user-defined positions:
 - Calibration & QC material
 - STAT samples
 - STAT repeats
- √ Fix Positions for
 - ISE cleaning and calibration
 - Reagent blank 1 & 2
- √ Cooled compartment
 - Store onboard Cals & Controls





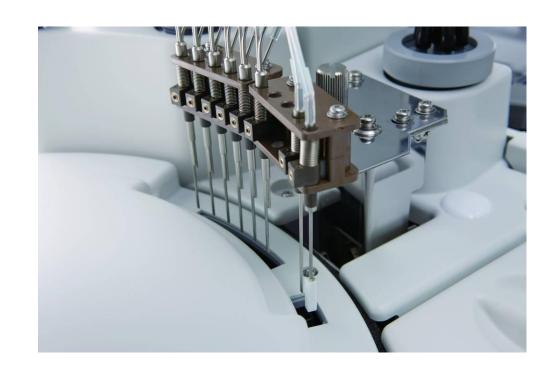
STAT Compartment

✓ 22 Positions for the STAT Samples or Calibrators or Controls





Cuvette Wash Station



Cuvette wash – 8 Probes (left to the right)

- 2 x wash with diluted Detergent
- 4 x wash with hot water
- 1 x Aspiration
- 1 x Drying



Mixer

2 Mixer (mixing after R1 dispensing)

2 Mixer (mixing after Sample dispensing)

2 Mixer (mixing after R2 dispensing)



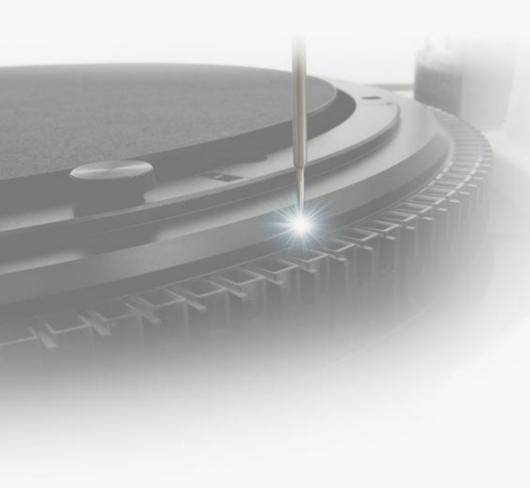


Mixer





Reaction Carousel

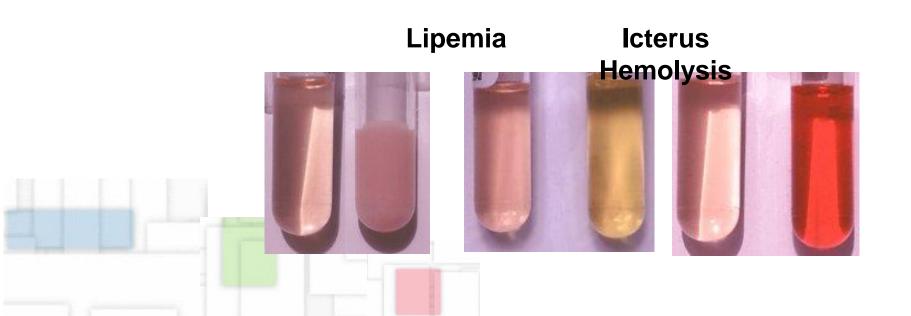


- Excellent optical system
- Cuvette Wheel
 - ✓ 88 Permanent, continuously cleaned, glass cuvettes
 - ✓ Reduces Maintenance -Lowers Inventory Cost
 - ✓ Minimizes Waste Cost
- Dry Bath Technology
 - ✓ No water bath
 - ✓ Reduces Maintenance



LIH – Serum Index

- Sample integrity for Hemolysis, Lipemia and Icterus will be measured: i.e. Hemolysis ++ , Lipemia +, Icterus n
- The LIH results will be cross linked to results so that assays sensitive to LIH are appropriately flagged, thus ensuring that correct decisions are made.





LIH – Serum Index

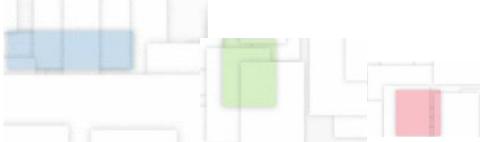
	Approximate Concentration of Chromatic Subs				
Flag	LIP (mg/dL Intralipid)	ICT (mg/dL Bilirubin)	HEM (mg/dL Haemoglobin)		
N	< 40	< 2.5	< 50		
+	40 – 99	2.5 – 4.9	50 – 99		
++	100 – 199	5.0 – 9.9	100 – 199		
+++	200 – 299	10 – 19.9	200 – 299		
++++	300 - 500	20 – 40	300 – 500		
+++++	> 500	> 40	> 500		

CO

AU480

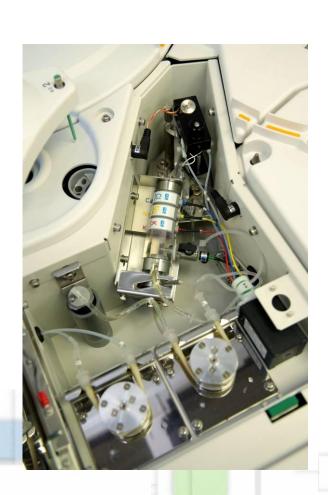
- AU 480 Features
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AU 480 - ISE





✓ Same Electrodes for all AU Systems

- NA, K, CI ready to use
- Separated electrodes Less costs
- Long life up to 6 months

✓ Easy to maintain

- No special tools
- Easy to replace electrodes

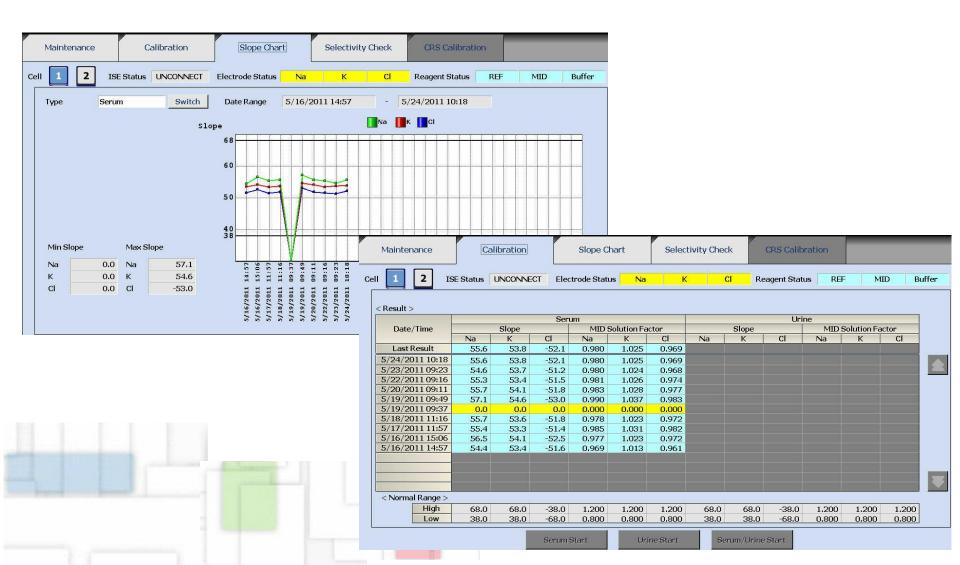
✓ Indirect Measurement

 Excellent precision and extended calibration stability of 24 hours

AU 480 - ISE



ISE – Calibration Monitor

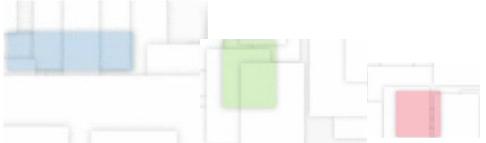


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AU480

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- AU 480 ISE
- AU 480 Software
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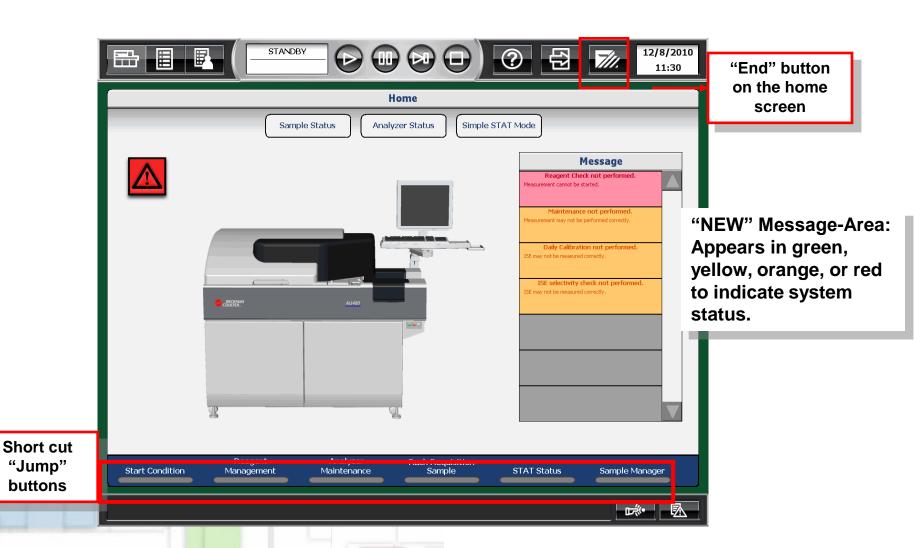




AU480 Improved - Touch Screen User Interface



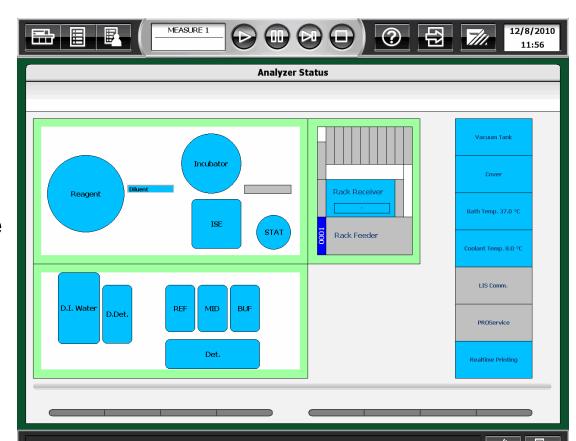






Analyzer Status

- Analyzer Status with rack tracking
- Volume display for dilution bottle and sample probe cleaner









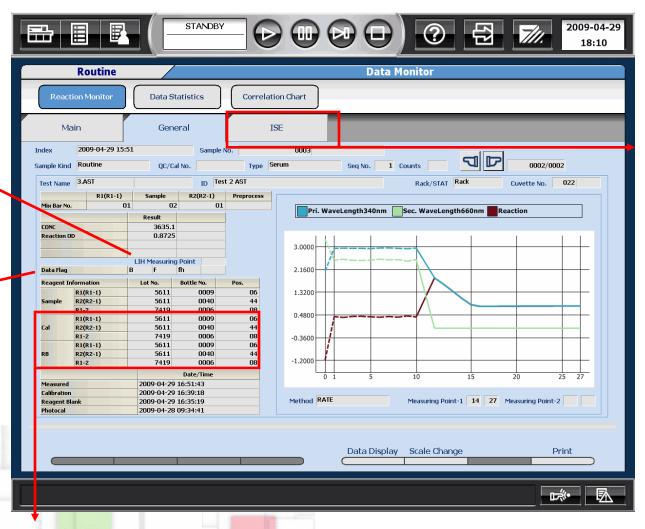
Results can be displayed, printed and transmitted as soon as the result is calculated







4 instead of 2 flags are displayed

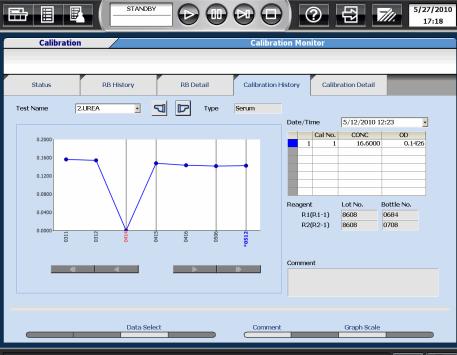


ISE data are displayed

Calibration and RB details







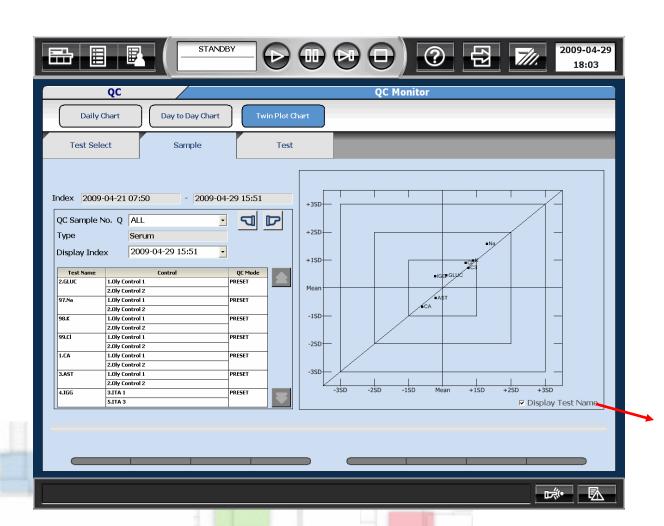


- •10 controls / test
- •To view the statistics select the Ctl.No



All QC samples displayed in one graph





Twin Plot display:

- All QC samples in one Plot
- Selective QC sample
- Tests

Test Name display



- Increased Data Storage on Harddrive
 - ➤ Samples up to 100,000
 - Reaction Monitors up to 200,000 (max 10,000 per index)
 - ➤ Indexes up to 300
 - Samples per Index up to 9999
- External Data Management
 - Floppy Disk, CD and Memo stick
 - Storage as csv files (easy to import in Excel)

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AU480

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AU 480 - Maintenance



• 3 x 60 = Simplifies Operator Interaction







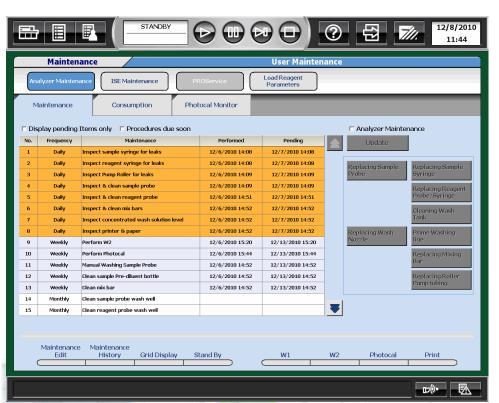


- ✓ No more than 3 steps
- ✓ No longer than 60 seconds
- ✓ No Tools

AU 480 - Maintenance



All user maintenance tasks are combined in the USER MAINTENANCE MENU



Improved and interactive Maintenance schedule

- Outstanding maintenance is highlighted in the table and appears on the home screen message area.
- Day of performance and next date of execution is shown in one table.
- If a maintenance is selected in the table, the corresponding maintenance task (on the right side i.e. Total prime) will be active.
- System start can be inhibit, when a maintenance task is outstanding.

AU 480 – Summary



- Small footprint and Large TEST MENU (FDA Approved)
- Through put: 800 tests per hour
- ISE with 24 hours Calibration Stability.
- Automatic Calibration and QC from on board tubes
- Sample Capacity: More than 100 samples (Continuous Loading)
- Reagent Positions: 76 Reagent
- Reagent Load / Unload without Stop.
- Mixers, seperate for Sample and reagent
- High-precision micro sampling (min 1 μl) Ideal for pediatric,
- 88 Permanent Cuvettes with automatic washing and Drying.
- Less Maintenance No Water Bath.
- All-In-One PC on a swing arm. Data storage on external memory device
- On Board Maintenance Log.





Questions?

