

TRANSASIA BIOMEDICALS LIMITED			TRANSASIA[®] Bio-Medicals Ltd.
INSTALLATION QUALIFICATION			
Instrument Name	Clinical Chemistry Analyzer	Instrument ID	


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Instrument Name	Clinical Chemistry Analyzer	Instrument ID	

1.0 PRE APPROVAL


1.1 Prepared By

Name	Designation	Signature	Date
Bign. N. m	St. ASM		12/4/21

1.2 Checked By

Name	Designation	Signature	Date
Bign. N. m	St. ASM		12/4/21

1.3 Approved By

Name	Designation	Signature	Date
Bign. N. m	St. ASM		12/4/21

Note: After the Pre-Approval, this document is effective for the execution.

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2.0 OBJECTIVE


The objective of this document is to provide an outline for the inspection of EM 200 (Bio-Chemistry Random Analyzer) and to verify that the following boundaries:

- Each Installed subcomponent complies with the engineering design and instrument data sheet / design specifications & manufacturer's recommendations.
- To ensure that all the safety features are defined before the start up of operational qualification exercise.
- The system meets the current regulatory requirements.
- To identify the Standard operating procedures for Operational Qualification.

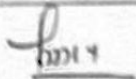
3.0 SCOPE

The scope of this protocol is to outline procedure for Installation qualification of the subjected instrument within the following boundaries:

- Identification and verification of its Major components / Accessories
- Identification, Classification and Verification of Process Control Instruments / Gauges / Devices
- Identification and verification of Material of Construction
- Identification and verification of Supporting Utilities
- Identification of Standard Operating Procedures
- Identification and Verification of Documents

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4.0 EXECUTION TEAM

Name	Department	Designation	Signature
Jiny R Chandran	Biochemistry Quality Manager	Biochemist Quality Manager	

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5.0 INSTRUMENT DESCRIPTION

The Clinical Chemistry Analyzer is an open, full automated, discrete, patient prioritized, random access, computerized analyzer.

Technical Specifications:

System Type	Open, Automated, Discrete, Random Access, Patient Prioritized, 1/2 Reagents
Analysis Speed	200 Biochemistry tests per hour 400 tests per hour (with ISE) for a cycle time of 18 seconds
Display resolution	1024 X 768
Analyzer Dimensions	810 (W) x 800 (D) x 600 (H) mm
Number of tests on board	Maximum: 50
Assay Modes	1-point, 2-point, Rate-A and Rate -B, ISE optional
Calibration	Linear (two point and multi point), Factorized and Non-linear multipoint
Sample (Tubes / Cups)	Primary tubes of 5, 7 or 10mL & sample cups
Photometric Optics	Mono and Bi-chromatic measurement using 8 wavelengths
Absorbance Range	0 – 2.5
Auxiliary Data	10,000 results
Interface	RS-232 C port for Bi-directional Communication
Stat Sampling	Total 30 positions

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Instrument Name	Clinical Chemistry Analyzer	Instrument ID	
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Purpose:

The purpose of this instrument is to analyze the bio-chemical parameters, such as Sugar, Cholestrol, Tri-glycerides, Proteins, etc.

The working unit of the analyzer comprises the following:

- Basic operating unit with an intelligent photometer
- Sophisticated robotics combined with an operating console and a central processing unit (CPU).

Operating Unit:

The operating unit of the analyzer includes the sample and reagent handling systems. The sample handling system consists of a sample tray, sample arm, sample syringe and a wash station for the sample probe.

Photometric System:

The photometric system consists of 45 hard glass cuvettes, multi wavelength diffracting photometer and a halogen lamp.

Operating Console:

The operating console consists of a touch screen (optional) color TFT monitor, a key board and a mouse.

CPU (Central Processing Unit):

CPU consists of Pentium – IV 1.7 GHz processor (or Higher) with a 48 x CD Drive, and minimum 256 MB memory. The application software can be installed on computers with operating systems of Windows XP.

Besides the above mentioned, this analyzer has got the unique Software and Hardware features.

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Instrument Name

Clinical Chemistry Analyzer

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6.0 IDENTIFICATION OF MAJOR COMPONENTS / ACCESSORIES

Details of each major component identified in this section, is recorded in a data sheet under the section 08.0.

Name of Component / Accessories	Present	Verified by Signature	Observations
	Yes / No		
Sample Tray / Disk	X		
Sample Syringe	X		/
Sample Probe	X		/
Wash Station for Sample Probe	U		/
Reagent Tray / Disk	U		/
Reagent Bottles	U		/
Reagent Probe	U		/
Stirrer	U		/
Permanent Reaction Cuvette	U		/
9 Stage Laundry System	U		/
Light Source	U		/
Sample Cups	U		/
Software of EM 200	U		/

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Instrument Name

Clinical Chemistry Analyzer

Instrument ID

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7.0 INSTALLATION CHECK / REVIEW

S. No.	Statement	Yes / No	Verified by Signature
1.	Verify that the "as built" drawings are complete and represent the design concept	Y	
2.	Verify that major components / accessories are securely anchored and shock proof.	Y	
3.	Verify that there is no observable physical damage.	Y	
4.	Verify that there is sufficient room of servicing provided	Y	
5.	Verify that all utilities and electrical connections have been done according to the drawings.	Y	
6.	Walking access to ground mounted instrument provided.	Y	
7.	Required electric connections are tight, weather proof and earthed.	Y	
8.	Instrument identification nameplate visible.	Y	
9.	Units installed on foundation and secure in place as per manufacturer's recommendations.	Y	
10.	Verify that the instruments installed and leveled properly on the floor.	Y	
11.	Verify that the Material of Construction is proper and meeting the requirements.	Y	

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8.0 INSPECTION CHECK / REVIEW

Instructions for completing the check / review

1. For each **data sheet**, record the required information with pen. Wherever required record "Yes" for acceptance, "No" for non-compliance and "NA" for not applicable.

"No" replies must be explained / justified.
2. When more than one component of same specification/type exists in the same equipment, individual data sheets should be filled for each component.
3. When a list of acceptable options is presented, tick (✓) the option that is actually present.
4. In the "**Method of Verification**" column indicate that item is installed and inspected according to manufacturer's specifications, such as by Visual / Physical, SOP, Test Certificate, Manual, etc.

TRINITY UNIVERSITY
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2011

Section	Section	Level	Status of Verification	Verified by
TRINITY UNIVERSITY (TRINITY COLLEGE)	TRINITY UNIVERSITY (TRINITY COLLEGE)	20	verified	[Signature]
TRINITY UNIVERSITY (TRINITY COLLEGE)	TRINITY UNIVERSITY (TRINITY COLLEGE)	20	verified	[Signature]
TRINITY UNIVERSITY (TRINITY COLLEGE)	TRINITY UNIVERSITY (TRINITY COLLEGE)	20	verified	[Signature]
TRINITY UNIVERSITY (TRINITY COLLEGE)	TRINITY UNIVERSITY (TRINITY COLLEGE)	20	verified	[Signature]
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INSTALLATION QUALIFICATION



Instrument Name Clinical Chemistry Analyzer Instrument ID

Instrument/ Component Name: Sample Tray / Disk

Date :

Description	Specified	Actual	Method of Verification	Verified by Signature
No. of patient cups / samples	30 positions	30	Verified	Joy & Charles <u>2014</u>
Standards / Stat	30 positions	9	verified	
Blank	Can be put on any position	1	verified	
ISE positions (Optional)	Can be programmed on any positions	Nil	verified	
Controls	Can be programmed on any positions	13	verified.	

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INSTALLATION QUALIFICATION




Instrument Name | Clinical Chemistry Analyzer | Instrument ID

Instrument/ Component Name: Sample Syringe

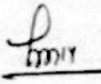
Date :

Description	Specified	Actual	Method of Verification	Verified by Signature
Dispensing Volume	2 - 70 µL	2-70µL	DONE	Jimmy R. Chua
Installed Location	Behind the instrument on the right side	Behind the instrument on the right side	DONE	
Quantity	01 No.	01 NO	DONE	
Increase in dispensing volume	0.2 µL	0.2µL	DONE	

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Instrument Name	Clinical Chemistry Analyzer	Instrument ID	

Instrument/ Component Name: Sample Probe

Date :

Description	Specified	Actual	Method of Verification	Verified by Signature
Aspiration Volume	2 - 70 μ L	2 - 70 μ L	Done	Jany R chandran 
MOC	Teflon coated	Teflon coated	Done	
Quantity	01 No.	01 No.	Done	
Increase in aspiration volume	0.2 μ L	0.2 μ L	Done	

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Instrument Name	Clinical Chemistry Analyzer	Instrument ID	

Instrument/ Component Name: Wash Station for Sample Probe

Date :

Description	Specified	Actual	Method of Verification	Verified by Signature
No. of position	01 No	01 No	Done	Janny R Chandra
Type of positions	i) Drain	i) Drain	Done	<u>Jm</u>
	ii) Trough	ii) Trough		

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INSTALLATION QUALIFICATION



Instrument Name	Clinical Chemistry Analyzer	Instrument ID	
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Instrument/ Component Name: Reagent Tray / Disk

Date :

Description	Specified	Actual	Method of Verification	Verified by Signature
Cool reagent disk	50 positions	✓		 / / / / / /
Outer Rings	25 positions	✓		
Inner Rings	25 positions	✓		
Adaptors of 5mL	50 positions	✓		
Maintenance of Temperature	8-12°C ± 2°C	✓		
Rotation of disk	Counter-Clockwise	✓		
Time for Rotation of one Cuvette	Every 18 seconds	✓		

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
INSTALLATION QUALIFICATION



Instrument Name	Clinical Chemistry Analyzer	Instrument ID
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Instrument/ Component Name: Reagent Bottles

Date :

Description	Specified	Actual	Method of Verification	Verified by Signature
Minimum Capacity	20 mL	Y		 / / / / / / / / /
Maximum Capacity	50 mL	Y		
Quantity (Large)	25 Nos'	Y		
Quantity (Smaller)	25 Nos'	Y		
Type	Screw Capped	Y		
Outer ring position	20 mL bottles & 5ml adaptors	Y		
Inner ring position	20 mL & 50 mL bottles & 5ml adaptors	Y		
MOC	Plastic	Y		
Adaptor	50 Nos'	Y		
Adaptor Capacity	5 mL	Y		
Identification of Reagents	Barcode labels on the reagent containers	Y		

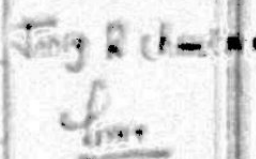
TRANSCIA EDUCATIONAL SUPPLIES
 INSTALLATION QUALIFICATION



Instrument Name: Clinical Chemistry Analyzer Instrument ID: _____

Instrument Component Name: Reagent Probe

Date: _____

Description	Specified	Actual	Method of Verification	Verified by Signature
Reagent Dispensing Volume	R1: 50 - 500 μ L	50 - 500 μ L	Done	 Tony R. Clark
	R2: 5000 - 500 μ L	5000 - 500 μ L	Done	
WBC	Teflon coated	Teflon coated	Done	
Quantity	42 Nos.	42 Nos.	Done	
Increase in reagent dispensing volume	1 μ L	1 μ L	Done	

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INSTALLATION QUALIFICATION



Instrument Name	Clinical Chemistry Analyzer	Instrument ID	
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Instrument/ Component Name: Reagent Syringe

Date :

Description	Specified	Actual	Method of Verification	Verified by Signature
Maximum capacity	500 µL	500µL	Done	Jimmy R Chandan
Installed Location	At the back of the instrument on the right side	At the back of the instrument on the right side	Done	
Quantity	01 No.	01 NO	Done	
Increase in dispensing volume	1 µL	1 µL	Done	

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INSTALLATION QUALIFICATION



Instrument Name	Clinical Chemistry Analyzer	Instrument ID	
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Instrument/ Component Name: Stirrer

Date :

Description	Specified	Actual	Method of Verification	Verified by Signature
Type	Single Stirrer	Y		
No. of paddles	01 No.	X		

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INSTALLATION QUALIFICATION




Instrument Name	Clinical Chemistry Analyzer	Instrument ID	
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Instrument/ Component Name: Permanent Reaction Cuvette

Tag/Identification No.:

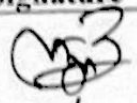
Date :

Description	Specified	Actual	Method of Verification	Verified by Signature
Quantity	45 Nos'	✓		 ✓ ✓
MOC	Hard Glass	✓		
Capacity	770 µL	✓		

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Instrument Name	Clinical Chemistry Analyzer	Instrument ID	

Instrument/ Component Name: 7 Stage Laundry System

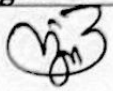
Date :

Description	Specified	Actual	Method of Verification	Verified by Signature
Nozzles	Nozzle - 1	✓		 / / / / / /
	Nozzle - 2	✓		
	Nozzle - 3	/		
	Nozzle - 4	/		
	Nozzle - 5	/		
	Nozzle - 6	/		
	Nozzle - 7	/		

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Instrument Name	Clinical Chemistry Analyzer	Instrument ID	

Instrument/ Component Name: Light Source

Date :

Description	Specified	Actual	Method of Verification	Verified by Signature
Watts	12 W	✓		 /
Volts	12 V	/		
MOC	Halogen	/		
Quantity	01 No	/		

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INSTALLATION QUALIFICATION



Instrument Name	Clinical Chemistry Analyzer	Instrument ID	
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Instrument/ Component Name: Sample Cups

Date :

Description	Specified	Actual	Method of Verification	Verified by Signature
Quantity	500 Nos'	✓		 / /
MOC	Plastic	✓		
Capacity	2 mL	✓		

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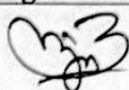
INSTALLATION QUALIFICATION



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Instrument/ Component Name: Software of EM 360

Date :

Description	Specified	Actual	Method of Verification	Verified by Signature
Version				 / / /
CD number				
Product	EM- 200	X		
Make	Erba Transasia	Y		

Instrument Name

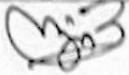
Clinical Chemistry Analyzer

Instrument ID

9.0 IDENTIFICATION AND VERIFICATION OF MATERIAL OF CONSTRUCTION

Identify and list down all components of the equipment for its material of construction.

Method of Test may be Molybdenum Test, Test Certificate, Manual, etc.

Component (s)	Material of Construction	Actual	Method of Verification	Verified by Sign & Date
Sample Probe	Teflon coated	γ		
Reagent Probe	Teflon coated	/		/
Permanent Reaction Cuvette	Hard Glass	/		/
Light Source	Halogen	/		/
Reagent Bottle	Plastic	/		/
Sample Cups	Plastic	/		/

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Instrument Name

Clinical Chemistry Analyser

Instrument ID

10.0 IDENTIFICATION AND VERIFICATION OF SUPPORTING UTILITIES

List the supporting utilities and record whether or not they are properly connected and identified.

Utilities	Observation / Result	Verified by Sign & Date
Power	Y	
Distilled Water	/	
Wash Solution	/	
UPS	/	

TRANSDUCER PERFORMANCE VERIFICATION
 INSTRUMENTATION QUALITY ASSURANCE

APPROVED NAME: _____

DATE: _____

REVISION: (0)

TRANS-001
 0-000-0

1.0 INSTRUMENTATION OF SYSTEMS OPERATING PROCEDURES

STEP NO.	DESCRIPTION
1.000000	Operation of the Chemistry Section Analyzers
1.010000	Operation of Parameters
1.020000	Control of Control Set Parameters
1.030000	Procedures for checking of distilled water, Waste, Wash solutions, Carriers and Sample probe wash and Water level
1.040000	Cleaning of Instrument surface

Instrument Name

Clinical Chemistry Analyzer

Instrument ID

11.0 IDENTIFICATION OF STANDARD OPERATING PROCEDURE

SOP No.	Title
Operation	Operation of Bio-Chemistry Random Analyzer
Calibration	Calibration of Parameters
Controls	Checking of Controls for Parameters
Maintenance	Maintenance / Checking of Distilled water, Waste, Wash solution, Cuvette rinse, Sample probe wash and Water save
Cleaning	Cleaning of Instrument surface

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Instrument Name

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Instrument ID

12.2 GENERAL DOCUMENTS

Title	Document No.	Verified by Sign & Date
General		
Purchase Order No.	γ	 / /
Warranty Certificate	/	
Invoice	/	
Test Certificates		
Material of Construction	/	/
Electrical Motor	/	/

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INSTALLATION QUALIFICATION



Instrument Name	Clinical Chemistry Analyzer	Instrument ID	
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16.0 POST APPROVAL:

16.1 Checked by

Name	Designation	Signature	Date
Jincy R Chandran	Biochemist Quality Manager	<u>Jincy</u>	12/4/21

16.2 Approved by

Name	Designation	Signature	Date
Jincy R Chandran	Biochemist Quality Manager	<u>Jincy</u>	12/4/21

Note: This report is effective from the date of approval.

Instrument Name

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PERFORMANCE QUALIFICATION



Instrument Name	Clinical Chemistry Analyzer	Instrument ID	
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1.0 PRE APPROVAL

1.1 Prepared By

Name	Designation	Signature	Date
Bijm N.M	Stb. ASM		12/4/21

1.2 Checked By

Name	Designation	Signature	Date
Bijm N.M	Stb. ASM		12/4/21

1.3 Approved By

Name	Designation	Signature	Date
Jincy R Chandran	BIOCHEMIST		12/4/21

Instrument Name	Clinical Chemistry Analyzer	Instrument ID	
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2.0 OBJECTIVE

The objective of this protocol is to establish documented evidence for the Performance Qualification of EM 200 (Bio-Chemistry Random Analyzer) and to ensure that the results obtained are within the pre-determined Acceptance Criteria.

3.0 SCOPE

The Scope of this protocol is applicable to EM 200 (Bio-Chemistry Random Analyzer).

4.0 PRE-REQUISITES:

Following Pre-requisites are required before the execution of Performance Qualification.

- Completion of Installation Qualification prior to PQ.
- Completion of Operational Qualification prior to PQ.

5.0 EXECUTION TEAM

Name	Department	Designation	Signature
<i>B. J. A. M.</i>			

TRANSASIA BIOMEDICALS LIMITED

PERFORMANCE QUALIFICATION



Instrument Name	Clinical Chemistry Analyzer	Instrument ID	
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11.0 POST APPROVAL

11.1 Checked by

Name	Designation	Signature	Date
Jancy R Chandran	Biochemist Quality Manager		12/4/21

11.2 Approved by

Name	Designation	Signature	Date
Jancy R Chandran	Biochemist Quality Manager		12/4/21

Note: This report is effective from the date of approval.

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OPERATIONAL QUALIFICATION CHECKLIST

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As part of Operational qualification, the following checks shall be done and each test shall be recorded:

Instrument Start-up

To check and establish the standard sequence to be followed, during start-up of the subjected instrument in Auto / Manual mode, to propose for correct operation and to avoid any damage to the instrument and personnel.

Functional Checks

To check and ensure that different functions (such as switching devices, indication / monitoring / recording devices, feedback system, etc.) for correct operation of the subjected instrument are working as expected.

Interlocks and Alarms Check

To check and ensure that the interlocks and alarms (such as status indication system, negative feed back system, control loops, sound alarms, etc.) for correct control and monitoring of the operation cycle are working as expected.

Safety / Security Checks

To check and ensure that the safety / security functions (such as program logging, process control, personnel safety systems, password check, etc.) to protect the instrument and personnel are working as expected.

Instrument Shut-down

To check and establish the standard sequence to be followed, during shut-down of the subjected instrument in Auto / Manual mode, to propose for correct operation and to avoid any damage to the instrument and personnel.


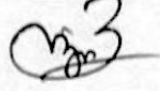


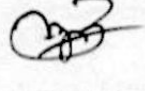

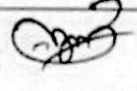
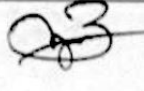

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OPERATIONAL QUALIFICATION CHECKLIST

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Instrument Name	Clinical Chemistry Analyzer	Instrument ID	
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1.0 INSTRUMENT START-UP:

Refer the Operator's Manual for the procedures, for the following activities:

Action	Observation	Verified by (Sign & Date)	Remarks
Ensure that all the required electrical connections are properly connected.	✓		
Ensure the proper filling of double distilled / de-ionized water and Cleaning solution in the respective cans.	✓		
Ensure the availability of XL Wash.	✓		
Ensure the availability of Biohazard Waste.	✓		
Ensure the availability of Normal Waste.	✓		
Switch ON the rear switch of the analyzer.	✓		
Switch ON the side switch of the analyzer.	✓		
Switch ON the computer and start the analyzer application software.	✓		
Initialization	✓		

TRANSASIA BIOMEDICALS LIMITED
OPERATIONAL QUALIFICATION CHECKLIST



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2.0 FUNCTIONAL CHECKS:

2.1 Maintenance:

Refer the Operator's Manual for the procedures, for the following activities:

Activity	Observation	Verified by (Sign & Date)	Remarks
Photometer functioning	OK		
Cuvette Rinse	OK		

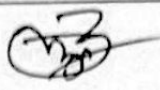
TRANSASIA BIOMEDICALS LIMITED
OPERATIONAL QUALIFICATION CHECKLIST



Instrument Name	Clinical Chemistry Analyzer	Instrument ID	
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2.2 Loading of Reagents:

Refer the Operator's Manual for the procedures, for the following activities:

Action	Observation	Verified by (Sign & Date)	Remarks
Reagent Level Scan, Dead Volume Check & 2 Reagent Chemistry	OK		

TRANSASIA BIOMEDICALS LIMITED

OPERATIONAL QUALIFICATION CHECKLIST



Instrument Name	Clinical Chemistry Analyzer	Instrument ID	
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2.3 Calibration:

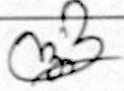

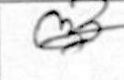
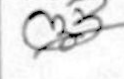
Refer the Operator's Manual for the procedures, for the following activities:

Action	Observation	Verified by (Sign & Date)	Remarks
Blank (Distilled Water)	ok		
Standard (Multical)	ok		

Instrument Name Clinical Chemistry Analyzer Instrument ID

3.0 INTERLOCKS AND ALARMS CHECK:

Refer the Operator's Manual for the procedures, for the following activities:

Action	Observation	Verified by (Sign & Date)	Remarks
Less volume of Distilled Water	ok		
Less volume of Wash Solution	ok		
More volume of Bio-Hazard waste	ok		
More volume of Normal / General waste	ok		

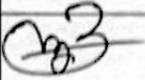

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OPERATIONAL QUALIFICATION CHECKLIST



Instrument Name	Clinical Chemistry Analyzer	Instrument ID	
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4.0 SAFETY / SECURITY CHECKS:

Refer the Operator's Manual for the procedures, for the following activities:

Action	Observation	Verified by (Sign & Date)	Remarks
Password Check for Test Parameters	ok		
Password Check for QC Mode	ok		




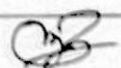
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OPERATIONAL QUALIFICATION CHECKLIST

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 Bio-Medicals Ltd.

Instrument Name	Clinical Chemistry Analyzer	Instrument ID	
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5.0 INSTRUMENT SHUT-DOWN:

Refer the Operator's Manual for the procedures, for the following activities:

Action	Observation	Verified by (Sign & Date)	Remarks
Sample Probe Wash	ok		
Water Save	ok		
Switch OFF the computer.	ok		
Switch OFF the side switch of the analyzer.	ok		
Switch OFF the rear switch of the analyzer.	ok	