

Date: 11/12/2022

CALIBRATION CERTIFICATE OF BA200

CUSTOMER NAME – **Navani Diagnostic Centre -Namakkal**

Serial Number = 832001199

User Software = V 5.4.2.0

Initialization Motor

Vertical Motors – S /R1 /R2 in Home

Polar Motors – S /R1 /R2 in Home

Reaction Rotor in home

Sample /Reagent rotor in Home

Ceramic Dispensing pump – S/ R1 /R2 in Home

Optics Initialization: Ok

Auto adjustment of the probe is done

Peltier cells and drivers test

Rotor Peltier/ Reagent Rotor peltier driver test: Ok

Temperature system initialized

LED test: ok

Hardware completely initialized

Parameters	Current value	Minimum	Maximum
Reading reference Position - Well 1	7896	7860	7905
Washing Solution Tank 0	0	-5	5
Washing Solution Tank 50	46	40	60
Washing Solution Tank 100	98	95	105
Waste Tank 0	-1	-5	5
Waste Tank 50	43	40	60
Waste Tank 100	100	95	105
Thermal adjustment of reaction rotor	37.0	36.0	39.0
Thermal adjustment of Wash station	44.9	44	50
Thermal adjustment of reagent tip 1	37.0	36	39

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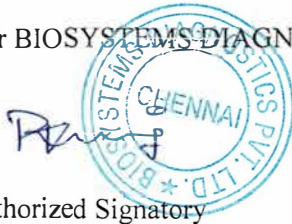
Registered office:

BioSystems Diagnostics Pvt. Ltd.,
A4, SIPCOT Industrial Park, Irungattukottai,
Tamil Nadu - 602105. India
Ph: +91 -44 - 30341911 / 12/ 13/14
Email: support@biosystems.in
CIN - U29297TN2003PTC051492

Thermal adjustment of reagent tip 2	37.0	36	39
Photometric Dark Current Adjustment	4035	3300	4500
Main Photo Diode Counts 340NM	901902	185377	950000
Main Photo Diode Counts 405NM	900206	717940	950000
Main Photo Diode Counts 505NM	900593	744269	950000
Main Photo Diode Counts 535NM	882617	551840	950000
Main Photo Diode Counts 560NM	898449	728466	950000
Main Photo Diode Counts 600NM	900750	642530	950000
Main Photo Diode Counts 635NM	901759	620434	950000
Main Photo Diode Counts 670NM	905788	662579	950000

Next calibration due on: 10/12/2023

For BIOSYSTEMS DIAGNOSTICS PVT. LTD.,



Authorized Signatory

BioSystems S.A.

Costa Brava 30,
08030 Barcelona (Spain)
t. +34 933 110 000

www.biosystems.in
www.biosystems.global

BA200 – Fully Auto Biochemistry Analyser

Installation Qualification Certificate

For

NAVANI DIAGNOSTIC CENTRE

Namakkal

BioSystems Diagnostics Pvt. Ltd

CERTIFICATE OF INSTALLATION

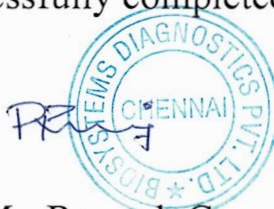
Instrument Name: BA200 Fully Auto Biochemistry Analyzer

Serial Number : 832001199


Customer : NAVANI DIAGNOSTIC CENTRE
Namakkal

The undersigned performer certifies that the installation Qualification Protocol has been successfully completed for the instrument stated above.

Engineer
Signature:



Name : Mr. Ramesh G
Designation : Assistant Manager Service
Company : BioSystems Diagnostics Pvt. Ltd.,

Customer
Signature : 
Name : Ms. Dr. R. Vanitha M.B.B.S., D.C.P.,
Designation : Clinical Pathologist
Company : NAVANI DIAGNOSTIC CENTRE NAMAKKAL

INSTALLATION REPORT

Customer Name : NAVANI DIAGNOSTIC CENTRE NAMAKKAL
Department : Bio-chemistry
Contact Person : Ms. Dr, R, Vanitha M.B.B.S., D.C.P.,
Instrument Model : BA200
Serial Number : 832001199
Date of Installation : 11/12/2022

The System was installed along with the necessary accessories. All basic requirements and adjustments were checked and are found to be satisfactory Preliminary customer training was provided and standardization of all parameters was done. The Instrument is found to be working satisfactorily.

INSTRUMENT SETUP :

- Instrument and computer installed
- Printer Installed
- User software 4.04.26 installed
- All necessary cable connections given

OPERATION INSPECTION :

- No air bubbles found in the Tubing
- Temperature of the Needles/Reaction & Rotor Chamber are within range
- No unusual noises produced in the system
- Warm up procedure within time limit
- Internal Dosing of all Needle's were fine
- External Dosing of all Wash Station is perfect
- Conditioning of Machine with Air/Wash solution/Distilled water done

For Biosystems Diagnostics Pvt. Ltd



Mr. Ramesh G
Assistant Manager Service



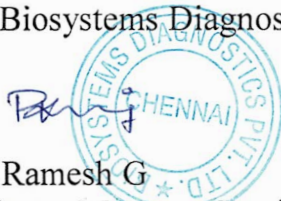
INSTALLATION QUALIFICATION

Customer Name : NAVANI DIAGNOSTIC CENTRE NAMAKKAL
Address : NAVANI DIAGNOSTIC CENTRE
NAMAKKAL
Instrument Model : BA200
Serial No. : 832001199

Operational requirement for the Instrument:

Requirement	Acceptable Range	Observed Range
Input Voltage	220 \pm 10 V	221 V
Line Frequency	50 or 60 Hz	50 Hz
Ambient Temperature	18 - 30 deg. C	23 deg. C
Distill Water	Type II NCCLS	Available

For Biosystems Diagnostics Pvt. Ltd



Mr. Ramesh G
Assistant Manager Service

BioSystems

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Ph: +91 -44 - 30341911 / 12/ 13/14
Email: support@biosystems.in
CIN - U29297TN2003PTC051492

BA200 - Fully Auto Biochemistry Analyzer

Operational Qualification

For

NAVANI DIAGNOSTIC CENTRE

Namakkal

BioSystems Diagnostics Pvt. Ltd

BA200 – Fully Auto Biochemistry Analyzer

OPERATIONAL QUALIFICATION

1. System Decontamination
2. Maintenance Procedures
3. System Performance check procedures
4. Customer Training Operation and Maintenance

System Decontamination

Users carrying out disinfection processes must wear gloves and protective apparel. All consumable materials (reaction rotor, reagent bottles and sample tubes) will be treated as potentially infectious waste.

Check whether there are any reaction rotors in their compartments or reagent bottles in the refrigerator. If there are, dispose of them.

Clean the fluidics of the instrument with 5% Hypo chloride.

Empty the high contamination waste tank and washing solution tank periodically.

Wash the inside of the equipment using a damp cloth and neutral soap. If there are splashes, wash them with alcohol

Follow the applicable national guidelines for disposing of waste that is considered potentially infectious.

Maintenance Procedures

Activities at the start of the day

- 1 Replenish the washing solution bottle.
- 2 Initialise the analyser. Perform the warm-up with the programme.
- 3 Perform 2 conditioning cycles (only when the analyser has been switched off for several days).
- 4 Check the temperature of the reaction rotor and the reagent rotor.
- 5 Check the reagent volume.
- 6 Calibrate the ISE module peristaltic pumps.
- 7 Calibrate the ISE electrodes.

Activities at the end of the day

- 1 Wash the ISE module.
- 2 Switch off the analyser by executing the Shut-down with the program.
- 3 Empty the high contamination bottle.
- 4 Remove the calibration solutions, controls and samples from the sample rotor.

Activities to be executed every week

- 1 Change the reaction rotor.
- 2 Calibrate the ISE module air bubble detector.
- 3 Clean the ISE module inlet cup with a cotton bud.
- 4 Clean the working surface.
- 5 Clean the interior of the samples and reagents rotor vessel.
- 6 Check the capacity of the ISE module reagent pack and replace it, if used up.
- 7 Rinse the ISE module waste tubes with distilled water.
- 8 Clean the stirrer paddle with a cloth soaked in washing solution.

CERTIFICATE OF OPERATION

Instrument Name : BA200 Fully Auto Biochemistry Analyzer

Serial Number : 834001771

Customer : NAVANI DIAGNOSTIC CENTRE
Namakkal

The undersigned performer certifies that the Operational Qualification Protocol has been successfully completed for the instrument stated above.

Engineer

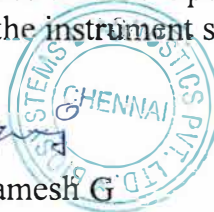
Signature

Name

Designation

Company


: Mr. Ramesh G
: Assistant Manager Service
: BioSystems Diagnostics Pvt. Ltd




Customer

Signature

Name

Designation

Company


: Ms. Dr. R. Vanitha M.B.B.S., D.C.P.,
: Clinical Pathologist
: NAVANI DIAGNOSTIC CENTRE NAMAKKAL

SYSTEM PERFORMANCE CHECK PROCEDURE

SYSTEM CHECK	PERFORMANCE
LED Photometric Check	Done
Warm Up	Done
Mechanical Adjustments	Done
Temperature Check	Done
Internal/External Dosing Check	Done


Customer Signature:

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CIN - U29297TN2003PTC051492

BA200 - Fully Auto Bio Chemistry Analyzer

Performance Qualification

For

NAVANI DIAGNOSTIC CENTRE
Namakkal

BioSystems Diagnostics Pvt. Ltd

BA200 Fully Auto Biochemistry Analyzer

PERFORMANCE QUALIFICATION:

The following parameters were checked and found to be within acceptable limits.

S.No	Measurement at 505 nm wavelength	Parameters	Result	Limit
1	Repeatability measured at 0 Abs	Standard Deviation	0.0001	< 0.0002 Abs
2	Stability measured at 0 Abs	Range	0.0006	< 0.0015 Abs
3	-	Darkness count	4052	1000 – 6000

Precision was checked for following parameters

PARAMETERS	INTRA RUN PRECISION	INTER RUN PRECISION
GLUCOSE	1.3%	0.9%
UREA	1.1%	2.9%
GGT	2.3%	1.7%
TOTAL BILIRUBIN	4.1%	1.7%

CERTIFICATE OF PERFORMANCE

Instrument Name : BA200 Fully Auto Biochemistry Analyzer
Serial Number : 832001199
Customer : NAVANI DIAGNOSTIC CENTRE
Namakkal

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