

Registered Office:
BioSystems Diagnostics Pvt. Ltd.,
A4, SIPCOT Industrial Park, Irungattukottai,
Thandalam Village, Sriperumbudur - 602105.
Ph: +91 - 44 - 3034 1911 / 12 /13
E-mail: customersupport@biosystems.in
Website: www.biosystems.in
CIN - U29297TN2003PTC051492



BTS 350 - Semi Auto BioChemistry Analyser

Installation Qualification Certificate

For

***PREM CLINICAL LAB,
CUDDALORE***

BioSystems Diagnostics Pvt. Ltd

Corporate Office:
BioSystems S.A. Costa Brava 30, 08030 Barcelona (Spain)
Tel +34-93 311 00 00, Fax+34-93 346 77 99
<http://www.biosystems.es>



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CERTIFICATE OF INSTALLATION

Instrument Name : BTS 350 Semi Auto Biochemistry Analyser

Serial Number : 801751324

**Customer : Prem Clinical Lab,
No. 82-c, Main Road,
Pudupalayam, Cuddalore.607001.**

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 : Asst Manager - Service
Company : BioSystems Diagnostics Pvt. Ltd

Quality Manager

Signature :
Name : R.JANAKIRAMAN
Designation : Quality Manager
Company : Prem Clinical Lab, Cuddalore.



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INSTALLATION REPORT

Customer Name : PREM CLINICAL LAB, CUDDALORE
Department : Quality Manager
Contact Person : R.JANAKIRAMAN
Instrument Model : BTS 350
Serial Number : 801751324
Date of Installation : 10/12/2010

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 a few parameters was done. The Instrument is found to be working satisfactorily.



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INSTRUMENT SETUP:

- Instrument installed
- Printer Installed
- User software 1.42 installed
- All necessary checks done

OPERATION INSPECTION:

- No air bubbles found in the Tubing
- Temperature of the Flow cell Chamber are within range
- No unusual noises produced in the system
- Warm up procedure within time limit

For Biosystems Diagnostics Pvt. Ltd.,

For

A. Pulyad



Mr. Ramesh.G
Asst Manager – Service



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INSTALLATION QUALIFICATION

Customer Name : PREM CLINICAL LAB, CUDDALORE

Address : PREM CLINICAL LAB,
No. 82-c, Main Road,
Pudupalayam, Cuddalore.607001.

Instrument Model : BTS 350

Serial No. : 801751324

Operational requirement for the Instrument:

Requirement	Acceptable Range	Observed Range
Input Voltage	220 \pm 10 V	222 V
Line Frequency	50 or 60 Hz	50 Hz
Ambient Temperature	18 – 30 deg. C	23 deg. C

For Biosystems Diagnostics Pvt. Ltd.,

Pon
A. P. Pradyumnachandran

Mr. Ramesh. G
Asst Manager - Service



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Operational Qualification

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OPERATIONAL QUALIFICATION

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



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CERTIFICATE OF OPERATION

Instrument Name : BTS350 - Semi Auto Biochemistry Analyser
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Customer : PREM CLINICAL LAB,
No. 82-c, Main Road,
Pudupalayam, Cuddalore.607001.

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

Engineer

For

A. P. Ramesh G



Signature :
Name : Mr. Ramesh. G
Designation : Asst Manager - Service
Company : BioSystems Diagnostics Pvt. Ltd.,

Quality Incharge

Signature :
Name : R. JANAKIRAMAN
Designation : Quality Manager
Company : Prem Clinical Lab, Cuddalore



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SYSTEM PERFORMANCE CHECK PROCEDURE

SYSTEM CHECK	PERFORMANCE
System Decontamination	Done
Photometer LED Check	Done
Start Up	Done
Pump Adjustments	Done
Temperature Check	Done

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OPERATIONAL QUALIFICATION

System Certification:

Study data has determined that the System described in this document either meets all criteria outlined in this Operational Qualification Protocol, or exceptional conditions have been identified and documentation included. Exceptional conditions, if any have been addressed. The system is ready for specified usage.

Protocol Performed By: BioSystems Diagnostics Pvt. Ltd
Name : Mr.Ramesh.G
Title : Asst Manager - Service
Company: BioSystems Diagnostics Pvt. Ltd

Customer Authorization PREM CLINICAL LAB, CUDDALORE
Name:R.JANAKIRAMAN
Title: Quality Manager

Poa
A. Palyadharan

ENGINEER SIGNATURE

CUSTOMER SIGNATURE

DATE:

DATE:

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Performance Qualification

For

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BTS350 SEMIAUTO BIOCHEMISTRY ANALYSER

PERFORMANCE QUALIFICATION:

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

<u>LED/Filters</u>	<u>Sensitivity (nA)</u> (Observed values)	<u>Minimum Value (nA)</u>	<u>Maximum Value (nA)</u>
340	30	12	40
405	25	12	60
505	23	12	100
535	60	12	100
560	173	150	450
600	23	12	100
635	12	12	30
670	32	12	120

DAC Analogic/Digital Converter

<u>Filters</u>	<u>Sensitivity (nA)</u> (Observed values)	<u>Minimum Value (nA)</u>	<u>Maximum Value (nA)</u>
340	67	50	90
405	95	75	140
505	98	75	140
535	88	75	140
560	117	60	120
600	78	75	140
635	92	75	140
670	84	75	140

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Engineer

Por

A. Palyad



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Name : Mr.Ramesh.G
Designation : Asst Manager - Service
Company : BioSystems Diagnostics Pvt. Ltd

Quality Manager

Signature :
Name : R.JANAKIRAMAN
Designation : Quality Manager
Company : Prem Clinical Lab, Cuddalore

