

BioSystems

human - centred biotech

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

BTS - Semi Auto Biochemistry Analyzer

Installation Qualification Certificate

For

***Enga Doctor Medical Diagnostic
Center***

BioSystems Diagnostics Pvt. Ltd

CERTIFICATE OF INSTALLATION

Instrument Name: BTS - Semi Auto Biochemistry Analyzer

Serial Number : 0000001860

Customer : **Enga Doctor Medical Diagnostic Center**

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

Authorized
Signature :

Name : Mr. RAJENDRA KAMILAS

Designation : Service Engineer

Company : BioSystems Diagnostics Pvt. Ltd

Customer
Signature :

Name : Ms. Bagavathy

Designation : Lab Incharge

Company : **Enga Doctor Medical Diagnostic Center**

INSTALLATION REPORT

Customer Name : **Enga Doctor Medical Diagnostic Center**

Department : Bio Chemistry Analyzer

Contact Person : Ms. Bagavathy

Instrument Model : BTS Semi Auto Analyzer

Serial Number : 0000001860

Date of Installation : 14-09-2021

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.

INSTRUMENT SETUP:

- Instrument 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.,

Mr. RAJENDRA KAMILAS
Service Engineer

INSTALLATION QUALIFICATION

Customer Name : **Enga Doctor Medical Diagnostic Center**

Address : # 10j,1, Triuvandram road, Palayamkottai,
Tirunelveli - 627002

Instrument Model : BTS

Serial No. : 0000001860

Operational requirement for the Instrument:

Requirement	Acceptable Range	Observed Range
Input Voltage	220 \pm 10 V	222 V
Line Frequency	50 or 60 Hz	51 Hz
Ambient Temperature	18 – 30 deg. C	22 deg. C

For Biosystems Diagnostics Pvt. Ltd.,

Mr. RAJENDRA KAMILAS
Service Engineer

BioSystems

human - centred biotech

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

BTS - Semi Auto Biochemistry Analyzer

Operational Qualification For

Enga Doctor Medical Diagnostic Center

BioSystems Diagnostics Pvt. Ltd.,

BTS– Semi Auto Biochemistry Analyzer

OPERATIONAL QUALIFICATION

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

CERTIFICATE OF OPERATION

Instrument Name : BTS - Semi Auto Biochemistry Analyser

Serial Number : 0000001860

Customer : **Enga Doctor Medical Diagnostic Center**

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

Authorized
Signature :

Name : Mr. RAJENDRA KAMILAS

Designation : Service Engineer

Company : BioSystems Diagnostics Pvt. Ltd.,

Customer
Signature :

Name : Ms. Bagavathy

Designation : Lab Incharge

Company : **Enga Doctor Medical Diagnostic Center**

SYSTEM PERFORMANCE CHECK PROCEDURE

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

Customer Signature:

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 Engineer

Name : Mr. RAJENDRA KAMILAS

Title : Service Engineer

Company: BioSystems Diagnostics Pvt. Ltd

Customer Authorization

Enga Doctor Medical Diagnostic Center

Name : Ms. Bagavathy

Title : Lab Incharge

AUTHORIZED SIGNATURE

CUSTOMER SIGNATURE

DATE:

DATE:

BioSystems

human - centred biotech

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

BTS - Semi Auto Biochemistry Analyzer

Performance Qualification

For

*Enga Doctor Medical Diagnostic
Center*

BioSystems Diagnostics Pvt. Ltd

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

www.biosystems.in
www.biosystems.global

BTS - SEMIAUTO BIOCHEMISTRY ANALYSER

PERFORMANCE QUALIFICATION:

- Pump Adjustment done and performance also checked
- Few test parameters, controls run and checked the results and found results are coming within the range

LED	INTENSITY	INTEGRATION TIME (ms)
340	100	05
405	201	30
505	205	10
535	95	07
560	100	16
600	201	36
635	197	09
670	94	14

CERTIFICATE OF PERFORMANCE

Instrument Name : BTS - Semi Auto Biochemistry Analyser

Serial Number : 0000001860

Customer : **Enga Doctor Medical Diagnostic Center**

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

Authorized
Signature :

Name : Mr. RAJENDRA KAMILAS

Designation : Service Manager

Company : BioSystems Diagnostics Pvt. Ltd

Customer
Signature :

Name : Ms. Bagavathy

Designation : Lab Incharge

Company : **Enga Doctor Medical Diagnostic Center**