



Installation Report

Name & Address of Customer <b>BRDC, Malda - 732101</b> <b>(Bisweswar Roy Diagnostic &amp; Poly</b> <b>Clinic Centre), 3/3, 3<sup>rd</sup> No. Govt. Colony</b> Contact Person: <b>English Bazar, Malda</b> Contact No:	Instrument Model: <b>BT1500</b> Instrument Ser. No.: <b>47236110</b> Installation Date: <b>06/04/24</b> Invoice No: Invoice Date: AMC Due Date:
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Power supply details:

Instrument connected to: Online UPS  Yes  No Offline UPS  Yes  No

Supply input to machine from UPS: LN: **229V** LE: **01V** LE: **230V**

Supply input to UPS from mains: LN: **NE** LE:

Accessories Provided: **Satisfactory**

Person Trained: **Mr. Amit Saha / Mrs. Sima Singha**

Demonstrated: **Satisfactory**

Remarks if any:

Note: The above machine is satisfactory installed at the site and staff adequately trained.  
 Reserved all accessories as per packing list

**B. R. DIAGNOSTIC CENTRE**  
**PVT. LTD.**  
**3<sup>RD</sup> GOVT. COLONY, MALDA**

Name of Department Head: **Amit Saha**  
 Signature & Stamp: **Amit Saha**  
 Date:

Company's Sales & Service Engineer:  
 Signature: **Subhankar Saha**  
 Date:

**Installation Qualification**  
**For**  
**BT1500**  
Random Access Biochemistry Analyzer

## Contents

- 1) Instrument Origin and Identification
- 2) Environment Condition
- 3) Instrument Delivery and Documentation
- 4) Instrument Safety
- 5) Assembly and Installation
- 6) Summary Report



1) Instrument Origin and Identification

**BT-1500 Analyzer ( Biotechnica Instruments S.p.A. Italy )**

Sr. No.	Specification	As per design qualification	Specification received	Match (Yes/No)
1	General Feature	RandomAccess Analyser ,Micro Quartz glass cuvette , multi channel photometer capable of measuring absorbance of contents from micro cuvettes	Yes	Yes
2	No of cuvette in reaction tray.	32	Yes	Yes
3	Filter range	340 to 700 nm	Yes	Yes
4	Communication port	Serial port for interface, USB port	Yes	Yes
5	Printer	Printer external		
6	Power requirement	1.1 KVA	Yes	Yes
7.	Ambient Conditions:	21°C Room Temperature, 33% RH	Yes	Yes.

Comments:



2) Environment Condition

Has the Instrument been adequately acclimatized since transport or storage?

YES:

NO:

Operating Parameters	Specified Range	Conditions Met
Ambient Temperature	18 °C to 32 °C	25°C
Relative Humidity	10% to 90% RH, non condensating	50%
Maximum Height from base ..	90 cm	Yes
Supply Voltage & Frequency	220-230V, 50 /60Hz	229V

Comments:



3) Instrument Delivery and Documentation

Unpack the Instrument carefully. Are any items missing against the Packing List?

YES:

NO:

If yes, state the missing Items: \_\_\_\_\_

Is there any damage to the Instrument or Accessories?

YES:

NO:

If yes: Description of Damage: \_\_\_\_\_

Corrective Action: \_\_\_\_\_

Manufacturing informed: YES:

NO:

Is all Standard Documentation Included?

Operating Manual: Yes Present: Yes Missing:

Warranty Card: Yes Present: Yes Missing:

Is all additional documentation Included:

Present: Yes Missing:

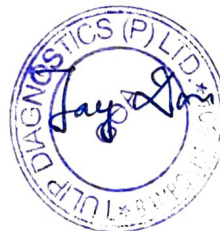
Calibration Certificate:

Installation Qualification:

Operational Qualification:

Performance Qualification:

Comments:



4) Instrument Safety

**Manufacturer Safety Recommendations:**

Allow enough space for the Instrument	YES: ✓	NO:
Position on level, non-combustible surface Indoors	YES: ✓	NO:
Area free from aggressive/ explosive chemical mixtures	YES: ✓	NO:
Ensure correct power supply and all power switches Easily accessible	YES: ✓	NO:
Beware of moving parts during working	YES: ✓	NO:
Do not use Heat material that could cause fire or other Hazards	YES: ✓	NO:
Read Operator Manual before use	YES: ✓	NO:

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**Comments:**



5) Assembly and Installation

Assembled and installed By: Subhankar Sarkar User: Biswas Hari Roy Specialized Engineer: Subhankar Sarkar  
Diagnostic & Polyclinic Centre OK N/A

Installation Procedure: OK.

Unpack and retain Packaging

Assembling the Instrument

Verifying the site before connecting to power supply

Checking the instrument before performing the Test

Comments:





6) Summary Report

Instrument Name: BT-1500

Sr. No.: 47236110

Manufacturer: Biotechnica Instruments S.p.A.

Assessment of complete Installation Qualification:

No Deviations: ✓

Deviations:

Deviation	Impact on Operation	Justification for Acceptance

Successful completion of the preceding activities and checks indicates that this Instrument is installed successfully as per the set protocol. The instrument has passed the Installation Qualification procedure and may now be released for use.

IQ Completed By:	Subhankar Sankar	Date: 06/14/2024	
Deviations Approved By:		Date:	
IQ Approved By:	Jay San	Date: 06/04/2024	

Comments:



**Operation Qualification**

**For**

**BT 1500**

Random access Biochemistry Analyzer

**Contents**

- 1) Safety Tests
- 2) Pre-Run Checks
- 3) Functional Tests
- 4) Training
- 5) Summary Report



1) **Safety Tests**

This instrument confirms to the following standards and is supplied fully tested by the Manufacturer.

- Electrical equipment for measurement, control and laboratory use.
- Instrument requirement for laboratory for Blood testing.

The following electrical safety tests should be carried out by a competent person after Installation.

Safety Tests	Pass	Fail	Date	Signed
Earthing	✓		06/04/2024	S.Sankar
ON LINE UPS Supply	229V		06/04/2024	S.Sankar

Comments:



2) Pre-Run Checks

BT-1500

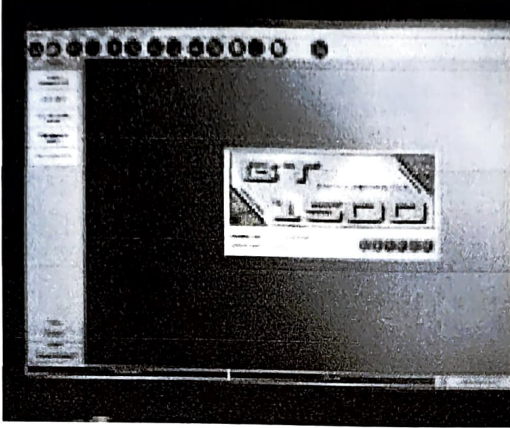
Pre run check	OK	N/A
Reagent Tray/ Sample tray Condition	OK.	
Cuvette Condition	OK.	
Dilution tube	OK.	
Distilled water connection check	OK.	
Waste container connection check	OK.	

Comments:



3) **Functional Tests**

**Elisa Reader (LisaQuant TS)**

Functional Test	Acceptance Criteria	Pass	Fail
Instrument power ON	Instrument initializes itself & shows the main menu as seen below: 	Pass.	
Plate carrier	Movement	Pass.	

Comments:



4) Training

Trained Operators	Read Operator Manual	Read SOP	Practical Training	Authorizing Signature
Amrit Saha	Yes	Yes	Done Satisfactorily	S.Sankar
Sima Singha	Yes	Yes	Done Satisfactorily	S.Sankar

Comments:



5) Summary Report

Instrument Name: BT 1500

Sr. No.: 47236110

Manufacturer: Biotecnica Instruments S.p.A.

Assessment of complete Operational Qualification:

No Deviations: No Deviation. Deviations:

Deviation	Impact on Operation	Justification for Acceptance

Successful completion of the preceding activities and checks indicates that this Instrument is operating satisfactorily following delivery and installation. The instrument has passed the Operational Qualification procedure and may now be released for use.

OQ Completed By:	<u>Subhankar Sarkar</u>	Date: <u>06/04/2024</u>	
Deviations Approved By:		Date:	
OQ Approved By:	<u>Jay Sin</u>	Date: <u>06/04/2024</u>	

Comments:





**Performance Qualification**  
**For**  
**BT 1500**  
Random Access Biochemistry Analyzer

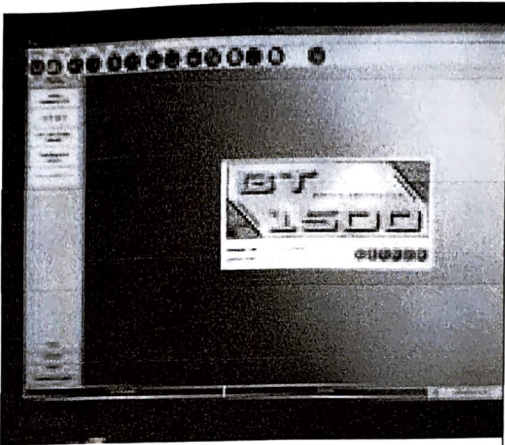
## Contents

- 1) Performance Check
- 2) Annual Maintenance
- 3) Safety Tests
- 4) Summary Report



1) Performance Check

BT-1500

Functional Test	Acceptance Criteria	Pass	Fail
Instrument power ON	Instrument initializes itself & shows the main menu as seen below: 	Pass.	
Washing Piston Valve		Pass.	
Arm Liquid Sensor		Pass.	
Diluter Valve, Peristaltic Pump & Needle		Pass.	

Comments:



**2) Annual Maintenance**

This instrument has been designed for Blood Testing. If any fault occurs, it is advised to contact Tulip Diagnostics Service Engineer.

The frequency with which routine maintenance tasks are being completed should be recorded below.

Routine Maintenance	Date	Done	Not Done

**Comments:**



**3) Safety Tests**

This instrument confirms to the following standards and is supplied fully tested by the Manufacturer.

- Electrical equipment for measurement, control and laboratory use.
- Instrument requirement for laboratory for Blood testing.

The following electrical safety tests should be carried out by a competent person after Installation.

Safety Tests	Pass	Fail	Date	Signed
Earthing	Pass		06/04/2024	S. Sankar
UPS Supply	Pass		06/04/2024	S. Sankar

Comments:



**4) Summary Report**

Instrument Name: BT- 1500

Sr. No.: 47236110

Manufacturer: Biotechnica Instruments S.p.A.

Assessment of complete Performance Qualification:

No Deviations: **No Deviation** Deviations:

Deviation	Impact on Operation	Justification for Acceptance

Successful completion of the preceding activities and checks indicates that this Instrument is operating satisfactorily following delivery and installation. The instrument has passed the Operational Qualification procedure and may now be released for use.

PQ Completed By:	Subhankar Sarkar	Date: 06/04/2024	
Deviations Approved By:		Date:	
PQ Approved By:	Jay Son	Date: 06/04/2024	

Comments:

