

## Service Report

Tata 1MG Technologies Pvt. Ltd.

Date: 17.08.2023

Tata Steel BSL Ltd, Plot no. 670 P  
Dhenkanal 759121

Ticket No: 728107137187

Service Type: Medical Installation

Complainant Name: SIEMENS TANMAY

Complainant Phone: 86974 65626 /EXT

The following services have been provided for Ticket No. **728107137187**

Equipment Details			
Model:	CLINITEK STATUS+		
Equipment Id:	1058409130	Serial No.:	355978
Location:	664-157051		
Contract No:	Contract Expired / NO Contract	Contract Type:	MED Installation

Service Call Reason
Installation of CLINITEK STATUS+


Observations & Actions Performed	
17.08.2023	Installation done successfully. Run several samples. Biorad QC does not have valid range for the existing system (software version 2.630.001). Requested customer to run other control which is valid for the analyser.

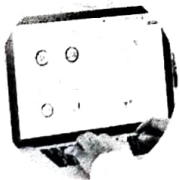
Service Call Efforts					
Date	ID	Engineer's / Application's Name	Start	End	Hrs:Min
17.08.2023	65763879	KARMAKAR, TANMAY	11:26	12:46	01:20

Material Consumed	
Description	QTY

  
17.08.2023



  
Tanmay Karmakar  
17.08.2023



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## Calibration and Preventive Maintenance Not Required for Small Clinitek Urine Chemistry Analyzers

Clinitek Advantus™, Clinitek® 500, Clinitek® 50, Clinitek Status®, Clinitek Status®+ Analyzers

### Calibration

Calibration chips and bars used on the small Clinitek Urine Chemistry analyzers do not require annual calibration. During instrument development, sufficient calibration chip/bar material for the product lifetime was obtained. Several samples from this single batch were tested on an Aviv reference spectrophotometer. The spectrophotometer was calibrated using tiles calibrated and value assigned by the National Institute of Standards and Technology (NIST). By calibrating the reference spectrophotometer with NIST traceable calibrators, we are able to show traceability to NIST.

The material used for the calibration chip/bar is not affected by sunlight, is chemically stable in contact with bleach and validated cleaners, and therefore does not degrade over time. If the calibration chip/bar is properly maintained and cleaned according to the respective analyzer's Operator's Manual, the original reflectance values are maintained.

No further calibration of the chip/bar material is necessary.

### Preventive Maintenance

No Field Service preventive maintenance is required for any of the small Clinitek analyzers. All small Clinitek analyzers have recommended cleaning and routine maintenance procedures in their respective Operator's Manual and/or Quick Reference Guide. These procedures are intended for use by the customer only.

### Trademark Information

Clinitek, Clinitek Status, and Clinitek Advantus are trademarks of Siemens Healthcare Diagnostics.

## **Installation Qualification for CT STATUS<sup>+</sup>**

**Customer Name** : Tata 1MG Technologies Pvt. Ltd.  
**Address** : Tata Steel BSL Ltd, Plot no. 670 P  
Dhenkanal 759121

**Instrument Model** : CLINITEK STATUS<sup>+</sup>

**Serial Number** : 355978

Initial Inspection of the Unit carried out and the details are as below.

### **System Condition Report:**

Found the System to have been delivered in satisfactory condition and no external physical damaged observed on the same. The Tilt-Indicator and the Shock-Indicators on the Packaging were found to be in Good Condition, indicating the System has not been subjected to mechanical shocks or stored in any manner, so as to cause any damage to the same.

Found all the required accessories as required.

### **Installation Procedure & Checklist**

#### **External requirements for Installation:**

- 1 Input Voltage of 220V / 50 Hz (UPS out-put)
- 2 Recommended Operating temperatures is 22 – 26 Degree Celcius, with relative Humidity 20 – 80% (No Condensation)

### **Installation Qualifications for CT STATUS+**

- Carried out all the necessary checks.
- Carried out all checks and tests for Movement for Moving Table.
- Carried out set up procedure as per the customer requirement.
- Checked the Touch Screen Calibration
- Handed over the Instrument for Operators Training & Qualifications.

### **Instrument Set Up**

- Take out the instrument from box and removed the packing carefully.
- Plugged the Adaptor of the instrument to available Voltage Protection device;
- Set up and configure the instrument.
- Installed the Moving Table;
- Installed the Printer Paper;

### **Siemens Healthcare Pvt. Ltd.**

Name : Tanmay Karmakar

Designation : Service Engineer

Date : 08/26/23

**CT STATUS Installation Qualification (IQ)**

Customer Name : Tata 1MG Technologies Pvt. Ltd.

Department : Pathology

Contact Person : Nicky Anand

Instrument Model : CT-Status +

Serial Number : 355978

Date of Installation : 17.08.2023

The Instrument was installed and was found to be working satisfactorily. Preliminary Customer Training was provided, and standardization of some parameters was done. The results were found to be within the expected range and the System found to be working satisfactorily.

Siemens Healthcare Pvt. Ltd,


Tata 1MG Technologies Pvt. Ltd.

Name : Tanmay Karmakar

Name : NICKY ANAND

Designation : Service Engineer

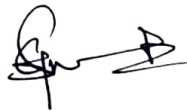
Designation: S.S.O

Signature : 

Signature: Nicky Anand

Date : 08/26/23

Date: 27/08/23



**CT STATUS + Operational Qualification (OQ)**

**Operational Inspection**

- Checked the Movement of Moving Table
- Checked the Calibration of Touch Screen;
- Checked the Lamps Voltage;
- Checked the Movement of Strip;
- Quality Control Processed for verification

**Operations Qualifications for CT STATUS+**

- |   |        |
|---|--------|
| 1. Verified the Calibrations of Touch Screen    | : Done |
| 2. Carried out set-up of parameters             | : Done |
| 3. Carried out Daily Cleaning Procedures        | : Done |
| 4. Carried out manual set-up                    | : Done |
| 5. Carried out Calibration of Moving Table      | : Done |
| 6. Imparted Operator's training and maintenance | : Done |

**Siemens Healthcare Pvt. Ltd.**

Name : Tanmay Karmakar

Designation : Service Engineer

Date : 08/26/23



**Operational Qualification Report**

Equipment name : CLINITEK STATUS+

Equipment Serial No : 355978

**Table 1 - Materials used for Performance Qualification**

S.No	Name of the material	Lot Number	Expiry date
1	Multi Stix 10SG	30220223	2024/07
2	Level 1 Control	80791	12/20/24
3	Level 2 Control	80792	12/20/24

**Table 2 – Training**

The following staffs are trained on operation, maintenance and routine trouble shooting of Clinitek Status+ - Semi automated urine chemistry analyzer.

S. No	Name of the Trainee	Signature with date
1	Nicky Anand	Nicky Anand
2	Dharam jeet	
3	Manoj Mallick	
4	Sujata Behera	
5	Ashis Samal	
6	Arabindo Khatua	
7	Kalpatau Parida	
8	Lijarani Swain	
9	Santoh Kumar Yadav	Santoh Kumar Yadav

**Name of the Trainer:** Tanmay Karmakar

**Designation:** Service Engineer

**Sign and date:**  09/11/24

**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 specific usage.**

Protocol Performed by: Siemens Healthcare Pvt. Ltd.,

Name : Tanmay Karmakar

Designation : Service Engineer


Customer Authorization: Tata IMG Technologies Pvt. Ltd.

Name : NICKY ANAND

Designation : S.S.O

Company Representative Name & Sign:

Customer Name & Sign

Date: 

Date:

Nicky  
27/08/23





**Performance Qualifications for CT STATUS +**

**Controls**

Checked and found all level Controls to be within the acceptable ranges.

Datasheet of Calibration and Controls attached.

**Materials used for Performance Qualification**

<b>S.No</b>	<b>Name of the material</b>	<b>Lot Number</b>	<b>Expiry date</b>
1	Multi Stix 10SG	30220223	2024/07
2	Level 1 Control	80791	12/20/24
3	Level 2 Control	80792	12/20/24

**Table 1 – Accuracy and Precision Testing**

**QC Material Name : Level 1 Control**

**Lot # : 80791**

**Expiry Date : 12/20/2024**

Parameter	GLU	BIL	KET	SG	BLD	PH	PRO	UBG	NIT	LEU
<b>Ranges</b>	Neg	Neg	Neg	1.005 – >_1.030	Neg	5 -6.5	Neg	0.2-1 EU/dL	Neg	Neg
<b>Run 1</b>	Neg	Neg	Neg	1.025	Neg	6	Neg	0.2	Neg	Neg
<b>Run 2</b>	Neg	Neg	Neg	1.025	Neg	6	Neg	0.2	Neg	Neg
<b>Run 3</b>	Neg	Neg	Neg	1.025	Neg	6	Neg	0.2	Neg	Neg
<b>Run 4</b>	Neg	Neg	Neg	1.025	Neg	6	Neg	0.2	Neg	Neg
<b>Run 5</b>	Neg	Neg	Neg	1.025	Neg	6	Neg	0.2	Neg	Neg
<b>Run 6</b>	Neg	Neg	Neg	1.025	Neg	6	Neg	0.2	Neg	Neg
<b>Run 7</b>	Neg	Neg	Neg	1.025	Neg	6	Neg	0.2	Neg	Neg
<b>Run 8</b>	Neg	Neg	Neg	1.025	Neg	6	Neg	0.2	Neg	Neg
<b>Run 9</b>	Neg	Neg	Neg	1.025	Neg	6	Neg	0.2	Neg	Neg
<b>Run 10</b>	Neg	Neg	Neg	1.025	Neg	6	Neg	0.2	Neg	Neg

**Table 2 – Accuracy and Precision Testing**

**QC Material Name : Level 2 Control**

**Lot # : 80792**

**Expiry Date : 12/20/2024**

1

Parameter	GLU	BIL	KET	SG	BLD	PH	PRO	UBG	NIT	LEU
<b>Ranges</b>	Trace - 3+	2+ - 3+	Trace - 4+	< 1.005 - 1.020	1+ - 3+	6.5 - 8.5	2+ - > 3+	4.0 - > 8.0 EU/dL	Positive	Trace - 3+
<b>Run 1</b>	2+	3+	3+	1.015	3+	7.5	3+	> 8.0	Positive	1+
<b>Run 2</b>	2+	3+	2+	1.015	2+	7.5	3+	> 8.0	Positive	3+
<b>Run 3</b>	2+	3+	2+	1.015	3+	7	3+	> 8.0	Positive	1+
<b>Run 4</b>	2+	3+	2+	1.015	3+	7.5	3+	> 8.0	Positive	1+
<b>Run 5</b>	2+	3+	3+	1.015	2+	7.5	3+	> 8.0	Positive	Trace
<b>Run 6</b>	2+	3+	3+	1.015	3+	7.5	3+	> 8.0	Positive	1+
<b>Run 7</b>	2+	3+	3+	1.015	3+	7.5	3+	> 8.0	Positive	3+
<b>Run 8</b>	1+	3+	3+	1.015	3+	7.5	3+	> 8.0	Positive	3+
<b>Run 9</b>	2+	3+	3+	1.015	3+	7.5	3+	> 8.0	Positive	1+
<b>Run 10</b>	2+	3+	3+	1.015	3+	7.5	3+	> 8.0	Positive	1+

**Performance Qualification:**

**System certification**

Study Data has determined that the System described in this document either meets all criteria outlined in this Performance Qualification Protocol, or exceptional conditions have been identified and documentation included.

**The System is ready for specific usage.**

Protocol Performed by: Siemens Healthcare Pvt. Ltd.,

Name : Tanmay Karmakar

Designation : Service Engineer

Customer Authorization: Tata IMG Technologies Pvt. Ltd.

Name : NICKY ANAND

Designation : S.S.O

Company Representative Name & Sign

Customer Name & Sign

Date: 08/08/23

Date:

Nicky Anand  
27/08/2023

