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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 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: TBM, Pune

Name: Swapnil Kamarikar

Designation: Service Engineer

Customer Authorization: Hospital:- MAHARASHTRA ACADEMY OF ENGINEERING AND EDUCATIONAL RESEARCH, PUNE

Name: Dr. Aniruddha Ranad

Designation: HOD. Laboratory

Company Representative Name & Sign
Swapnil Kamarikar

Date:

Customer Name & Sign

Date:

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UNMATCHED SERVICE
SINCE 1979...

## Installation Qualification for Laura M (Automated Urine Analyzer)

**Customer Name** : MAHARASHTRA ACADEMY OF ENGINEERING AND EDUCATIONAL RESEARCH, PUNE

**Address** : Pune

**Instrument Name** : Laura M (Automated Urine Analyzer)

**Serial Number** :8381160315

**Initial Inspection of the unit carried out and the details are as follows:**

**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 Attached for records.

**External Requirements for Installation**:

1. TEMPERATURE:-
   Ambient Conditions (10~37° C)RH ≤ 80 % (Optimum)
   Utmost Conditions (0~40° C)RH ≤ 85 %
   with Relative Humidity 30-85% and Atmospheric Pressure 70-106 kPa.

2 POWER SUPPLY:- Input :100-250V
Out put DC12 V,3A

## Installation Certificate for Laura M (Automated urine Analyzer)

This is to certify that the Laura M Instrument Serial No. 8381160315 is successfully Installed and Commissioned at TBM, Pune and the Installation Protocol / checklist has been successfully completed for the above instrument.

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**TBM, Technical Services Department**

**Name** : Swapnil Kamarikar

**Designation** : Service Enginner

**Date** :

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**Installation Qualifications for Laura M (Automated Urine Analyzer)**

Carried out all the Installation Procedures as per the Installation Procedure & Checklists.

Carried out all the necessary checks and alignments.

Carried out all the necessary system checks and tests.

Carried out Priming and Cleaning Operations

Checked the counts by running the samples and found OK.

Performed all due maintenance activities.

Handed over the Instrument for Operators Training & Qualifications

**For TBM, Technical Services Department**

**Name:** Swapnil Kamarikar

**Designation**: Service Engineer

Date:

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**Installation Report for**

**Customer Name** : MAHARASHTRA ACADEMY OF ENGINEERING AND EDUCATIONAL RESEARCH, PUNE

**Department** : Sample collection

**Contact Person** :

**Instrument Model** : Laura M(Automated Urine Analyzer )

**Serial Number** : 8381160315

**Date of Installation** :

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

TBM. Technical Services Department

Name :Swapnil Kamarikar

Designation : Service Engineer

Signature :

TRASASIA BIO MEDICALS LTD.

CUSTOMER

Name : Dr. Aniruddha Ganid

Contact Person :

Designation : HOD - Lab

Signature :

Date :

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**Instrument Setup**

1. Assembled the instrument accessories.
2. Slide and fix the plate into the middle of the instrument
3. Connect the AC adapter to the port on the backside of instrument
4. Connect the Key board in such a way that 2 USB Signal should coincide
5. Mount Printer Paper roll

**Operational Inspection**

1. Calibrate the analyzer before Sample Run
2. To Check Optics of System run the Calibration Strip.it should be 333(+/-10)
3. Check the mode of Analyzer. when not using Switch to Stand by Mode.
4. Check the colour of blank/unreacted Strip with the Chart on bottle before Run.
5. Reagent Strip Should be immersed into urine for about 2 sec
6. Use fresh & well mixed Sample & ensure it for no Concentration or Dilution

**TBM, Technical Services Department**

**Name** : Vijay Shahu

**Designation** : Application Specialist

**Date:**

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**Operations Qualifications for Laura M Sr. No.8381160315**

1. Verified Motor function : Done
2. Verified Plate Sensor & Lamp : Done
3. Verified LCD & Printer : Done
4. Verified Optics of System : Done
5 Verified Funcitional Key board : Done

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**Performance Qualifications for Laura M (Automated Urine Analyzer)**
**Sr. No. 8381160315**

## 1. Calibration Parameters

a. Calibrated 12 parameters

Checked and found that reflectance of all test parameters are within the acceptable range

b. Performance Qualification:
Checked & found that Sensitivity of each Parameter is set as per %Value Change Method

Data Sheet Attached

## 2. 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: Vijay Shahu
Application Specialist
TBM Pune