

Electrolyte Calibration.

ML 200

S/W VERSION:24SW5.5USCMF.M026
May-24-22 11:08:56

CLEANING PERFORMED

-----CAL B mV-----
Na = -3.00 mV
K = 20.22 mV
iCa = 41.78 mV
pH = 3.42 mV
Cl = 65.22 mV

-----CAL A mV-----
Na = 18.69 mV
K = 39.92 mV
iCa = 30.49 mV
pH = -32.03 mV
Cl = 45.51 mV

PUMP CAL A TEST
7565

-----CAL B mV-----
Na = -2.13 mV
K = 20.98 mV
iCa = 42.19 mV
pH = -1.74 mV
Cl = 66.40 mV

-----CAL A mV-----
Na = 19.07 mV
K = 40.18 mV
iCa = 30.73 mV
pH = -37.47 mV
Cl = 45.84 mV

CALIBRATION SLOPE

Na = 67.66
K = 63.76
iCa = 40.01
pH = 73.93
Cl = 58.36

May-24-22 11:29:45

24/May Calibration
11:29 AM

ML 200

S/W VERSION:24SW5.5USCMF.M026
May-25-22 12:25:44

PUMP CAL A TEST
7648

-----CAL B mV-----
Na = -2.33 mV
K = 20.05 mV
iCa = 42.15 mV
pH = -7.07 mV
Cl = 65.91 mV

-----CAL A mV-----
Na = 18.72 mV
K = 39.16 mV
iCa = 30.38 mV
pH = -43.07 mV
Cl = 45.04 mV

CALIBRATION SLOPE

Na = 67.20
K = 63.48
iCa = 41.12
pH = 74.48
Cl = 59.27

May-25-22 12:30:29

25/May 12:30 PM
Calibration

ML 200

S/W VERSION:24SW5.5USCMF.M026
May-25-22 18:35:30

PUMP CAL A TEST
7296

-----CAL B mV-----
Na = -2.50 mV
K = 21.03 mV
iCa = 42.30 mV
pH = -8.77 mV
Cl = 66.22 mV

-----CAL A mV-----
Na = 18.44 mV
K = 40.08 mV
iCa = 30.50 mV
pH = -44.48 mV
Cl = 45.16 mV

CALIBRATION SLOPE

Na = 66.86
K = 63.26
iCa = 41.22
pH = 73.89
Cl = 59.81

May-25-22 18:51:51

25/May 18:51 PM
Calibration

ML 200

S/W VERSION:24SW5.5USCMF.M026
May-26-22 13:20:30

PUMP CAL A TEST
7485

-----CAL B mV-----
Na = -2.59 mV
K = 22.20 mV
iCa = 44.26 mV
pH = -8.86 mV
Cl = 67.26 mV

-----CAL A mV-----
Na = 16.11 mV
K = 39.07 mV
iCa = 30.78 mV
pH = -45.97 mV
Cl = 44.85 mV

CALIBRATION SLOPE

Na = 59.70
K = 56.02
iCa = 47.07
pH = 76.77
Cl = 63.64

May-26-22 13:23:35

26/May 13:23 PM
Calibration

Installation Qualification Protocol

System/Equipment: ML200

Location: 7/8 Sunflower, Royal Complex, Eksar Road, Borivali (w), Mumbai-91.

MEDIQUIP DIAGNOSTICS

“ML200”

ELECTROLYTE ANALYZER

Installation Qualification

For

Minu Clinical Laboratory

(7/8 Sunflower, Royal Complex, Eksar Road, Borivali (W), Mumbai-91)

Installation Qualification Protocol

System/Equipment: ML200

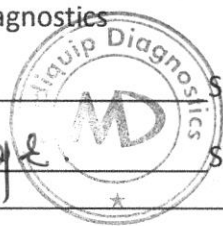
Location: 7/8 Sunflower, Royal Complex, Eksar Road, Borivali (w), Mumbai-91.

Validation Protocol # 01 : **Installation Qualification**

System / Equipment : ML200 Electrolyte Analyzer

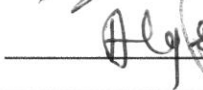
Protocol written by : Mediquip Diagnostics

Dept. Approval by :



Signature & Date: 01.02.2022

QA Approval by :



Signature & Date: 01.02.2022

Objective

To provide the documented evidence to assure that the system/equipment has been installed in accordance with its specifications.

Scope

To be performed at the time of installation, modification or relocation.

Responsibility

1. The responsible person, who supervises the installation, will perform the qualification, and record all the necessary information.
2. The recorded data will be verified by the responsible engineer and a report will be made.
3. Quality Assurance will review and approve the IQ Protocol and Report.

Installation Qualification Protocol

System/Equipment: ML200

Location: 7/8 Sunflower, Royal Complex, Eksar Road, Borivali (w), Mumbai-91.

System/ Equipment: ML200

Instrument Serial No.: 188

I) Description of the system/equipment being installed:

The instrument, ML200, is an Ion Selective Method based analyzer for measuring electrolytes in serum/plasma; lithium-heparin based whole blood, diluted urine samples and QC materials.

Characteristics:

The advantages of the system/equipment:

- Automatic and on demand calibration.
- Results can be stored in the memory database.
- Easy operation for the routine functions.
- Easy to maintain and it needs very less maintenance.

II) List of the main components:

- Reference housing with electrodes as per the parameter combinations
- Pump module and valve module
- Probe and tubing
- Printer
- Power adapter with its cord

Packing list includes:

- Main unit with power adapter/cord
- Reagent pack
- Troubleshooting kit
- Tri-level set of controls
- Daily cleaner solution
- Control sheet and flowchart for routine operations

Installation Qualification Protocol

System/Equipment: ML200

Location: 7/8 Sunflower, Royal Complex, Eksar Road, Borivali (w), Mumbai-91.

Procedure

Prepare a checklist for all components and parts according to the purchase order and specifications.

Record the information for each part or component and make a comparison with the specifications.

Perform:

- Installation of Hardware
- Installation Checks



Record the system/equipment deviation, if any.

Prepare a deviation report with its justification of acceptance and impact on the function.

Prepare an Installation Qualification report, and submit it to QA for review and approval.

The following installation procedures have been performed at the original installation of the system/equipment.

| Installation Procedure | Location | Performed Yes/No |
|-----------------------------|--|------------------|
| Hardware Installation Guide | Guided by the system during installation | Yes |
| Software Setup Guide | Guided by the system during installation | Yes |

| | | | |
|-----------------------|---------------------|-------------------------|--|
| Performed by | : Anup Mali | Sign & date: |  12/22 |
| Deviations | : NIL | | |
| QA Approved by | : Shantaji Shantaji | Sign & date: |  01/02/2022 |



Installation Qualification Protocol

System/Equipment: ML200

Location: 7/8 Sunflower, Royal Complex, Eksar Road, Borivali (w), Mumbai-91.

Deviation Report





Deviation(s) : NIL
Justification for acceptance : All Installation Specification qualified
Impact on operation : Instrument is ready for its Operational Qualification test
Prepared by : Anup Mali
Date : 01.02.2022

Installation Qualification Report

Date of study :
Observation : IQ protocol qualifies as per the manufacturer recommendations
Problems encountered : NIL
Results : Acceptable results
Conclusions : Study data has determined that the system described in the document meets all Criteria outlined in this installation qualification protocol.

Installation Qualification completed successfully.

The system is ready for its performance qualification.

Prepared by : Anup Mali
Sign & Date :  01/2/22
QA Approved by :  
Sign & Date :  01/02/2022

Operational Qualification Protocol

System/Equipment: ML 200

Location: 7/8 Sunflower, Royal Complex, Eksar Road, Borivali (w), Mumbai- 91

MEDIQUIP DIAGNOSTICS

“ML200”

ELECTROLYTE ANALYZER

Operational Qualification

For

Minu Clinical Laboratory

(7/8 Sunflower, Royal Complex, Eksar Road, Borivali (w), Mumbai-91)

Operation Qualification Protocol

System/Equipment: ML 200

Location: 7/8 Sunflower, Royal Complex, Eksar Road, Borivali (w), Mumbai- 91

Preparation

System/ Equipment: ML200 Instrument Serial No.: 188

Document Check

| SOP and number | File Location | QA/QC approval date |
|-----------------------------|--|---------------------|
| Basic Operational Procedure | Operator's Manual (Page - 21 to 71) | _____ |
| Maintenance Procedure | Operator's Manual (Page - 75) | _____ |
| Troubleshooting | Operator's Manual (Page - 80 to 90) | _____ |

Training Records

| Staff Name | Designation | Sign & Date |
|------------|----------------|----------------|
| | Lab Supervisor | Dr Chirag Shah |
| | Technician | Ms. Taruna |
| | Technician | _____ |

ML200 Operator Manual Available Y [] N []

Performed by : Anup Mahi
Deviations : NIL
Verified by : Dhanraj Phengar

Sign & date: *[Signature]* 11/2/22

Sign & date: *[Signature]* 01/02/2022



Operation Qualification Protocol

System/Equipment: ML 200

Location: 7/8 Sunflower, Royal Complex, Eksar Road, Borivali (w), Mumbai- 91

Quality Control Data

Electrolyte Controls

Lot No.: UQC2004A

Exp.: Mar'22

Level 1:

| Parameter | Control Value Observed | Control Expected Ranges | Pass/Fail |
|-----------------|------------------------|-------------------------|-----------|
| Sodium | 118.3 | 106 - 126mmol/L | Pass |
| Potassium | 2.01 | 1.80 - 2.20mmol/L | Pass |
| Ionized Calcium | 1.94 | 1.70 - 2.10mmol/L | Pass |
| Chloride | 81.00 | 70.0 - 88.0mmol/L | Pass |

Level 2:

| Parameter | Control Value Observed | Control Expected Ranges | Pass/Fail |
|-----------------|------------------------|-------------------------|-----------|
| Sodium | 136.9 | 128 - 150mmol/L | Pass |
| Potassium | 3.98 | 3.85 - 4.35mmol/L | Pass |
| Ionized Calcium | 1.24 | 1.05 - 1.35mmol/L | Pass |
| Chloride | 100.6 | 90 - 110mmol/L | Pass |

Level 3:

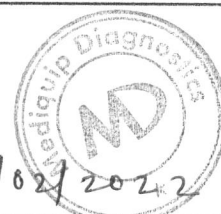
| Parameter | Control Value Observed | Control Expected Ranges | Pass/Fail |
|-----------------|------------------------|-------------------------|-----------|
| Sodium | 154.6 | 146-170mmol/L | Pass |
| Potassium | 6.18 | 5.90-6.50mmol/L | Pass |
| Ionized Calcium | 0.80 | 0.60 - 0.80mmol/L | Pass |
| Chloride | 120.00 | 108 - 130mmol/L | Pass |

For Calibration and Quality Control data, Refer to the attachment.

Performed by : Anup mali
Deviations : NIL
Verified by : Dhansraj Phangar

Sign & date: [Signature] 21/2/22



Sign & date: [Signature] 01/02/2022




Operational Qualification Protocol

System/Equipment: ML 200

Location: 7/8 Sunflower, Royal Complex, Eksar Road, Borivali (w), Mumbai- 91

| | | | |
|--------------------------|---|---|--------------------------------------|
| Validation Protocol # 02 | : | Operational Qualification | |
| System / Equipment | : | ML200 Electrolyte Analyzer | |
| Protocol written by | : | Mediquip Diagnostics | |
| Dept. Approval by | : |  | Signature & Date : <u>01.02.2022</u> |
| QA Approval by | : |  | *Signature & Date: <u>01.02.2022</u> |



Objective

To provide the documented evidence to assure that the system/equipment operates and performs the intended functions as per the specifications.

Scope

To be performed after installation, modification or relocation, after Installation Qualification has been completed.

Responsibility

1. The trained personnel responsible for operating the system / equipment will perform the Operation Qualification and record the information/data under the supervision of lab supervisor.
2. The completed records of data will be verified, and the deviation reports in the Operational Qualification Report will be written by the supervisor.
3. Quality Assurance will review and approve the OQ Protocol and Report.

Operational Qualification Protocol

System/Equipment: ML 200

Location: 7/8 Sunflower, Royal Complex, Eksar Road, Borivali (w), Mumbai- 91

Operation Qualification report

Results : Acceptable results

For QC Results refer to the attachment.

Conclusions : Study data has determined that the system described in the document meets all Criteria outlined in this operation qualification protocol.

Operation Qualification completed successfully.

The system is ready for its performance qualification.

Prepared by : Anup Mali

Sign & Date :  01/21/22

QA Approved by : Shanraj Shanyar

Sign & Date :  01/02/2022



Operational Qualification Protocol

System/Equipment: ML 200

Location: 7/8 Sunflower, Royal Complex, Eksar Road, Borivali (w), Mumbai- 91

Materials, SOPs, Documents

Following are the topics course needed to perform the Operational Qualification

- 1) Basic Operational Procedures
 - Daily Startup
 - Preparing samples
 - Analyzing samples
 - Working with results and
 - Standby / Shut down

- 2) Special Operation
 - ✓ Quality Control
- 3) Maintenance
 - ✓ Daily Maintenance
 - Check Reagent pack levels
 - Clean the sample inlet ports
 - Check the priming result
 - Check the electrode slope
 - ✓ Periodic Maintenance
 - Flow path maintenance cycle
 - Replacing pump tubing
 - Running Daily Cleaner
 - ✓ Non Routine Maintenance
 - Replacing electrode
 - Replacing probe

Operation Qualification Protocol

System/Equipment: ML 200

Location: 7/8 Sunflower, Royal Complex, Eksar Road, Borivali (w), Mumbai- 91

Maintenance Procedures of the equipment or system

Test in normal conditions: List and protocols for Maintenance under normal conditions mentioned in Operator's Manual.

Performed by : Anup Mahi.

Sign & date:

Deviations : NIL

Verified by : Dhanraj Dhengar

Sign & date:



Deviation Report

Deviation(s) : NIL

Justification for acceptance : All Operational Requirements Qualified

Impact on operation : Instrument is ready for its Performance Qualification

Prepared by : Anup Mahi.

Date : 01/02/2022.

Performance Qualification Protocol

System/Equipment: ML200

Location: 7/8 Sunflower, Royal Complex, Eksar Road, Borivali (w), Mumbai-91

MEDIQUIP DIAGNOSTICS

“ML200”

ELECTROLYTE ANALYZER

Performance Qualification

For

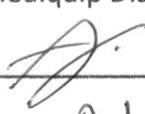
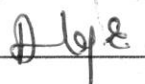
Minu Clinical Laboratory

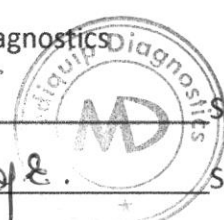
(7/8 Sunflower, Royal Complex, Eksar Road, Borivali (w), Mumbai-91)

Performance Qualification Protocol

System/Equipment: ML200

Location: 7/8 Sunflower, Royal Complex, Eksar Road, Borivali (w), Mumbai-91

| | | | |
|--------------------------|---|---|--------------------------------------|
| Validation Protocol # 03 | : | Performance Qualification | |
| System / Equipment | : | ML200 Electrolyte Analyzer | |
| Protocol written by | : | Mediquip Diagnostics | |
| Dept. Approval by | : |  | Signature & Date : <u>01.02.2022</u> |
| QA Approval by | : |  | Signature & Date: <u>01.02.2022</u> |



Objective

To demonstrate that the system/equipment is capable of producing the consistent results on repeatedly running the system on its intended schedules and they meet pre-determined specifications under normal conditions.

Scope

To be performed after installation, modification or relocation, after Installation Qualification and Operational Qualification have been completed.

Responsibility

1. The trained personnel responsible for operating the system / equipment will perform the Qualification and record the information/data under the supervision of lab superior.
2. The completed records of data will be verified, and the deviation reports and performance Qualification Report will be written by the supervisor.
3. Quality Assurance will review and approve the PQ Protocol and Report.

Procedure

For precision study, run a sample/control 10 times, and record all required data and any deviation to the procedure.

Perform the reproducibility check in the Quality assurance menu

Performance Qualification Protocol

System/Equipment: ML200

Location: 7/8 Sunflower, Royal Complex, Eksar Road, Borivali (w), Mumbai-91

Table 1.1 Reproducibility CV (%) Limits

| Parameters | %CV* | Value Obtained | Remarks |
|------------|------|----------------|---------|
| Na | <2% | 0.25% | Passed |
| K | <2 % | 2.00% | Passed |
| iCa | <2 % | 0.66% | Passed |
| Cl | <2 % | 0.23% | Passed |

| No. of Readings | Na (mmol/L) | K (mmol/L) | iCa (mmol/L) | Cl (mmol/L) |
|-----------------|-------------|------------|--------------|-------------|
| 1 | 141.2 | 3.55 | 1.28 | 97.5 |
| 2 | 140.9 | 3.63 | 1.27 | 97.9 |
| 3 | 140.6 | 3.73 | 1.27 | 97.8 |
| 4 | 140.1 | 3.72 | 1.26 | 97.9 |
| 5 | 140.3 | 3.61 | 1.26 | 97.3 |
| 6 | 140.5 | 3.61 | 1.26 | 97.3 |
| 7 | 140.1 | 3.54 | 1.25 | 97.7 |
| 8 | 140.4 | 3.73 | 1.27 | 97.7 |
| 9 | 140.2 | 3.72 | 1.26 | 97.5 |
| 10 | 140.5 | 3.65 | 1.26 | 97.6 |
| | | | | |
| | | | | |
| Mean | 140.48 | 3.649 | 1.264 | 97.62 |
| Std. Deviation | 0.352 | 0.073 | 0.008 | 0.220 |
| CV% | 0.250 | 2.007 | 0.667 | 0.237 |
| | | | | |

The following activities, mentioned below, have been performed to complete the performance qualification.

| Sr. No. | Activity | Remark |
|------------|----------------------------------|--------|
| 1.1 | Performance Qualification | |
| 1.1.1 | Reproducibility Checks | Pass |
| 1.1.2 | Accuracy Checks | |
| | QC Level 1 | Pass |
| | QC Level 2 | Pass |
| | QC Level 3 | Pass |

Performance Qualification Protocol

System/Equipment: ML200

Location: 7/8 Sunflower, Royal Complex, Eksar Road, Borivali (w), Mumbai-91

Deviation Report

Deviation(s) : NIL
Justification for acceptance : The correlation study results are found acceptable.
Impact on operation, function or process : Precision CV %found within acceptable criterion. Instrument functioning satisfactorily.

Prepared by : Anup Mali

Date : 01.02.2022

Performance Qualification Report

Results : Acceptable results

Conclusions : Study data has determined that the system described in the document meets all Criteria outlined in this performance qualification protocol.

Performance Qualification completed successfully.

The system is ready for its routine use.

Prepared by : Anup Mali

Sign & Date :  01/2/22

QA Approved by :  Dhannraj Dhannraj

Sign & Date :  01/02/2022

