





# NIHON KOHDEN INDIA PRIVATE LIMITED

## TECHNICAL SERVICE REPORT

TOLL FREE NUMBER: 1800 103 8182

FORM NO.: CS/02/01

147394

Report No.: NKI/CS/ Service Notification Number: Customer ID:

CALL ATTEND DATE: 13-09-21 TIME: 10:25 am CALL CLOSE DATE: 13-09-21 TIME:

Lab/Hospital Name: Minu Clinical Laboratory

Address: Shop no-7/8, Sunflower, Royal complex, Ekasa Rd, Borivali(W)

City: Mumbai State: Maharashtra Pin: 400091

Contact Person: Department Pathlab

Tel./Mob.No.: 28915692 Email Id: minulab@rediffmail.com

EQUIPMENT STATUS:  WARRANTY  AMC/CMC/RENTAL/DEMO  CHARGABLE CALL

AMC/CMC/WARRANTY PERIOD: FROM 13-09-21 TO 12-09-23 EXPIRED ON:

SITE VOLTAGE: L-N: 218 VAC L-G: 229 VAC N-G: 1V VAC STABILIZER/UPS:  Y  N

SITE CONDITION:

SITE RECOMANDATION

EQUIPMENT NAME: CBC MODEL: MEK1305 SR. NO.: 224

PROBLEM REPORTED: Installation

PROBLEM OBSERVED:

ACTION TAKEN Done installation, Done calibration, checked controls, readings are in specified range. Machine is working ok. gave user training to customer. Handover all accessories to customer as per abs.

### FUNCTIONINGS STATUS & SERVICING CHECKLIST OF MEK SERIES (Mandatory):

|                   |   |                    |   |                     |   |                  |   |      |
|-------------------|---|--------------------|---|---------------------|---|------------------|---|------|
| Normal Startup    | <input type="checkbox"/> OK <input type="checkbox"/> N.OK | Rinsing unit clean | <input type="checkbox"/> Y <input type="checkbox"/> N | Hb LED ON           | Volts   | WBC L-manometer  | Volts   | Fac. |
| Pump Tube checked | <input type="checkbox"/> OK <input type="checkbox"/> N.OK | Strong Cleaning    | <input type="checkbox"/> Y <input type="checkbox"/> N | Hb LED OFF          | Volts   | WBC U-manometer  | Volts   | Fac. |
| All Tubes Status  | <input type="checkbox"/> OK <input type="checkbox"/> N.OK | Normal Cleaning    | <input type="checkbox"/> Y <input type="checkbox"/> N | RBC Electrode       | Volts   | RBC L-manometer  | Volts   | Fac. |
| Display Contrast  | <input type="checkbox"/> OK <input type="checkbox"/> N.OK | Filters Cleaning   | <input type="checkbox"/> Y <input type="checkbox"/> N | WBC Electrode       | Volts   | RCC L-manometer  | Volts   | Fac. |
| Priming Check     | <input type="checkbox"/> OK <input type="checkbox"/> N.OK | Bath cleaning      | <input type="checkbox"/> Y <input type="checkbox"/> N | Background Noise    | <input type="checkbox"/> Y <input type="checkbox"/> N | Circuit Check    | <input type="checkbox"/> OK <input type="checkbox"/> N.OK |      |
| Partical Test     | <input type="checkbox"/> OK <input type="checkbox"/> N.OK | Apertur Cleaning   | <input type="checkbox"/> Y <input type="checkbox"/> N | Mechanical Scaling  | <input type="checkbox"/> Y <input type="checkbox"/> N | Touch Screen     | <input type="checkbox"/> OK <input type="checkbox"/> N.OK |      |
| Fine gain adjust  | <input type="checkbox"/> OK <input type="checkbox"/> N.OK | Flowcell Cleaning  | <input type="checkbox"/> Y <input type="checkbox"/> N | Mechanical Cleaning | <input type="checkbox"/> Y <input type="checkbox"/> N | Background Noise | <input type="checkbox"/> OK <input type="checkbox"/> N.OK |      |
| Sampling Nozzle   | <input type="checkbox"/> OK <input type="checkbox"/> N.OK | Air pressure       | <input type="checkbox"/> Y <input type="checkbox"/> N | Sensitivity & Thrd. | <input type="checkbox"/> Y <input type="checkbox"/> N | Valve Check      | <input type="checkbox"/> OK <input type="checkbox"/> N.OK |      |
| Input CAL data:   | WBC- RBC- Diluter- Y                                      | Diluent Volts-     | Factor-   | Lyse: Volts-        | Factor-   |                  |   |      |

ACCESSORIES USED BY CUSTOMER (FOR ME & NEURO):  ORIGINAL  THIRD PARTY

Details of Test performed (Please attach the instrument generated result printout):

| TEST DESCRIPTION | RESULT OBTAINED | REMARKS |
|------------------|-----------------|---------|
| controls & CBC   | ok              |         |

Following parts replaced/ need to be replaced

| PARTS CODE | DESCRIPTION | QTY. | OLD SPARES SRL NO. | NEW SPARES SRL NO. |
|------------|-------------|------|--------------------|--------------------|
|            |             |      |                    |                    |
|            |             |      |                    |                    |
|            |             |      |                    |                    |
|            |             |      |                    |                    |

Above parts are on  Free of Cost  will be invoiced to Customer

NOS. OF SAMPLE/DAY: 15 NOS. of ICU BED:

Engineer's Remarks: Customer's remarks:

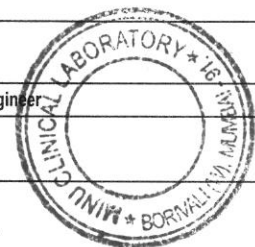
NKI Engineer's Name: Pufesh K. Pagdhare / Pufesh Asher Customer's Name: Dr. CHITRA S. SHAI Name of Biomedical Engineer:

Signature: [Signatures]

WHITE: CUTOMER, PINK: HO, YELLOW: ENGINEER

N.B.: Please ansure filling and sending of Installation Chack list along with report at the time of installation. Subject to Gurugram Jurisdiction

Nihon Kohden India Pvt. Ltd., 308, Tower-A, Spazodge, Sector 47, Sohna Road, Gurgaon, Haryana, Pin-122 002, India Tel.: +91-0124-4931000-28, Fax: +91-0124-4931029 CIN No.: U33110HR2011PTC041863, www.nihonkohden.com



*Input data*



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|                    |                               |
|--------------------|-------------------------------|
| Instrument Name    | Automated 3 Part Cell Counter |
| Make               | Nihon Kohden                  |
| Model              | MEK-1305                      |
| Serial no          | 224                           |
| Calibration date   | 13th Sep 21                   |
| Installation place | Minu Clinical Laboratory      |

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Name : Ritesh Pagdhare  
Designation : Sr. Engineer CS



## Calibration Data

Instrument Name : Automated 3 Part Cell Counter  
 Make : Nihon Kohden  
 Model : MEK-1305  
 Serial no : 224  
 Calibration date : 13th Sep 21  
 Installation place : Minu Clinical Laboratory

| CALIBRATION RUN DATA |      |      |       |       |        |
|----------------------|------|------|-------|-------|--------|
| Sample No.           | WBC  | RBC  | HGB   | HCT   | PLT    |
| 1                    | 8.89 | 4.61 | 13.46 | 46.8  | 253.8  |
| 2                    | 8.84 | 4.63 | 13.42 | 46.9  | 249.3  |
| 3                    | 8.95 | 4.68 | 13.48 | 47.7  | 247.9  |
| 4                    | 9.07 | 4.68 | 13.43 | 47.3  | 253.3  |
| 5                    | 8.94 | 4.67 | 13.25 | 47.2  | 246.1  |
| 6                    | 8.90 | 4.67 | 13.38 | 47.4  | 239.6  |
| 7                    | 9.08 | 4.61 | 13.34 | 47.3  | 243.1  |
| 8                    | 8.94 | 4.59 | 13.26 | 46.3  | 240.7  |
| 9                    | 8.97 | 4.71 | 13.31 | 47.5  | 246.7  |
| 10                   | 9.13 | 4.68 | 13.35 | 47.2  | 246.5  |
| Mean                 | 8.97 | 4.41 | 13.37 | 47.16 | 246.70 |
| SD                   | 0.09 | 0.04 | 0.08  | 0.40  | 5      |
| CV%                  | 1.04 | 0.90 | 0.60  | 0.8   | 1.9    |

|                |             |             |             |             |           |
|----------------|-------------|-------------|-------------|-------------|-----------|
| Acceptable CV% | Within 2.0% | Within 1.5% | Within 1.5% | Within 1.5% | Within 4% |
| Result status  | PASS        | PASS        | PASS        | PASS        | PASS      |

\*Precision study performed on the analyzer using a blood samples.

For Nihon Kohden India Pvt. Ltd.  
 Name : Ritesh Pagdhare  
 Designation : Sr. Engineer CS





## Precision Check Data

Instrument Name : Automated 3 Part Cell Counter  
 Make : Nihon Kohden  
 Model : MEK-1305  
 Serial no : 224  
 Calibration date : 13th Sep 21  
 Installation place : Minu Clinical Laboratory

| PRECISION RUN DATA |      |      |       |      |       |
|--------------------|------|------|-------|------|-------|
| Sample No.         | WBC  | RBC  | HGB   | HCT  | PLT   |
| 1                  | 7.01 | 4.83 | 12.82 | 39.4 | 404.9 |
| 2                  | 7.06 | 4.82 | 12.77 | 39.3 | 386.8 |
| 3                  | 6.84 | 4.77 | 12.85 | 38.9 | 398.9 |
| 4                  | 6.94 | 4.86 | 12.89 | 39.6 | 375.6 |
| 5                  | 6.94 | 4.86 | 12.91 | 39.2 | 381.6 |
| 6                  | 7.13 | 4.81 | 12.91 | 39.7 | 380.7 |
| 7                  | 6.92 | 4.86 | 12.79 | 39.6 | 389.1 |
| 8                  | 6.84 | 4.85 | 12.89 | 40.0 | 383.7 |
| 9                  | 7.08 | 4.78 | 12.84 | 38.8 | 402.4 |
| 10                 | 7.01 | 4.81 | 12.87 | 39.2 | 388.3 |
| Mean               | 6.98 | 4.73 | 12.85 | 39.4 | 389   |
| SD                 | 0.10 | 0.0  | 0.05  | 0.4  | 10    |
| CV%                | 1.41 | 0.7  | 0.38  | 0.9  | 3     |

| Acceptable CV% | Within 2.0% | Within 1.5% | Within 1.5% | Within 1% | Within 4% |
|----------------|-------------|-------------|-------------|-----------|-----------|
| Result status  | PASS        | PASS        | PASS        | PASS      | PASS      |

\*Precision study performed on the analyzer using a blood samples.

For Nihon Kohden India Pvt. Ltd.

Name : Ritesh Pagdhare

Designation : Engineer CS



## Certification of Calibration

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|                    |                                 |
|--------------------|---------------------------------|
| Instrument Name    | : Automated 3 Part Cell Counter |
| Make               | : Nihon Kohden                  |
| Model              | : MEK-1305                      |
| Serial no          | : 224                           |
| Calibration date   | : 13th Sep 21                   |
| Installation place | : Minu Clinical Laboratory      |

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This is to certify that the above mentioned instrument has been successfully calibrated on **13th Sep 2021** with MEK-CAL lot no-**PLUS 219** bearing expiry till **5th Oct , 2021**. During the calibration of the analyser, all CBC parameters were calibrated.

Ran Quality Controls **MEK-3D (Low, Normal, and High)** Lot no-**218** bearing expiry of **5th Nov 2021**. Result found within specified range.

Based on the manufacture recommended calibration interval the next due date of calibration is on **12th Sep 2022**. Validity  $\pm$  30days. Or depends on QC performance/subject to replacement or change in hardware.

For Nihon Kohden India Pvt. Ltd.

Name : Ritesh Pagdhare

Designation : Sr. Engineer CS



## **Installation Qualification**

## **Operation Qualification**

**&**

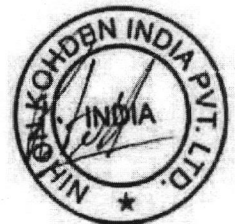
## **Performance Qualification**

|                 |   |                               |
|-----------------|---|-------------------------------|
| Instrument Name | : | Automated 3 Part Cell Counter |
| Make            | : | Nihon Kohden                  |
| Model           | : | MEK-1305                      |
| Serial no       | : | 224                           |



## Validation Report

|                        |   |                                    |
|------------------------|---|------------------------------------|
| Instrument Name        | : | Automated 3 Part Cell Counter      |
| Make                   | : | Nihon Kohden                       |
| Model                  | : | MEK-1305                           |
| Serial no              | : | 224                                |
| Supplier Name          | : | Nihon Kohden India Private Limited |
| Contact Name & Address | : | Minu Clinical Laboratory           |





## Approval of IQ/OQ/PQ Procedure

Both Minu Clinical Laboratory and Nihon Kohden India Private Limited  
jointly responsible for the installation of Automated 3 Part Cell CounterMEK-1305 (224)  
in the pathology laboratory

VALIDATION TEAM FROM VENDOR:

Name : Ritesh Pagdhare

Designation : Sr. Engineer CS

Signature : \_\_\_\_\_

Nihon Kohden India Private Limited



VALIDATION TEAM FROM PATHOLOGY LABORATORY:

Name :

Designation :

Signature :

Date :

CUSTOMER AUTHORIZATION:

Name :

Designation :

Signature :

Date :

**II. INSTRUCTIONS**

1 This document is to be completed at the time the instrument is installed at its current location Minu Clinical Laboratory and set up for operation.

2 An authorized (Company) representative will check the instrument and enter the specific data related to installation, operational and performance qualification.

3 Employee of Pathology laboratory will verify each result and sign the result. Validation team will carry this out.

4 All validation from the normal specification to include and problems with installation will be noted under COMMENTS.

**III. SCOPE**

This installation qualification protocol is performed on the Automated 3 Part Cell Counter MEK-1305 (224) located in pathology.

This protocol defines the documentation that is used to evaluate the instrument installation in accordance with the manufacturer's specifications and intended usage.

Successful completion of this protocol verifies that this instrument has been installed, operated in accordance with the intended usage.

Installation checks are performed to verify that the instrument has been installed with proper connection and utilities.

Operational qualification will evaluate the instrument have operational features available for the successful operation of instrument in accordance with the manufacturer's specifications.

Performance qualification will verify the actual functioning or performance of instrument manufacturer's specifications.



**IV. CERTIFICATE OF PURCHASE ORDER COMPLIANCE:**

I certify to the best of my knowledge, the instrument Automated 3 Part Cell Counter MEK-1305 (224) has been installed in pathology is in compliance with the specification of the agreement order

**V. INSTRUMENT DESCRIPTION:**

| S.no. | Instrument identification          | Verified | Date       |
|-------|------------------------------------|----------|------------|
| 1     | Automated 3 Part Cell Counter      | Yes      | 6th Aug-21 |
| 2     | Nihon Kohden                       | Yes      | 6th Aug-21 |
| 3     | Model:MEK-1305                     | Yes      | 6th Aug-21 |
| 4     | Instrument ID                      | Yes      | 6th Aug-21 |
| 5     | Serial no.224                      | Yes      | 6th Aug-21 |
| 6     | Size : As per speciifcation given  | Yes      | 6th Aug-21 |
| 7     | Power : As per speciifcation given | Yes      | 6th Aug-21 |

**VI. UTILITIES :**

| S.no. | Instrument identification  | Yes/No | Date       |
|-------|--|--------|------------|
| 1     | Environmental condition as required.<br>(Free from dust, electrical and magnetic interference)<br>Temperature: 15 – 30 OC<br>Humidity: 30 to 85 % non condensing | Yes    | 6th Aug-21 |
| 2     | Adequate space for installation:<br>(As per the specification given)   | Yes    | 6th Aug-21 |
| 3     | Electrical Outlets:<br>Actual voltage on site (228 VAC)  | Yes    | 6th Aug-21 |
| 4     | Grounded   | Yes    | 6th Aug-21 |
| 5     | Connected through UPS  | Yes    | 6th Aug-21 |
| 6     | Waste Liquid   | Yes    | 6th Aug-21 |



**VII. THE INSTRUMENT HAS BEEN CHECKED FOR THE FOLLOWING :**

| S.no. | Instrument identification                 | Yes/No | Date       |
|-------|---|--------|------------|
| 1     | Instrument is identified                  | Yes    | 6th Aug-21 |
| 2     | Manufacturer's specification are included | Yes    | 6th Aug-21 |
| 3     | Accessories / Consumables are listed      | Yes    | 6th Aug-21 |
| 4     | Equipment manual from the manufacturer    | Yes    | 6th Aug-21 |

**ACCESSORIES / CONSUMABLES:**

The following accessories were supplied with the instrument

| S.no. | Description     | Qty | Verified by | Date       |
|-------|-----------------|-----|-------------|------------|
| 1     | Accessories box | 1   | Yes         | 6th Aug-21 |
|       |                 |     |             |            |

**VIII. LIST OF MANUALS AND CERTIFICATES**

Supplier provided the following with the instrument

| S.no. | Particulars                           | Available or not | Date       |
|-------|---------------------------------------|------------------|------------|
| 1     | Operating Manual                      | Yes              | 6th Aug-21 |
| 2     | Invoice                               | Yes              | 6th Aug-21 |
| 3     | Safety instruction (equipment manual) | Yes              | 6th Aug-21 |
| 4     | Training records                      | Yes              | 6th Aug-21 |
| 5     | if any other                          | NO               | 6th Aug-21 |

**IX. MAINTENANCE:**

The instrument listed within this document will be placed under the control of Minu Clinical Laboratory Pathology laboratory institution with respect to proper maintenance procedure as detailed in the operator's manual.

A trained analyst using the manual provided with the instrumentation can perform basic and operation maintenance. Upon expiration of the warranty period vendor will offer.

Several levels of maintenance agreement and performance testing service to assist you in maintaining compliance. Contacting your local representative and requesting the additional service agreement can supply additional information.



**X. INSTALLATION PROCEDURE:**
**1 Installation of Hardware and Software**

Follow the instruction mentioned in the installation guide.

**2 Installation of Printer**

Follow the instruction mentioned in the installation guide.

## Operation Qualification:

|                 |   |                               |
|-----------------|---|-------------------------------|
| Instrument Name | : | Automated 3 Part Cell Counter |
| Make            | : | Nihon Kohden                  |
| Model           | : | MEK-1305                      |
| Serial no       | : | 224                           |

**XI. OPERATIONAL QUALIFICATION:**

Following features/ functions are available in the instrument as per manufacturer's specification and verified e.g. Start-up, Calibration, quality control, maintenance checks.

| S.no. | Test Name           | Y/N | Test Procedure          | Date       |
|-------|---------------------|-----|-------------------------|------------|
| 1     | Start up            | Yes | Retest Testing          | 6th Aug-21 |
| 2     | Calibration Feature | Yes | Calibration Performance | 6th Aug-21 |
| 3     | Quality Control     | Yes | Control Running         | 6th Aug-21 |
| 4     | Maintenance         | Yes | Operation Maintenance   | 6th Aug-21 |

Printouts of the above features / tests attached (Yes/No)

Yes





## CERTIFICATE OF TRAINING:

### 1. Operator and Maintenance Training

This certifies that the technicians listed below have received basic user training for the system described.

| S.no. | Training Program      | Signature | Date        |
|-------|-----------------------|-----------|-------------|
| 1     | Instrument Set-up     | Yes       | 13th Sep-21 |
| 2     | System Operation      | Yes       | 13th Sep-21 |
| 3     | Basic troubleshooting | Yes       | 13th Sep-21 |

Traning given by : Name : Ritesh Pagdhare  
Designation : Sr. Engineer CS

Training attended by :  
Dr Chirag Shah



## Performance Qualification :

|                 |   |                               |
|-----------------|---|-------------------------------|
| Instrument Name | : | Automated 3 Part Cell Counter |
| Make            | : | Nihon Kohden                  |
| Model           | : | MEK-1305                      |
| Serial no       | : | 224                           |

Following are the steps required to validate your instrument and method.

- 1 Run QC samples (Low, Normal and Abnormal) and verifies the values with acceptable range given in the insert of quality control samples

Printouts attached from instrument (Yes/No) Yes

- 2 Run 10 time patient sample into the system and calculate the %CV. Acceptance limits of %CV ( $\leq 5\%$ ) shall be considered.

Printouts attached from instrument (Yes/No) Yes

QC RESULTS : PASS/FAIL= PASS  
PRECISION CHECK : PASS/FAIL= PASS

VALIDATION TEAM FROM VENDOR:

Name : Ritesh Pagdhare  
Designation : Sr. Engineer CS

Signature : \_\_\_\_\_  
Nihon Kohden India Private Limited



VALIDATION TEAM FROM PATHOLOGY LABORATORY:

Name :  
Designation :  
Signature :  
Date :

CUSTOMER AUTHORIZATION:

Name :  
Designation :  
Signature :