

# Automated Hematology Analyzer

## MEK-9200

### Intended Purpose

*For in vitro diagnostic use only.*




The Automated Hematology Analyzer MEK-9200 is intended for in vitro diagnostic use for automated classification and quantification of following parameters (complete blood count, CBC, white blood cells five-part differential, and reticulocyte) in EDTA treated human whole blood as an aid of diagnosis of patient populations found in clinical laboratories:

White Blood Cells (WBC), Neutrophil Count and Percent (NE and NE%), Lymphocyte Count and Percent (LY and LY%), Monocyte Count and Percent (MO and MO%), Eosinophil Count and Percent (EO and EO%), Basophil Count and Percent (BA and BA%), Red Blood Cells (RBC), Hemoglobin Concentration (HGB), Hematocrit Percent (HCT), Mean Corpuscular Volume (MCV), Mean Corpuscular Hemoglobin (MCH), Mean Corpuscular Hemoglobin Concentration (MCHC), Red Blood Cell Distribution Width in Coefficient of Variation (RDW-CV), Red Blood Cell Distribution Width in Standard Deviation (RDW-SD), Platelet Count (PLT), Platelet Crit (PCT), Mean Platelet Volume (MPV), Platelet Distribution Width (PDW), Platelet Large Cell Ratio (P-LCR), Platelet Large Cell Count (P-LCC), Reticulocyte Percent (RET%), Reticulocyte Count (RET), Immature Reticulocyte Fraction (IRF), Low Fluorescence Ratio (LFR), Middle Fluorescence Ratio (MFR) and High Fluorescence Ratio (HFR)

The measurement of CBC, WBC five-part differential and reticulocyte can aid in diagnosis of anemia, inflammation and infection.

Testing population are general population patients undergoing evaluation for the associated conditions. The Automated Hematology Analyzer MEK-9200 is intended for laboratory professional use only.

### Safety Information

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|  <b>DANGER</b>  | A danger alerts the user to a hazardous situation which causes death or serious injury.   |
|  <b>WARNING</b> | A warning alerts the user to possible injury or death associated with the use or misuse of the instrument.  |
|  <b>CAUTION</b> | A caution alerts the user to possible injury or problems with the instrument associated with its use or misuse such as instrument malfunction, instrument failure, damage to the instrument, or damage to other property. |

Pay attention to all safety information in the Operator's Manual.

#### **DANGER**

If the detergent contacts the eyes, wash immediately with plenty of water for at least 15 minutes and see a physician. The detergent can cause blindness.

#### **WARNING**

Never use the analyzer in the presence of any flammable anesthetic gas or high concentration oxygen atmosphere. Failure to follow this warning may cause explosion or fire.

#### **WARNING**

Never use the analyzer in a hyperbaric oxygen chamber. Failure to follow this warning may cause explosion or fire.

#### **WARNING**

Do not use the analyzer near an ESU. Noise from the ESU may cause the analyzer to malfunction.

#### **WARNING**

The sampling needle and venting needle are sharp and potentially contaminated with infectious materials. Be careful when handling the sampling needle and venting needle.

**⚠ WARNING**

- Be careful not to directly touch any place where blood sample is or may have contacted.
- Always wear rubber gloves to protect yourself from infection.

**⚠ WARNING**

Do not disassemble anything unless specified by the operator's manual. This may result in exposure to laser radiation.

**⚠ WARNING**

Install the analyzer and external instruments outside the patient environment. If they are installed inside the patient environment, the patient or operator may receive electrical shock or injury.

**⚠ WARNING**

Do not leave the SD card near the patient or in reach of children. This may lead to an accident such as the patient or child swallowing the SD card.

**⚠ WARNING**

Do not diagnose a patient based only on data acquired by the analyzer. Overall judgement must be performed by a physician who understands the features, limitations and characteristics of the analyzer and by reading the biomedical signals acquired by other instruments.

**⚠ WARNING**

Always wear rubber gloves to protect yourself from infection.

**⚠ WARNING**

- Dispose of the analyzer, replaced parts (such as sampling needle and venting needle), waste fluid and parts used for collecting sample blood (such as needles, syringes and vials) according to your local laws for disposing of infectious medical waste (for incineration, melt treatment, sterilization and disinfection).
- Before disposing of the analyzer, perform strong cleaning and remove the sampling needle and venting needle from the analyzer.  
If the above warning is not followed, it causes infection or environmental contamination.

**⚠ CAUTION**

Only use the provided power cord and connect it to a 3-pin AC outlet which is properly grounded. Otherwise, it may result in electrical shock or injury to the operator.

**⚠ CAUTION**

When several medical instruments are used together, ground all instruments to the same one-point ground. Any potential difference between instruments may cause electrical shock to the operator.

**⚠ CAUTION**

Connect only the specified instrument to the analyzer and follow the specified procedure.

**⚠ CAUTION**

Before connecting or disconnecting instruments, make sure that each instrument is turned off and the power cord is disconnected from the AC outlet. Otherwise, the patient or operator may receive electrical shock or injury, data may be lost or the instrument may malfunction.

**⚠ CAUTION**

- If the waste fluid enters the mouth or eyes or comes in contact with the skin, wash thoroughly and immediately with water and see a physician.
- If the waste fluid is swallowed, see a physician.

**⚠ CAUTION**

- Wear protective equipment when handling the detergent.
- Do not mix the detergent with acid. This produces chlorine gas.
- Do not inhale fumes from the detergent. If detergent fumes are inhaled, move to fresh air and take a rest.
- Do not swallow the detergent.  
If the detergent is swallowed or contacts the mouth, rinse the mouth immediately. Do not force vomiting. See a physician.
- If the detergent contacts the skin, wash with plenty of water. See a physician if there are skin abnormalities.

**⚠ CAUTION**

Only use Nihon Kohden specified consumables for the analyzer. Otherwise the accuracy of the measurement result cannot be guaranteed.

**⚠ CAUTION**

Do not reuse disposable parts and accessories.

**⚠ CAUTION**

A measurement result with a message might not be correct because of analyzer error or sample error. Do not diagnose the patient based on the result especially when “!” appears on the measurement result.

**⚠ CAUTION**

Connect the analyzer to the network as specified. Otherwise the operator may receive electrical shock or injury and cybersecurity may be compromised. To connect the network, contact your Nihon Kohden representative.

**⚠ CAUTION**

Do not put your hand on the rack or sample tube holder during measurement.

**⚠ CAUTION**

Set the ID correctly. Otherwise, the examination data may be mixed up with data of another examination.

**⚠ CAUTION**

Use more than one person to move or install the hematology analyzer. Otherwise, it may cause injury from dropping the hematology analyzer.

**⚠ CAUTION**

Before moving the analyzer, do the following.

- Perform cleaning and drain the cups. If the analyzer is lifted or tilted without cleaning and draining it, the liquid in the cups may spill and damage the electronic circuit or the operator may receive electrical shock.
- Turn off the analyzer main power and disconnect the power cord from the AC outlet. If the analyzer is moved while the power is on, the operator may receive electrical shock or the analyzer may start unexpectedly when a key is pressed.

**⚠ CAUTION**

Before maintenance, perform cleaning, drain the cups, and turn off the analyzer main power and disconnect the power cord from the AC outlet. If the analyzer is lifted or tilted without cleaning and draining it, the liquid in the cups may spill and damage the electronic circuit or the operator may receive electrical shock. If maintenance is performed while the power is on, the operator may receive electrical shock or the analyzer may start unexpectedly when a key is pressed.

**⚠ CAUTION**

To ensure the cybersecurity of the analyzer, implement the following network security measures under the supervision of the information security manager of the medical facility.

1. When a device in the LIS (Laboratory Information System) network is connected to an external network including the internet, access to sensitive information is protected by firewalls and ACL (access control lists).
2. When a device in the LIS network is connected to a network with a different protocol (HIS, office area, etc.), access control is implemented on routers and switches to restrict communication to the designated source and destination devices only.

**⚠ CAUTION**

Certain data, settings and operations on the analyzer may only be accessed, changed or performed by an administrator with the appropriate authority. Manage the password allocated to the administrator carefully to prevent unauthorized access. Set a password that is difficult to guess and change it regularly.

**⚠ CAUTION**

Personal information stored on this analyzer, or the PC on which the provided software is installed, is vulnerable to unauthorized access. Follow the provisions of the user agreement for this analyzer related to information security.

**⚠ CAUTION**

Use the analyzer in a securely managed environment.

**⚠ CAUTION**

- Wear protective gloves when handling the reagent.
- Do not swallow the reagent. If swallowed, rinse the mouth immediately. Do not force vomiting. See a physician.
- If the reagent contacts the eyes or mouth, wash immediately with plenty of water and see a physician.
- If the reagent contacts the skin, wash with plenty of water.

**⚠ CAUTION**

Do not use a damaged network cable. The operator may receive electrical shock when the damaged part is touched.

This Safety and Performance Information is an extract from the general and safety information sections of the most recent edition of Operator's Manual or Installation Guide. Therefore, the contents of your Operator's Manual or Installation Guide may differ from those of this Safety and Performance Information. For detailed operating procedures, follow the instructions of your Operator's Manual or Installation Guide.



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