SAFETY AND PERFORMANCE INFORMATION

NIHON KOHDEN

Automated Hematology Analyzer
MEK-1301, MEK-1302

Intended Purpose

For in vitro diagnostic use only.

The Automated Hematology Analyzer MEK-1301/MEK-1302 is intended for in vitro diagnostic use for automated classification and quantification of following parameters (complete blood count, CBC) in EDTA treated human whole blood as an aid of diagnosis of patient populations found in clinical laboratories:

White Blood Cells (WBC), Lymphocyte Count and Percent (LY and LY%), Monocyte Count and Percent (MO and MO%), Granulocyte Count and Percent (GR and GR%), Red Blood Cells (RBC), Hemoglobin Concentration (HGB), Hematocrit Percent (HCT), Mean Corpuscular Volume (MCV), Mean Corpuscular Hemoglobin (MCH), Mean Corpuscular Hemoglobin Concentration (MCHC), Platelets (PLT), Red Blood Cell Distribution Width in Coefficient of Variation (RDW-CV), Red Blood Cell Distribution Width in Standard Deviation (RDW-SD), Platelet crit (PCT), Mean Platelet Volume (MPV), Platelet Distribution Width (PDW), and Platelet Large Cell Ratio (P-LCR)

The measurement of CBC can aid in the diagnosis of anemia, inflammation, and infection.

Testing population are general population patients undergoing evaluation for the associated conditions. The Automated Hematology Analyzer MEK-1301/MEK-1302 is intended for laboratory professional use only.

Safety Information

⚠ **WARNING**	A warning alerts the user to possible injury or death associated with the use or misuse of the instrument.
⚠ **CAUTION**	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.

⚠ 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

If CLEANAC•3 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

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

⚠ 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

Install the analyzer and external devices 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.

⚠ WARNING

During and after setting a glass capillary pipette to the capillary adapter, handle the glass capillary pipette carefully to avoid breaking it.

⚠ 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 hematology analyzer and follow the specified procedure. Failure to follow this instruction may result in electrical shock or injury 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 socket. 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 contacts the skin, eyes or mouth, wash thoroughly and immediately with water and see a physician.

⚠ 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

- Wear protective equipment when handling CLEANAC•3 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 reagents and consumables. Otherwise the measurement result cannot be guaranteed and incorrect reagent concentration can cause equipment damaged.

⚠ CAUTION

Do not remove any parts that are not specified in this manual.

⚠ CAUTION

Do not reuse disposable parts and accessories.

⚠ CAUTION

A measurement result with a message added may be incorrect because of analyzer error or sample error. Avoid diagnosing a patient based on such results.

⚠ CAUTION

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

⚠ CAUTION

Only connect the analyzer and its perioheral and optional devices to the network in the medical facility.

⚠ CAUTION

Before moving the analyzer, do the following.

- Perform strong cleaning and drain the cups. If the analyzer is lifted or tilted without draining, 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 strong 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 draining, 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 or when the power cord is connected, the operator may receive electrical shock or the analyzer may start unexpectedly when a key is pressed.

⚠ CAUTION

Before moving the analyzer, do the following.

- Perform cleaning and discharge the fluid. If the analyzer is lifted or tilted without draining, 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, discharge the fluid, and turn off the analyzer main power. If the analyzer is lifted or tilted without cleaning and draining, 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

Check that the sampling nozzle is not broken, bent or clogged, or contaminated with coagulated blood. Correct measurement results cannot be acquired if the sampling nozzle is abnormal.

⚠ 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

Connect the analyzer to the network as specified. Otherwise the security of the network may be compromised or the operator may receive an electrical shock. For further information about connecting to the network, contact your Nihon Kohden representative.

⚠ 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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