OPERATOR'S MANUAL

CLEANAC•3

MEK-620

NIHON KOHDEN

General

Intended Purpose

For in vitro diagnostic use only.

CLEANAC•3 is for in vitro diagnostic use as a hypochlorous acid-based detergent for the purpose of removing blood stains in order to clean the flow path of Nihon Kohden hematology analyzers.

Read the hematology analyzer operator's manual together with this manual before and during use.

NOTE: Read the SDS (Safety Data Sheet) carefully before use. The SDS is available from your Nihon Kohden representative.

Devices Intended for Use in Combination with

MEK-1301, MEK-1302, MEK-1303, MEK-1305, MEK-6400, MEK-6410, MEK-6420, MEK-6500, MEK-6510, MEK-7222, MEK-7300, MEK-8222

Intended Users

For laboratory professional use only, in laboratories with suitable equipment for hematological testing. Qualified personnel, e.g. laboratory technicians trained in hematology analysis techniques, will be able to use according to this operator's manual.

Symbols

The following symbols are used with the detergent. The descriptions of each symbol are given in the table below.

Symbol	Description
	Use by
LOT	Lot number
REF	Catalogue number
	Fragile
	Keep away from sunlight
	Temperature limits
	This way up
	Keep away from rain
n	Stacking limit by number ("n" is the limiting number)

Symbol	Description
	Caution
	Operator's manual; operating instructions
IVD	In vitro diagnostic medical device
	Manufacturer
	Use no hand hooks
EC REP	European representative
CE	The CE mark is a protected conformity mark of the European Union.

0614-907968

Safety Information

⚠ **DANGER**	A danger is used to alert the user to a hazardous situation which will cause death or serious injury.
⚠ **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 this 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.

⚠ 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.

Hazards Identification

Signal Word

Danger

Hazard Statement

- H290 May be corrosive to metals
- H318 Causes serious eye damage
- H401 Toxic to aquatic life
- H412 Harmful to aquatic life with long lasting effects
- EUH210 Safety data sheet available on request

Precautionary Statement Prevention

- P234 Keep only in original packaging.
- P273 Avoid release to the environment.
- P280 Wear protective gloves/eye protection/face protection.

Precautionary Statement Response

- P305+P351+P338
  IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- P310 Immediately call a POISON CENTER/doctor.
- P390 Absorb spillage to prevent material-damage.

Precautionary Statement Storage

- P406 Store in a corrosion resistant container with a resistant inner liner.

Precautionary Statement Disposal

- P501 Dispose of contents/container in accordance with local and national regulations.

Sodium hypochlorite: 1.3%

Using the Detergent

Operation Principles

CLEANAC•3 is a detergent for hematology analyzers mainly composed of hypochlorous acid. The biggest factors that pollute the flow path of a hematology analyzer are the proteins and lipids in the blood, which fall into the "hard" category of dirt. Therefore, this product is prepared for powerful removal of such strong blood stains. It contains a hypochlorous acid that chemically dissolves blood proteins and lipids. By flowing a constant amount of this detergent through the flow path of hematology analyzer at regular intervals, dirt adhering to the flow path can be cleaned.

For details, refer to the hematology analyzer operator's manual.

Procedure

Connect the container with the detergent to a Nihon Kohden hematology analyzer. For the connection method, refer to the hematology analyzer operator's manual.

NOTE
- Use the detergent without diluting or sterilizing it.
- Be careful of splashing liquid when replacing the detergent.
- Do not refill the detergent.
- Leave the detergent in the box during use to keep it away from light.
- When using the detergent, be careful that no dust, bacteria or other contaminants enter the container.

Technical Information

Composition

Active ingredients:

Sodium hypochlorite: 1.3%

Environmental Conditions

Storage and Transport Environment

Temperature: 1 to 30°C (34 to 86°F)
(Do not freeze and keep away from sunlight.)

Operating Environment

Temperature: 15 to 30°C (59 to 86°F)

Expiration Date

The expiration date is shown on the package.

Shelf Life Date After Opening the Package

Use the detergent within 90 days of opening.

Package and Catalog Number

Model	Qty	Catalog Number
MEK-620	5 L × 1 container	T438D
MEK-620S	500 mL × 1 container	T438E

Disposal

When disposing of the detergent, such as when the expiration date is past, follow the instructions on the SDS of the detergent.

NOTE: Dispose of the detergent according to your local laws and your facility's guidelines for waste disposal (for incineration, melt treatment, sterilization and disinfection). Otherwise, it may affect the environment.

Revision History

Edition	Date	Details	Code Number
1st Edition	01 Dec 2014	Initial issue	0614-907473
2nd Edition	14 Feb 2022	IVDR compliance	0614-907968

NOTE
- The code number of this manual was changed from 0614-907473 to 0614-907968 when the manual was updated from 1st Edition to 2nd Edition.
- Changes made in the most recent edition are indicated by a bar in the left margin of each page.

Note for users in the territory of the EEA and Switzerland:
Any serious incident that has occurred in relation to the device must be reported to the European Representative designated by the manufacturer and the Competent Authority of the Member State of the EEA and Switzerland in which the user and/or patient is established.

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