

ISOTONAC•4

MEK-641

General

Intended Purpose

For in vitro diagnostic use only.

ISOTONAC•4 is for in vitro diagnostic use as a diluent for human venous whole blood samples for to aid analysis by Nihon Kohden hematology analyzers to measure complete blood count (CBC).

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, MEK-9100, MEK-9200

Analyte or Marker

Complete blood count in whole blood

Target Treated Population

The target populations are linked to the Nihon Kohden hematology analyzers. The target patient populations are populations found in clinical laboratories.

Specimen Collection and Preparation

- Use a sample of human whole blood only.
- When using a sampling tube, use EDTA as an anticoagulant.
- For collection and handling of blood samples, refer to the hematology analyzer operator's manual.

















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.

0614-907972

Symbols

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

Symbol	Description	Symbol	Description
	Use by		Caution
	Lot number		Operator's manual; operating instructions
	Catalogue number		In vitro diagnostic medical device
	Fragile		Manufacturer
	Keep away from sunlight		Use no hand hooks
	Temperature limits		European representative
	This way up		The CE mark is a protected conformity mark of the European Union.
	Keep away from rain		
	Stacking limit by number ("n" is the limiting number)		

Safety Information

- NOTE**
- Do not swallow the diluent.
 - If the diluent contacts the eye, wash thoroughly and immediately with running water.

Using the Diluent

Measurement Principles

ISOTONAC•4 is a diluent for measuring total blood cell count (CBC).

ISOTONAC•4 is a conductive isotonic solution with a pH close to that of blood, so the morphology of diluted blood cells is maintained during measurement.

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

Procedure

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

- NOTE
- Use the diluent without diluting or sterilizing it.
 - Use the diluent at a liquid temperature of 15 to 30°C (59 to 86°F). Otherwise the measurement data may be inaccurate.
 - Do not refill the diluent.
 - When using the diluent, be careful that no dust, bacteria or other contaminants enter the container.

Technical Information

Composition

Active ingredients:

- Sodium chloride: 0.40%
- Sodium sulphate anhydrous: 0.98%

Environmental Conditions

Storage and Transport Environment

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

NOTE: Do not freeze the diluent. If the diluent is frozen, the measurement data may be inaccurate due to precipitation of diluent ingredients.

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 diluent within 60 days of opening.

Package and Catalog Number

Model	Qty	Catalog Number
MEK-641	18 L × 1 container	T436B

Disposal

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

NOTE: Dispose of the diluent 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	22 Feb 2022	Initial issue, IVDR compliance	0614-907972

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.

Copyright Notice

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