














Melet Schloesing Pharmaceuticals | Rue du Collège 90 | CH-2300 La-Chaux-de-Fonds | Suisse

Instruction for Use

ISOFLUX[®]

Explanation of symbols

	Reference Catalog
	Expiration date
	Lot number
	Manufacturer
	Consult the instructions for use
	Compliance with European Directive 98/79 / EC
	When followed by "WARNING", this symbol means "Attention! Failure to do so may lead to erroneous examination results and / or degradation of the device."
	In vitro diagnostic medical device
	Protect from the sun
	Keep away from moisture
	Temperature limits (lower and upper)




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Introduction

This document provides the necessary information for the use of ISOFLUX® with the MS4 and MS9 automatic hematology analyzer meters manufactured by MELET SCHLOESING Laboratories.

This document is provided in electronic format (e-ifu), using the following URL: <http://www.mslabos.com/infos>

 **WARNING** This user manual contains important information regarding the safe use of ISOFLUX®. Please read this document as a whole before using the product.

Identification of the legal manufacturer



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Product designation	CE IVD	product reference
ISOFLUX®		3MSR0214 RMSIFLX5L0 RMSIFLX2L5

Description
ISOFLUX® is an isotonic diluting agent.
Kit Contents
ISOFLUX® combines in different capacities: a) A carton containing a plastic bag of 20 liters of reagent. b) One 5-liter bottle of reagent c) One vial of 2.5 l of reagent
Indication for Use
ISOFLUX® is an in vitro diagnostic device intended for use by healthcare professionals and only in combination with the conductimetric hematology devices of the MS4 and MS9 range manufactured by MELET SCHLOESING Laboratoires.
Intended Use
ISOFLUX® reagent is a diluting agent that makes it possible to carry out 2 sequential dilutions. These dilutions allow a mechanical separation of the red cells / platelets from those of the white ones.
Composition
ISOFLUX® is composed of the following elements: • A tampon • ADA (<1%) • DimethylUrea (<1%) • Sodium Fluoride (<1%) • • Conservative
Storage conditions - Shelf life - Stability
ISOFLUX® must never be subjected to temperatures below 15 ° C and above 25 ° C. ISOFLUX® can be stored for 120 days (16 weeks) after opening. ISOFLUX® can be stored for 3 years (see expiration date on the product label) from the date of manufacture
Installation
ISOFLUX® is ready to use and requires no preparation. A detailed description of the reagent installation / replacement is available in the relevant analyzer user guide.



Collection and preparation of the sample

When collecting the blood sample, avoid any violent aspiration to avoid the phenomenon of hemolysis that could influence the results of the hematological analysis. Also be sure to limit the sampling time to avoid micro-coagulation problems.

The blood sample to be analyzed should be collected in a collection tube containing EDTA K3 anticoagulant. The use of the sampling tube must be carried out according to the instructions of the supplier.

Conservation of samples:

Whole blood samples are stable for about 4 hours at room temperature and 24 hours at 2-6 ° C.

Gentle and prolonged homogenization of the blood / anticoagulant mixture is essential before any analysis, refer to the supplier's instructions.

It is recommended, but not essential, to carry out the analysis no earlier than 30 minutes and no later than 8 hours after collection.

Test principle

The combination of the ISOFLUX® with the meter-analyzers of the MS4 and MS9 type from the company MELET SCHLOESING LABORATORIES makes it possible to perform two sequential dilutions performing a mechanical partitioning of the red cells / platelets and white cells. This mechanical separation is necessary in view of the too different number of white and red cells (platelets).

Disposal of the product

Respect the protocol applied by your laboratory for the neutralization and elimination of waste.

Warnings and precautions

Precautions:

- Use only for in vitro diagnostics.
- Please read the Safety Data Sheet (MSDS) before use.
- Please follow all pre-analytical steps in the laboratory.
- Handle reagents with care to prevent the formation of bubbles.
- Do not use directly after transport or directly after handling. Ensure that the operating temperature conditions are reached.

Warnings:

- Reagents can cause irritation of the eyes, skin and mucous membranes.
- In case of contact, rinse with plenty of water and seek immediate medical attention. In case of accidental ingestion, call a doctor immediately!
- Avoid particles or bacteria coming into contact with the reagent.
- Do not use reagents beyond the expiry date or beyond the open bottle time.
- Place the reagents at the main unit of the device.
- Do not transfer / mix reagents whether they are of the same type or batch.
- Do not reuse an empty container as this may distort the results or damage the machine.



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- Do not use the product in case of deterioration of the protective packaging.
- If a reagent has been accidentally spilled, wipe it off immediately with a damp cloth.
- Do not use the product if there is any sign of deterioration (turbidity, color change, etc.)

Performance change

The following substances are likely to interfere with the results of the analysis:

- High lactose serums.
- Hemolyzed serums