

 <p>ISE S.r.l. CUSTOMISED SOLUTIONS FOR YOUR LABORATORY</p>	<p>I.S.E. S.r.l. Sistemi Intelligenti Elettronici Via Delle Driadi, 45 – 00133 Roma</p>	<p>Code MM-M009E Rev. 0 del 12/11/08 pag. 1 / 1</p>
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REF P3140000113	MIURA RINSE SOLUTION (Ew Cvt) 6x50 ml	
Solution	Quantity	Physical state
Extra Wash Cuvette	6 vial of 50 ml	Ready for use
IVD For in vitro diagnostic use only		

CLINICAL APPLICATIONS

This solution must be used on board of the automatic analyzers class MIURA for extra on line cuvettes washing.

STABILITY OF THE SOLUTION

The kit should be stored at the temperature + 2-25°C. The expiry date of each reagent is indicated on its relative label. When stored at +2-25°C and protected from light, the solutions are stable until the expiry date stated on the label.

NECESSARY MATERIAL NOT FURNISHED WITH THE KIT

- Automatic analyzer and / or for clinical chemistry class MIURA.
- User manual of the relative instrument.

AVERTISMENTS:

To obtain correct and reproducible results on the instrument, it is necessary to observe the following recommendations:

- Do not use solutions after its expiry date.
- Avoid accurately the contamination .
- Avoid direct exposure to sunlight.

PRECAUTIONS:

To avoid personal and ambiental contaminations it is necessary to observe the following security directives:

- Use protection glasses and monouse gloves during the manipulation
- Do not pipette reagent using your mouth.
- Do not smoke, eat, drink or use cosmetics. .
- The waste produced by the use of the product must be considered as dangerous waste and the dismantling of the same should be done according the local laws.

PREPARATION OF THE SOLUTION

Open one vial very carefully, avoiding liquid leakages.

Ready for use.

It is necessary that the solution, at the moment of the use, is at ambient temperature.

OPERATIONAL PROCEDURE

See the instrument user manual.

REGULATORY INFORMATION



C



Symbol

Risk Phrases

(R 35) GHS05 Corrosive – Causes severe burns

(R 37) GHS08 Irritating to respiratory system.

Warnings

H315-H318- (S 26) – In the case of contact with the eyes, wash immediately with plenty of water and consult a doctor.

H335 – (S 37/39) – Use suitable gloves and protect eyes and face.

P311- (S 45) – In the case of an accident or malaise, consult a doctor immediately (if possible, show the label).

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REF P3140000115	MIURA RINSE SOLUTION (Ew Prb) 6x20 ml	
Solution	Quantity	Physical state
Extra Wash Probe	6 vial of 20 ml	Ready for use
IVD For in vitro diagnostic use only		

CLINICAL APPLICATIONS

This solution must be used on board of the automatic analyzers class MIURA for extra on line cuvettes washing.

STABILITY OF THE SOLUTION

The kit should be stored at the temperature + 2-25°C. The expiry date of each reagent is indicated on its relative label. When stored at +2-25°C and protected from light, the solutions are stable until the expiry date stated on the label.

NECESSARY MATERIAL NOT FURNISHED WITH THE KIT

- Automatic analyzer and / or for clinical chemistry class MIURA.
- User manual of the relative instrument.

AVERTISMENTS:

To obtain correct and reproducible results on the instrument, it is necessary to observe the following recommendations:

- Do not use solutions after its expiry date.
- Avoid accurately the contamination .
- Avoid direct exposure to sunlight.

PRECAUTIONS:

To avoid personal and ambiental contaminations it is necessary to observe the following security directives:

- Use protection glasses and monouse gloves during the manipulation
- Do not pipette reagent using your mouth.
- Do not smoke, eat, drink or use cosmetics. .
- The waste produced by the use of the product must be considered as dangerous waste and the dismantling of the same should be done according the local laws.

PREPARATION OF THE SOLUTION

Open one vial very carefully, avoiding liquid leakages.

Ready for use.

It is necessary that the solution, at the moment of the use, is at ambient temperature.

OPERATIONAL PROCEDURE

See the instrument user manual.

REGULATORY INFORMATION



Symbol

Risk Phrases

(R 35) GHS05 Corrosive – Causes severe burns
(R 37) GHS08 Irritating to respiratory system.

Warnings

H315-H318- (S 26) – In the case of contact with the eyes, wash immediately with plenty of water and consult a doctor.
H335 – (S 37/39) – Use suitable gloves and protect eyes and face.
P311- (S 45) – In the case of an accident or malaise, consult a doctor immediately (if possible, show the label).

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REF P3140000274	RINSE SOLUTION (Ew Cvt) 6x35 ml	
Solution	Quantity	Physical state
Extra Wash Cuvette	6 vial of 35 ml	Ready for use
IVD For in vitro diagnostic use only		

CLINICAL APPLICATIONS

This solution must be used on board of the automatic analyzers class MIURA & HEMO ONE for extra on line cuvettes washing.

STABILITY OF THE SOLUTION

The kit should be stored at the temperature 15-25°C. The expiry date of each reagent is indicated on its relative label. When stored at 15-25°C and protected from light, the solutions are stable until the expiry date stated on the label.

NECESSARY MATERIAL NOT FURNISHED WITH THE KIT

- Automatic analyzer and / or for clinical chemistry class MIURA.
- User manual of the relative instrument.

AVERTISMENTS:

To obtain correct and reproducible results on the instrument, it is necessary to observe the following recommendations:

- Do not use solutions after its expiry date.
- Avoid accurately the contamination .
- Avoid direct exposure to sunlight.

PRECAUTIONS:

To avoid personal and ambiental contaminations it is necessary to observe the following security directives:

- Use protection glasses and monouse gloves during the manipulation
- Do not pipette reagent using your mouth.
- Do not smoke, eat, drink or use cosmetics. .
- The waste produced by the use of the product must be considered as dangerous waste and the dismantling of the same should be done according the local laws.

PREPARATION OF THE SOLUTION

Open one vial very carefully, avoiding liquid leakages.

Ready for use.

It is necessary that the solution, at the moment of the use, is at ambient temperature.

OPERATIONAL PROCEDURE

See the instrument user manual.

REGULATORY INFORMATION



C



Symbol

Risk Phrases

(R 35) GHS05 Corrosive – Causes severe burns
(R 37) GHS08 Irritating to respiratory system.

Warnings

H315-H318- (S 26) – In the case of contact with the eyes, wash immediately with plenty of water and consult a doctor.
H335 – (S 37/39) – Use suitable gloves and protect eyes and face.
P311- (S 45) – In the case of an accident or malaise, consult a doctor immediately (if possible, show the label).

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REF P3140000275	RINSE SOLUTION (Ew Prb) 6x15 ml	
Solution	Quantity	Physical state
Extra Wash Probe	6 vial of 15 ml	Ready for use
IVD For in vitro diagnostic use only		

CLINICAL APPLICATIONS

This solution must be used on board of the automatic analyzers class MIURA& HEMO ONE for extra on line cuvettes washing.

STABILITY OF THE SOLUTION

The kit should be stored at the temperature 15-25°C. The expiry date of each reagent is indicated on its relative label. When stored at 15-25°C and protected from light, the solutions are stable until the expiry date stated on the label.

NECESSARY MATERIAL NOT FURNISHED WITH THE KIT

- Automatic analyzer and / or for clinical chemistry class MIURA.
- User manual of the relative instrument.

AVERTISMENTS:

To obtain correct and reproducible results on the instrument, it is necessary to observe the following recommendations:

- Do not use solutions after its expiry date.
- Avoid accurately the contamination .
- Avoid direct exposure to sunlight.

PRECAUTIONS:

To avoid personal and ambient contaminations it is necessary to observe the following security directives:

- Use protection glasses and monouse gloves during the manipulation
- Do not pipette reagent using your mouth.
- Do not smoke, eat, drink or use cosmetics. .
- The waste produced by the use of the product must be considered as dangerous waste and the dismantling of the same should be done according the local laws.

PREPARATION OF THE SOLUTION

Open one vial very carefully, avoiding liquid leakages.

Ready for use.

It is necessary that the solution, at the moment of the use, is at ambient temperature.

OPERATIONAL PROCEDURE

See the instrument user manual.

REGULATORY INFORMATION



Symbol

C

Risk Phrases

(R 35) GHS05 Corrosive – Causes severe burns
(R 37) GHS08 Irritating to respiratory system.

Warnings

H315-H318- (S 26) – In the case of contact with the eyes, wash immediately with plenty of water and consult a doctor.
H335 – (S 37/39) – Use suitable gloves and protect eyes and face.
P311- (S 45) – In the case of an accident or malaise, consult a doctor immediately (if possible, show the label).

HEMOLYSING SOL. FOR HBA1C

Code	Product description	Packaging
R3140000042	HEMOLYSING SOL. FOR HBA1C	500 ml

Intended use

Items to be used with the HBA1C reagent kit cod. A-R0200000900.

Precautions and Warnings

To avoid personal and ambiental contaminations it is necessary to observe the following security directives:

- Use protection glasses and monouse gloves during the manipulation
- Do not pipette reagent using your mouth.
- Do not smoke, eat, drink or use cosmetics. .
- The waste produced by the use of the product must be considered as dangerous waste and the dismantling of the same should be done according the local laws.

Reagent preparation

The reagents are ready for use.

Storage and stability

The kit should be stored at the temperature + 15-25°C. The expiry date of each reagent is indicated on its relative label. When stored at +15-25°C and protected from light, the solutions are stable until the expiry date stated on the label.

Operational Procedure

See the IFU of the HBA1C reagent kit cod. A-R0200000900.

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REF P3140000366	SYSTEMIC SOLUTION 8x13 ml	
Solution	Quantity	Physical state
Systemic	8 bottles of 13 ml	Liquid
IVD For in vitro diagnostic use only		

CLINICAL APPLICATIONS

This solution must be used to prepare the systemic solution used by the automatic analyzers HEMO ONE for ordinary on line cuvette and needles washing.

STABILITY OF THE SOLUTION

The kit should be stored at the temperature + 2-25°C. The expiry date of each reagent is indicated on its relative label. When stored at +2-25°C and protected from light, the solutions are stable until the expiry date stated on the label.

NECESSARY MATERIAL NOT FURNISHED WITH THE KIT

- Automatic analyzer and / or for clinical chemistry HEMO ONE.
- User manual of the relative instrument.
- Filling funnel.

AVERTISMENTS:

To obtain correct and reproducible results on the instrument, it is necessary to observe the following recommendations:

- Do not use solutions after its expiry date.
- Use perfectly clean and not contaminated tanks.
- Use bidistilled water, stored in perfectly clean containers.
- Avoid direct exposure to sunlight.

PRECAUTIONS:

To avoid personal and ambient contaminations it is necessary to observe the following security directives:

- Use protection glasses and monouse gloves during the manipulation and during the working preparation.
- Do not pipette reagent using your mouth.
- Do not smoke, eat, drink or use cosmetics during the preparation of the working reagent.
- The waste produced by the use of the product must be considered as dangerous waste and the dismantling of the same should be done according the local laws.

PREPARATION OF THE SOLUTION

Open one vial very carefully, avoiding liquid leakages.

Fill one tank of 5lt of bidistilled water with **13 ml** of systemic solution, using the supplied vial as measurement unit, and shortly shake the tank.

Spill the prepared solution in the systemic solution tank of the instrument; use the apposite clean funnel for refilling.

It is necessary that the solution, at the moment of the use, is at ambient temperature.

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P3140000252	SYSTEM CLEANER HEMO ONE 1x1000 ml	
Solution	Quantity	Physical state
Solution	1 bottle of 1000 ml	Liquid
IVD For in vitro diagnostic use only		

CLINICAL APPLICATIONS

This solution must be used on board of the HEMO ONE automatic analyzers for reaction cuvette washing.

STABILITY OF THE SOLUTION

The kit should be stored at the temperature + 2-25°C. The expiry date of each reagent is indicated on its relative label. When stored at +2-25°C and protected from light, the solutions are stable until the expiry date stated on the label.

NECESSARY MATERIAL NOT FURNISHED WITH THE KIT

- Automatic analyzer and / or for clinical chemistry HEMO ONE.
- User manual of the relative instrument.

To obtain correct and reproducible results on the instrument, it is necessary to observe the following recommendations:

- Do not use solutions after their expiry date.
- Avoid accurately their contamination .
- Avoid direct exposure to sunlight.

PRECAUTIONS:

To avoid personal and environmental contaminations it is necessary to observe the following safety directives:

- Use protection glasses and disposable gloves during the manipulation
- Do not pipette reagent using your mouth.
- Do not smoke, eat, drink or use cosmetics. .
- The waste produced by the use of the product must be considered as dangerous waste and the dismantling of the same should be done according the local laws.

WARNINGS: · Classification of the substance or mixture

· Classification according to Regulation (EC) No 1272/2006/548/EEC or Directive 1999/45/EC



GHS07

Skin Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2 H319 Causes serious eye irritation.



Xi; Irritant

R36/38: Irritating to eyes and skin.

PREPARATION OF THE SOLUTION

READY TO USE, THE 1 LT BOTTLE SHOULD BE CONNECTED TO THE INSTRUMENT WITH THE KIT TUBES REF. P3140000369.

It is necessary that the solution, at the moment of the use, is at ambient temperature.

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REF P3140000102	MIURA SYSTEMIC SOLUTION 2x1000 ml	
Solution	Quantity	Physical state
Systemic	2 bottles of 1000 ml	Liquid
IVD For in vitro diagnostic use only		

CLINICAL APPLICATIONS

This solution must be used to prepare the systemic solution used by the automatic analyzers class MIURA for ordinary on line cuvette and needles washing.

STABILITY OF THE SOLUTION

The kit should be stored at the temperature + 2-25°C. The expiry date of each reagent is indicated on its relative label. When stored at +2-25°C and protected from light, the solutions are stable until the expiry date stated on the label.

NECESSARY MATERIAL NOT FURNISHED WITH THE KIT

- Automatic analyzer and / or for clinical chemistry class MIURA.
- User manual of the relative instrument.
- Filling funnel.

AVERTISMENTS:

To obtain correct and reproducible results on the instrument, it is necessary to observe the following recommendations:

- Do not use solutions after its expiry date.
- Use perfectly clean and not contaminated tanks.
- Use bidistilled water, stored in perfectly clean containers.
- Avoid direct exposure to sunlight.

PRECAUTIONS:

To avoid personal and ambient contaminations it is necessary to observe the following security directives:

- Use protection glasses and monouse gloves during the manipulation and during the working preparation.
- Do not pipette reagent using your mouth.
- Do not smoke, eat, drink or use cosmetics during the preparation of the working reagent.
- The waste produced by the use of the product must be considered as dangerous waste and the dismantling of the same should be done according the local laws.

PREPARATION OF THE SOLUTION

Open one vial very carefully, avoiding liquid leakages.

Fill one tank of 20lt of bidistilled water with **50 ml** of systemic solution, using the supplied vial as measurement unit, and shortly shake the tank.

Spill the prepared solution in the systemic solution tank of the instrument; use the apposite clean funnel for refilling.

It is necessary that the solution, at the moment of the use, is at ambient temperature.

OPERATIONAL PROCEDURE

See the instrument user manual.

P3140000282	SYSTEM CLEANER 2x100 ml	
Solution	Quantity	Physical state
Solution	2 vials of 100 ml	Liquid
IVD For in vitro diagnostic use only		

CLINICAL APPLICATIONS

This solution must be used on board of the class MIURA automatic analyzers for reaction cuvette washing.

STABILITY OF THE SOLUTION

The kit should be stored at the temperature + 2-25°C. The expiry date of each reagent is indicated on its relative label. When stored at +2-25°C and protected from light, the solutions are stable until the expiry date stated on the label.

NECESSARY MATERIAL NOT FURNISHED WITH THE KIT

- Automatic analyzer and / or for clinical chemistry class MIURA.
- User manual of the relative instrument.

WARNINGS:

To obtain correct and reproducible results on the instrument, it is necessary to observe the following recommendations:

- Do not use solutions after their expiry date.
- Avoid accurately their contamination .
- Avoid direct exposure to sunlight.

PRECAUTIONS:

To avoid personal and environmental contaminations it is necessary to observe the following safety directives:

- Use protection glasses and disposable gloves during the manipulation
- Do not pipette reagent using your mouth.
- Do not smoke, eat, drink or use cosmetics. .
- The waste produced by the use of the product must be considered as dangerous waste and the dismantling of the same should be done according the local laws.

PREPARATION OF THE SOLUTION

Open the vial very carefully, avoiding liquid leakages.

The content of one single vial (100 ml) of the System Cleaner solution must be diluted into 5L of bi-distilled water in the tank for Cleaner Solution (REF:P314000023).

It is necessary that the solution, at the moment of the use, is at ambient temperature.

OPERATIONAL PROCEDURE

See the instrument user manual.