	REPEATABILITY / REPEATABILITY / REPEATABILITY (Blood Samples, N=300 per level) / (Blood Samples, N=300 per level) / (Blood Samples, N=300 per level)					INTERMEDIATE PRECISION / INTERMEDIATE PRECISION / INTERMEDIATE PRECISION (Control Material, N=300 per level) / (Control Material, N=300 per level) / (Control Material, N=300 per level)		
Glucose Level / Glucose Level / Glucose Level mg/dL (mmol/L)	30-50 (1,7-2,8)	51-110 (2,8-6,1)	111-150 (6,2-8,3)	151-250 (8,4-13,9)	251-400 (13,9-22,2)	30-50 (1,7-2,8)	96-144 (5,3-8,0)	280-420 (15,5-23,3)
Average / Average / Average mg/dL (mmol/L)	53 (2,9)	73 (4,1)	132 (7,3)	224 (12,4)	340 (18,9)	40 (2,2)	121 (6,7)	382 (21,2)
SD / SD / SD mg/dL (mmol/L)	2,1 (0,1)	2,0 (0,1)	3,1 (0,2)	5,1 (0,3)	5,7 (0,3)	3,6 (0,2)	3,6 (0,2)	10,8 (0,6)
CV% / CV% / CV%	NA	NA	2,3	2,3	1,7	NA	3,3	3,0

Fig. 1

According to / According to / According to EN ISO 15197:2003

Glucose concentration / Glucose concentration / Glucose concentration < 75 mg/dL (4,2 mmol/L) (N=102)

Within / Within / Within ± 5 mg/dL (0,28 mmol/L)	78/102 (76,5%)
Within / Within / Within ± 10 mg/dL (0,56 mmol/L)	102/102 (100%)
Within / Within / Within ± 15 mg/dL (0,83 mmol/L)	102/102 (100%)

Glucose concentration / Glucose concentration / Glucose concentration ≥ 75 mg/dL (4,2 mmol/L) (N=498)

Within / Within / Within ± 5%	375/498 (75,3%)
Within / Within / Within ± 10%	484/498 (97,2%)
Within / Within / Within ± 15%	497/498 (99,8%)
Within / Within / Within ± 20%	498/498 (100%)

Combined results / Combined results / Combined results (N=600)

Within / Within / Within ± 15 mg/dL (0,83 mmol/L) or 20%	600/600 (100%)

According to / According to / According to EN ISO 15197:2013

Glucose concentration / Glucose concentration / Glucose concentration < 100 mg/dL (5,6 mmol/L) (N=198)

Within / Within / Within ± 5 mg/dL (0,28 mmol/L)	146/198 (73,7%)
Within / Within / Within ± 10 mg/dL (0,56 mmol/L)	196/198 (99,0%)
Within / Within / Within ± 15 mg/dL (0,83 mmol/L)	198/198 (100%)

Glucose concentration / Glucose concentration / Glucose concentration ≥ 100 mg/dL (5,6 mmol/L) (N=402)

Within / Within / Within ± 5%	317/402 (78,9%)
Within / Within / Within ± 10%	393/402 (97,8%)
Within / Within / Within ± 15%	401/402 (99,8%)

Combined results / Combined results / Combined results (N=600)

Within / Within / Within ± 15 mg/dL (0,83 mmol/L) or 15%	599/600 (99,8%)

Fig. 2

Substance / Substance / Substance	Test Concentration / Test Concentration / Test Concentration
Acetaminophen	10 mg/dL
Acetylsalicylic acid	40 mg/dL
Ascorbic acid	6 mg/dL
Bilirubin	20 mg/dL
Cholesterol	500 mg/dL
Creatinine	5 mg/dL
Dopamine	0,1 mg/dL
EDTA	0,5 mg/dL
Galactose	15 mg/dL
Gentisic acid	2 mg/dL
Glutathione	1,5 mmol/L
Hemoglobin	200 mg/dL

Substance / Substance / Substance	Test Concentration / Test Concentration / Test Concentration
Heparin	3000 U/L
Ibuprofen	40 mg/dL
Icodextrin	1094 mg/dL
L-DOPA	3 mg/dL
Maltose	50 mg/dL
Methyl-Dopa	15 mg/dL
Pralidoxime Iodide (PAM)	50 mg/dL
Tolazamide	23 mg/dL
Tolbutamide	10 mg/dL
Triglycerides	1500 mg/dL
Uric Acid	15 mg/dL
Xylose	25 mg/dL

Fig. 3

Symbols / Symbols / Symbols

	Manufacturer / Manufacturer / Manufacturer
	Caution, read instructions for use / Caution, read instructions for use / Caution, read instructions for use
REF	Catalogue number / Catalogue number / Catalogue number
LOT	Batch code / Batch code / Batch code
	Temperature limitation / Temperature limitation / Temperature limitation
	Use by / Use by / Use by
CE 0123	CE marking. The product fulfills the requirements for directive 98/79/EC / CE marking. The product fulfills the requirements for directive 98/79/EC / CE marking. The product fulfills the requirements for directive 98/79/EC
IVD	*In Vitro* Diagnostic Medical Device / *In Vitro* Diagnostic Medical Device / *In Vitro* Diagnostic Medical Device
	Significant additions or changes from previous instructions for use revision / Significant additions or changes from previous instructions for use revision / Significant additions or changes from previous instructions for use revision
	Recyclable package / Recyclable package / Recyclable package

References / References / References

- Definition and diagnosis of diabetes mellitus and intermediate hyperglycaemia. Report of a WHO/IDF, World Health Organization, 2006.
- American Diabetes Association, Standards of Medical Care in Diabetes-2014. Diabetes Care, 37, Suppl 1, 2014.
- Oliver N. S., Toumazou C., Cass A. E. G., Johnston D. G., Glucose sensors: a review of current and emerging technology. Diabetic Medicine, 26, 197–210, 2009.

Availability / Availability / Availability

REF **XXXXX** - 10 GlucoMen® areo Sensor: 1 vial x 10 test strips / 1 vial x 10 test strips / 1 vial x 10 test strips
REF **XXXXX** - 50 GlucoMen® areo Sensor: 1 vial x 50 test strips / 1 vial x 50 test strips / 1 vial x 50 test strips
REF **XXXXX** - 100 GlucoMen® areo Sensor: 2 vial x 50 test strips / 2 vial x 50 test strips / 2 vial x 50 test strips

Date of issue: May 2015 / Date of issue: May 2015 / Date of issue: May 2015

Made in Taiwan

A. MENARINI DIAGNOSTICS Srl
Via Sette Santi, 3
50131 Firenze - Italy

If you have any question about GlucoMen® areo Sensor, please contact:
If you have any question about GlucoMen® areo Sensor, please contact:
If you have any question about GlucoMen® areo Sensor, please contact:

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GlucoMen® areo Sensor

- **Glucose Test Strips Instructions for use**
- **Glucose Test Strips Instructions for use**
- **Glucose Test Strips Instructions for use**

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A.MENARINI diagnostics

MASTER

Before using the test strips carefully read these instructions for use and the user manual of the GlucoMen® areo 2K blood glucose and β-ketone monitoring system. If you have any questions, please contact the A. Menarini Diagnostics Customer Service.

Intended use

The GlucoMen® areo system is designed to quantitatively measure the glucose level in fresh capillary whole blood. GlucoMen® areo Sensor is an *in vitro* diagnostic medical device to quantitatively measure the glucose level in fresh capillary whole blood. They are intended for self-testing to monitor and control blood glucose levels by people with diabetes mellitus; they can also be used in a clinical setting by healthcare professionals.
They are not intended for diagnosis or screening of diabetes or for neonatal use. Do not alter your treatment on the basis of test results of this meter without previously consulting your doctor or healthcare professional.
The GlucoMen® areo Sensor is only for use with the GlucoMen® areo 2K meter.

Measurement principle

The glucose present in the blood sample mixes with reagents on the test strip and this reaction produces a small electric current, the intensity of which is proportional to the concentration of glucose in the blood. The meter measures this current and calculates your blood glucose level.

Reagent composition (per cm^2)

- Glucose Oxidase (*Aspergillus Niger* sourced), 3,5%
- Mediator: Hexacyanoferrate(III) ion, 17,5%
- Non-reactive substances, 79%

Storage and usage conditions

- Store the test strip vial in a dry place (RH 20-90%), at a temperature of 4 - 30 °C (39,2 - 86 °F). Do not freeze. Avoid heat and direct sunlight.
- Keep all unused test strips in the original vial and after having removed one, close the cap tightly to maintain their quality. Do not transfer them into any other container.
- Do not use the test strips past their expiry date.
- Do not use the test strips for more than 9 months after first opening the test strip vial. We recommend writing the discard date (opening date + 9 months) on the label.

Warning and safety information

- Keep the meter, test strips and other items out of the reach and sight of children. Small items may represent choking hazards.
- Handle the test strips with clean, dry hands.
- Dispose of the vial and used test strips according to local regulations.
- **HANDLING BLOOD CAN BE DANGEROUS**. You or other individuals could be infected by pathogenic microorganisms due to incorrect or imprecise procedures. **USE EXTREME CAUTION** when handling blood, test strips, lancets and meter.

Sample

This meter can test the glucose level of blood from your fingertip, palm, and forearm. However, test results from sites other than the fingertip (Alternative Site Testing, AST) may give different measurements. Consult your doctor or healthcare professional before performing AST.

Procedure for blood glucose testing

Materials provided. GlucoMen® areo Sensor test strips.
Materials required but not provided. GlucoMen® areo 2K meter, lancing device, lancets.

See the user manual of your GlucoMen® areo 2K meter for more details.

- For accurate test results, allow the test strips and meter to adjust to their surroundings for at least 30 minutes before testing your blood glucose. Operating conditions are: temperature 5-45 °C (41-113 °F); relative humidity 20-90%.

1. Remove 1 test strip from the vial with clean, dry hands.
   • The test strips are for single-use only. **Do not** use test strips if wet, damaged, or stored in a damaged vial.
   • Tightly close the bottle immediately after taking out a test strip.
   • Use the test strip immediately.
2. Insert a new test strip into the test strip port. The drop icon will start blinking on the screen.
3. Collect blood using a lancing device and a new lancet, according to the relative instructions for use.
4. Apply the drop of blood to the tip of the test strip until the check window is full.
   • Do not test blood that runs or spreads out from the puncture site.
   • Do not smear blood onto the test strip.
   • Do not forcefully push the test strip against the puncture site.
   • Do not touch the test strip after the meter starts the countdown.
5. The test result will appear on the screen once the test is completed.
6. Press the release button to remove the test strip.
   • Test strips and lancets qualify as biohazardous waste once used to test blood glucose. They must therefore be disposed according to local regulations on biohazardous waste.

- **If the test result does not match with how you feel**
  Make sure you performed the test correctly as explained in the user manual. Then conduct a control test to check that the system is working properly. If you tested blood from your palm or forearm, repeat the test **using a blood sample taken from a fingertip (do not use an alternative site)**. If the test results still do not match how you feel, contact your doctor or healthcare professional.

Control solution test

If you need to perform a control test, read the user manual for your GlucoMen® areo 2K meter and the package insert for your GlucoMen® areo Control solution.

Restrictions

- DO NOT use plasma or serum samples. DO NOT test venous or arterial blood samples.
- DO NOT test samples from newborn infants.
- Altitudes up to 3150 m (10335 feet) will not affect the test results.
- Allowed haematocrit range: 10 - 70%.
- Icodextrin and its metabolites (maltose, maltotriose and maltotetraose) do not significantly affect test results.
- The following drugs may affect test results: dopamine (>0,1 mg/dL), L-DOPA (>3 mg/dL), acetaminophen (>10 mg/dL).
- The glucose reading for GlucoMen® areo 2K is not affected by sample oxygen conditions (pO_2) from 52-115 mmHg (6,9-15,3 kPa). Under 52 mmHg (6,9 kPa) the GlucoMen® areo system overestimates the glucose values, whereas over 115 mmHg (15,3 kPa) the system underestimates the measurements.

Measurement range

The results are equivalent to the plasma glucose concentration. The measurement range of the GlucoMen® areo Sensor is 20 - 600 mg/dL (1,1 - 33,3 mmol/L).

Calibration and traceability

The GlucoMen® areo system is calibrated using reference plasma values determined with a YSI analyser. The YSI analyser is calibrated (as a secondary reference measurement procedure) using a series of YSI standards (primary calibrators) taken from the NIST (National Institute of Standards and Technology, USA).

Performance of GlucoMen® areo Sensor

The performance of GlucoMen® areo Sensor fully complies with EN ISO 15197:2003 and with the additional requirements introduced by EN ISO 15197:2013.
Precision. Repeatability and intermediate precision results are shown in *Fig. 1*.
Accuracy. A comparison of the results of the GlucoMen® areo Sensor with those obtained using capillary plasma tested with the glucose oxidase method performed on a laboratory analyser (YSI Model 2300 STAT Plus), indicated a high level of accuracy. The results were obtained by testing samples from 100 diabetic subjects (*Fig. 2*). 100% of individual glucose measured values falls within zones A and B of the Consensus Error Grid for type 1 diabetes.
Interference Testing. The substances listed in *Fig. 3* have been tested for interference with the GlucoMen® areo system. The table reports the maximum concentration with no interfering effect according to EN ISO 15197:2013.
User performance evaluation. A study evaluating glucose values from fingertip capillary blood sample obtained by 105 lay persons showed the following results: 100% within ± 15 mg/dL (0,83 mmol/L) of the reference values at glucose concentration < 100 mg/dL (5,6 mmol/L) and 98,9% within ± 15% of the reference values at glucose concentration ≥ 100 mg/dL (5,6 mmol/L).

MASTER

Before using the test strips carefully read these instructions for use and the user manual of the GlucoMen® areo 2K blood glucose and β-ketone monitoring system. If you have any questions, please contact the A. Menarini Diagnostics Customer Service.

Intended use

The GlucoMen® areo system is designed to quantitatively measure the glucose level in fresh capillary whole blood. GlucoMen® areo Sensor is an *in vitro* diagnostic medical device to quantitatively measure the glucose level in fresh capillary whole blood. They are intended for self-testing to monitor and control blood glucose levels by people with diabetes mellitus; they can also be used in a clinical setting by healthcare professionals.
They are not intended for diagnosis or screening of diabetes or for neonatal use. Do not alter your treatment on the basis of test results of this meter without previously consulting your doctor or healthcare professional.
The GlucoMen® areo Sensor is only for use with the GlucoMen® areo 2K meter.

Measurement principle

The glucose present in the blood sample mixes with reagents on the test strip and this reaction produces a small electric current, the intensity of which is proportional to the concentration of glucose in the blood. The meter measures this current and calculates your blood glucose level.

Reagent composition (per cm²)

- Glucose Oxidase (*Aspergillus Niger* sourced), 3,5%
- Mediator: Hexacyanoferrate(III) ion, 17,5%
- Non-reactive substances, 79%

Storage and usage conditions

- Store the test strip vial in a dry place (RH 20-90%), at a temperature of 4 - 30 °C (39,2 - 86 °F). Do not freeze. Avoid heat and direct sunlight.
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- Do not use the test strips past their expiry date.
- Do not use the test strips for more than 9 months after first opening the test strip vial. We recommend writing the discard date (opening date + 9 months) on the label.

Warning and safety information

- Keep the meter, test strips and other items out of the reach and sight of children. Small items may represent choking hazards.
- Handle the test strips with clean, dry hands.
- Dispose of the vial and used test strips according to local regulations.
- **HANDLING BLOOD CAN BE DANGEROUS**. You or other individuals could be infected by pathogenic microorganisms due to incorrect or imprecise procedures. **USE EXTREME CAUTION** when handling blood, test strips, lancets and meter.

Sample

This meter can test the glucose level of blood from your fingertip, palm, and forearm. However, test results from sites other than the fingertip (Alternative Site Testing, AST) may give different measurements. Consult your doctor or healthcare professional before performing AST.

Procedure for blood glucose testing

Materials provided. GlucoMen® areo Sensor test strips.
Materials required but not provided. GlucoMen® areo 2K meter, lancing device, lancets.

See the user manual of your GlucoMen® areo 2K meter for more details.

- For accurate test results, allow the test strips and meter to adjust to their surroundings for at least 30 minutes before testing your blood glucose. Operating conditions are: temperature 5-45 °C (41-113 °F); relative humidity 20-90%.

1. Remove 1 test strip from the vial with clean, dry hands.
   - The test strips are for single-use only. **Do not** use test strips if wet, damaged, or stored in a damaged vial.
   - Tightly close the bottle immediately after taking out a test strip.
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  Make sure you performed the test correctly as explained in the user manual. Then conduct a control test to check that the system is working properly. If you tested blood from your palm or forearm, repeat the test **using a blood sample taken from a fingertip (do not use an alternative site)**. If the test results still do not match how you feel, contact your doctor or healthcare professional.

Control solution test

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Restrictions

- DO NOT use plasma or serum samples. DO NOT test venous or arterial blood samples.
- DO NOT test samples from newborn infants.
- Altitudes up to 3150 m (10335 feet) will not affect the test results.
- Allowed haematocrit range: 10 - 70%.
- Icodextrin and its metabolites (maltose, maltotriose and maltotetraose) do not significantly affect test results.
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Measurement range

The results are equivalent to the plasma glucose concentration. The measurement range of the GlucoMen® areo Sensor is 20 - 600 mg/dL (1,1 - 33,3 mmol/L).

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Warning and safety information

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- Handle the test strips with clean, dry hands.
- Dispose of the vial and used test strips according to local regulations.
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Materials required but not provided. GlucoMen® areo 2K meter, lancing device, lancets.

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Measurement range

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