iDia blood glucose test strips

Please read this package leaflet carefully and follow the instructions.
If any questions arise please contact **IME-DC** customer service by dialing:
+49 9281 | 85 01 6-0

User information
The i**Dia** test strips serve to quantitatively determine glucose in whole blood. The i**Dia** blood glucose meter is to be used for evaluation exclusively (*in vitro* diagnostics; suitable for self-application).

Principle of the process
The test strip analysis is based on the GDH-FAD (Glucose-Dehydrogenase-Flavin-Adenin-Dinucleotide), which is specific to β-D-glucose with the biosensor technology used. The blood sample is drawn into the reaction zone by way of capillary forces. The glucose's chemical reaction with the GDH-FAD enzyme results in a measurable current of electrons, which is analysed by the i**Dia** blood glucose meter. The strength of the current correlates with the concentration of blood glucose, which is shown on the display as a measurement result.

Note ⚠
Determining the blood glucose level is an important way of monitoring diabetes. The i**Dia** test strips help you to adjust your blood glucose optimally. However, before you start measuring your blood glucose, you should first familiarise yourself with the entire measurement system (refer to the i**Dia** blood glucose meter user manual).

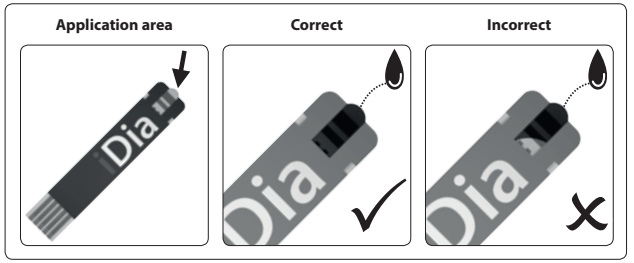
Required quantity of blood:	0.7 µL
Measurement range:	10 – 600 mg/dL or 0.6 – 33.3 mmol/L
Storage temperature:	+4 °C to +32 °C
Measurement temperature:	+10 °C to +40 °C
Haematocrit value:	20 % – 70 % *
Air humidity:	< 85 %
Shelf life:	18 months after date of manufacture / 180 days after opening **
Sample type:	Fresh capillary blood, venous blood, arterial blood, neonatal blood
Callibration:	Plasma equivalent

* *Applies to all categories of individuals (adults, children and infants).*
** *Please note the date of opening on your test strip vial.*

Chemical components of the test strip
21.8 % w/w Glucose-Dehydrogenase Flavin-Adenin-Dinucleotide
41.6 % w/w Potassium Ferrocyanide
36.6 % w/w Non-reactive ingredients

i**Dia** test strips are suitable for clinical use and for patient self-testing.

Determining the blood glucose level
1. Only use i**Dia** test strips for the i**Dia** blood glucose meter.
2. Wash your hands with warm water before taking a measurement. Then dry your hands thoroughly.
3. Insert the test strip into the blood glucose meter's test strip insertion area. The measurement device will automatically turn on and ask you to administer blood.
4. Obtain a drop of blood using a lancing device.
5. Now place the test strip's application area against the drop of blood.



6. The blood will be drawn in automatically. A beep confirms that the measurement is commencing. You may halt the intake procedure. (Please make sure that the reaction zone is completely filled).
7. The measurement results will be displayed to you after 7 seconds, along with the date, time and measurement unit, and automatically saved.

Factors that may affect measurement results
- The blood to be measured was expressed from the finger with great force and therefore contains tissue fluid.
- The blood glucose test strips are past their expiration date.
- The blood glucose test strips were stored at an improper temperature (the proper storage temperature is +4 °C to +32 °C).
- The test strips were not adequately protected against moisture.
- The disinfecting agent had not completely evaporated following a prior disinfection procedure.
- Your hands were contaminated prior to measuring blood glucose.
- After washing your hands, you did not dry them for subsequent blood glucose measurement.
- Excessively high blood pressure can result in false readings with erroneously lowered measurement values.
- Blood glucose meters should not be used to test seriously ill patients.

Please consult your specialist physician in the instance of frequent, inexplicable measurement results.

Interference
Bilirubin, uric acid, glutathione, triacyglycerol and cholesterol, substances that occur naturally in the human body, and the other medicinal substances listed in the table do not significantly influence the i**Dia** blood glucose meter's glucose measurement results if the normal concentrations are not exceeded and/or the usual therapeutic doses are administered. Otherwise, measurement results yielded may be erroneous:

Substance	Interference occurring from
Paracetamol	> 10 mg/dL
Bilirubin	> 15 mg/dL
Pralidoxime iodide	> 50 mg/dL
Triacylglycerol	> 500 mg/dL
Cholesterol	> 200 mg/dL
Glutathione	> 1.5 mg/dL
Uric acid	> 15 mg/dL

Haematocrit values below 20 % may result in erroneously high blood glucose measurement results being displayed. Haematocrit values above 60 % may result in erroneously low blood glucose measurement results.

When measuring EDTA-treated blood samples with the i**Dia** blood glucose meter, the blood glucose values ascertained may differ from those of an untreated blood sample. Therefore, the use of lithium heparin-treated test tubes is recommended.

Note ⚠
Our **IME-DC** customer service department will be happy to address any questions you may have.

Additional information
- Please do not make any important medical decisions without consulting your specialist physician.
- Clinical facilities and care personnel: Please dispose of used test strips in accordance with your regulations. Please be aware that used test strips may involve potentially infectious substances.
- Private users: Please dispose of used test strips in accordance with local regulations.
- To check that the blood glucose monitoring system is working properly, you have the option of taking measurements using i**Dia** control solutions (available separately).

System accuracy
To assess the system accuracy of the blood glucose meter system i**Dia** in accordance with **EN ISO 15197:2013**, an external laboratory (accredited by the FDA) ascertained blood glucose values in capillary whole blood taken from 100 test subjects. A total of three test strip batches were tested. The blood glucose values ascertained were compared with the associated reference values (YSI 2300; YSI Incorporated, Brannum Lane, Yellow Springs, Ohio, USA). The evaluation was conducted in accordance with the specifications of the guideline.

Table 1
System accuracy for blood glucose values below 100 mg/dL (< 5.55 mmol/L)

	Within ± 5 mg/dL (within ± 0.28 mmol/L)	Within ± 10 mg/dL (within ± 0.56 mmol/L)	Within ± 15 mg/dL (within ± 0.83 mmol/L)
YSI vs. iDia	107/177 (60.45 %)	156/177 (88.14 %)	176/177 (99.44 %)

Table 2
System accuracy for blood glucose values exceeding 100 mg/dL (≥ 5.55 mmol/L)

	Within ± 5 %	Within ± 10 %	Within ± 15 %
YSI vs. iDia	235/423 (55.56 %)	363/423 (85.82 %)	417/423 (98.58 %)

Table 3
System accuracy of all blood glucose values ascertained

Within ± 15 mg/dL; < 100 mg/dL (± 0.83 mmol/L; < 5.55 mmol/L) oder ± 15 %; ≥100 mg/dL (≥ 5.55 mmol/L)
593/600 (98.83 %)

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Accuracy (repeatability)
The repeatability of the measurements was checked using 5 venous whole blood samples and glucose concentrations ranging from 40 to 324 mg/dL. 100 repeat measurements were carried out using the **iDia** blood glucose meter and **iDia** blood glucose test strips (three each per test strip batch).

Average glucose concentrations		Standard deviation (s)		Coefficient of variation (CV) in %
40 mg/dL	(2.20 mmol/L)	2.5 mg/dL	(0.14 mmol/L)	6.2
79 mg/dL	(4.40 mmol/L)	2.2 mg/dL	(0.12 mmol/L)	2.8
130 mg/dL	(7.20 mmol/L)	3.5 mg/dL	(0.19 mmol/L)	2.7
198 mg/dL	(11.00 mmol/L)	3.7 mg/dL	(0.21 mmol/L)	1.9
324 mg/dL	(18.00 mmol/L)	4.3 mg/dL	(0.24 mmol/L)	1.3

Intermediate precision
The intermediate precision of the measurements was ascertained using control solutions that correspond to hypoglycaemic, euglycaemic and hyperglycaemic glucose concentrations.

Average glucose concentrations		Standard deviation (s)		Coefficient of variation (CV) in %
40 mg/dL	(2.20 mmol/L)	2.4 mg/dL	(0.13 mmol/L)	6.1
120 mg/dL	(6.70 mmol/L)	2.6 mg/dL	(0.14 mmol/L)	2.2
349 mg/dL	(19.40 mmol/L)	4.7 mg/dL	(0.26 mmol/L)	1.4

Assessing user performance
A study conducted to assess glucose values in blood samples from capillary fingertip blood, obtained from 112 persons who had not received any special instruction, yielded the following results:

- 95.0 % within ± 0.83 mmol/L (± 15 mg/dL) of the laboratory procedure results for glucose concentrations below 5.55 mmol/L (100 mg/dL)
- 97.8 % within ± 15 % of the values obtained in a medical laboratory setting for glucose concentrations of at least 5.55 mmol/L (100 mg/dL).

REF	Article number
LOT	Lot number
IVD	*In vitro* diagnostic tool
	Follow user instructions
	Can be used until
	Manufacturer
	Date of manufacture
	Do not reuse
4 °C 32 °C	Temperature limits
	Keep dry
	Keep away from sunlight
	Important: read product documentation
CE 0123	This product meets the requirements of the IVD Directive in accordance with 98/79/EC

Packing size:
1 x 50 units

EAN:
4260155930188

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