

Part no.	312-4119101-010
Product name	單罐試片說明書/MEDISAFE EX /英(共用單片包)(Terumo)
Spec	L250*W288mm/4折/雜誌紙65P/單面/Pantone647C/無處理
Designer	JF
Color	 Pantone 647C

### Warnings

- ▶ For *in vitro* diagnostic use (for use outside of the body only).
- ▶ For single use only.
- ▶ Healthcare professionals and other users testing multiple patients with this system should handle everything that has come into contact with human blood carefully to prevent transmitting infectious diseases, including sanitized objects.
- ▶ Please read this sheet and your Blood Glucose Monitoring System Owner's Manual before you use this test strip. Use MEDISAFE EX Test Strip with MEDISAFE EX Blood Glucose Monitoring System to obtain accurate results, and be covered by the manufacturer's warranty.
- ▶ Results may be inaccurate when testing on patients with abnormally low blood pressure or those who are in shock.
- ▶ Low results may be inaccurate when testing on patients in hyperglycemic-hyperosmolar state, with or without ketosis.
- ▶ Keep test strips and lancets away from children. If swallowed, consult a doctor immediately for advice.

### Intended Use

Test strips, when used together with Blood Glucose Monitoring System, allow your blood glucose levels to be measured by yourself at home or by healthcare professionals. It uses fresh whole blood samples from the finger. This system is not intended for use in the diagnosis or screening of diabetes mellitus and be careful when using with Neonate since it may deviate from actual result due to hematocrit.

Professionals may use test strips to test capillary, venous, and arterial, home use is limited to capillary whole blood testing.

### Limitations

- ▶ Xylose: Do not test blood glucose during or soon after a xylose absorption test. Xylose in the blood can give falsely elevated results.
- ▶ Hematocrit: The hematocrit level is limited to between 0% and 70%. Please ask your healthcare professional if you do not know your hematocrit level.
- ▶ This test strip is used for testing fresh capillary and venous whole blood.
- ▶ There are no significant interference in the presence of galactose, maltose, or fructose observed in blood glucose tests.
- ▶ Lipemic Effects: Blood triglycerides up to 3000 mg/dL (33.9 mmol/L) do not affect the results significantly, but may affect results at higher levels.
- ▶ Altitude Effects: Altitudes up to 10,742 feet (3,275m) do not affect test results.
- ▶ Use only heparin for anticoagulation of fresh capillary or venous whole blood.

The following compounds when determined to be in excess of their limitation and tested with the MEDISAFE EX glucose meter may produce elevated glucose results:

**Table 1. Summary of substances and concentrations in excess of limitation with interference**

Substance	Concentration Tested (mg/dL)	Therapeutic / Physiologic Concentration Range (or Upper Limit) (mg/dL)
Acetaminophen (Paracetamol)	> 6.25	0.45 - 3
Ascorbic Acid	> 5	2
Bilirubin (UnConjugated)	> 20	0 - 2
Dopamine	> 1.25	0.03
Glutathione Reduced	> 23	47 - 100 (intracellular)
Levo - Dopa	> 0.7	0.02-0.28
Lipemic Samples (Triglycerides)	> 3000	30 - 300
Mannitol	> 5000	0.0128
Mannose	> 250	1.15
Methyl - Dopa	> 0.625	0.1 - 0.5
Pralidoxime Iodide	> 5	~ 10 (i.v. Dose 500 mg)
Tolazamide	> 6.25	1.6
Uric Acid	> 10	2 - 8
Xylose	> 6.25	N/A

**Table 2. Summary of anticoagulant and concentrations with interference**

Substance	Concentration Tested (mg/dL)	Concentration of Blood Drawing Tube (mg/dL)
K2EDTA	< 180	180
K3EDTA	< 175.5	175.5
Na-Fluoride/K-Oxalate	< 250/200	250/200

**Note: Fluoride/Oxalate and EDTA should not be used as a sample preservative.**

### Storage and Handling

**IMPORTANT:** Do not use the test strips if they have expired.

#### Test Strip with Individual Package

- ▶ Store the test strips in a cool, dry place between 4°C and 30°C (40°F and 86°F) and below 85% relative humidity.
- ▶ Keep the test strips away from direct sunlight. Do not store the test strips in high humidity.
- ▶ Do not touch the test strips with wet hands.
- ▶ Use each test strip immediately after taking it out of the individual sheet.
- ▶ Do not bend, cut, or alter the test strip.

#### Test Strip in Vial

- ▶ Test strips expire 3 months after first opening. Write the first opening date on the test strip vial when you first opened it.
- ▶ Store the test strips in a cool, dry place between 2°C and 32°C (36°F and 90°F) and below 85% relative humidity.
- ▶ Keep the test strips away from direct sunlight. Do not store the test strips in high humidity.
- ▶ Store the test strips in their original vial ONLY. Do not transfer them to a new vial or any other containers.
- ▶ Do not touch the test strips with wet hands.
- ▶ Use each test strip immediately after taking it out of the vial. Close the vial immediately after taking out a strip.
- ▶ Keep the vial closed at all times.
- ▶ Do not bend, cut, or alter the test strip.

### Strip Appearance



#### 1. Absorbent Hole

Apply a drop of blood here. The blood will automatically be absorbed.

#### 2. Confirmation Window

This is where you confirm if enough blood has been applied to the absorbent hole in the strip.

#### 3. Test Strip Handle

Hold this part to insert the test strip into the slot.

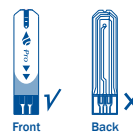
#### 4. Contact Bars

Insert this end of the test strip into the meter. Push it in firmly until it will go no further.

#### ATTENTION



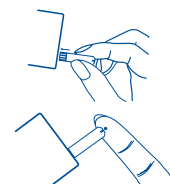
Test results might be wrong if the contact bar is not fully inserted into the test slot.



The front side of the test strip should face up when inserting the test strip.

### Testing Your Blood Glucose

**PLEASE WASH AND DRY YOUR HANDS BEFORE PERFORMING ANY TESTING.**



#### STEP 1

Insert the test strip fully into the slot of the meter until it will go no further. When the strip is fully inserted, the meter will do several self-checks.

#### STEP 2

Collect a blood sample with the test strip. A sufficient quantity of blood is required for the test to provide accurate results. Touch the blood drop with the absorbent hole of the test strip, and wait until the confirmation window is fully covered. **Do NOT** apply a smeared blood sample. The meter will start counting down.

#### STEP 3

After a few seconds, the meter will display your blood glucose level. The last reading will be automatically saved in the meter. Turn it off by removing the test strip and throw away the used test strip.



Please refer to your Owner's Manual for more information.

The used lancet and test strip are potentially biohazardous. Please dispose of them carefully according to your local regulations.

### Reading Your Result

Your blood glucose readings deliver plasma equivalent results and are displayed in milligrams of glucose per deciliter of blood (mg/dL). The measurement range of this meter is 10-600 mg/dL (0.5-33.3 mmol/L).

#### Reference values

Time of day	Normal plasma glucose range for people without diabetes (mg/dL)
Fasting and before meal	< 100 mg/dL (5.6 mmol/L)
2 hours after meals	< 140 mg/dL (7.8 mmol/L)

Source: American Diabetes Association. Standards of medical care in diabetes-2016; 39 (suppl.1 Diabetes Care):S16.

**Please consult your doctor to determine a target range that works best for you.**

### Questionable or inconsistent results

If your test results are unusual or inconsistent with how you are feeling:

- Make sure the confirmation window of the test strip is completely filled with blood.
- Check the expiration date of the test strips.
- Check the performance of your meter and test strip with the control solutions.

**PLEASE NOTE: Unusually high or low blood glucose levels may be symptoms of a serious medical condition. If most of your results are unusually high or low, please contact your healthcare professional.**

### Quality Control Testing

Our control solutions contain a known amount of glucose that can react with test strips. You can check the performance of the meter, test strip and your technique by comparing the control solution results with the range printed on the label of test strip vial or on the label of individual package. Checking regularly can ensure your test results are accurate. Please refer to the Owner's Manual for complete testing instructions.

**IMPORTANT:** The reference range of the control solutions may vary with each new vial of test strips. Make sure you check the range on the label of your current vial.

### Chemical Components

> Glucose dehydrogenase (E. Coli)	8%
> Electron shuttle	55%
> Enzyme protector	8%
> Non-reactive ingredients	29%

### Additional Information for Healthcare Professionals

Always wear gloves and follow your facility's biohazard control policy and procedures when performing tests involving patient blood samples. Use fresh whole blood samples only. Professionals may use test strips to test capillary, venous, and arterial, home use is limited to capillary whole blood testing.

**Sample Size:** 1.1 µL

**Reaction Time:** 5 seconds

**System Measurement Range:** 10 mg/dL to 600 mg/dL

**Hematocrit Range:** 0% to 70%

#### Accuracy

Within ±15 mg/dL (0.83 mmol/L) at glucose concentration < 100 mg/dL (5.55 mmol/L) and within ±15% at glucose concentration ≥ 100 mg/dL (5.55 mmol/L).

#### Precision

CVs (%) of intermediate precision and repeatability are less than 5%. The product has been tested to meet the requirements of ISO 15197:2013.

### Symbol Information

Symbol	Referent
	<i>In vitro</i> diagnostic medical device
	Authorised representative in the European Community
	Manufacturer
	Use by
	Batch code
	Consult instructions for use
	Temperature limitation (Test Strip in Vial)
	Temperature limitation (Test Strip with Individual Package)
	Biological risks

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**Blood Glucose Monitoring System**



For self-testing.