OMRON

OMRON blood glucose test strip HEA-STP30

For Self-Testing

* Please read this information before using HEA-230 & HEA-232 system. This instruction is helpful to understand the operation process.

How to use it?

The OMRON blood glucose test strip HEA-STP30 should be used with OMRON Blood Glucose meters HEA-230 & HEA-232, and is intended for blood glucose monitoring by people with diabetes. HEA-STP30 test strips only need 1μL fresh capillary blood for one testing. Blood glucose concentration result will be showed in 5 seconds after you apply a blood sample into the test zone.

Intended use

The OMRON blood glucose test strips HEA-STP30 are intended to use for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips. The OMRON blood glucose test strips HEA-STP30 must be used with the OMRON blood glucose Meter HEA-230 & HEA-232. Testing is done outside the body. They are designed for self-testing to monitor the effectiveness of diabetes control. The device should not be used for screening or diagnosis of diabetes or for testing neonates.

⚠ Warning:

1. OMRON HEA-230 & 232 system should not be used for screening or diagnosis of diabetes or for testing neonates.
2. For in vitro diagnostic use only.
3. Do not alter your treatment based on the test result of these systems without instructions from your doctor.
4. Read the instruction manual for your meter before use. If your have any question, contact your distributors.

How to storage strips?

- Do not use HEA-STP30 strips if the vial is opened or damaged.
- Write the open date on the vial label when you first open it. You should discard your strips by 3 months from first opening the vial.
- Store HEA-STP30 strip vial in a cool, dry place. Keep away from light and heat.
- Do not store your HEA-STP30 strips in the refrigerator.
- Store your strips in their original vial only.
- Do not transfer test strips to any other container.
- Immediately replace the vial cap after you remove a HEA-STP30 test strip.

⚠ Warning:
Need to tightly seal the cap of the container provided to protect test strips

Checking HEA-230 & HEA-232 system

* When to run the glucose control solution test:

- You think your test strips have been damaged.
- Test result com paring with how you feelis not compatible with how you feel.
- You think your glucose meter could be broken.

⚠ Warning:
If you will like to perform control solution test or have any question, please contact your local authorized distributor for more information.

How it works

The OMRON blood glucose monitoring system HEA-230 & HEA-232 uses the state-of-art bioelectrochemistry detecting technology.

Assure you get an accurate test result

Read user guide and strip instruction before using.
Use control solution to check the HEA-230 & HEA-232 regularly.
Well store the HEA-230 & HEA-232 meter, HEA-STP30 strips, and control solution.

Top Edge- Apply blood sample here.

Inserting Bar- Insert this test strip port with this side facing up.

You should prepare following material before testing

- HEA-230 or HEA-232 meter
- HEA-STP30 test strips
- Alcohol prep pad
- Lancing device
- Sterile lancet

* Please place HEA-230 & HEA-232 meter, control solution, and HEA-STP30 test strips at room temperature before testing. Rapidly temperature change may yield falsely inaccurate results.

Test procedure of blood glucose measurement

Step 1: Test strip preparation

Take a test strip from the vial. To protect test strips from exposure to air, please press the cap of the vial till it "clicks". Insert the test strip, contact bars end first and facing up into the test port. The meter will turn on and the display will show the most recent test result then symbol of finger tip and blood drop. Be sure the meter and the test strip codes match. Please refer to the instructions in user manual for more details.

Step 2: Insert a lancet

Please use a new lancet to avoid unexpected contamination before testing. Insert the lancet into lancet holder and twist the protective disk until it separated from the lancet. Adjust the puncture depth setting to an appropriate depth.
Slide the ejection / cocking control back until it click. The lancing device is now ready for use.

Step 3: Blood sampling

Use soap water or alcohol prep pad to clean your hands and punch site. Massage the fingertip gently will help you obtain a round drop of blood. You can choose a different puncture site each time you test to decrease the pain feel. Do not squeeze excessively blood volume. OMRON blood glucose test strips HEA-STP30 just need one micro liter volume for each test.

⚠ Warning: Keep lancet device away from children, it is harmful if incorrect use

⚠ Please make sure your hand is dried before taking the blood sample

Step 4: Apply sample

Use the lancing device to obtain a blood sample. When the flashing fingertip and blood drop symbol appear on the display, apply a drop of blood to the narrow channel in the top edge of blood-in window. Your blood glucose test result will appear on the display after the meter count down from 5 to 1.

- Important information about HEA-230 & HEA-232 testing :
- Check the confirmation window is full with blood.
- Do not add more blood to the test strip.
- The blood sample must be 1 μL in volume.
- Testing immediately after obtaining a blood sample.

⚠ Caution: Please follow proper precautions in accordance with local regulation

⚠ when disposing of all materials.

Glucose unit

The units used in HEA-230 & HEA-232 glucose meter was set as mg/dL or mmol/L by the manufacturer. Please be aware of what unit your meter is. The glucose value can be transferred between these two units by the equation. 1 mmol/L = 18.02 mg/dL.

Test results

The unit of HEA-230 & HEA-232 measure is mg/dl (mmol/L) means by different countries. Your blood glucose test result will show after the meter count down from 5 to 1. Test range: 20 - 600 mg/dL (1.1 ~ 33.3 mmol/L). The meter will appear “HI” indicating a high glucose level if your test result is higher than 600 mg/dL (33.3 mmol/L). You should repeat your test and if the message appears again, call your healthcare professional immediately.

Expected glucose value

Blood glucose management requires the helps of a healthcare professional. Together you can set your own range of expected blood glucose values arrange your testing times, and discuss the meaning of your blood glucose results.[1][3]

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

⚠ Caution:The HEA-230 & HEA-232 meter measurement unit was set as mg/dL or mmol/L from manufacturer side. the unit exchange ratio is as the followings: 1 mmol / L = 18.02 mg/dL

- “LO” (< 20 mg/dL)or ”HI”(> 600 mg/dL) readings might indicate a potentially serious medical condition. Please repeat a test, and consult your healthcare professionals if a similar result is achieved again.
- If test results still do not match how you feel, contact your doctor.
- If your reading is not consistent with your symptoms or if your blood glucose result is less than 70 mg/dL (3.9 mmol/L) or higher than 180 mg/dL (10.0 mmol/L), you should contact your healthcare professional and follow his or her treatment advice.

Limitation of procedure

HEA-STP30 test strips give accurate results when the following limitation is observed:

- The test strips are for single use only, do not reuse the strip.
- Do not use for the testing of newborn.
- Use only fresh capillary whole blood.
- Do not use serum or plasma.
- Hematocrit is the percentage of red blood cell in blood. Extremes in hematocrit may affect test results. Hematocrit level less than 30% may cause falsely high reading and hematocrit level greater than 55% may cause falsely low reading.
- The temperature of test condition is between 10 ~ 40 ℃ (50 ~ 104 ℉).
- The humidity of test condition is below 90 % RH.
- Keep the strip vial away from light and high heat. Storage temperature range is between 4 ~ 30 ℃ (39 ~ 86 ℉) and humidity should be below 75 % RH.

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- Do not use the blood sample contained anticoagulation or preservatives.
- OMRON blood glucose test strips HEA-STP30 may be used at altitudes up to 10,000 feet (3048 meters) without an effect on test results.
- Hemolysis may affect test results. The effect of hemolysis in a whole blood sample was reported to interfere the glucose meter measurement.(2)
- Please contact your healthcare professionals if the result does not consist with the way you feel and please not to change your medication without approval of a healthcare provider.
- Patients undergoing oxygen therapy may yield falsely low results.
- If the patient is severely dehydrated in shock or in a hyperosmolar state, the test results may be incorrect.

Limitation of interferences

Interfering substances which have been tested:
Exogenous substances: ascorbic acid (Vitamin C), acetaminophen, dopamine, gentisic acid, Ibuprofen, levodopa, methyldopa, maltose, salicylic acid, tetracycline, tolazamide, and tolbutamide.
Endogenous substances: bilirubin, creatinine, cholesterol, triglyceride, uric acid, urea, and glutathione.
These substances will not cause significant interference in blood glucose measurement when their concentrations are normal in human body or below therapeutic level.

Reagent composition

Each test strip contains:
Glucose oxidase (Aspergillus niger) ≧ 5%,
Electron shuttle 30%
Enzyme stabilizer 5%
Other ingredients 60%

HEA-230 & HEA-232 performance characteristics

HEA-230 performance characteristics
Traceability:
The test result of OMRON blood glucose monitoring system HEA-230 is plasma calibrated by chemistry analyzer, and the analyzer was calibrated with a NIST traceable glucose standard solution.

Measurement range:
HEA-230 system display results between 20 - 600 mg/dL (1.1 ~ 33.3 mmol/L).

Accuracy:
The accuracy of the HEA-230 system was assessed by comparing blood glucose results obtained by patients with those obtained using clinical analyzer. The following results were obtained 120 subjects at two clinical centers.

⚠Caution:The HEA-230 & HEA-232 meter measurement unit was set as mg/dL or mmol/L from manufacturer side. the unit exchange ratio is as the followings: 1 mmol / L = 18.02 mg/dL

Slope	1.0384
y-intercept	1.6664 mg/dL (0.0925mmol/L)
Correlation factor (R2)	0.9827
Test number (n)	240
Test range	40~443 mg/dL(2.2~24.6mmol/L)

Number and % of results within reference (for values were < 75 mg/dL(4.2mmol/L)

Within ± 5 mg/dL (0.3mmol/L)	Within ± 10 mg/dL(0.6mmol/L)	Within ± 15 mg/dL(0.8mmol/L)
26/40 (65%)	34/40 (85%)	39/40 (97.5%)

Number and % of results within reference (for values were ≧ 75 mg/dL(4.2mmol/L)

Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
67/200 (33.5%)	135/200 (67.5%)	178/200 (89%)	197/200 (98.5%)

Precision:
This study shows the variability from strip to strip in sample tests. The results are shown in the following table.

Within Run Precision		
Samples	Mean glucose concentration	measured CV
Sample 1	57.1 mg/dL(3.2mmol/L)	SD=4.4 mg/dL (0.2 mmol/L)
Sample 2	99.6 mg/dL(5.5mmol/L)	3.0%
Sample 3	152.4 mg/dL(8.5mmol/L)	2.8%
Sample 4	247.8 mg/dL(13.8mmol/L)	2.9%
Sample 5	400.0 mg/dL(22.2mmol/L)	3.1%
Between Day Precision		
Control solution 1	56.2 mg/dL(3.1mmol/L)	SD=4.2 mg/dL (0.2mmol/L)
Control solution 2	104.1 mg/dL(5.8mmol/L)	3.2%
Control solution 3	306.1 mg/dL(17.0mmol/L)	2.9%

HEA-232 performance characteristics
Traceability:
The test result of OMRON blood glucose monitoring system HEA-232 is plasma calibrated by chemistry analyzer, and the analyzer was calibrated with a NIST traceable glucose standard solution.

Measurement range:
HEA-232 system display results between 20 - 600 mg/dL (1.1~33.3 mmol/L).

Accuracy:
The accuracy of the HEA-232 system was assessed by comparing blood glucose results obtained by patients with those obtained using clinical analyzer. The following results were obtained 115 subjects at two clinical centers.

Slope	1.0722
y-intercept	-6.2869mg/dL (-0.4mmol/L)
Correlation factor (R2)	0.9733
Test number (n)	230
Test range	22~537mg/dL (1.2~29.8mmol/L)

Number and % of results within reference (for values were < 75 mg/dL(4.2mmol/L)

Within ± 5 mg/dL (0.3mmol/L)	Within ± 10 mg/dL (0.6mmol/L)	Within ± 15 mg/dL (0.8mmol/L)
10/32 (31.3 %)	26/32 (81.3 %)	32/32 (100 %)

Number and % of results within reference (for values were ≧ 75 mg/dL(4.2mmol/L)

Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
104/198 (52.5 %)	149/198 (75.3 %)	177/198 (89.4 %)	194/198 (98.0 %)

Precision:
This study shows a variability from strip to strip in sample tests. The results are shown in the following table.

Within Run Precision		
Samples	Mean glucose concentration	measured CV
Sample 1	32.9 mg/dL (1.8mmol/L)	SD=1.8 mg/dL(0.1mmol/L)
Sample 2	71.9 mg/dL (4.0mmol/L)	2.7%
Sample 3	134.0 mg/dL (7.4mmol/L)	1.7%
Sample 4	214.4 mg/dL (12mmol/L)	1.5%
Sample 5	396.6 mg/dL (22mmol/L)	1.7%
Between Day Precision		
Control solution 1	40.3 mg/dL (2.2mmol/L)	SD=1.5 mg/dL(0.1mmol/L)
Control solution 2	119.8 mg/dL (6.7mmol/L)	1.6%
Control solution 3	328.9 mg/dL (18.3mmol/L)	1.5%

Reference:
1.Kilpatrick E.S., Rumley A. G. and Rumley C. N.: Diabetes Medicine (1995), p.341.
2.Burtis, C.A. Ashwood, E.R., eds.: Tietz Textbook of Clinical Chemistry. 2nd Edition. Philadelphia: W.B. Saunders. (1994), 2190.
3.Standards of Medical Care in Diabetes——2010, Diabetes Care January 2010 vol. 33 no. Supplement 1 S11-S61 2010, ADA

	MANUFACTURER		CONSULT INSTRUCTIONS FOR USE
	PAPER RECYCLE	LOT	BATCH CODE
	TEMPERATURE LIMITATION	EC REP	AUTHORISED REPRESENTIVE IN THE EUROPEAN COMMUNITY
IVD	IN VITRO DIAGNOSTIC MEDICAL DEVICE	CE	Council Directive 98/79/ EC on in vitro diagnostic medical devices
	DO NOT REUSE		KEEP AWAY FROM SUNLIGHT
	KEEP DRY		DO NOT USE IF PACKAGE IS DAMAGED
	USE BY		

IVD **For self-testing**

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