The next generation in Point Of Care monitoring…

FreeStyle Optium Neo H

The dedicated hospital blood glucose meter

Frequently Asked Questions

FreeStyle Optium Neo H

Blood Glucose and Ketone Monitoring System

FreeStyle Optium Neo H System Frequently Asked Questions

Performance

1 Does the FreeStyle Optium Neo H system meet the newly adopted ISO 15197:2013 accuracy standard?

Yes. The FreeStyle Optium Neo H system is designed to meet the newly adopted ISO 15197:2013, with 98.7% of results within ± 15 mg/dL (0.83 mmol/L) or 15% of the laboratory reference.[1]

2 What is the reference method for evaluating system accuracy?

The reference method used for is the Yellow Springs Instrument, (YSI).

3 What is the measuring range of the FreeStyle Optium Neo H system?

Glucose = 1.1 – 27.8 mmol/L
Ketone = 0.0 – 8.0 mmol/L

4 How long does a Glucose / Ketone reading take after sampling?

Glucose = 5 seconds
Ketone = 10 seconds

5 Which sample types can be tested for blood glucose?

Capillary, venous, arterial and neonatal whole blood.

6 Why does venous blood need to be marked for a glucose test?

Venous blood needs to be marked to ensure the FreeStyle Optium Neo H system delivers the most accurate result possible specific to venous blood. If the operator does not mark a venous blood sample, venous results may not be as accurate.

7 Is the FreeStyle Optium Neo H available to members of the public?

No. The FreeStyle Optium Neo H is designed specifically for hospital use.

1. Evaluation of the FreeStyle Optium Neo Blood Glucose and Ketone Monitoring System, sponsored by Abbott Diabetes Care, 2013. Data on file.

Range of Patients

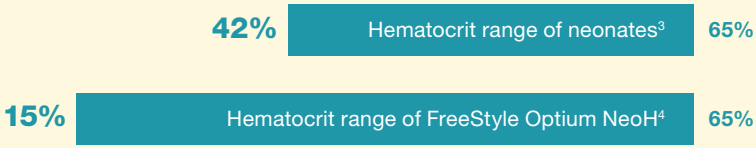
1 What is the haematocrit range for the FreeStyle Optium Neo H system?

The FreeStyle Optium Neo H system has a blood glucose haematocrit range of 15-65% and meets haematocrit performance requirements of ISO 15197:2013.

2 Can the FreeStyle Optium Neo H be used on neonates?

Designed as a glucose meter for inpatient populations, the properties and features of the Freestyle Optium Neo H meter make it particularly relevant to neonates.

- Only a small sample volume (0.6µL) is required to perform an accurate test.
- Maintains an accuracy across a wide range of haematocrit values[2] making it suitable for use across a broad range of patients including neonates.[3]



2. Evaluation of the FreeStyle Optium Neo H blood glucose and blood ketone monitoring system (Data on file, study conducted April-May 2013, Abbott Diabetes Care Inc). 3. Jopling J, Henry E, Wiedmeier SE, Christensen RD. Reference Ranges for Hematocrit and Blood Hemoglobin Concentration During the Neonatal Period: Data From a Multihospital Health Care System. Pediatrics. 2009 February 1, 2009;123(2):e333-e7. 4. According to manufacturer recommendations and package inserts and data on file with Abbott Diabetes Care

FreeStyle Optium Neo H System Frequently Asked Questions

Quality Control[5]

1 Is the Quality Control Reminder enabled out of the box?

No. The Quality Control Reminder is off out of the box and needs to be enabled if a hospital wants to use this.

2 At what intervals can the Quality Control Reminder be set to appear?

The QC Reminder can be customised to the institution's QC protocol.

The QC Reminder can be set to appear at hourly intervals (every 1-23 hours) or daily intervals (every 1-30 days).

3 How will staff know when to perform a quality control test once the Quality Control Reminder has been enabled?

The Quality Control Reminder will be displayed as 'qc' on the meter.

4 What happens if a quality control test is not performed when the Quality Control Reminder is displayed?

When a quality control test is due, the Quality Control Reminder is displayed and remains on screen until a quality control test is performed.

5 If the Quality Control Reminder is displayed, will the operator be locked out until a quality control test is performed?

No. The operator will not be locked out and a glucose test can still be performed.

6 Is the Quality Control test recorded?

Yes. The time and date of each quality control test is stored and displayed in the logbook. A Quality Control report, available via the FreeStyle Auto-Assist Neo software, can facilitate hospital audits and reviews of quality control compliance. To mark a quality control test, the operator presses the control solution mark whilst the strip is in the port.

5. FreeStyle Optium Neo H User Guide

FreeStyle Optium Neo H System Frequently Asked Questions

Out Of Range Indicators[5]

1 What do the out-of-range indicators look like?

When blood glucose is below the value for the low Out-of-Range Indicator, a red arrow appears.

When blood glucose is above the value for the high Out-of-Range Indicator, a yellow arrow appears.

2 Are the Out-of-Range Indicators enabled out of the box?

No. The Out-of-Range Indicators are not enabled out of the box and need to be enabled via a 2-button press combination if a hospital/ institution want to use them.

3 What are the default levels for the Out-of-Range Indicators?

Parameter *Out-of-Range Indicator*	Default values when enabled *mmol/L*
Low	3.9
High	13.3

4 What are the ranges for the customisable Out-of-Range Indicators?

Parameter *Out-of-Range Indicator*	Allowable ranges *mmol/L*
Low	1.1 – 6.6
High	6.7 – 27.8

5 If an operator changes the High Out-of-Range Indicator limit, will the ketone warning level also change?

The ketone warning level is fixed and cannot be changed by the operator. The ketone warning will appear for glucose results equal to or above 13.3 mmol/L.

5. FreeStyle Optium Neo H User Guide

FreeStyle Optium Neo H System Frequently Asked Questions

Blood Ketone Testing

1 Which Blood Ketone test strips are for use with the FreeStyle Optium Neo H meter?

The FreeStyle Optium H blood ß-Ketone test strips.

2 How does the meter indicate to operators that blood ketone level is being checked?

A **KET** icon will be displayed on the screen.

3 Does the meter warn when I should check for blood ketones?

Yes. The **KET** icon will appear and blink three times on the screen[6] when the blood glucose test result is 13.3 mmol/L or higher, indicating that the blood ketone should be tested.

4 Which sample types can be tested for blood ketone testing?

Capillary and venous whole blood.

5 Does venous blood need to be marked when testing for ketones using a venous sample?

No. Venous blood marking is for glucose tests only.

6. Tang Z et al. Effects of Different Hematocrit levels on glucose measurements with hand held meters for point-of-care testing; Arch Pathol Lab Med. 2000;124:1135–1140

FreeStyle Optium Neo H System Frequently Asked Questions

Test Strips

1 Are the same test strips used for Glucose and Ketone measuring?

No. There are specific strips for Glucose and Ketone measuring.

2 Do I need to calibrate the strips with the meter?

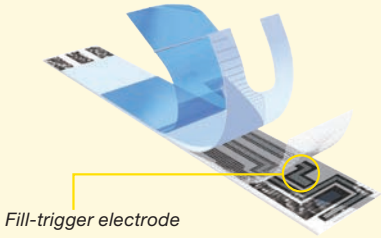
Yes. Each box of strips come with a unique calibration stick. The calibration procedure programs the meter with the lot number and test strip technology*. This prevents the user from testing strips that are past their expiry date.

3 Do I need to calibrate the meter each time I do a test?

No. You also don't need to calibrate the meter each time you switch from Glucose to Ketone testing. The meter must only be calibrated when you open a new box of strips.

3 How do I know I have applied sufficient blood to the meter?

Only a small sample of 0.6µL blood is required. The patented Fill-trigger electrode ensures that the test starts only when enough blood is applied, so the potential for error due to "short" samples is minimised.



4 Why are the test strips individually wrapped?

FreeStyle Optium Neo H test strips are the only leading brand of hospital blood glucose strips that are individually foil-wrapped.†

- suitable for use in a multi-patient setting
- helps to minimise bacterial cross contamination in a multi-user setting[7]
- single use packaging may reduce strip waste costs associated with dedicated vials[8]
- No need to date the box when the box is first opened

*Glucose strips only †As of June 2015 among leading hospital brands of blood glucose test strips (Roche,AMSL). Source: Manufacturers's websites. 7. Pérez-Ayala M, Oliver P, Rodríguez Cantalejo F. Prevalence of bacterial contamination of glucose test strips in individual single-use packets vs multi-use vials. J Diabetes Sci Technol. 2013;7:854-862. 5. 8. Nichols JH. Estimated strip wastage from glucose meter infection control recommendations. Clinica Chimica Acta 414 (2012) 91–92

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Error Messages

Message	What it means	What to do
E-1	The temperature is too hot or too cold for the meter to work properly	1. Move the meter and test strips to a location where the temperature is within the test strip operating range. (See test strip instructions for use for the appropriate range.) 2. Wait for the meter and test strips to adjust to the new temperature. 3. Repeat the test using a new test strip. 4. If the error reappears, contact Customer Care.
E-2	Meter error	1. Turn off the meter. 2. Repeat the test using a new test strip. 3. If the error reappears, contact Customer Care.
E-3	Blood drop is too small or Incorrect test procedure or There may be a problem with the test strip	1. Review the testing instructions. 2. Repeat the test using a new test strip. 3. If the error reappears, contact Customer Care.
E-4	The blood glucose level may be too high to be read by the system or There may be a problem with the test strip	1. Repeat the test using a new test strip. 2. If the error reappears, contact the prescribing physician **immediately**.
E-5	Blood was applied to the test strip too soon	1. Review the testing instructions. 2. Repeat the test using a new test strip. 3. If the error reappears, contact Customer Care.
E-6	Calibration error or Test strip error	1. Check the date setting on the meter. 2. Check the expiration date on the test strip foil packet. 3. Repeat the calibration using the calibrator that came with the test strip you are using. 4. If the error reappears, contact Customer Care.
E-7	Test strip may be damaged, used, or the meter does not recognize it	1. Check that you are using the correct test strip for this meter. (See test strip instructions for use to verify the strip is compatible with this meter.) 2. Repeat the test using a test strip for use with the meter. 3. If the error reappears, contact Customer Care.
E-8 E-9	Meter error	1. Turn off the meter. 2. Repeat the test using a new test strip. 3. If the error reappears, contact Customer Care.

Icon Guide

	Logbook
	Meter ready for sample application
CtL	Control solution result
KET	Ketone
PC	Connected to computer
	High Out of Range indicator
	Low Out of Range Indicator
	Setup mode
	Control solution mark
PC	Quality Control Test is due
24	Number of days
	Control Solution Test
	Low Battery
V	Venous blood mark
	Venous blood test

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Abbott Diabetes Care