DO NOT PRINT FROM THIS FILE -FOR REFERENCE ONLY



Symbols

These symbols are associated with your meter.

[]i	Consult instructions for use	Σ	Use-by date
\mathbf{x}	Temperature limit	IVD	<i>In vitro</i> diagnostic r
444	Manufacturer	REF	Catalogue number
CE	CE Mark	TA A	Recycle
LOT	Batch code	SN	Serial number
\sim	Date of manufacture	Ś	Biological risks
T.	The European Battery Directive requires	STERILE R	Sterilized using irra
	separate collection of spent batteries, aiming to facilitate recycling and to protect the environment. The batteries in this	2	Do not re-use
	product should be removed and disposed in accordance with local regulations for separate collection of spent batteries.	$\langle \mathbf{x} \rangle$	Do not drink

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Intended Use

The FreeStyle Optium Neo H Blood Glucose and Ketone Monitoring System is for professional use to measure glucose and ketone (β -hydroxybutyrate) in fresh whole blood outside the body (*in vitro* diagnostic use).

IMPORTANT:

 Use only FreeStyle Optium Neo H blood glucose test strips and FreeStyle Optium H blood β-Ketone test strips. Other test strips may produce inaccurate results.

Potential infection risk: Healthcare professionals performing blood tests with this system on multiple patients must always wear gloves and should follow the infection control policies and procedures approved by their facility.

- See test strip instructions for use for more information about sample types.
- Read the instructions in this Operator's Manual. Failure to follow instructions may cause incorrect results. Practice the testing procedures before using the meter.
- Observe caution when using around children. Small parts may constitute a choking hazard.

How FreeStyle Optium Neo H Blood Glucose Monitoring System Works

When you insert a test strip into the meter, the sample drop symbol shows on the meter's display window. When a blood sample or control solution sample is applied to the test strip, the glucose or ketone reacts with the chemicals on the test strip. This reaction produces a small electrical current that is measured. The result shows on the meter's display window.

FreeStyle Optium Neo H At-A-Glance



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Logbook

Up Button

Mark a venous blood test Adjust settings

Power Button

Turn meter on and off Return to the Home screen Save settings



Strip Port

Insert a test strip here

Test Strip

Insert the test strip into the meter

2

Meter Symbols Symbol What It Means Symbol What It Means 2 C Logbook Control solution mark qc Quality Control test is due Meter ready for sample application ② 24 CEL Control solution result Number of days KET Ketone Control solution test PC -+[] Low battery Connected to computer $\mathbf{\Lambda}$ High Out-of-Range indicator X7 Venous blood mark 2 Low Out-of-Range indicator Venous blood test Ø_Ø Setup mode 3

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Using the Meter

Turning the Meter On and Off

To turn the meter on:	To turn the me
• Press 🖌, or	• Press and hold 🔰 for 3 sec
Insert a strip	 Do nothing for 2 minutes

Checking the Meter Screen Every Time You Turn It On



The meter screen should be fully black when powered off. Each time you turn on the meter, a white start-up test screen will appear for 1 second.

If you see any white segments in the black off screen, or any black segments in the white test screen, there may be a problem with the meter. Contact Customer Services.

Note: If the meter battery is low, -+ $\begin{bmatrix} \\ \\ \\ \end{bmatrix}$ will appear in both the meter off screen and start-up test screen.

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Setting Up the Meter

To confirm that the date and time are set correctly, follow the steps below.

Set Time

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Step	Action
1	 Start with meter off (no test strip inserted). Press Y to turn on the meter
2	Press and hold the time (for example 11:50) on the screen for 3 seconds until the screen changes.
5	

Step		Action
3	I2 h Time Format 24 h Time Format	 Set Time Format (12-hour or 24-hour clock Press → or to change Press → to continue Note: The meter can display either a 12-h (1: time format. If you prefer the 12-h format, th PM time, continue to press until you see
4	+ 	Set Hour • The hour blinks. Press → or ∧ to set t • Press → to continue
5	• ۱ التَّحُانِ Minute	 Set Minutes The minutes blink. Press ✓ or to so Press to continue

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Set Date



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Enabling Out-of-Range Indicators and Quality Control Reminder

Introduction

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The out-of-range indicators and the quality control reminder can be enabled on the meter to support compliance with your facility's policies and procedures.

- The out-of-range indicators notify the user with a ${f \downarrow}\,$ if the patient's blood glucose is lower than the set low-glucose threshold or a \uparrow if the patient's blood glucose is higher than the set high-glucose threshold.
- The quality control reminder will display **qc** when a quality control test is due. Once the quality control test has been performed, this reminder will disappear until the next scheduled reminder. This reminder can be set for hourly (1-23 hours) or daily (1-30 days) intervals.

Note: Quality control reminder is for glucose control solution tests only. Performing a ketone control solution test will not clear the reminder.

In order to enable these features, use the following instructions.

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Preparing the Meter for Glucose and Ketone Testing

Calibrating the Meter for Glucose and Ketone Testing

Calibrate the meter to:	Calibration is re
Match the test strips being used	• When using the meter for the

• When using a new carton of test strips



Remove the glucose calibrator (white) or the ketone calibrator (purple) from the new carton of test strips.

Peel the clear cover away from the corner with three bumps to open the calibrator package.

IMPORTANT: Use only the calibrator that is packaged in the carton of test strips you are using.

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first time



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Preparing the Meter



Confirm the LOT Number

Check to see that the LOT number matches on all the following areas:

Meter display
 Test strip calibrator
 Test strip instructions for use
 Test

IMPORTANT: Contact Customer Services if the LOT number does not match. **Do not** test your patient's blood glucose and blood ketone. The meter may produce inaccurate results.

LOT Number	What It Means	Wh
Glucose Match last five digits: XXXXX 67984 (example)	The meter is calibrated for the carton of test strips you are using.	You may now tes glucose or blood
Ketone Match first five digits: 75001 XXX (example)		
Does not match all	The meter may not be calibrated for the carton of test strips you are using.	Check to see that calibrator that ca carton of test stri Recalibrate the m

Remove the calibrator from the meter and store it in the carton of test strips.

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Test strip foil packet

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est your patient's blood d ketone.



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Testing Blood Glucose or Blood Ketone

IMPORTANT: Only use a test strip once. Read the test strip instructions for use before performing a blood glucose or ketone test. It contains important information and will tell you how to store and handle the test strips.

Test Site

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Performing a Blood Glucose or Blood Ketone Test

Step	Action
1	Open the foil test strip packet at the notch an remove the test strip.
2	 Insert the test strip into the meter until it stop the meter. Notes: Check that the meter screen is working prope turn the meter on. If you see any white segme screen, or any black segments in the white test be a problem with the meter. See "Using the M more details. The meter turns off after 3 minutes of inactivity reinsert the unused test strip to restart the meter

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and tear down to

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perly each time you ments in the black off test screen, there may e Meter" section for

ivity. Remove and neter.

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Low Blood Glucose Results

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If You See	What It Means	What To Do
A solid red arrow	If out-of-range indicators are enabled, appears when result is lower than the range set by your facility.	Follow your facility's procedure for handling out-of-range results.
LD Appears when result is lower than 20 mg/dL	Severe low blood glucose or There may be a problem with the test strip.	Repeat the test with a new test strip. This requires immediate action as defined by your facility's policies and procedures.

High Blood Glucose Results

If You See	What It Means	w	
A solid yellow arrow	If out-of-range indicators are enabled, appears when result is higher than the range set by your facility.	Follow your for handling	
	blinks three times and then disappears when: Blood glucose level is higher than or equal to 240 mg/dL.	Check blood your facility procedures.	
Appears when result is higher than 500 mg/dL	Severe high blood glucose or There may be a problem with the test strip.	Repeat the t strip. This re action as de policies and	

Note: If you see the error message E-4, consult the "Error Messages" section in this Operator's Manual.

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r facility's procedure g out-of-range results.

od ketone or follow y's policies and s.



test with a new test equires immediate efined by your facility's d procedures.

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Understanding Blood Ketone Test Results

The meter displays ketone results in mmol/L, from 0.0 - 8.0 mmol/L. The unit of measurement is preset. You cannot change this setting.

Blood ketone is expected to be below 0.6 mmol/L.² High blood ketone may be caused by illness, fasting, vigorous exercise or uncontrolled blood glucose levels.¹⁻³

Repeat a blood ketone test using a new blood ketone test strip when:

- HI appears on the display
- The result is unusually high
- You question the result
- The blood ketone result is 0.0 mmol/L, but the blood glucose is higher than 300 mg/dL

Display	What It Means	What To Do
Result is between 0.6 – 1.5 mmol/L.	High blood ketone. A problem requiring medical assistance may be occurring.	Follow your facility's policies and procedures on how to handle elevated blood ketone results.

Display	What It Means	W
Result is higher than 1.5 mmol/L.	The patient may be at risk of developing diabetic ketoacidosis (DKA). ²⁶	Follow your f procedures c high blood k
Appears when result is higher than 8.0 mmol/L.	Very high blood ketone or There may be a problem with the test strip.	Repeat the to strip. This rec action as def facility's polic

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What To Do

r facility's policies and s on how to handle ketone results.

test with a new test equires immediate efined by your licies and procedures.



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View Logbook

The meter logbook can store up to 1,000 events - including blood glucose, blood ketone and control solution results, and other meter information.

Viewing Logbook Events



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Control Solution Result

Venous Blood Glucose Result

11:41

The **LEL** screen and control solution test result screen alternate.

Note: Check mark in the box indicates a control solution test and not that the result was within range.

Viewing Blood Glucose Averages

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While in the logbook, press 🍸 any time to view the 7-day average. []-d84]

- Press 🛩 to view the 14-day average. [14-dRy]
- Press > to view the 30-day average. [3]-dAY]
 Press 1 to return to the logbook events.

Notes:

Number of tests

in this average

- Averages do not include glucose control solution results.
- Control solution results not marked as control solution tests may cause averages to be inaccurate.
- **—** appear on the meter screen when there are no current events or averages to view.
- L blood glucose test results are included as 20 mg/dL when calculating averages.
- H | blood glucose test results are included as 500 mg/dL when calculating averages.

Press \checkmark or \checkmark to scroll through 7-, 14- and 30-day averages.

WARNING: Averages should not be used if the meter is used on multiple patients. If the meter is used on multiple patients, the device cannot identify if data on the meter is from more than one patient.

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Glucose and Ketone Control Solution Tests



A control solution test should be performed when:

- You are unsure of your patient's blood glucose or blood ketone results, or
- You receive a **qc** test reminder indicating that a quality control test is due.

Note: Once completed, **q**^c will disappear.

IMPORTANT:

- Use only MediSense glucose and ketone control solutions with the meter.
- Control solution results should fall within the control solution range printed on the test strip instructions for use.
- Check that the LOT number printed on the test strip foil packet and instructions for use match.
- Do not use control solution past its expiry date. Discard control solution 3 months after opening or on the expiry date printed on the bottle, whichever comes first. (Example: open April 15, discard July 15; write the discard date on the side of the bottle.)
- The control solution range is a target range for control solution only, not for blood glucose levels.
- Replace the cap securely on the bottle immediately after use.
- **Do not** add water or other liquid to control solution.
- Contact Customer Services for information on how to obtain control solutions.

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Performing a Control Solution Test



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The 💧 blinks. Press the 🍼 until the 💽 appears. The meter is now ready for you to apply control solution to the

Action

test strip.

Note: KET will appear on the screen if you have inserted a purple blood ketone strip.

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Step

Shake the control solution bottle to mix the solution. Apply a drop of control solution to the white area at the end of the test strip in the area shown. The control solution is drawn into the test strip.



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11:41

Glucose Control

Solution Result

example

Y

11:41

Ketone Control

Solution Result example

Action

View the result.

The test is complete (examples shown) when the result appears on the meter screen. The result is stored in the memory as a control solution result.

Compare the control solution result with the range printed on the blood glucose or blood ketone test strip instructions for use. The result should fall within the range.

Note: KET appears with the result if performing a ketone control solution test.

Out-of-Range Control Solution Results:

- Repeat the test if control solution results are outside the range printed on the test strip instructions for use.
- Stop using the meter if control solution results are consistently outside the range printed on the test strip instructions for use. Contact Customer Services.





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Transferring Meter Data to a Computer

Transferring meter data to a computer requires a compatible data management system. You will also need a micro USB cable to connect the meter's USB port to a computer.

For more information, contact your Sales Representative or Customer Services.

WARNING: To avoid the possibility of electric shock, never perform a test while the meter is connected to the computer.

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	 Move the meter and test strips to the temperature is within the test range. (See test strip instructions appropriate range.) Wait for the meter and test strips temperature. Repeat the test using a new test If the error reappears, contact Cu
E-3	Meter error	 Turn off the meter. Repeat the test using a new test If the error reappears, contact Cu

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Message What It Means	What To Do	Message	What It Means
E-B Blood drop is too small or Incorrect test procedure or There may be a problem with the test strip	 Review the testing instructions. Repeat the test using a new test strip. If the error reappears, contact Customer Services. 	E-6	Calibration error or Test strip error
E-H The blood glucose level may be too high to be read by the system or There may be a problem with the test strip	 Repeat the test using a new test strip. If the error reappears, contact the prescribing physician immediately. 	E-7	Test strip may be damaged, used or the meter does not recognise it
E-S Blood was applied to the test strip too soon	 Review the testing instructions. Repeat the test using a new test strip. If the error reappears, contact Customer Services. 	E-9	Meter error

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Maintenance

Replacing the Batteries

You will see this screen when the batteries are low. Notes: • Meter settings and logbook information will be saved when you change the batteries. • The time and date will need to be set again if the batteries are not replaced within 1 minute. -+000 Step Action Turn meter over and slide open the battery door on the side as 1 shown. Remove the old batteries. 2

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Note: The next time you turn the meter on, it may prompt you to reset the time and date. See "Setting Up the Meter" section for more details.

Note: When you no longer need the meter, remove the batteries and dispose of batteries and meter in compliance with your local regulations.



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The European Battery Directive requires separate collection of spent batteries, aiming to facilitate recycling and to protect the environment. The batteries in this product should be removed and disposed in accordance with local regulations for separate collection of spent batteries.



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Cleaning the Meter



Troubleshooting

Problem	What It Means	What 1
Test strip is inserted in the strip port and nothing happens.	Test strip is not inserted properly or fully into the meter	 With the contact bars up, insert the test strip it stops. This turns on If the meter still does Customer Services.
	No batteries are installed; Batteries installed incorrectly	See "Maintenance" section install batteries.
	Dead batteries	Change batteries. Reset needed.
	Meter may be plugged into a computer (PC appears on meter screen)	Unplug the meter from
	Problem with the test strip	Try a new test strip.
	Problem with the meter	Contact Customer Servio

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(3 black lines) facing p into the meter until the meter. not turn on, contact	
on on how to properly	
date and time, if	Ð
the computer.	
ces.	
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7/13/15	11:40 AM

Problem	What It Means	What To Do
The test does not start after applying the blood sample.	Blood sample is too small	 See test strip instructions for use for re- application instructions. Repeat the test using a new test strip. If the test still does not start, contact Customer Services.
	Sample applied after meter turns off	 Review the testing instructions. Repeat the test using a new test strip. If the test still does not start, contact Customer Services.
	Problem with meter or test strip	 Repeat the test using a new test strip. If the test still does not start, contact Customer Services.

Meter Specifications

Assay method	Amperometry
Automatic shutoff	At least two minutes of inactivity
Battery life	Up to 3,000 tests
Measurement range	For blood glucose testing 20 - 500 mg/dL For blood ketone testing 0.0 - 8.0 mmol/L
Memory	Up to 1,000 events, including blood glucose, blood ketone results, and other meter information
Minimum computer requirements	System must only be used with EN60950-1 rated computer cable
Operating relative humidity	10% to 90% (non-condensing)
Operating temperature	Meter: 10 °C to 50 °C (50 °F to 122 °F) System: See test strip instructions for use

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Power source	Two CR 2032 lithium (coin cell) batteries
Size	5.97 cm (w) x 8.68 cm (l) x 0.87 cm (d) 2.35 in (w) x 3.42 in (l) x 0.34 in (d)
Storage temperature	-20 °C to 60 °C (-4 °F to 140 °F)
Altitude	See test strip instructions for use
Weight	33 g to 37 g (1.2 oz. to 1.3 oz.) including batteries

Note: For test strip specifications, see test strip instructions for use.

Electromagnetic Compatibility (EMC): FreeStyle Optium Neo H meter has been tested for both electrostatic discharge and radio frequency interference. Emissions are low and unlikely to interfere with other nearby electronic equipment. To limit radio frequency interference do not use the FreeStyle Optium Neo H meter near cellular or cordless telephones, radio transmitters or other electrical or electronic equipment that are sources of electromagnetic radiation, as these may interfere with the proper operation of the meter. Avoid use of the device in very dry environments, as electrostatic discharges from synthetic materials (e.g., carpets) could cause damage.

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Warranty Statement

Limited Warranty

Abbott Diabetes Care Inc. ("Abbott") warrants that the Abbott Diabetes Care Blood Glucose Monitor ("Meter") shall be free from defects in material and workmanship for a period of two (2) years from the original date of purchase or delivery date, whichever is later, provided it is not modified, altered or misused. Under this Limited Warranty, if the Meter is defective in material or workmanship, Abbott's sole obligation is to replace the Meter, free of charge, with a same or similar meter as determined by Abbott in its sole discretion.

Abbott warrants the performance of the Meter in accordance with its specifications if it is used as directed and provided that the failure to perform or misperformance of the Meter has not been caused in whole or in part by the use of test strips that are not the test strips manufactured by Abbott.

This Limited Warranty covers only the Meter and shall not apply to auxiliary equipment or disposable accessories, extends only to the original purchaser, and is not assignable or transferable.

Please see the User's Manual for Instructions for Use, distributor and manufacturer information.

For warranty service, contact Customer Services for assistance and/or instructions for obtaining a replacement Meter. See User's Manual for your Customer Services contact information. Abbott may require as a condition to obtaining warranty service that you return your Meter, postage prepaid, to an address specified by Customer Services.

TO THE EXTENT POSSIBLE UNDER LAW, THESE ARE ABBOTT'S COMPLETE EXPRESS WARRANTIES FOR THE METER AND STATE YOUR EXCLUSIVE REMEDIES, ABBOTT MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, AND ABBOTT EXCLUDES AND DISCLAIMS ANY OTHER WARRANTIES INCLUDING, BUT NOT LIMITED TO, THE IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, AND NONINFRINGEMENT AND ANY OTHER REMEDIES INCLUDING, BUT NOT LIMITED, TO COMPENSATIONS UNDER CONTRACT OR TORT LAWS. ABBOTT DOES NOT WARRANT THAT OPERATION OF THE METER WILL BE UNINTERRUPTED OR ERROR FREE.

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Limitation of Liability

TO THE EXTENT POSSIBLE UNDER LAW, ABBOTT WILL NOT BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING DIRECTLY OR INDIRECTLY FROM USE OF THE METER OR FAILURE OF THE METER TO PERFORM IN ACCORDANCE WITH SPECIFICATIONS.

Some jurisdictions do not allow the exclusion or limitation of other express or implied warranties or incidental or consequential damages, so the above limitations or exclusions may not apply to you.

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