







North East London Blood Glucose Test Strips Guideline

Document Approval

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Introduction

These guidelines are intended to assist healthcare professionals in the selection of appropriate blood glucose (BG) meters and test strips for patients to self-monitor their blood glucose levels.

The recommendations on the choice of meter in this guideline reflects a multi-disciplinary review of several requirements including:

- Compliance with the new ISO standards EN ISO 15197:2015 for glucose testing meters
- o Price < £10.00 per 50 glucose test strips
- o Memory capacity of more than 450 readings which cannot be deleted so as to comply with <u>DVLA</u> requirements
- o A minimum of 6 months expiry once the container of test strips is opened
- Auto coding device
- Set to read in mmol/L as per MHRA guidance.
- o Clinical and technical features of meters (connectivity, suitability for particular patient groups, support for patient self-management)

The need for a meter for people diagnosed with diabetes will be assessed by a healthcare professional, and if required, a **suitable formulary meter** will be supplied to the patient. These meters will be provided free of charge from GP surgeries or specialist diabetes clinics.

There should be no need for a patient to purchase a meter and patients should be dissuaded from doing so without consulting their diabetes healthcare professional first.

This guideline does **not** include continuous intermittently scanned <u>continuous glucose monitoring</u> (isCGM, commonly referred to as 'flash'), real-time continuous glucose monitoring (rtCGM) or guidance on <u>continuous glucose monitoring</u> for pregnant women. The list of meters in this guidance is divided into **TWO** categories:

- Specialist Blood Glucose Testing Meters
- o Non-Specialist Blood Glucose Testing Meters

Please note that this guideline is for use of healthcare professionals during initiation for new patients and for any existing patients during point of review.

Blood Glucose Monitoring Inclusion and Exclusion Criteria

When to Offer Blood Glucose Monitoring³

- All patients with Type 1 diabetes
- All patients with Type 2 diabetes and on insulin or where there is evidence of hypoglycaemic episodes
- Non-insulin managed patients with T2DM who:
 - o Are prescribed sulfonylureas or 'glinides, and also drives
 - Have been newly initiated or dose titrated with a GLP analogue (e.g. exenatide) for short term only (<3 months)
- ALL patients that are pregnant, or are planning to become pregnant. For more information, see the NICE guideline on diabetes in pregnancy. [NICE's guideline on diabetes in pregnancy]

When not to Offer Blood Glucose Monitoring³

- Those with Type 2 DM controlled by diet and exercise alone
- Patients with Type 2 diabetes controlled by any of the following oral agents (alone or in combination with one another): metformin, pioglitazone, acarbose, a gliptin or an SGLT2 inhibitor

Review Date: September 2024

Getting the most from capillary blood glucose monitoring⁶

- Accurate user technique is critical and the person performing the test must have received appropriate training.
- Test strips should be stored in the original container, and at the correct temperature according to manufacturer's directions.
- The container should be promptly closed after removing a strip to keep the contents stored in the correct condition.
- The BG meter should show results in mmol/L not mg/dL.
- The user should be aware of the degree of error, especially in the low BG result range.
- The user should be trained to relate meter readings to their symptoms and seek their healthcare professional's support as needed.
- People having abnormalities with haematocrit, haemoglobinopathies or anaemia may experience inaccurate readings.
- Only specific meters are suitable for people on peritoneal dialysis, so the appropriate meter should be initiated by the healthcare professional initiating
 the meter.
- Every person who is asked to perform glucose or ketone monitoring should be provided with the correct means of safe disposal of their sharps, i.e. lancets.

Type of Diabetes	Treatment Group	Suggested Monitoring Guide	Reasonable test strip requirement (NB: 1 box = 50 strips)
Type 1 Diabetes	All children and adults with Type 1 diabetes	 ✓ SMBG is integral in the treatment of all people with Type 1 diabetes. ✓ All people with Type 1 diabetes should be educated to use SMBG effectively through structured education to ensure they have the skills and knowledge to adjust insulin according to glucose intake and make corrective doses. ✓ Self-testing four times a day or more will be required to gain optimal control, avoid hypoglycaemia, and avoid metabolic emergencies such as diabetic ketoacidosis (although less frequent testing may be appropriate in patients with good control and good hypoglycaemia awareness). 	 ✓ Regular testing required. ✓ Should be prescribed as a repeat prescription – quantities depend on patient's monitoring frequency ✓ Guide requirement = 3-6 boxes per month³⁵
Type 1 and Type 2 diabetes in pregnant women & gestational diabetes	All pregnant women with diabetes	 ✓ All pregnant women with Type 1, Type 2 or gestational diabetes controlled with insulin, tablets or diet alone should self-test seven times day in order to achieve tight diabetic control.¹⁵ ✓ Self-testing should include both fasting and postprandial 	 ✓ Regular testing required. ✓ Supply according to agreed management plan ✓ Guide requirement = 3-5 boxes per month³⁵
Type 2 Diabetes	Insulin therapy with or without hypoglycaemic agents	On initiation,regular monitoring 2 to 4 times a day is required to achieve optimum glycaemic control. ✓ For stable patients where glycaemic control is achieved, self-testing may be reduced to 2 or 3 times a week. ✓ Increase self-testing during periods of illness, instability or use of oral steroids, and following changes in insulin dosage ✓ Regular self testing is required for patients who adjust their insulin dose according to blood glucose. ✓ Assess patients understanding and use of results to adjust diet, lifestyle and treatment. Provide extra training/education if required.	 ✓ Guide requirement = 3 boxes per month ³⁵. ✓ Additional test strips will be necessary for those who require monitoring for DVLA vocational licensing requirement – assess_on an individual basis ✓ Generally: Group 1: 2-3 boxes per month for driving. Group 2: 3 boxes per month³⁵

Type 2 Diabetes	Sulfonylurea/repagli nide alone or in conjunction with other therapies	 ✓ Patients on sulfonylureas/repaglinide should not need to routinely self-monitor blood glucose, but SMBG may be considered if there is: ✓ identified hypoglycaemia especially in the first 3 months of starting sulfonylurea ✓ is asymptomatic hypoglycaemia ✓ suspected asymptomatic hypoglycaemia ✓ use of oral steroids ✓ risk of hypoglycaemia due to renal impairment or high alcohol intake ✓ certain occupations (see DVLA guidance) ✓ Self-monitoring regime should be agreed as part of a management plan 	 ✓ Guide requirement = 1 box per month for initial 3 months³⁵ then 1-2 ✓ boxes per year ✓ Driving: 1-2 boxes per month. ✓ Impaired awareness of hypoglycaemia: prescribe 1 box per month.³⁵
Type 2 Diabetes	Diabetic patients controlled with Pioglitazone, gliptins, or SGLT-2 inhibitors GLP-1mimentic (once stabilised)	Self-testing should not routinely be recommended. ✓ Glycaemic control is best monitored through HbA1c testing. ✓ On diagnosis and treatment initiation, motivated patients may wish to monitor effects of changes in diet and physical activity. ✓ SMBG should only be offered as part of a structured plan with education on how to interpret the results. ✓ Regular long term testing is unnecessary ✓ With exception to those undergoing significant changes in pharmacotherapy or fasting, for example, during Ramadan	✓ Testing not recommended ✓ Maximum 4 boxes a year ³⁵
Type 2 Diabetes	Diabetic patients controlled with diet and exercise or metformin alone.	 ✓ SMBG not routinely recommended. ✓ Glycaemic control is best monitored through HbA1c testing 	Testing unnecessary

Blood Glucose self-monitoring for drivers¹

Treated with Insulin

Group 2 Drivers (lorries/buses)

- o At least twice daily blood glucose monitoring including on days when not driving
- o No more than 2 hours before the start of the first journey and every 2 hours after driving has started
- o A maximum of 2 hours should pass between the pre-driving glucose test and the first glucose check performed after driving has started.
- More frequent self-monitoring may be required with any greater risk of hypoglycaemia
- Use glucose meter with non-deletable memory function sufficient to ensure 3 months of readings available.

Group 1 Drivers (cars/motorcycles):

- Glucose testing no more than 2 hours before the start of the first journey and every 2 hours after driving has started (More frequent self-monitoring may be required with any greater risk of hypoglycaemia)
- o A maximum of 2 hours should pass between the pre-driving glucose test and the first glucose check performed after driving has started

• Treated with tablets which carry a risk of hypoglycaemia (Sulfonylureas and Glinides)

Group 2 Drivers (lorries/buses):

Should monitor blood glucose at least twice daily and at times relevant to driving

Group 1 Drivers (cars/motorcycles):

- The frequency of testing depends upon the clinical context, it may be appropriate to monitor blood glucose at times relevant to driving to enable the detection of hypoglycaemia
- The greatest risk of hypoglycaemia with sulphonylureas is in the first three months of treatment therefore people who are just starting treatment, experiencing hypoglycaemia, or have reduced awareness are likely to need to test more frequently

HbA1c is measured alongside with blood glucose monitoring. It is defined as average blood glucose (sugar) levels for the last two to three months. If you have diabetes, an ideal HbA1c level is 48mmol/mol (6.5%) or below with **exception** to patients that is on antidiabetic that may cause hypoglycaemia²⁵.

*Glycosylated haemoglobin (HbA1c) may be unreliable in the following situations:

- ✓ Patients with anaemia;
- ✓ Patients with polycythaemia;
- ✓ Patients with haemoglobinopathies;
- ✓ Patients in whom venesection is not possible^{20,21}

Table 1: Non-Specialist Blood Glucose Testing Monitor

	Palmdoc 2®	Finetest Lite Technical	Palmdoc 1® Technical	Contour® Plus Blue	GLUCOFIX® TECH	On Call Extra	On Call Extra mobile	Tee2
Product photo (and approx. size and weight)	96 x 54 x 22mm / 79g	83.1 x 56.2 x 17.7 ± (mm)/ 43±1g	95 x 53 x 16 mm/ 69g	78.5x 56 x18mm/ 53g	85.5x 56x 18mm	81x 48x 16mm/ 47g	75 x 40 x 13mm/ 36g	108 x 56 x 15mm / 70g
Memory	900 tests	500 tests	450 tests	800 tests	730 tests	500 tests	500 tests	500 tests
Can readings be deleted from memory	No	No	No	No	No	No	No	No
Compatible test strips	Palmdoc	Fine Test Lite	Palmdoc	Contour® Plus	GLUCOFIX® TECH Sensor	On Call Extra	On Call Extra	Tee2
Glucose test strips Box of 50	£5.90	£5.95	£5.90	£5.95	£5.95	£5.20	£5.20	£7.75
Lancets ¹² Box of 100	Palmdoc (£2.85)	Greenlan (£3.00)	Palmdoc (£2.85)	Microlet Next (£3.72 - £3.90)	GlucoRx (£2.25)	On Call (£2.75)	On Call (£2.75)	CareSens (£2.95)
Limitations	Drugs that contains maltose or galactose e.g. abatacept peritoneal dialysis, immunoglobulin ⁹	Xylose in the blood will cause interference ¹⁰	Drugs that contain/ metabolise to maltose or galactose e.g. abatacept, peritoneal dialysis, immunoglobu-lin ⁹	 No known interference with medication/drugs Severe illness may affect results e.g. hypotension dehydration 	Some drugs may affect test results: dopamine (>0.1 mg/dL), L-DOPA (>3 mg/dL), acetaminophen (>10 mg/dL) ¹¹	 High levels of ascorbic acid Oxygen therapy Severe illness (hypotension, dehydration may affect results 	 High levels of ascorbic acid Oxygen therapy Severe illness (hypotension, dehydration may affect results 	No known interference with medication/drugs

	Palmdoc 2®	Finetest Lite Technical	Palmdoc 1® Technical	Contour® Plus Blue	GLUCOFIX® TECH	On Call Extra	On Call Extra mobile	Tee2
Does meter meet the ISO 15197 standards	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Is haematocrit range between 30- 60% (or more)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Is the measurement range between 1.1 to 33.3mmol/L or more	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Expiry date of from opening	6 months ²⁶	6 months ²⁷	6 months ²⁶	24 months ²⁸	12 months ²⁹	12 months ³⁰	12 months ³⁰	12 months ³¹
Additional considerations for choice of meter	 Speak 5 languages Drivers, who require large test memory for DVLA (900 tests sufficient for testing 10 times daily)⁹ 	Unlimited memory once connected to the Finetest™ Lite Management App ¹⁰	N/A	 Allows second sample application Easy to understand Connects to CONTOUR DIABETES app 	Alarm feature that allows you to set your high (hyperglycaemia) and low (hypoglycaemia) blood glucose thresholds.	Suitable for patient with dexterity problems	 Bluetooth enabled for wireless data management Auto-sync for easy data upload to Diasend GHCP portal 	 Drivers requiring up to 11 tests/day Bluetooth enabled Compatible with diabetes manageme nt APP⁹
Patient helpline details	0800 994 9995 (Freephone) Website: https://www.palmdoc. co.uk/palmdoc-2/	0800 131 3378 (Freephone) Website: https://www.neond iagnostics.co.uk/bl ood-glucose- monitors/finetest- lite	0800 994 9995 (Freephone) Website: http://www.palmdoc. co.uk/palmdoc-1/	0345 600 6030 Email: diabetessupport@ ascensia.com Website: https://www.diabet es.ascensia.co.uk/ products/contour- plus-blue/	0800 243667 (Freephone) Website: https://www.glucom en.co.uk/glucofix- tech/	02033074646 Email: info@connect2pharm a.co.uk Website: https://www.aconlabs. com/brands/on- call/on-call-extra- family/	020 3307 4646 Email: info@connect2phar ma.co.uk Website: https://www.oncallm eters.co.uk/healthca re-professional/on- call-extra-mobile-2/	0800 093 1812 (Freephone) Website: http://www.spirit- health.co.uk

Table 2: Specialist Blood Glucose Testing Monitor

	Palmdoc 2 voice® Technical	AgaMatrix WaveSense JAZZ Wireless	GlucoRx HCT&Ketone	GlucoMen Areo 2k	TRUEyou Meter (Trividia)	On Call Extra Voice
Product photo (and approx. size and weight)	96 x 54 x 22mm / 79g	30x 65x10 mm/ 18.4 g	96 x 61x 26mm/ 67.2 g	85.5x56x18.2mm	89x 55x17mm/ 47g	100 ×60.8×23.9 mm/ 90g
Speciality	Voice for Visually	Gestational	Gestational	Glucose & Ketones	Glucose, Audible	Voice for Visually
NA	Impaired	4005 ((.	4000 1 - 1	700 1 - 1	feature	Impaired
Memory	900 tests	1865 tests	1000 tests	730 tests	500 tests	500 tests
Can readings be deleted from the memory	No	No	No	No	No	No
Compatible test strips	Palmdoc	Wavesense JAZZ	GlucoRx HCT Glucose GlucoRx HCT Ketone	GlucoMen Areo Ketone Sensors GlucoMen Areo Sensors	TRUEyou	On Call Extra Voice
Glucose test strips Box of 50	£5.90	£8.74	£8.95	£8.95	£7.95	£5.20
Ketone test strips Box of 10	N/A	N/A	£9.95	£9.95	N/A	N/A
Lancets ¹²	Palmdoc (£2.85)	AgaMatrix (£2.72)	GlucoRx (£2.25)	GlucoJect PLUS 33G (£2.75 - £3.77)	TRUEplus (£2.90)	On Call (£2.75)
Limitations	Drugs that contains maltose or galactose e.g. peritoneal dialysis, immunoglobulin, abatacept ⁹	Patients with high ascorbic acid concentrations and/or oxygen therapy can affect results	Captopril, Dopamine Gentisic acid, Paracetamol, Unconjugated bilirubin, Cholesterol, L-DOPA, Uric acid, Ascorbic acid and Triglycerides may affect results ¹⁴	No known interference with medication/drugs	N/A	Results affected by: High levels of ascorbic acid Patients on Oxygen therapy Severe dehydration
	Palmdoc 2 voice® Technical	AgaMatrix WaveSense JAZZ Wireless	GlucoRx HCT&Ketone	GlucoMen Areo 2k	TRUEyou Meter (Trividia)	On Call Extra Voice

Does meter meet the ISO 15197:2015 standards	Yes	Yes	Yes	Yes	Yes	Yes
Is haematocrit range between 30- 60% (or more)	Yes	Yes	Yes	Yes	No	Yes
Is the measurement range between 1.1 to 33.3mmol/L or more	Yes	Yes	Yes	Yes	Yes	Yes
Expiry date from opening?	6 months ²⁶	6 months	18 months (Ketone test strips) ³³ 6 months (Glucose test strips) ³⁴	12 months ³²	4 months ²³	12 months ³⁰
Additional considerations on choice of meter	 Speak 5 languages Drivers who require large test memory for DVLA (900 tests sufficient for testing 10 times daily) 	Share your data: Send a pre- formatted email to your Healthcare Professional or a family member	Ketone warning	Large, Glow in the Dark display for ease to read	 4 testing reminder alarms Large display and digits for easy legibility Automatic on/off 	 Audible instructions in up to 3 languages The high contrast strip port is easy to see Large display with bold numbers.
Patient helpline details	0800 994 9995 (Freephone) Website: https://www.palmdo c.co.uk	08000931812 (Freephone) Website: https://agamatrix.co.uk	0800 007 5892 (Freephone) Website: https://www.glucorx.co.u k	0800 243 667 (Freephone) Website: https://www.glucomen.c o.uk	0800 08 58808 (Freephone) Website: https://professionals.tri vidiahealth.co.uk	020 3307 4646 Email: info@connect2pharma.c o.uk Website: https://www.oncallmeter s.co.uk/healthcare- professional/on-call- extra-mobile-2/

Ketone testing in people with diabetes: Advice for prescribers in primary care where applicable

Ketone testing is usually indicated for people with **type 1 diabetes** mellitus but may also be applicable to:

- A small group of **high-risk** patients with type 2 diabetes (e.g. those with multiple dosing injections (MDI) who are ketosis prone i.e. DKA in the past, or who are known to have low endogenous production)⁷
- Those with pancreatic disease-induced diabetes, i.e. type 3c diabetes⁷

What do the results on ketone test strips mean?⁵

Results on blood testing strips are presented as mmol/L. Results on urine testing strips are presented as numbers of + and graduation of colour intensity, and these correlate approximately with mmol/L levels. The individual's management plan (continued monitoring required, insulin dosage adjustment and when to seek medical assistance) should cover actions needed for at least the ranges listed below:

Urine strip reading	Nil	+	++	+++ or ++++
Blood strip reading	Below 0.6	0.6 to 1.5 mmol/L	1.5 to 3 mmol/L	Above 3 mmol/L

Please click here for full management of diabetic ketoacidosis.

Safe disposal of sharps

Local councils are responsible for collecting and disposing of clinical waste including sharps e.g. syringes from patients' homes. Please click <u>here</u> for more information.

For free collection of sharps within Barking and Dagenham, City and Hackney, Havering, Redbridge, please contact: 03301 224220

Adverse Incidents²²

An adverse incident is an event that caused, or almost caused, an injury to a patient or other person or a wrong or delayed diagnosis and treatment of a patient. If such an incident occurs with a blood glucose meter or testing strips, e.g., a faulty batch of test strips for a blood glucose meter giving wrong readings, this should be reported to the Medicines Healthcare and products Regulatory Agency (MHRA) via the <u>Yellow Card Scheme</u>.

^{*}Patients who are required to self-test for ketones will be identified by the diabetes specialist service and provided with the initial supply of ketone testing strips and compatible meter by the specialist service. Primary care can continue to prescribe such strips. Supply is not expected to exceed more than one pack (10 strips) per year, with the exception of insulin pump patients.

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