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Lincolnshire Clinical Commissioning Groups, Lincolnshire Community Health Services,
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Prescribing and Clinical Effectiveness Bulletin

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PRESCRIBING LOWER COST BLOOD GLUCOSE TESTING METERS AND STRIPS

Key Points

- An increasing number of lower cost blood glucose testing meters and strips are reaching the UK market. Many of these products offer a real cost advantage in comparison to established brand leaders.
- PACEF have reviewed the range of lower cost blood glucose testing meters and strips now available and have approved the following for inclusion on the *Lincolnshire Joint Formulary: Accu-Chek Active, Element, Glucolab, GlucoRx Nexus, GlucoRx Nexus Mini and GlucoRx Nexus Voice, iCare Advanced, Microdot+, MyLife Pura, Omnitest 3 (modified version with memory capacity of 500 tests and non deletable memory), TRUEyou and WaveSense JAZZ.*
- Each of the products was evaluated against a range of criteria including: (1) Compliance with accuracy standards stipulated in ISO 15197: 2013; (2) memory capacity (450 tests or more); (3) results not easily deletable; (4) ability to download, store and manipulate test results within a personal computer; (5) calibration not required before use; (6) results reported in mmol/l only and; (7) automatic turn-on when a strip is inserted. The results of the evaluation are tabulated in the main text with additional detail given in *Appendix 2.*
- Omnitest 3 meter did not meet the PACEF specification when first assessed as the meter had a memory capacity of 365 tests and results could be easily deleted. B.Braun have now introduced a modified version of the Omnitest 3 meter which has an increased memory capacity of 500 test results and for which the tests results can no longer be deleted. New Omnitest 3 meters supplied after 28th April 2014 will meet the Lincolnshire specification, but those supplied before 28th April 2014 do not.
- There are currently no plans to replace the older style Omnitest 3 meters that already have been distributed. If a healthcare professional considers that a patient will benefit from a meter with an increased individual arrangements can be made to replace with the updated version.

- All of the approved lower cost products can be considered as part of a review and switch programme. A step-by-step guide on how to do this and the necessary exclusions are detailed below.
- A small number of lower cost blood glucose testing meters did not make the PACEF approved list due to insufficient memory capacity and deletable memory (see Table 1: *Evaluation Results*). Clinicians are reminded that the DVLA stipulate that group 2 drivers (i.e. those who drive lorries or buses) on insulin must provide 3 months of continuous blood glucose records at their annual examination by an independent consultant diabetologist. Products with a limited memory capacity or deletable memory are not suitable for this patient group. Care should be taken to ensure that these products are not prescribed for group 2 drivers. Where review and switch to any of these products is considered, group 2 drivers must be excluded.
- Individual practices or CCGs wishing to utilize clinical support services funded by product manufacturers to undertake switching from high cost BGTS to lower cost products are advised to discuss this with their local Prescribing and Medicines Optimisation Adviser before proceeding.

Reviewing and changing blood glucose testing meters and strips

- (1) Patients who are currently monitoring their blood glucose who do not fall into the exclusion groups defined below should be identified for review and considered for a switch to a lower cost preferred product.
- (2) Such a review should take into account whether the patient should continue to test at all. Blood glucose testing is unlikely to be necessary in patients controlled on diet and exercise alone. If diagnosed with type 2 diabetes, blood glucose testing is particularly advocated if the patient is on insulin, sulfonylureas or glinides (i.e. glucose lowering therapy) or is experiencing hypoglycaemia, hyperglycaemia or other symptoms of poor diabetic control; it can also be a useful addition to education on diet and lifestyle and for patients with inter-current illness. Blood glucose testing is strongly recommended in all patients with type 1 diabetes mellitus.
- (3) Where a patient is judged to be appropriate for testing, but suitable for a PACEF approved lower cost meter and strip, switching should be done as part of a face to face consultation with provision made for further follow-ups if required.
- (4) Where there is shared care between primary care and hospital based specialist teams, it is important that the decision to change meter in primary care is communicated to the specialist service to avoid any potential confusion or misunderstanding.
- (5) Patients should be advised that if their test results with a new meter are radically different from those recorded previously, particularly if they are not experiencing any signs or symptoms that indicate a change in their condition, they should seek urgent medical advice.

Exclusions: When lower cost blood glucose meters and testing strips are not recommended

Following consultation with local diabetic specialists, it has been agreed that the following patient groups should either be excluded from any switch or special consideration should be given before any change takes place.

Patient group	Reason for exclusion or special consideration
Children / adolescents aged less than 18 years of age	Recommend getting agreement with relevant specialist on an individual basis. (Many from this group will also be excluded from switch due to meeting other criteria as specified within this table).
Those with existing or gestational diabetes during pregnancy	Patients should continue with their current test strips. The majority of these patients within Lincolnshire will be using <i>Contour Next</i> .
Those using insulin pumps	May be using specific meters that provide dosing advice on insulin requirements
Those patients, mainly type 1 diabetics, who need the facility to test for ketones	Three meters currently measure ketones: <i>Glucomen LX Plus, Medisense Optium and Optium Xceed</i>
Those who use their meters that support insulin dose calculations or provide additional information on carbohydrate requirements.	Meters supporting insulin dose calculation: <i>Avia Expert, Freestyle Insulinex</i> Meters providing information on carbohydrate requirements: <i>Contour Next</i>
Those who are registered blind or partially sighted.	Will use meters with large displays or with voice guidance. Meters with voice guidance: <i>Caresens N Voice, GlucoRx Nexus Voice,</i>
Those who are being remotely managed by systems such as “Telehealth” or those who are reliant on healthcare professionals to download and retain a log of their results	Meter of choice will vary within this group.
Any patient for whom the GP considers it appropriate that they remain on a specific meter	Meter in use will vary due to individual circumstances. For example those diabetics who are classed as hypoglycaemic unaware and do not experience the usual signs and symptoms of hypoglycaemia.

Please note that the second part of this evaluation, *Prescribing Higher Cost Blood Glucose Testing Meters and Strips*, will be published later in the year.

Introduction

It is common practice in the UK for blood glucose monitoring meters to be provided free of charge direct from the manufacturers to hospital and community based diabetic clinics and to the majority of GP practices. These meters are then provided free to patients with the associated blood glucose testing strips (BGTS) provided on prescription in primary care. Traditionally, the escalating cost of provision of blood glucose testing strips (BGTS) on prescription has caused concern both locally and nationally; in Lincolnshire alone the cost of prescribing of BGTS in 2012/13 was over £2.5M.

Until recently, the different brands of BGTS have been comparably priced, with the main thrust of PACEF advice focusing on reduction in inappropriate use in patients

who either do not need to test at all or who do not need to test as frequently as they do. More recently a number of new products have been launched in the UK that are significantly lower in cost than the brand leaders. The cost comparison provided in Appendix 1 identifies all of the lower cost products and reveals the price difference between them and the brand leaders. It is the purpose of this special edition of the *PACE Bulletin* to:

- (1) Publish the results of a comprehensive review of the products that has recently been undertaken by PACEF. This review results in a number of new products being approved for use for the first time.
- (2) Identify clearly the types of patients that can monitor their blood glucose with a PACEF approved lower cost product.
- (3) Identify clearly the types of patients that will continue to require the more sophisticated higher cost products.
- (4) Review and update existing guidance on appropriateness and frequency of testing.
- (5) Consider the implications of Driver and Vehicle Licensing Agency (DVLA) recommendations on the monitoring of blood glucose in diabetic patients who drive.

Selection of meters included within the review

From a preliminary cost comparison (see Appendix 1), the following products were identified as significantly lower in cost than brand leaders: *Accu-Chek Active* glucose strips, *Element* test strips, *GlucoLab* test strips, *GlucoMen GM Sensors* test strips, *GlucoRx Nexus* test strips, *iCare Advanced* test strips, *Microdot+* test strips, *Mylife Pura* test strips, *Omnitest 3* test strips, *SD Codefree* test strips, *TRUEyou* test strips, *WaveSense JAZZ* test strips and *WaveSense JAZZ Duo* test strips. All of these products are less than £10 for 50 strips compared to the brand leader products that are commonly in excess of £14 for 50 strips. All of the products were evaluated against a list of key criteria to enable PACEF to objectively determine which of the BGTS products should be approved for use and within which patient groups.

Evaluation criteria

The evaluation criteria were as follows:

- (1) Compliance with accuracy standards stipulated in ISO 15197: 2013.
- (2) Memory capacity (450 tests or more); results not easily deletable.
- (3) Ability to download, store and manipulate test results within a personal computer.
- (4) Calibration not required before use.
- (5) Results reported in mmol/l only.
- (6) Automatic turn-on when a strip is inserted.

Additional features and services that were also taken into account were:

- Patient support and clinical review services.
- Volume of blood required for the test sample.

- Acoustic blood glucose reading function for the visually impaired.

Further details on all of these criteria are provided in Appendix 2. Individual product performance against each of the criteria is tabulated below.

Exclusions from the review

At the time of review, no information had been received from the manufacturer relating to *SD Codefree*. This product will be reviewed through the PACEF New Drug Assessment programme once information has been received.

GlucorX original is no longer actively promoted by the manufacturer and has also been excluded from the review. Supplies of strips and accessories are still available for existing patients. New patients requiring a *GlucorX* meter will need to be initiated onto *GlucorX Nexus*.

Table 1: Evaluation Results

Blood Glucose Testing Meter and Strip	Compliance ISO 15197: 2013	Memory capacity (number of test results stored) Minimum 450 tests	Memory not easily deletable	Pack size Number of strips	Expiry of strips after opening	Download result	Calibration not required	Results in mmol/l	Automatic turn-on
<i>Accu-chek Active</i>	Yes	500	√	1 x 50	Approx 18 months post production	Yes	Yes	Yes	Yes
<i>Element</i>	Yes	500	√	2 x 25	Pot has 3 month expiry: 2 x 25 will last 6 months if used consecutively	Yes	Yes	Yes	Yes
<i>GlucorLab</i>	Yes	500	√	2 x 25	Pot has 3 month expiry: 2 x 25 will last 6 months if used consecutively	Yes	Yes	Yes	Yes
<i>GlucorMen GM</i>	Yes	250	√	1 x 50	6 months	Yes	Yes	Yes	Yes
<i>GlucorX Nexus</i>	Yes	1000	√	2 x 25	Pot has 6 month expiry: 2 x 25 will last 12 months if used consecutively	Yes	Yes	Yes	Yes
<i>GlucorX Nexus Mini</i>	Yes	1000	√	2 x 25	Pot has 6 month expiry: 2 x 25 will last 12 months if used consecutively	Yes	Yes	Yes	Yes
<i>GlucorX Nexus</i>	Yes	450	√		Pot has	Yes	Yes	Yes	Yes

Voice					6month expiry: 2 x 25 will last 12 months if used consecutively				
iCare Advanced	Yes	450	√	1 x 50	6 months	Yes	Yes	Yes	Yes
Microdot +	Yes	500	√	1 x 50	6 months	Yes	Yes	Yes	Yes
MyLife Pura	Yes	500	√	2 x 25	Pot has 6month expiry: 2 x 25 will last 12 months if used consecutively	Yes	Yes	Yes	Yes
Omnitest 3	Yes	365	X	2 x 25	Pot has 6month expiry: 2 x 25 will last 12 months if used consecutively	Yes	Yes	Yes	Yes
Omnitest 3 Updated version (available from 28th April 2014)	Yes	500	√	2 x 25	Pot has 6month expiry: 2 x 25 will last 12 months if used consecutively	Yes	Yes	Yes	Yes
TRUEyou	Yes	500	√	50	4 months	Yes	Yes	Yes	Yes
WaveSense JAZZ	Yes	1865	√	50	6 months	Yes	Yes	Yes	Yes
WaveSense JAZZ Duo	Yes	1865	√	50	Pot has 6month expiry: 2 x 25 will last 12 months if used consecutively				

PACEF Recommendation:

After consideration of performance against the set criteria tabulated above, the PACEF approved products are: *Accu-Chek Active, Element, Glucolab, GlucoRx Nexus, GlucoRx Nexus Mini and GlucoRx Nexus Voice, iCare Advanced, Microdot+, MyLife Pura, Omnitest 3 (modified meter available since 28th April 2014) TRUEyou and WaveSense JAZZ*. All of these products can be considered as part of a review and switch programme subject to exclusions detailed below. A small number of lower cost blood glucose testing meters did not make the PACEF approved list due to insufficient memory capacity and deletable memory. Clinicians are reminded that the DVLA stipulate that group 2 drivers (i.e. those who drive lorries or buses) on insulin must provide 3 months of continuous blood glucose records at their annual examination by an independent consultant diabetologist. Products with a limited memory capacity or deletable memory are not suitable for this patient group. Care should be taken to ensure that these products are not prescribed for group 2 drivers. Where review and switch to any of these products is considered, group 2 drivers must be excluded.

Reviewing and changing blood glucose testing meters and strips

- (1) Patients who are currently monitoring their blood glucose who do not fall into the exclusion groups defined below should be identified for review and considered for a switch to a lower cost preferred product.
- (2) Such a review should take into account whether the patient should continue to test at all. Blood glucose testing is unlikely to be necessary in patients controlled on diet and exercise alone. If diagnosed with type 2 diabetes, blood glucose testing is particularly advocated if the patient is on insulin, sulfonylureas or glinides (i.e. glucose lowering therapy) or is experiencing hypoglycaemia, hyperglycaemia or other symptoms of poor diabetic control; it can also be a useful addition to education on diet and lifestyle and for patients with inter-current illness. Blood glucose testing is strongly recommended in all patients with type 1 diabetes mellitus.
- (3) Where a patient is judged to be appropriate for testing, but suitable for a PACEF approved lower cost meter and strip, switching should be done as part of a face to face consultation with provision made for further follow-ups if required.
- (4) Where there is shared care between primary care and hospital based specialist teams, it is important that the decision to change meter in primary care is communicated to the specialist service to avoid any potential confusion or misunderstanding.
- (5) Patients should be advised that if their test results with a new meter are radically different from those recorded previously, particularly if they are not experiencing any signs or symptoms that indicate a change in their condition, they should seek urgent medical advice.

When lower cost blood glucose meters and testing strips are not recommended

Individual patient circumstances need to be taken into consideration when deciding if they are appropriate to be switched to a new blood glucose meter and testing strip. Following consultation with local diabetic specialists, it has been agreed that the following patient groups should either be excluded from any switch or special consideration should be given before any change takes place.

Patient group	Reason for exclusion or special consideration
Children / adolescents aged less than 18 years of age	Recommend getting agreement with relevant specialist on an individual basis. (Many from this group will also be excluded from switch due to meeting other criteria as specified within this table).
Those with existing or gestational diabetes during pregnancy	Patients should continue with their current test strips. The majority of these patients within Lincolnshire will be using <i>Contour Next</i> .
Those using insulin pumps	May be using specific meters that provide dosing advice on insulin requirements
Those patients, mainly type 1 diabetics, who need the facility to test for ketones	Three meters currently measure ketones: <i>Glucomen LX Plus</i> , <i>Medisense Optium</i> and <i>Optium Xceed</i>
Those who use their meters that support insulin dose calculations or provide additional information on carbohydrate requirements.	Meters supporting insulin dose calculation: <i>Avia Expert</i> , <i>Freestyle Insulinex</i> Meters providing information on carbohydrate requirements: <i>Contour Next</i>
Those who are registered blind or partially sighted.	Will use meters with large displays or with voice

	guidance. Meters with voice guidance: <i>Caresens N Voice</i> , <i>Glucorx Nexus Voice</i> ,
Those who are being remotely managed by systems such as “Telehealth” or those who are reliant on healthcare professionals to download and retain a log of their results	Meter of choice will vary within this group.
Any patient for whom the GP considers it appropriate that they remain on a specific meter	Meter in use will vary due to individual circumstances. For example those diabetics who are classed as hypoglycaemic unaware and do not experience the usual signs and symptoms of hypoglycaemia.

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Appendix 1

Cost Comparison: Blood Glucose Testing Strips

<u>Blood glucose testing strip (to be read only with the appropriate meter)</u>	<u>Meter (not prescribable on the NHS)</u>	<u>Indication</u>	<u>Test time</u>	<u>NHS Price per pack of 50</u>
Active glucose strips (Roche Diagnostics)	Accu-Chek Active) Glucotrend (no longer available)	Detection of blood glucose in range 0.6-33.3 mmol/l		£9.95
Advantage Plus test strips (Roche Diagnostics)	Accu-Chek Advantage (no longer available)	Detection of blood glucose in range 0.6-33.3 mmol/l	26 seconds	£15.89
Aviva test strips (Roche Diagnostics)	Accu-Chek Aviva	Detection of blood glucose in range 0.6-33.3 mmol/l	5 seconds	£15.59
BGStar test strips (Sanofi)	BGStar iBGStar	Detection of blood glucose in range 1.1-33.3 mmol/l	6 seconds	£14.73
Breeze 2 test strips (Bayer Diabetes)	Breeze 2	Detection of blood glucose in range 0.6-33.3 mmol/l	5 seconds	£14.87
CareSens N test strips (Spirit Healthcare)	CareSens N	Detection of blood glucose in range 1.11-33.3 mmol/l	5 seconds	£12.75
Compact test strips (Roche Diagnostics)	Accu-Chek Compact Accu-Chek Compact Plus	Detection of blood glucose in range 0.6-33.3 mmol/l		£16.01 (51 strips) £3.89 (17 strips)
Contour test strips (Bayer Diabetes Care)	Contour	Detection of blood glucose in range 0.6-33.3 mmol/l	5 seconds	£15.11 (50) £9.79 (25)
Contour Next test strips (Bayer Diabetes Care)	Contour Next USB Contour Next XT	Detection of blood glucose in range 0.6-33.3 mmol/l	5 seconds	£15.04
Element test strips (Neon Diagnostics)	Element	Detection of blood glucose in range 0.55-33.3 mmol/l	3 seconds	£9.89
FreeStyle test strips (Abbott)	FreeStyle Freedom (no longer available) FreeStyle Mini (no longer available)	Detection of blood glucose in range 1.1-27.8 mmol/l	5 seconds	£15.60
FreeStyle Lite test strips (Abbott)	FreeStyle Lite FreeStyle Freedom Lite (no longer available)	Detection of blood glucose in range 1.1-27.8 mmol/l	5 seconds	£15.60
FreeStyle Optium test strips (Abbott)	FreeStyle Optium	Detection of blood glucose in range 1.1-27.8 mmol/l	5 seconds	£15.50
Glucolab test strips (Neon Diagnostics)	Glucolab	Detection of blood glucose in range 0.55-33.3 mmol/l	5 seconds	£9.89
Glucomen Sensors test strips (Menarini Diagnostics)	Glucomen Glyco (no longer available) Glucomen PC (no longer available)	Detection of blood glucose in range 1.1-33.3 mmol/l	30 seconds	£14.59
Glucomen GM Sensors test strips (Menarini Diagnostics)	Glucomen GM	Detection of blood glucose in range 0.6-33.3 mmol/l	7 seconds	£9.95
Glucomen LX Sensors (Menarini Diagnostics)	Glucomen LX (no longer available)	Detection of blood glucose in range 1.1-33.3 mmol/l	4 seconds	£15.39
Glucomen Visio Sensor (Menarini Diagnostics)	Glucomen Visio (no longer available)	Detection of blood glucose in range 1.1-33.3 mmol/l	10 seconds	£15.50

GlucorX Original test strips (GlucorX)	GlucorX Original	Detection of blood glucose in range 1.1-33.3 mmol/l	7 seconds	£9.45
GlucorX Nexus test strips (GlucorX)	GlucorX Nexus	Detection of blood glucose in range 1.1-33.3 mmol/l	5 seconds	£9.45
iCare Advanced test strips (iCare)	iCare Advanced	Detection of blood glucose in range 1.1-33.3 mmol/l	6 seconds	£9.70
<i>iCare Advanced Solo test strips (iCare)</i>	<i>iCare Advanced</i>	Detection of blood glucose in range 1.1-33.3 mmol/l	6 seconds	£13.50
<i>IME-DC test strips (Arctic)</i>	<i>IME-DC</i>	Detection of blood glucose in range 1.1-33.3 mmol/l	10 seconds	£14.10
<i>Mendor Discreet (Merck Serono)</i>	<i>Mendor Discreet</i>	Detection of blood glucose in range 1.1-33.3 mmol/l	5 seconds	£14.75 (2x25 test strip cassette)
Microdot+ test strips (Cambridge Sensors)	Microdot+	Detection of blood glucose in range 1.1-29.2 mmol/l	10 seconds	£9.99
<i>Mobile Test Cassette (Roche Diagnostics)</i>	<i>Accu-Chek Mobile</i>	Detection of blood glucose in range 0.3-33.3 mmol/l	5 seconds	£31.54 (100 tests)
<i>MyGlucoHealth test strips (Entra Health)</i>	<i>MyGlucoHealth</i>	Detection of blood glucose in range 0.6-33.3 mmol/l	3 seconds	£15.98
MyLife Pura test strips (Ypsomed)	MyLife Pura MyLife Pura X	Detection of blood glucose in range 0.6-33.3 mmol/l	5 seconds	£9.50
MyLife Unio test strips (Ypsomed)	MyLife Unio	Detection of blood glucose in range 0.6-33.3 mmol/l	5 seconds	£9.50
Omnitest 3 test strips (B.Braun)	Omnitest 3	Detection of blood glucose in range 0.6-33.3 mmol/l		£9.89
<i>One Touch test strips (LifeScan)</i>	<i>One Touch Profile (no longer available)</i>	Detection of blood glucose in range 0-33.3 mmol/l	45 seconds	£14.48 (can't find on C&D)
<i>One Touch Ultra test strips (LifeScan)</i>	<i>One Touch Ultra2 One Touch Ultra Easy One Touch Ultra Smart (no longer available) One Touch Ultra (no longer available)</i>	Detection of blood glucose in range 1.1-33.3 mmol/l	5 seconds	£11.99
<i>One Touch Verio test strips (LifeScan)</i>	<i>One Touch Verio Pro One Touch Verio IQ</i>	Detection of blood glucose in range 1.1-33.3 mmol/l	5 seconds	£14.99
<i>One Touch Vita test strips (LifeScan)</i>	<i>One Touch Vita</i>	Detection of blood glucose in range 1.1-33.3 mmol/l	5 seconds	£15.07
<i>Prestige Smart System test strips (Nipro Diagnostics)</i>	<i>Prestige Smart System (no longer available)</i>	Detection of blood glucose in range 1.4-33.3 mmol/l	10-50 seconds	£14.79
SD Codefree test strips (SD Biosensor)	SD Codefree	Detection of blood glucose in range 0.6-33.3 mmol/l	5 seconds	£6.99
<i>Sensocard test strips (BBI Healthcare)</i>	<i>Sensocard Plus</i>	Detection of blood glucose in range 1.1-33.3 mmol/l	5 seconds	£16.30
<i>TRUEone test strips (Nipro Diagnostics)</i>	<i>TRUEone</i>	Detection of blood glucose in range	5 seconds	£14.99

		1.1-33.3 mmol/l		
<i>TRUE</i> result test strips (NiproDiagnostics)	<i>TRUE</i> result <i>TRUE</i> result twist	Detection of blood glucose in range 1.1-33.3 mmol/l	4 seconds	£14.99
<i>TRUE</i> Track Smart System (NiproDiagnostics)	<i>TRUE</i> Track	Detection of blood glucose in range 1.4-33.3 mmol/l	10 seconds	£14.99
<i>TRUE</i>you test strips (NiproDiagnostics)	<i>TRUE</i>you	Detection of blood glucose in range 1.1-33.3 mmol/l	4 seconds	£9.92
<i>WaveSense</i> JAZZ test strips (AgaMatrix)	<i>WaveSense</i> JAZZ	Detection of blood glucose in range 1.1-33.3 mmol/l	6 seconds	£9.87
<i>WaveSense</i> JAZZ Duo test strips (AgaMatrix)	<i>WaveSense</i> JAZZ	Detection of blood glucose in range 1.1-33.3 mmol/l	6 seconds	£9.95

Testing strips costing £10 or less for 50 strips are highlighted in **bold**. All prices quoted are from the *Chemist and Druggist* Price List February 2014.

Appendix 2: Evaluation Criteria

The following evaluation criteria were identified:

(1) Compliance with accuracy standards stipulated in ISO 15197: 2013

Blood glucose meters have to comply with accuracy requirements stipulated by the International Organisation for Standardisation (ISO). The most recent revision of this standard was published earlier this year and is referred to as ISO 15197:2013. The table below summarizes the requirements of ISO 15197: 2013 compared to the previous standard, ISO 15197: 2003:

Standard	ISO 15197:2003	ISO 15197:2013
Accuracy of tests	95% of all readings within $\pm 20\%$ of reference glucose levels $>75\text{mg/dl}$ and within $\pm 15\text{ mg/dL}$ of the reference for glucose levels $\leq 75\text{mg/dl}$	95% of all readings within $\pm 15\%$ of the reference glucose levels $\geq 100\text{mg/dl}$ and within $\pm 15\text{ mg/dL}$ of the reference for glucose levels $\leq 100\text{mg/dl}$
Specifications for outlier results	None	99% of reading within zones A & B of the consensus error grid.
Number of reagent lots required for testing	1	3

The 2013 standards are more stringent and require a greater level of accuracy than the 2003 version. There is an agreed transition period with the new standards becoming mandatory within the next 3 years. PACEF were concerned to determine which of the products met 2013 standards already.

PACEF Comment:

Of the lower cost meters evaluated, the following already meet ISO 15197: 2013 accuracy standards: *Accu-Chek Active, Element, GlucoLab, GlucoMen GM, and GlucoRx Nexus, GlucoRx Nexus Mini, GlucoRx Nexus Voice, iCare Advanced, Mylife Pura, Omnitest 3, TRUEyou and WaveSense JAZZ*. The manufactures of *Microdot+* (Cambridge Sensors) have confirmed that they are compliant with ISO 15197: 2013 although this was confirmed following assessment by a third party and not by a study funded by their own company.

(2) Memory capacity (450 tests or more); results not easily deletable

This is defined as the number of test results that can be stored in the internal memory of the meter. The DVLA now stipulate that drivers receiving treatment with insulin who drive lorries or buses are required to provide 3 months of continuous blood glucose records at their annual examination by an independent Consultant Diabetologist. DVLA guidance relating to prospective licence applications also states that a meter with a memory function must be used and that all meters must be taken to the medical examination when the person's GP or diabetic consultant will complete the DVLA questionnaire with the applicant. If a person is testing at each mealtime and/or insulin dose and before they drive they could be testing at least 5 times a day; this equates to 450 tests based on an average 3 month period of 90 days and explains the significance of the meter having to have a memory capacity in the region of 450 tests. DVLA recommendations are summarized in Appendix 3.

Due to the driving regulations described above and the necessity for patients with type 1 diabetes in particular to keep an accurate record of blood glucose readings, it is important that test results cannot easily be deleted from the meter's memory. Healthcare professionals need to be able to download results either directly from the meter or to have access to already downloaded results to inform their consultation with the patient.

PACEF Comment:

Memory capacity

Of the lower cost products evaluated, the following have a memory capacity of at least 450 tests: *Accu-Chek Active, Element, GlucoLab, GlucoRx Nexus, GlucoRx Nexus Mini, GlucoRx Nexus Voice, iCare Advanced, Microdot +, Mylife Pura, Omnitest 3 - modified meter available since 28th April 2014, TRUEyou and WaveSense JAZZ. WaveSense Jazz has the largest memory capacity of 1865 tests; at test 1866, result number 1 is over-written and so on; 1865 tests equates to 1 years' worth of tests for a patient testing 5 times daily.*

***Omnitest 3* supplied before 28th April 2014 has the capacity to store 365 tests which equates to approximately 4 tests a day; *Glucomen GM* has the capacity to store 250 tests. None of these products currently has sufficient memory capacity to comply with DVLA guidance in patients that need to test more than 4 times a day.**

Delete memory function

Of the lower cost products evaluated, the following do not present the risk of having their memory accidentally deleted; *Accu-Chek Active, Element, GlucoLab, Glucomen GM, GlucoRx Nexus, GlucoRx Nexus Mini, Glucorex Nexus Voice, iCare Advanced, Microdot +, Mylife Pura, TRUEyou and WaveSense JAZZ.*

***Omnitest 3* had a function which allows for test results stored in the memory to be deleted. The manufacturer confirmed that they were unable to remove this function and that it is widely unrecognized as it is never promoted to patients.**

Since 28th April 2014 a modified version of Omnitest 3 has been made available which has had the delete test result function removed. B Braun the manufacturer of this meter has confirmed that priority will be given for supplies of the modified meter to areas such as Lincolnshire that have included the updated version for use on their approved lists/formularies.

There are currently no plans to replace the older style Omnitest 3 meters that already have been distributed. However for those patients who are group 2 drivers or those where the healthcare professional think they would benefit from having the meter with the larger memory capacity individual arrangements can be made to replace with the updated version.

- (3) Ability to download, store and manipulate test results within a personal computer

Most meters offer the facility for blood glucose readings to be downloaded onto the patient's own personal computer with many companies also providing software to enable patient information to be presented in a variety of ways (e.g. log book of results, graphs showing trends etc.). Some meters also enable results to be uploaded to a password protected web-based site from which healthcare professionals such as the patient's diabetic nurse specialist or GP can download or view results. Some patients are insufficiently IT literate to fully benefit from these features.

PACEF Comment:

Of the lower cost products evaluated, the following had this facility: *Accu-Chek Active, Element, GlucoLab, GlucoMen GM, and GlucoRx Nexus, iCare Advanced, Microdot + Mylife Pura, Omnitest 3, TRUEyou and WaveSense JAZZ.*

- (4) Calibration not required before use

PACEF reviewed whether each meter required calibration before use. Frequent need to re-calibrate equipment is a clear disadvantage that can compromise ease of use.

PACEF Comment:

Of the lower cost products evaluated, the following do not require recalibration before each use: *Accu-Chek Active, Element, GlucoLab, GlucoMen GM, and GlucoRx Nexus, iCare Advanced, Microdot +, Mylife Pura, Omnitest 3, TRUEyou and WaveSense JAZZ.*

- (5) Results reported in mmol/l only

It is standard practice within the UK for all blood glucose meters to report results in terms of mmol/l. This practice varies across Europe where some countries report results in mmol/dl. PACEF preference was for mmol/l only.

PACEF Comment:

Of the lower cost products evaluated, the following report results in mmol/l only: *Accu-Chek Active, Element, GlucoLab, GlucoMen GM, GlucoRx Nexus, GlucoRx Nexus Mini and GlucoRx Nexus Voice, iCare Advanced, Microdot +, Mylife Pura, Omnitest 3, TRUEyou and WaveSense JAZZ.*

- (6) Automatic turn on when a strip is inserted

The majority of meters are intuitive and turn on automatically when a strip is inserted. Some people may experience problems if they have to switch on the meter before use.

PACEF Comment:

Of the lower cost products evaluated, the following turn on automatically when a strip is inserted: *Accu-Chek Active, Element, Glucolab, GlucoMen GM, GlucoRx Nexus, Glucorex Nexus Mini, GlucoRx Nexus Voice, iCare Advanced, Microdot +, MyLife Pura, Omnitest 3, TRUEyou, WaveSense Jazz.*

Additional features/ services

Patient support and clinical review services

PACEF were concerned to determine whether the lower cost products were less well supported with added value services than the brand leaders (e.g. provision of a patient help-line).

PACEF Comment:

Of the lower cost products evaluated, all offer a patient helpline within office hours, although, from the information provided it was difficult for PACEF to objectively evaluate and compare these services. A number of the companies offer clinical review services designed to support practices to identify appropriate patients, review appropriateness of testing and support switching from higher cost products. PMOS Prescribing Advisors have more information on what support is available to support, reviews and the provision of training and education to both health care professionals and patients, alternatively practices may wish to contact the suppliers/ manufacturers of the strips and meters themselves.

Volume of blood required for the test sample

The volume of blood required for the test sample is important as it can be difficult for some patients (e.g. the elderly) to obtain an adequately sized sample. For the purposes of the evaluation, 0.3µl was considered a small volume, 0.5 µl average volume.

PACEF Comment:

Of the lower cost products evaluated, the following require a low volume blood sample: *Element (0.3µl), and Omnitest 3 (0.3µl).*

Acoustic blood glucose reading function for the visually impaired

Patient who are registered blind or partially sighted may benefit from the use of meters which provide an acoustic blood glucose reading function.

PACEF Comment:

Of the lower cost products evaluated, the *GlucoRx Nexus Voice* provides guidance for those who are visually impaired. It has a lower memory capacity than the other *Glucorex* meters; 500 tests compared to 1000 tests for the *GlucoRx Nexus* and *GlucoRx Nexus Mini*. However, patients using the voice

meter will not be driving and therefore the lower memory capacity is of limited significance.

Expiry dates of test strips

The minimum expiry date for these lower cost blood glucose test strips is three months from the time the pot of test strips is opened. For those testing on average twice a day this means that the supply of strips will be exhausted before this three month period is over. For those that test infrequently i.e. once or twice a week then test strips with an expiry date of at least 6 months from the time the pot is opened might be a more cost effective option.

The table below lists all of the low cost blood glucose test strips on the approved list and states what the expiry date is from the time the pot of strips is opened.

To extend the expiry date of useable strips, a number of manufacturers have packaged their strips in small pack sizes e.g. 2 x 25 strips. Therefore if the pots of strips are opened consecutively this extends the total time the supply of 50 strips can be used. For example 2x25 strips with an expiry date of 3 months at the time of opening if used consecutively can last in total a maximum of 6 months.

Comparison of expiry dates

Blood glucose strip	Pack size	Shelf life of strips once opened.
Accu-Chek Active	50	Expiry date on strip pot usually approx. 18 months post production
Element	2 x 25	*6 months
Glucolab	2 x25	*6 months
GlucoRX Nexus	2x25	**12 months
Icare Advanced	50	6 months
Microdot +	50	6 months
Mylife Pura	2 x 25	**12 months
Omnitest 3	50	6 months
TRUEyou	50	4 months
WaveSense JAZZ	1 x 50	*6 months
WaveSense JAZZ Duo+	2 x 25	**12 months

*Pot has 3 month expiry. 6 months if used consecutively

** Pot has 6 month expiry. 12 months if used consecutively

+ WaveSense Jazz test strips available in duo pack of 2 x 25 for those who test infrequently.

Appendix 3: Driver and Vehicle Licensing Agency (DVLA) Recommendations

DVLA Recommendations are as follows:

Insulin-treated: Group 1 (i.e. those who drive motor bikes or cars) – Must not have more than one episode of hypoglycaemia requiring assistance of another person within the preceding 12 months. There must be appropriate BGM;

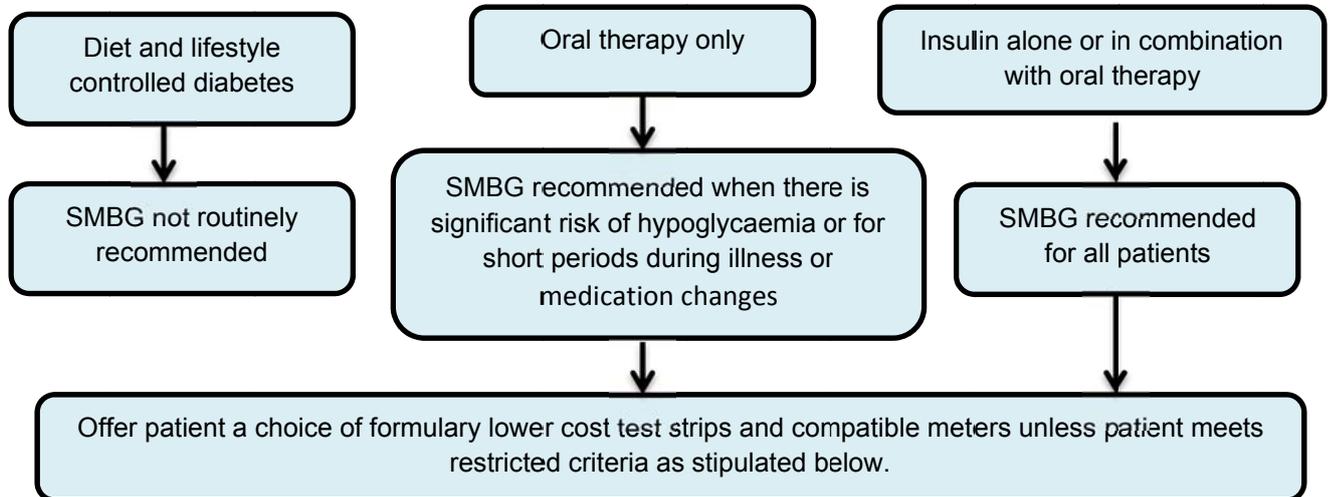
Insulin-treated: Group 2 (i.e. those who drive lorries or buses) – Must have no episodes of hypoglycaemia requiring the assistance of another person within the preceding 12 months. The patient must regularly monitor BG at least twice daily and at times relevant to driving using a glucose meter with a memory function to measure and record BG levels. At the annual examination by the independent Consultant Diabetologist, 3 months of BG readings must be available.

Managed by medicines carrying a risk of hypoglycaemia (including sulfonylureas and glinides): Group 1 – Must not have more than one episode of hypoglycaemia requiring assistance of another person within the preceding 12 months. It may be appropriate to monitor BG regularly and at times relevant to driving to enable the detection of hypoglycaemia.

Managed by medicines carrying a risk of hypoglycaemia (including sulfonylureas and glinides): Group 2 – Must have no episodes of hypoglycaemia requiring the assistance of another person within the preceding 12 months. The patient must regularly monitor BG at least twice daily and at times relevant to driving.

PACEF guidance on use of lower cost blood glucose strips

Guidance on Self-Monitoring blood glucose (SMBG)



Meter	Test strips	Price (for 50 strips)	Comments This column provides some details of the features of each meter. It is meant only as a guide, for more detail please refer to the product information for each meter.
Accu-Chek Active	Accu-Chek Active	£9.95	Additional features the meter can provide blood glucose averages for 7, 14, 30 & 90 days. The meter screen is back lit which aids visibility in poor light conditions. The meter has inbuilt alarms to notify if too little blood applied to test strip, strip expiry warning, pre & post meal markers and test reminders. Expiry of test strips on pot – not reduced on opening – usually 18 months post production so suitable for infrequent testers.
Element	Element	£9.89	Large display, meal exercise & medication settings Low volume blood sample 0.3µl
Glucolab	Glucolab £9.89 for 50	£9.89	Medium size meter that is easy to hold, meal exercise & medication settings, large display.
GlucorX Nexus	GlucorX Nexus	£9.95	Large LCD screen with backlight. Before & after meal settings. Large memory – 1000 test results
GlucorX mini	GlucorX Nexus	£9.95	Compact design, before & after meal settings. Large memory – 1000 test results
GlucorX Nexus Voice	GlucorX Nexus	£9.95	Voice guidance for the visually impaired, ketone warning, 4 alarms, and meal markers.
iCare advanced	iCare Advanced	£9.70	Large display, light meter with battery weighs 50g.
Microdot +	Microdot	£9.99	Insulin data entry, suitable for telemedicine.
MyLife Pura	MyLife Pura	£9.50	Medium size meter with strips suitable for those with impaired vision. Extra-large display.
Omnitest 3 9 modified meter available since 28th April 2014.	Omnitest 3	£9.89	Modified meter now with increased memory capacity of 500 tests and with the delete test result function removed. Large screen, 5 alarm settings,
TRUEyou Mini	TRUEyou	£9.92	Small USB style meter
WaveSense Jazz	WaveSense Jazz	£9.87	Large display with backlight. No slip rubber grip. Pre-set meal time settings. Large memory - 1865 test results

Patient groups which should either be excluded from any switch or special consideration should be given before any change takes place

Patient group
Children / adolescents aged less than 18 years of age
Those with existing or gestational diabetes during pregnancy
Those using insulin pumps
Those patients mainly type 1 diabetics who require the facility to test for ketones
Those who use their meters to provide insulin dose calculations or additional information on carbohydrate requirements.
Those who are registered blind or partially sighted.
Those who are being remotely managed by systems such as "Telehealth"
Any patient for whom the GP considers it appropriate that they remain on a specific meter