**Home Blood Glucose Monitoring (BGM) in Type 2 Diabetes**

**Background**

Glucose testing meters licensed for use in the United Kingdom must now conform to International Organisation for Standardization (ISO 15197) which are a detailed set of standards which have recently been updated. It is clear that there has been concern at the lack of consistent performance of many BGTS after regulatory clearance and as a result the new standard and tighter accuracy will be an important criterion for consideration\(^1\). The ISO 15197 standard requires a complex series of tests and requirements to be completed internally with the results assessed by a regulatory notifying body. All manufacturers who produce glucose testing meters must conform to an ISO guideline\(^1\).

The move to the tighter 2013 standards is a positive advance as it will mean blood glucose meters will need to be more accurate and therefore provide greater confidence to us as users of the meters.

It is recognised that there needs to be a balance between the provision of a meter that meets the needs of the individual patient and a need to restrict the number of meters that are being used in primary care for quality and safety reasons. The availability of a large number of glucose testing meters on the market and the large disparity in pricing of the associated testing strips necessitates the need for a robust approach to ensure only cost effective and accurate devices are being used by the NHS.

**Aim of the guidance**

- To ensure that meters used locally have surpassed the accuracy requirements for ISO 15197:2013
- To standardise and rationalise blood glucose testing meters across our local footprint and reduce variation and waste.
- To assist clinicians and patients in the selection of appropriate blood glucose meters to enable self-monitoring of blood glucose levels
- To provide patients with a choice of meters that are patient friendly, reliable and represent good value for money to the NHS

**This guidance does NOT apply to the following groups:**

- **People with diabetes on dialysis** - Not all meters are suitable for people with diabetes on dialysis. Please consult your Diabetes Specialist Nurse for further advice.
- **Patients with type 1 diabetes** - Patients with type 1 diabetes will be using meters selected depending on their individual requirements and should not be switched to meters on this formulary.

**This guidance includes:**

- An approved list of blood glucose testing meters for non-complex patients with type 2 diabetes that are not being managed by secondary care or the diabetes clinic
- An approved specialist formulary of blood glucose testing meters for patients with specific needs, including a meter that meets specific requirements for pregnancy
- Advice on who should be self-testing blood glucose and in which circumstances
- Advice on DVLA Guidance on Glucose monitoring in diabetics
The guidance encourages clinicians to switch appropriate patients with type 2 diabetes mellitus to one of the blood glucose testing meters from the formulary, ensuring that the meter is suitable for the individual patient in terms of ease of use and patient acceptability.

This guidance has only selected devices which conform to the updated quality standards. Patients who purchase a meter for use outside the recommendations made in these guidelines should not be prescribed strips and lancets in Primary Care.

This document is for guidance only and there will be circumstances where an alternative machine may be required, however it is paramount that the blood glucose testing machine recommended conforms to the new ISO15197 regulations.

**ISO Guidance**

ISO 15197:2013 specifies requirements for *in vitro* glucose monitoring systems that measure glucose concentrations in capillary blood samples, for specific design verification procedures and for the validation of performance by the intended users. ISO 15197:2013 is applicable to manufacturers of such systems and those other organizations (e.g. regulatory authorities and conformity assessment bodies) having the responsibility for assessing the performance of these systems.

**DVLA Guidance on Glucose monitoring in diabetics**

Table 1: DVLA guidance which advises of the requirements for patients with type 2 diabetes managed with medication other than insulin.
Patients being treated with insulin must be prescribed BGTS to ensure that they adhere to the requirements of the DVLA. Those patients undergoing changes to their treatment or treated with oral medication which can cause hypoglycaemia (sulfonylureas, glinides) should also be prescribed BGTS and be hypoglycaemia aware; individuals should not drive if they are hypoglycaemic. For further information please follow the link: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/526635/assessing-fitness-to-drive-a-guide-for-medical-professionals.pdf

All drivers with diabetes must follow the information provided by the Driver and vehicle Licensing Authority (DVLA) which may Include notifying the DVLA of changes in health status.

Due to maximal driving time allowed by UK Law for bus and lorry drivers, Glucose testing meters should have a minimum memory of 450 readings to be eligible for inclusion in a doctors assessment of the patients diabetes.

Guidance for Self- Monitoring of blood Glucose Testing

Following recent NICE guidance for type 2 Diabetes it has been highlighted that not all patients will benefit from glucose testing therefore guidance on those patients who would benefit has been included². When offering self-monitoring of blood glucose levels for adults with type 2 diabetes, it is paramount that the current medical standards of fitness to drive is taken in to account.

NICE guidelines [NG28] Type 2 diabetes in adults: Management (December 2015) clearly sets out for whom glucose testing is appropriate and advise that self-monitoring is not encourage routinely for all patients. The guidelines in relation to self-monitoring is summarised as follows:

Do not routinely offer self-monitoring of blood glucose levels for adults with type 2 diabetes unless:
- the person is on insulin or
- there is evidence of hypoglycaemic episodes or
- the person is on oral medication that may increase their risk of hypoglycaemia while driving or operating machinery or
- the person is pregnant, or is planning to become pregnant.

Consider short-term self-monitoring of blood glucose levels in adults with type 2 diabetes (and review treatment as necessary):
- when starting treatment with oral or intravenous corticosteroids or
- to confirm suspected hypoglycaemia.

Be aware that adults with type 2 diabetes who have acute intercurrent illness are at risk of worsening hyperglycaemia. Review treatment as necessary

If adults with type 2 diabetes are self-monitoring their blood glucose levels, carry out a structured assessment at least annually.

The assessment should include:
- the person's self-monitoring skills
- the quality and frequency of testing
- checking that the person knows how to interpret the blood glucose results and what action to take
- the impact on the person’s quality of life
- the continued benefit to the person
- the equipment used

Selection on meters

All manufacturers were requested to provide detailed information of the devices to be considered for formulary inclusion. An initial minimum selection criteria was used as specified below to exclude any meters that did not meet the desired criteria.

1. ISO compliance which can be independently verified
2. Price < £10.00 per 50 strips
3. Memory of more than 450 readings which cannot be deleted to comply with DVLA requirements
4. Strips should have at least 6 months expiry once opened
5. Price stability guaranteed by Manufacturer
6. Autocoding device
7. Set to read in mmol/l as per MHRA guidance

A detailed review of the manufacturer’s evidence was undertaken by a Prescribing Advisor and Lead Diabetes Nurse. Devices which met the required selection criteria were taken to a multidisciplinary working group consisting of various stakeholders working across both Bart’s Health and Primary care, which are detailed below.

- Diabetes Specialist nurses (Representing Waltham forest, Tower Hamlets and Barts Health NHS trust)
- GP with specialist interest in Diabetes (Waltham Forest)
- Medicines Management pharmacists (Representing Tower Hamlets and Waltham forest CCG)
- Community Pharmacist (LPC representative)

A scoring process was undertaken to evaluate the preferred BGTS and meter.

Devices were selected on added value parameters including

- Blood sample size
- Time taken for sample to be read (Seconds)
- Quantity of strips provided with the device

The final list constitutes of the meters that met all the essential criteria based on the recommendations of a focus group.

Supplies of recommended meters

Company representatives can be contacted for stocks of the recommended meters and control solutions to supply to patients. The details of the representatives can be found on the formulary guidance. The meter will be provided free of charge by the manufacturer via their General Practice or Specialist Nurse, and the testing strips and lancets will be supplied on prescription by the patient’s GP.
This evaluation will not be re-reviewed until May 2018. Any new BGTS listed in the Drug Tariff before this review date will only be evaluated by the Waltham Forest and East London Prescribing Group (WEL) if it is considered to have a significant impact on the WEL health economy. WEL group will not accept any new information or evidence for any BGTS unless directed by the GMMMG sub-groups for review.

**Training**

Most meters have the same basic functions with regards to testing of blood glucose. However, it is important that patients should be given training on how to use the meter that is supplied. Training should cover the following:

- The purpose of testing
- How often to test and when to test
- How to use the meter and strips and lancing device
- How to dispose of sharps and expired strips
- When to seek advice from their healthcare professional
- How to register with the company for advice and support with meter and to in order to receive free batteries and control solutions

**Reference:**

Last accessed: 2th June 2016


### Table 1: NHS Waltham Forest and Tower Hamlets recommended BGM Meters for patients with type 2 diabetes

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th><em>GlucoRx</em></th>
<th>Neon Diagnostics</th>
<th>Lifescan Uk</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Name of meter</strong></td>
<td><em>GlucoRx Nexus</em></td>
<td><em>GluNEO</em></td>
<td><em>One Touch Select Plus</em></td>
</tr>
<tr>
<td><strong>Name of strips</strong></td>
<td><em>Nexus Test strips</em></td>
<td><em>GluNEO Test Strips</em></td>
<td><em>One Touch Select Plus</em></td>
</tr>
<tr>
<td><strong>Expiry after opening</strong></td>
<td>2x25 strips – 6 months expiry each</td>
<td>2x25 strips – 6 months expiry each</td>
<td>1x 50 strips – 18 months</td>
</tr>
<tr>
<td><strong>Key Features</strong></td>
<td>• 0.5µL blood volume; &lt;br&gt;• 30 – 60% haematocrit range &lt;br&gt;• 1.1– 33.3mmol/L Test Range &lt;br&gt;• Memory – up to 1000 readings &lt;br&gt;• Large LCD screen with backlight &lt;br&gt;• 5 seconds reaction time &lt;br&gt;• Strip ejection avoids blood contact &lt;br&gt;• Battery life for up to 500 tests</td>
<td>• 0.5ul Sample Volume required &lt;br&gt;• 20 ~ 65% haematocrit Range &lt;br&gt;• 0.6 ~ 33.3 mmol/L Test Range &lt;br&gt;• Memory for 500 tests &lt;br&gt;• Large screen, back light feature &lt;br&gt;• Results in just 5 seconds &lt;br&gt;• Tests Strip ejector &lt;br&gt;• Battery Life runs for 1,000 tests</td>
<td>• 1.0 µl sample volume &lt;br&gt;• 30-55% Haematocrit Range &lt;br&gt;• 1.1 to 33.3mmol/L Test Range &lt;br&gt;• Memory for 500 tests &lt;br&gt;• Battery Life runs for 3000+ tests &lt;br&gt;• Results in just 5 seconds</td>
</tr>
<tr>
<td><strong>Unique features</strong></td>
<td>• Ketone warning, 4 alarms and discreet testing and day averages function &lt;br&gt;• A PC download link facility &lt;br&gt;• All meter accessories are free</td>
<td>• Easy to use</td>
<td>• 3-Colour Range Indicator instantly informing patients if your results are low, high or in range &lt;br&gt;• Day averages function</td>
</tr>
<tr>
<td><strong>Ideally suited for :</strong></td>
<td>• Ideal for those with dexterity issues &lt;br&gt;Test strip area lights up to help patients who are visually impaired</td>
<td>• Patients with dexterity problems &lt;br&gt;-Large screen for patients with visual impairment &lt;br&gt;-Company has multi-lingual advisors</td>
<td>• Multi-lingual advisors to provide support &lt;br&gt;-Colour sure technology ideal for newly diagnosed patients with type 2 diabetes</td>
</tr>
<tr>
<td><strong>Customer Care contact number</strong></td>
<td>Sunil Bedi 07880031034</td>
<td>Heidi Earl 07852 393 778</td>
<td>Hamedah Shkokani 07500 063 316</td>
</tr>
</tbody>
</table>
### Table 2: NHS Waltham Forest approved formulary for patients with type 2 diabetes with specific requirements

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Menarini Diagnostics</th>
<th>GlucoRx</th>
<th>GlucoRx</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of meter</td>
<td>GlucoMen Areo</td>
<td>GlucoRx Nexus mini</td>
<td>GlucoRx Nexus Voice</td>
</tr>
<tr>
<td><img src="image" alt="GlucoMen Areo" /></td>
<td><img src="image" alt="GlucoRx Nexus mini" /></td>
<td><img src="image" alt="GlucoRx Nexus Voice" /></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Name of strips</th>
<th>GlucoMen Areo Sensor</th>
<th>GlucoRx Nexus Test Strips</th>
<th>GlucoRx Nexus Test Strips</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expiry after opening</td>
<td>1x 50 – 6 months</td>
<td>2 x 25pcs with 6 months expiry each</td>
<td>2x25 strips – 6 months expiry each</td>
</tr>
</tbody>
</table>

**Key Features**

- 0.5ul Sample Volume required
- Large, Glow in the Dark display
- Large Memory for 730
- 10 - 70% Haematocrit Range
- Test Range - 1.1 - 33.3 mmol/L
- Min of 1000 tests or about a year

- 0.5µL blood volume;
- 30 – 60% haematocrit range
- 1.1– 33.3mmol/L Test range
- Memory – up to 1000 readings
- 5 seconds reaction time
- Battery life for up to 500 tests

- 0.5µL blood volume;
- 30 – 60% haematocrit range
- 1.1– 33.3mmol/L Test range
- Memory – Up to 450 readings
- 5 seconds reaction time
- Battery life for up to 500 tests
- Tests Strip ejector

**Unique Features**

- Meal marker functionality
- Quick link technology
- Hypo/hyper alerts
- Free diabetes diary application for your smartphone or tablet device
- Contactless Download

- More compact & convenient size.
- multiple language meter guides
- discreet
- testing option and day averages
- function

- Talking meter ideal for the visually impaired

**Ideally suited for:**

- Larger strip to address dexterity issues
- Large screen for patients who are visually impaired
- Patients who are pregnant
- Patients who require a discreet meter
- Designed with visually impaired patients

**Customer Care contact number**

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