



North West  
Commissioning Support Unit

# **Blood Glucose Test Strip (BGTS) evaluation protocol and results**

*May 2015*

*Version 2.0*

*(Not to be reviewed before May 2016)*



## DOCUMENT CONTROL

### Document Location

Copies of this document can be obtained from:

|                   |  |
|-------------------|--|
| <b>Name:</b>      | Medicines Optimisation Team  |
| <b>Address:</b>   | North West CSU<br>St James's House<br>Pendleton Way<br>Salford<br>M6 5FW |
| <b>Telephone:</b> | 0161 212 5680  |

### Revision History

The latest and master version of this document is held on the Medicines Management SharePoint:

| REVISION DATE | ACTIONED BY | SUMMARY OF CHANGES  | VERSION |
|---------------|-------------|---|---------|
| 25/02/2014    | J Cheung    | Initial draft produced for review by GMCSU MO Team  | 0.1     |
| 26/02/2014    | J Cheung    | Comments from GMCSU MO Team   | 0.2     |
| 11/03/2014    | J Cheung    | Comments from local MO Teams  | 0.3     |
| 11/04/2014    | J Cheung    | Comments from Oldham CCG BGTS Steering Group  | 0.3     |
| 23/05/2014    | J Cheung    | Comments following v0.3 review  | 0.4     |
| 27/01/2014    | J Cheung    | Re-evaluation following updated Drug Tariff(January 2015) and new evidence submitted by manufacturers | 1.1     |
| 31/03/2015    | J Cheung    | Further update following pending evidence submitted by manufacturers noted in draft v1.1              | 1.2     |
| 27/04/2015    | J Cheung    | Updated following GMMMG and responder comments  | 1.3     |

### Approvals

This document must be approved by the following before distribution:

| NAME      | TITLE   | DATE OF ISSUE | VERSION |
|-----------|---|---------------|---------|
| CCG Leads | Blood Glucose Test Strip (BGTS) evaluation protocol             |               | 0.4     |
| CCG Leads | Blood Glucose Test Strip (BGTS) evaluation protocol and results |               | 1.1     |
| GMMMG     | Blood Glucose Test Strip (BGTS) evaluation protocol and results | 23/04/2015    | 1.2     |

### Distribution

This document has been distributed to:

| NAME          | TITLE   | DATE OF ISSUE | VERSION | DATE OF REVIEW |
|---------------|---|---------------|---------|----------------|
| CCG Leads     | Blood Glucose Test Strip (BGTS) evaluation protocol             |               | 1.0     |                |
| GMMMG members | Blood Glucose Test Strip (BGTS) evaluation protocol and results | 11/05/2015    | 2.0     | May 2016       |
|               |   |               |         |                |

*Whilst this document may be printed, the electronic version maintained on the Greater Manchester Medicines Management Group (GMMMG) website is the controlled copy and should be used in its entirety. Any printed copies of this document are not controlled. It is the responsibility of every individual to ensure that they access the most current version of this document.*

## 1 Background

1.1 The Greater Manchester Medicines Management Group (GMMMGM) aims to identify and champion the appropriate use of medicines across Greater Manchester taking into account cost effectiveness, quality, equity and patient safety. The group consists of General Practitioners (GP), pharmacists and other key healthcare professionals and is formally accountable to the Greater Manchester collaboration of 12 clinical commissioning groups (CCG), NHS England Area Team and local NHS providers. The GMMMGM work plan is facilitated and supported by the Regional Drug & Therapeutics Centre in Newcastle and the North West Commissioning Support Unit (NWCSU).

In addition to medicines management, the GMMMGM's role has recently been broadened to monitor the use and prescribing of specific medical devices.

1.2 The aim of this decision aid is to provide a description of the process, methodology and scoring mechanism to select a preferred Blood Glucose Testing Strip or strips (BGTS) for Greater Manchester. This intends to support GMMMGM to recommend which BGTS available on the UK market offer comprehensive and high level accuracy monitoring whilst being cost effective to the health economy.

## 2 Introduction

2.1 It is recognised that self-monitoring of blood glucose (SMBG) is an integral part of the management of diabetes for some individuals – especially those individuals with type 1 diabetes and those with type 2 diabetes treated with insulin. It can allow individuals to see what impact particular behaviours, such as dietary habits or exercise, can have on their glycaemic control, thus allowing them to understand results and adjust their behaviour in a beneficial way.

2.2 The NICE guideline on type 2 diabetes (Clinical Guideline 87)<sup>1</sup> recommends the following for blood glucose testing:

- a) Offer SMBG to a person newly diagnosed with type 2 diabetes only as an integral part of his or her self-management education. Discuss its purpose and agree how it should be interpreted and acted upon.
- b) SMBG should be available:
  - to those on insulin treatment
  - to those on oral glucose-lowering medications to provide information on hypoglycaemia
  - to assess changes in glucose control resulting from medications and lifestyle changes
  - to monitor changes during intercurrent illness
  - to ensure safety during activities, including driving.
- c) Assess at least annually and in a structured way:
  - self-monitoring skills
  - the quality and appropriate frequency of testing
  - the use made of the results obtained
  - the impact on quality of life
  - the continued benefit
  - the equipment used.
- d) If self-monitoring is appropriate but blood glucose monitoring is unacceptable to the individual, discuss the use of urine glucose monitoring.

There has already been work undertaken to implement this NICE guidance across Greater Manchester and as such this guidance will concentrate on the existing use of BGTS.

- 2.3 In 2013 there are over 149,000 patients with diabetes in Greater Manchester according to the latest QOF figures<sup>2</sup> and this number has been increasing every year. Individuals with diabetes monitor their blood glucose to educate themselves, maintain better blood glucose control and to minimise the risks of hypoglycaemia.
- 2.4 In 2014, the total spend across Greater Manchester on BGTS was in excess of £8.2m, an increase of over £350K from 2013<sup>3</sup>. As of January 2015 there are 58 varieties of BGTS funded within the NHS<sup>4</sup> with prices ranging from £6.99 - £16.30 for 50 strips. The wide range of BGTS and meters enables individuals with diabetes to select a system that best meets their needs, albeit whilst adding complexity for healthcare professionals.
- 2.5 BGTS and meters are medical devices, not medicines. As such the process to market is different and less robust. For a medicine, randomised controlled trials (RCT) and a product licence are required. To obtain a drug tariff listing in England for a BGTS the process is to complete a DT1 form<sup>5</sup>. This form requires information regarding the manufacturer, the product and the supporting material regarding accuracy and the Conformité Européenne (CE) mark (as opposed to RCT data for a medicine).
- 2.6 The European Association for the Study of Diabetes (EASD) issued a position statement in March 2013<sup>6</sup> questioning the robustness of the procedure by which medical devices in diabetes, including BGTS and meters get to market and are evaluated post marketing. As these devices are potentially used to alter the dose of an administered medication i.e. insulin, it is vital that blood glucose meters and strips give accurate results when used to avoid any serious consequences.

Considering the position statement from the EASD this document will also consider data beyond the drug tariff listing and will include a review of available published accuracy data for BGTS and meter to international accuracy standards.

- 2.7 BGTS and meters have an international standard that they should be manufactured to - ISO 15197. The standard from 2003 was recently updated in 2013<sup>7</sup>. The new standard has implications not only for the manufacturers of currently available and future devices but also for the end-users. The manufacturers have 3 years from the date of the new standard update to meet the new requirements before compliance becomes mandatory from June 2016.

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. 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<sup>7</sup>.

The ISO 15197: 2013 requirements for BGTS and meters differ from the previous 2003 version on the following points in terms of accuracy requirements<sup>7</sup> (Figure 1).

**Figure 1:**

|   | <i>ISO 15197: 2003</i>    | <i>ISO 15197:2013</i>     |
|---|---------------------------|---------------------------|
| <i>Higher level accuracy</i>                    | >4.2mmol/l +/- 20%        | >5.5mmol/l +/- 15%        |
| <i>Lower level accuracy</i>                     | <4.2mmol/l +/- 0.83mmol/l | <5.5mmol/l +/- 0.83mmol/l |
| <i>Number of lots</i>                           | 1                         | 3                         |
| <i>Results in zone A/B of Clarke Error Grid</i> | n/a                       | 99%                       |

*Note: There are many other differences published by the international standard but these are the key accuracy differences.*

For a BGTS and meter to surpass the accuracy requirements for ISO 15197:2013 it is required to have the above high and low level accuracy across 3 lots (or batches) of test strips, with all results in Zone A/B of a Clarke Error Grid<sup>7</sup>.

### 3 Aims

3.1 In line with the principles of GMMMG, the aim of the protocol was:

- ✓ To provide better support for patients in the effective utilisation of BGTS
- ✓ To improve the cost effective use of BGTS in Greater Manchester
- ✓ To support CCGs and NHS providers in the delivery of an evidence based rationale on selection of a preferred brand of BGTS from the large variety available

3.2 **The intentions of this protocol were NOT to:**

There are widely available reports of individuals with diabetes being denied access to BGTS<sup>8</sup>. It is therefore important to state that this protocol was not intended to deny access to BGTS nor was it an exercise in cutting cost. However it is possible that cost savings may be a consequence of the recommendations following the protocol findings.

This protocol was an evaluation tool to enable clear and transparent assessment of available data in relation to BGTS provisions to the CCG's of Greater Manchester looking to optimise expenditure and support for individual patients requiring SMBG. It was not a tender process, as no contract award will be made as a consequence of this protocol.

### 4 Review Process

4.1 A scoring process was undertaken to evaluate the preferred BGTS and meter. Some elements of the process were a pass or fail and some required scoring by a specialist project group. If any BGTS received a fail then they were excluded from any further scoring within the process.

- 4.2 The following representatives were involved in the project group:
- Specialist nursing and clinicians with interest in SMBG
  - Patient representation through specialist clinicians
  - Commissioners and;
  - Medicines optimisation leads/pharmacists
- 4.3 The BGTS currently included within the NHS Drug Tariff (January 2015) were all assessed and scored according to the following review process below.

**Stage 1: A review of existing guidance using the internet to identify existing guidance available on BGTS**

This stage did not result in scoring for a BGTS but helped with the selection of the type of guideline categories used in other areas of the country. The group reserved the right to select meters based upon characteristics for unique categories of patients. Any categories identified at this stage were scored within the questions to suppliers as part of the non-essential criteria.

**Stage 2: A review of the currently available manufacturers and independent accuracy evidence of blood glucose meters and strips**

A detailed review of the manufacturer's evidence and its source, plus an independent comprehensive literature search was undertaken to identify BGTS and meters that met the following essential criteria. This stage was undertaken in advance of stages 3 and 4. Any blood glucose systems not meeting this essential criterion below did not proceed to stages 3 and 4.

**Essential Criteria: Pass or Fail**

- Group 1 (1st choice): Manufacturers' provide independent and published evidence of attainment of ISO 15197: 2013 accuracy standards as set out in Figure 1.  
**AND**
- Group 2: Manufacturers provide Independent evidence only of attainment of ISO 15197: 2013 accuracy standards as set out in Figure 1.

Note: As this protocol will be in place for at least 1 year it is vital that ISO 15197:2013 is considered as this will be enforceable by June 2016.

**Stage 3: A review of the acquisition cost of BGTS – Weighted scored 1-10**

The acquisition cost of all BGTS was taken from the NHS Drug Tariff at the time of the assessment. Those that did not fulfil Stage 2 were excluded from the review process. Thereafter the NWCSU ranked BGTS deemed to offer cost effectiveness to the health economy by calculating a weighted score.

**Stage 4: A review of features and the available support that is offered to users of these devices**

Further information was requested from all manufacturers that met the essential requirements of Stage 2. Suppliers were requested to complete the questionnaire and provide any additional information on the following points.

**Essential criteria: Pass or Fail**

- ✓ Free meters to NHS locations and service users (minimum UK current stock 10,000 meters). Essential to mitigate against the risk of significant change in use within a locality the size of Greater Manchester.
- ✓ Free replacement batteries, log books, lancing pens.
- ✓ Technical support provided via freephone number (not answering machine).
- ✓ Free support material and meter training for all healthcare professionals.
- ✓ Free internal control solution.
- ✓ Measures only in mmol/L units and cannot be changed.
- ✓ Provides plasma-calibrated meter readings.
- ✓ Hematocrit range between 30-60% (or more).
- ✓ Measurement range between 1.1 to 33.3mmol/L (or more).
- ✓ Unable to delete readings from memory.
- ✓ No calibration or coding required.
- ✓ Expiry date of BGTS – minimum 6 months from opening.

**Non-essential criteria (but provides added value): Scored 0 – 1 based on project panel decisions**

- ✓ Guarantee stability of pricing and available BGTS and meters.
- ✓ Starter meter pack available which includes BGTS and lancets.
- ✓ Sample under-fill detection.
- ✓ Able to apply more blood to the same test strip; if under-fill.
- ✓ Capillary fill function.
- ✓ Small sample size required ( $\leq 0.5\mu\text{l}$ ).
- ✓ Measurement time ( $\leq 5$  seconds).
- ✓ Sufficient memory capacity as per project group expectations.
- ✓ Meter set-up is not required (e.g. date and time). However minor adjustment maybe required in BST/battery changes.
- ✓ The manufacturer can provide material and deliver training to patients and carers free of charge
- ✓ Manufacturers to provide records and evaluation of all training to all recipients and highlight learning outcomes achieved and any areas of concerns.
- ✓ The manufacturer supports any promotion of local guidelines for SMBG.
- ✓ Allow electronic download to personal computers and clinical systems.
- ✓ The manufacturer has alternative meters that may support other patient cohorts e.g. measures ketones, supports visually impaired, dexterity issues, gestational diabetes, paediatrics, insulin pump users.
- ✓ Manufacturer provides information of their MHRA product recall process and actions to be taken.
- ✓ Free independent external quality assurance for healthcare professionals in GP practices and insulin users who self-monitors blood glucose.

**Manufacturers were also given the opportunity to provide other additional features which may be considered by the project panel evaluation**

## 5 Results

In summary, of the 58 BGTS available on the NHS (March 2015) the results were as follows:

**Figure 2: BGTS results overview**

|   | <b>Number of BGTS</b> |
|---|-----------------------|
| <b>Group 1 (First choice BGTS)</b> – submitted independent and published evidence of meeting ISO 15197: 2013 accuracy standards as per protocol | <b>7</b>              |
| <b>Group 2 (Alternative choice)</b> – submitted independent evidence of meeting ISO 15197: 2013 accuracy standards as per protocol              | <b>12</b>             |
| Manufacturers unable to submit the required evidence as per protocol and excluded from Stages 3 and 4 of the evaluation                         | <b>9</b>              |
| Declined to partake and excluded  | <b>22</b>             |
| Non-responders to evaluation and excluded   | <b>8</b>              |

Figure 3 below presents the partaking manufacturers and their BGTS that were able to provide independent and published evidence demonstrating ISO 15197: 2013 accuracy standards i.e. Group 1. A summary of the available evidence for Group 1 BGTS can be found in Appendix 3.

**Figure 3: Group 1 (First choice) - BGTS and evaluation results**

| <b>Manufacturer</b>                         | <b>Bayer</b>        | <b>Roche</b>  |                | <b>Spirit Healthcare</b> |               | <b>Ypsomed</b>       | <b>Life Scan</b>      |
|---|---------------------|---------------|----------------|--------------------------|---------------|----------------------|-----------------------|
| <b>Blood Glucose Test Strip</b>             | <b>Contour Next</b> | <b>Aviva</b>  | <b>Active*</b> | <b>CareSens N</b>        | <b>TEE2**</b> | <b>Mylife Unio##</b> | <b>OneTouch Verio</b> |
| <b>Cost per 50 strips</b>                   | <b>£15.04</b>       | <b>£15.72</b> | <b>£9.95</b>   | <b>£12.75</b>            | <b>£7.75</b>  | <b>£9.50</b>         | <b>£15.12</b>         |
| <b>Evaluation process score (out of 26)</b> | 19.65               | 17.45         | 21.03          | 20.48                    | 24.02         | 19.36                | 19.62                 |

\*Roche Active Non-Coding meter is expected to be available in the UK from Q1 2015/16 (requires confirmation with manufacturer)

\*\*Spirit Healthcare TEE2 - from March 2015 increasing memory capacity to 500 and can be recommended in non-complicated diabetics

## Ypsomed Ltd - Mylife Unio test strips. 1 vial with 25 strips = 3 months expiry from opening. 2 vials with 50 strips = 6 months. Manufacturers confirm from autumn 2015, all Mylife Unio test strips will include 6 months expiry from opening per vial.

12 BGTS (Figure 4) were able to provide independently assessed but non-published evidence of conformity to ISO 15197: 2013 accuracy standards i.e. Group 2. Although such BGTS could not provide published evidence, it was felt the submitted independent evidence could be taken into consideration by Greater Manchester providers or commissioners.

**Figure 4: Group 2 (Alternative choice) BGTS and evaluation results**

| <b>Manufacturer</b>         | <b>Blood Glucose Test Strips</b> | <b>Cost per 50 strips</b> | <b>Evaluation process score (out of 26)</b> |
|-----------------------------|----------------------------------|---------------------------|---|
| <b>GlucRx</b>               | <b>GlucRx Nexus</b>              | <b>£9.95</b>              | <b>23.03</b>                                |
| <b>Agamatrix</b>            | <b>WaveSense Jazz</b>            | <b>£9.87</b>              | <b>20.08</b>                                |
|                             | <b>WaveSense Jazz Duo</b>        |                           |   |
| <b>Roche</b>                | <b>Mobile</b>                    | <b>£15.95</b>             | <b>18.38</b>                                |
| <b>Bayer</b>                | <b>Contour TS*</b>               | <b>£9.50</b>              | <b>21.36</b>                                |
| <b>Neon Diagnostics</b>     | <b>Element</b>                   | <b>£9.89</b>              | <b>21.07</b>                                |
|                             | <b>GluNeo</b>                    | <b>£9.89</b>              | <b>21.07</b>                                |
| <b>Menarini Diagnostics</b> | <b>GlucMen LX</b>                | <b>£15.52</b>             | <b>18.51</b>                                |
|                             | <b>GlucMen Areo</b>              | <b>£9.95</b>              | <b>22.03</b>                                |
| <b>Nipro Diagnostics</b>    | <b>TRUEyou</b>                   | <b>£9.92</b>              | <b>21.05</b>                                |
| <b>Ypsomed</b>              | <b>Mylife Pura</b>               | <b>£9.50</b>              | <b>21.36</b>                                |
| <b>Abbott</b>               | <b>Freestyle Optium</b>          | <b>£15.64</b>             | <b>20.47</b>                                |

\* Submitted letter of conformity to ISO 15197: 2013 standards. CSU await accompanying report to support conformity compliance claims. Commissioners / providers are advised to contact manufacturer if such BGTS is a product of choice in the locality.

Group 1 and 2 BGTS were further assessed and scored against a set of project group approved criteria based on cost, essential functions or services, and non-essential, added-value functions. The maximum score any BGTS could achieve was 26 and full results of the further assessment can be found in Appendix 2 and 4.

## 6 Conclusion

Inaccurate SMBG readings can potentially adversely impact clinical decision making and outcomes. The current application process of a CE mark on a SMBG system is a one-time procedure and it is generally assumed that these systems are equal in providing accurate test results. Unfortunately, regular and independent quality controls are not mandatory after market approval and SMBG systems may not all consistently meet the requirements outlined in ISO 15197 criteria.

The recently revised and more stringent ISO 15197: 2013 standard should enhance patient safety by improving accuracy of SMBG systems but the adherence to the updated ISO standard remains based on manufacturers only submitting internal data on file (often non-published) to their certifying bodies demonstrating compliance.

At the point of writing this conclusion, the evaluation identified only five manufacturers (of 29), could provide robust independent and published evidence demonstrating compliance to the updated ISO 15197: 2013 accuracy standards. Of the five manufacturers, seven BGTS (of 58) were identified in Group 1. Surprisingly many manufacturers were unable to provide the level of evidence at the time of request and those that did participate provided non-published internal evidence.

It is acknowledged that potential limitations of this evaluation include:

- Manufacturers have until 2016 to demonstrate ISO 15197: 2013 compliance and are not mandated to provide independent published data demonstrating conformity
- Even the highest quality published research can be vulnerable to publication bias
- Although there is no official requirement of further regulatory proof in accuracy performance after the marketing process; many companies ensure the quality of their products through comprehensive, internal quality assurance proficiency testing. This is an essential and on-going step for companies to mitigate their liability risk as a device and strip manufacturer.

The evaluation acknowledges the limitations and although internal data is considered adequate for BGTS market approval processes and even Drug Tariff listing, the validity and quality of an unpublished and non-peer reviewed evidence is unknown. In addition, it may be argued that since there are no mandatory reviews after market approval of BGTS (including beyond the 2016 mandate); there remains a gap in the on-going policing and compliance to ISO 15197 standards.

In summary, a high accuracy blood glucose monitoring system is an obvious requirement in ensuring patient safety and treatment quality in daily routine. During the last few decades and in line with the development of more sophisticated glucose meter technologies, the accuracy performance requirements have become more and more strict. Although several variables (e.g. user technique) are known to affect the accuracy of SMBG results, clinicians can reduce controllable variables by prescribing accurate and evidence based reproducible SMBG systems with minimal lot-to-lot variations. This evaluation process requests both independent and published evidence and consequently it is felt that Group 1 - BGTS provided greater and more robust evidence confirming compliance to ISO 15197: 2013 accuracy standards.

In addition to the findings, GMMMG has recommended that those BGTS that did not fall into either Group 1 or 2 shall also be considered for the *Greater Manchester Do Not Prescribe* list. This is due to their inability to demonstrate compliance with the standards requested in this process.

## 7 References

1. NICE Clinical Guideline 87 – Type 2 Diabetes - <http://www.nice.org.uk/nicemedia/pdf/CG87NICEGuideline.pdf>
2. <http://www.gpcontract.co.uk/browse/UK/Diabetes%20mellitus/13>. Accessed 31st January 2015.
3. Electronic Prescribing Analysis and Cost data (ePACT). Accessed 31st January 2015.
4. [http://www.ppa.org.uk/edt/January\\_2015/mindex.htm](http://www.ppa.org.uk/edt/January_2015/mindex.htm) Accessed 2nd January 2015.
5. <http://www.nhsbsa.nhs.uk/PrescriptionServices/3399.aspx> Accessed 31st January 2014.
6. EASD Report on medical device accuracy. Accessed 19th January 2014. [http://www.easd.org/images/easdwebfiles/press/EASD%20Press%20Release%20on%20medical%20dev  
ices.pdf](http://www.easd.org/images/easdwebfiles/press/EASD%20Press%20Release%20on%20medical%20devices.pdf)
7. ISO website: [http://www.iso.org/iso/home/news\\_index/news\\_archive/news.htm?refid=Ref1749](http://www.iso.org/iso/home/news_index/news_archive/news.htm?refid=Ref1749).
8. [http://www.diabetes.org.uk/About\\_us/News\\_Landing\\_Page/People-with-diabetes-denied-vital-test-strips/](http://www.diabetes.org.uk/About_us/News_Landing_Page/People-with-diabetes-denied-vital-test-strips/)

Production and reviewed by:  
Jimmy Cheung (Medicines Optimisation Pharmacist)

## 8 Future Evaluation Review

This evaluation will not be re-reviewed until May 2016.

The NWCSU/ GMMMG evaluation process of BGTS provides guidance to Greater Manchester on the methodology and the required evidence that all existing and new BGTS manufacturers/ distributors must provide.

Any new BGTS listed in the Drug Tariff before this review date will only be evaluated by the NWCSU if it is considered by GMMMG sub-groups to have a significant impact on Greater Manchester health economy. NWCSU Greater Manchester Medicines Optimisation team will not accept any new information or evidence for any BGTS unless directed by the GMMMG sub-groups for review.

### Appendix 1: Review process and scoring of blood glucose systems

#### Stage 1

**Results** - An internet search of the available BGTS guidance was undertaken on the 13/02/2014 and this revealed that a large number of published guidelines were available from differing NHS organisations. Guidelines can be broadly separated into two cohorts. Those that have focused on appropriate use of BGTS and those that have focused on acquisition cost. A significant number of guidelines recommend using meters with strips that cost less than £10 although there appear to be minimal or no reviews of available evidence associated with these. Other guidelines appear to focus on the appropriate use of BGTS and separate individual users into existing treatments and define as to whether a patient should be testing.

A small number of guidelines separate individual users into different subsets based upon need, and within these the common categories are as follows:

- Users with type 2 diabetes, not using insulin (low frequency tester) who may benefit from testing
- Users with type 1 / type 2 diabetes using insulin (high frequency user)
- Visually impaired users
- Insulin pump users
- Patients with gestational diabetes
- Paediatric patients

#### Stage 2

All manufacturer evidence of meeting ISO 15197: 2013 was requested and evaluated. NWCSU ensured all submitted data were reviewed, without bias and confirmed accuracy to standards claimed. In addition, a search of the available independent published evidence was undertaken on the 01/06/14 for all blood glucose system manufacturers that were able to provide evidence of meeting ISO 15197:2013 accuracy standards. The search will include the following publication types:

- Evaluation studies
- Research Support
- Non-U.S. Gov't

The following Medical Subject Headings (MeSH) terms were utilised:

*diabetes mellitus/blood, diabetes mellitus/therapy, humans, blood glucose, blood glucose/analysis, self-monitoring/ instrumentation, self-monitoring/ standards, self-monitoring methods, self-care /instrumentation, reagent strips, blood glucose.*

The following databases will be searched:

- Cochrane Library
- Ovid
- EMBASE
- NHS Evidence
- Pubmed

Following search results the only independent papers that meet the following criteria are to be reviewed:

- Contained information relating to accuracy of SGBM
- Contained information within the paper as to the methodology used

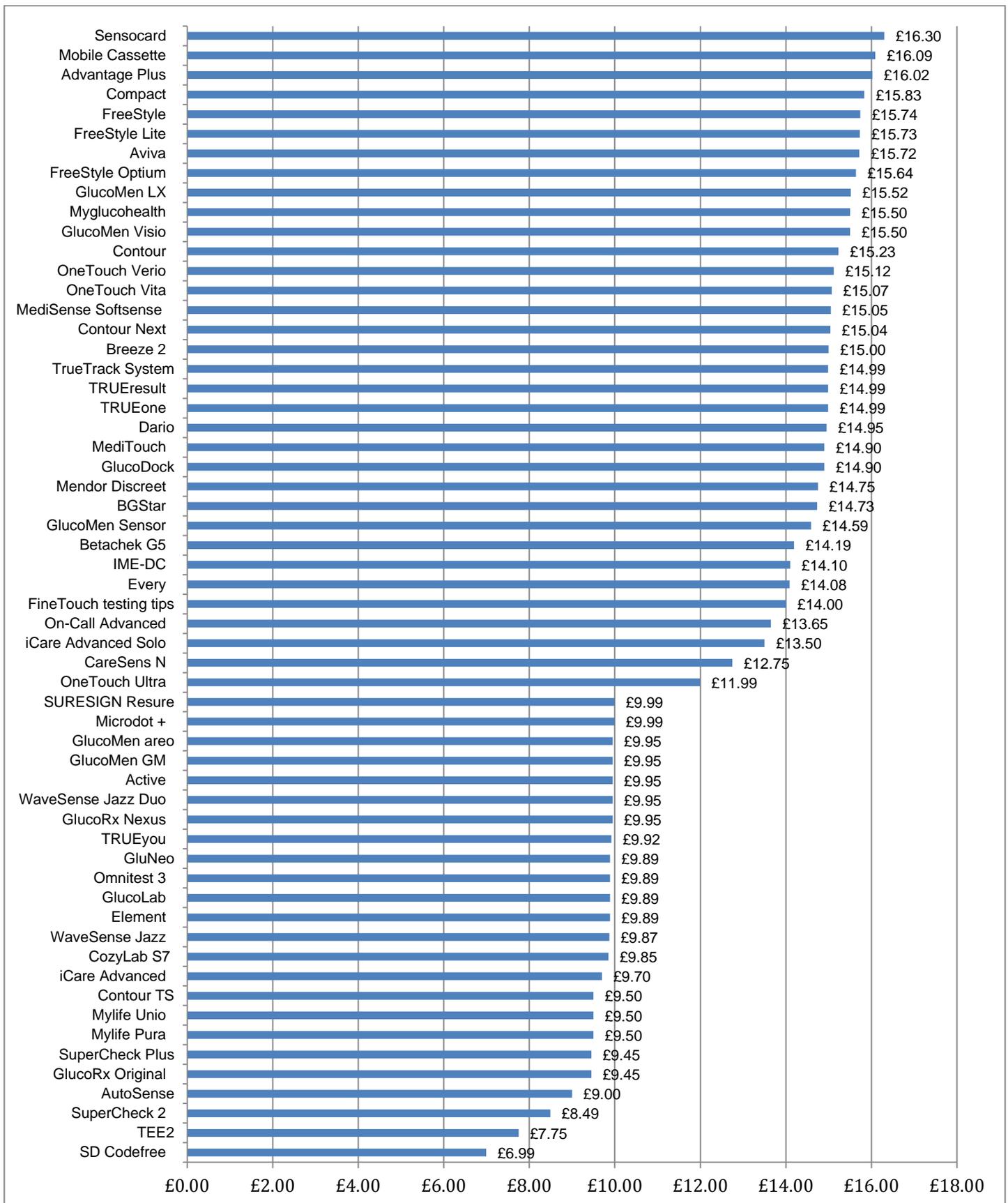
The results from the evidence review will be separated to show blood glucose meters accuracy according to ISO 15197:2003 and the ISO 15197:2013 accuracy standard. A number of papers may compare to the 15% accuracy but do not use three batches as per ISO 15197:2013. These discrepancies will also be clearly identified.

### **Stage 3**

To date based on the January 2015 Drug Tariff there are 58 varieties of BGTS funded within the NHS with prices ranging from £6.99 - £16.30 for 50 strips (Figure 5). The cost is then evaluated by the following steps:

- The cost of the strip will be converted into a weighted score (WS) against BGTS available.
- $WS = (\text{Lowest cost BGTS per 50 strips} \div \text{current BGTS price per 50 strips}) \times \text{the weighted score i.e. 10}.$
- This will allow each strip to achieve a weighted score, calculated to two decimal points, out of the weighting for the priced element of the evaluation.
- The strip with the lowest price will be awarded a score of 10 i.e. 100% of the weighting. The remaining strips will be allocated a pro rata weighted score using the formula above.

**Figure 5: Blood Glucose Test Strips, Cost per 50 strips, £s, Drug Tariff, Jan 2015**



#### **Stage 4**

This stage involves a review of the available essential and non-essential support for users of BGTS. There are a wide range of support packages offered from manufacturers of BGTS from free meters and batteries to telephone support lines and educational packages. In addition quality assurance services are offered – especially for healthcare professionals.

- **Essential criteria: Pass or Fail**

- ✓ Free meters to NHS locations and service users (minimum UK current stock 10,000 meters). Essential to mitigate against the risk of significant change in use within a locality the size of Greater Manchester.
- ✓ Free replacement batteries, log books, lancing pens.
- ✓ Technical support provided via freephone number (not answering machine).
- ✓ Free support material and meter training for all healthcare professionals.
- ✓ Free internal control solution.
- ✓ Measures only in mmol/L units and cannot be changed.
- ✓ Provides plasma-calibrated meter readings.
- ✓ Hematocrit range between 30-60% (or more).
- ✓ Measurement range between 1.1 to 33.3mmol/L (or more).
- ✓ Unable to delete readings from memory.
- ✓ No calibration or coding required.
- ✓ Expiry date of BGTS – minimum 6 months from opening.

- **Non-essential criteria (but provides added value): Scored 0 – 1 based on project panel decisions**

- ✓ Guarantee stability of pricing and available BGTS and meters.
- ✓ Starter meter pack available which includes BGTS and lancets.
- ✓ Sample under-fill detection.
- ✓ Able to apply more blood to the same test strip; if under-fill.
- ✓ Capillary fill function.
- ✓ Small sample size required ( $\leq 0.5\mu\text{l}$ ).
- ✓ Measurement time ( $\leq 5$  seconds).
- ✓ Sufficient memory capacity as per project group expectations.
- ✓ Meter set-up is not required (e.g. date and time). However minor adjustment maybe required in BST/battery changes.
- ✓ The manufacturer can provide material and deliver training to patients and carers free of charge
- ✓ Manufacturers to provide records and evaluation of all training to all recipients and highlight learning outcomes achieved and any areas of concerns.
- ✓ The manufacturer supports any promotion of local guidelines for SMBG.
- ✓ Allow electronic download to personal computers and clinical systems.
- ✓ The manufacturer has alternative meters that may support other patient cohorts e.g. measures ketones, supports visually impaired, dexterity issues, gestational diabetes, paediatrics, insulin pump users.
- ✓ Manufacturer provides information of their MHRA product recall process and actions to be taken.
- ✓ Free independent external quality assurance for healthcare professionals in GP practices and insulin users who self-monitors blood glucose.

- **Manufacturers were also given the opportunity to provide other additional features which may be considered by the project panel evaluation**

Appendix 2: Summary of blood glucose monitoring system with independent and published evidence demonstrating ISO 15197: 2013 accuracy standards as per evaluation process (Group 1)

|  |  | Group 1      |        |         |                   |                   |                 |                |
|--|--|--------------|--------|---------|-------------------|-------------------|-----------------|----------------|
| Manufacturer/ Distributor  |  | Bayer        | Roche  |         | Spirit Healthcare |                   | Ypsomed Ltd     | Life Scan      |
| Blood Glucose Test strips  |  | Contour Next | Aviva  | Active* | CareSens N        | TEE2 <sup>#</sup> | MyLife Unio     | OneTouch Verio |
| <b>1. Essential criteria – ISO 15197: 2013 accuracy standards</b>  |  |              |        |         |                   |                   |                 |                |
| Manufacturers reference provided   | see Appendix 4:<br>Evidence<br>Summary | ✓            | ✓      | ✓       | ✓                 | ✓                 | ✓               | ✓              |
| Independent evidence   |  | ✓            | ✓      | ✓       | ✓                 | ✓                 | ✓               | ✓              |
| Published evidence   |  | ✓            | ✓      | ✓       | ✓                 | ✓                 | ✓               | ✓              |
| <b>2. Essential criteria - Information supplied by submitting companies</b>  |  |              |        |         |                   |                   |                 |                |
| Free support material and meter training for all healthcare professionals  | Pass / Fail                            | ✓            | ✓      | ✓       | ✓                 | ✓                 | ✓               | ✓              |
| Free Internal Control Solution   | Pass / Fail                            | ✓            | ✓      | ✓       | ✓                 | ✓                 | ✓               | ✓              |
| Measures only in mmol/L units and cannot be changed  | Pass / Fail                            | ✓            | ✓      | ✓       | ✓                 | ✓                 | ✓               | ✓              |
| Provides plasma-calibrated meter readings  | Pass / Fail                            | ✓            | ✓      | ✓       | ✓                 | ✓                 | ✓               | ✓              |
| Haematocrit range between 30-60% (or more)   | Pass / Fail                            | ✓            | ✓      | ✓       | ✓                 | ✓                 | ✓               | ✓              |
| Measurement range between 1.1 to 33.3mmol/L (or more)  | Pass / Fail                            | ✓            |        | ✓       | ✓                 | ✓                 | ✓               | ✓              |
| Unable to delete readings from memory  | Pass / Fail                            | ✓            | ✓      | ✓       | ✓                 | ✓                 | ✓               | ✓              |
| No calibration or coding required  | Pass / Fail                            | ✓            | ✓      | ✓       | ✓                 | ✓                 | ✓               | ✓              |
| Expiry date of test strips - minimum 6 months from opening   | Pass / Fail                            | ✓            | ✓      | ✓       | ✓                 | ✓                 | ✓ <sup>##</sup> | ✓              |
| <b>3. Non-Essential criteria - Cost</b>  |  |              |        |         |                   |                   |                 |                |
| Cost of 50 test strips   | According DT Jan 2015                  | £15.04       | £15.72 | £9.95   | £12.75            | £7.75             | £9.50           | £15.12         |
| Weighted Score   | (A) = score out of 10                  | 4.65         | 4.45   | 7.03    | 5.48              | 9.02              | 7.36            | 4.62           |
| <b>4. Non-Essential criteria - Information supplied by submitting companies (one point per criteria met)</b>       |  |              |        |         |                   |                   |                 |                |
| Guarantee stability of pricing and available BGTS and meters   | Yes / No                               | ✓            | ✓      | ✓       | ✓                 | ✓                 | ✓               | ✓              |
| Starter meter pack available which includes BGTS and lancets   | Yes / No                               | ✓            | ✓      | ✓       | ✓                 | ✓                 | ✓               | ✓              |
| Sample under-fill detection  | Yes / No                               | ✓            | ✓      | ✓       | ✓                 | ✓                 | ✓               | ✓              |
| Able to apply more blood to the same test strip; if under-fill   | Yes / No                               | ✓            | No     | ✓       | No                | No                | No              | No             |
| Capillary fill function  | Yes / No                               | ✓            | ✓      | ✓       | ✓                 | ✓                 | ✓               | ✓              |
| Sample size (≤ 0.5µl)  | Yes / No                               | No           | No     | No      | ✓                 | No                | No - 0.7µl      | ✓              |
| Measurement time (≤ 5 seconds)   | Yes / No                               | ✓            | ✓      | ✓       | ✓                 | ✓                 | ✓               | ✓              |
| Sufficient memory capacity as per project group expectations   | Yes / No                               | ✓            | ✓      | ✓       | ✓                 | ✓                 | ✓               | ✓              |
| Meter set-up is not required (e.g. date and time). However minor adjustment maybe required in BST/battery changes. | Yes / No                               | ✓            | ✓      | ✓       | ✓                 | ✓                 | No              | ✓              |

|  |          |              |                                    |              |              |              |              |
|--|----------|--------------|------------------------------------|--------------|--------------|--------------|--------------|
| <i>The manufacturer can provide material and deliver training to patients and carers free of charge.</i>   | Yes / No | ✓            | ✓                                  | ✓            | ✓            | ✓            | ✓            |
| <i>Manufacturers to provide records and evaluation of all training to all recipients and highlight learning outcomes achieved and any areas of concerns.</i>   | Yes / No | ✓            | ✓                                  | ✓            | ✓            | ✓            | ✓            |
| <i>The company supports any promotion of local guidelines for SMBG</i>   | Yes / No | ✓            | ✓                                  | ✓            | ✓            | ✓            | ✓            |
| <i>Allow electronic download to personal computers and clinical systems</i>  | Yes / No | ✓            | ✓                                  | ✓            | ✓            | ✓            | ✓            |
| <i>Manufacturers has alternative meters that may support other patient cohorts e.g. measures ketones, support visually impaired, dexterity issues, gestational diabetes, paediatrics, insulin pump users</i> | Yes / No | ✓            | ✓                                  | ✓            | ✓            | ✓            | ✓            |
| <i>Manufacturers provides information of their MHRA product recall process and actions to be taken</i>   | Yes / No | ✓            | ✓                                  | ✓            | ✓            | ✓            | ✓            |
| <i>Free independent external quality assurance for healthcare professionals in GP practices and insulin users who self monitors blood glucose</i>  | Yes / No | ✓            | No, but can be discussed in detail |              | ✓            | No           | ✓            |
| <b>Section 4. Sub Total (score out of 16) (B)</b>  |          | <b>15</b>    | <b>13</b>                          | <b>14</b>    | <b>15</b>    | <b>12</b>    | <b>15</b>    |
| <b>Total score (A + B) out of 26</b>   |          | <b>19.65</b> | <b>17.45</b>                       | <b>21.03</b> | <b>20.48</b> | <b>24.02</b> | <b>19.36</b> |
| <b>Total score (A + B) out of 26</b>   |          | <b>19.65</b> | <b>17.45</b>                       | <b>21.03</b> | <b>20.48</b> | <b>24.02</b> | <b>19.36</b> |

Note:

\* Roche Active Non-Coding meter are available worldwide except UK until Q1 2015/16 (requires confirmation with Roche representative)

# Spirit Healthcare BGTS - TEE2 - from March 2015 increasing memory capacity to 500 and can be recommended in non-complicated diabetics (Previously had memory capacity of 100 and were only recommended in non-insulin diabetic users only – please confirm with Spirit Healthcare representative).

### Ypsomed Ltd - Mylife Unio test strips. 1 vial with 25 strips = 3 months expiry from opening. 2 vials with 50 strips = 6 months. Manufacturers confirm from autumn 2015, all Mylife Unio test strips will include 6 months expiry from opening per vial.

**Appendix 3: Summary of Evidence of Group 1 blood glucose monitoring system demonstrating ISO 15197: 2013 accuracy standards as per evaluation process**

| Blood Glucose System                       | ISO 15197: 2003<br>(+/- 20%<br>>4.2mmol/L<br>AND +/-<br>0.83mmol/L<br><4.2mmol/L) | ISO 15197: 2013<br>(+/- 15%<br>>5.5mmol/L<br>AND +/-<br>0.83mmol/L<br><5.5mmol/L) | Criteria met in 3 batches, as per ISO 15197: 2013 criteria | % age in Clarke Error Grid zones A & B, as per ISO 15197: 2013 criteria | Published evidence reference<br><br>Note: Additional independent evidence was also submitted under strict confidential agreement to the NWCSU. Other NHS organisation (if required) can request this information.   | Passes ISO 15197: 2013 Blood glucose accuracy criteria  |
|--|---|---|--|---|---|---|
| Contour XT, NEXT, NEXT USB and NEXT LINK   | Yes   | Yes   | Yes  | 100%  | <i>Bernstein et al (2013) A New Test Strip Technology Platform for Self-Monitoring of Blood Glucose. J Diabetes Sci Technol; 7(5):1386-1399</i>   | Yes<br><br>Contour Next BGTS in all Contour meter listed (XT, NEXT, NEXT USB and NEXT LINK)                                   |
| Accu-Chek Aviva And Accu-Chek Aviva Expert | Yes   | Yes   | Yes  | 100%  | <i>Pleus et al (2014) Accuracy Assessment of Two Novel Systems for Self-Monitoring of Blood Glucose ISO 15197:2013. J Diabetes Sci Technol; DOI: 10.1177/1932296814536030. 25 May 2014</i>  | Yes<br><br>Aviva BGTS in Accu-Chek Aviva Meter<br>Note: Accu-Chek Aviva Expert meter uses the Accu-Chek Aviva strip platform. |
|  |   | Yes   | All 4 lots exceed the 2013 standard                        |   | <i>Baumstark et al (2012) Lot-to-Lot Variability of Test Strips and Accuracy Assessment of Ssystems for Self-Monitoring of Blood Glucose according to ISO 15197. J Diabetes Sci Technol; 6(5):1076-1086</i>   |   |
| Accu-Chek Active                           | Yes   | Yes   | Yes  | 99%   | <i>Baumstark et al. Accuracy Assessment of an Advanced Blood Glucose Monitoring System for Self Testing with three reagent system lots following ISO 15197: 2013</i>  | Yes   |
| CareSens N and CareSens N POP              | Yes   | Yes   | Yes  | 100%  | <i>Link M et al (2014) Accuracy Evaluation of Three Systems for Self-monitoring of Blood Glucose With Three Different Test Strip Lots Following ISO 15197. J Diabetes Sci Technol; 8(2):422-424<br/>Please note that TEE2 is the Alfacheck Professional Strip with an alternative name across continental Europe.</i> | Yes<br><br>Caresens N BGTS in all CareSens meter listed<br>And<br>TEE2 BGTS in TEE2 meter                                     |
| TEE2                                       | Yes   | Yes   | Yes  | 100%  |   |   |
| Mylife Unio                                | Yes   | Yes   | Yes  | 100%  | <i>Huang Ta-you et al Evaluation of accuracy of FAD-GDH and mutant Q-GDH based blood glucose monitors in multi-patient populations. Clinica Chimica Acta. 2014, 433:28-33.<br/>Please note the GM700 testing strip relates to Mylife Unio</i>   | Yes   |
| OneTouch Verio IQ and OneTouch Verio       | Yes   | Yes   | Yes  | 100%  | <i>Katz L et al (2015) A comprehensive evaluation of strip performance in multiple blood glucose monitoring systems. Expert Review of Medical Devices Early online, 1–9 (2015)<br/><br/>Please note that this study includes VerioPro, VerioVue and OmniPod</i>   | Yes<br><br>OneTouch Verio BGTS in OneTouch Verio and Verio IQ meter   |

**Appendix 4: Summary of blood glucose monitoring system with independent evidence demonstrating ISO 15197: 2013 accuracy standards as per evaluation process (Group 2)**

|  | <b>Group 2</b> |                          |        |              |                  |        |                      |               |                   |             |                  |
|--|----------------|--------------------------|--------|--------------|------------------|--------|----------------------|---------------|-------------------|-------------|------------------|
| <b>Manufacturer/Distributor</b>  | GlucoRx        | Agamatrix                | Roche  | Bayer        | Neon Diagnostics |        | Menarini Diagnostics |               | Nipro Diagnostics | Ypsomed     | Abbott           |
| <b>Blood Glucose Test Strip</b>  | GlucoRx Nexus  | WaveSense Jazz (and Duo) | Mobile | Contour TS** | Element          | GluNeo | GlucoMen LX          | GlucoMen Areo | TRUEyou           | Mylife Pura | Freestyle Optium |
| <b>1. Essential criteria – ISO 15197: 2013 accuracy standards</b>  |                |                          |        |              |                  |        |                      |               |                   |             |                  |
| <i>Manufacturers reference provided</i>  | ✓              | ✓                        | ✓      | ✓            | ✓                | ✓      | ✓                    | ✓             | ✓                 | ✓           | ✓                |
| <i>Independent evidence</i>  | ✓              | ✓                        | ✓      | ✓            | ✓                | ✓      | ✓                    | ✓             | ✓                 | ✓           | ✓                |
| <i>Published evidence</i>  | x              | x                        | x      | x            | x                | x      | x                    | x             | x                 | x           | x                |
| <b>2. Essential criteria - Information supplied by submitting companies</b>                                  |                |                          |        |              |                  |        |                      |               |                   |             |                  |
| <i>Free support material and meter training for all healthcare professionals</i>                             | ✓              | ✓                        | ✓      | ✓            | ✓                | ✓      | ✓                    | ✓             | ✓                 | ✓           | ✓                |
| <i>Free Internal Control Solution</i>  | ✓              | ✓                        | ✓      | ✓            | ✓                | ✓      | ✓                    | ✓             | ✓                 | ✓           | ✓                |
| <i>Measures only in mmol/L units and cannot be changed</i>   | ✓              | ✓                        | ✓      | ✓            | ✓                | ✓      | ✓                    | ✓             | ✓                 | ✓           | ✓                |
| <i>Provides plasma-calibrated meter readings</i>   | ✓              | ✓                        | ✓      | ✓            | ✓                | ✓      | ✓                    | ✓             | ✓                 | ✓           | ✓                |
| <i>Haematocrit range between 30-60% (or more)</i>  | ✓              | ✓                        | ✓      | ✓            | ✓                | ✓      | ✓                    | ✓             | ✓                 | ✓           | ✓                |
| <i>Measurement range between 1.1 to 33.3mmol/L (or more)</i>   | ✓              | ✓                        | ✓      | ✓            | ✓                | ✓      | ✓                    | ✓             | ✓                 | ✓           | ✓                |
| <i>Unable to delete readings from memory</i>   | ✓              | ✓                        | ✓      | ✓            | ✓                | ✓      | ✓                    | ✓             | ✓                 | ✓           | ✓                |
| <i>No calibration or coding required</i>   | ✓              | ✓                        | ✓      | ✓            | ✓                | ✓      | ✓                    | ✓             | ✓                 | ✓           | ✓                |
| <i>Expiry date of test strips - minimum 6 months from opening</i>  | ✓              | ✓                        | ✓      | ✓            | ✓                | ✓      | ✓                    | ✓             | ✓                 | ✓           | ✓                |
| <b>3. Non-Essential criteria - Cost</b>  |                |                          |        |              |                  |        |                      |               |                   |             |                  |
| <i>Cost of 50 test strips</i>  | £9.95          | £9.87                    | £15.95 | £9.50        | £9.89            | £9.89  | £15.52               | £9.95         | £9.92             | £9.50       | £15.64           |
| <i>Weighted Score</i>  | 7.03           | 7.08                     | 4.38   | 7.36         | 7.07             | 7.07   | 4.51                 | 7.03          | 7.05              | 7.36        | 4.47             |
| <b>4. Non-Essential criteria - Information supplied by submitting companies (one point per criteria met)</b> |                |                          |        |              |                  |        |                      |               |                   |             |                  |
| <i>Guarantee stability of pricing and available BGTS and meters</i>  | ✓              | ✓                        | ✓      | ✓            | ✓                | ✓      | ✓                    | ✓             | ✓                 | ✓           | ✓                |
| <i>Starter meter pack available which includes BGTS and lancets</i>  | ✓              | ✓                        | ✓      | ✓            | ✓                | ✓      | ✓                    | ✓             | ✓                 | ✓           | ✓                |
| <i>Sample under-fill detection</i>   | ✓              | ✓                        | ✓      | ✓            | ✓                | ✓      | ✓                    | ✓             | ✓                 | ✓           | ✓                |
| <i>Able to apply more blood to the same test strip; if under-fill</i>  | ✓              | No                       | No     | No           | No               | No     | No                   | ✓             | No                | ✓           | ✓                |
| <i>Capillary fill function</i>   | ✓              | ✓                        | ✓      | ✓            | ✓                | ✓      | ✓                    | ✓             | ✓                 | ✓           | ✓                |
| <i>Sample size (≤ 0.5µl)</i>   | ✓              | ✓                        | ✓      | No           | ✓                | ✓      | ✓                    | ✓             | ✓                 | No -1.0µl   | ✓                |
| <i>Measurement time (≤ 5 seconds)</i>  | ✓              | ✓                        | ✓      | ✓            | ✓                | ✓      | ✓                    | ✓             | ✓                 | ✓           | ✓                |

|  |              |              |                                    |              |              |              |                           |              |              |              |                           |
|--|--------------|--------------|------------------------------------|--------------|--------------|--------------|---------------------------|--------------|--------------|--------------|---------------------------|
| <i>Sufficient memory capacity as per project group expectations</i>  | ✓            | ✓            | ✓                                  | ✓            | ✓            | ✓            | ✓                         | ✓            | ✓            | ✓            | ✓                         |
| <i>Meter set-up is not required (e.g. date and time). However minor adjustment maybe required in BST/battery changes.</i>  | ✓            | ✓            | ✓                                  | ✓            | ✓            | ✓            | ✓                         | ✓            | ✓            | ✓            | ✓                         |
| <i>The manufacturer can provide material and deliver training to patients and carers free of charge.</i>   | ✓            | ✓            | ✓                                  | ✓            | ✓            | ✓            | ✓                         | ✓            | ✓            | ✓            | ✓                         |
| <i>Manufacturers to provide records and evaluation of all training to all recipients and highlight learning outcomes achieved and any areas of concerns.</i>   | ✓            | ✓            | ✓                                  | ✓            | ✓            | ✓            | ✓                         | ✓            | ✓            | ✓            | ✓                         |
| <i>The company supports any promotion of local guidelines for SMBG</i>   | ✓            | ✓            | ✓                                  | ✓            | ✓            | ✓            | ✓                         | ✓            | ✓            | ✓            | ✓                         |
| <i>Allow electronic download to personal computers and clinical systems</i>  | ✓            | ✓            | ✓                                  | ✓            | ✓            | ✓            | ✓                         | ✓            | ✓            | ✓            | ✓                         |
| <i>Manufacturers has alternative meters that may support other patient cohorts e.g. measures ketones, support visually impaired, dexterity issues, gestational diabetes, paediatrics, insulin pump users</i> | ✓            | No           | ✓                                  | ✓            | No           | No           | ✓Plus can measure Ketones | ✓            | ✓            | ✓            | ✓Plus can measure Ketones |
| <i>Manufacturers provides information of their MHRA product recall process and actions to be taken</i>   | ✓            | ✓            | ✓                                  | ✓            | ✓            | ✓            | ✓                         | ✓            | ✓            | ✓            | ✓                         |
| <i>Free independent external quality assurance for healthcare professionals in GP practices and insulin users who self monitors blood glucose</i>  | ✓            | No           | No, but can be discussed in detail | ✓            | ✓            | ✓            | No                        | No           | No           | No           | ✓                         |
|  | 16           | 13           | 14                                 | 14           | 14           | 14           | 14                        | 15           | 14           | 14           | 16                        |
|  | <b>23.03</b> | <b>20.08</b> | <b>18.38</b>                       | <b>21.36</b> | <b>21.07</b> | <b>21.07</b> | <b>18.51</b>              | <b>22.03</b> | <b>21.05</b> | <b>21.36</b> | <b>20.47</b>              |

Note:

Group 2 listed BGTS above provided independent non-published evidence to confirm ISO: 2013 accuracy standards. It is not mandatory for manufacturers to provide independent published evidence for their CE application within the European Union. However, the evidence provided does not completely satisfy the evaluation process. It will be at the discretion of the provider / commissioner if they wish to use the following BGTS. The independent evidence is submitted under strict confidential agreement to the NWCSU. Other NHS organisation (if required) can request this information.

\*\* Bayer submitted independent letter of conformity to ISO 15197: 2013 standards. CSU await accompanying report to support conformity compliance claims. Commissioners / providers are advised to contact manufacturer if such BGTS is a product of choice in the locality.

## Appendix 5: Recommendations at a Locality Level (Updated: March 2015)

Below is a list of recommendations following the evaluation process that CCGs and local providers may wish to consider.

1. **Group 1 BGTS (First Choice)** provided greater and preferable independent and published evidence confirming conformity to ISO 15197: 2013 accuracy standards (see Appendix 2 and 3)
2. **Group 2 BGTS (Alternative Choice)** provided independently assessed evidence of conformity to ISO 15197: 2013 accuracy standards (see Appendix 4)
3. If clinically appropriate, review and consider discontinuing or recommending an alternative BGTS to those patients using BGTS from manufacturers/ distributors not wishing to partake in the evaluation process (Figure 6).

**Figure 6: BGTS/ Manufacturer declined to participate in evaluation**

| <i>Manufacturer</i>              | <i>Blood Glucose Test Strip Name</i> | <i>Reasons from manufacturer/distributor</i> |
|----------------------------------|--------------------------------------|--|
| <i>Apollo Medical</i>            | <b>SuperCheck 2</b>                  | No reason specified                          |
| <i>Merck Serono</i>              | <b>Mendor Discreet</b>               | No independent review available              |
| <i>Cambridge Sensors</i>         | <b>Microdot +</b>                    | BGTS does not meet criteria                  |
|                                  | <b>Every</b>                         |  |
| <i>Point Of Care Testing Ltd</i> | <b>On-Call Advanced</b>              | No reason specified                          |
| <i>Terumo UK Ltd</i>             | <b>FineTouch testing tips</b>        | Terumo has no BGTS promoted in UK            |
| <i>Arctic Medical</i>            | <b>IME-DC</b>                        | No reason specified                          |
| <i>BBI Healthcare</i>            | <b>Sensocard</b>                     | No longer distributes BBTS                   |
| <i>Roche</i>                     | <b>Compact</b>                       | No longer promoted by manufacturer           |
|                                  | <b>Advantage Plus</b>                | No longer promoted by manufacturer           |
| <i>Abbott Laboratories Ltd</i>   | <b>MediSense Softsense</b>           | No longer promoted by manufacturer           |
|                                  | <b>FreeStyle</b>                     | No longer promoted by manufacturer           |
| <i>Lifescan</i>                  | <b>OneTouch Vita</b>                 | No longer promoted by manufacturer           |
|                                  | <b>OneTouch Ultra</b>                | No longer promoted by manufacturer           |
| <i>Menarini Diagnostics</i>      | <b>GlucoMen Sensor</b>               | No longer promoted by manufacturer           |
|                                  | <b>GlucoMen Visio</b>                | No longer promoted by manufacturer           |
| <i>Bayer</i>                     | <b>Breeze 2</b>                      | No longer promoted by manufacturer           |
|                                  | <b>Contour</b>                       | No longer promoted by manufacturer           |
| <i>Nipro Diagnostics</i>         | <b>TRUEone</b>                       | No longer promoted by manufacturer           |
|                                  | <b>TRUEresult</b>                    | No longer promoted by manufacturer           |
|                                  | <b>TrueTrack System</b>              | No longer promoted by manufacturer           |
| <i>GlucRx</i>                    | <b>GlucRx Original</b>               | No longer promoted by manufacturer           |

4. If clinically appropriate, review and consider discontinuing or recommending an alternative BGTS of those non-responding manufacturers/distributors during the evaluation process (Figure 7). Each of the manufacturer/ distributors below was contacted via email and telephone on two separate occasions.

**Figure 7: No response from manufacturers - Excluded from evaluation**

| <i>Manufacturer</i>                         | <i>Blood Glucose Test Strip Name</i> |
|---|--------------------------------------|
| <i>SD Biosensor</i>                         | <b>SD Codefree</b>                   |
| <i>Health Integrated Technologies Ltd</i>   | <b>CozyLab S7</b>                    |
| <i>National Diagnostic Products Pty Ltd</i> | <b>Betachek G5</b>                   |
| <i>Medisana</i>                             | <b>GlucuDock</b>                     |
|   | <b>MediTouch</b>                     |
| <i>Elektronika Kft</i>                      | <b>AutoSense</b>                     |
| <i>Farla Medical Ltd</i>                    | <b>Dario</b>                         |
| <i>Apollo</i>                               | <b>SuperCheck Plus</b>               |

5. If clinically appropriate, review the use of those BGTS listed in Figure 8 as they were unable to meet the essential criteria of the evaluation process (Figure 8).

**Figure 8: Manufacturers unable to meet the essential criteria of the evaluation process**

| <i>Manufacturer</i>         | <i>Blood Glucose Test Strip Name</i> | <i>Details of Essential criteria not meet</i>  |
|-----------------------------|--------------------------------------|--|
| <i>iCare Medical UK Ltd</i> | <b>iCare Advanced</b>                | Unable to provide independent evidence meeting ISO15197: 2013 accuracy standards as per evaluation |
|                             | <b>iCare Advanced Solo</b>           |  |
| <i>BBraun</i>               | <b>Omnitest 3</b>                    | Unable to provide independent evidence meeting ISO15197: 2013 accuracy standards as per evaluation |
| <i>Menarini</i>             | <b>Glucomen GM</b>                   | Provided independent evidence as per evaluation process. However, insufficient heamatocrit range   |
| <i>Entra Health</i>         | <b>MyGlucOHealth</b>                 | Unable to provide independent evidence meeting ISO15197: 2013 accuracy standards as per evaluation |
| <i>Ciga Healthcare</i>      | <b>SURESIGN Resure</b>               | Unable to provide independent evidence meeting ISO15197: 2013 accuracy standards as per evaluation |
| <i>Neon Diagnostics</i>     | <b>GlucOlab</b>                      | Unable to provide independent evidence meeting ISO15197: 2013 accuracy standards as per evaluation |
| <i>Abbott</i>               | <b>Freestyle Lite</b>                | Unable to provide independent evidence meeting ISO15197: 2013 accuracy standards as per evaluation |

Note: CSU is currently awaiting clarification on the submitted independent and/or published evidence of ISO: 2013 accuracy standard from **Sanofi (BGStar test strips)**. It is unclear if the recently submitted evidence fully meets the criteria of the evaluation process. The CSU is aware of the delay and consequently at the point of writing these recommendations (March 2015) the CSU did not list **BGStar testing strips** in Figure 8 above. Please consult with the manufacturer representative if BGStar remains a product of choice in your locality.

6. As manufacturers have until June 2016 to comply with the new ISO 15197: 2013 update, it is envisaged that the on-going assessment of SMBG system is required and the preferred shortlist of BGTS updated.