Blood Glucose Test Strip (BGTS) evaluation protocol and results

Update – April 2016

Version 4.0

Note:
Following comments from NHS colleagues, the Greater Manchester Shared Service (GMSS) Medicines Optimisation team have been requested to carry out a review of any new evidence of BGTS meeting the international accuracy standards (ISO 15197: 2013).

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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
12/11/2015	J Cheung	Following Sept/October 2015 re-review and changes to the evaluation scoring. Updated report.	2.1
07/12/2015	J Cheung	Updated report following NICE type 2 diabetes guidance publication and response to changes to evaluation scoring.	2.2
01/04/2016	J Cheung	Evaluation and summary sheet updated following new independent and published evidence - Contour TS and Contour testing strips. Summary sheet amended as per communication with the following manufacturers/distributors: TRUEyou - Haematocrit range. Corrected and reflected in scoring FreeStyle Lite and Optium - Blood glucose reading range. Corrected and reflected in scoring Footnote added on Summary sheet beside criterion - ***Haematocrit range between 30-60% (or more).*** Section 5 and 6 amended as per changes above.	3.1

Approvals

This document must be approved by the following before distribution:

NAME	TITLE	DATE OF ISSUE	VERSION
GMMMG	Blood Glucose Test Strip (BGTS) evaluation protocol and results	13/11/2015	2.1
GMMMG	Blood Glucose Test Strip (BGTS) evaluation protocol and results	17/12/2015	2.2
H. Burgess	Chair of GMMMG	08/04/2016	3.1

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	June 2016
GMMMG members	Blood Glucose Test Strip (BGTS) evaluation protocol and results	Dec 2015	3.0	June 2016
H. Burgess	Chair of GMMMG	08/04/2016	3.1	
GMMMG members	Blood Glucose Test Strip (BGTS) evaluation protocol and results	Apr 2016	4.0	June 2016

1 Background

1.1 The Greater Manchester Medicines Management Group (GMMMG) 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 GMMMG work plan is facilitated and supported by the Regional Drug & Therapeutics Centre in Newcastle and the Greater Manchester Shared Services (GMSS).

In addition to medicines management, the GMMMG'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 GMMMG 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 NICE guideline recommends that SMBG is indicated for all individuals with type 1 diabetes[1, 2, 3] and to only adults with type 2 diabetes[4] if one or more of the following applies:

- the person is on insulin or
- there is evidence/ suspected 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 or
- the person is starting with oral or intravenous corticosteroids.

There has already been work undertaken to implement NICE guidance across Greater Manchester and as such this guidance will concentrate on the selection of ISO (international standards) compliant SMBG systems.

2.3 In 2015 there are over 156,000 patients with diabetes in Greater Manchester according to the latest QOF figures[5] 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 2015, the total spend across Greater Manchester on BGTS was in excess of £8.5m, an increase of over £500K from 2014[6]. As of October 2015 there are 62 varieties of BGTS funded within the NHS[7] 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[8]. 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[9] 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 has also considered data beyond the drug tariff listing and includes 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[10]. 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[10].

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

Figure 1:

	ISO 15197: 2003	***ISO 15197:2013***
Higher level accuracy	*>4.2mmol/l +/- 20%*	*>5.5mmol/l +/- 15%*
Lower level accuracy	*<4.2mmol/l +/- 0.83mmol/l*	*<5.5mmol/l +/- 0.83mmol/l*
Number of lots	*1*	*3*
Results in zone A/B of Clarke Error Grid	*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[10].

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[11]. 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 since all devices are freely available via NHS Drug Tariff listing

4 Review Process

4.1 Initially, a review of existing evaluations using the internet was undertaken to identify 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.

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.

4.2 In Greater Manchester, a pass or fail and scoring process was undertaken to evaluate the preferred BGTS and meter. If any BGTS received a fail at Stage 1 (see overleaf) then they were excluded from any further scoring within the process.

4.3 The following representatives were involved in the project group in 2014/15:

- Specialist nursing and clinicians with interest in SMBG
- Patient representation through specialist clinicians
- Commissioners and;
- Medicines optimisation leads/pharmacists

The project 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 evaluation.

4.4 The BGTS currently included within the NHS Drug Tariff (October 2015) were all assessed and scored according the following review process overleaf.

Stage 1: 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. GMSS Medicines Optimisation team ensured all submitted and searched data were reviewed, without bias and confirmed accuracy to standards claimed.

This stage was undertaken in advance of *stages 2, 3 and 4*. Any blood glucose systems not meeting this essential criterion below did not proceed.

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 2: A review of desirable features that is offered to users

The previous GMMMG BGTS evaluation process (archived - *version 2.0 May 2015)* required a review of the BGTS essential features (agreed by the project group) with a strict pass/fail response only. A fail at this stage of the evaluation meant that the BGTS was excluded completely from the review. Following comments from NHS colleagues and specialist in the field, the essential criteria could be seen as subjective and excluding potentially quality assured options could be considered biased and unfair for local decisions to be made. As a result, the 'essential' criteria has been renamed as 'desirable' features and scored accordingly i.e. 2 points per desirable criteria met.

The manufacturers and suppliers that fulfilled mandatory requirements of Stage 1 were subsequently required to provide additional information on the following below points.

Desirable criteria: Scored 0 or 2

- ✓ 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.

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. The GMSS Medicines Optimisation team ranked BGTS deemed to offer cost effectiveness to the health economy by calculating a weighted score (WS).

The WS was evaluated against cost of available BGTS by the following steps:

- WS = (Lowest cost BGTS per 50 strips divided by current BGTS price per 50 strips) multiplied by the weighted score i.e. 10.
- This will allow each strip to achieve a WS, calculated to one decimal point, 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.

Stage 4: A review of added-value features and support offered to users

Stage 4 required all partaking manufacturers/ distributors to review the non-essential but added-value features and support offered. Each criterion (agreed by the project group) met were awarded one point.

Added-value features (based on project group decisions): Scored 0 or 1

- ✓ 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 (≤ 0.5µl).
- ✓ Measurement time (≤ 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 GMSS Medicines Optimisation team.

Note: Any evaluations carried out must be done in such circumstances to allow unbiased comparison of like for like features and consequently all stages of the review criteria were applied in an objective manner. Whilst we acknowledge there is always an element of subjectivity in any scoring system there is a transparent and auditable process to minimise the risk of a challenge should this occur at a later stage.

5 Results

In summary, of the 62 BGTS available on the NHS (October 2015) the results were as follows:

Figure 2: BGTS results overview

	Number of BGTS
Group 1 (First choice BGTS) *– submitted independent and published evidence of meeting ISO 15197: 2013 accuracy standards as per protocol*	***22***
Group 2 (Alternative choice) *– submitted independent evidence of meeting ISO 15197: 2013 accuracy standards as per protocol*	***6***
Manufacturers unable to submit the required evidence as per protocol and excluded from further evaluation	***8***
Excluded - No longer promoted and declined to partake	***15***
Non-responders to evaluation and excluded	***9***
Excluded - New BGTS added to Drug Tariff post GMMMG re-evaluation start date	***2***

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 1*.

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

Manufacturer	***Blood Glucose Test Strips***	***Cost per 50 strips***	***Evaluation process score (out of 50)***
Abbott	**FreeStyle Lite**	***£15.80***	*41.4*
	FreeStyle Optium	***£15.71***	*41.4*
Bayer	**Contour Next**	***£15.04***	*42.7*
	Contour TS	***£9.50***	*44.4*
	Contour	***£9.95***	*44*
GlucoRx	**GlucoRx Nexus**	***£9.95***	*45*
LifeScan	**OneTouch Verio**	***£15.12***	*42.6*
	OneTouch Select Plus	***£9.99***	*42*
Menarini Diagnostics	**GlucoMen Areo**	***£9.95***	*45*
	GlucoMen LX	***£15.52***	*42.5*
Neon Diagnostics	**Element**	***£9.89***	*44.1*
	GluNeo	***£9.89***	*44.1*
Nipro Diagnostics	**TRUEyou**	***£9.92***	*40*
Roche	**Aviva**	***£15.79***	*42.4*
	Active	***£9.95***	*44*
	Performa	***£9.95***	*45*
	Mobile	***£15.95***	*41.3*
Sanofi	**BGStar**	***£14.73***	*39.7*
Spirit Healthcare	**CareSens N**	***£12.75***	*44.5*
	TEE2	***£7.75***	*48*

Ypsomed	**MyLife Pura**	***£9.50***	*43.4*
	MyLife Unio	***£9.50***	*40.4*

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

Manufacturer	*Blood Glucose Test Strips*	*Cost per 50 strips*	*Evaluation process score (out of 50)*
Agamatrix	**WaveSense Jazz (and Duo)**	***£9.87***	*45.1*
Apollo Medical	**SuperCheck Plus**	***£9.45***	*41.4*
	SuperCheck 2	***£8.49***	*42.2*
B. Braun	**Omnitest 3**	***£9.89***	*43.1*
HomeHealth UK	**SD Codefree**	***£6.99***	*47*

Group 1 and 2 BGTS were further assessed and scored against a set of project group approved criteria based on cost, desirable functions or services, and added-value features. The maximum score any BGTS could achieve was 50 and full results of the assessment can be found in the Excel document link below – Figure 5.

Figure 5: Group 1 and 2 BGTS evaluation results summary

BGTS Evaluation Summary April 2016 v

Note: GMMMG accepts that due to potential subjective responses in the evaluation and a changing dynamic market; local decision makers may not select their preferred testing device based on the results of the above evaluation score. The above evaluation score provides guidance and support for local commissioners to consider when selecting preferred blood glucose monitoring devices.

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 22 BGTS (Group 1) could provide robust independent and published evidence demonstrating compliance to the updated ISO 15197: 2013 accuracy standards.

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 decision not to partake in the evaluation and/or their inability to demonstrate compliance with the standards requested in this process (see *Appendix 2*).

7 Future Evaluation Review

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

The GMSS/ 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 GMSS if it is considered by GMMMG sub-groups to have a significant impact on Greater Manchester health economy. GMSS Medicines Optimisation team will not accept any new information or evidence for any BGTS unless directed by the GMMMG sub-groups for review.

8 References

1. *National Institute for Health and Care Excellence (NICE) Clinical guideline NG17 – Type 1 diabetes in adults: diagnosis and management. August 2015. Accessed August 2015.*
2. *National Institute for Health and Care Excellence (NICE) Clinical guideline NG3 –Diabetes in pregnancy: management from preconception to the postnatal period. February 2015. Accessed October 2015.*
3. *National Institute for Health and Care Excellence (NICE) Clinical guideline NG18 –Diabetes (type 1and type 2) in children and young people: diagnosis and management. August 2015. Accessed October 2015.*
4. *National Institute for Health and Care Excellence (NICE) Clinical guideline NG28 – Type 2 diabetes in adults: management. December 2015. Accessed December 2015.*
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10. *ISO website: http://www.iso.org/iso/home/news_index/news_archive/news.htm?refid=Ref1749.*
11. *http://www.diabetes.org.uk/About_us/News_Landing_Page/People-with-diabetes-denied-vital-test-strips/ Accessed. Accessed 19th January 2014*

Updated and reviewed by:
J Cheung (Medicines Optimisation Pharmacist)

9 Appendices

Appendix 1: Published evidence of ISO 15197: 2013 accuracy standards

Blood Glucose Testing Strip	Manufacturer/ Distributor	Published evidence of meeting ISO 15197: 2013 accuracy standards
Aviva	Roche	(1) 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 (2) 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
BGStar	Sanofi	Freckmann G et al (2015) System accuracy evaluation of different blood glucose monitoring systems following ISO 151:2013 by using two different comparison methods. J Diabetes Sci Technol; Vol 17 (9), 2015. DOI: 1089/dia.2015.0085 2014
CareSens N	Spirit Healthcare	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):422-424Different Test Strip Lots Following ISO 15197.
Contour Next	Bayer	(1) Bernstein et al (2013) A New Test Strip Technology Platform for Self-Monitoring of Blood Glucose. J Diabetes Sci Technol; 7(5):1386-1399 (2) Freckmann G et al (2015) System accuracy evaluation of different blood glucose monitoring systems following ISO 151:2013 by using two different comparison methods. J Diabetes Sci Technol; Vol 17 (9), 2015. DOI: 1089/dia.2015.0085 2014
Contour TS	Bayer	Pleus et al (2016) Performance of two updated blood glucose monitoring systems: an evaluation following ISO 15197:2013. Current Medical Research and Opinion, DOI: 10.1185/03007995.2016.1146666. 23 Feb 2016
Contour	Bayer	Pleus et al (2016) Performance of two updated blood glucose monitoring systems: an evaluation following ISO 15197:2013. Current Medical Research and Opinion, DOI: 10.1185/03007995.2016.1146666. 23 Feb 2016
Element	Neon Diagnostics	Jeanny G and Hope P (2015) Surveillance of the system accuracy of two systems for self-monitoring of blood glucose after market approval. J Diabetes Sci Technol; DOI: 10.1177/1932296815608871. 30 Sept 2015.
FreeStyle Lite	Abbott	Freckmann G et al (2015) System accuracy evaluation of different blood glucose monitoring systems following ISO 151:2013 by using two different comparison methods. J Diabetes Sci Technol; Vol 17 (9), 2015. DOI: 1089/dia.2015.0085 2014 [FreeStyle Lite test strips and FreeStyle InsuLinx meter]
FreeStyle Optium	Abbott	Brannan C (2015) Evaluation of the FreeStyle Precision Neo blood glucose and ketone monitoring system .Perfusion 2015; 28: 4-13. [FreeStyle Optium test strips and FreeStyle Precision Neo meter (alternatively named FreeStyle Optium Neo meter in the UK)]
GlucoMen areo Sensor	Menarini	Berti F et al (2015) Accuracy evaluation of two blood glucose monitoring systems following ISO 15197:2013. J Diabetes Sci Technol; DOI: 10.1177/1932296815595986. 29 July 2015.
GlucoMen LX Sensor	Menarini	(1) Pfutzner et al. Evaluation of system accuracy of the GlucoMen LX Plus blood glucose monitoring system with reference to ISO 15197: 2013. J Diabetes Sci Technol; DOI: 10.1177/1932296815613803. 9th November 2015
GlucoRx Nexus Strips	GlucoRx	Salzsieder E and Berg S (2015) Accuracy evaluation of a CE-marked system for self monitoring of blood glucose with three reagent system Its following ISO15197: 2013. J Diabetes Sci Technol; DOI: 10.1177/1932296815606471. September 2015
GluNEO	Neon Diagnostics	Jeanny G and Hope P (2015) Surveillance of the system accuracy of two systems for self-monitoring of blood glucose after market approval. J Diabetes Sci Technol; DOI: 10.1177/1932296815608871. 30 Sept 2015.
Mylife Pura	Ypsomed	Freckmann G et al (2015) System accuracy evaluation of different blood glucose monitoring systems following ISO 151:2013 by using two different comparison methods. J Diabetes Sci Technol; Vol 17 (9), 2015. DOI: 1089/dia.2015.0085 2014
Mylife Unio	Ypsomed	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.

OneTouch Select Plus	*Lifescan*	*Evaluation of the performance of the OneTouch Select Plus blood glucose test system against ISO15197: 2013. Expert review of medical device journal. 21st October 2015. Vol 6. DOI:10.1586/17434440.2015.1102049*
OneTouch Verio	*Lifescan*	*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)* *Please note that this study includes VerioPro, VerioVue and OmniPod*
Performa	*Roche*	*(1) Pleus S 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.* *(2) Freckmann G et al (2015) System accuracy evaluation of different blood glucose monitoring systems following ISO 151:2013 by using two different comparison methods. J Diabetes Sci Technol; Vol 17 (9), 2015. DOI: 1089/dia.2015.0085 2014.*
TEE2	*Spirit Healthcare*	*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):422-424Different Test Strip Lots Following ISO 15197.*
TRUEyou	*Nipro Diagnostics*	*Jendrike N et al. ISO 15197:2013 Accuracy Evaluation of Two CE-Marked Systems for Self-Monitoring of Blood Glucose. Journal of Diabetes Science and Technology. DOI:10.1177/1932296815582223. 2015*
Active	*Roche*	*Baumstark et al. Accuracy Assessment of an Advanced Blood Glucose Monitoring System for Self Testing with three reagent system lots following ISO 15197: 2013*
Mobile	*Roche*	*Baumstark A et al (2015) Accuracy evluation of an integrated blood glucose monitoring system with improved test cassesttes following ISO15197:2013. J Diabetes Sci Technol; DOI: 10.1177/193229681560928. 25 May 2014.*

Appendix 2: GMMMG Do Not Prescribe List (Updated: April 2016)

GMMMG has recommended that those BGTS that did not fall into either Group 1 or 2 will also be considered for the *Greater Manchester Do Not Prescribe* list. Healthcare professionals are advised to review and consider discontinuing BGTS listed below and if required consider an alternative approved SMBG device:

Blood Glucose Test Strip	Manufacturer/ Distributor	Reasons for exclusion
Advantage Plus	*Roche*	No longer promoted by manufacturer
Advocate Redi-Code+	*Pharma Supply Inc*	Excluded – insufficient evidence meeting ISO15197: 2013 accuracy standards as per evaluation
AutoSense	*Elektronika Kft*	Excluded – No response
Betachek C50	*National Diagnostic Products Pty Ltd*	Excluded – No response
Betachek G5	*National Diagnostic Products Pty Ltd*	Excluded – No response
Breeze 2	*Bayer*	No longer promoted by manufacturer
Compact	*Roche*	No longer promoted by manufacturer
CozyLab S7	*Health Integrated Technologies Ltd*	Excluded – No response
Dario	*Farla Medical Ltd*	Excluded – No response
FineTouch testing tips	*Terumo UK Ltd*	Excluded – No response
FreeStyle	*Abbott Laboratories Ltd*	No longer promoted by manufacturer
GlucoDock	*Medisana*	No longer promoted by manufacturer
GlucoLab	*Neon Diagnostics*	Excluded – insufficient evidence meeting ISO15197: 2013 accuracy standards as per evaluation. In October 2015 Neon diagnostics have confirmed with the GMSS medicines optimisation team that independent and published evidence will be available confirming the system meets updated international standards. No further information had been provided within the evaluation period.
GlucoMen GM	*Menarini Diagnostics*	No longer promoted by manufacturer
GlucoMen Sensor	*Menarini Diagnostics*	No longer promoted by manufacturer
GlucoMen Visio	*Menarini Diagnostics*	No longer promoted by manufacturer
GlucoRx Original	*GlucoRx*	No longer promoted by manufacturer
iCare Advanced	*iCare Medical UK Ltd*	Excluded – insufficient evidence meeting ISO15197: 2013 accuracy standards as per evaluation
iCare Advanced Solo	*iCare Medical UK Ltd*	Excluded – insufficient evidence meeting ISO15197: 2013 accuracy standards as per evaluation
IME-DC	*Arctic Medical*	Excluded – insufficient evidence meeting ISO15197: 2013 accuracy standards as per evaluation
MediSense Softsense	*Abbott Laboratories Ltd*	No longer promoted by manufacturer
MediTouch	*Medisana*	No longer promoted by manufacturer
Mendor Discreet	*Merck Sorono*	Excluded – No response
Microdot +	*Cambridge Sensors*	Excluded – No response
MyGlucoHealth	*Entra Health*	Excluded – insufficient evidence meeting ISO15197: 2013 accuracy standards as per evaluation

On-Call Advanced	*Point Of Care Testing Ltd*	Excluded – insufficient evidence meeting ISO15197: 2013 accuracy standards as per evaluation
OneTouch Ultra	*LifeScan*	No longer promoted by manufacturer
OneTouch Vita	*LifeScan*	No longer promoted by manufacturer
Sensocard	*Elektronika Kft*	Excluded – No response
SURESIGN Resure	*Ciga Healthcare*	Excluded – insufficient evidence meeting ISO15197: 2013 accuracy standards as per evaluation
TRUEone	*Nipro Diagnostics*	No longer promoted by manufacturer
TRUEresult	*Nipro Diagnostics*	No longer promoted by manufacturer
TrueTrack System	*Nipro Diagnostics*	No longer promoted by manufacturer

Note:
*The following BGTS - **MODZ** and **iHealth;** were NOT evaluated. The BGTS were added to Drug Tariff September and October 2015 respectively, post re-evaluation start date. Both BGTS will be invited for the next planned review in 2016.*

		GROUP 1																					GROUP 2				
Manufacturer/ Distributor		Abbott		Bayer			GlucoRx	LifeScan		Menarini Diagnostics		Neon Diagnostics		Nipro Diagnostics	Roche				Sanofi	Spirit Healthcare		Ypsomed		Agamatrix	Apollo Medical		B. Braun	Home Health UK
BGTS approved by GMSS evaluation process		FreeStyle Lite	FreeStyle Optium	Contour Next	Contour TS	Contour	GlucoRx Nexus	OneTouch Verio	OneTouch Select Plus	Glucomen Areo	GlucoMen LX	Element	GluNeo	TRUEyou	Aviva	Active	Performa	Mobile	BGStar	CareSens N	TEE2	MyLife Pura	MyLife Unio	WaveSense Jazz (and Duo)	SuperCheck Plus	SuperCheck 2	Omnitest 3	SD Codefree
1. Essential criteria – ISO 15197: 2013 accuracy standards																											
Manufacturers reference provided	Pass/Fail	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Independent evidence	Pass/Fail	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Published evidence	Pass/Fail	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	×	×	×	×	×
2. Desirable criteria - Information supplied by manufacturer/distributor (two points per criteria met)																											
Free meters to NHS locations and service users (minimum UK current stock 10,000 meters)	Yes / No	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Free replacement batteries, log books, lancing pens	Yes / No	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Technical support provided via freephone number (not answering machine)	Yes / No	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Free support material and meter training for all healthcare professionals	Yes / No	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Free Internal Control Solution	Yes / No	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Measures only in mmol/L units and cannot be changed	Yes / No	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Provides plasma-calibrated meter readings	Yes / No	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Haematocrit range between 30-60% (or more)[T]	Yes / No	✓	✓	✓	✓	✓	✓	✓	×	✓	✓	✓	✓	×	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Measurement range between 1.1 to 33.3mmol/L (or more)	Yes / No	×	×	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Unable to delete readings from memory	Yes / No	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
No calibration or coding required	Yes / No	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	×	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Expiry date of test strips - minimum 6 months from opening	Yes / No	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	×	✓	✓	✓	×	✓	✓	✓	✓	×	✓	×	×	✓	✓
	Shelf life	2 yrs	18 months	2 yrs	2 yrs	2 yrs	2 yrs	2 yrs	18 months	2 yrs	2yrs	2yrs	2yrs	2yrs	18 months	18 months	18 months	18 months	2 yrs	2 yrs	2 yrs	2 yrs	2yrs	22 months	18 months	18 months	2 yrs	2 yrs
	Expiry from opening vial/ cassette	2 yrs	18 months	2 yrs	2 yrs	2 yrs	6months per vial (2x25 vials)	6 months	18 months	6 months	9 months	6months per vial (2x25 vials)	6months per vial (2x25 vials)	4 months	18 months	18 months	18 months	1x50 cassette. 3 months	6months	2 yrs	2 yrs	6 months	3 months	6 months per vial (Duo = 2x25 vials)	3months per vial (2x25vials)	3months per vial (2x25vials)	6months per vial (2x25 vials)	6 months
Section 2. Sub-Total [A] (max. score = 24)		22	22	24	24	24	24	24	22	24	24	24	24	20	24	22	24	22	24	24	24	24	22	24	22	22	24	24
3. Cost																												
Cost of 50 test strips	According DT Oct 2015	£15.80	£15.71	£15.04	£9.50	£9.95	£9.95	£15.12	£9.99	£9.95	£15.59	£9.89	£9.89	£9.92	£15.79	£9.95	£9.95	£16.09	£14.73	£12.75	£7.75	£9.50	£9.50	£9.87	£9.45	£8.49	£9.89	£6.99
Section 3. Weighted Score [B] (max. score = 10)		4.4	4.4	4.7	7.4	7	7	4.6	7	7	4.5	7.1	7.1	7	4.4	7	7	4.3	4.7	5.5	9	7.4	7.4	7.1	7.4	8.2	7.1	10
4. Added-value features - Information supplied by manufacturer/distributor (one point per criteria met)																												
ENZYME TECHNOLOGY (see below)		GDH-FAD	GDH-NAD	GDH-FAD	GDH-FAD	GDH-FAD	GDH-FAD	GDH-FAD	GoX	GoX	GoX	GoX	GDH-FAD	GDH-FAD	Mut. Q-GDH	Mut. Q-GDH	Mut. Q-GDH	Mut. Q-GDH	GoX	GoX	GoX	GoX	GDH-FAD	GoX	GDH-FAD	GoX	GoX	GoX
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	✓	✓	✓	×	×	×	×	×	×	×	×	×	×	×	✓	×	×	×	×	×	×	×	×	×	×	×	×
Capillary fill function	Yes / No	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Sample size (≤ 0.5µl)	Yes / No	✓	✓	×	×	×	✓	✓	×	✓	✓	✓	✓	✓	×	×	×	✓	✓	✓	✓	×	×	✓	✓	✓	✓	×
Measurement time (≤ 5 seconds)	Yes / No	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	×*	✓	✓	✓	✓	✓	✓	✓	✓	✓
Sufficient memory capacity as per project group expectations	Yes / No	✓	✓	✓	✓	✓	✓	✓**	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Memory capacity	1,000	1,000	800	250	480	1,000	500	500	730	400	500	500	500	1,000	500	500	2,000	1,865	1,000	500	500	1,000	1,865	500	500	500	500
Meter set–up is not required (e.g. date and time). However minor adjustment maybe required in BST/battery changes.	Yes / No	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	×	✓	✓	✓	×	✓	✓	✓	✓	✓
The manufacturer can provide material and deliver training to patients and carers free of charge.	Yes / No	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Manufacturers to provide records and evaluation of all training to all recipients and highlight learning outcomes achieved and any areas of concerns.	Yes / No	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	×	×	✓	✓
The company supports any promotion of local guidelines for SMBG	Yes / No	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	×	×	✓	✓
Allow electronic download to personal computers and clinical systems	Yes / No	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
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	Yes / No	✓	✓◊	✓	✓	✓	✓	✓	✓	✓	✓◊	×	×	×	✓	✓	✓	✓	×	✓	✓	×	×	×	✓	✓	×	×
Manufacturers provides information of their MHRA product recall process and actions to be taken	Yes / No	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Free independent external quality assurance for healthcare professionals in GP practices and insulin users who self monitors blood glucose	Yes / No	×	×	×	×	×	×#	×	×	×#†	×#†	×#	×#	×	✓†	✓†	✓†	✓†	×	✓†	✓†	×	×	✓†	×†	×†	×#†	✓†
Section 4. Sub-Total [C] (max. score = 16)		15	15	14	13	13	14	14	13	14	14	13	13	13	14	15	14	15	11	15	15	12	11	14	12	12	12	13
Total score (A + B +C) out of 50		41.4	41.4	42.7	44.4	44	45	42.6	42	45	42.5	44.1	44.1	40	42.4	44	45	41.3	39.7	44.5	48	43.4	40.4	45.1	41.4	42.2	43.1	47

NOTE: *All responses are based on the direct information provided by the representatives of the manufacturer/distributor. Every effort has been made to ensure all information is correct and accurate at the time of publication (December 2015). The publication should be used as a guidance in its entirety by any users of this document. We acknowledge this is a very dynamic market and commissioners/providers are advised to directly contact any maufacturers/distributors shortlisted locally to confirm the information above is correct at point of decision making. The above evaluation score provides guidance and support for local commissioners to consider when selecting preferred blood glucose monitoring devices.*

Key:

Mut. Q-GDH	*Mutant variant of the quino protein glucose dehydrogenase*
GoX	*Glucose Oxidase*
GDH-FAD	*Glucose Dehydrogenase - Flavine -adenine dinucleotide*
GDH-NAD	*Glucose Dehydrogenase - nicotinamide adenine dinucleotide*
*	*Sanofi response to the evaluation is with respect to their BGStar meter. Sanofi alternative meter (MyStar Extra) has measurement time ≤ 5secs*
**	*LifeScan OneTouch VerioIQ meter has a memory capacity of 750*
#	*External quality assessment service (EQA) is offered to healthcare professionals only*
†	*Manufacturer/distributor request further dialogue to discuss logistics and implementation of EQA (should this be required)*
◊	*The corresponding meter can also measure ketones using FreeStyle Optium B-ketone strips (Abbott) or GlucoMen LX ketone strips (Menarini)*
T	*Under ISO 15197: 2013 standards manufacturers are required to demonstrate blood glucose readings meet the acceptance criteria at each haematocrit level. They are NOT required to demonstrate within a set haematocrit percentage range. The results of the criterion - **Haematocrit range between 30-60% (or more)** is based on internal assessment and feedback from the manufacturer/distributor and product manual. Every effort has been made to ensure all information is correct, however, if this range is of particular concern, please directly contact the manufacturer/distributor for up to date percentage haematocrit range.*