NHS
Purchasing and Supply Agency

Centre for Evidence-based Purchasing

Buyers' guide

Blood glucose systems

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Informing procurement - Encouraging innovation

Contents

Introduction

Glucose meters are portable, hand held, battery operated instruments used in conjunction with disposable test strips to rapidly measure glucose concentration in a small sample of whole blood. Their use is well established and incremental advances in meter and strip technology result in frequent introduction of new models.

The number of people with diabetes in England in 2006 is estimated to be 2.4 million [1], with another 500,000 undiagnosed. By 2010 the number is estimated to increase to 2.6 million (5.1% prevalence). Of these 2.4 million, 5 – 15% have type 1 diabetes (approximately 500,000) and 85 to 95% have type 2 diabetes. According to the Department of Health "*approximately 5% of the total NHS spend and up to 10% of hospital in-patient spend is used for the care of people with diabetes*" [1].

The main aim of treatment in both type 1 and type 2 diabetes is to avoid hypo- and hyperglycaemic episodes and maintain near normal blood glucose levels. Tight control of blood glucose levels achieved through frequent blood glucose monitoring has been shown to be effective in reducing complications such as retinopathy, nephropathy, and neuropathy [2-3].

Field of Use

Meter systems are widely used in both secondary and primary care. In secondary care they are used to monitor the diabetic inpatient population and critically ill patients with glucose imbalance due to major organ failure, septicaemia etc. In primary care, they are used by health care professionals and at home by people with diabetes for self monitoring. Healthcare professional use constitutes approximately 20% of the total test strip market; the remaining 80% is home usage. Blood glucose systems can be used for opportunistic diabetes screening (but not to diagnose diabetes) and monitoring of gestational diabetes which occurs in up to 14% of all pregnancies.

Glucose status can also be checked by urine testing. However due to the lag phase in urine collection it does not truly reflect blood glucose levels and hypoglycaemic episodes can be missed. Long term glucose status can also be assessed by measuring blood HbA1c which correlates strongly with the mean blood glucose concentration over 120 days. Developments in minimally-invasive continuous glucose monitoring systems (CGMS) have seen an increase in their availability and use.

Clinical importance

Blood glucose systems enable immediate treatment as instant, real time glucose results are generated. Glucose meters are particularly useful to patients who are on insulin and require frequent self monitoring to control and adjust their treatment. They provide clear potential benefits when used correctly and when the results are acted upon.

National guidance

The Diabetes National Service Framework sets out standards for diabetes care in the UK. It states that support should be given to optimise the control of blood glucose levels [4]. The

Introduction

National Institute for Health and Clinical Excellence (NICE) has issued guidelines on the frequency of self-monitoring of blood glucose levels in both types 1 and 2 diabetes [5-7].

Self-monitoring is considered suitable for patients with type 1 and type 2 diabetes on insulin and sulphonylurea in order to adjust their dose to achieve treatment goals or identify hypo- or hyperglycaemia. It is particularly important to self monitor when changing insulin, during illness, before driving, participating in sports or making lifestyle changes [5-7].

NICE guidelines for type 2 diabetes [6] state that "*self-monitoring should not be a stand-alone intervention, but form part of an integrated self-care programme, and is appropriate and recommended for type 2 diabetics on insulin treatment who adjust their dose as a result of blood glucose testing*". Use of self-monitoring in patients with type 2 diabetes on oral medication, diet and exercise control is controversial and recommendations on its frequency and use are based on consensus opinion [8-15].

NICE states that whilst continuous glucose monitoring systems "have not yet established their usefulness beyond problem-solving in the occasional person with recurrent blood glucose control problems at the same time of day", they do have a role in the assessment of glucose profiles and should be offered to all type 1 diabetics, including children and young people, on insulin therapy who have persistent problems with hypoglycaemia unawareness or repeated hypoglycaemia or hyperglycaemia [5].

Issues related to the safety and management of point-of-care devices are covered in guidance issued by the Medicines and Healthcare products Regulatory Agency (MHRA) [16,17].

Scope of report

This buyers' guide reviews commercially available blood glucose systems, purchasing mechanisms and considerations, and provides an overarching view of the technical, operational and value/economic issues which need to be considered when selecting a meter.

Technical considerations

Blood glucose meters are classified as in-vitro medical devices and must be CE marked under the IVD Directive [18]. Glucose systems consist of a meter and single use disposable test strips based on dry reagent, enzyme chemistry. A lancing device is included for obtaining capillary blood samples. A buyers' guide to lancing systems is available to download from www.pasa.nhs.uk/cep [19].

A test strip is inserted into the meter and a blood sample applied to the strip's chemically active area. The responses from reactions occurring on the strip are translated by the meter to a glucose concentration which is subsequently shown on the meter display. The used test strip is removed and discarded. Some meters have an ejection mechanism for safe removal of the contaminated strip.

The International Standards Organisation (EN ISO 15197) and the American Diabetes Association have published performance guidance for minimum proficiency standards required for accuracy (less than15%), imprecision (CV less than 5%) and total allowable error (less than 10%) with blood glucose meters [20,21].

Blood glucose meters

All meters have a display window, test strip slot, battery compartment and a data port or infra red window for data transfer. The number of buttons required to operate the system is limited to one or two, with many tasks accomplished automatically.

The meter is powered by one or more conventional or coin cell lithium batteries capable of approximately 1000 measurements in normal use. A large display, font and icons, together with audible feedback are helpful for patients who have visual impairment. A limited number of talking meters are available which guide the operator through the measurement procedure.

Blood glucose meters have a built in memory capable of automatically storing glucose results with date, time and event markers. Results can be viewed on the meter's display or by downloading to a personal computer using an RS link and software.

Systems for professional use have additional data management capabilities for patient and staff identification achieved electronically through connectivity to minimise transcription errors.

MHRA recommends that the units of measurements for blood glucose systems in the UK are hard fixed to display results as mmol/l. Results expressed as mg/dl are higher by a factor of 18 than results expressed in mmol/l (ie 6.5 mol/l will be expressed as 117 mg/dl). This could lead the user to think that the glucose result is high and thus alter the treatment regime. Operators should check the units displayed and be aware of this difference [22].

Technical considerations

Blood glucose test strips

Dry reagent test strips utilise one of two glucose specific enzymes, glucose oxidase or glucose dehydrogenase, and measurements are based on electrochemical (biosensor) or colour (reflectance) responses which are automatically measured and equated to glucose concentration in the sample.

For optimal performance, test strips need to be stored at recommended temperatures and humidity, in a capped vial containing a desiccant. Individually foil wrapped strips have the advantage of only exposing the strip in use briefly to the atmosphere. To minimise exposure, a test strip should only be removed and placed in the meter when the entire meter and patient preparations have been completed.

Test strips generally have a shelf life of approximately two years and the test strip expiry date is printed on the packaging. Once the strip vial is opened the shelf life is reduced to approximately 90 - 180 days as specified in manufacturers' user guides. Individually foil wrapped test strips remain viable to the stated expiry date. Several glucose systems designed for single patient, home use have eliminated test strip handling by providing multiple strips packaged in a drum or a disc which slots into the meter.

Calibration

Manufacturers calibrate meters and strips against different reference methods which can lead to between-system variation in glucose results. Calibration against a glucose oxidase or a hexokinase reference methodology can produce approximately a 6% difference in results. All meters use a whole blood sample and are factory calibrated to express the result either as whole blood or plasma values. Plasma values are approximately 11 to 12% higher than whole blood values.

Reagent test strips from different production lots can vary in their performance. This variation is minimised by inputting a lot-specific code into the meter's memory for calculating the results. The coding information is entered via a code key, a calibration electrode, by manually inputting a code number, automatic calibration upon insertion of the test strip into the meter or scanning of information on strip packaging. Many new systems do not require any calibration due to stringent manufacturing processes which limit lot variation.

Quality Assurance

Quality assurance and analytical quality control measures in glucose testing consist of training and overall assessment of performance, including pre- and post-analytical processes. As part of clinical governance it is necessary to implement reliable quality assurance, internal quality control and local external quality assurance schemes to monitor and improve the use of blood glucose systems. This is generally handled by the local hospital laboratory.

Internal quality control

Quality control materials are made available by the manufacturer and operate within a particular testing site. Quality control is designed to monitor and detect errors in the testing procedure to provide real time reassurance to the operator that the strips and meter are working correctly. However, it does not measure the operator's sample collection technique. Aqueous, coloured control solutions, generally at two levels, are provided by the manufacturer. They are meter and lot specific with result ranges which are printed on the test strip packaging or canister. They are not interchangeable between different glucose systems.

The frequency of quality control for hospital use depends on the level of testing done in a unit and should be specified in the standard operating procedure. Hospital systems have lockout features that can allow a patient's blood glucose measurement to be made only once a quality control test has been successfully carried out. Patients self monitoring at home rarely (<1%) use quality control materials even though they are provided free-of-charge (manufacturers own data).

External quality assessment schemes (EQA)

EQA schemes compare results between multiple sites to provide valuable information on performance and systematic analytical bias. It is retrospective and unlike internal quality control is not in real time. EQA schemes work by each individual site analysing identical specimens and comparing results across all the sites. Relevant information must be given to the user promptly to allow remedial action to be taken.

Limitations

Blood glucose meters have certain limitations caused by interference with the analytical process or biological effects from components of specimens from patients on complex treatment regimes [23-25]. A comprehensive list of limitations of use and details of interferences is provided in the manufacturer's instructions for use leaflet included with the reagent test strips. Pre-analytical factors such as exercise, body position, stress and endocrine disturbances can all have a bearing on glucose concentrations. Time since last intake of food and smoking can increase glucose levels, whilst alcohol decreases levels.

Natural physiological differences occur between capillary, venous and arterial samples and are shown in table 1.

Table 1: Sample type and result interpretation

Capillary fingerstick glucose result compared to:			
Venous	Arterial	Alternative site	Venous Plasma
Venous is 11% lower at normal haematocrit	Generally no marked difference	Approximately 30% higher than capillary fingerstick however, hypo and hyperglycaemic episodes may be missed	Approximately 15% higher

Different meter/strip systems are affected to differing degrees by environmental, analytical and physiological interferences. Frequently encountered interferences are listed in table 2.

Table 2: Common interference with blood glucose measurements

	Interference	Effect of Interference
Environmental	Temperature	Test strip deterioration can occur if strips are not stored within manufacturer's specified ranges or if subjected to temperature extremes
	Humidity	The dry reagents can deteriorate when strips are exposed to the atmosphere. This can be avoided by removing test strips just prior to a measurement and recapping the strip canister immediately
	Altitude	Erroneous results can be obtained at very high altitudes. Test strips can be used up to an altitude of approximately 3500 meters
Analytical	Haematocrit	Any imbalance in the plasma water available for the chemical reaction can give erroneous results. Low haematocrit (↑plasma water) gives high glucose results. High haematocrit (↓ plasma water) gives lower glucose results
	Contaminants	Samples collected from an in-dwelling line used to administer dextrose, if not flushed, will give erroneously high glucose results. Strict hand hygiene is required to avoid introducing contaminants to the sample
	Bilirubin	High levels in neonates and patients with liver failure (levels greater than 300 µmol/L) may cause falsely elevated blood glucose readings
	Lipids	Hyperlipidaemia can cause interference in glucose measurement. High total cholesterol and or triglycerides will give lower glucose results. Similar effects can occur in adults and neonates on total parental nutrition
	Maltose	Overestimation of glucose results with strips using the enzyme glucose dehydrogenase and coenzyme pyroloquinoline quinone (PQQ). Affects a small group of renal patients on continuous ambulatory peritoneal dialysis where icodextrin is added to the dialysis fluid, or in patients receiving treatment containing maltose or certain immunoglobulin preparations
	Galactose	Causes falsely elevated glucose results with strips using the enzyme glucose dehydrogenase and coenzyme PQQ
	Xylose	Used in xylose absorption tests. Falsely elevates glucose results with strips using the enzyme glucose dehydrogenase and coenzyme PQQ
	Oxygen saturation (pO_2)	Critically ill patients on oxygen therapy or with impaired oxygen transport may give discrepant glucose results with systems using glucose oxidase methodology by either an over (low pO_2) or under estimation (high pO_2)
	Reducing substances	Paracetamol, uric acid and vitamin C can give erroneously low or high glucose results depending on the enzyme and methodology
Patient status	Diabetic ketoacidosis with or without hyperosmolar, hyperglycaemia; dehydration; vomiting etc	In critically ill patients with; decreased peripheral blood flow caused by severe dehydration due to diabetic ketoacidosis or hyperosmolar non-ketotic state, hypotension, shock or peripheral vascular disease - results will be significantly lower than the true glucose concentration in the central circulation. In such situations a venous blood sample should be sent to the laboratory for analysis.

Operational considerations

Ergonomics

Blood glucose systems need to be intuitive and easy to use, incorporating features that eliminate or minimise operator dependency. Errors can occur during blood sample collection and application to the test strip, and incorrect input of lot specific calibration codes. Inappropriate specimen collection and processing can invalidate results regardless of the quality, accuracy and precision of the glucose system. Automatic checks by the meter highlight procedural or analytical errors via warning messages or audible signals. Important meter and test strip features are outlined in table 3.

Table 3: Features of meters and test strips to be considered

Meter features
Shape and materials which allow easy handling
Large display and font size
Large easy to manipulate buttons
Minimal input for initial set up of time, date, language etc
Automatic internal electronic checks to ensure meter integrity
Prevention of use of test strips from different manufacturers
Automatic start and timing of measurement
Automatic shutdown to conserve battery life
Accessible battery for quick and easy replacement
Audible feed back of sufficient sample addition
Simple warning messages for procedural or analytical errors
Automatic ejection of used test strips
Test strip features
Easy to access test strips e.g. easy to open packaging, low risk of perforating unopened strips
Large strip size and shape for easy handling and visibility of active area to assess any damage
Requires small sample volume (less than 1.5µl) and automatic capillary uptake
Prevention of use of damaged, incorrectly inserted or previously used test strips
Minimal test strip handling to prevent contamination and damage

Operational considerations

Safety

Meters are battery or mains operated. Although safety does not have a direct bearing on the quality of results, patients and operators may be at risk of cross-infection from a contaminated meter in multi-patient use. Ideally blood glucose systems where a test strip containing blood does not come into direct contact with the internal meter components should be used.

Needlestick injury from contaminated sharps can transmit infection. In multiple patient environments a single-use disposable lancing device with automatic retraction of the needle, or a non-disposable multiple-patient system should be used by healthcare professionals as they minimise the associated risks with re-use of a blood-contaminated lancet. MHRA has issued guidance relating to the safe use of lancing devices that highlights the risks associated with inappropriate use [26,27].

People with diabetes using a system for personal use can do so with minimal risk. However, when used by a carer, there is a risk of cross-infection from needle-stick injury or handling potentially contaminated blood.

Resources

Glucose measurements are performed by a single operator. For professional use sufficient time to perform quality procedures and maintenance and troubleshooting should be allocated. In secondary care input should be provided by a point-of-care co-ordinator to maintain, support and manage all relevant activities, including IT support and infection control.

For self monitoring, help in the selection and training of a suitable system as well as additional support and troubleshooting is provided by a diabetes specialist or practice nurse or via a manufacturers' customer care help line.

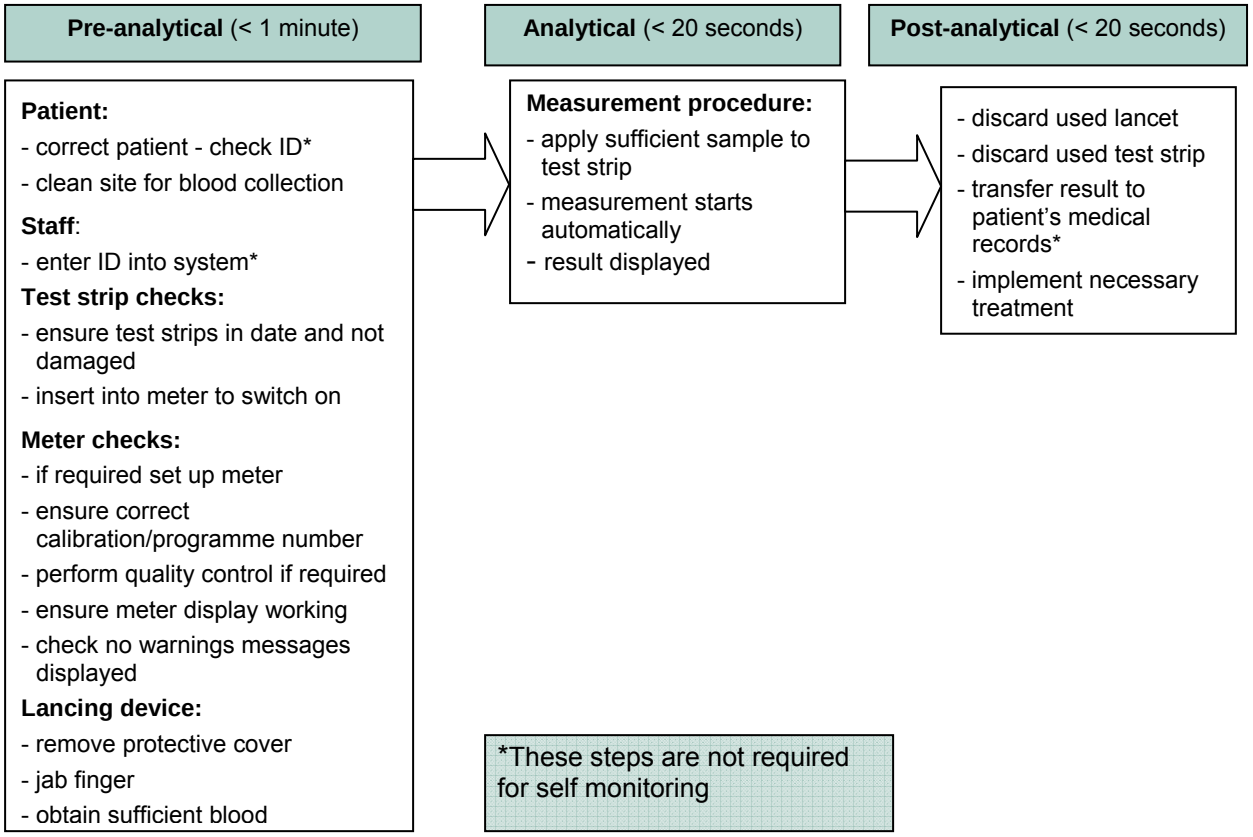
Additional accessories required for blood glucose measurement are alcohol wipes to clean a patient's finger, gauze to wipe the initial drop of blood (where recommended) and stem blood flow, a plaster to prevent contamination, a sharps bin for disposal of contaminated sharps, yellow bags for clinical waste, quality control materials, decontamination materials and spare batteries.

Workflow

Whether for home or professional use, once initial set up and quality control of the meter has been performed, a glucose measurement takes a matter of minutes. To facilitate workflow, the glucose meter, test strips and other consumables should be easily accessible. Location of equipment and sharps bins must ensure that safety is not compromised. In a busy unit with high usage more than one system may be required. A dedicated meter for sole use in high risk patients may also be necessary.

Workflow can be divided into pre-analytical, analytical and post-analytical stages, each consisting of short, multiple sequential steps (figure 1).

Figure1: Work flowchart of steps involved in blood glucose measurement



Training

Point-of-care-testing is performed extensively by non-laboratory personnel. Healthcare professionals should be trained and certified to carry out the necessary testing. On site training is provided by the manufacturer either for all staff or key personnel. Training must be logged, co-ordinated and consistent with provision for staff who work unusual shifts or agency and temporary staff. A standard operating procedure should be in place which includes the manufacturers' instructions for use and should be kept with the equipment and be directly available to the user [22].

The manufacturers' user guide or instructions for use included with the meter and reagent test strips respectively provide guidance for people who self-monitor their glucose status. Additional support and troubleshooting may be provided by a diabetes specialist or practice nurse.

Servicing

For both professional and home use major servicing of the meter is unnecessary. However, minimal maintenance may be necessary to keep the meter clean by wiping down with a damp cloth or with a 5% household bleach solution. In professional settings local infection control standards for scheduled, regular decontamination and cleaning procedures should be followed and the activity recorded.

Data management

Patients who self test may manually record results in a paper diary, or use the meter's in-built memory for storage of blood glucose and quality control results with a date and time stamp. These results can be viewed individually, or as 7-, 14- or 21- day averages. The results can also be downloaded to a personal computer by using an RS link cable, Bluetooth or Zigbee wireless connection. Once all the data has been downloaded results can be viewed as charts with event categories using the supplied software.

In secondary and primary care connectivity is increasingly incorporated for auditing patient pathways. Connectivity is the ability of a system or device to connect with other systems or devices to allow data transfer, such as to the hospital or laboratory information systems. Examples of how some of the blood glucose devices connect include:

- Docking stations
- USB connections
- docking Station with LAN/WAN connectivity
- wireless transmission to a PDA where the blood glucose results are incorporated with other healthcare data and sent to a hospital information system.

Under Clinical Governance and NHS Litigation Authority guidelines [28], connectivity is advocated to help reduce errors and improve staff compliance. Blood glucose results are often recorded manually, which increases the risk of transcriptional errors and omissions from patient records.

Setting up the devices to connect to other devices requires qualified personnel be they from the vendor or the local IT department. This should comply with the POCT-2P Standards of the Clinical and Laboratory Standards Institute (ISO 11073-90101), which stipulates that *"connectivity should be easy to use and share a common interface and data manager system with all other point-of-care-testing devices. It should be bi-directional to allow downloading of additional information from the Hospital Information System"* [29].

Continuous Glucose Monitoring Systems (CGMS)

CGMS are generally used under the supervision of a clinician on patients with poor glycaemic control as they give greater insight into the direction, magnitude, duration, frequency and possible causes of glucose fluctuations in response to meals, insulin injections, hypoglycaemic episodes and exercise throughout the day. Compared to conventional blood glucose measurements performed 4 to 6 times per day, results are provided every 10 minutes for up to 72 hours. However, a blood glucose meter is still required by users as a conventional finger-stick is needed several times a day to calibrate the system. CGMS systems work by inserting a small catheter containing the sensor subcutaneously. The sensor measures the glucose in the interstitial fluid and results are transmitted to a monitor for storage or immediate display.

Economic considerations

Glucose monitoring by healthcare professionals in secondary care accounts for 15 - 20% of the test strip market and about 2% in primary care. Approximately 80% of the test strip market is home use by patients who obtain meters free of charge from healthcare professionals or by purchasing from a pharmacist. According to the Department of Health publication Turning the corner: Improving Diabetes Care "*blood glucose testing strips prescribed in general practice cost the NHS £130 million pound a year, nearly a third of the total spend on primary care prescribing for diabetes"* [30].

Numerous studies highlight the economic benefits of using blood glucose systems for monitoring and aiding self management. Although several studies have failed to show the cost benefit of point of care testing, evidence suggests that effective disease management leads to reduced morbidity, which in turn can translate to reduced costs [31].

In critically ill inpatients, intensive insulin therapy to maintain blood glucose levels below 6.1 mmol/l reduces morbidity and mortality [32]. Studies using an intensive insulin protocol and point-of-care glucose testing have shown improved glucose control and significant reduction in mortality, reduced duration of intensive care [33,34] with the potential for substantial cost savings [35].

The potential for developing retinopathy, nephropathy and neuropathy is significantly reduced in patients who are type 1 insulin dependent [36] and in patients with type 2 diabetes with intensive blood glucose control and medication [2]. The United Kingdom Diabetes Prospective Study (UKPDS) cost analysis of intensive blood glucose control in patients with type 2 diabetes concluded that the increased therapy costs are largely offset by significantly reduced cost of complications and estimated that the cost per event free year of intensive blood glucose control is about £1,166 and is a small fraction of the total NHS annual budget [31,37].

For professional use glucose meters are essentially a low cost instrument capable of performing over a thousand tests and therefore contribution to cost per test is very low. Reagent strips are approximately 20 to 24 pence each dependent on the contract in place, a lancet costs about 9 pence. Staff time contributes to the majority of the cost and any feature of a system which reduces this component will result in the biggest saving. A variety of other miscellaneous costs include: IQC and EQA, gloves, gauze, disposal of contaminated goods and costs associated with training of staff but these will be minimal. The average costs per test done by a healthcare professional are shown in table 4.

Table 4: Illustrative costs per test for hospital professional use

Staff time	Strip cost	Lancet cost	Miscellaneous cost	Total cost
£1.20	£0.24	£0.09	£0.02	£1.55

For a health care professional, if it is assumed that it takes approximately on average 5 minutes to conduct and record each test, this equates to £1.20 per test assuming a salary of £28,000 per annum (agenda for change bands 5 to 7).

For self testing, each patient requires an individual meter, but this will generally be provided free of charge indirectly by the manufacturer or purchased by the patient from a local pharmacist. Test strips are prescribed by the GP and cost approximately 30 pence per strip (drug tariff listed price including pharmacist's dispensing fees). The cost per test is dependent on the healthcare professional staff involvement in a patient's training and review, and the number of tests performed by the patient. Illustrative costs per test are shown in table 5.

Table 5: Illustrative costs per test for self testing by patients

Staff time	Strip cost	Lancet cost	Total cost
<£0.01*	£0.30	£0.04	£0.35
<£0.15**	£0.30	£0.04	£0.49

*Costs assume an average salary of £28,000 per annum for the healthcare professional performing the training, *10 minutes training time and 500 tests carried out by the patient; ** 60 minutes training time and 100 tests.*

The number of tests conducted will vary depending on the patient and their treatment regime. Features that simplify training, or ensure that the patient performs the test appropriately, gets the correct result first time and acts on it are important in minimising costs.

Meter tests can provide savings in numerous ways including helping to avoid acute episodes of hypo- and hyperglycaemia and diabetes ketoacidosis, necessitating medical treatment, or the avoidance of long term disease complications which can, for example, lead to amputation with associated in-patient costs of approximately £8,500 [37]. Appropriate control of diabetes with the aid of a blood glucose meter can help minimise both direct costs and the use of healthcare services and indirect costs associated with lost workdays, restricted activity days and permanent disability as a result of diabetes complications and mortality. The presence of diabetic complications increases NHS costs for a patient more than five-fold [38].

One in twenty people with diabetes incur social services costs, and the presence of complications increases costs four-fold [38]. The UKPDS and the DCCT [2,3] have demonstrated that all complications could be reduced with tight control of blood glucose, best achieved through proper treatment strategies and self monitoring of blood glucose. As patients with diabetes begin to take control of their disease and manage it with self blood glucose monitoring, it is important to recognize the impact that it has on quality of life.

Economic aspects of glucose monitoring are complicated by micro- and macroeconomic perspectives. These involve local economic implications, such as on a budget of a single healthcare department, or the wider economic impact. Expenditure on glucose monitoring from one budget may produce savings from the budget of a different department or even sector in both the short and long terms.

Economic considerations

Value

Different components contribute to the value of point-of-care systems such as blood glucose meters. Features that ensure tests are performed appropriately and accurately are of value. Any feature of a system which results in less staff input will produce significant cost savings via the staff cost component. For both patient and healthcare professionals ease of use, comfort, speed, accuracy and performance, reductions in need for calibration or repeats, reliability and ease of result recording will improve provision of care, correct delivery of treatment and patient compliance leading to increased patient benefit.

The technical, clinical performance and characteristics of a system determine its suitability, safety and effectiveness of use. These are outlined in the previous technical and operational sections. Systems available for specific applications in hospital and self testing, together with their value-added features are outlined in the market review.

There are a number of different stakeholders involved in using, supplying, purchasing and funding blood glucose monitoring systems. Whilst all aspects of value may be considered by stakeholders, they have different concepts of value and may focus on different components. Stakeholders include:

- patients - who experience health benefits and may be self-testing
- healthcare professionals - who use the system
- industry - manufacturers supply strips to the NHS via a network of interactive relationships and make revenue on strip sales
- NHS - indirectly or directly pays for the use of the systems by healthcare professional and patients
- NHS Supply Chain - manages the procurement of a range of products for NHS Trusts, hospitals and other healthcare organisations
- NHS Procurement Hubs - regional purchasing organisations working on behalf of a number of member Trusts to accelerate savings through collaborative purchasing
- Prescription Pricing Division, NHS Business Service Authority - sets the level of drug tariff for test strips and lancets and calculates the reimbursement to dispensing pharmacists
- Department of Health - National Service Framework for diabetes
- NICE - provides guidance on diabetes management
- pharmacists - dispense strips to the public via a prescription and also sell certain meters
- trade and patient organisations - the British in vitro Diagnostics Association (BIVDA) represents manufacturers and Diabetes UK is a charitable body whose membership includes patients with diabetes and healthcare professionals
- MHRA - regulatory government agency.

Service quality

Innovation in meter systems is generally incremental; however, similar products can be differentiated by service provision. This reflects the added-value aspects provided to support meters and their use. Some services are common to both hospital and self monitoring, and manufacturers may attempt to differentiate their products via innovations in the services provided. Little independent assessment data are available to compare and contrast these different service offerings and their quality. A wide range of added value components or services are provided by certain, but not necessarily all, manufacturers. Often it is difficult to determine the cost of added value components and services as they are included in the quoted price of the test strip.

Manufacturer services which contribute to value for healthcare professionals and patients use are outlined in tables 6 and 7 respectively.

Table 6: Manufacturer's services which contribute value for healthcare professional use

Services
Technical and service support
Training, audit and certification of users competency
Enrolment into EQA schemes
Single batch test strip reservation and long term storage and delivery
Supply of meters in correct packaging
Sustainable procurement ensuring green issues are addressed both in production and supply, and ensuring appropriate disposal mechanisms for used meters
Installation of connectivity
Flexibility and dependability of manufacturer service provision

Table 7: Manufacturers services which contribute to value for patients

Services
Multilingual educational materials on aspects of diabetes and glucose monitoring to help obtain correct results and motivate the patient to understand and take control of their disease
Supply of free replacement meters and lancing device, upgrades, free batteries, free record diaries, and quality control materials
Customer care – web based and telephone support.

Service packages aim to empower the patient to manage their disease rather than just monitoring their blood glucose status. If not supplied by manufacturers such services and materials (table 7) would need to be provided at significant additional cost to the NHS. Services help ensure correct use of the meter and that accurate results are produced, correctly interpreted and treatment adjusted when necessary. This is particularly important in self monitoring where patient motivation, empowerment and education are essential and to

ensure testing provides optimal value for money. If the patient does not monitor and adjust treatment correctly, the entire cost and value of the process is wasted.

Selection of glucose systems with incremental innovative features, new technologies or radical innovation should be based on consideration of fitness for purpose and effectiveness from user, patient and healthcare system perspectives together with ‘best price’. The ‘best’ may depend on local circumstances and care is needed to ensure that short-term measures do not lead to purchasing at lowest price, rather than purchasing of best value.

When tendering for blood glucose meters consider:

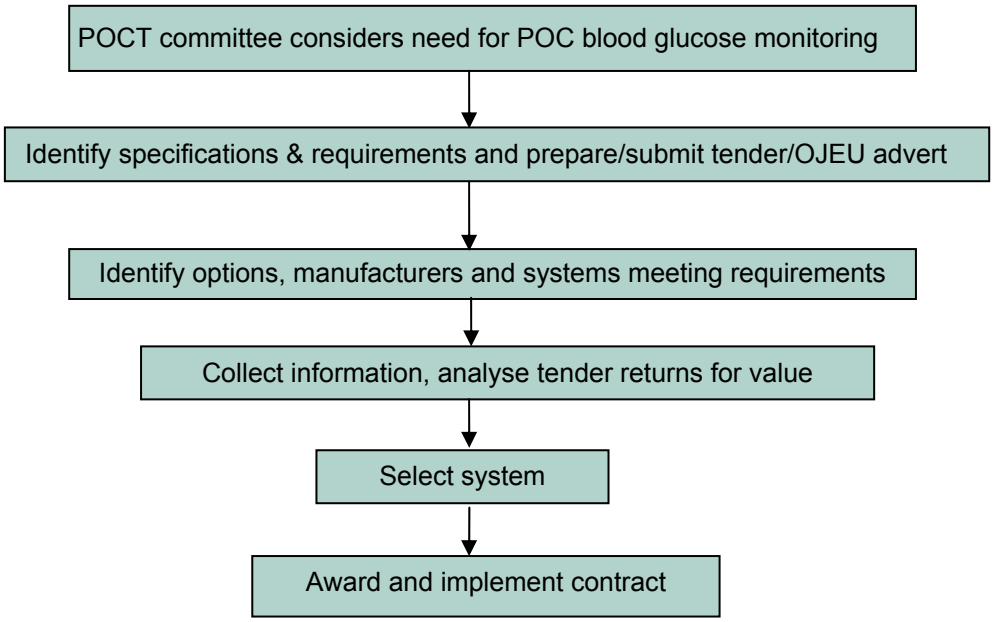
- establishing advisory groups to take into account the needs of all interested parties. This should involve a point-of-care committee comprising laboratory, clinical, diabetes specialist nursing, pharmacy, procurement, finance and infection control personnel
- local and national acquisition policies, whole life costs and methods of acquisition.

The mechanisms for purchasing blood glucose systems vary depending on whether they are used by healthcare professionals in secondary or primary care, or by patients for self monitoring. Primary Care Trusts can opt to standardise across all GP practices and in line with their local hospital provider.

For self monitoring, meters are generally provided by the practice nurse or diabetes specialist nurse free-of-charge, sometimes from a “preferred list”, or purchased by the patients from a local pharmacist. The choice may be governed by the price, special offers, brand loyalty, manufacturer support and value added benefits. Test strips and lancets for self testing are available on prescription.

For professional use the cost of blood glucose meters, test strips and accessories is generally negotiated through tendering in line with an individual Trust’s financial instructions. In secondary care the most popular method for obtaining blood glucose systems is through strip purchase or under a managed service contract where the hospital does not own the equipment but merely provides the staff. Leasing agreements are a less popular option. A simplified purchasing process for blood glucose meter systems is shown in figure 2.

Figure 2: Simplified purchasing process for blood glucose meters in secondary care



The tender notice sets out the requirements needed for the supply of the blood glucose monitoring system. It includes technical and operational specifications, additional services, length of contract and the number and types of systems needed. Manufacturer's costs and financial terms will be proposed in the tender return. Questions regarding typical technical, operational and financial specifications to be addressed are outlined in Appendix 3.

Various approaches to tender analysis have been adopted. Selection criteria are chosen and scored from relevant tender specifications. A range of criteria are used, which can include technical aspects, whole life costs, details of the manufacturers and services, and flexibility. This helps ensure that the purchasing decision incorporates value based evidence and is not centred on cost and strip price alone. Users should develop both technical and commercial weightings that are applied to each criterion to produce a total score and provide a clear decision making mechanism for the final selection. Flexibility in the weightings is needed to account for different trusts and their priorities.

Purchasing procedures

The Trust Operational Purchasing Procedures Manual provides details of the procurement process [39].

European Union procurement rules apply to public bodies, including the NHS.

The purpose of these rules is to open up the public procurement market and ensure the free movement of goods and services within the EU.

In the majority of cases, a competition is required and decisions should be based on best value.

The EU procurement rules apply to contracts worth more than £90,319 (from January 1st 2008) [40]. Further details of the process are detailed in Appendix 2.

NHS Supply Chain (NHS SC) offers national contracts or framework agreements for some products, goods and services. Use of these agreements is not compulsory and NHS organisations may opt to follow local procedures.

Sustainable procurement

The UK Government launched its current strategy for sustainable development, Securing the Future [41] in March 2005. The Strategy describes four priorities to progress sustainable development, in the UK and in the world as a whole:

- sustainable production and consumption - working towards achieving more with less
- natural resource protection and environmental enhancement - protecting the natural resources and habitats upon which we depend

- sustainable communities - creating places where people want to live and work, now and in the future
- climate change and energy - confronting the greatest identified threat facing the global community.

The strategy also highlights the key role of public procurement in delivering sustainability.

This section identifies relevant sustainability issues and provides some guidance on how these can be incorporated into procurement decision making processes.

End of life disposal

Consideration should be given to the likely financial and environmental costs of disposal at the end of the product's life. Where appropriate, suppliers of equipment placed on the market after the 13th August 2005 should be able to demonstrate compliance with the UK Waste Electrical and Electronic Equipment (WEEE) regulations (2006) [42]. The WEEE regulations place responsibility for financing the cost of collection and disposal on the producer. Electrical and electronic equipment is exempt from the WEEE regulations where it is deemed to be contaminated at the point at which the equipment is scheduled for disposal by the final user. However, if it is subsequently decontaminated such that it no longer poses an infection risk, it is again covered by the WEEE regulations, and there may be potential to dispose of the unit through the normal WEEE recovery channels.

Energy demand

The energy demand of POCT equipment is assessed to be relatively low, especially where units are not in constant use. Units fitted with auxiliary energy features to extend battery life and/or reduce mains energy consumption while on standby, are preferable. For battery powered products, the cost of replacement batteries should be considered throughout the expected life of the product. Where rechargeable batteries are supplied then rechargers should also be provided. Any failure of the rechargeable batteries that occurs within the expected life time of the unit should be replaced at no additional cost to the user.

Blood glucose systems available in the UK

Currently 29 glucose systems are available in the UK. Suppliers contact details are provided in Appendix 1. Glucose systems cater for:

- secondary care professional use
- primary care professional use
- home use
- continuous glucose monitoring systems.

The choice and range of systems available for primary care use is greater as glucose systems listed for use in secondary care can be used as a stand alone system without connectivity or a docking station. However, the one restriction when using these systems for multi-patient use is that the lancing device provided for patients' own use is not suitable for use by the healthcare professional. Manufacturers supplying the system are required to provide a meter excluding the single-patient lancing device.

The technical specifications in tables 8 - 10 give an overview of the range of systems available in the UK. Many features which are common to all the blood glucose systems are not mentioned in the tables. Features which differ are highlighted below.

Secondary care

The technical specifications are shown in table 8. Additional features and services for individual blood glucose systems provided by the manufacturer/supplier for professional use in secondary care are shown in Appendix 4.

Technology

All current glucose systems for hospital use are biosensors, with the exception of the HemoCue which uses the measurement principle of absorbance.

Sample type

Systems for use in neonates should be checked to ensure that they are intended for use in pre-term babies. The Roche systems are also intended for use with cord blood.

Market review

Table 8: Blood glucose meters for secondary care professional use

	Abbott Precision PCx	Abbott Precision Xceed Pro*	Abbott Optium Xceed	Bayer Contour Pro	Bayer Contour	HemoCue Glucose 201+	HemoCue Glucose 201+ DM
							
Test strips name	Precision PCx Plus	Precision PCx Plus*	Optium H	Ascensia Microfill	Ascensia Microfill	Glucose 201 microcuvettes	Glucose 201 microcuvettes
Test strip packaging	Individually foil wrapped	Individually foil wrapped	Individually foil wrapped	Canister	Canister	Individually foil wrapped or in a canister	Individually foil wrapped or in a canister
Enzyme principle	GDH / NAD	GDH / NAD	GDH / NAD	GDH / FAD	GDH / FAD	Modified GDH	Modified GDH
Lot specific calibration code	Scan barcode	Scan barcode	Smartchip	Self coding	Self coding	None	None
Sample volume (µl)	3.5	3.5	2.5	0.6	0.6	5	5
Sample underfill detection	✓	✓	✓	✓	✓	×	×
Measurement time (seconds)	20	20	20	5	5	45 to 60	45 to 60
Measurement range (mmol/l)	1.1 - 27.8	1.1 - 27.8	1.1 - 27.8	0.6 - 33.3	0.6 - 33.3	0 - 22.2	0 - 22.2
Haematocrit range (%)	20 - 70 at <16.7 mmol/L; 25 - 60 at >16.7 mmol/L	20 - 70 at <16.7 mmol/L; 25 - 60 at >16.7 mmol/L	20 - 70 at <16.7 mmol/L; 25 - 60 at >16.7 mmol/L	Measures and corrects in the range 0 - 70%	Measures and corrects in the range 0 - 70%	No limits	No limits
Memory - patient results **quality control** **other logs**	4000 1000 NA	2500 1000 22	450 NA NA	Infinite when interfaced to LIS/HIS	480 NA NA	600 NA NA	4000 500 500
Connectivity to LIS / HIS	Yes	Yes	No	Yes	No	No	Yes

Notes: *New Precision Xceed Pro blood glucose strip to be launched 2008. NA - not applicable.

Market review

Table 8: Blood glucose systems for secondary care professional use (continued)

	Nova StatStrip	Nova StatStrip Xpress	Roche Accu-Chek Inform 2	Roche Accu-Chek Performa	Roche Accu-Chek Inform*	Roche Accu-Chek Advantage*
						
Test strips	StatStrip glucose	StatStrip glucose	Accu-Chek Performa	Accu-Chek Performa	Accu-Chek Advantage Plus	Accu-Chek Advantage Plus
Test strip packaging	Canister	Canister	Canister	Canister	Canister	Canister
Enzyme principle	Modified glucose oxidase	Modified glucose oxidase	GDH / PQQ	GDH / PQQ	GDH / PQQ	GDH / PQQ
Lot specific calibration code	None	None	Centralised coding	Code chip	Code chip	Code chip
Sample volume (µl)	1.2	1.2	0.6	0.6	4	4
Sample underfill detection	✓	✓	✓	✓	✓	✓
Measurement time (seconds)	6	6	5	5	26	26
Measurement range (mmol/l)	0.5 - 33.3	0.5 - 33.3	0.6 - 33.3	0.6 - 33.3	0 - 33.3	0.6 - 33.3
Haematocrit range (%)	Measures and corrects for haematocrit	Measures and corrects for haematocrit	Corrects in range 10 - 70%	Corrects in range 10 - 70%	20 – 65 <11.1 mmol/l; 20 - 55 >11.1 mmol/l	20 – 65 <11.1 mmol/l; 20 - 55 >11.1 mmol/l
Memory - patient results **control results** **other logs**	1000 500 4000	250 NA NA	2000 4000}	250 NA NA	1000 4000}	250 NA NA
Connectivity to LIS / HIS	Yes	No	Yes (wireless)	No	Yes	No

Note: *These systems will be plasma calibration from 2008. NA - not applicable.

Primary care professional use and home use

All systems, with the exception of the Roche Compact Plus, available for home use can be used by healthcare professionals for multiple patients testing. Table 9 shows the technical specification of the glucose systems for primary care and home use.

Technology

All blood glucose systems listed are biosensors with the exception of the Accu-Chek Roche Compact Plus which is a reflectance meter intended for home use only.

Result type

All meters give plasma equivalent results with the exemption of Roche Aviva and Compact Plus which gives results as whole blood values (all Roche systems will be switching to plasma calibration from 2008).

Services

Many additional free 'value-added' benefits such as telephone support and troubleshooting facilities are offered by manufacturers and are shown in Appendix 5.

Market review

Table 9: Blood glucose systems for home use by diabetics at home and primary care professional use

	Abbott Optium Xceed	Abbott FreeStyle Lite	Abbott FreeStyle Freedom Lite	Bayer Contour*	Bayer Breeze 2	BBI Healthcare SensoCard Plus
						
Test strips	Optium Plus	FreeStyle Lite	FreeStyle Lite	Ascensia Microfill	Breeze 2 test strip disc	SensoCard blood glucose
Test strip packaging	Individually foil wrapped	Canister	Canister	Canister	Disc of 10 test strips	Canister
Enzyme principle	GDH/NAD	GDH/PQQ	GDH/PQQ	GDH/FAD	Glucose oxidase	Glucose oxidase
Lot specific calibration code	Code chip	No coding	No coding	Self coding	Self coding	Bar coded card
Sample volume (µl)	0.3	0.3	0.3	0.6	1.0	0.5
Sample underfill detection	✓	✓	✓	✓	✓	Not available
Measurement time (seconds)	3	Average 5	Average 5	5	5	5
Measurement range (mmol/l)	1.1 - 27.8	1.1 - 27.8	1.1 - 27.8	0.6 - 33.3	0.6 - 33.3	1.1 - 33.3
Haematocrit range (%)	30 - 55	15 - 65	15 - 65	Measures and corrects in range 0 - 70	20 - 55	30 - 55
Memory	450	400	400	480	420	500
Data Management	✓	✓	✓	✓	✓	✓

Note: *Contour LINK blood glucose meter integrated with Medtronic insulin pump to wirelessly transmit blood glucose results (launch May 2008)

Table 9: Blood glucose systems for home use by diabetics at home and primary care professional use (continued)

	Cambridge Sensors Ltd microdot	HDI UK Ltd TrueTrack	LifeScan OneTouch Ultra Easy	LifeScan OneTouch Ultra 2	LifeScan OneTouch UltraSmart
					
Test strip	Microdot Test Strips	TrueTrack SmartSystem	OneTouch Ultra	OneTouch Ultra	OneTouch Ultra
Test strip packaging	Canister	Canister	Canister	Canister	Canister
Enzyme system	GDH/NAD	Glucose oxidase	Glucose oxidase	Glucose oxidase	Glucose oxidase
Lot specific calibration code	Manually input code number	Code chip	Manually input code number	Manually input code number	Manually input code number
Sample volume (µl)	0.6	1	1	1	1
Sample underfill detection	✓	✓	✓	✓	✓
Measurement time (seconds)	10	10	5	5	5
Measurement range (mmol/l):	1.1 - 29.2	1.1 - 33.3	1.1 - 33.3	1.1 - 33.3	1.1 - 33.3
Haematocrit range (%)	25 - 55	30 - 55	30 - 55	30 - 55	30 - 55
Memory	500	365	500	500	3000+
Data Management	✓	✓	✓	✓	On Board

Market review

Table 9: Blood glucose systems for home use by diabetics at home and primary care professional use (continued)

	Menarini GlucoMen LX	Menarini GlucoMen Visio	Nova StatStrip Xpress	Roche Accu-Chek Aviva*	Roche Accu-Chek Compact Plus*	Acon Laboratories OnCall Plus
						
Test strip	GlucoMen LX sensors	GlucoMen Visio sensors	StatStrip glucose	Accu-Chek Aviva	Accu-Chek Compact	OnCall Plus
Test strip packaging	Canister	Canister	Canister	Canister	17 individually packaged test strips in a drum	Canister
Enzyme system	Glucose oxidase	Glucose oxidase	Modified Glucose oxidase	GDH / PQQ	GDH / PQQ	Glucose oxidase
Lot specific calibration code	None required	Code chip	None	Code chip	Self coding	Code chip
Sample volume (µl)	0.3	0.8	1.2	0.6	0.8	1.0
Sample underfill detection	✓	✓	✓	✓	✓	✓
Measurement time (seconds)	4	10	6	5	5	10
Measurement range (mmol/l):	1.1 - 33.3	1.1 - 33.3	0.5 - 33.3	0.6 - 33.3	1.1 - 33.3	1.1 - 33.3
Haematocrit range (%)	30 - 60	30 - 55	Measures and eliminates haematocrit	Auto-corrects in range 20 - 70	20 - 70	30 - 55
Memory	400	250	250	500	500	300
Data Management	✓	✓	✓	✓	✓	✓
Note: *These systems will be plasma calibration from 2008.						

Continuous glucose monitoring system

Currently, four devices (table 10) are available in the UK.

Table 10: Continuous glucose monitoring systems available in the UK

	Medtronic Ltd MiniMed CGMS System Gold	Medtronic Ltd MiniMed Guardian REAL-Time	Medtronic Ltd MiniMed Paradigm REAL-Time	Menarini GlucoDay S
				
Sensor location on body	Abdomen, upper thigh, upper buttock	Abdomen, upper thigh, upper buttock	Abdomen, upper thigh, upper buttock	Periumbilical area or area with good vascularisation
Sensor mechanism / enzyme principal	Enzyme tipped catheter / glucose oxidase	Enzyme tipped catheter glucose oxidase	Enzyme tipped catheter / glucose oxidase	Microdialysis / glucose oxidase
Initial warm up period (hours)	1	2	2	2 - 6
Number of calibrations per sensor	12	12	12	1 per day
Sensor lifetime (hours)	72	72	72	48
Measurement frequency (seconds)	10	10	10	1
Result display intervals (minutes)	5 (Retrospective)	5	5	3
Number of readings per day	288	288	288	480
Result type	Retrospective	Every 5 minutes 24 hours per day	Every 5 minutes 24 hours per day	Real time or retrospective
Result trends	Yes	Yes	Yes	No
Safety alarms for hypoglycaemia or hyperglycaemia	No	Yes	Yes	Yes

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Abbott Diabetes Care

Acon Laboratories

Bayer Diabetes Care

BBI Healthcare

Cambridge Sensors Ltd

HDI UK Ltd

HemoCue

LifeScan

Medtronic

Menarini Diagnostics

NHS Supply Chain

Nova Biomedical UK

Roche Diagnostics

Glossary

Accuracy

A measure of the agreement in the result obtained compared to a ‘true’ result with a laboratory reference method.

Alternative site testing

Alternative site testing allows glucose measurements to be made using blood samples collected from the palm, forearm, upper arm, thigh or waist. It provides an alternative less painful means of obtaining blood, especially in very young children with diabetes and those suffering from painful neuropathy. Physiological variation, in the rate of equilibration between glucose in highly vascular tissues, such as the fingertip, and the less vascular alternative sites is substantial. Therefore the relationship between finger-stick blood glucose measurements and alternative sites is not constant.

Biosensor

Biosensors use an enzyme to detect measure or analyse chemicals. The chemical reaction produces a small electric current which is proportional to the blood glucose concentration in the sample. Metallic contacts carry the current from the reagent area, along the strip and to the instrument where a result is displayed. The biosensor reagent section with blood is not inserted into the body of the meter hence reducing the risk of meter contamination.

Co-enzymes

Co-enzymes such as nicotinamide adenine dinucleotide (NAD), paraquinone quinoline (PQQ), flavin adenine dinucleotide (FAD) are metabolic intermediates involved in the biochemical measurement of blood glucose.

Continuous Glucose Monitoring System

CGMS measure glucose levels in interstitial fluid through insertion of an implantable glucose sensor subcutaneously into the arm or abdominal wall.

Haematocrit

Haematocrit is a measure of the percentage of a blood sample that consists of red blood cells. It is measured after the blood has been centrifuged and the cells compacted. The haematocrit range over which the glucose measurements should be made are quoted in the manufacturers instructions for use. This is important in diabetic pregnant women, neonates, and polycythaemic and anaemic patients.

Professional use systems have extended haematocrit ranges to cover the wider ranges encountered in hospital population.

HbA1c (Glycated haemoglobin)

Is a measure of diabetes control in a patient over the past 120 days and correlates strongly with the mean blood glucose concentration.

Imprecision

Is a measure of the variation in results obtained repeatedly on an identical sample and is expressed as standard deviation or coefficient of variation. High standard deviation and coefficient of variation values indicate that the system is imprecise.

Medical Device Alerts

Adverse incidents relating to the use of a medical device must be reported to the Medicines and Healthcare products Regulatory Agency (MHRA) at www. mhra.gov.uk

Reflectance meter

Reflectance meters measure the light reflected from the coloured test strip and convert the signal into glucose concentration.

References

1. Prescribing for diabetes in England. An analysis of volume, expenditure and trends. November 2007. National Diabetes Support Team, Department of Health. http://www.yhpho.org.uk/Download/Public/1265/1/Prescribing%20for%20Diabetes%20in%20England%20Nov%202007%20FINAL.pdf

2. The UKPDS Study Group: Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). Lancet 1998; 352: 837-853.

3. The diabetes control and complications trial (DCCT): the effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin dependent diabetes mellitus. The New England Journal of Medicine 1993; 329 (14): 977-986.

4. National service framework for diabetes standards performance indicators. Department of Health. 2001. http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/Browsable/DH_4096591

5. NICE guideline. CG15 Type 1 diabetes in children, young people and adults: NICE guideline 2004. http://www.nice.org.uk/nicemedia/pdf/CG015_fullguideline_adults_main_section.pdf

6. NICE guideline. Type 2 diabetes (update): national clinical guideline for the management in primary and secondary care. Draft for consultation, September 2007. http://www.nice.org.uk/nicemedia/pdf/T2DNICEdraftguidelinev7numberingcorrected.pdf

7. Diabetes in pregnancy: management of diabetes and its complications from pre-conception to the postnatal period. NICE guidelines 2008. http://www.nice.org.uk/guidance/index.jsp?action=byID&o=11946

8. The National Academy of Clinical Biochemistry Laboratory Medicine Practice Guideline: Evidence-based practice for point-of-care testing. Clinica Chimica Acta, 2007; 379: 14-28.

9. Owens D, Barnett AH, Pickup J et al. Blood glucose self-monitoring in type 1 and type 2 diabetes: reaching a multidisciplinary consensus. Diabetes and Primary Care 2004; 6 (1): 8-16.

10. Implementing intensive control of blood glucose concentration and blood pressure in type 2 diabetes in England: cost analysis alongside randomised controlled trial (UKPDS 63). BMJ 2002; 325: 860-865.

References

11. Karter AJ, Parker MM, Moffet HH et al. Longitudinal study of new and prevalent use of self-monitoring of blood glucose. Diabetes Care 2006; 29 (8):1757-1763.

12 Martin S, Schneider B, Heinemann L et al. For the ROSSO Study Group. Diabetalogia 2006; 49: 271-278.

13. Farmer A, Wade A, Goyder E et al. Diabetes Glycaemic Education and Monitoring Trial Group. Impact of self-monitoring of blood glucose in the management of patients with non-insulin treated diabetes: open parallel group randomized trial. BMJ 2007; 335:132-139.

14. Davis WA, Bruce DG, Davis TME. Is Self-Monitoring of blood glucose appropriate for all Type 2 diabetic patients? The Fremantle Diabetes Study. Diabetes Care 2006; 29:1764-1770.

15. International Diabetes Federation. Global guidelines for Type 2 diabetes. Chapter 6. Glucose control levels. http://www.idf.org/webdata/docs/IDF%20GGT2D.pdf

16. DB2006(05) Device Bulletin. Managing Medical Devices - Guidance for healthcare and social services organizations. November 2006. http://www.mhra.gov.uk/home/idcplg?IdcService=GET_FILE&dDocName=CON2025143&RevisionSelectionMethod=LatestReleased

17. DB 2002(03) Management and use of IVD point-of-care devices. March 2002.

18. The In Vitro Diagnostic Medical Devices Directive (98/79/EC). http://www.mhra.gov.uk/Howweregulate/Devices/InVitroDiagnosticMedicalDevicesDirective/index.htm or http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:1998:331:0001:0037:EN:PDF

19. Nayyar P, Batki AD, Thorpe GH. Buyers' Guide: Lancing Systems. NHS Purchasing and Supply Agency, Centre for Evidence-based Purchasing report 2007. Report CEP 07025.

20. In Vitro diagnostic test systems – requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus. EN ISO 15197:2003. From: International Organization for Standardization (ISO), 1 ch. de la Voie-Creuse, Case postale 56 CH-1211 Geneva 20, Switzerland.

21. Position Statement. Standards of Medical Care in Diabetes – 2007. American Diabetes Association. Diabetes Care 2007; 30 (Suppl. 1):S4-S41.

22. MHRA guidance. Point of Care Testing Blood glucose meters. Advice for health care professionals. 2005.

http://www.mhra.gov.uk/home/idcplg?IdcService=GET_FILE&dDocName=CON2015464&RevisionSelectionMethod=LatestReleased

23. Tang Z, Xiaogu D, Louie R et al. Effects of drugs on glucose measurements with handheld glucose meters and a portable glucose analyzer. Am J Clin Pathol 2000; 113: 75-86.

24. Nichols JH. A critical review of blood glucose testing. Point of Care 2003; 2 (1): 49-61.

25. Dungan K, Chapman J, Braithwaite S et al. ADA Statements. Glucose measurement: confounding medical issues in setting targets for inpatient management. Diab Care 2007; 30 (2): 403-409.

26. MDA/2006/066 Medical Device Alert. Lancing devices used in nursing homes and care homes. Update April 2007. http://www.mhra.gov.uk/home/idcplg?IdcService=GET_FILE&dDocName=CON2025416&RevisionSelectionMethod=LatestReleased

27. MDA/2004/044 - Lancing devices for obtaining blood samples. September 2004. http://www.mhra.gov.uk/home/idcplg?IdcService=GET_FILE&dDocName=CON008508&RevisionSelectionMethod=LatestReleased

28. NHS Litigation Authority. NHSLA Risk Management standards for Acute Trusts. April 2007. http://www.nhsla.com/RiskManagement

29. Point-of-care Connectivity; approved Standard. POCT-A2, volume 26, no. 28. Clinical and Laboratory Standards Institute. 2007. http://www.clsi.org

30. Turning the corner: improving diabetes care. Department of Health 2006. http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4136141?IdcService=GET_FILE&dID=1081&Rendition=Web

31. Gray A, Raikou M, McGuire A et al. Cost effectiveness of an intensive blood glucose control policy in patients with type 2 diabetes: economic analysis alongside randomised controlled trial (UKPDS 41). BMJ 2000; 320:1373-1378.

32. Van den Bergh G, Wouters P, Weekers F et al. Intensive insulin therapy in the critically ill patients. New Engl J Med 2001; 345:1359-1367.

34. Van den Bergh G, Wilmer A, Hermans G et al. Intensive insulin therapy in the medical ICU. New Engl J Med 2006; 354:449-461.

35. Reed C, Stewart RM, Sherman M et al. Intensive insulin protocol improves glucose control and is associated with a reduction in intensive care unit mortality. 2007; Journal American College of surgeons: 204 (5); 1048-1054.

36. Clement S, Braithwaite S, Magee MF et al. Technical review. Management of diabetes and hyperglycaemia in hospitals. Diabetes Care 2004; 27 (2): 553-591.

37. The Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications (DCCT/EDIC) Study Research Group. Intensive diabetes treatment and cardiovascular disease in patients with type I diabetes. New Engl J Med 2005; 353: 2643-2653.

38. Department of Health NHS Reference Costs 2005-06. http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_062884

39. Diabetes in the NHS: Commissioning and providing specialist services. Last modified 11.01.2008. http://www.diabetes.nhs.uk/news-folder/diabetesinthenhs.pdf2

40. Purchasing and Supplies Agency (PASA): Trust Operational Purchasing Procedures Manual. [Online]. Available from: http://home.pasa.nhs.uk/PASAWeb/Guidance/TOPPM/LandingPage.htm

41. Office of Government Commerce EU Procurement Thresholds. [Online]. Available from: http://www.ogc.gov.uk/procurement_policy_and_application_of_eu_rules_eu_procurement_thresholds_.asp

42. UK Government Strategy for Sustainable Development; Securing the Future http://www.sustainable-development.gov.uk/publications/uk-strategy/index.htm

43. EC Directive on Waste Electrical and Electronic Equipment http://www.berr.gov.uk/files/file35992.pdf

44. Purchasing and Supplies Agency (PASA): Leasing. [Online]. Available from: http://www.pasa.nhs.uk/pasaweb/productsandservices/leasing

45. Office of Government Commerce http://www.ogc.gov.uk/stdtoolkit/reference/documentation/p13_buscase.html

46. Purchasing and Supplies Agency (PASA): Operational Purchasing Procedures Manual. [Online]. Available from: http://home.pasa.nhs.uk/PASAWeb/Guidance/OPPM/LandingPage.htm

47. Department of Health. European Union Tendering Timetable. [Online]. Available from: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsProcurement/DH_4070620

48. Department of Health. Desk guide to procurement. 2005. [Online]. Available from: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsProcurement/DH_4109316

Appendix 1: Supplier details

Supplier contact details

Abbott Diabetes Care
Abbott House
Vanwall Business Park
Maidenhead
Berkshire
SL6 4UD
Tel: 01235 542000
www.abbottdiabetescare.co.uk

Acon Laboratories
Azure Institute
4108 Sorrento Valley Blvd
San Diego
CA 92121
USA
Tel: 001 858 875 8041
www.aconlabs.com

Bayer Healthcare plc
Diabetes Care Division
Bayer House
Strawberry Hill
Newbury
Berkshire
RG14 1JA
Tel: 01635 563000
www.ascensia.co.uk

BBI Healthcare, Unit A
Kestrel Way
Garngoch Industrial Estate
Gorseinon
Swansea
SA4 9WN
Tel: 01792 229333
www.bbihealthcare.com
www.sensocardplus.com

Cambridge Sensors Ltd
Units 9 and 10 Cardinal Park
Godmanchester
Huntingdon
Cambridgeshire
PE29 2XG
Tel: 01480 482920
www.cs-limited co.uk

HemoCue Limited
Viking Court
31 Princes Road
Dronfield
Derbyshire
S18 2LX
Tel: 01246 292955
www.hemocue.co.uk

Home Diagnostics (UK) Ltd
25 Barnes Wallis Road
Segensworth East
Fareham
Hampshire
PO15 5TT
Tel: 01489 569469
www.homediagnostics.com

LifeScan
50 -100 Holmers Farm Way
High Wycombe
Buckinghamshire
HP12 4DP
Tel: 01494 450423
www.lifescan.co.uk

Appendix 1: Supplier details

Medtronic Ltd
Sherbourne House
Suite One
Croxley Business Park
Watford
Hertfordshire
WD18 8WW
Tel: 0923 212213
www.medtronic-diabetes.co.uk

Menarini Diagnostics
Wharfdale Road
Winnersh
Wokingham
Berkshire
RG41 5RA
Tel: 0118 9444100
www.menarinidiag.co.uk

Nova Biomedical (UK)
C3-5 Evans Business Centre
Deeside
Flintshire
CH5 2JZ
Tel: 01244 287087
www.novabiomedical.com

Roche Diagnostics Ltd
Charles Avenue
Burgess Hill
West Sussex
RH15 9RY
Tel: 01444 256000
www.accu-chek.co.uk or
www.roche-diagnostics.com

Appendix 2: Purchasing

EU procurement procedure

Lease options

National frameworks are in place for operating leases to help the NHS procure leases more cost efficiently and effectively. The framework came into place on 1st April 2007 and runs for two years. Further details are available from the PASA website [43].

EU procedures

The Public Sector Directive (2004/18/EC) has been transposed into UK law. This has been achieved by means of the following statutory instruments:

- the Public Contracts Regulations SI 2006 No.5 (the regulations)
- the Utilities Contracts Regulations SI 2006 No. 6 (not relevant to this guide).

The regulations apply to contracts worth more than £90,319 (from January 1st 2008) [40] over their whole life, and specify the procedures to be followed for public sector contracting, including adherence to strict timetables, requirements for advertising, invitation to tender and the award of contract. Organisations undertaking a procurement exercise covered by the regulations must give all suppliers an equal opportunity to express an interest in tendering for the contract by placing a contract notice in the Official Journal of the European Union (OJEU).

At all stages of the procurement process, the purchaser must be demonstrably fair, as any decision made can be challenged by the unsuccessful suppliers.

Establishing a procurement strategy

To achieve a successful outcome, decisions need to be made on:

- whether an existing contract/agreement can be used
- the need to consider sustainable development issues
- whether EU directives apply
- the type and form of contract
- sourcing potential suppliers
- duration of contract and opportunity to review/extend
- payment schedules
- how to minimise any risks with the chosen strategy, including supplier appraisal and evaluation/clarification of suppliers' bids.

Preparing a business case

A business case should be drafted and approved before conducting any procurement exercise. Further guidance on preparing business cases is available from the Office of Government Commerce [44] and an illustrative example is provided in the NHS PASA Operational Purchasing Procedures Manual, Procedure 1-01 [45].

Appendix 2: Purchasing

The EU tendering exercise

EU procurements usually take between 4 and 6 months to complete. This needs to be taken into account in the planning stages. The length of the exercise depends on the chosen procedure (open or restricted). Further information is available from the Department of Health [46].

The procurement panel

A multidisciplinary team should be selected to guide the purchase. Representatives from clinical, user, technical, estates and financial areas should be considered.

Identifying potential suppliers

Criteria for supplier selection must be established. A supplier pre-qualification questionnaire may be employed as an initial screen to exclude unsuitable suppliers that asks for details such as skills and experience of the service engineers.

Evaluation criteria

Performance specifications should be derived from local operational requirements, and agreed by the procurement panel. They will form the basis for assessing the adequacy of suppliers' technical specifications, provided in response to the technical specification questionnaire.

It is important to have agreed on the performance specifications of the product as they will be used in the adjudication against company specifications.

Requests for features which are supplier-specific are not permitted under the regulations. Very specific features which are not supported by operational requirements are also not allowed.

Award of contract

Following award of the contract to the successful supplier; unsuccessful suppliers may need to be debriefed. This is at the supplier's request.

Buyers must be aware of the 'Alcatel' procedure (see the Trust Operational Purchasing Procedures Manual [39], Procedure No.T-08, section 6 - 'Mandatory Standstill Period').

For more information on procurement please refer to the Department of Health Website [47].

Appendix 3: Tender specifications

Tender specifications for blood glucose monitoring systems

	Specifications
Technical	Analytical performance – levels of accuracy, imprecision and clinical acceptability
	Technology and enzyme principle used
	Specimen type. Intended for use with capillary, arterial, venous or neonatal bloods. Check for suitability of system for use in pre term infants
	Whole blood or plasma calibrated result. Preferred plasma calibrated
	Haematocrit range. Preferred - systems with wide range for hospital use or that correct for haematocrit
	Lot-specific calibration. Preferred - none required or systems with minimal operator input
	Units of measurement. Preferred - hard fixed to mmol/l
	Sample volume. Preferred - less than 3 µl
	Measurement time. Preferred - less than 20 seconds
	Measurement range - Check level of accuracy and imprecision, especially in the hypoglycaemic range for use in neonates
	Batteries. Preferred - rechargeable batteries, automatic shutdown for conserving battery power
	Limitations and Interferences. Level of interference and measures taken to avoid them
	Quality control materials. Preferred -at minimum two levels
	EQAS. Preferred -enrolment into EQA scheme
	Memory size. Separate memory for QC, patient and user ID
	Pre- and post-installation site visits to check facilities
Operational	Safety of operator and patients. Safety features and any known hazards or problems in use of product or Medical Device Alerts issued
	Training. Competency certification - yearly review, training updates. Instruction manuals and education charts and materials
	Data management and connectivity. Preferred - wireless connection, protections to continue using system in case of system failure, in built bar-code scanner and alpha-numeric key pad
	Frequency and time taken for maintenance
	Warranty and after sales support
Financial	Total cost including price per strip and services. Whole of life costs and benefits to be considered
	Terms of contract - duration, number of meters with connectivity where necessary, test strips and QC materials. Conditions negotiated for upgrades and enhancements and additional units
	Guaranteed, continuous high level of service and supplies. Batch reservation and long term strip storage
	Market risk analysis
	Sustainable procurement. Use of rechargeable batteries; disposal of packaging and recycling of waste after installation, end of life removal and disposal of systems.

Appendix 4: Additional features (secondary care)

Additional features and services of blood glucose systems in secondary care

Meter	Additional features	Additional services
Abbott **Precision PCx** **Precision Xceed Pro** **Optium Xceed H (hospital test strip)**	• Integrated barcode scanning of patient, operator and test strip information • all stored data uploaded using serial cable or optional docking station. **Precision Xceed Pro:** • Ketone measurements using β-ketone test electrodes with capillary or venous blood • alpha numeric keypad. **Optium Xceed with Optium H test strip:** • Ketone measurements using β-ketone test electrodes with capillary or venous blood • backlight • SmartChip™ automatically updates the meter as test strips develop.	• Full control from central laboratory computer terminal • full cascade training programme • training and product support specialist team to deliver training and hospital QC audits.
Bayer **Contour and Contour Pro**	• Both system use the same glucose test strip • additional correction electrode reduces interferences from common reducing substances • automatically mark QC result in the memory • automatic temperature compensation • six month expiry of test strip and QC material after first opening.	• Bayer Nurse Educator Service to provide training and support for professional users • ward manuals and work stations provided.
HemoCue **HemoCue 201⁺ and HemoCue 201⁺ DM**	• Both system use the same glucose micro cuvettes • system can be used for diagnosis of diabetes, including screening and monitoring • microcuvettes need refrigeration for long term storage • blood applied to the microcuvettes externally. **HemoCue 201⁺ DM:** • Stored data can be printed directly to an external printer • touch screen display, built-in barcode scanner and infrared transmitter for data transfer to docking station.	• HemoCue Academy training programme for healthcare program • warranty program included in cost for 2 years, extension available • EQAS using whole blood QC materials offered • e-learning education and training programme.

Appendix 4: Additional features (secondary care)

Meter	Additional features	Additional services
Nova Biomedical **StatStrip and StatStrip Xpress**	• Both systems use the same glucose test strip • four well glucose measuring strip designed to measure and eliminate interference from haematocrit, acetoaminophen, uric acid, ascorbic acid, oxygen, maltose, galactose, xylose, lactose and icodextrin. **StatStrip**: • Colour touch screen with built in barcode scanner • docking station for desk mount charging, extra battery slot recharges and stores spare battery, LED indicators for charging, transmitting and receiving data • results downloaded to PC using strip port connection to USB and the Nova Microsoft-Excel based data transfer software.	• Technical support hotline • training and audit programme • web based training. **StatStrip:** • On-meter training mode • vendor neutral connectivity package for connection to other point-of-care devices.
Roche **Inform 2 / Performa**	• Both systems use the same glucose test strip • six gold electrodes monitors sample and strip integrity for temperature, humidity, strip damage, underdosage and haematocrit and compensate results accordingly • automatically detects a QC sample • factory set for mmol/l, date and UK time, with separate smart battery to retain information. **Inform 2:** • Optional wireless connectivity enabling real time data transfer • central coding allows all meters to be coded at same time • alpha numeric touch screen, integral barcode scanner, base unit allowing hands free data transfer and battery recharging.	• Batch reservations on glucose test strips for an agreed period ensuring consistent strip lot delivery, avoiding miscoding and ensuring security of supply • Roche Nurse educator service to provide training, support and audit for professional users • web-based Cobas academy e-learning education and training programme • WEQAS scheme offered • ward manuals and workstations provided • technical support hotline.
Roche **Inform / Advantage**	• Both systems use the same glucose test strip. **Inform:** • Alpha numeric touch screen, integral barcode scanner, base unit allowing hands free data transfer and battery recharging • option to enter information for six manual point-of-care tests.	

Appendix 5: Additional features (primary care/home)

Additional features and services of blood glucose systems for primary care and diabetics at home use

	Additional features	Additional services
Abbott **Optium Xceed**	• Additional ketone measurements made using β-ketone test electrodes with capillary or venous blood • backlight • SmartChip™ automatically updates meter as test strips develop.	• Lifetime warranty with free replacement for faulty meter and lancing device • free telephone helpline • free control materials, batteries, data management software and cable, educational materials, paper log book • training materials for nurses under “Abbott Inspire” programme • patient loyalty programme with free patient magazine.
Abbott **FreeStyle Lite / FreeStyle Freedom Lite**	• Same test strip for both systems • additional blood sample can be applied up to 60 seconds after initial drop • blood can be applied to the test strip from either side • four reminder alarms to test.	
Bayer **Contour / Contour LINK**	• Third reference electrode to minimise interference • 6 months test strip stability after first opening canister • automatic QC detection and result marking in memory. **Contour LINK:** • Wirelessly transmits glucose results directly to a compatible Medtronic insulin pumps with bolus wizard.	• Lifetime warranty with free replacement for faulty meter and lancing device • local rate telephone helpline • free control materials, batteries, data management software and cable, educational materials and paper log book.
Bayer **Breeze 2**	• No strip handling - 10 test strips supplied in a disc • strip eject mechanism.	
BBI Healthcare **SensoCard Plus**	• Spoken instructions and readings for visually impaired • all readings repeated on demand • full operating instructions available on audio CD or Braille.	• One year warranty with free replacement for faulty meter and lancing device within 24 hours • telephone helpline (national rate) • free control materials, batteries, data management software and cable, educational materials and paper log book.

Appendix 5: Additional features (primary care/home)

	Additional features	Additional services
Cambridge Sensors Ltd **Microdot**	• Strip eject mechanism • insulin data entry • four alarms to remind to test, event marking of results.	• 3 year warranty with free replacement for faulty meter • telephone helpline (national rate) • data management software and cable purchased separately.
HDI UK Ltd **TrueTrack**	• 14 and 30 day morning average values (results between 4.00 am and 9.59 am) • check strip to assess meter function • temperature compensation.	• Lifetime warranty with free replacement for faulty meter and lancing device • free telephone helpline • free control materials, batteries, data management software and cable and paper log book/diary • range of patient and professional education materials • membership to “self-check” patient support program.
LifeScan **OneTouch UltraEasy**	• Discrete size meter • strip precision check – second electrode • no initial meter set up required as factory set units of measurements, time, date.	
LifeScan **OneTouch Ultra2**	• Display with backlight • four test on screen summary • strip precision check – second electrode • meal time flagging with 7,14 & 30 day trend averages.	• Free warranty replacement for faulty meter and lancing device • free telephone helpline • free control materials, batteries, data management software and cable, educational materials, paper log book/diary.
LifeScan **OneTouch UltraSmart**	• Meter plus on board electronic log book with on screen review of results displayed as trend graphs with event markers • detailed, personalised multi type event marking food, medication, and exercise to blood glucose levels • stores insulin pump information.	
Menarini **GlucoMen LX**	• 9 months test strip stability after first opening canister • factory set for date and UK time • data management software and cable available for purchase separately.	• Lifetime warranty with free replacement for faulty meter and lancing device • free telephone helpline • free control materials, batteries, educational materials and paper log book/diary.
Menarini **GlucoMen Visio**	• Second drop of blood can be added within 2 seconds • data management software and cable available for purchase separately.	

Appendix 5: Additional features (primary care/home)

	Additional features	Additional services
Nova Biomedical UK **StatStrip Xpress**	• For professional use only • four well glucose measuring strip designed to measure interference from haematocrit; acetoaminophen; uric acid; ascorbic acid; oxygen; maltose; galactose; xylose; lactose; and icodextrin.	• Technical support hotline • training and audit programme • web based training.
Roche **Accu-Chek Aviva**	• Eight gold electrodes monitor sample and strip integrity for temperature, humidity, strip damage, underdosage and haematocrit and compensate results accordingly • automatically detects a QC sample • factory set for mmol/l, date and UK time with a separate smart battery for retaining the information • infrared download facility • supplied with Multiclix lancing device containing 6 lancets in a drum.	• Lifetime warranty with free replacement for faulty meter and lancing device • free telephone helpline 365 days a year, 7days a week • free control materials, batteries, data management software and cable, educational materials and paper log book.
Roche **Accu-Chek Compact Plus**	• For self monitoring use only • no strip handling as 17 strips (x3) provided in a drum • strip eject mechanism • integrated lancing device • factory set for mmol/l, date and UK time with a separate smart battery for retaining the information • acoustic mode for visually impaired • glow in the dark display.	
Acon Laboratories **OnCall Plus**	• Individually foil wrapped test strip also available.	• Five years warranty with free replacement for faulty meter and lancing device • free telephone helpline • free control materials, batteries.

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Buyers' guide: Blood glucose systems

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