

Buyers' guide

Blood gas analysers

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CEP buyers' guides are intended to provide prospective purchasers of healthcare products on the UK market with general guidance on the technical, operational, and economic considerations to be taken into account in selecting the most appropriate product where a range of similar products exists. They do not include product-specific information, which is published separately via market reviews (which contain product specifications only) or evaluation reports (which contain additional technical and / or user evaluation data). Readers are encouraged to check CEP's web site for updates.

Scope

This buyers' guide covers blood gas analysers intended to be used in laboratories, and hospital point-of-care settings where rapid availability of results is critical. Also included are portable blood gas analysers that are used in the community to monitor patients on long-term oxygen therapy.

Blood gas analysers

Blood gas analysers have been available for approximately 55 years [1-3]. The earlier analysers were complex to use and maintain and were mainly located in central or satellite laboratories and operated by trained laboratory staff. This entailed transporting blood samples to a laboratory, usually located at considerable distance from the patient, leading to delay in issuing results and increasing the risk of pre- and post- analytical errors.

Blood gas analysers directly measure pH, partial pressure of oxygen (pO_2), partial pressure of carbon dioxide (pCO_2), electrolytes, metabolites, and haematological parameters on arterial or capillary blood samples. Measured results may be used to derive additional calculated parameters.

Clinical impact

The Carter review of NHS pathology services [4] indicates that locating test equipment near to the patient produces a faster result which can improve patient outcomes both acutely and in the longer term. In critically ill patients, such as those with major organ failure, severe trauma, severe sepsis, or those recovering from general anaesthesia, clinical status can change rapidly, requiring prompt blood gas results to effect immediate patient management [5-9]. A short therapeutic turn-around time (TAT) can be achieved by locating blood gas analysers closer to the patient at the point-of-care [5-9] in intensive care units, accident and emergency, neonatal units and delivery wards, theatres, surgical units, and in the field (eg in community testing, war zones, air ambulances and disaster areas). Arterial blood gas testing is the most frequently ordered test in the intensive care unit and the operating room [10].

Blood gas analysis is typically performed on arterial blood samples, or capillary samples in the case of neonates, to determine whether a patient has an imbalance of oxygen and carbon dioxide in the blood or an acid-base imbalance (*ie* blood is too acidic or alkaline). It is employed in a wide range of respiratory, metabolic, and organ disorders. Blood gas analysers may also be used to monitor the effectiveness of oxygen therapy, during and after prolonged anaesthesia.

National guidance

There are no national guidelines related to the use of blood gas analysers. The British Thoracic Society recommendations for patients on long term oxygen therapy require measurement of blood gases in samples of arterial or capillary ear lobe blood [11] in the patients' homes.

Review of the literature

The databases Medline, Embase, Web of Science, British Nursing Index, Cochrane library and CINAHL were searched for the following terms:

Blood gas analy*

Blood gases **AND** point of care

Blood gas **AND** point of care

Blood gas **AND** economic **OR** cost effectiveness **OR** cost benefit analysis

Blood gas analysis **AND** interference*

Blood gas analysis **AND** connectivity

Searches were limited to these terms appearing in the title, abstract or keywords and to papers available in English and published between 1994 and 2009.

The following organisations' websites were also searched:

National Institute for Health and Clinical Excellence - www.nice.org.uk

College of American Pathologists - www.cap.org

Clinical Pathology Accreditation (UK) - www.cpa-uk.co.uk

International Federation of Clinical Chemistry and laboratory Medicine - www.ifcc.org

NHS Litigation Authority - www.nhsla.com

Institute of Biomedical Science - www.ibms.org

Association for Clinical Biochemistry - www.acb.org.uk

Royal College of Pathologists - rcpath.org

Medicines and Healthcare products Regulatory Agency - www.mhra.gov.uk

ECRI - www.ecri.org

American Association of Clinical Chemistry - www.aacc.org

The literature search highlighted publications that demonstrated the importance of blood gas analysers in point-of-care testing in critical care, with many comparing the performance of the analysers. Articles featuring the use of blood gas analysers in critical care discussed the benefits of locating the analysers at the point of care, with the main advantage being the rapid turn-around-time of results and the potential for improvement in patient outcome [5-9]. An important feature of blood gas analysers is the low sample volumes required. In critically ill patients who are continually monitored, especially neonates, blood loss due to phlebotomy can lead to iatrogenic anaemia requiring blood transfusions [12-15]. It is vital that blood gas analysers are accurate and comparable with reference methodologies, are easy to use with minimal operator interaction, require low levels of maintenance and have minimal downtime. To avoid post-analytical errors with result documentation, blood gas analysers should have robust data management systems [16-18]. Publications also highlighted sources of pre-analytical error, due to sample collection and handling, and sample deterioration during transportation to the laboratory [19-26].

In the UK and European Union (EU), analytical systems are required to conform to the IVD directive 98/79/EC [27]. BS EN ISO 22870 sets out the requirements for quality and competence of point-of-care testing [28]. The Medicines and Healthcare products Regulatory Agency (MHRA) has published guidance on issues related to point-of-care testing and the use of point-of-care devices [29, 30]. Professional bodies, the Royal College of Pathologists / Association for Clinical Biochemistry and Institute of Biomedical Science have also produced guidelines [31, 32].

Blood gas analysers

Blood gas analysers range in size and weight from small hand-portable systems to larger analysers transported using a trolley. Depending on an analyser's capability, the test menu can be customised to include any combination of analytes and calculated parameters. Generally the test menu allows measurement of blood gases, electrolytes, metabolites, and CO-oximetry. Various calculated parameters are also available.

Reagent and sensor electrodes

For use by non-laboratory healthcare professionals at the point-of-care, blood gas analysers that are easy to use with minimal operator intervention, maintenance and troubleshooting are preferable. Single-use cassette or multi-use cartridge-based systems are suitable for point-of-care testing as they utilise closed system pre-packaged electrodes and reagent modules that do not require gas cylinders and have sealed waste containment.

Single-use cartridge systems

A single-use cartridge contains the calibration solution and miniaturised electrochemical sensors necessary for analysis. These single-use systems are 'hand-portable' and easy to transport and are the most cost-effective analysers in units with a low test volume of less than 10 samples per day. Sensor electrodes in these types of systems are self-calibrating and can flag calibration errors. Other advantages of these systems are that:

- the analyser and electrodes do not require any maintenance
- prior to sample analysis, a calibration is performed and any calibration errors are flagged and the measurement suppressed
- problems due to blockage from blood clots are confined to the cassette in use
- after measurement the cassette containing the waste, blood and calibration fluid, is removed from the analyser and disposed of in clinical waste.

Multi-use cartridge systems

In locations with medium to high sample throughput, blood gas analysers utilising multi-use cartridge reagent systems, customised to the specific analyte menu and

volume of testing, are the most cost-effective. The number of samples analysed on a cartridge varies from 25 to 750. Once loaded into the analyser, the 'in-use life' of the cartridge is generally between 14 and 30 days. To be cost effective the appropriate size of cartridge must be selected to meet the unit's workload within the cartridge expiry period eg the larger reagent packs have shorter 'in-use life' of approximately 14 days.

These are larger analysers that provide the required sensor electrodes, and reagents such as calibrators, wash solution and liquid quality controls in a modular format or in individual reagent containers. A closed waste collection system is also included. Although the majority require minimal maintenance and have reduced downtime, some analysers may require maintenance to re-membrane or replace the sensor electrodes, tubing or peristaltic pumps, and possibly to replace a gas cartridge, and may therefore require technical support.

Measurement principle

Measurements of blood gases, electrolytes and metabolites utilise a variety of different technologies such as potentiometry, amperometry or fluorescence. The electrolytes Na^+ , K^+ , Ca^{++} , Cl^- and Mg^{++} are measured using ion selective electrodes. The haematocrit is measured using conductivity, and haemoglobin concentrations can be calculated from this. Haematological parameters are measured using CO-oximetry, based on optical measurements of analytes at a number of wavelengths (7 to 1000).

Calibration

Calibration allows the analyser responses to be set and adjusted to a known standard reference. All calibration materials should be traceable to certified reference materials such as the National Institute of Standards and Technology (NIST) gases and standards [33]. On the newer blood gas analysers, aqueous tonometered solutions to calibrate the analysers are available in sealed units, eliminating the need for gas cylinders and humidifiers.

A 1-point calibration adjusts the electrode at one level, either high or low, and is usually performed at frequent intervals and may even be conducted prior to each measurement. A 2-point calibration, adjusts the electrode at two levels, both high and low, and generally is set by the operator to take place at set intervals ranging from 2 to 24 hours. These calibrations can be preset to occur automatically at scheduled intervals. A barcode with information relating to lot-specific calibration data, in-use expiry date and expiry date *etc* are included in a 'smart chip' or printed on the reagent packs. This information is transmitted to the analyser automatically or using a barcode reader or keypad.

Analytical quality control

Reliable internal quality control and local external quality assurance schemes should be implemented to monitor and improve the use of blood gas systems.

Internal quality control

Internal quality control is designed to monitor and detect errors in the testing procedure but generally will not detect errors in sample collection and handling. It provides real time reassurance to the operator that the reagents and analyser are working correctly and identifies any problems. The frequency of quality control depends on the level of testing done and should be specified in the standard operating procedure (SOP).

Internal quality control on blood gas analysers is conducted manually using individual glass ampoules containing aqueous control solutions equilibrated with gas mixtures or automatically using on-board quality control materials. Automated QC helps simplify QC procedures and reduce the operator workload as it can be set to occur at regular intervals.

Electronic QC, requires no user input and is available on some blood gas analysers. It automatically detects, corrects, and continuously monitors the status of the analyser's internal electronics and circuitry to assure quality results. Additional analyser specific 'world-wide peer group review' of internal quality control results is provided by some manufacturers.

External quality assessment schemes

EQA schemes compare results between multiple sites to provide valuable information on relative performance and systematic analytical bias. The results are retrospective, unlike those for internal quality control. EQA schemes operate by individual sites analysing identical specimens with the results compared across all sites. To allow remedial action to be taken, relevant and prompt feedback must be given. Operators of point-of-care testing for blood gas measurement are strongly encouraged to enrol in an external quality assessment scheme such as that organised by WEQAS (www.wegas.com).

Sources of error

The accuracy and precision of results are related to the robustness of the analytical technology, and pre- and post-analytical errors. The quality of results depends on how and by whom the test is performed. Testing in the central laboratory is conducted by appropriately trained personnel who maintain regulatory compliance. Non-laboratory personnel using point-of-care systems may not fully appreciate the influence of physiological and analytical factors on the final result which could lead to

inappropriate treatment decisions. Up to 68% of errors in blood gas measurements at the point-of-care are related to sample collection, handling and preparation [19-23], invalidating the results regardless of the accuracy and precision of the analyser. Table 1 lists common sources of pre-analytical, analytical and post-analytical errors.

Table 1. Pre-analytical, analytical and post-analytical errors

Pre-analytical errors

Sample type

Ensure that analyser is intended for the sample type *ie* dialysate, cerebrospinal fluid, pleural fluid *etc*.

Sample collection and handling

- Ensure that the patient is in a stable steady state when collecting the blood sample.
- Blood samples must be collected anaerobically using the correct sampling technique and appropriate syringes or capillary tubes.
- Blood sample may become contaminated during collection *eg* use of petroleum jelly and amniotic fluid contamination during fetal scalp blood collection, contamination from inadequately flushed in-dwelling arterial lines *etc*
- Blood sample must be collected using the correct anticoagulant *ie* balanced heparin anticoagulated syringes are required for Na⁺, K⁺, ionised Ca⁺⁺ and ionised Mg⁺⁺ measurements.
- Excess anticoagulant, especially in liquid form, has a diluting effect, decreasing pCO₂ values and increasing pH and pO₂ values.
- Inadequate sample mixing with the anticoagulant can lead to formation of blood clots which can block the sample path, giving incorrect results, and in multi-use cartridge systems, may affect subsequent samples. Many blood gas analysers have automatic clot detection and removal systems [26]. An additional precautionary measure to prevent introduction of clots in the sample pathway is by fitting a disposable 'clot catcher' adapter to a syringe or capillary.
- Incorrect mixing technique or placing samples on ice can cause in-vitro haemolysis leading to falsely elevated K⁺ and reduced ionised Ca⁺⁺ values.
- Insufficient samples will give incorrect result. Analysers with a visible sample pathway allow checks for insufficient sample, air bubbles or clots.
- All air bubbles must be removed before mixing the blood as this can falsely reduce pCO₂ values and elevate pO₂ and pH values.
- Samples for blood gas measurements collected in plastic syringes should not be transported on ice as it falsely reduces pO₂ values [21-23].
- All blood samples must be correctly labelled to avoid results being mismatched.
- Correct documentation of patient status must be made *eg* FiO₂, O₂ delivery device, mode of ventilation.
- Ensure sample is presented to the analyser using the correct technique *eg* injection or aspiration.

Sample transport

- Blood gas analysis must be carried out within 30 minutes of sample collection to avoid falsely elevating the pCO₂ and decrease pO₂ and pH values due to continued blood metabolism
- Transporting samples via a pneumatic tube system may affect the pO₂ values, cause in-vitro haemolysis leading to increased potassium levels and affect the haemoglobin measurement [24-25].

Table 1. Pre-analytical, analytical and post-analytical errors (continued)

Analytical errors

Calibration - on-board calibrators may be prone to drift with age, especially with larger reagent packs which remain in situ for long periods leading to gases being displaced from the solution.

Measurement principle - haematocrit measurements on blood gas analysers, using conductivity, may give falsely low or high results in certain groups of patients eg cardiopulmonary bypass and post-operative ICU [34, 35].

Interferences - Interferants which affect the measurement of a particular analyte are stated by the manufacturer in their instructions for use. These should be highlighted during training and in the SOP.

- Sample haemolysis falsely elevates potassium levels, reduces ionised calcium, and affects haematocrit and haematological measurements.
- Prolonged light exposure may lead to degradation of bilirubin.
- Haemoglobin measurements on COoximetry are affected by high lipid concentrations and red cell fragments [35].

Post-analytical errors [16-18]

Transcription errors - incorrect recording of patient ID and results.

Result documentation - failure to report results to clinician and document results correctly in patients' record may lead to inappropriate treatment or failure to treat. This may be controlled by integration of results automatically into patients' records through connectivity.

Result interpretation - incorrect result interpretation due to lack of awareness of pre-analytical and analytical influences on the measurements, and failure to recognise and act on results outside the normal range.

Analyser selection

The clinical performance and characteristics of a system determine its suitability, safety and effectiveness for use. Systems must have high levels of accuracy and precision comparable with reference methods. Other important features are the ability to customise the test menu for a specific location and workload, ease of use, minimal maintenance, and remote troubleshooting. The safety of the operator and patients is paramount. Any known hazards or problems in using the product; or Medical Device Alerts issued should be considered when selecting a blood gas analyser.

Facilities and resources

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. Facilities must take into account the provision of:

- adequate space to accommodate the analyser and associated equipment in a dedicated location
- mains power supply. For energy conservation, the analyser should go into a sleep mode. Where batteries are required, they should be re-chargeable
- reagent storage, including refrigerated storage where appropriate
- IT infrastructure for connectivity
- clinical waste disposal facilities
- appropriate support in respect of health and safety and infection control.

Work flow

Sufficient time should be allocated to order the reagents and consumables, set-up the analyser, conduct the maintenance, quality control procedures and the test. To facilitate workflow, the analyser, reagents and other consumables should be easily accessible. The location of equipment and sharps bins must ensure that safety is not compromised. Additional consumables such as anticoagulated syringes, needles, capillary tubes, caps, gauze, gloves, decontamination materials, and quality control materials are also required.

Training

Point-of-care testing within a hospital is assessed as part of the laboratory accreditation process that verifies and monitors technical competence [28]. To support NHS organisations to train staff in the use of POCT systems, the Department of Health is developing an accreditation system for POCT with the NHS, professional bodies, other stakeholders and e-Learning for Healthcare (eLfh www.e-lfh.org.uk).

This will provide a comprehensive resource to complement and enhance existing practical POCT user training programmes currently provided by suppliers [36].

Consistent, well documented training conducted by a competent trainer is essential as POCT is performed extensively by non-laboratory personnel from various healthcare backgrounds with little technical experience [37]. Healthcare professionals using point-of-care analysers must be certified and their competency proven annually. They must be capable of correctly carrying out specimen collection, handling and measurement; performing necessary quality control procedures and maintenance; ensuring all procedures are well documented whilst adhering to infection control protocols.

Training requirements are stipulated in the tender documents and are customised by the supplier to suit the organisation. Training of all staff by suppliers is ideal, as they have the technical expertise to cover all issues concerning the analyser. However, the number of staff to be trained is often large and NHS trusts might therefore decide to train key members of staff who then cascade training to others. Additional training materials such as training manuals, CDs and e-training made available for dissemination via the hospital intranet are also available from suppliers.

Quality assurance

Quality assurance measures require the operator to understand the importance of obtaining consistently accurate measurements with correct result interpretation. This includes training and overall assessment of analytical performance, including pre- and post-analytical processes [38, 39]. Sufficient time should be allocated for staff to perform quality procedures, implement reliable quality assurance processes and practices including internal quality control (IQC) and external quality assessment (EQA) schemes.

Safety

Operators of POCT systems should be aware of potential hazards, including those identified in safety advice from the MHRA, the manufacturer or other relevant bodies. They should be aware of the importance of device-related adverse incidents, be capable of recognising when a device is not working properly, and follow the appropriate procedures for reporting incidents to the MHRA (www.mhra.gov.uk).

Safety in the use of a blood gas system also applies to the proper use of accessories and following correct procedures as outlined in the standard operating procedures (SOPs). The SOPs should include protocols for staff training, monitoring equipment performance and logging any errors. They should also state measures to be taken with samples outside reference ranges.

Patients and operators may be at risk of infection from a contaminated system. Suitable infection control and decontamination procedures should be implemented by staff handling blood samples and they should have the necessary immunisations.

In neonates capillary blood sample are collected from a heelstick for blood gas analysis. Capillary blood samples from the ear lobe are collected from adults receiving oxygen therapy at home. In these circumstances appropriate lancing devices should be used to prevent needlestick injury, prevent infection and in neonates control the depth of puncture to prevent bone damage. CEP has produced a buyers' guide and a market review for lancing systems that is available on www.pasa.nhs.uk/cep [40, 41] and the MHRA has issued guidance relating to the safe use of lancing devices and the risks associated with inappropriate use [42].

Consumables such as used gloves, tissues, cassettes contaminated with blood must be disposed of in clinical waste bags. However, sharps such as needles, lancing devices, capillary blood collection tubes/ syringes must be discarded in a sharps bin.

Maintenance

Scheduled maintenance at set intervals may be required with some blood gas analysers to change the peristaltic tubes or pump, blood gas cylinders or remembrance electrodes which may require technical support. The start up time after such procedures may be between 20 and 45 minutes, including warm up time, a 2-point calibration and quality control measurement. Regular maintenance and service should be scheduled to occur at times when it is likely to cause least disruption, as during periods of 'downtime' the analyser cannot be used.

Maintenance of single-use cassette systems is minimal requiring visual inspection to ensure they are clean. Cartridge based multiple-use blood gas analysers require additional maintenance to replace reagent pack(s) or the printer paper when necessary. The newer generation of multi-use blood gas analysers can detect blockages caused by a clotted sample, and either catch or clear the clot automatically thereby minimising maintenance time required to resolve the problem.

Connectivity

Point-of-care test results are often recorded manually, which increases the risk of transcriptional errors and omissions from patient records. Connectivity is the ability of a system or device to connect with other systems or devices to allow data transfer to the hospital or laboratory information systems (HIS or LIS). Connectivity is increasingly incorporated for auditing patient pathways and the Clinical Governance and NHS Litigation Authority guidelines [43] advocate connectivity to help reduce errors and improve staff compliance.

Setting up the devices to connect to other devices should comply with the POCT-2P standards of the Clinical and Laboratory Standards Institute (ISO 11073-90101), which stipulate 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*' [44]. Protections must be in place to allow the use of the analyser in case of IT system failure.

Cost effectiveness

Blood gas measurements are performed in critical care for the management of physiologically unstable patients. By locating blood gas analysers at the point-of-care results are available immediately, providing the clinician with an assessment of real time patient status on which to make a therapeutic decision. The possible benefits of a reduction in the turnaround time are improved patient management and treatment outcomes, reduced length of stay in expensive critical care units, and reduced medication costs [45-47]. Point-of-care blood gas analysis may be associated with a decreased incidence of adverse clinical events or their earlier detection, which has the potential to produce significant cost savings, eg reducing blood transfusions to treat iatrogenic anaemia [46]. Point-of-care testing also reduces the cost of transporting samples to the central laboratory. Although point of care testing in critical care settings is generally accepted to improve patient outcomes, well-designed clinical studies are necessary in order to provide definitive evidence of this [5].

Cost considerations for blood gas analysers

The cost of arterial blood gas testing is made up of several contributing factors. Direct costs apply to the purchase of capital equipment and its depreciation, reagents, labour, quality assurance, additional consumables, training, maintenance and servicing. Purchase costs are generally negotiable with suppliers and special NHS or volume related discounts may apply depending on the type of contract and level of services required. Purchasers may choose to standardise by procuring blood gas analysers, for different sites requiring customised test menus, from a single supplier. Likely benefits of a single contract, standardising analysers across all hospital sites include larger price discounts, consistent training easing staff deployment, improved technical support, and simplifying consumable orders. The indirect costs for space, heating, electricity and waste disposal and other sustainability issues such as power consumption should be considered by purchasers.

Capital equipment

The cost of purchasing blood gas analysers should be considered over the working lifetime of the system and amortised over a 5 to 7 year period. All instruments are supplied with a manufacturer's warranty of at least one year. Additional or extended warranties can be purchased separately. Installation or networking equipment for connectivity to LIS / HIS including data management software and optional accessories such as a printer, barcode reader or trolley for transporting the analyser may involve additional costs. The purchase of a refrigerator may be necessary for reagent storage or a centrifuge if plasma or serum samples are required.

When purchasing the analyser, and to ensure cost-effectiveness, careful consideration should be given to the location of the equipment, the test parameters

required and the work throughput to avoid indiscriminate testing and waste of reagents.

Analyser reagents and consumables

Reagents are packaged in various test configurations and pack sizes. The majority of reagents are presented as single or multi-use cartridges, which contain all the reagents, calibration fluid, sensors and quality control solutions, and act as sealed receptacles for storage of waste products. Multi-use cartridge systems have a finite life once installed and sample throughput must be maximised for the analyser to be cost-effective. The cost of a faulty reagent cartridge may be reimbursed by the supplier either by returning the cartridge or sending a printout or compact disc containing relevant information downloaded from the analyser.

Individual reagent bottles, separate rinse and waste containers, gas cylinders, sensor electrodes and membranes are utilised by some large analysers. Although this format may produce minimal reagent wastage with longer on board life, giving greater economy, this is offset against greater staff costs for a higher level of maintenance and technical support. Additional costs for consumables such as peristaltic pumps, tubing and printer paper should also be considered.

Labour

In performing arterial blood gas testing, the major cost is staff time spent on sample collection, analysis, instrument set-up, maintenance, quality control and ordering consumables. Cost savings can be made with analysers having features that reduce staff time on maintenance and troubleshooting, eg dedicated software allowing remote monitoring of blood gas analysers.

Quality assurance

Internal quality control requires the appropriate control materials, which with some blood gas analysers are provided in the reagent pack, cartridge or cassette. Separate verification liquid control solutions for haematocrit and at three different levels for blood gases, may have to be purchased. The cost of reagents for conducting the tests on quality control materials must also be taken into consideration.

The cost of enrolment in an EQA scheme, such as WEQAS must be considered. Registration with an individual manufacturer's worldwide peer review scheme for comparison of quality control values may also incur additional charge.

Training

Costs associated with the training, accreditation and certification of staff competency must be considered. Training credits may be awarded by the manufacturer according to the number of analysers purchased, which can be offset against the cost of

training required throughout the contract period. Web-based e-training packages can reduce the need for more expensive face-to face training and competency certification.

Maintenance

There may also be additional costs in conducting regular maintenance and quality procedures. Features such as automatic quality control, automatic clot detection and on board diagnostics help to reduce maintenance requirements and analyser downtime.

Service costs

Analyser servicing and technical support is provided by the manufacturer at additional cost, which will be dependent on the type and level of service cover required.

Additional consumables

A variety of other miscellaneous costs for additional consumables for specimen collection include gloves, alcohol swabs, gauze, lancets, needles, arterial blood collection devices/syringes, capillary tubes, end caps / plugs, mixers and disposal of contaminated waste.

Purchasing procedures

The Trust Operational Purchasing Procedures Manual provides details of the procurement process [48].

European Union procurement rules apply to public bodies, including the NHS, for all contracts worth more than £90,319 (from January 1st 2008) [49] (appendix 1). 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.

NHS Supply Chain (www.supplychain.nhs.uk), a ten year contract operated by DHL on behalf of the NHS Business Services Authority, offers OJEU compliant national contracts or framework agreements for a range of 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* [50] in March 2005. The strategy describes four priorities in progressing sustainable development:

- 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 a significant global threat.

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

Sustainable development in blood gas analysers

The major sustainability considerations for blood gas analysers are the materials used in their manufacture, consumables, and packaging, and the disposal of waste materials, consumables and packaging after use.

Materials

High levels of plastic are used in the manufacture of medical devices and associated consumables. The type of plastic used could have an impact on product sustainability which can be minimised by using biodegradable plastics, recycle or natural

products from sustainably managed sources. Blood gas analysers also contain a high number of electronic components but the European directive on the restriction on the use of certain hazardous substances in electrical and electronic equipment (RoHS) [51] does not currently apply to medical devices.

Power supply and demand

Blood gas analysers are predominantly mains powered, but there are several portable systems which have the facility to use rechargeable batteries. Units fitted with auxiliary energy features to extend battery life and/or reduce mains energy consumption while on standby, are preferable. Some of the features employed by blood gas analysers to conserve power are automatic shutdown or switch to standby / economy mode and the use of liquid crystal displays (LCD), LEDs, fluorescent or solid state lighting technologies.

Waste disposal and recycling

Consumable waste comprises predominantly used test cartridges, cassettes, sensors, calibration packs and contaminated waste collected in sealed units or bottles. It must be treated as bio-hazardous material and disposed of in appropriate clinical waste containers. Most paper and cardboard packaging is recyclable, although some plastics are not.

End-of-life disposal

It is desirable for products to be designed for ease of disassembly in order to maximise recovery of components/materials for recycling, where possible, at the point of 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) [52]. 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.

Batteries contain toxic materials and should be treated as hazardous waste for the purposes of disposal, in line with existing regulatory control measures and sustainable disposal practices [53, 54].

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Appendix 1: EU procurement procedure

Lease options

National frameworks are in place for operating leases to help the NHS procure leases more cost efficiently and effectively. Further details are available from the PASA website [\[55\]](#).

EU procedures

The Public Sector Directive (2004/18/EC) has been transposed into UK law via 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) [\[49\]](#) 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.

Appendix 1: EU procurement procedure

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 [56] and an illustrative example is provided in the *NHS PASA Operational Purchasing Procedures Manual*, Procedure 1-01 [57].

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 [58].

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 pre-qualification questionnaire, seeking background information (eg on the skills and experience of the service engineers) may be employed as an initial screen to exclude unsuitable suppliers.

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.

Appendix 1: EU procurement procedure

Buyers must be aware of the 'Alcatel' procedure (see the *Trust Operational Purchasing Procedures Manual* [\[48\]](#), Procedure No.T-08, section 6 - *Mandatory Standstill Period*).

For more information on procurement please refer to the Department of Health Website [\[59\]](#).

Buyers' guide: Blood gas analysers

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About CEP

The Centre for Evidence-based Purchasing (CEP) is part of the Policy and Innovation Directorate of the NHS Purchasing and Supply Agency. We underpin purchasing decisions by providing objective evidence to support the uptake of useful, safe and innovative products and related procedures in health and social care.

We are here to help you make informed purchasing decisions by gathering evidence globally to support the use of innovative technologies, assess value and cost effectiveness of products, and develop nationally agreed protocols.

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