

Reporting adverse incidents:

We prefer to receive reports via our website:

www.mhra.gov.uk

you can also download a form from our website and e-mail or fax it to us:

E-mail: aic@mhra.gsi.gov.uk

Fax: 020 7084 3109

Hotline: 020 7084 3080

Further information:

We have extensive guidance in our publication:

DB 2002(03) Management and Use of IVD Point of Care Test Devices

This is available on our website in full text:

- www.mhra.gov.uk

If you would like more copies of this leaflet please contact us on:

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Point of Care Testing

Blood glucose meters

Advice for health care professionals

Involve your local hospital laboratory

Your local hospital laboratory can play a supportive role in providing advice on a range of issues including the purchase of devices, training, interpretation of results, troubleshooting, quality control and health and safety.

Management

Many people will be involved in the creation, implementation and management of a blood glucose testing service. It is important that an appropriate service co-ordinator is identified and that the local point of care testing committee is involved.

Choice of equipment

There is a wide variety of blood glucose meters and lancing devices available. Careful and systematic selection of appropriate equipment is essential.

- Has the meter been designed for use by non-laboratory staff?
- Is it suitable for use in the setting you intend to use it?
e.g. In a neonatal unit, in an ambulance, in a GP surgery
- Can the meter/lancing device be used on multiple patients or is it for single patient use?
- Does its design suit the needs and requirements of the patient/user?
- Is it CE marked under the IVD directive (ask the manufacturer)?
- Has the meter been independently evaluated? Contact the Device Evaluation Service on 020 7972 8181.

See the following leaflets available on the MHRA website www.mhra.gov.uk

'A guide to lancing devices on the UK market'.

'A guide to blood glucose meters on the UK market'.

Training

Training must be provided for staff who use blood glucose meters and should be refreshed at appropriate intervals. Only staff whose training and competence has been established and recorded should be permitted to carry out blood glucose testing.

Staff involved in training and advising people with diabetes should ensure that they inform them of potential sources of error and give advice on how to interpret results.

Training should include:

- basic principles of measurement
- expected results in normal and pathological states
- demonstration of the proper use of the equipment in accordance with the manufacturer's specification
- demonstration of the consequences of improper use
- knowledge of operator dependent steps
- instruction in the collection of appropriate blood samples
- health and safety aspects
- instruction in the importance of complete documentation of all data produced
- appropriate calibration and quality control techniques
- practical experience of the procedures, including a series of analyses to satisfy the instructor that the trainee is competent
- information regarding contra-indications
- information on basic troubleshooting, error messages and potential sources of error.

Standard Operating Procedure (SOP)

There must be an SOP in place wherever blood glucose testing is performed. SOPs must include the manufacturer's instructions for use and should be directly available to the user and be kept with the equipment.

Contra-indications/interferences

The instructions for use for all glucose meters/strips detail a number of situations/conditions where the test result may be affected and when the meter/strips should not be used. Staff must be aware of the need to perform a laboratory measurement of glucose using a venous sample in cases where contra-indications are observed or suspected and when abnormal or unexpected results are obtained.

Contra-indications	Examples
Dialysis treatments	CAPD fluids may contain maltose which can interfere with some test strip methodology
Peripheral circulatory failure	Severe dehydration, hyperglycaemic-hyperosmolar state with or without ketosis. Hypotension, shock, peripheral vascular disease
Severe dehydration	Vomiting or diarrhoea, prescription drugs (diuretics), sustained uncontrolled diabetes
Variations in blood oxygen tension	Patients receiving intensive oxygen therapy
High concentrations of non-glucose reducing substances in the blood	Intravenous infusion of ascorbic acid
High bilirubin values	Jaundice
Extremes of haematocrit	Neonatal blood samples, pregnancy
Hyperlipidaemia	Total parenteral nutrition, hyperlipidaemia

Internal Quality Control (IQC)/External Quality Assessment(EQA)

IQC: Appropriate control material must be analysed according to local hospital procedures and manufacturer's recommendations. It can provide reassurance that the device is working correctly and assure the operator of the reliability of patient results.

EQA: It is advisable that all sites performing blood glucose analysis also undertake the analysis of EQA samples. EQA is the analysis of samples with an undisclosed value from an external source. Participation in an EQA scheme will establish comparability between sites.

Record keeping

It is essential that accurate records are kept for all aspects of blood glucose testing. This could include test strip lot number, meter maintenance, calibration, QC, patient results, patient and operator identity, battery change. In the event of an adverse incident or product recall such information would be essential in performing a risk analysis of the situation, enabling appropriate action to be taken.

Consumables

Care should be taken to ensure that consumables (test strips, lancets etc) are compatible with the glucose meter and give reliable results, and that they are stored according to the manufacturer's instructions. Some test strips rely on a colour change and these in particular are susceptible to temperature extremes and moisture.

Results

Ensure that procedures are in place so staff know what to do with abnormal or unexpected results. Results should be reviewed by appropriately qualified staff with particular reference to patient's history and current condition and expected results. Results should be recorded in the instrument log book and the patient's notes.

Sample quality and type

Make sure sufficient sample volume is applied to the test strip and that you have taken it from an appropriate site. If a sample is taken from an alternative site such as the forearm then you must make sure that the meter and test strips have been validated for this purpose and be aware that the results may differ from capillary fingerstick samples. Excessive massaging of the finger should be avoided.

Plasma/whole blood

Blood glucose meter test strips generally use capillary whole blood as a sample. Laboratory measurements of glucose use plasma as a sample. Some blood glucose meter test strips are calibrated to give results that are comparable with laboratory glucose results and these are termed 'plasma calibrated'. Plasma calibrated test strips give results that are approximately 12% higher than whole blood results. Check the instructions for the test strips to find out how they are calibrated and make sure that you are using the appropriate reference range.

See the leaflet entitled 'Blood glucose monitoring: know your systems' available on the MHRA website www.mhra.gov.uk

Units

The units used for glucose measurement in the UK are mmol/l but in other countries, the units are mg/dl. Always check that the meter you are using, or that patients are using, is set to mmol/l, particularly if they appear to be experiencing problems.