HOSPITAL BLOOD BANKS IN WALES

SPECIFICATION FOR A TEMPERATURE DATA LOGGER.

General Requirements.

The Transfusion Laboratories wish to purchase temperature data logging devices for measuring, logging and monitoring temperature of blood component storage and transport in order to comply with the European Blood Directive and Blood Safety and Quality Regulations 2005.

The Laboratories will specifically want to review and evaluate suitable options for:

1. **Transport validation.** Transport of blood and blood components with different temperature requirements. (4°C to 25°C).

2. **Mapping of fridges/freezers for component storage.** Storage of red cells (4°C), Platelets (22°C), and frozen plasma products (-40°C).

3. **Mapping of commercial product storage areas (25°C)**

4. **Appropriate on site training must be provided.**

5. **Pre-calibrated units must be supplied with calibration certificate.**

Physical Requirements.

1. **LCD display of temperature for instant checks and to ensure logger set up has been activated.**

2. **Indication of active logging.** Alarm function with programmable limits with audible/visible alarm warning.

3. **Setup with start/stop functionality.** Pre-programmable for manual start to run for a defined period of time.

4. **User programmable logging frequency with large memory capacity.**

5. **Accuracy to within 0.5°C for a temperature range of 30°C to +25°C.**
   **Accuracy to within 1°C for -40°C**

6. **Robust construction, waterproof.**

7. **Long battery life with integral battery life indicator.**

8. **Option of a hard probe for measurement of core temperature.**

9. **Units must be CE marked**
IT/Software requirements.

1. Appropriate software should be provided to enable set up and download of information from logger to PC application.

2. Software should allow data to be stored, displayed and/or printed in tabular and graphical form.

3. Suitable port connection between logger and PC with automatic detection should be provided.

4. A single cradle or interface to connect between PC and logger that will be suitable for temperature range of -40°C to +40°C together with single software package for similar range.

5. Identify minimum PC specification for software and whether software is compatible with a network environment (Ethernet connection) or individual PC platform.

Calibration requirements.

6. Calibration should be traceable to National and International standards (UKAS) and documentary evidence should be provided.

7. 4 point calibration at following temperatures for each individual piece of equipment.
   - -40°C
   - +4°C
   - +20°C
   - +30°C

8. Calibration status must be displayed on each logger (date calibrated, by whom and next calibration due date).

9. Cost of annual calibration by manufacturer should be provided.

Additional Information

1. Clear instructions for use should be provided.

2. What training will be provided?

3. Delivery time from receipt of order.

4. Details of customer support network provided by supplier
   - Mechanism for problem solving
   - Servicing/ replacement provision of faulty units
   - Warranty period of units and level of cover