

Information Sheet: Equipment validation

As part of the SOS study, clinical observations need to be taken and recorded, as per routine clinical care. These readings are then required to complete the week 1 follow up. As part of Good Clinical Practice you need to ensure that any equipment used to obtain these readings has been calibrated and is in good working order. You need to be able to provide evidence for this calibration during monitoring and audit procedures and inspections.

If the equipment you are using is used as part of general care then you need to consult your trust to obtain evidence that the machines are regularly calibrated. This might be in the form of certificates, or may be written confirmation from the department responsible for testing and calibrating the equipment.

This evidence needs to be stored in the Investigator Site File.