



JPen Medical Calibration & Testing Scope of Works for Well

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Blood Pressure Monitor

- Visual inspection of the case, screen, buttons and connections- checking for function and cracks that may be infection control risks
- Switch on the device and ensure it has functionality
- Record make, model and serial number on PDA
- Record deterioration of the device, including any replacement parts that will be required
- Confirm that the equipment is suitable for use for the intended purpose
- Check battery installation date (if applicable), and check of the battery terminals for corrosion and record if any replacements are required
- Assign a unique ID number and barcode to the device that will stay with the device throughout its life
- Linear pressure check at a minimum of 5 set points
- Must be within tolerance of +/- 3mmHg or that specified by the manufacturer if different
- Results recorded on the PDA along with any test equipment used
- Visual inspection and check the correct functioning of the cuff in conjunction with the device
- Electrical safety test conforming to IEC 62353
- Ensure device is clearly labelled with the appropriate label, either pass or fail and the site contact notified of any fails

CO Meter (Smokerlyser)

- Visual inspection of the case, screen, buttons and connections- checking for function and cracks that may be infection control risks
- Switch on the device and ensure it has functionality
- Record make, model and serial number on PDA
- Record deterioration of the device, including any replacement parts that will be required
- Confirm that the equipment is suitable for use for the intended purpose
- Check battery installation date (if applicable), and check of the battery terminals for corrosion and record if any replacements are required
- Assign a unique ID number and barcode to the device that will stay with the device throughout its life
- Unit is placed into calibration mode and calibrated with either 20ppm or 50ppm carbon monoxide as per manufacturer guidelines
- If calibration is not possible, calibration accuracy is checked with device in test mode and device is checked whether it is within tolerance limits
- Check functioning of device in normal operation
- Ensure device is clearly labelled with the appropriate label, either pass or fail and the site contact notified of any fails

Defibrillator (AED)

- Visual inspection of the case, screen, buttons and connections- checking for function and cracks that may be infection control risks
- Switch on the device and ensure it has functionality
- Record make, model and serial number on PDA
- Record deterioration of the device, including any replacement parts that will be required
- Confirm that the equipment is suitable for use for the intended purpose
- Assign a unique ID number and barcode to the device that will stay with the device throughout its life
- The pads expiration date is recorded and it is ensured that they are in date
- The defibrillator is connected to a patient simulator through a set of test leads
- The patient simulator is set to simulate a patient in ventricular fibrillation
- The defibrillator is turned on and will analyse the heart rhythm
- It is ensured that the defibrillator recognises the shockable ventricular fibrillation and charges its capacitor
- The shock is delivered to the patient simulator and the energy level recorded
- The heart rhythm of the patient simulator is changed automatically to a normal sinus rhythm
- When the defibrillator analyses the rhythm again, it must recognise this rhythm is normal and not recommend a shock
- If displayed, the level of the battery is recorded. If not, it is ensured that it is not recommending a battery change
- If a self-test is available, this is run through to ensure it passes
- Readings are checked that they are acceptable energy levels for a shock output
- Check for loose electrical connections
- Electrical safety test conforming to IEC 62353
- Ensure device is clearly labelled with the appropriate label, either pass or fail and the site contact notified of any fails

Hearing Loop

- Visual inspection of the buttons and connections- checking for function and cracks that may be infection control risks
- All leads are checked to ensure no bare wires are visible
- Switch on the device and ensure it has functionality
- Record make, model and serial number on PDA
- Record deterioration of the device, including any replacement parts that will be required
- Confirm that the equipment is suitable for use for the intended purpose
- Assign a unique ID number and barcode to the device that will stay with the device throughout its life
- The device is switched off at the mains point (where applicable) along with any other audio induction loop equipment in the immediate area and a measurement of the background electrical noise taken, ensuring the reading is no greater than -27dB
- The device is then turned back on and the correct functioning of the induction loop system is confirmed by the engineer by observing noise from the microphone in headphones
- Where possible the drive control on the amplifier is adjusted so the reading peaks to 0dB
- Check for loose electrical connections
- Electrical safety test conforming to IEC 62353
- Ensure device is clearly labelled with the appropriate label, either pass or fail and the site contact notified of any fails

Height Measure

- Visual inspection of the case, screen, buttons and connections- checking for function and cracks that may be infection control risks
- Switch on the device and ensure it has functionality
- Record make, model and serial number on PDA
- Record deterioration of the device, including any replacement parts that will be required
- Confirm that the equipment is suitable for use for the intended purpose
- Check battery installation date (if applicable), and check of the battery terminals for corrosion and if any replacements are required
- Assign a unique ID number and barcode to the device that will stay with the device throughout its life
- Accuracy of height measure is checked using a calibrated ruler of one meter in length
- Measurement of height measure is recorded to ensure it lies within tolerance limits +/- 5mm
- Correct functioning of device is checked in normal operation
- Ensure device is clearly labelled with the appropriate label, either pass or fail and the site contact notified of any fails

Otoscope/ Ophthalmoscope

- Visual inspection of the body, case, switches and connections- checking for function and cracks that may be infection control risks
- Switch on the device and ensure it has functionality
- Record make, model and serial number on PDA
- Record deterioration of the device, including any replacement parts that will be required
- Confirm that the equipment is suitable for use for the intended purpose
- Check battery installation date (if applicable), and check of the battery terminals for corrosion and if any replacements are required
- Assign a unique ID number and barcode to the device that will stay with the device throughout its life
- Integrity of bulb and lenses are checked
- Correct functioning of device is checked in normal operation
- Electrical safety test conforming to IEC 62353
- Ensure device is clearly labelled with the appropriate label, either pass or fail and the site contact notified of any fails

Pulse Oximeter

- Visual inspection of the case, screen, buttons and connections- checking for function and cracks that may be infection control risks
- Switch on the device and ensure it has functionality
- Record make, model and serial number on PDA
- Record deterioration of the device, including any replacement parts that will be required
- Confirm that the equipment is suitable for use for the intended purpose
- Check battery installation date (if applicable), and check of the battery terminals for corrosion and if any replacements are required
- Assign a unique ID number and barcode to the device that will stay with the device throughout its life
- Pulse oximeter probe is placed on SpO2 simulator, and it is set to simulate 97% SpO2 at 60 beats per minute
- Readings on pulse oximeter are recorded to ensure they lie within tolerance limits
- Pulse oximeter probe is placed on SpO2 simulator, and it is set to simulate 80% SpO2 at 120 beats per minute
- Readings on pulse oximeter are recorded to ensure they lie within tolerance limits +/-2%
- Correct functioning of device is checked in normal operation
- Electrical safety test conforming to IEC 62353
- Ensure device is clearly labelled with the appropriate label, either pass or fail and the site contact notified of any fails

Scales

- Visual inspection of the case, screen, buttons and connections- checking for function and cracks that may be infection control risks
- Switch on the device and ensure it has functionality- if digital scales
- Record make, model and serial number on PDA
- Record deterioration of the device, including any replacement parts that will be required
- Confirm that the equipment is suitable for use for the intended purpose
- Assign a unique ID number and barcode to the device that will stay with the device throughout its life
- 20Kg weights are placed centrally on the scale and the reading recorded in 20Kg increments from 20Kg to 120Kg
- As the weights are removed from the scale, the readings are recorded again at each of the increments
- A 20Kg weight is placed in each corner of the scale and the off-centre readings are recorded
- Weights that total approximately half of the limit of the scale are placed on the scale again, to ensure the repeatability of weights is accurate
- This repeatability test is repeated a total of three times
- Readings are checked that they are within the manufacturer's tolerance limits
- Check for loose electrical connections
- Electrical safety test conforming to IEC 62353
- Ensure device is clearly labelled with the appropriate label, either pass or fail and the site contact notified of any fails

Thermometer (tympanic)

- Visual inspection of the case, screen, buttons and connections- checking for function and cracks that may be infection control risks
- Switch on the device and ensure it has functionality
- Record make, model and serial number on PDA
- Record deterioration of the device, including any replacement parts that will be required
- Confirm that the equipment is suitable for use for the intended purpose
- Check battery installation date (if applicable), and check of the battery terminals for corrosion and if any replacements are required
- Assign a unique ID number and barcode to the device that will stay with the device throughout its life
- Thermometer is tested with heat block set at 36.0°C and reading recorded
- Reading is recorded and checked that it lies within tolerance limits 0.3°C
- Ensure device is clearly labelled with the appropriate label, either pass or fail and the site contact notified of any fails