




Validation Test Report

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| Protocol | ALT002-VAL020 |
| Date | 2 December 2008 |
| Tester | Geoff Daly, Operations Manager |
| Result |  Pass |

Requirement

ISO 8536-4:2004 Section 6.2:

6.2 Leakage

The infusion set, when tested in accordance with A.2, shall show no signs of air leakage.

Setup and Method

ISO 8536-4 Annex A.2:

A.2 Tests for leakage

A.2.1 In the beginning of the test, condition the whole system at the test temperature.

A.2.2 Immerse the infusion set, with one end blocked, in water at 20°C to 30°C and apply an internal air pressure of 50 kPa above atmospheric pressure for 15 s. Examine the infusion set for air leakage.

A.2.3 Fill the infusion set with degassed, distilled water, connect it with its openings sealed to a vacuum device and subject it to an internal excess pressure of - 20 kPa at (23 ± 1)°C and (40 ± 1)°C for 15 s. Atmospheric pressure shall be the reference pressure. Excess pressure, according to ISO 31-3, can assume positive or negative values. Inspect whether air enters the infusion set.

Apparatus

- 10 new AutoStart burette devices from production LOT 081108. Devices were marked 081108-1 to 081108-10.



- Distilled Water.
- Vacuum Pump.
- Vacuum tubing.
- Syringe (to generate pressure for A.2.2).
- Watch / Stopwatch.
- Pressure gauge.
- Tubing and fittings to mate with burettes.
- Thermometer(s) (for ambient air temp and water temp).
- Kettle (for heating water for 40°C vacuum test).
- Vessel large enough to submerge pressure test units.

Setup for Pressure Test:



Setup for Vacuum Test:

Injecting water:





Results

Pressure Test.

All 10 units were tested. No evidence of leak was detected on any device either through bubbles becoming evident, or from any change in the pressure gauge reading. The room and fluid were at 23 degrees celsius.

Vacuum Test

All 10 units were tested with fluid at 23 degrees celsius and again heated to 40 degrees celsius. No evidence of leak was detected on any device either through bubbles becoming evident, or from any change in the pressure gauge reading on the vacuum pump.

Result

Based on the results of this test, these 10 devices from LOT 081108 comply with ISO 8536-4:2004 Section 6.2.

End of report
