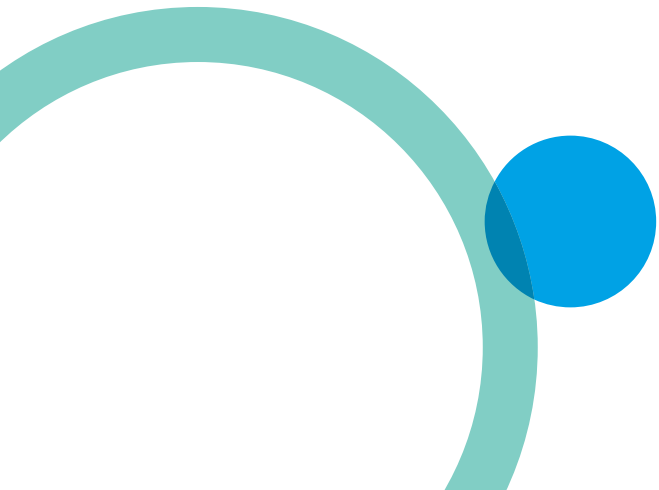
NHS National Services Scotland

Scottish Health Technical Memorandum 01-01

Decontamination of medical devices in a Central Decontamination Unit

Part B: Test equipment/methods



September 2018

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1. Introduction

1.1 The Scottish Health Technical Memorandum (SHTM) 01-01 series provides best practice guidance on the decontamination of medical devices in Central Decontamination Units (CDU). SHTM 01-01 Part A 'Management': 2018 should be used in conjunction with this guidance.

1.2 Part B of the series covers test equipment/methods that are used on decontamination process equipment such as ultrasonic cleaners, thermal washer disinfectors, porous load sterilizers and low temperature sterilizers.

1.3 The test equipment/methods are primarily concerned with directly testing decontamination process equipment to verify that the process equipment is fit for purpose in producing safe product. Other tests include where product is tested to confirm satisfactory performance of the process equipment and health and safety tests related to staff safety as opposed to product quality.

1.4 A large range of parameters (see Figure 1) are required to be measured by test equipment.

Note 1: For the purposes of this series "medical device" is taken to mean as applicable both a reusable medical device and a single use medical device that is supplied non sterile to the CDU for processing once prior to use. The term medical device as used in the SHTM 01-01 series only applies to those processed through a CDU.

Note 2: Elements of the medical device decontamination process that are applicable to the clinical environment can be found in the SHTM 01-01 supplement guidance GUID 5017 'Guidance for Service Users'. The guidance indicated that surgical instruments were medical devices.

Parameter tested	Test equipment	Reference Paragraph in Part B	Application
Temperature*	Dataloggers with Platinum sensors or thermocouples	2.43	Thermometric test for thermal disinfection & sterilization.
Pressure	Pressure gauge with required scale and resolution for the application	2.51	Vacuum leak testing, diff pressure across water filters, steam sterilizers, low temp sterilizers, water supply pressure, diff pressure across air filters.
Flow – liquids: water & process chemicals Flow – gas: air	Liquid flow meter Airflow meter	2.58 2.73	Recording of liquid flows at each stage of the thermal washer disinfector (WD) cycle.
Volume	Graduated vessel (EN 384)	2.68	Recording of process chemicals in WD cycle.
Weight	Laboratory balance/ analytical balance	2.74	Steam dryness tests, load dryness test, calibration of flow meters, coolant quality tests. TDS in feedwater. Weighing of standard test pack and metal load.
Gas concentration	Gas meter – Hydrogen peroxide H_2O_2 or Ethylene oxide EO	2.77	Under COSHH regulations – monitoring exposure levels.
Airfilter integrity	Aerosol generator & particle counting photometer	2.80	Checking air filter performance is satisfactory in WDs.
Time	Calibrated time piece	2.86	Measurement of stage times for automatic control tests, verification of chart recorder timebase.
Relative humidity	Calibrated humidity meter	2.87	Measuring relative humidity in sterilizer standard test pack as EN 285.
Conductivity	Calibrated conductivity meter	2.88	Water quality testing of conductivity.
Residual protein on a medical device	In-situ testing equipment or use of swabs	2.89	Monitoring protein levels on medical devices to meet the ACDP TSE 2015 Annex C guidance.

Figure 1: Parameters to be measured by test equipment

* Celsius will be used in place of Kelvin in this guidance (though Kelvin is a S.I. unit).

2. Decontamination test equipment

General considerations

2.1 This section reviews the key items of portable test equipment necessary to carry out the test procedures described in this guidance.

2.2 Specifications for instruments fitted permanently to decontamination equipment are given in the relevant European and international standards.

2.3 Instrumentation technology continues to advance rapidly, making it increasingly difficult to provide detailed specifications for the equipment to be used in testing washer-disinfectors and sterilizers, etc. Computer-controlled data recorders with software, which enables the system to verify attainment of the required conditions and then to produce a detailed written report accompanied by tabulated or graphed data are now common place. These systems offer advantages in clarity of presentation, as well as reduced operator time. However traditional instruments, such as chart recorders, remain equally acceptable where they meet the accuracy defined in this section of SHTM 01-01 Part B.

Note: Retention of data for long-term use is important. Where modern technology/data-recording equipment is used, it should be equipped with memory devices that enable data to be retrieved at a later date to allow final data storage at a secure and accessible location.

2.4 Some test equipment traditionally consisted of separate instruments (a data recorder) and sensors but is increasingly supplied as combined units where the sensor is integrated into a self contained datalogger. The objectives of this section are to ensure that both these new and traditional measurement methods are supported adequately and to define clearly the essential requirements that apply to the test equipment whether it is based upon the latest technology or a traditional system.

2.5 When it is proposed to use measurement and/or recording techniques that are not covered in this guidance, the advice of an Authorising Engineer (Decontamination) should be sought throughout the assessment.

2.6 All test equipment should be calibrated by an accredited laboratory in accordance with EN ISO/IEC 17025: 2017.

Measurement errors

2.7 Errors of measurement occur for a number of reasons. These include inherent factors such as the design of the measuring instrument, common problems with sensors (such as loose or imperfect connections), damaged insulation, and broken conductors, combined with changes in the environmental temperature around the instrument. Variations in the sensors themselves, the method of introducing the sensors into the machine and their location within the load may add to the error in the temperature measurement. Changes in conditions other than the one being sensed may also lead to errors, for example, temperature fluctuations within pressure-sensing elements may lead to errors in pressure measurement. The integrity of the measuring system is essential in order to obtain meaningful results. Significant

errors can arise through improper use of test equipment and calibration instruments and it is therefore important that staff are trained and skilled in their use. Two types of errors exist: Intrinsic and Introduced. Intrinsic errors relate mainly to the instruments best capability and usually cannot be improved upon without modification. Introduced errors may be very small or great, depending upon the skill of the person used in the process.

2.8 Careful attention to detail including the location of the test equipment, effective maintenance and the skill of personnel trained in the application, handling and use of the test equipment are required to eliminate or minimise these errors. Systematic errors can be reduced by careful calibration.

Test equipment calibration

2.9 Test equipment should be subject to a planned maintenance and calibration programme, in accordance with the manufacturer's recommendations, occurring at least annually. The drift status of test equipment should be monitored to ensure that they remain within their intrinsic specification. The stability of the equipment should be reviewed to ensure the maximum calibration interval of 1 year is satisfactory. If not the interval may require shortening. Each instrument or piece of test equipment should be labelled with a unique identifier, calibration date and a reference from which its current calibration status may be traced.

2.10 Calibration of the test equipment should be carried out in accordance with the equipment manufacturer's instructions by a validated method, using a reference standard of suitable accuracy that has been certified within the previous 12 months by an EN ISO/IEC 17025 accredited test laboratory. The calibration laboratory should be instructed to adjust the test equipment under test to read true values, and to report before and after calibration results so that instrument drift can be monitored. A full history record, including all maintenance and calibration details, should be kept for each test instrument. A written procedure that describes the calibration method should be prepared and made available for the AE(D) to review. Be aware of the difference between a calibration check and a calibration.

2.11 The test equipment should have a valid calibration test certificate. The calibration data should cover the range of measurement required for the parameter being tested and include at least one measurement within the process operating band. Examples would include:

- a temperature within the disinfection temperature band;
- a pressure within the operating range of the water pump during the wash stage for washer-disinfectors and a pressure under vacuum in sterilizer cycle used for drying stage;
- a temperature within the sterilizing temperature band and a pressure within the equivalent sterilization pressure range.

2.12 In use, all test equipment instruments, where applicable, should be located in a position protected from draughts and not subjected to rapid temperature variations.

Test equipment instruments, where applicable, should be allowed a period of time to stabilise within the environment of the test site. The manufacturer's instructions should be followed.

Self-contained measurement and recording systems

2.13 A number of different designs of small self-contained single or multi channel data loggers for the measurement of temperature and pressure are commercially available. They are independently powered, may be programmed to take readings at the required rate for the required duration, and may either transmit data wirelessly in real time or require it to be downloaded.

2.14 These can be used for most temperature and pressure measurements but are especially useful where it is impractical to insert sensor leads into processing equipment. In some cases, where either real time data transmission is not required or the wireless system has sufficient power to transmit the data through the sterilizer chamber wall, the chamber integrity does not need to be disturbed to undertake testing of a sterilizer. This can lead to a considerable reduction in time associated with leak testing after insertion and removal of sensors.

2.15 Care needs to be taken in selecting units that are capable of withstanding the high temperatures found in sterilizers and washer-disinfectors. Those housed in protective cases rated at IP68 (as defined in EN 60529:1992+A2:2013) are suitable for inclusion in washer-disinfectors.

2.16 The accuracy, resolution and sampling rate requirements should be as detailed in the Test equipment specification section. Self-contained measurement and recording systems should comply with the requirements of EN 285: 2015 or EN ISO 15883-1: 2009+A1:2014 & EN ISO 15883-2:2009.

2.17 They should be capable of measuring the temperature of the test load items described in Part C, D and E of SHTM 01-01:2018 and not only the temperature of the datalogger (e.g. within the jaws of an instrument or the surface of a chamber). This will necessitate the use of loggers with flying leads.

2.18 The temperature sensors contained within these devices are usually platinum resistance thermometers. These do not suffer from short term calibration drift to the extent that thermocouple based system do. Therefore, if short term drift of the device can be demonstrated to be negligible between annual calibration intervals, the requirements of the test equipment verification section do not apply. However if this cannot be demonstrated to the satisfaction of the AE(D) with calibration data, it is not acceptable to undertake testing using self-contained data loggers without undertaking test equipment verification of calibration. This will necessitate the use of loggers with flying leads for temperature measurement that can be immersed in an independent temperature reference source. Pressure measurement data loggers will need to allow connection to a pressure calibrator for the same reason.

2.19 Where two or more data loggers are used together on the same process, the time bases of the instruments should be synchronised. For presentation of results it must be possible to show the graphical representation of all the loggers used during a particular test onto the same chart.

2.20 Sufficient data loggers to meet the testing requirements of the SHTM 01-01 Parts C, D and E, EN ISO 15883-1 & 2 and EN 285 will be needed.

Data recorders with separate sensors

2.21 Data recorders are required to measure temperature and pressure in all types of decontamination equipment and may also be required for the measurement of flow rates and other critical parameters. They should be designed for use with the appropriate sensors, independent of those fitted to the machine.

2.22 Sufficient input channels and connections to meet the testing requirements of the SHTM 01-01:2018 Parts C and D, EN ISO 15883-1&2 and EN 285: 2015 should be provided.

2.23 The accuracy, resolution and sampling rate requirements should be as detailed in the Test equipment specification section. Data recorders should comply with the requirements of EN 285 or EN ISO 15883.

2.24 The accuracies quoted by data recorder manufacturers are measured under controlled reference conditions and do not include the errors from connected sensors. The whole system should be calibrated.

Test equipment specification

2.25 Data from digital test equipment can be presented graphically or as a listing of numerical values, or as a combination of both. In many cases, parts of the operating cycle can be expanded and re-plotted for closer examination.

2.26 They should have the facility to record data immediately that can then be removed for secure storage. Alternatively, the digital test equipment may be connected to a central computer and the data recorded to the hard drive. Software used with digital test equipment should be developed and validated under a recognised quality system (e.g. EN ISO 9000 series or if appropriate EN ISO 13485: 2016).

2.27 The detailed specification will depend upon the range of equipment with which it is to be used. The complete measurement system (both recorder and sensors in the case of data recorders) should be capable of measuring cycle variables to the required accuracy of the instruments fitted to the machine.

2.28 The accuracy with which a variable can be read will be affected not only by the sources of error discussed above but also by the precision of the calibration, the scale range, the integration time, the sampling interval and the intrinsic accuracy of the test equipment. Digital instruments may display measured values with a greater level of discrimination than the accuracy of the system as a whole: care needs to be taken with the configuration of outputs and the interpretation of the measured values.

2.29 The scale ranges should include the expected maximum and minimum values of the cycle variables throughout the operating cycle, with sufficient leeway to accommodate any deviations resulting from a malfunctioning machine.

2.30 At all stages of the washer-disinfector or sterilizer operating cycle, the values of the variables are critical and the equipment should be capable of measuring them to sufficient accuracy to confirm that the process conditions have been attained.

2.31 For digital test equipment, the sampling interval should not exceed 1 second per channel and be short enough for the holding time to contain at least five independent measurements in each recording channel. For pen recorders, the chart speed should be fast enough to allow fluctuations on that scale to be clearly resolved. The duration of the holding time should be measurable to within 1%.

2.32 The integration time of the system (the response time) should be short enough to enable the output to follow significant fluctuations in the cycle variables and to ensure that successive measurements are independent of each other. It should not be longer than the sampling interval.

2.33 It should be accurate enough to show clearly whether the measured temperatures are within the band or not. For all the types of equipment covered by this guidance, the repeatability of the temperature measurements should be ± 0.25°C or better, and the uncertainty of measurement of the complete measurement system including sensors should be no more than ± 0.5°C taking all component errors into consideration. Temperature measurement errors due to ambient temperature changes should not exceed 0.04°C per °C rise.

2.34 For analogue instruments the minor mark interval for temperature should not exceed 0.5°C and the chart speed should be not less than 10 mm per minute/600 mm per hour. The resolution should be not less than 0.5°C.

2.35 Digital instruments should register and record in increments of not more than 0.1°C for temperature.

2.36 For pressure measurement, the uncertainty of measurement should be no more than 0.5% of the absolute pressure during the plateau period.

2.37 Attention should also be paid to the accuracy of the time base of the recording system, particularly on longer cycles where any error will become more obvious. This can be by means of a calibrated timepiece against a calibrated time signal.

2.38 The scale range for each variable to be measured should be optimised to cover all values occurring during the process. As well as having calibration certificates for each item of the measuring chain, the complete system should be verified in the working environment (for example, the CDU).

Test equipment verification

2.39 The test equipment should be calibrated and/or adjusted in a controlled environment or laboratory with relevant EN ISO/IEC 17025 certification and traceable laboratory references. However, before and after each series of tests on any item of decontamination equipment, the measured temperature and pressure test equipment should be verified by comparison with an independent reference source at the process temperatures and pressures. The exception being for self contained measurement and recording systems discussed earlier.

2.40 The heat source should be of a design that meets the recommendations of publication EURAMET cg-13 Version 3 (previously EA-10.13) ‘Calibration of temperature block calibrators’. Precautions regarding temperature block calibrators should be adhered to. Procedures used when applying comparison calibrations

should also be in accordance with these guidelines. The comparison reference sources used, such as a digital thermometer and digital or analogue pressure gauge should be traceable to EN ISO/IEC 17025 calibration standards. No adjustment to the test instrumentation should be made on site in an uncontrolled environment unless the test contractor or organisation holds a site calibration procedure and EN ISO/IEC 17025: 2017 certification. This includes adjustment which should be available for inspection or audit. Any adjustments made to test instrumentation should be recorded and included within the test report.

2.41 The temperature measured by all temperature sensors when immersed in a temperature source at a temperature known within ±0.1^{o}C and within the process temperature band should not differ by more than 0.5 ^{o}C. Consider the error of the whole system.

2.42 The pressure measured by all pressure sensors when compared to a pressure reference standard and within the process pressure band should not differ by more than 50 mBar.

Temperature measurement

Temperature sensors

2.43 Unless self contained measurement and recording systems are used, temperature sensors should be used to sense the temperature in locations specified in the tests described in this guidance. The sensors should be either platinum resistance elements and comply with class A (of EN 60751:2008 Table 3) or thermocouples and comply with Tolerance Class 1 (of EN 60584-1:2013 Table 12). Other sensors of demonstrated equivalence can be used.

2.44 Thermocouple wire should be single-strand, not exceeding 0.7 mm diameter over the covering of one core of a twin cable. The width of the cable should not exceed 2 mm. If thicker cable is used, the tracking of steam along the outside of the cable may invalidate certain tests, such as those which require temperatures to be measured in the centre of a standard test pack (the standard test pack is described in EN 285).The cross sectional area of any part of the probe for testing and its connecting wires within the usable space should not exceed 3.1 mm^2.

2.45 Thermocouples may be argon arc-welded or micro-welded. However, experience has shown that, provided the wires are cleaned, they may be satisfactorily twisted together to form the hot junction. Brazing, silver brazing and welding with filler rods is no more reliable in respect of accuracy than freshly twisted wires and is therefore discouraged. Thermocouples should not be fitted with a heat sink.

2.46 The performance characteristics of the temperature sensor should not be adversely affected by the environment in which it is placed, for example, pressure, hot detergent solution etc. Certain environments in which thermocouples may be used may be corrosive to certain metals. Thermocouple junctions should be regularly inspected for corrosion and remade and recalibrated as necessary.

Thermometric recording instrument(s)

2.47 Thermometric recording instruments should be used in conjunction with the temperature sensors to record the temperatures measured in the locations specified in the tests described in this guidance.

2.48 Guidance on test apparatus designed to introduce thermometric measuring equipment into the sterilizer chamber and washer-disinfector chamber is provided in EN 285 and EN 15883-1 and 15883-2 respectively. Other methods of introducing temperature sensors into a chamber, which guarantee a watertight or gas-tight seal, are equally acceptable.

2.49 All reporting software should be validated, backed-up (with backed-up data being kept in a secure location off-site) and secure to ensure no unauthorised access.

Use of temperature sensors

2.50 Guidance on use of sensors for sterilizers and WDs is provided in EN 285: 2015 and EN ISO 15883-1: 2014 and 15883-2: 2009.

Pressure measurement

Measurement ranges

2.51 Pressure measurement ranges for WDs should be up to 1000 kPa [10 bar] (for example, for the water supply pressure). Differential pressures of 0.1 - 10 kPa [1-100 mbar] may need to be measured (for example, for the determination of the pressure drop across filters).

2.52 Pressure measurement ranges for steam sterilizers may be from 3 to 10 kPa [30-100 mbar] (in vacuum leak testing) to typically 400 kPa [4000mbar] at the working pressure of a high-temperature steam sterilizer.

Pressure sensors and gauges

2.53 Pressure sensors should be used in the tests described in this guidance and EN 837-2: 1998 Pressure gauges. Selection and installation recommendations for pressure gauges should be consulted.

2.54 The performance characteristics of the pressure sensor should not be adversely affected by the environment in which it is placed (for example, temperature, hot detergent solution etc). Certain environments in which sensors may be used may be corrosive to certain materials. Compatibility should be confirmed with manufacturers' instructions.

2.55 The scale range requirements for gauges required for testing decontamination equipment vary dependent on the application (see Figure 2).

2.56 Pressure gauges should be temperature compensated and, except for the differential pressure gauge, be Bourdon-tube gauges conforming to EN 837-1: 1998 of nominal size 150mm and accuracy class 0.25 (that is, the error should not exceed 0.25% of full scale deflection).

Scale range	Mark Interval	Calibration	Application
0 to 16 kPa [0 to 160 mbar]	0.1 kPa [1 mbar]	Gas	Vacuum leak-testing
0 to 100 kPa [0 to 1 bar]	1 kPa [10 mbar]	Liquid	Differential pressure across water filters
0 to 500 kPa [0 to 5 bar]	5 kPa [50 mbar]	Liquid	Steam sterilizers
0 to 1000 kPa [0 to 10 bar]	5 kPa [50 mbar]	Liquid	Water supply pressure. Recirculating pump pressure
0 to 50 kPa [0 to 500 mbar]	1 kPa [10 mbar]	Air	Differential pressure across air filter

Figure 2: Scale range requirements for pressure measurements

2.57 Gauges not designed for direct connection to steam at 380 kPa [3.8 bar absolute] should be connected via a siphon or similar device to ensure that the accuracy of the gauge is maintained over the temperature range associated with changing steam pressure. If the low-pressure gauge used for vacuum leak testing cannot withstand the pressure in the chamber during sterilization, an automatic valve should be provided to protect it.

Flow measurement

Water flow

2.58 The volume of water used for each stage of the operating cycle may be measured using a water meter complying with EN ISO 4064-1: 2014 Class A.

2.59 The meter should be designed to operate at temperatures up to 90°C with a supply pressure up to 1700 kPa [17 bar].

2.60 The meter should have a minimum scale division of 0.1 L or less and be designed to measure flow rates over the range 1 L/min to 25 L/min.

2.61 A single jet turbine system is sufficiently accurate for the purpose. Other systems such as multi-jet turbine or semi-positive displacement systems complying with EN ISO 4064-1: 2014 Class B or Class C may also be used.

2.62 The calibration of the flow meter should be verified by comparing the indicated flow rate with a measured volume collected over a measured time period. The collected volume of liquid may be determined by either gravimetric or volumetric measurement. The gravimetric method is generally more accurate as the temperature of the liquid increases.

Process chemicals flow measurement

2.63 The volume of process chemicals used for each stage of the operating cycle may be measured using a flow meter. A number of commercially available flow sensors designed to monitor flows in the range 0 to 2 L/min are suitable for interfacing to a recorder or data logger.

2.64 The sensor should be suitable for use with fluids having viscosity in the range 0.8 to 20 centiStokes and should be calibrated for the viscosity of the fluid to be measured.

2.65 The sensor should be designed to operate at temperatures up to 70°C with a supply pressure up to 1100 kPa [10 bar].

2.66 The meter/recorder should have a minimum scale division of 10 mL or less and be designed to measure flow rates over the range 50 mL/min to 1500 mL/min. The system should have an accuracy of ± 2.5% of full scale or better.

2.67 The calibration of the meter should be verified by determining the indicated volume flowing to a collecting vessel and comparing this with the collected volume determined by gravimetric or volumetric measurement.

Note 1: When the meter is connected in the pipe there will be a noticeable pressure drop across the meter. Although this should be less than 1 bar it may interfere with the normal operation of the washer-disinfector and therefore should not be used during tests for other characteristics than the volume of water used.

Note 2: A meter of the rotating vane type calibrated using water at 20°C as the flowing medium and then subsequently used to measure the flow of a detergent solution with a viscosity of 30 centistokes would have an error of 15–20% if no correction was applied.

Volume measurement

2.68 The volume of process chemicals and the volume of water used in each stage are critical variables in the control of the washing-disinfecting process.

2.69 The volume used may be measured directly by collection in a graduated vessel of appropriate size.

2.70 Alternatively, for liquids of known density, the volume may be determined by collection in an appropriate size vessel of known mass (empty), determination of the mass of the vessel and contents, calculation of the mass of the liquid and hence (by dividing this volume by the density) calculating the volume of liquid.

2.71 Whichever method is used, the accuracy should be such that the error is less than ± 2%.

2.72 Volumetric measuring containers complying with EN ISO 384: 2015 are suitable.

Airflow metering device

2.73 A metering device (such as a needle valve) is required to admit air into the sterilizer chamber for the air detector tests, and vacuum and pressure leak tests. The device

should be capable of controlling the flow of air into an evacuated chamber. It should be adjustable and have a range that includes a flow of 0–5 mL/min per litre volume of the sterilizer chamber. The error in repeatability between 10% and 90% of the setting range should not exceed -5%. The device is connected to the chamber by a valved port provided by the sterilizer manufacturer.

Balance for measuring weight

2.74 A laboratory balance is required for steam dryness tests, load dryness tests, calibration of flow meters (for measuring the flow of water and/or process chemicals) and coolant quality tests. It should be capable of measuring the mass of loads up to 4 kg to an accuracy of 0.1g and up to 400g to an accuracy of 0.01g. Note: all balances should be sited in a level manner prior to measurement.

2.75 An analytical balance is required for determination of the Total Dissolve Solids (TDS) (evaporative residue) in feed water. It should be capable of measuring a mass of up to 100g with an accuracy of 0.1mg.

2.76 A balance is also required for weighing the standard textile test pack (7kg) and the metal load (15–20kg) to a 10g resolution.

Gas-monitoring equipment

2.77 A gas-monitoring instrument is required for tests on equipment using process chemicals that have a significant vapour pressure and are a potential risk to human health (e.g. toxic) or the safety of the environment in which the equipment is installed (e.g. flammable). This is not for the monitoring of levels for product quality or success of the process.

2.78 The nature of the instrument will depend on the substance to be monitored. In case of doubt, advice should be sought from the manufacturer of the process chemical or the AE(D).

2.79 The scale range of the measuring instrument should include the appropriate short-term exposure limit or occupational exposure limit and extend to at least ten times that exposure limit.

Aerosol generator for use when testing air filters

2.80 An aerosol generator is required for tests on machines incorporating air filters intended to deliver air free from most microorganisms.

2.81 The device should be capable of generating a polydisperse aerosol with particles having the size distribution shown in Table 2 of EN ISO 14644-3: 2005.

Particle-counting photometer

2.82 A particle counter is required for tests on machines incorporating air filters intended to deliver air free from most microorganisms. The particle counter should be suitable for estimation or comparison of the mass concentration of airborne particles (see Figure 3).

2.83 It should have an accuracy of better than ±5% over the range of a five expandable, six-decade resolution (that is 0.01% to 100% of the test cloud) as specified in EN ISO 14644-3: 2005.

2.84 The photometer should have a minimum threshold sensitivity of 0.0001 µg/L and should be capable of measuring aerosol concentration in the range 80 to 120 µg/L.

2.85 The sampling flow rate should be 0.40 ± 0.05 L/s and sampling should be via a suitable probe.

Particle size [µm]	Fraction % by mass
<0.5	>20
<0.7	>50
<1.0	>75

Figure 3: Mass concentration airborne particles at varying particle sizes

Timepiece for measuring time

2.86 Measuring time using a calibrated time piece is required. Examples of applications included measurement of stage times for automatic control test, verification of chart recorder timebase which is often overlooked as a measurement.

Relative humidity measurement

2.87 Measurement of relative humidity using a calibrated probe is required. Applications include EN285: 2015 for sterilizer standard test pack using calibrated temp/humidity meter ‘sword hygrometer’).

Conductivity measurement

2.88 Measuring conductivity using a calibrated probe is a requirement. This may be used as part of a series of water quality tests. Be aware that the ambient temperature variation can affect the conductivity measurement.

Methods to measure residual protein on medical devices

2.89 Refer to SHTM01-01 Part A chapter 12 ‘QA Exercise for Testing the Protein Levels on RMDs’.

2.90 The protein detection test systems listed in the NP 143 contract for decontamination consumables should be used. A standard operating procedure for each test system on the NP 143 contract will be developed which will take account of the manufacturer’s instructions. Research on test systems was carried out in 2016 and reported by Holmes et al, 2017.

2.91 If a swabbing technique is used, the swabbing should include the crevices, hinges and other areas accessible for the swab head to access.

2.92 If reagents are added to instruments, the whole medical devices set should re-enter the decontamination route process according to local protocols.

2.93 Any equipment/system/chemicals used should be maintained, calibrated (if applicable), stored and used in according to manufacturers' instructions. The results should be interpreted in accordance with the manufacturer instructions.

Note 1: Interpretation of the results should take account of the possibility of false negative and false positive results.

Note 2: Adherence to the relevant test SOP, which will take account of the test equipment manufacturer's instructions, is required to avoid inaccurate results. This includes sample incubation, time, amount of reagent and technique.

References

These references were current at the time this document was produced. Anyone using this document should ensure that they refer to the current versions of any references.

Standards

EN 285:2015 - Sterilization. Steam sterilizers. Large sterilizers. CEN.

EN 837-1: 1998 - Pressure gauges. Bourdon tube pressure gauges. Dimensions, metrology, requirements and testing. CEN.

EN 837-2: 1998 - Pressure gauges. Selection and installation recommendations for pressure gauges. CEN.

EN ISO 384: 2015 Laboratory glass and plastics ware. Principles of design and construction of volumetric instruments. CEN.

EN ISO 4064-1: 2014 - Measurement of water flow in closed fully charged conduits - Meters for cold potable water and hot water. Part 1: Specifications. CEN.

EN ISO 11140-1: 2014 Sterilization of health care products – chemical indicators Part 1: General requirements. CEN.

EN ISO 11140-3: 2009 Sterilization of health care products – chemical indicators Part 3: class 2 indicator systems for use in Bowie and Dick-type steam penetration test

EN ISO 13485: 2016 - Medical devices. Quality management systems. Requirements for regulatory purposes. CEN.

EN ISO 14644-3: 2005 - Cleanrooms and associated controlled environments. Test methods. CEN.

EN ISO 15883-1: 2009+A1: 2014 - Washer-disinfectors. General requirements, terms and definitions and tests. CEN.

EN ISO 15883-2: 2009 - Washer-disinfectors. Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc. CEN.

EN 60584-1: 2013 Thermocouples. EMF specifications and tolerances. CEN.

EN 60751: 2008 - Industrial platinum resistance thermometers and platinum temperature sensors. CEN.

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