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ANNEX 1

to

Guideline

for Testing, Validation and Monitoring of Automated Cleaning and Disinfection Processes for Medical Devices

in conformance with prEN ISO 15883 Parts 1, 2 and 5

Status: April 2005

Please send any suggestions for improving this Guideline or your experiences of implementing it to the following email address:

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ANNEX 1 to Guideline for Testing, Validation and Monitoring of Automated Cleaning and Disinfection Processes for Medical Devices

1 Purpose and field of application

The specified test methods are used for verification of the cleaning and disinfection performance of washer-disinfectors (WDs) used to reprocess surgical instruments, including minimally invasive surgical (MIS) instruments, anaesthesia (AN) accessories and containers as well as, optionally, for operating-room (OR) shoes. The methods can be used during the type test, operational qualification (test conducted after installation), performance qualification or periodic testing as per prEN ISO 15883 Part 1 and 2.

Any restrictions on the scope of testing or changes to the test methodology shall be made at the discretion of the person responsible for testing, bearing in mind the equipment to be tested and the locally prevailing circumstances (in particular in respect of patient safety or the contractually agreed terms for provision of care). The reasons for any deviations from the following test methods must be explained and recorded. The forms in Annex 2 can be used to compile the report, which can also serve as a test protocol.

2 Introduction

Based on the respective washer-disinfector and the programmes to be tested, testing can be broken down into the following steps:

- *Thermoelectric testing of disinfectant action in thermal disinfection processes and a check of the temperature course in all cycle steps*
- *Microbiological testing of disinfectant action in chemothermal processes*
- *Verification of cleaning performance*
  - Chamber walls, loading racks and containers [test soil (TS): KMNE*]
  - Programmes for anaesthesia (AN) accessories (TS): MNE**)
  - Programmes for surgical instruments and MIS instruments (TS: reactivated sheep blood)
- *Verification of dosing precision (optional for periodic tests)*
- *Investigation of operating media (water quality)*
- *Investigation of rinse water quality (optional for periodic tests)*

* German acronym for potato starch, flour paste, nigrosin, egg

** German acronym for flour paste, nigrosin, egg

3 Conductance of tests

3.1 Thermoelectric testing of disinfectant action in thermal disinfection processes and check of temperature course in all cycle steps in thermal and chemothermal disinfection processes

3.1.1 Purpose

- *Verification of disinfectant action (A_0 value)*
- *Verification of specifications (compliance with provisions of prEN ISO 15883-1)*
- *Verification of accuracy of temperature display*
- *Verification of reproducibility*

3.1.2 Equipment and materials

- *Multi-channel process recorder (or thermologger) with at least 6 thermoelements [TE] (requirements as per prEN ISO 15883-1)*
- *Mounting materials*

3.1.3 Conductance

- *Placing the thermoelements in the WD as per 3.1.3.1 (see below)*
- *Start WD programme*
- *Measurements carried out for duration of selected cycle (cleaning, disinfection or both – the entire drying phase need not be recorded)*

3.1.3.1 Positioning the thermoelements (by way of example):

Caution: be careful when positioning TEs because of rotating cleaning arms:

3.1.3.1.1 Chamber walls and loading racks

- *TE 1: Tank (in vicinity of measuring sensor for automatic control of WD)*
- *TE 2: Chamber wall, left middle*
- *TE 3: Chamber wall, right middle*
- *TE 4: Loading and unloading doors, inside middle*
- *TE 5: Loading rack, top level left back*
- *TE 6: Loading rack, bottom level right front*

3.1.3.1.2 Load

TE 1: Tank (in vicinity of measuring sensor for automatic control of WD)

TE 2-6: on/in instruments (preferably heavy single items, lumened devices, poorly accessible sites)

At the end of the cycle one can see whether the measuring sensors have remained in position.

3.1.3.2 Acceptance criteria:

1) A_0 value reached
2) The temperatures recorded on the surface of the load, loading rack or chamber walls
   a) are throughout the entire holding time of the disinfection phase in the range –0 °C and +5 °C of the disinfection temperature;
   b) are throughout the entire holding time of all other phases within ±5 °C of the temperature set for the respective treatment phase;
   c) the temperature measured at the surface of each item in the load does not fluctuate by more than ±2 °C and does not differ by more than 4 °C from that of other items in the load;
3) The temperatures displayed or recorded by the WD during the entire holding time of the disinfection phase deviate in the range ±2 °C from those recorded by the test instrument for the measuring sensor beside the reference measuring sensor;
4) The temperature profile obtained for the temperature-controlled phases of the process cycle concords within a range of ±2.5 °C for the last two of three test cycles.
5) The temperatures correspond to the temperatures recommended by the manufacturers of chemical products

Number of measurements: see Chapter 4

3.2 Microbiological testing of disinfectant action of chemothermal processes (outside the scope of prEN ISO 15883)

3.2.1 Equipment and materials

- *Appropriate bioindicators containing an adequate microbial count (10^5) and resistant to the disinfection processes used (e.g. Simicon CTD or EN: plastic tubes or plastic discs with Siran beads with Enterococcus faecium 10^5 and defibrinated sheep blood as organic challenge)*

3.2.2 Conductance

Place at least 2 bioindicators in the WD as per the manufacturer's instructions

Start WD programme

On completion of programme, withdraw bioindicators under aseptic conditions and place in contamination-proof packaging and dispatch to laboratory for evaluation (make provision for positive control)

3.2.2.1 Acceptance criteria

Reduction in microorganism population by at least 5 log levels.

3.3 Verification of cleaning of chamber walls, loading racks, containers and OR shoes (optional)

3.3.1 Materials

- *Nigrosin (1% aqueous suspension)*
- *Wheat flour suspension (medium-fine flour supernatant)*
- *Hen's eggs*
- *Dried potato flakes*

3.3.2 Equipment

- *Usual laboratory equipment*
- *Brush (approx. 40 mm width)*
- *Whisk with six or seven whorls made of 1 mm strong steel wire and forming a head with a diameter of around 70 mm*

3.3.3 Preparation of test soil

3.3.3.1 Nigrosin suspension

6 g nigrosin powder is added to 600 ml hand-warm tap water, heated to around 80 °C and dissolved by stirring evenly.

3.3.3.2 Wheat flour suspension

115 g medium-fine wheat flour is added to 800 ml cold tap water and heated while stirring continuously; once boiling point reached, continue to boil for 3 min.

3.3.3.3 Flour-nigrosin (*MN*) mixture

600 ml of nigrosin suspension is mixed with 800 ml of wheat flour suspension.

This mixture can be prepared in bigger quantities.

3.3.3.4 Preparation of *KMNE* test soil

700 g nigrosin-wheat flour mixture is heated to around 35 °C just before use. To this are added the white and yolk of three medium-sized raw hen's eggs and then mixed. If necessary, the temperature is set again to around 35 °C.

While stirring constantly, around 100 g of dried potato flakes is added in small quantities until the requisite consistency is reached.

To obtain that consistency the whisk is immersed by a depth of around 70 mm in the mixture, slowly rotated and carefully withdrawn from the mixture. Once the mixture is of the right consistency, it will flow slowly downwards between the whorls, and after 5 s to 10 s the remaining clumps of test soil in the head of the whisk should have a diameter of between 40 mm and 50 mm.

3.3.4 Storage

The basic test soil (*MN* mixture) can be kept in a refrigerator for up to three days.

The *KMNE* test soil should be used as soon as it has been prepared.

3.3.5 Process challenge devices (PCDs)

- *Chamber walls, loading racks*
- *An adequate number of containers on site to collect the used supplies to ensure that a full load will be available for the test WD.*
- *An adequate number of OR shoes on site to ensure that a full load will be available for the test WD.*

3.3.6 Application of the test soil to the process challenge devices

If the test soil had been refrigerated, it must be brought to room temperature.

3.3.6.1 Chamber walls and loading rack

The chamber walls and loading rack must be dry and their surface temperature should not be more than around 35 °C. With a 40 mm wide brush, the test soil is applied to all surfaces of the chamber and loading rack, in a layer thickness of maximum 1 mm.

The test soil should be left to stand at ambient temperature and ambient air humidity for at least 5 min but for no more than 10 min.

3.3.6.2 Containers/ OR shoes (OPTION)

Provision should be made for an adequate number of containers/OR shoes so that a full load will be available for the test WD. The containers/OR shoes should be thoroughly cleaned and dried and then heated to around 35 °C and should have a temperature of between 20 and 35 °C. With a 40 mm wide brush, the test soil is applied to all inner and outer surfaces of the containers (including handles)/OR shoes in a layer thickness of maximum 1 mm.

Provision should be made for an adequate number of containers so that a full load will be available for the test WD. The test soil should be left to stand at ambient temperature and ambient air humidity for at least 60 min but for no more than 90 min.

3.3.7 Test methods

3.3.7.1 Chamber walls and loading rack

The washer-disinfector is operated without a load while using a representative programme as per the operating instructions.

The programme is interrupted immediately after the cleaning phase (before disinfection) and the cleaning result is evaluated.

The test should be performed at least once.

3.3.7.2 Containers/ OR shoes (OPTION)

The soiled containers / OR shoes are placed in the washer-disinfector and the machine is operated with a full load while using an appropriate programme as per the operating instructions.

The programme is interrupted immediately after the cleaning phase (before disinfection) and the WD is unloaded.

The test should be performed at least once for each type of load.

3.3.8 Method for evaluation of results

After cleaning in the washer-disinfector, carry out visual inspection of the chamber walls, loading rack, containers and OR shoes.

3.3.8.1 Acceptance criteria

The cleaning performance deemed to be satisfactory if there are no visible residues on any of the PCDs.

3.4 Verification of cleaning of anaesthesia accessories

3.4.1 Materials

- *Nigrosin (1% aqueous suspension)*
- *Wheat flour suspension (medium-fine flour supernatant)*
- *Hen's eggs*

3.4.2 Equipment

- *Usual laboratory equipment*
- *Brush (approx. 25 mm width)*
- *Syringes (20 ml).*

3.4.3 Preparation of the test soil

3.4.3.1 Nigrosin suspension

6 g nigrosin powder is added to 600 ml hand-warm tap water, heated to around 80 °C and dissolved by stirring evenly.

3.4.3.2 Wheat flour suspension

115 g medium-fine wheat flour is added to 800 ml cold tap water and heated while stirring continuously; once boiling point reached, continue to boil for 3 min.

3.4.3.3 *MN* mixture

600 ml of nigrosin suspension is mixed with 800 ml of wheat flour suspension.

This mixture can be prepared in bigger quantities.

3.4.3.4 Preparation of the test soil

700 g nigrosin-wheat flour mixture is heated to around 35 °C just before use. To this are added the white and yolk of three medium-sized raw hen's eggs and then mixed. If necessary, the temperature is set again to around 35 °C.

3.4.4 Storage

The basic test soil (*MN* mixture) can be kept in a refrigerator for up to three days.

The *KMNE* test soil should be used as soon as it has been prepared.

3.4.5 Process challenge devices

Provision should be made for an adequate number of the normally used anaesthesia accessories so that a full load will be available for the test WD (transparent/ see-through tubes should be used). It is recommended that in-house test materials be used since discoloration of tubes after use cannot be ruled out.

3.4.6 Inoculation of process challenge devices

If the test soil had been refrigerated, it must be brought to room temperature. The PCDs are thoroughly cleaned and dried and then the bigger PCDs (respiratory tubes) are filled with the test soil (e.g. using a syringe). The PCDs are

placed on a horizontal surface and rolled to distribute the test soil over the inner surfaces. Then they are held vertically to allow any excess test soil to drain away. Next, a thin layer of *MNE* test soil is applied to the outer surfaces with a brush. Smaller PCDs, such as endotracheal tubes and connectors must be treated in the same way.

The soiled instruments are connected to the appropriate nozzles and positioned on the loading rack in accordance with the manufacturer's instructions.

All instruments should be prepared and positioned within 30 min.

The test soil should be left to stand at ambient temperature and ambient air humidity for at least 60 min but for no more than 90 min.

3.4.7 Test methods

The soiled anaesthesia accessories are placed in the washer-disinfector as per the manufacturer's instructions and the WD is operated with a full load while using an appropriate programme as per the operating instructions.

The programme is interrupted immediately after the cleaning phase (before disinfection) and the cleaning result is evaluated.

The test should be performed at least once for each type of load.

3.4.8 Methods for evaluation of results

The outer (and inner, if applicable) surfaces of PCDs are visually inspected. The number of clean (no residues of the *MNE* test soil visible when inspected with the naked eye or using best corrected vision in normal light) and non-clean instruments are counted and recorded. Instruments to which the test soil was not applied are not evaluated.

As far as possible, the inner surfaces should also be rubbed off additionally with a suitable swab and the swab then inspected for residual contamination. If no residues can be detected, the swabs are examined with the biuret reaction for protein residues and evaluated as per the manufacturer's instructions.

3.4.8.1 Acceptance criteria

The cleaning process is deemed to be satisfactory for anaesthesia accessories if:

- *None of the PCDs harbour any residual contamination.*
- *The residual protein content is below the detection limit, as applicable.*

3.5 Verification of cleaning of surgical instruments, incl. MIS instruments

3.5.1 Materials

3.5.1.1 Test soil

- *Blood from a laboratory sheep*
- *Heparin*

NOTE 1 Use Liquemin 5000, Roche AG, Emil-Barell-Strasse 1, 79639 Grenzach-Whylen, Germany.

- *Protamine sulphate (or protamine hydrochloride)*

NOTE 2 A ready-to-use test kit is available from Acila AG, Opelstrasse 14, D-64546 Mörfelden-Walldorf.

3.5.2 Equipment

- *Usual laboratory equipment*
- *Brush (25 mm width) with synthetic fibres*

- *Syringes (20 ml)*

3.5.3 Preparation of the test soil

3.5.3.1 Heparinised sheep blood

Immediately after taking the blood sample, 0.1 ml heparin is added to aliquots of 100 ml sheep blood.

3.5.3.2 Preparation of the test soil

The heparinised sheep blood is brought to room temperature and aliquots of 10 ml are mixed in a suitable vessel with 0.15 ml of the protamine compound (record the substance used), ensuring that it is well mixed. The blood should coagulate in around 10 min. Note the actual coagulation time.

3.5.4 Storage

Store the blood and protamine compound in a refrigerator at 4-8 °C as per the manufacturer's instructions. Once prepared, the soil should not be stored!

3.5.5 Process challenge devices

3.5.5.1 Standard surgical instruments

Position surgical instruments with joints (scissors with normal joints and clamps with fitted joints in a ratio 1:1) in standard trays (BxHxD = 300 x 600 x 70 mm), using 20 instruments per tray.

NOTE: If enough instruments are not available for a full load, run as many cycles as necessary to cover all possible positions in the tray, placing other (non-soiled) instruments at the unoccupied sites in the tray until the load is full.

3.5.5.2 MIS instruments

Steel dummies, with a length of 150 mm and an inner diameter of 8 mm or a length of 300 mm and inner diameter of 4 or 6 mm, are used as a substitute for rigid endoscopes. The wall thickness should be around 1 mm.

3.5.6 Inoculation of the process challenge devices

3.5.6.1 Standard surgical instruments

If the test soil had been refrigerated, it must be brought to room temperature. The PCDs are thoroughly cleaned and dried, if necessary The test soil is applied with a brush to the joints and grooved surfaces at ambient conditions, while ensuring that the blood is processed within 10 min after adding protamine (in any case before complete coagulation). A tray with soiled instruments should be placed at each level of the loading trolley.

Around 20 of the soiled jointed instruments are placed on each tray (joints opened at an angle of around 90 °) and positioned on the loading trolley as per the loading instructions.

All instruments should be prepared and positioned within 30 min.

The contaminated instruments are first left for around 30 min on the trays at ambient temperature and ambient humidity. Then each instrument and each tray is checked for any excess test soil (e.g. blood coagula > 5mm on the bottom side, blocked tray openings), which, if detected, should be removed with an absorbent swab or similar. Then the instruments are positioned on another tray with the side that had previously faced downwards now facing upwards and left to dry for at least a further 30 min but no more than 60 min.

NOTE: Record the ambient conditions (temperature and ambient humidity).

3.5.6.2 MIS instruments

If the test soil had been refrigerated, it must be brought to room temperature. The PCDs are thoroughly cleaned and dried and then filled with the test soil (e.g. using a syringe), so that the inner surfaces are completely wetted. Ensure that the blood is processed within 10 min after adding protamine (in any case before complete coagulation). Then

make sure that the lumens are free (e.g. by purging the lumens with compressed air or using mandrins). Next, a thin layer of blood is applied with a brush to the outer surfaces of the PCDs.

The contaminated instruments are connected to the corresponding nozzles or Luer lock adapter, at least 3 per connection type) and positioned on the loading rack as per the manufacturer's instructions.

All instruments should be prepared and positioned within 30 min.

The test soil should be left to stand at ambient temperature and ambient air humidity for at least 60 min but for no more than 90 min.

NOTE: Record the ambient conditions (temperature and ambient humidity).

3.5.7 Test method

3.5.7.1 Standard surgical instruments

The soiled instruments are placed in the washer-disinfector and the machine is operated with a full load while using the programme for surgical instruments as per the operating instructions.

The programme is interrupted immediately after the cleaning phase (before disinfection) and the WD is unloaded.

The test should be performed at least twice for each type of load. A single test suffices if a type test has already been conducted with the same programme settings and using the same detergents and amounts of detergent.

In addition, suitable commercially available cleaning indicators can be used (e.g. TOSI gap PCDs), which are placed on the instrument trays as per the manufacturer's instructions and evaluated at the end of a complete cycle.

3.5.7.2 MIS instruments

The soiled instruments are placed in the washer-disinfector as specified by the manufacturer and the machine is operated with a full load while using the test programme as per the operating instructions.

The programme is interrupted immediately after the cleaning phase (before disinfection) and the WD is unloaded.

The test should be performed at least once for each type of load.

NOTE: Clean instruments should be connected to the unoccupied nozzles as per the manufacturer's instructions. If this is not possible, the unoccupied nozzles should be closed

In addition, suitable commercially available cleaning indicators can be used (e.g. TOSI LumCheck), which are connected as per the manufacturer's instructions to the corresponding cleaning nozzles and evaluated after the cleaning step.

3.5.8 Methods for evaluation of results

3.5.8.1 Standard surgical instruments

Spot checks of the cleaning results should be carried out after cleaning in the washer-disinfector, while inspecting each instrument by opening and closing the joints. The number of clean (no residues of the blood test soil visible when inspected with the naked eye or using best corrected vision in normal light) and non-clean instruments are counted and recorded.

The ratio of instruments with residual contamination to the number of initially soiled instruments is expressed as a percentage.

NOTE: In cases where there is uncertainty as to whether visible residues are due to the test soil, a protein detection test (e.g. biuret reaction) should be used.

Instruments to which the test soil was not applied are not evaluated.

The cleaning indicators, if used, are inspected as per the manufacturer's instructions to ascertain whether satisfactory results have been obtained

3.5.8.1.1 Acceptance criteria

The cleaning process is deemed to be satisfactory for standard surgical instruments, if:

- *At least 95 % of PCDs are free of residual contamination;*
- *The indicators, if used, show results that are within the range of acceptance criteria specified by the manufacturer (if TOSI PCDs are used, levels 0 and 1 can be tolerated);*
- *The residual protein content is < 20 µg/ PCD or within the range of acceptance criteria specified by the manufacturer, if applicable.*

3.5.8.2 MIS instruments

The outer surfaces of PCDs are visually inspected. The number of clean (no residues of the *MNE* test soil visible when inspected with the naked eye or using best corrected vision in normal light) and non-clean instruments are counted and recorded. Instruments to which the test soil was not applied are not evaluated.

The inner surfaces should be rubbed off additionally also with a suitable swab and the swab then inspected for residual contamination. If no residues can be detected, the swabs are examined with the biuret reaction for protein residues and evaluated as per the manufacturer's instructions.

The cleaning indicators, if used, are inspected as per the manufacturer's instructions to ascertain whether satisfactory results have been obtained.

3.5.8.2.1 Acceptance criteria

The cleaning process is deemed to be satisfactory for MIS instruments, if:

- *None of the PCDs harbours any residual contamination.*
- *The residual protein content is < 100 µg/ PCD or within the range of acceptance criteria specified by the manufacturer, if applicable.*
- *The indicators, if used, show results that are within the range of acceptance criteria specified by the manufacturer*

NOTE 1: The difference between the permitted residual protein content and the value tolerated for surgical instruments is generally due to larger test surface.

NOTE 2: In the event of failure to meet the acceptance criteria, the possible causes should be investigated (proper nozzle, proper connection, retained position?). If the causes can be established, repeat the test cycle.

3.6 Safety considerations

3.6.1 Protective clothing

Protective clothing should be worn when handling the test soil (gown, gloves).

3.6.2 Disposal

All chemicals, blood and items to be discarded can be disposed of as non-hazardous and non-clinical waste.

3.6.3 Environment

Environmental surfaces that were contaminated with the test soil should be wiped off with a suitable surface disinfectant in accordance with regional and practices and procedures.

3.7 Verification of dosing precision

3.7.1 Materials

- *2 measuring cylinders (500 ml)*

or

- *weighing scales (weight range: 10 kg, resolution: 1g)*

3.7.2 Conductance

Either volumetric or gravimetric tests can be conducted. Each measurement must be performed at least twice (the first value is normally discarded on using the volumetric method because there could still be air in the suction lines).

3.7.2.1 Volumetric

- *Fit suction pipe of dosing pump into measuring cylinder,*
- *Fill with the appropriate chemicals,*
- *After dosing by the WD, fill the missing liquid with the 2nd measuring cylinder,*
- *Record chemical consumption during the respective cycle,*
- *Compare with the manufacturer's instructions and specifications.*

3.7.2.2 Gravimetric

- *Place detergent on scales*
- *Note weight and dry weight*
- *Read weight after dosing*
- *Calculate consumption of dosed agent, bearing in mind the density*

3.7.3 Acceptance criteria

The deviation from the specified set point value must not exceed +/-10 %. If the set point cannot be ascertained (e.g. time control) and if the cleaning performance is satisfactory with the current setting, only the reproducibility can be verified (max. deviation +/- 10 %), Use the value obtained as set point for revalidation.

3.8 Investigation of the water quality used for reprocessing

3.8.1 Materials

- *pH meter*
- *Hardness kit (e.g. Aquamerck total hardness test)*
- *Conductivity meter*

3.8.2 Sampling

Take suitable water sample (e.g. softened demineralised water) from the water-supply pipe

3.8.3 Chemical-physical investigation / acceptance criteria

3.8.3.1 Softened water

- *pH: 6-8*
- *Hardness: as per WD manufacturer's instructions*
- *Turbidity: clear, colourless, without any precipitates*

3.8.3.2 Demineralised water

The criteria governing steam generator feed water as per Austrian standard ÖNORM EN 285 are used (apart from pH), i.e.:

- *pH: 6-8*
- *Hardness: < 0.02 mmol/l alkaline earths*
- *Conductivity: < 15µS/ cm (or as per manufacturer's instructions)*
- *Turbidity: clear, colourless, without any precipitates*

Other parameters can be investigated at the operator's request.

3.8.4 Bacteriological investigation / acceptance criteria

3.8.4.1 Demineralised water

Bacteriological testing is conducted as per standard laboratory methods (standard and in-house standard operating procedure - SOP)

Requirements: colony forming units (cfu) (36 +/- 2 °C/ 48 +/- 4 h) < 100/ ml, *Pseudomonas aeruginosa* not detectable /100ml

3.9 Residues in final rinse water

3.9.1 Materials

- *pH meter*
- *Hardness test kit (e.g. Aquamerck total hardness test kit)*
- *Conductivity meter*
- *If applicable, silicium test kit (e.g. Merck-Aquaquant silicium test, Merck-Microquant silicium test)*
- *If applicable, chorine test kit (e.g. Merck chorine test 14801)*

3.9.2 Sampling

Sample the last rinse water from the tank by interrupting the programme before the water is pumped out or using other methods.

3.9.3 Chemical-physical investigation/ acceptance criteria

The acceptance criteria given here serve as provisional guide values and must be revised once more data are available.

- *pH: 6-8*
- *Hardness: < 0.1 mmol/l alkaline earths*
- *Conductivity: LF demineralised water + ?? % (not yet defined)*
- *Turbidity: clear, colourless, without any precipitates*
- *If applicable, silicium: ≤ 1 mg/l*
- *If applicable, chlorine: < 0.1 mg/l*

3.9.4 Bacteriological investigation/ acceptance criteria

Bacteriological testing is conducted as per standard laboratory methods (standard and in-house SOP)

Requirements: cfu (36 +/- 2 °C/ 48 +/- 4 h) < 100/ ml, P. *aeruginosa* not detectable /100ml

3.10 Drying (optional)

The drying test is conducted as per prEN 15883 -1

3.11 Protein detection by means of the biuret reaction

3.11.1 Purpose

The method is used during operational qualification to check the cleaning performance at sites with potentially poor cleaning results or in hollow devices (MIS instruments). It is also used during performance qualification after running a full WD with instruments harbouring everyday soils. See also prEN ISO 15883-1 ANNEX E.

3.11.2 Material

e.g.

- *Biotrace Protect M (supplier: Austria: Noack, Vienna)*
- *Merck test kit for determination of protein residues on surgical instruments after cleaning (supplier: Miele)*
- *Pierce BCA Protein Assay Kit (Supplier: VWR, Vienna)*

3.11.3 Conductance

- *As per manufacturer's instructions.*

3.11.4 Acceptance criteria

The cleaning performance is deemed to be satisfactory, if:

- *During operational qualification with a blood soil for MIS dummies, a residual protein content 100 µg/ PCD is not exceeded (Protect M: level xx)*
- *During performance qualification a residual protein content 20 µg/ instrument is not exceeded (Protect M: level x)*

or

- *The residual protein content is below the detection limit or within the range of acceptance criteria specified by the manufacturer.*

3.12 OPTION: Testing with cleaning indicators

3.12.1 Purpose

The method can be used for additional evaluation of the cleaning performance of the programmes to be used. The results can also serve as baseline ("zero value") for routine checks. In the former case, the PCDs are used in a full load (during one of the tests using a test soil); for the latter they are used during performance qualification (with a full on-site load during a full cycle).

3.12.2 Conductance

3.12.2.1 Standard surgical instruments

- *In addition, place cleaning indicators (e.g. TOSI PCDs) at various sites (preferably corners) in the trays*
- *Start programme and, depending on requirement, run cleaning or full cycle*
- *Evaluate PCDs as per manufacturer's instructions and record results.*

3.12.2.2 MIS instruments

- *In addition, place cleaning indicators (e.g. TOSI Lum-Check) at 3 different connection nozzles*
- *Start programme and, depending on requirement, run cleaning or full cycle*
- *Evaluate PCDs as per manufacturer's instructions and record results.*

3.12.2.3 Acceptance criteria

As per the manufacturer's instructions for the respective indicator. If TOSI or TOSI Lum-Check is used, the cleaning performance is deemed to be satisfactory if levels 0 and 1 of the 5-part evaluation scale (0-5) have been reached.

4 Orientational table: tests conducted within the framework of validation of cleaning and disinfection processes based on EN ISO 15883

Test	Brief description	Requirement	OQ / commissioning	PQ	Revalidation
1. Cleaning performance					
Chamber	As far as possible, coat with *KMNE* test soil	No visible residues	1 x	-	-
Loading rack			1 x	-	-
Container (OR shoes):	*KMNE*	No visible residues	1x/Config.*	1x/Config. (on-site-load with everyday soils – pract.config.)	1x /Config with. standard - TS [1], 1x/config. (on-site-load with everyday soils)
AN accessories	*MNE*				
Surg. instruments	React. sheep blood	• Ø max. 5% residual soils in 3 cycles • PQ: No visible residues, residual protein < 20 µg/instrument	3x/Config.		
MIS	React. sheep blood	• No visible residues, residual protein < 100 µg/PCD • PQ: <20 µg/instrument <	1x/Config.		
2. Thermoelectric tests					
2.1 Temperature control of thermal disinfection					
Chamber walls, Loading rack	3 TE on chamber walls or corners, 1 TE on loading rack, if appliable, 1 TE near chamber sensor, 1 TE near sensor for display/recorder	A_0 reached (-0/+5K)	1 x	-	-
Load	1 TE in supplies at each corner 1 TE near chamber sensor 1 TE near sensor for display/ recorder (if appliable, the fastest and slowest site)	A_0 reached (-0/+5K) Fluctuation ± 2 °C, Max. diff.4 °C	3 x (for identical progr. seq. if appliable, other prog. 1x) [2,3]		1 x/ prog. sequence
-Tank for rinse water	TE in geom. centre	min 60 °C or disinfected in desin. phase	1 x	-	
2.2 Temperature control of other phases (excl. dDrying)					
Chamber walls Loading rack	during 2.1	• *CW, BT, Load: within ±5 °C of set temperature* • *Rate of increase: K/min as per manufacturer's instructions* • *Prerinse phase: < 45 °C* • *Wash phase: within specified tolerances of a) WD manufacturer b) WD media manufacturer* • *Deviation permitted between sensor and display/recording and control: ± 2 °C*	during 2.1		-
Load			during 2.1		during 2.1

[1] if the result is within 5% or the initial validation rates

[2] A single test suffices if a type test has already been conducted with the same programme settings and using the same detergernts and amounts of detergent

[3] optionally for commissioning or performance qualification

Test	Brief description	Requirement	OQ / commissioning	PQ	Revalidation
2.3 Accuracy of display/ recording					
Accuracy of display versus reference value		+/- 1 °C	during 2.1		
2.4 Reproducibility					
Temperature profile	during 2.1	+/- 2.5 °C Temperature range[4]	during 2.1		Compare with evaluation values
4 Water quality					
Softened water	- pH: 6-8, - Hardness as per manufacturer's instructions, - No turbidity		1 x	-	1 x
Demineralised water	- pH: 6-8 - Hardness: ≤ 0.02 mmol/l alkaline earths - Conductivity: ≤ 15µS/ cm (or as per manufacturer's instructions) - Turbidity: clear, colourless, without any precipitates				
	Bact. investigation	<100 cfu/ ml (36 +/- 2°C/ 48 +/- 4 h) *P. aeruginosa* n.n./100ml			
5 Residues in final rinse water					
letztes Spülwasser	- pH: 6-8 - Hardness: ≤ 0.1 mmol/l alkaline earths - Conductivity: cond. demin. water + ?? % (not yet defined) - Turbidity: clear, colourless, without any precipitates - If applicable, silicium: ≤ 1 mg/l - If applicable, chlorine: ≤ 0.1 mg/l		1 x		1 x
	Bact. investigation	<100 dfu/ ml (36 +/- 2°C/ 48 +/- 4 h) *P. aeruginosa* n.d. / 100 ml			
	Residues of reprocessing media	As per chemicals' manufacturer			
6 Dosing chemicals					
Measurement reliability and repeatbility	Volumetrc: lance in measuring cylinder, retain qty. for 2nd and 3rd cycle	Compare with manufacturer's instructions (max. deviation ±10 %)	1 x lt. TR	-	1 x lt. TR
7 Chemical disinfection (option)					
Microb. testing	Bioindicators (E. faecium, 10^5) or contaminated TS	n.n.	1 x		1x
8 Dryness of load (option)					
Dryness of load	Test for dryness using crepe paper or compressed air and mirror (hollow devices)	No residual moisture detectable after 5 min	1 x	-	-
9 Liquid escape (option)					
- Chamber tightness	Visual inspection during one test	No liquid escape	1 x	-	-
10 Pipelines (option)					
Drain to emptying point	Note horizontal slope (poss. water balance)	All liquids must drain away	1 x	-	-

* Configuration = combination of programe and loading rack

TS: Test soil, n.d.: not detectable, TR: test regulation, PCD: process challenge device

Tab. 1: Summary of test programmes for WD

[4] if not reached with cold start, additional warm start needed