Recommendations by the Quality Task Group (42) Using Process Challenge Devices To Verify Cleaning Performance for Validation of Washer-Disinfector Processes

Guideline drafted by DGKH, DGSV and AKI for validation and routine monitoring of automated cleaning and disinfection processes for heat-sensitive medical devices

Standard prEN ISO 15883 stipulates that for verification of the cleaning performance a defined test soil and contamination method as well as soiled instruments that genuinely reflect everyday routine operations be used. The ➜ **GUIDELINE** compiled jointly by German Society for Hospital Hygiene (DGKH), German Society of Sterile Supply (DGSV) and Working Group Instrument Preparation (AKI) for validation and routine monitoring of automated cleaning and disinfection processes for heat-sensitive medical devices, – see *Central Service* Supplement 1, 2005 – describes a defined process challenge device (PCD) for verification of the cleaning performance during validation. This PCD meets the requirements for verification of the cleaning performance and using blood as a soil it simulates the contaminant most commonly encountered on surgical instruments in a real-life setting. Using defined PCDs, the reproducibility of the cleaning process, in addition to the minimum cleaning performance, can be verified and if required the performance can be optimized, for example by changing factors of influence or load specifications. To that effect, the PCD must have met appropriate standardization criteria and must have been manufactured in line with ➜ **QUALITY ASSURANCE** practices. As can be expected, in-depth quality assurance measures set high standards for PCD manufacturing procedures.

➜ **QUALITY ASSURANCE** sets high standards for PCD manufacture.

Test Piece

An arterial ➜ **CRILE CLAMP** is used as a defined test piece (Fig. 1). The material and surface composition must be standardized, especially if the clamps are repeatedly reused to cut costs. Of importance in this respect are factors such as the quality of the alloy, passivated surface, rust, residues, care and sterilization.

➜ **A CRILE ARTERIAL CLAMP** is used as a test piece.

Test Soil

The test soil used is heparinized ➜ **SHEEP BLOOD** to which a corresponding quantity of protamine sulphate is added to negate the anticoagulant effect of the heparin. 0.1 ml of this test soil is pipetted into the clamp joint (Fig. 1) and dried using a standardized method.

Neither in man nor in the sheep does blood have absolutely the same constituents or the same coagulation properties. The same holds true for this test soil. Therefore when producing PCDs a check must be carried out to establish whether each blood load is within a specified tolerance range. In all cases, ➜ **REPRODUCIBILITY** of the test results must be assured.

➜ **REACTIVATED SHEEP BLOOD** is used as a test soil.

➜ **REPRODUCIBILITY** of the test results must be assured.

Important prerequisites for consistent blood quality include, inter alia, maintenance of the cold chain when delivering the blood, observance of blood expiry dates and minimization of the amount of oxygen supplied from the air for processing and storage of the PCDs.

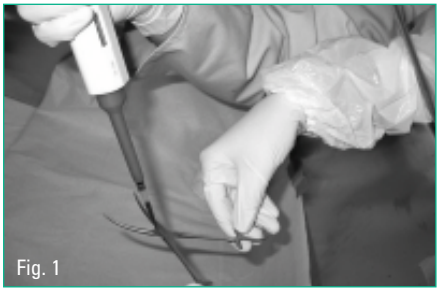
Fig. 1

PCDs – Release and Dispatch by the PCD Manufacturer

Before PCDs are released the manufacturer must check their quality, investigating among other things the cleaning behaviour in a defined cleaning process. Batch assignment must be assured by the manufacturer on the basis of an internal quality management system. The PCD packaging must be appropriately labelled to reflect this.

To ensure that no adverse changes occur during dispatch, the storage characteristics – in respect of time and temperature as well as vacuum packaging – must be investigated and specified.

PCD Management during Validation

Before using PCDs, the user/validation officer must rigorously observe the expiry date and other ➜ **INSTRUCTIONS SPECIFIED BY THE MANUFACTURER**. The clamps must be placed in the test positions as specified for the WD reference load, see form enclosed with Guideline. The test process is started and the clamps are withdrawn before the disinfection step. The ➜ **VERIFICATION PROCEDURE** consists of visual inspection for cleanliness and measurement of protein residues using the biuret/BCA method. Once inspected, the clamps must be cleaned again without delay, followed by disinfection and drying. This prevents rust formation in the region of the joint.

If the PCDs are to be sent to a ➜ **LABORATORY** for assessment, they must be dried at room air immediately after removal from the WD and visual inspection, then be placed in the return packaging provided, labelled as per their positions and dispatched.

➜ **INSTRUCTIONS** specified by the PCD manufacturer must be observed.

➜ **THE VERIFICATION PROCEDURE INCLUDES** visual inspection of cleanliness and measurement of protein residues with the biuret/BCA method.

➜ **IF PCDS ARE TO BE INSPECTED IN A LABORATORY,** dispatch them immediately after removal from WD.

Visual Inspection of PCDs

A certain amount of experience is needed to distinguish with the naked eye between minute quantities of the test soil and rust. Therefore a protein detection method is used to clarify such issues.

Fundamental Remarks

Blood residues are the contamination most commonly encountered on surgical instruments. Apart from blood, medical devices can also harbour other types of contaminants, e.g. fat, mucus, bone meal, drugs, antiseptics, etc. The PCD described serves as a model for verification of the cleaning performance where there is exposure to blood contamination. In this respect, it can be used for performance qualification of WDs that comply with the pertinent standard as well as for those older WDs that do not meet the provisions of this standard. This verification procedure is conducted on site using specified reference loads that reflect everyday operations. This procedure is also able to identify mistakes made, e.g. loading errors or drawbacks in the process.

During validation the efficacy of a cleaning process is checked additionally by means of a ➜ **REAL LIFE TEST**, i.e. on the basis of instruments with everyday soils that are also subjected to visual inspection for cleanliness and to measurement of protein residues with the biuret method. By virtue of their specific design and of the various factors of influence that play a role during the process as well as the drying times, additional weaknesses inherent in the decontamination process can come to light.

The validation officer must note all these factors when carrying out tests and take them into account when evaluating the cleanliness results after visual inspection and also when measuring protein residues with the biuret/BCA method.

Enlisting the ➜ **COOPERATION OF THE USER** on site is of paramount importance for preparation and conductance of validation.

➜ **INSPECTION OF REAL INSTRUMENTS,** i.e. contaminated during actual use, is performed during validation.

➜ **ENLISTING THE USER'S COOPERATION** is of paramount importance.