Recommendations by the Quality Task Group (57): Physical Data for Routine Control in Washer-Disinfectors

For automated reprocessing of medical devices in a washer-disinfector (WD) each batch must be released. This can be done by comparing the results obtained with the measured values ➜ **(PARAMETERS)** defined at the time of validation. Physical measurements are the basis used for parametric release of the automated processes used for decontamination of medical devices. The most important data are recorded and documented. Faults are signalled. In WDs that conform to the specified regulations, this is done using their measurement facilities that are calibrated and adjusted at the time of validation. The measuring points are positioned such that the measurement data can be extrapolated to the entire process.

➜ **PARAMETERS** are e.g. time, temperature, pressure etc.

The most important data listed in standard DIN EN ISO 15883 are:

- Temperature-time course for the cleaning step
- Temperature-time course for the disinfection step (A_0 value)
- Water quantity for each step of the batch
- Dosage quantity of ➜ **PROCESS CHEMICALS**
- Furthermore, the following must be checked: chemical residues and the quality of the water used, based on the electrical conductivity

➜ **PROCESS CHEMICALS** are e.g. detergents, neutraliser, rinse aid, etc.

In the guideline compiled by the German Society for Hospital Hygiene (DGKH), German Society of Sterile Supply (DGSV) and the Instrument Preparation Working Group (AKI), attention is also drawn to the importance of pressure monitoring, since the pressure in the spray system can be considerably reduced by negative influences (e.g. foam formation from preceding treatment steps), and therefore the process quality can no longer be assured.

The ➜ **TEST INTERVALS** are determined at the time of risk assessment. The standard provides information only on WDs that conform to the standard. The guideline drafted by DGKH, DGSV and AKI gives additional recommendations for conductance of measurements and for control measures both for WDs that do and do not conform to the standard.

➜ **THE TEST INTERVALS** must be set based on risk assessment.

The quantity of water and of process chemicals is determined as per the manufacturer's instructions.

Carrying out measurements as routine tasks

Temperature-time course

Rugged thermologgers can be used for routine checks of the temperature-time course unlike the delicate measuring sensors used for validation. One logger positioned at the site where, based on the validation protocol, the temperature is reached most slowly is enough if differences are noticed between various loads. If two loggers are used, diagonal positioning between the instruments is recommended. When calculating the ➜ **A_0 VALUE** it must be borne in mind that it is only the disinfection step that is taken into account (zoom in), and not the cleaning or drying steps.

➜ **THE A_0 VALUE** applies only to disinfection.

Pressure measurement

The pressure of the system is checked with a data logger. It is connected to a loading trolley or at a separate site. The pressure course for the different phases of the WD process can be compared with the values recorded for the validation protocol. Any drop during the cleaning step can be detected immediately. Such a drop may be due to the type of load (greatly contaminated instruments) or to the effect of pretreatment products giving rise to a lot of ➜ **FOAM.** The reason for a drop in pressure must be investigated, because neither the cleaning nor the disinfection performance is assured if there is a major drop in pressure.

➜ **FOAM FORMATION** leads to a drop in pressure.

Determination of the water quality and of tolerable residues of process chemicals on the basis of the electrical conductivity

In the interest of patient protection, there must not be any, or only a minute amount of, residues on medical devices. To assure this, the manufacturer of such process chemicals provides information on the maximum amounts of ➜ **CHEMICAL RESIDUES** that can be tolerated and on the measurement methods to be used.

➜ **CHEMICAL RESIDUES** can be measured on the basis of the conductivity of the final rinse water .

A suitable way to determine this is to use an indirect method for measurement of the electrical conductivity of the final rinse water. If demineralised water is used for all process steps, the conductivity of the incoming demineralised must be measured first of all. This value must be subtracted from the conductivity value measured for the final rinse water. The value obtained must not exceed that specified by the manufacturer of the process chemicals used.

If other water qualities are used, a blank batch containing no chemicals or medical devices must first be run, so that the water conductivity value obtained can be used for the measurements carried out for the last rinse step.

If detergents with a very low conductivity are used (e.g. neutral detergents), this measuring method cannot be used. The instructions of the process chemicals' manufacturer must be consulted for the procedure to be used here.

In the event of any deviations for the set point values, the cause must be elucidated and remedial measures taken.

The following measuring instruments are needed as a minimum for routine measurements regardless of the WD type:

– Thermologger system (with calculation of A_0 value)
– Pressure logger system
– Conductivity measuring instrument