Introduction of an in-house standard for quality assurance

T. Blechschmidt

This paper describes the steps leading up to the introduction of an in-house standard for routine control of a washer-disinfector (WD). There are no clearly defined specifications as to how this is done. But the operator must ensure that the results of performance qualification at the time of validation are routinely verified and recorded. In that way the unchanging quality of the process can be guaranteed. The frequency and scope of routine checks must be defined by the operator since the conditions prevailing in each Central Sterile Supply Department (CSSD) will differ. The final decision on routine checks is taken by the user, who then must answer to the supervisory bodies.

It was necessary to take a look at all the (operating) media used in the cleaning and disinfection process in order to be able to formulate a good and robust in-house standard.

Besides, the performance of different test systems was compared with that of one of the test instruments specified in DIN EN ISO 15883-5. That comparison helped to reach a decision on which test system should be used to assure optimum routine monitoring.

A standard on test soil would be beneficial as its use would be binding for the manufacturers, too, and the use of just any test systems chosen by the manufacturer would be a thing of the past.

The activities described in this article led to the introduction of the in-house standard for routine checks of WDs at Orthopädie Bad Hersfeld.

Introduction

Standard DIN EN ISO 15883-1 unequivocally states that routine tests must be carried out and recorded. It is not enough to repeat performance qualification (revalidation) on an annual basis, because one cannot guarantee that cleaning and disinfection in a WD will not have changed over the course or a year. Changes to the water quality, demineralised water quality or to the chemical substances cannot be ruled out.

Annex A, Table A.1, of DIN EN ISO 15883-1 explains which processes should be checked on a routine basis, and how often testing should be performed. This table is very detailed and by no means self-explanatory. Therefore it can only serve as a guide to compiling one’s own standard for routine testing.

Since the design and fittings of a WD play an important role in routine activities, details of routine testing are given in the validation report. For the WDs in our establishment these details were confined to annual servicing (to be carried out by a service engineer) and six-monthly check of the cleaning pressure. But a six-monthly check is by no means enough to demonstrate the repeatability of a validated process.

The manufacturer’s instructions contain information and data on the fittings required in the WD. One must ensure that only a WD that complies with the pertinent standards is used.

The greater the number of processes monitored by a WD itself, the fewer the checks that need to be carried out by the user. The WD takes charge of many monitoring tasks as a routine measure, e.g. of the temperature-time course for the cleaning and disinfection step (A0 value), dosage quantity of process chemicals and amount of water used for each process step. More checks are performed by new WD models (e.g. monitoring of the rotational speed of the cleaning arms). This can reduce the costs incurred for routine tests and should be borne in mind when purchasing a new WD. The German Society of Sterile Supply (DGSV), in particular its Quality Task Group, also publishes recommendations on routine checks. These, too, are based on DIN EN ISO 15883 and are a valuable guide to compilation of an in-house standard.

Routine checks needed

Demineralised water quality and tap water quality

Water, as a medium, plays a pivotal role in the cleaning process conducted in a WD. For that reason, this too must be routinely tested. The use of demineralised water for the entire cleaning and disinfection process offers many advantages, e. g. a constant pH value in the mildly alkaline range.

Key Words

- cleaning
- validation
- WD
- routine control
- quality assurance

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Key Words: such that optimum cleaning results can (depending on the chemical substance) Chemical substances are used in the cleaning process only for a cold pre-supply system on an annual basis is sufficient, as the p. be assigned to well-trained personnel who have the necessary expertise. While the test, used for validation, has a lower detection level of 1 µg protein, it is suitable only to an extent for everyday practice because it is very comprehensive and complex. Therefore the rapid biuret protein test is used to check for any protein residues. This produces an evaluable result within 10 min. Such tests are available with different detection limits. In the establishment described here, we used a rapid test with a detection limit of 15 µg protein. The cleaning batch, data and instrument documentation must definitely be recorded in the final documentation.

Chemical detergents
Chemical substances are used in the cleaning process to increase the pH value (depending on the chemical substance) such that optimum cleaning results can be achieved for the instruments and chlorine-induced pitting corrosion prevented. Dosage mistakes can result in poorer cleaning and, as such, successful decontamination is not assured. Besides the risk of chlorine-induced pitting corrosion at a pH value of 10.5 is very high, hence the likelihood of damage to the instruments and WD must be borne in mind. For that reason the filling level of chemical substances must be checked daily before placing the WD in operation.

Checking mechanical fitting
Daily, before running the first WD process, the cleaning arms and all Luer lock tube connections, wheels, pump sump and filter sieves are inspected. The loading trolleys are also checked on the docking systems in the WD (seals intact?). The inside of the WD is also visually inspected for cleanliness or deposits (rust, silicates) and the door seals are also checked. Next visual inspection of the outside of the WD is performed to detect any damage or leaks. Routine checks of problem instruments Our institution reprocesses orthopaedic instruments. These are very complex, have several joints and can only be partially dismantled. To ensure that these instruments, too, are free of residual soils and protein residues, they must definitely be used to simulate a worst-case load at the time of validation. As a routine measure these instruments are subjected to spot checks as needed (e. g. suspected poor cleaning), but at least once weekly. It is important that this task be assigned to well-trained personnel who have the necessary expertise.

Loggers for monitoring $A_v$ value and cleaning pressure
A logger system must be used to provide for monitoring of the $A_v$ value independently of the WD. However, the $A_v$ value is monitored by the WD itself in the case of WDs that conform to the pertinent standards, hence routine control is not needed. This will, nonetheless, be elaborated on here, i. e. in the context of monitoring the cleaning pressure. The cleaning pressure is vital for good cleaning. The rotational speed of the cleaning arms is determined by the cleaning pressure, and that speed is needed to assure adequate flushing of instrument lumens.
While based on the validation report of the establishment described here, the cleaning pressure need only be monitored once every six months, I believe that this must be done much more frequently. I deem a monthly routine check of the cleaning pressure to be advisable and adequate.

To that effect a logger system that concurrently checks the $A_0$ value and cleaning pressure is used. This system is easy to programme and use. Once successfully programmed it is fitted to a Luer lock connected in the WD and placed in the tray. The logger is read on successful completion of the process and evaluated using the software supplied.

A logger system confers many benefits even if there are problems with the WD, e. g. poor cleaning results.

**Visual inspection of instruments for residual soils and deposits**

Probably the most important routine check is visual inspection of instruments for residual soils and deposits. This check is done using a magnifying lamp in order to be able to detect even the most minute soils, deposits or pitting corrosion.

![Image of test series results]

<table>
<thead>
<tr>
<th>Time window</th>
<th>BAG indicator</th>
<th>SIMICON</th>
<th>gke yellow</th>
<th>gke green</th>
<th>gke blue</th>
<th>gke red</th>
</tr>
</thead>
<tbody>
<tr>
<td>30 seconds</td>
<td>Optimum result</td>
<td>Test soil slightly visible</td>
<td>Protein detection: negative</td>
<td>Protein detection: positive</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 minute</td>
<td>Optimum result</td>
<td>Test soil completely removed</td>
<td>Protein detection: negative</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 minutes</td>
<td>Optimum result, also with standing complete PCD</td>
<td>Test soil completely removed</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5 minutes</td>
<td>Optimum result</td>
<td>Test soil completely removed</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10 minutes</td>
<td>Optimum result</td>
<td>Test soil completely removed</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remarks</td>
<td>pH value ≈ 10.7</td>
<td>Dosage: 3 ml Basic 2 ml Zym</td>
<td>pH value ≈ 10.7</td>
<td>Dosage: 3 ml Basic 2 ml Zym</td>
<td>pH value ≈ 10.7</td>
<td>Dosage: 3 ml Basic 2 ml Zym</td>
</tr>
<tr>
<td></td>
<td>Protein detection: negative</td>
<td>Test soil very slightly visible</td>
<td>Protein detection: negative</td>
<td></td>
<td>Test soil completely removed</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Test soil completely removed</td>
<td>Protein detection: negative</td>
<td></td>
<td>Test soil completely removed</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Test soil completely removed</td>
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<tr>
<td></td>
<td></td>
<td>Test soil completely removed</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Table 2: Test series 1 (detergent: Dismoclean Twin)</td>
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<td></td>
</tr>
</tbody>
</table>

This visual inspection and checking of the $A_0$ value are of paramount importance for batch release after a successful process outcome. If there are still residual soils on the instruments, this can point to a faulty cleaning process, resulting in failure to release the respective batch. This batch must be recleaned and visually inspected again.

For that reason an experiment was carried out on the spray apparatus in a test laboratory. This apparatus simulates the spray activity of a WD, enabling accurate setting of the flow rate, temperature, dosage of chemicals, and thus producing reproducible results.

Since in our establishment we intend changing the chemical detergents, I conducted the experiment with different detergents. As such, the experiences gleaned can be used in the selection process.

To test how the indicator responds to mistakes/malfunctions, a test series was also run without chemical detergents, using only demineralised water. It is imperative that mistakes be signalled during routine checks.

**Fixed variables used in the experiment**

The following fixed variables were used for the experiment:

- **Temperature**: 55 °C (optimum cleaning temperature as stated by the detergent manufacturers Bode Chemie and Dr. Weigert)
- **Flow rate**: 0.5 l/min (the flow rate used in a normal WD in our establishment is
3.5 l/min. The lower rate was selected so that the rinse process would not unfold too rapidly, and differences could be identified more easily.

- **Demineralised water** in the entire process only then is the exact pH value specified in the manufacturer’s instructions reached.

**Changeable variables in the experiment**

The changeable variables in the experiment were:

- **Chemical detergents**: Dismoclean Twin System (manufacturer: Bode Chemie) is a two-component system consisting of an alkaline and an enzymatic detergent; pH value with demineralised water 3 ml/L: approx. 10.7. Neodisher Mediclean Forte is a single-component system with alkaline and enzymatic components; pH value with demineralised water 2 – 10 ml/L: 10.5 – 11.0. Neutralization can be omitted in the process for both detergents since their components are gentle on materials (cost savings).

- **Time**: different time windows for recording the cleaning performance 30 seconds, 1, 3, 5 and 10 minutes.

- **Indicators**: BAG, Simicon, gke yellow (Level 1), gke green (Level 2), gke blue (Level 3), gke red (Level 4), sheep blood indicator.

**Preparation of indicators**

The PCD from the firms BAG and Simicon are vacuum packed and have been stored under optimum conditions of between 2 °C and 25 °C in sealed protective foil, where they were also protected against exposure to disinfectant and chemical vapours. The expiry dates were observed: 18 months as from the date of manufacture. They were unpacked and used only immediately before they were inserted into the spray apparatus.

The cleaning indicators from the manufacturer gke were packed in a foil pouch and were also stored under optimum conditions.

Preparation of the sheep blood indicators was outsourced to a company since I did not have the necessary conditioning facilities. The discs, to which the test soil had been applied, were conditioned overnight at 30 °C and at a relative ambient humidity of 45 % and then stored in sealed dishes until just before being placed in the spray apparatus.

**Conduct of test series**

After preparation of the indicators and spray apparatus (selection and dosage of chemical detergents, demineralised water kept in stock), testing was initiated by selecting the programme. First, the detergent Dismoclean Twin (manufacturer: Bode Chemie, Hamburg) and the 10-minute programme were selected, testing all indicators with that programme. Next came the 5-minute, 3-minute, 1-minute and the 30-second programme, using indicators in each case.

The results were evaluated immediately on the basis of the evaluation sheets supplied by the indicator manufacturers. The terms specified in the evaluation sheets were used in order to achieve reproducible results.

The gke indicators were stuck on a documentation sheet specially designed to that
### Evaluations and results of the test series

On using Dismoclean Twin (test series 1; Table 1) optimum results were achieved already after the 3-minute for the test soils of all indicators used. The test soils used in all indicators were removed without any residues. The protein tests were also negative. This was a very good result since it attests to a very good cleaning performance in the process.

On using Neodisher Mediclean Forte (test series 2; Table 2) after 3 min the test soils from BAG, Simicon as well as the denatured sheep blood indicator were completely removed. The protein tests were also negative. However, colour residues could still be detected for difficulty Level 3 of the gke indicators, and in Level 4 no rinse reaction could still be observed. Only after 10 min was Level 3 completely, and Level 4, partially, removed. That result is also suggestive of a good cleaning performance in the process since blood and protein residues were completely removed. That the gke indicator (Difficulty Level 4) was not completely cleaned attests to a level of difficulty encountered when cleaning that indicator. While gke indicators were not placed in a PCD in the process, the cleaning response was similar to that evinced by an indicator that had been placed in a PCD.

Test series 3 (demineralised water; Table 3) produced surprising results. All indicators with blood soils had been completely cleaned off in a short time, the BAG was clean after 30 seconds, Simicon after 3 min and the sheep blood indicator after 1 min. The protein tests were negative. Only in the case of the gke indicators was the colour completely removed after 10 min in Difficulty Level 1, Level 2 was partially removed but no cleaning reaction could be observed for Level 3 and 4.

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**Table 4: Test series 3 (demineralised water)**

<table>
<thead>
<tr>
<th>Time window</th>
<th>BAG indicator</th>
<th>SIMICON</th>
<th>gke yellow</th>
<th>gke green</th>
<th>gke blue</th>
<th>gke red</th>
<th>Indicator as per EN ISO 15883-5 (sheep blood)</th>
</tr>
</thead>
<tbody>
<tr>
<td>30 seconds</td>
<td>Optimum result</td>
<td>Protein detection: negative</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Complete removal</td>
</tr>
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<td></td>
<td></td>
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<tr>
<td>1 minute</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>3 minutes</td>
<td>Test soil completely removed</td>
<td>Protein detection: negative</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5 minutes</td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10 minutes</td>
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<td></td>
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</tr>
</tbody>
</table>

Remarks: Only demineralised water.
These results show that only the gke indicators pointed to deviations in the cleaning process, since a particular pH value was needed in order for these indicators to be cleaned off.

As regards the in-house standard it is important to know:
- Which indicators are used for routine checks in a WD. Do these detect faults in the process?
- Which chemical detergents are chosen prior to validation so that optimum results can be achieved in the process?

In practice the appearance of instruments after a successful cleaning process is, of course, important. Do they still perhaps harbour protein residues? The following results were obtained from these series of tests for the in-house standard.

1. For reprocessing in the WD, municipal water is used only for the cold preliminary rinse phase, with demineralised water being used for all subsequent process steps. Only on using demineralised water can a pH value be maintained for the process, as specified in the manufacturer’s instructions.

2. For the routine checks of the WD gke indicators are chosen, using the Level 4 indicator with a clip for the trays as well as the flow PCD. These give the added sense of security that malfunctioning of the cleaning process will be signalled.

3. The chemical detergent to be used in future is Dismoclean Twin System from the manufacturer Bode. Above average cleaning results can be expected with this detergent. These insights will be taken account at the time of WD revalidation.

Content of an in-house standard for routine checks in a WD

The outcome of all these endeavours is the final standard for routine checks in a WD. This is broken down into the following periods of time: daily, weekly, 4-weekly, 6-monthly and annual routine checks.

Standard for routine checks in a WD for in-house quality assurance

Checks to be carried out once daily, before placing the WD in operation for the day:
- Visual inspection of the WD, including the inside, for any damage or deposits
- Check the loading trolley, cleaning arms for unimpeded movement, that nozzles are not blocked, docking system intact; check wheels and Luer lock connections
- Check pump sump
- Check filter sieves
- Visual inspection of detergent storage containers
- Competent parties: specialist personnel in CSSD (i.e. who have acquired the requisite expertise by successful completion of the relevant training courses, levels I, II and III)

Checking after completion of each batch in the WD:
- Visual inspection of instruments for residual soils and deposits, with the aid of a magnifying lamp
- Check the Aₚ value on the basis of the WD batch release data in the batch documentation software
- Competent parties: specialist personnel in CSSD (as described above)

Checks to be carried out once weekly:
- Checking problem instruments by means of the buret protein test, evaluate using the manufacturer’s evaluation sheet
- Competent parties: specialist personnel in CSSD (as described above)

Checks to be carried out once every 4 weeks:
- Check the spray pattern with gke Level 4 cleaning indicators. Distribute the indicators beneath the spray arms and at the corners of the loading trolley, using at least five indicators per batch. Record results on evaluation sheets available in the CSSD
- Competent personnel: shift manager (successful completion of training courses, levels II and III)
- Check the cleaning pressure and Aₚ value with a logger system, documentation via logger system software
- Competent personnel: shift manager (successful completion of training courses, levels II and III)

Checks to be carried out once every six months:
- Microbiological testing of the demineralised water
- Competent personnel: infection control team/microbiologist and test laboratory
- Chemical testing of demineralised water
- Competent personnel: infection control team/microbiologist and test laboratory

Checks to be carried out once every year:
- Test municipal water quality: request values from water supplier
- Competent party: Engineering Department
- Servicing and inspection of WD, sensor calibration, revalidation
- Competent party: Customer Service and CSSD management

The standard described above is not valid for general use. Rather, it has been compiled for application in our establishment. One often hears the view expressed that routine monitoring can be completely dispensed with so long as standards and guidelines do not stipulate anything to the contrary. This is a misunderstanding and such a view amounts to an erroneous perception. What is correct is that – as pointed out in the introduction – routine monitoring is absolutely required, but its nature and scope have not yet been specified. Therefore to date there is, unfortunately, no other solution other than for each establishment to devise a routine monitoring regimen for its own reprocessing activities, while justifying this and then imposing it as an in-house standard. This is the only way to guarantee that the process quality verified at the time of validation is maintained in everyday operations and that any changes will not go unnoticed.

References