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Automated Reprocessing

Inter-related Process Parameters in Washer-disinfectors

Contents

Transmission Instruments in Dentistry

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In dentistry, a number of different instruments are used for treatments. These instruments are matched to the needs of their users. In this context, transmission instruments are particularly important. They are used in virtually all treatments and are the main tool in every dental practice. These instruments also form a special group for reprocessing as their design and structure pose a challenge.

Turbines versus straight and contra-angle handpieces – air-driven and electric

In general, a distinction is made between electric and air-driven transmission instruments. Straight and contra-angle handpieces are electric transmission instruments, while turbines are air-driven. However, the drive is not the only difference; the design and structure of the instrument, and sometimes the area of application, also vary.

Electric instruments are available in different versions with various gear ratios and reductions as well as speeds, meaning that there are numerous applications. Furthermore, they have a uniform motor interface, which is standardized and complies with ISO 3964. In addition to the instruments used for cavity preparation, the “high-speed” handpieces (red contra-angle handpiece), there are also contra-angle handpieces for excavating and finishing, which reach a motor speed of 40,000 revolutions per minute, and reducing contra-angle handpieces, which reduce the motor speed. Additionally, there are special

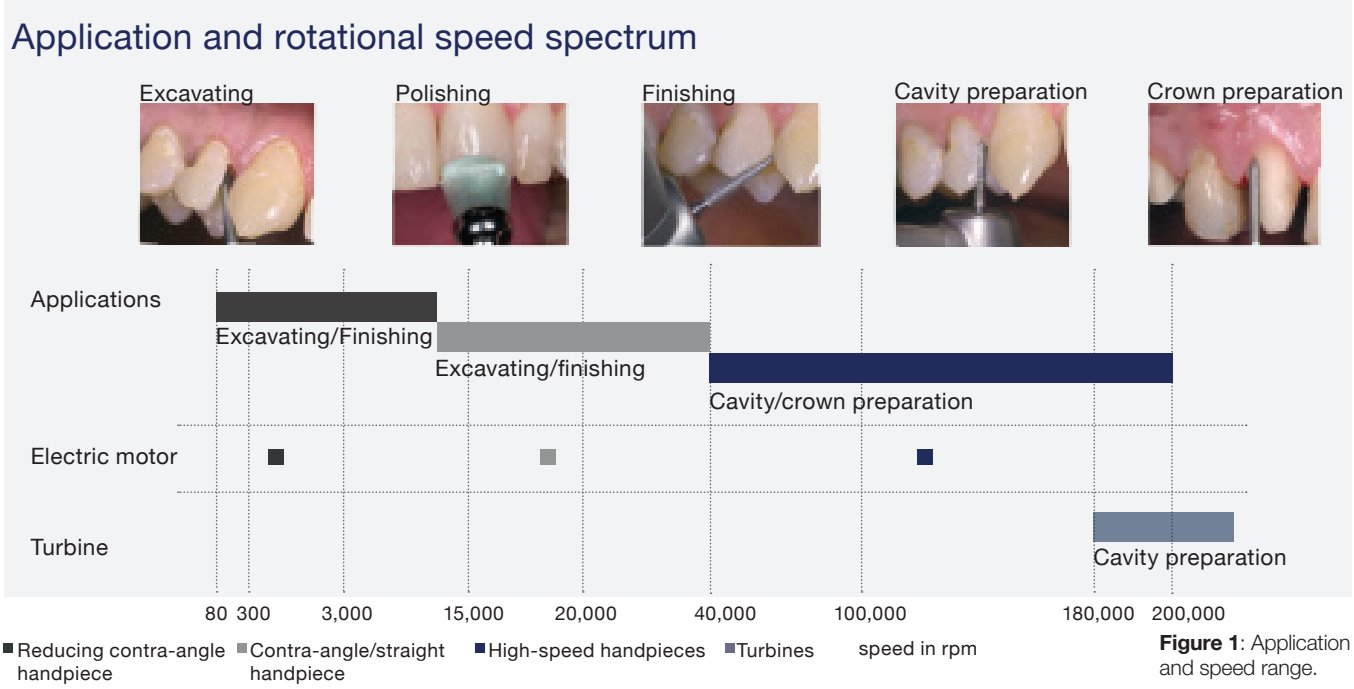

Figure 1: Application and speed range.

contra-angle handpieces that were developed for endodontic treatments, for example, or that are suitable for implants. These feature special gear reductions, but their design and structure are also adapted to their tasks (e.g. no internal spray control). The handpiece

Figure 2: Contra-angle handpiece, red.

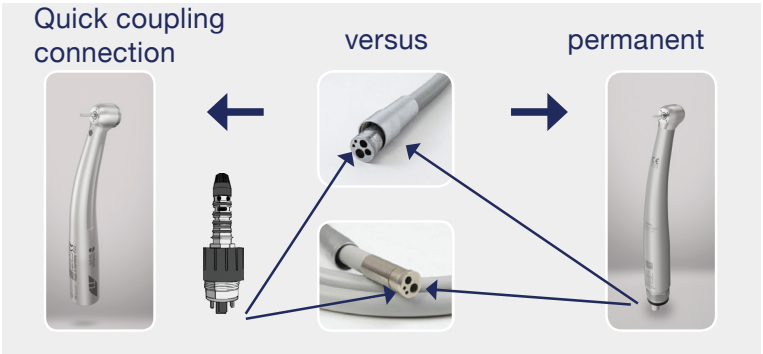

Figure 3: : Quick coupling versus fixed connection.

The speed and gear ratio of air-driven instrument turbines cannot be adjusted. The inflowing air is fed directly to the rotor. There are turbines with quick coupling, enabling quick removal of the instrument after treatment, as well as turbines with a fixed connection. Fixed connection means that the turbine is firmly connected to the supply hose via a screw connection, and the turbine has to be unscrewed when it needs to be changed.

Design and structure

If you take a look at the cross-sections of the contra-angle handpiece and the turbine, you will

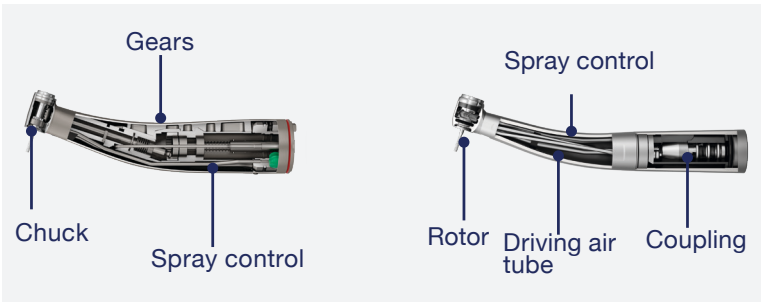

Figure 4: Cross-sectional model with contra-angle handpiece.

Figure 5: Cross-sectional model with turbine.

Figure 6: Exploded-view drawing of an angle piece head.

immadietly notice the very different structures. While the contra-angle handpiece has a complex structure and hard-to-access areas due to the gears, the turbine has large hollow spaces and a rather "tidy" interior. If you take a look at the exploded view of parts of the transmission instruments for example, it quickly becomes apparent that these instruments have elaborate structures depending on the version. The example used here is the head of a contra-angle handpiece. This shows the connection between the bur and the drive. The fine gear wheels transfer the power of the motor to the bur, which is held by the chuck, at speeds of up to 200,000 revolutions per minute.

Challenges for reprocessing

It is not just the design and structure of a transmission instrument that pose particular challenges for reprocessing; the working environment of the instrument also plays a major role. Saliva, blood, or other infectious media can come into contact with the transmission instruments. Furthermore, abraded material and oil residue in the gear paths form a certain amount of soiling to which special attention should be paid during reprocessing. Furthermore, the narrow media channels of the water-bearing parts in the transmission instrument pose a challenge for reprocessing. Turbines can also have a so-called backflow effect, whereby potentially infectious material may be sucked up into the turbine head after stopping the turbine rotor due to physical properties. This happens because negative pressure forms once the rotor has been stopped. The rotor continues to rotate for a short time even after the driving air has been switched off due to its mass inertia and can thus have a suctioning effect depending on the design of the turbine. In spite of the back-suction stops that are installed in many turbines, small amounts of contaminated material can reach the heads of the turbines.

Every manufacturer of transmission instruments must specify which reprocessing options can be used for their instruments. It is important that this information is observed during reprocessing. It includes important information regarding authorized chemicals such as cleaning agents or disinfectants, for example. The information also describes how corrosion or other surface changes are avoided. The manufacturer tests the recommended reprocessing options for material compatibility and effectiveness. Generally, preference should be given to mechanical reprocessing procedures.

In addition to information regarding correct reprocessing, manufacturer's specifications also include information on lubrication. Generally, this must be

performed after every patient since the protective oil film is removed after reprocessing and has to be reapplied in the instrument for the next treatment. It is important to maintain the gear paths as well as regularly maintaining the chuck. This should be done at least once a week in order to preserve the sensitive holding mechanism for the bur and guarantee easy insertion and removal of the bur.

Regardless of which transmission instrument is selected, each instrument has special requirements for reprocessing due to its structure and design as well as the exposure of the instrument during treatment. All manufacturers provide detailed information on this in their reprocessing instructions. This information has been checked by the manufacturer regarding material compatibility and effectiveness and ensures that the transmission instrument will have a long service life. Generally, preference must be given to mechanical reprocessing procedures.

"Generally, this must be performed after every patient since the protective oil film is removed after reprocessing and has to be reapplied in the instrument for the next treatment. It is important to maintain the gear paths as well as regularly maintaining the chuck.

Figure 7: Disassembled angle piece with contamination due to improper reprocessing.

Automated Reprocessing: Inter-related Process Parameters in Washer-disinfectors

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A lot has changed in recent years in the area of automated instrument reprocessing. The changes range from new instruments with new materials and designs that place special requirements on reprocessing to new procedures and flexible loading technologies in washer-disinfectors (WDs) that place special requirements on equipment technology (e.g. variable speed pump) in order to ensure constant process parameters (e.g. rinsing pressure) to new formulations and combinations for processing chemicals.

Therefore, it is definitely reasonable to poise the question of whether the current recommendations (e.g. cleaning step at 55°C with alkaline media with pH > 10 and a holding time of 10 minutes) are still valid, or whether the user/operator could adapt his or her processing steps appropriately, provided the result complies with the guidelines.

Pursuant to Section 8 of the Medical Device Operator Ordinance, the reprocessing […] of medical devices that are used in accordance with provisions requiring that they have a low microbial count or be sterile is performed with attention to the manufacturer's specifications and with suitable validated procedures in such a way that the success of these procedures is logically ensured and that the safety and health of patients, users or third parties are not jeopardized […].[1]

These "suitable validated procedures" yield a defined result (in particular: cleanliness, sterility or low microbial count, functionality), which must be reproducible and verifiable.[2] In addition, parameters that are necessary for adhering to the validated conditions in the particular process are established and defined.[2]

Step 1: Pre-rinse

Because the conditions and reprocessing procedures differ for each reprocessing unit for medical devices (RUMED), these different parameters and individual process steps must be determined on site and in a user-specific manner. This occurs during validation, which must be repeated regularly.

Automated reprocessing should be favoured over manual reprocessing, since washer-disinfectors allow for standardised reprocessing and thus provide a high level of process safety and thus reproducibility of results. The reprocessing step in the washer-disinfectors follows specific process steps and parameters (see Figure 2). Thus, a cold pre-rinsing step, generally fed with softened water, comes first in order to remove any adhered dirt and other water-soluble and adhered contaminants.

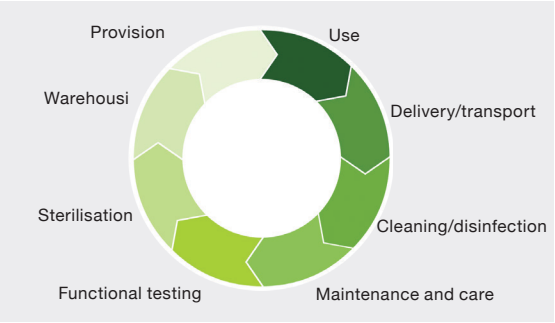

Figure 1: Instrument cycle.

Step 2: Cleaning

In the second step, the main cleaning should preferably be performed with softened or demineralized water. Depending on the articles being reprocessed and the processing chemicals being used, this may, for example, take place at a processing temperature of 55°C and a holding time of 10 minutes. In accordance with the AKI recommendation, the use of demineralized water is recommended in all program steps in order to optimize the process and achieve consistent quality of results in all program steps.[3]

Object-specific parameters (time, temperature, concentration) should be selected based on the material compatibility of the items being reprocessed and the optimal effectiveness of the detergent being used. Detergents based on enzymes, tensides, complex-forming agents, corrosion inhibitors and/or alkaline carrier agents are usually optimally effective at 50-55°C, highly alkaline detergents at 60- 70°C. Currently, the most commonly used cleaning agents in Germany and throughout Europe are (mild) alkaline detergents with different enzyme components that work at about 55°C and a pH value of between 9.5 and 10.5. Some manufacturers now include cleaning agents with pH values in the neutral-mild alkaline range in their portfolio. They are characterized by compatibility with a wide range of materials, especially with sensitive instruments, as well as by excellent cleaning performance. When selecting the cleaning agent, the pH value should

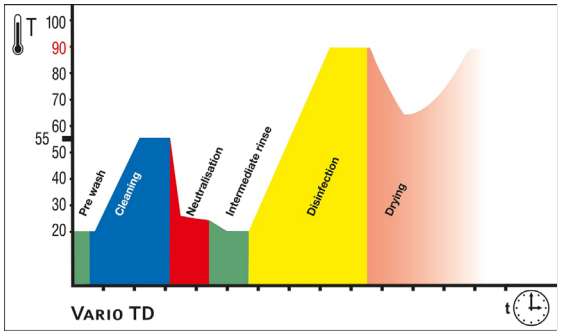

Figure 2: Conventional course of the process in a washer-disinfector.

play a secondary role, since the proven cleaning performance is most decisive.[2] For alkaline media, neutralisation is performed after cleaning in order to neutralise the alkalinity that remains on the articles being reprocessed and in the washer-disinfector chamber and systems that carry or come into contact with water. For (mild) alkaline products, this is not usually necessary, since the alkalinity is diluted in the next process step (interim rinse). In the authors' opinion, conventional neutralisation using acid is to be recommended, because it strengthens the passive layer of the instrument's surface (improves the chrome-to-iron ratio) and therefore helps preserve the value of the instrument.

Step 3: Interim rinse

In order to rule out chemical residues in the rest of the process, a rinsing step (interim rinse) is performed. The result should comply with the biocompatibility values for final rinse water indicated by the manufacturer of the processing chemicals to prove absence of processing chemical residues. When reprocessing instruments from highly specialised fields (e.g. ophthalmology), an additional interim rinse step may be necessary. The guide value in µS/cm is often used as a parameter for allowable processing chemical residues (cleaning and neutralising agents)[2]. The manufacturers of the process chemicals make available the relevant overviews of biocompatibility values and allowable residual amounts.

> The reprocessing procedures must deliver the valid process and the corresponding parameters in a batch-specific, reproducible manner.

Step 4: Thermal disinfection

Finally, thermal disinfection takes place, for example at temperatures between 90 and 95°C and for 5 minutes (A0 value of 3000). Depending on how the risk of the articles to be reprocessed is classified, a lower A0 value can also be used. If permissible in terms of biocompatibility and materials compatibility, a final rinsing agent can be used in this processing step in order to shorten the drying time. The rinsing agent reduces the water's surface tension, so the instrument surfaces dry faster because the layer of water droplets is not as thick. Depending on the equipment, drying can occur as a next step of mechanical reprocessing in the washer-disinfector.

The reprocessing procedures must deliver the valid process and the corresponding parameters in a batch-specific, reproducible manner. Approval depends on compliance with the parameters and is based on visual inspection. Process indicators can be used in addition and regularly. These process indicators are added to the reprocessing procedures and evaluated. Different models are available on the market, ranging from

visual evaluation through objective reading of these indicators with subsequent manual/digital storage and documentation.

Conclusion

Automated reprocessing procedures are validated in an object-specific fashion, and the results meet reprocessing requirements such as the acceptance criteria in the guidelines of the German Society of Hospital Hygiene (DGKH), the German Society for Sterile Supply (DGSV) and the Instrument Reprocessing Working Group for the validation and routine monitoring of mechanical cleaning and thermal disinfection processes (2017).[4] The final parameters for valid reprocessing depend:

> What is decisive for the use of a mechanical cleaner is not the pH value but rather, as a rule, the proven cleaning performance.

- on the articles being reprocessed: design, materials used, classification of risk.
- the initial contamination: different challenges in the case of contamination and residues in fields like orthopaedics, gynaecology, etc.
- the washer-disinfector.: in accordance with relevant standards, assurance of and adherence to the permissible parameters with respect to dose monitoring, temperature range, rinse pressure on the basis of the loading configuration and program phases.
- the process chemicals: contents, concentration, cleaning performance, optimal temperature, dosing temperature.
- the available water quality and temperature.

Modern cleaning agents may have a pH value <10, thereby making possible cleaning performance as described in the guidelines. These enzyme-tenside combinations can now be found in many sterile processing departments, as they can be dosed at low concentrations and also offer broad materials compatibility. What is decisive for the use of mechanical cleaner is not the pH value but rather, as a rule, the proven cleaning performance. Instrument manufacturers have also continually introduced new materials, and supplemented conventional stainless steel instruments (which can be reprocessed without being compromised at pH values > 10) with new materials like anodised aluminium and titanium. These materials react sensitively to alkaline reprocessing, so surface changes may occur more frequently. Automated reprocessing involves interrelationships among instrument, washer-disinfector and the process chemicals being used.

In 2014, the Robert Koch Institute[5] took up the question of prion-effective processing again, specifically the question of "What pH value is necessary for prion-effective processing?", considering the matter independently of the discussion about "Prion cleaning and prion-inactivating characteristic". For the evaluation of cleaning processes, the particular proven cleaning performance, regardless of pH value or cleaning time and temperature, has been found to be decisive.

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Validation of Automated Reprocessing Processes – Decoupling of Maintenance from Performance Requalification

Dieter Reifig

In the validation guidelines for validation and routine monitoring of automated cleaning and thermal disinfection processes for medical devices (2008) and automated cleaning and disinfection processes for reprocessing of thermolabile endoscopes (2011) of the German Society of Hospital Hygiene (DGKH), the German Society for Sterile Supply (DGSV) and the Instrument Reprocessing Working Group (AKI), the annexes on routine (annual) performance requalification bindingly require adherence to a four-to six-week period between maintenance and performance requalification.

The fourth edition of the validation guidelines on validation and routine monitoring of automated cleaning and thermal disinfection processes for medical devices (2014) already redefined the relationship between maintenance and routine performance requalification (2014 Guidelines, Annex 7: Routine performance requalification (Leistungsqualifikation, LQ), p. 28): "New, modern and more economical maintenance plans are customized for customers, projects and purposes of use. Because manufacturers increasingly distinguish between 'safety-relevant inspection and maintenance' and 'preventive maintenance', this is only possible independently of the performance requalification intervals. Recently, KRINKO/BfArM recommendations, standards and guidelines have increasingly tended to require performance requalification/evaluation after each instance of maintenance (see DIN EN ISO 17665 Part 1/Point 12.5 as well as KRINKO recommendation). The aforementioned points and notes justify removal of the 4-week period."

This text remains unchanged in the fifth edition of the validation guidelines (2017). However, in that edition it is found in Annex 9: "Performance requalification for a particular reason (after maintenance work)." However, it is still the case that many sites adhere to this four-to-six-week period even though it is not necessary. Adherence to this period often turns out to constitute a hindrance when dates for performance requalification and re-evaluation are postponed because regularly scheduled maintenance has not occurred or has been postponed.

The "modern maintenance plans" described in the text of the validation guidelines are now based on factors including equipment cycle counts rather than on the calendar. One reason for this is that in recent years more and more reprocessing units have begun working as two- or three-shift operations; therefore, wear and tear and the associated need for maintenance doubles or even triples. This necessarily leads to a divergence between maintenance due dates and performance requalification dates.

Moreover, it is noted in the text of the validation guidelines that performance requalification/re-evaluation must occur after each instance of maintenance. In this context, reference is made to Point 12.5, "Evaluation of changes", of DIN EN ISO 17665 Part 1. So, what does that mean?

Under Point 12.4, "Performance Requalification", DIN ISO/TS 17665-2 describes how this should be understood and handled: The scope of the re-evaluation depends on the reasons for performance instability.

This means that if a component is replaced (see 12.5 of ISO 17665-1:2006) or the controlling system is modified, it may just be necessary to demonstrate that the sterilisation cycle being evaluated is repeatable. If, in procedures for packaged products and porous loads, air leakage into the sterilisation chamber turns out to be the cause, it may just be necessary to repeat the air leakage test on the sterilisation chamber and then perform a steam penetration test.

With respect to maintenance on washer-disinfectors (WDs), this specifically means, independently of whether maintenance or repair is being performed, that

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after repair and any needed calibration of a dosing mechanism the scope of the performance requalification consists of checking (and documenting) that the actual dosing amount still, or again, matches the programmed dosing amount and thus the specification. By this point at the latest, it becomes clear that a temporal relationship (four-to-six-week period) between maintenance and annual performance requalification is not necessary.

The topic is discussed repeatedly in professional circles, and some experts are of the opinion that annual performance requalification (of washer-disinfectors) and performance re-evaluation of sterilisation processes should be carried out immediately prior to the maintenance that is due. This makes it possible, they argue, to prove that the equipment functioned correctly throughout the year and that worn parts, for example, did not already impair operations at an earlier point in time.

> A temporal relationship (four-to-six week period) between maintenance and annual performance requalification is not necessary.

From the point of view of processing safety, equipment must work correctly at any given point in time and not just four weeks after maintenance. It is thus insignificant whether maintenance dates are based on the number of batches or operational hours, or whether postponement of scheduled maintenance leads to temporal dissociation of that maintenance from validation dates. In this context, it is also interesting to note that annual performance requalification then tends rather to occur sometimes before and sometimes after maintenance. Any differences between equipment condition and proper equipment functioning before and after maintenance can thereby be recognized. In individual cases, maintenance measures can be individually adapted.

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New Validation Equipment for DAC Universal Touch MK IV

Robert Streller, Iven Kruse

Dentsply Sirona introduced the new DAC Universal Touch MK IV at the IDS dental convention in Cologne. The new validation concept developed by Sirona helps orient the individuals who perform the validation and shows manufacturer recommendations regarding the methods and procedures to be used for process validation of the DAC Universal Touch MK IV.

The previous validation concept of the predecessor model, DAC Universal MK III

The DAC Universal MK III is a small steriliser that also cleans, thermally disinfects and maintains medical devices. The norm for small steam sterilisers, DIN EN 13060[1]; the validation norm for steam sterilisers, DIN EN ISO 17665[2]; and the guidelines for validation of small steam sterilisers, DIN SPEC 58929[3], describe the sterilisation process and the process validation for the sterilisation process. In its function as a washer- disinfector, the DAC MK III complies with the norms of DIN EN ISO 15883 with its parts 1[4], 2[5] and 5[6]. For the validation of the cleaning process, the guidelines[7] of the German Society of Hospital Hygiene (DGKH), the German Society for Sterile Supply (DGSV) and the Instrument Reprocessing Working Group (AKI) for the validation comand routine monitoring of mechanical washing and thermal disinfection processes for medical devices are used.

The new DAC Universal Touch MK IV validation concept

Unlike the MK III, the DAC Universal Touch MK IV is strictly a washer-disinfector; it washes, thermally disinfects and maintains medical devices. For the DAC Universal Touch, Parts 1[4], 2[5] and 5[6] of the DIN EN ISO 15883 series of norms apply, as do the DGKH, DGSV and AKI guidelines[7] for the validation and routine monitoring of mechanical washing and thermal disinfection process for medical devices. This results in a number of changes and simplifications for the process validation.
As for the MK III, the manufacturer, Dentsply Sirona, has also prepared a validation concept for the DAC Universal Touch as a guideline for process validation.

Scope of testing for reprocessing procedures

Evaluation of reprocessing procedures generally consists of three parts:

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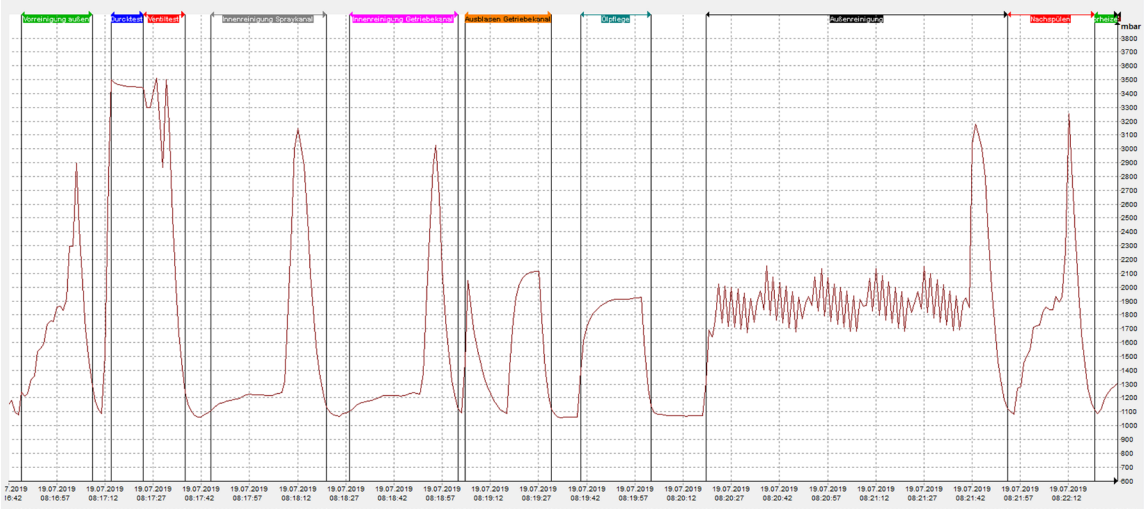

Figure 1: Course of pressure during cleaning in the DAC Universal Touch MK IV. The curves differ significantly from the MK III.

- Installation Qualification (IQ)

IQ involves providing and documenting the evidence that the equipment was delivered and installed in accordance with its specifications. The equipment-specific documents are viewed.

- Operation Qualification (OQ)

OQ involves providing and documenting the evidence that operation of the installed equipment occurs within predetermined limits when used in accordance with the procedures for its operation.

- Performance Qualification (PQ)

PQ involves providing and documenting the evidence that the equipment, as installed and when operated in accordance with the operating procedures, consistently functions in accordance with the predetermined criteria, and that products that meet their specifications are thereby obtained.

General information on Performance Qualification

To demonstrate reproducibility, a program must be tested three times. The "Blue Lid" – for reprocessing hand- and angle pieces and turbines – and the "Green Lid" – for reprocessing ultrasound handpieces and tips, multi-function nozzles, powder-jet equipment and handpieces – are each designed to carry out the function of a washer-disinfector's injector rail. The instruments are fitted directly onto the lid using a connection adapter. This ensures that the individual lumens are rinsed in a targeted way with water, air or steam and then lubricated. In the case of lid combinations, runs can be combined as long as the cleaning or disinfection program sequences are identical. Within the context of routine performance requalification processes, the tests are each conducted once. An extension of the validation interval is described in the validation concept. After initial validation of the equipment, another performance assessment should be conducted after twelve months and then again after twelve months. After that, the validation interval can be extended to up to 24 months or 4,000 cycles, based on an assessment of risk.

Figure 2: Test adapter with test bodies and actual contaminated instrument on the MK IV.

Figure 3: Test adapter with test bodies and actual dirty instrument MK III.

Cleaning performance testing (PQ)

Cleaning performance is tested with three test bodies contaminated in a defined fashion with sheep's blood

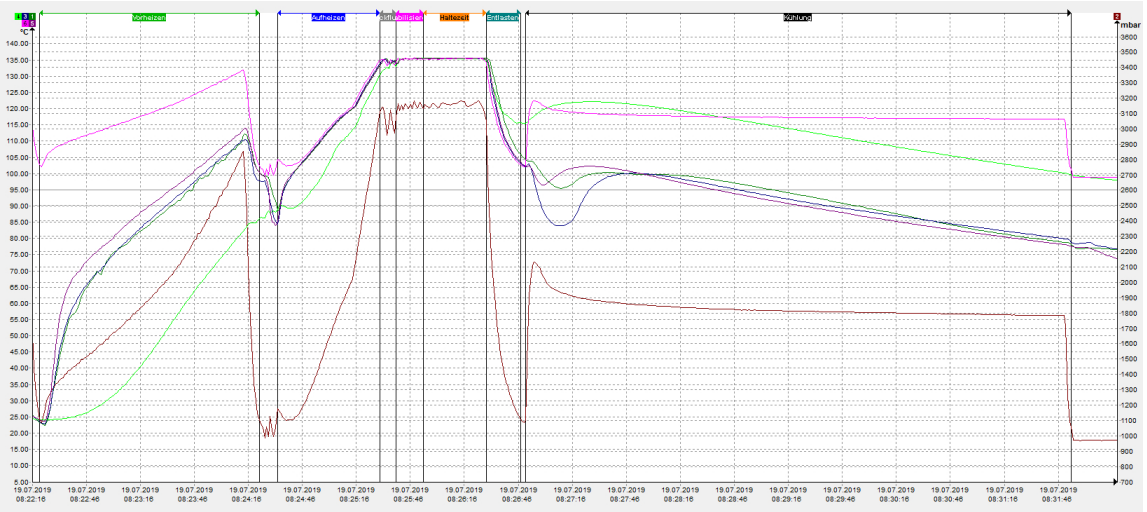

Figure 4: Temperature and pressure course during thermal disinfection in the DAC Universal Touch MK IV. The curves differ significantly from the MK III.

in accordance with DIN EN ISO 15883-5[6] for interior cleaning and for exterior cleaning as well as three actual contaminated instruments. The process is like that for the predecessor model, DAC MK III.

Thermal disinfection testing (PQ)

When testing thermal disinfection in the DAC Universal Touch MK IV, the disinfection performance is checked. The Process Challenge Device (PCD) test body that is used serves to provide evidence of internal disinfection. In order to provide evidence of disinfection performance, four temperature sensors and one pressure sensor are used in the chamber; the way they are arranged is unchanged from the DAC MK III.

Figure 5: Data logger of the EBI 11 series.

Course of validation (PQ)

As with the DAC MK III, the cleaning performance is tested first. This ensures that the DAC Universal Touch MK IV does not heat up the instruments and the test bodies, thereby fixing proteins. This makes it possible to ensure adequate cleaning of existing contamination. ebro®, in collaboration with Dentsply Sirona, has developed a new adapter set (Figures 5 and 7) for the Universal Touch MK IV and the MK III. In addition to simplifying handling, both the test bodies for exterior and interior cleaning as well as actual contaminated instruments can be adapted together in one test. This is a big advantage over the old lid adapter of the DAC MK III, since that requires that another test be conducted. The disinfection parameters are thermally tested after the cleaning performance is tested. Those parameters are measured in the DAC Universal Touch MK IV using thermologgers (Figure 4), and then the A0 value is calculated in the software. For safe and reproducible positioning of the ebro® EBI 11 data logger, on the MK III the ebro® logger holder (Figure 5) is fixed onto and snapped into the channel intended for the Class 5 indicator's clamp. Safe and reproducible thermal testing

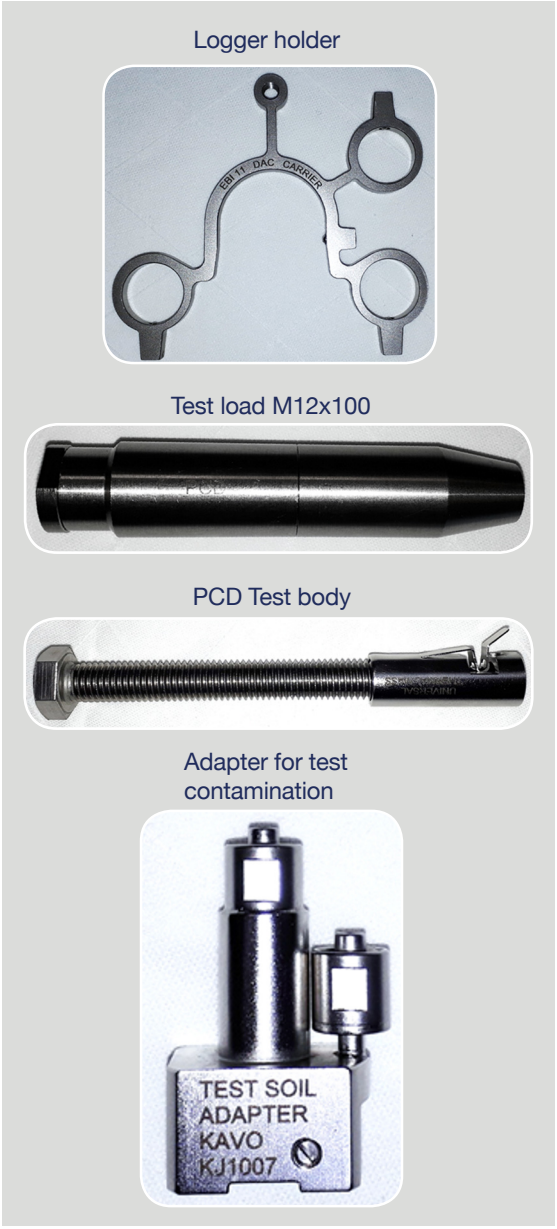

Figure 6: Overview of adapter.

Thermal load (5 x M12x100), PCD test body, column with logger holder and loggers on the lid of the DAC Universal MK III.

PDC test body, centre with logger holder and centre Loggers on the lid of the DAC Universal Touch MK IV

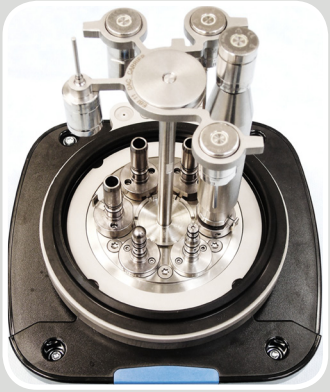

Figure 7: Configuration of an assembly for thermal testing.

under actual conditions is thus possible. The DAC Universal Touch MK IV lid is no longer supplied with media via the base of the chamber but rather via connections that are next to the lid. In order to be able to position the ebro® data logger EBI 11 here too, a new, additional centre column (Figure 7) has been constructed.

The centre column is screwed into the middle of the DAC Universal Touch MK IV lid and positions the logger holder. The loggers can be attached to it as usual. The position of the machine's reference sensor has, in the DAC Universal Touch MK IV, been switched from the left side (under Connection 1) to the right side (under Connection 4). This means that the open side of the clamp must be above Connection 1 with the DAC Universal Touch MK IV and that the PCD is fixed onto Connection 1. This positioning ensures that the EBI 11 sensor in the chamber below is as close to the reference sensor of the DAC Universal Touch MK IV as possible.

Thermal disinfection at 134 °C

The most important new development on the DAC Universal Touch MI IV is the reduction in hold time. Because the DAC Universal Touch MK IV is defined as a washer-disinfector, and therefore sterilisation with an F_0value of 15 minutes is not required, the hold time has been reduced. For disinfection, reduction to a microbial level of 10^{-5} is required. The DAC Universal Touch MK IV disinfects with steam, meaning the A_0formula cannot be used. The A_0formula applies only for hot water, but not for water steam. If the A_0formula were nevertheless used, it would result in an A_0 value of >20,000,000. Therefore, the F_0formula is used, and the target value is reduced by a factor of 10. This results in a target lethality value of 1.5 minutes. In order to be able to carry out automatic assessment as usual, a new user-defined program (Figure 10) has been developed for process validation in the ebro® Software Winlog. Validation. Simple assessment of all processes, as with the DAC MK III, is thus possible.

Figure 8: Centre column for positioning the data loggers in the MK IV.

The following have been defined as assessment criteria for a positive result:

- Temperature range 134 – 137° C,
- Duration > 30 seconds,
- Lethality (F_0value) > 1.5 min.

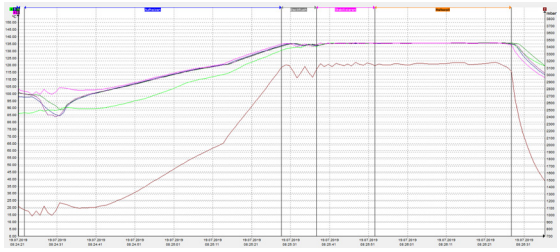

Figure 9: Disinfection phase including heating.

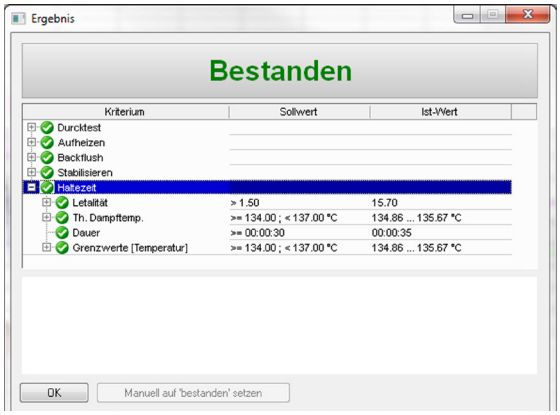

Figure 10: Result from the software.

Pre-heating has already been performed in a similar fashion since August, 2017 with the DAC MK III. The second backflash at the end of the plateau period is likewise omitted.

Conclusion: Simplified validation

Because of the new construction of the DAC adapter for the DAC Universal Touch MK IV with the additional centre column and the new user-defined software program, validation of processes in the DAC Universal Touch MK IV is more easily possible compared with the MK III predecessor model. ebro® offers the corresponding validation training for the DAC Universal Touch MK IV through various seminars.

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Birthing Pools at the Katholisches Klinikum Mainz

Heike Kiesel, Markus Kiesel & Hubert Holz

Pregnant women frequently ask about the possibility of using tubs for relaxation prior to giving birth and about special pools for water births. Such tubs and pools are an important factor in their selection of a hospital for labour and delivery, and are therefore kept on hand in many obstetrical departments.

Our experience in the labour and delivery ward of the Katholisches Klinikum Mainz (kkm) shows that during tours of the labour and delivery rooms almost 80 percent of pregnant women ask whether a tub is available for giving birth or relaxing. However, only a small percentage of the women then actually use the birthing pools, while the relaxation tubs are used very frequently. A water birth has some advantages for the mother-to-be and the child: It involves a shortened dilation phase, significantly fewer episiotomies and a lower level of analgesic usage1. Provided any contraindications are observed, the child's safety is ensured in a water birth.

In terms of infectiology, there are also no disadvantages compared with "land births" for the women giving birth or the new-born2, as long as certain hygienic precautions are observed. The provisions and measures to be observed can be found, among other places, in the recommendations of the DGKH3, the AWMF4 and the RKI/ KRINKO recommendations for surface disinfection5. For this reason, kkm's hospital hygiene department has, analogously to the HACCP system for kitchens, defined critical control points for the process of "preparing and using birthing tubs". Below we present our experiences from the controlling process and address various problems that are frequently not considered. The explanations below apply both for traditional birthing pools and for the relaxation tubs used at kkm.

Relaxation tubs are essentially like regular home bathtubs. A birthing pool, on the other hand, should be accessible from at least three sides, and the labouring woman should be able to get out of it easily in an emergency. It must not have an overflow or air jets. The drain must be large enough to ensure rapid draining of the water in an emergency. Both relaxation tubs and birthing pools must be easy to clean and disinfect. No anti-slip mats may be laid down in the tub or pool.

Critical control points for birthing pools

At kkm, we have defined the following critical control points (ccp) and established standard measures for preventing risks. Regular monitoring of the measures, with pre-defined limit values, ensures that any risk to patients can be ruled out. If a limit value is nevertheless exceeded, the further procedure is likewise already established.

Figure 1: Birthing pool at kkm.

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Figure 2: relaxation tub at kkm.

Critical control point: Water

One of the critical control points is the water used for filling. Microbiologically, the water that is used must be of at least drinking-water quality and must also contain no pathogens such as legionella or pseudomonas bacteria. Because the possibility of occasional inflow through tap water lines can never be entirely excluded, it is generally recommended that appropriate water filters be used to make sure legionella is kept out. Nevertheless, the water used must still be monitored quarterly in accordance with the German Drinking Water Ordinance (Trinkwasserverordnung, TrinkwV). In addition, surface samples of the filter are taken to rule out retrograde contamination. At kkm, the hospital hygiene department does this in coordination with the particular area. Water filters must be changed regularly as per manufacturer specifications. At kkm, this is organized centrally via the technology department and is carried out using a checklist. This ensures that the standing time is not exceeded.

Critical control point: The woman who is giving birth

Another critical control point is the potential microbial flora of the pregnant woman. At kkm, it has been established that the pregnant woman may use the relaxation tub provided her waters have not yet broken. If her waters have already broken, full immersion involves the risk of contracting an infection from the microbe-containing bathing water. In this case, the pregnant woman may shower, provided the baby's head

Table 1:
Critical control points (CCP) for water births; *Limit value of the surface sample as specified by the Rhineland-Palatinate state testing office.

CCP	Problem	Standard measure	Controls	Limit value	Measure to be taken in the event of deviation
Inflow water	Contaminated water jeopardizes mother and child	General use Water filter, 0.2 µm, documentation of standing time	Control of filter change	Standing time as per manufacturer's specification	Filter change and employee training
			Surface sampling on water filter	Max 12 CFU/24cm² *	Filter change, clarification of cause
			Inflow water sample	TrinkwV and DIN 19643	Decommissioning of tub, clarification of cause, repair/ technical measures
Woman who is giving birth	Infection/colonisation with particular pathogens * > Risk posed to staff/ child	Exclusion from tub use in the case of evidence of certain pathogens	Prenatal MRSA screening Negative serology Gonorrhoea ruled out	MRSA negative	If no findings: Labouring woman may not use tub
Disinfection of tub	Transmission of pathogens to other people	Adhere to full exposure time as per manufacturer indications Disinfectant block siphon Checklists	Surface sampling of tubs	HAV, HBV infection, HIV- and HCV-negative	Controls, decommissioning of tub if needed, clarification of cause, employee training
			Scoop sample of tub water	Max. 12 CFU/24cm² *	Decommissioning of tubs, clarification of cause, repair, employee training
Labour and delivery area employees	Improper use or preparation	Use only by trained employees	Training and evidence of instruction	Documented evidence	Conduct follow-up trainings

is firmly in place in her pelvis. For each individual case, the treating physician decides whether the woman giving birth may use the birthing pool or relaxation tub. However, women giving birth must not be permitted to have water births if an existing infectious disease means there is an unreasonable risk to staff or the child (e.g. HAV, HBV infection, HIV and HCV positivity, gonorrhoea). A positive MRSA test is also a criterion for ruling out water birth.

> At kkm, it has been established that a pregnant woman may use a relaxation tub provided her waters have not yet broken.

Critical control point: Surface disinfection

Because of the potential transmission of pathogens to woman, surface disinfection is another critical control point. The tubs must therefore always be prepared as per the specifications of the Commission for Hospital Hygiene and Infection Prevention of the Robert Koch Institute (Kommission für Krankenhaushygiene und Infektionsprävention, KRINKO). It is especially important to bear in mind that according to KRINKO, the full time of exposure to the surface disinfectant must be observed at all times. The reason for this is that the tubs must be rinsed out with drinking water before being used again in order to remove residual disinfectant. In order to avoid retrograde contamination, especially through the larger drains in birthing pools, the siphon must be regularly "blocked" with a disinfectant with an expanded spectrum of effectiveness. At kkm, this is conducted daily and after use. Here too, the full time of exposure to the disinfectant must be observed.

Critical control point: Employees

The fourth critical control point relates to employees. First of all, only employees who have been instructed and training may be involved with the use of tubs and pools. Moreover, it has been shown that the quality of preparation by in-house employees who are permanently assigned to the unit is significantly better.

Experiences with the birthing pools

At kkm, the plan for preparing and testing birthing pools and relaxation tubs has proven to be effective. Therefore, a sample of the inflow water, a scoop sample and six surface tests are taken at defined sites during the regular sampling regimen. The sample results for the filtered water have always been fine. Likewise, no microbial growth was detected in the surface samples from the filter. Thus, the inflow water can be ruled out as a source of abnormal results.

Abnormal scoop samples, surface testing and plate with skin microbes

Occasionally, there were abnormal findings in scoop samples. Through discussion with the employees in charge, improper blocking was found to be the cause. The situation occurred when reprocessing was performed by a substitute rather than by the regular cleaning staff. The problem was rectified by training the substitute in advance and having that person carry out the reprocessing together with the regular employee beforehand.

Another time, some surface tests and the scoop sample were both abnormal. The controls were then intensified, but the findings continued to be abnormal. The hospital hygiene department accompanied the cleaning employee during reprocessing, but no deviations were seen. Nevertheless, the controls continued to be abnormal, and the cause remained unclear. Until the hygiene official saw, during a control, that the husband of a woman who was giving birth had laid jackets and bags on the tub that had already been prepared. To prevent this from happening, from then on the tubs were covered

Figure 3: A husband's jacket on the birthing pool.

with sheeting each time after reprocessing. This ruled out recontamination after correct reprocessing, and subsequent controls were normal again.

During a further control, only one surface plate was abnormal; coagulase-negative staphylococci were detected here, while the results of the water samples were normal. A conversation with the cleaning employee revealed that she had forgotten to disinfect her hands before removing the sheeting. The employee was given additional training, and since then the problem has not recurred.

Combined inlet and drain & mobile birthing pools

Prior to acquisition of a birthing pool or relaxation tubs, it is also important to check whether the manner of construction could lead to hygiene risks. There are models that have a combined inlet and drain. This makes it impossible to prevent retrograde contamination of the water and is thus not suitable for use in a hospital. Mobile birthing pools, used primarily at home, must also be viewed critically. In these heatable tubs, the water is often retained several weeks without being treated, which leads to an incalculable risk of microbial contamination. This also led to a warning by the RKI.6 At kkm, of course, such tubs are not used.

Conclusion

Relaxation baths and the option of a water birth are an important component of peripartum care. Safe hygiene practices are absolutely essential in this area. Experience shows that even minor causes can have significant effects. When monitoring results are abnormal, pointing fingers at employees is not helpful. Instead, the hospital hygiene department's job is not just to take samples, but also to critically investigate abnormal results in dialogue with the employees, to find the causes and then to rectify them.

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Innovative Methods for Digitalising RUMED (Reprocessing Unit for Medical Devices) Processes

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In a Reprocessing Unit for Medical Devices (RUMED) there are numerous processes that must be documented in accordance with local quality management requirements. The reprocessing, compliance and safeguarding of properly processed instruments must meet high standards in order to prevent infections in hospitals. Correct reprocessing not only means preventing infections but also preserving the value of the instruments. It is thereby also possible to guarantee a smooth process from the use of the medical product, to storage, and then to its reuse.

Validation and checks

The majority of all the processes in a Reprocessing Unit for Medical Devices (RUMED) are validated. That means that all processes and all the steps within them are checked annually to ensure that they deliver the desired guideline-compliant reprocessing result, and are reproducible. All process steps are documented and they apply as work instructions for the respective process after the validation.

As part of process monitoring, the results obtained are checked intermittently during the year, in some cases daily, to see whether they comply with the validation. As a rule, this review is carried out using checklists. For the washer disinfector (WD) unit, process indicators are used and the batch report is checked. This inspection/batch report is then documented and filed, usually by hand. This documentation makes it possible to track which medical product has been processed, and how, and whether the process was carried out in compliance with the guidelines/validation.

Routine checks of automated processes at the Evangelisches Stiftungsklinikum St. Martin

The Reprocessing Unit for Medical Devices (RUMED) at the Evangelisches Stiftungsklinikum St. Martin is one of three that belong to the Gemeinschaftsklinikum Mittelrhein group, which has five locations in the

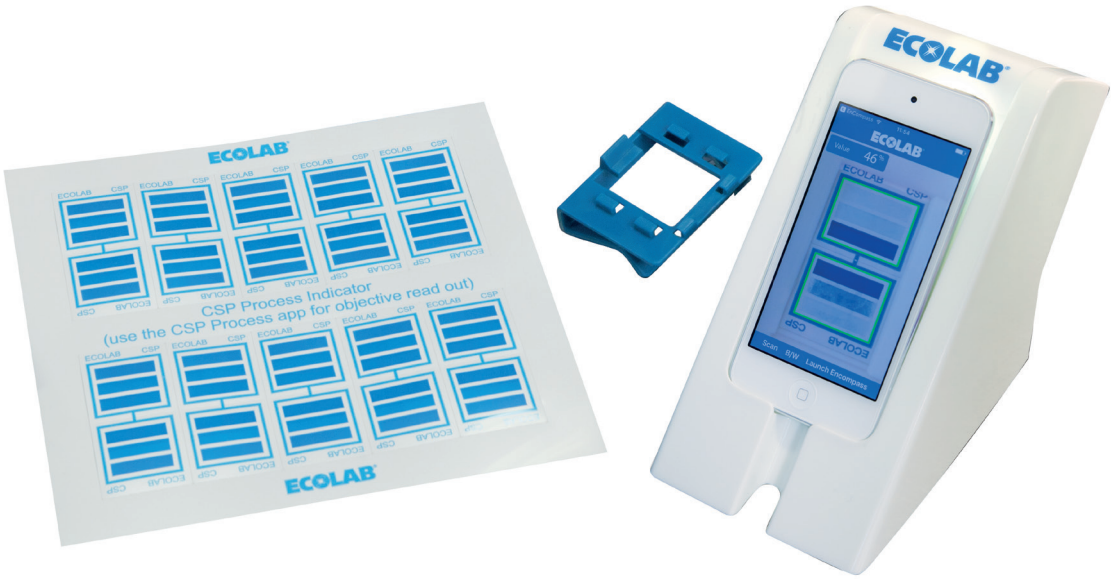

Figure 1: Central Sterile Program equipment by Ecolab.

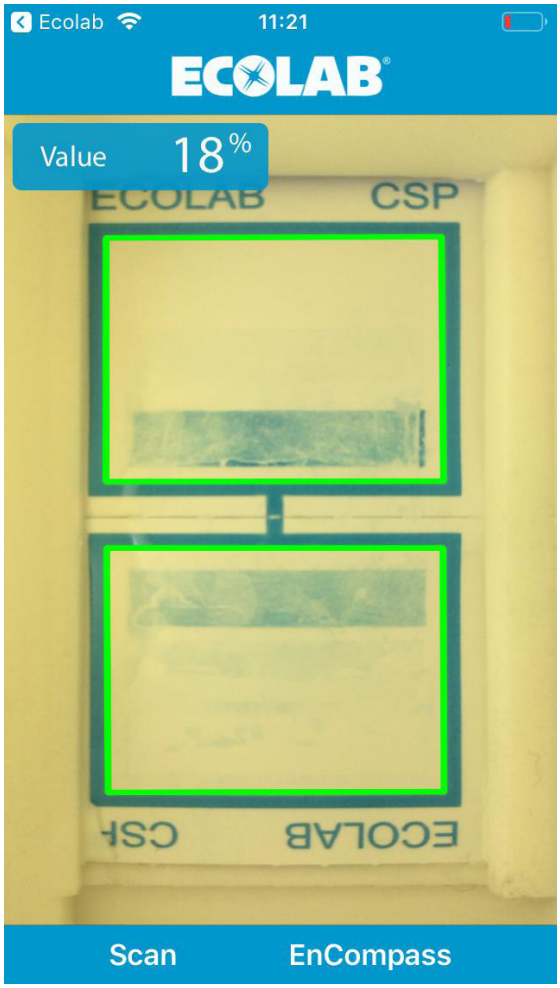

Figure 2: Evaluation of the indicators using the iPod camera.

Koblenz area. We process around 30,000 sterile items each year using five WDs by the Steelco company and one container washing system (CWS) by the Belimed company. The machinery used by the Evangelisches Stiftungsklinikum St. Martin is validated annually, as part of which the performance of the WDs is checked. In order to carry out additional monitoring between the validation dates, we use indicators (load check) by the Albert Browne Ltd company to check the cleaning performance, in accordance with the manufacturer's specifications. Once a week, we put in several indicators per WD/CWS. The staff member who performs this task then analyses this indicator by carrying out an inspection to determine whether the impurities have been completely washed away or whether there are remaining residues. This is no problem for experienced members of staff. However, if the employee is unsure, a colleague or the shift supervisor is consulted to decide whether the batch can be released as it is or whether a more detailed examination is necessary. In the past the result was documented manually, the indicator examined, and then a signed document filed by the employee. Back then we were already looking for ways to simplify processes and we introduced results analysis by EuroSDS, the sterile materials and instruments management system. This switch alone resulted in a time saving of 50 per cent for employees since manual work was no longer necessary.

New digital pathways for routine checks

In the past, we also documented most processes manually at the Evangelisches Stiftungsklinikum St. Martin. This procedure involved a great deal of work and required a correspondingly high level of resources. As a result, we began engaging with the topic of digitalisation at an early stage in an attempt to find new ways of doing as much as possible digitally. One possible solution we have been testing since April 2019 is the new Central Sterile Program by the Ecolab company.

The program includes process indicators for carrying out routine checks of the WD processes on the basis of constant performance parameters. The implementation procedure starts with establishing the baseline. In addition, with the validation, a corresponding number of process indicators is evaluated for each WD in order to create the baseline for a digital reading of the indicators. The indicators are not evaluated visually as has been the case until now, but rather objectively using an iPod camera, and are photographed immediately for documentation purposes (see Figure 2). All further routine checks are then measured against this baseline, and thereby in parallel with the validation. Whether the value lies within the tolerance range or not is immediately displayed visually (see Figure 3).

It is also possible to document a photo of the load with the respective batch. In accordance with the manufacturer's specifications, two indicators are always put in the WD per batch for double checking. If only one shows a deviation, it can be attributed to a misplacement or to an unwashed area. The photo of the load is therefore important in order to understand these results. The evaluation of the indicators and the

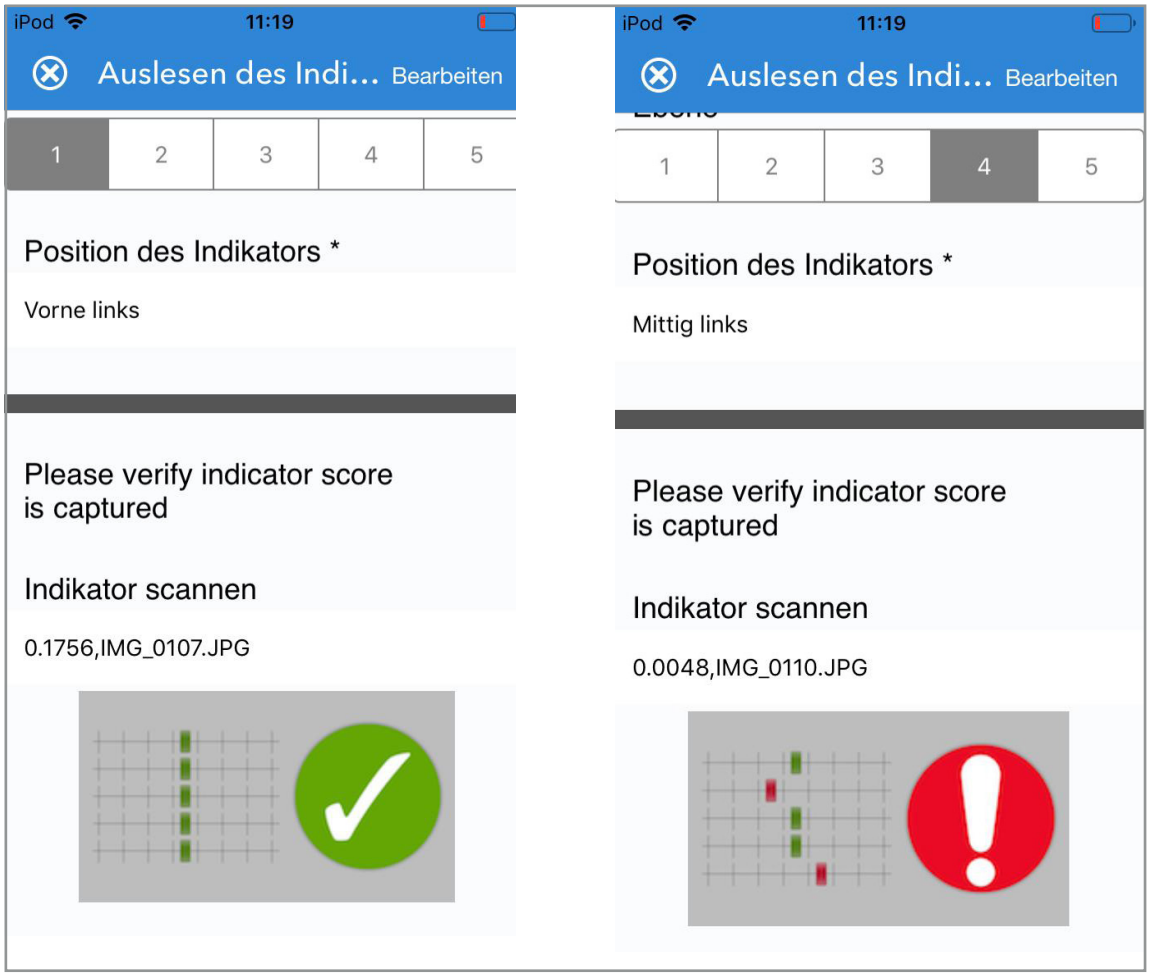

Figure 3: Reading the indicator and tolerance deviation.

documentation of the routine check is thereby simplified and eliminates the human component of the assessment. In addition to the routine checks, checklists (e.g. the WD's daily checklist or periodic checklists) can also be displayed. These are also entered digitally using the supplied iPod. The iPod, and the apps installed on it, is generally the program's input medium. We have set up all our employees so that they are able to use the app and can perform inputs via the app. As a result, the data is also personalised and trackable.

Digitalising processes in this way offers us great advantages because not only have we seen a reduction in time expenditure but also a clear improvement in process quality and thereby in process safety. The routine checks, in particular, help us to respond to even the smallest changes because we use the indicators with every batch and can therefore immediately identify deviations from the validated process. Another major advantage of digitalising our processes with the Central Sterile Program is the analysis function. It can be used in the short and long term to evaluate all our machinery via the customer portal as all the collected data points are saved. In the customer portal we have been able to see the entered data both in tabular and graph form, allowing us to examine the overall performance of our WDs and identify deviations. It is possible to trace the digital documentation of the load photos and the input of the corrective measures carried out. Furthermore, it quickly becomes clear whether the performance of a specific WD diminishes over time and whether the treatment process needs to be reviewed.

Conclusion

All the processes in the RUMED are validated, should remain constant between these validation dates and lead to a reproducible result in order to guarantee an

appropriate processing quality. Routine checks such as the WD processes can help with this, but they are usually subjectively evaluated at present and documented manually, which is very time consuming.

A new, digital and innovative approach is offered by Ecolab's Central Sterile Program, which delivers an objective evaluation and subsequent digitalisation of process indicators for the routine checking of WD processes. The direct information in cases of deviation, and the easy and intuitive operation using the iPod and accompanying app, allow us to respond immediately to process changes. All data is collected on a customer portal and represented clearly. As a result, we can examine our WD process performance and produce various analyses. These help us to achieve process reliability and thereby also to improve quality. For us, this digital solution represents a significant step towards making processes safer, responding immediately to deviations and using capacities in the RUMED more efficiently.

> This digitalisation of processes brings with it great advantages for us because we have been able to cut time expenditure and improve process quality and process safety.

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