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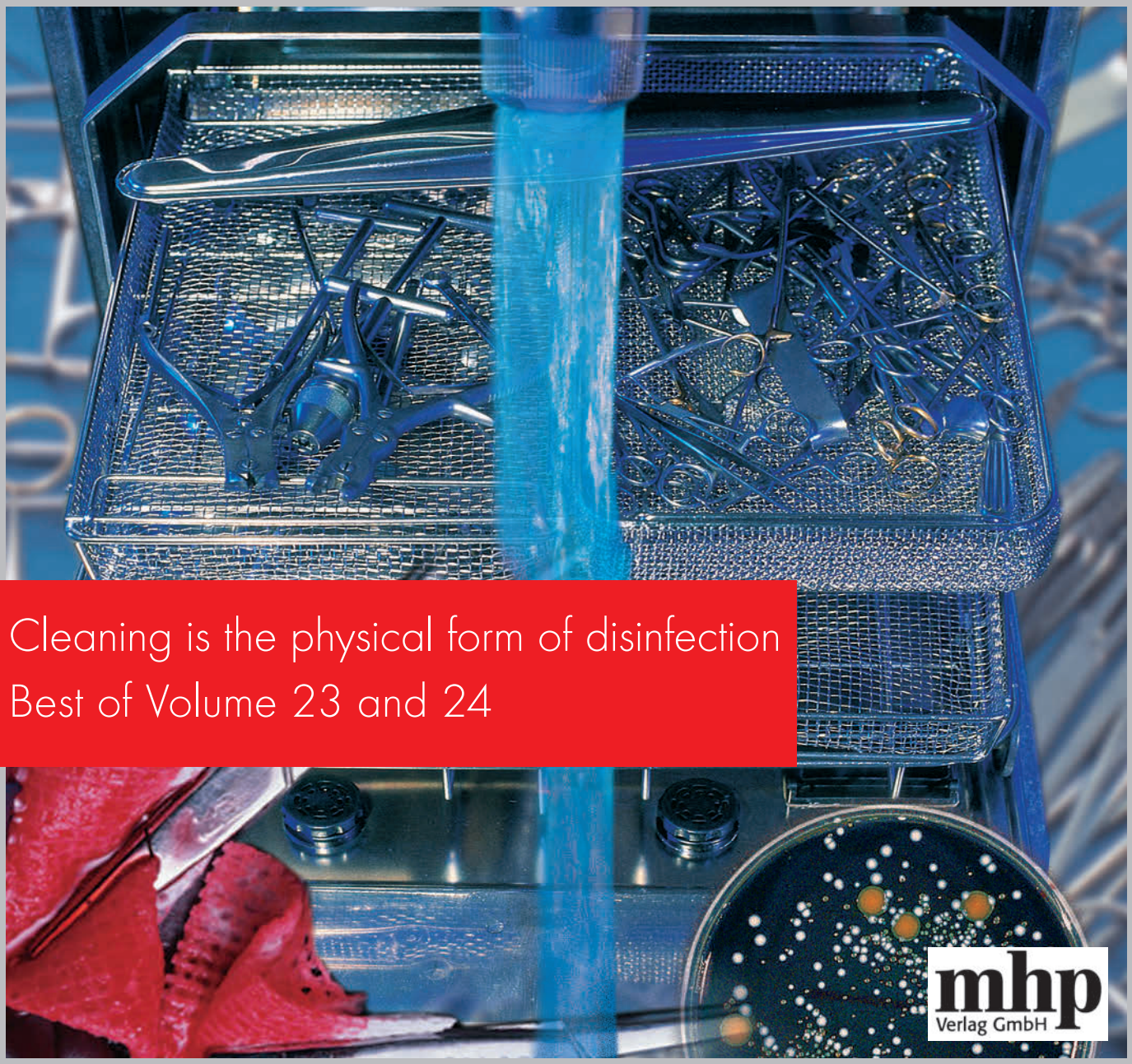

Cleaning is the physical form of disinfection

Best of Volume 23 and 24

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Black Box Cleaning

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Cleaning equals Dis-Infection?

The intention of the process step of the cleaning of medical devices is decontamination, the purpose being disinfection, among others. Depletion is carried out for both functional and hygienic reasons, since many medical devices have moving parts and consist of fine-mechanically sensitive structures. These must be able to slide in order to function properly. And they must not make you sick by transmission of infectious or toxic particles (including allergic reactions).
Hazards caused by medical devices are certainly only a small part of the potential hazards to which a person is exposed in the hospital. Some may even claim that reprocessing is more of an organizational topic than one of hygiene. The objective of hygiene is prevention, she builds ramparts and encourages a behavior that impedes the transmission of microorganisms. She is there to help prevent worse, since the patient is probably already weakened and expects help, not additional pathogens!
Various medical devices come up close to the patient, wether it be (semi)-critical endoscopes or "critical" surgical instruments, cutting through tissue at times, hurting. The doctor may only do what he does in order to heal!
A transmission of pathogens may occur through

– contact with/without injury, with/without object or instrument
– transport of particles
– by squandered liquids/droplets

It is the following proliferation of the microorganisms, that makes this transfer so severe. This should be prevented by disinfection and sterilization measures.
Example endoscopy: (e.g. intraoperative endoscopy, cholangioscopy) for interventions into regions of the body that are not microbially populated, not only a high level disinfection, but an effective method of sterilization needs to be chosen.
Therapeutic endoscopy is getting to be more and more like surgery! We will have to deal with questions of dis-infection (in this extended meaning of the word) increasingly, with adequate methods, measurements and the verification of achieved and achievable results of depletion and biozidal effects (disinfection). We need to make them verifiable by means of appropriate procedures. Therefore, standards bodies and guidance groups worldwide strive to agree on terms and procedures, in order to describe the requirements.
Current thinking within the scope of guidelines on process validation does not always include the actual processes themselves and the sub-processes of manual and machine-assisted cleaning, the reliable production of a sterile barrier system, as packaging of medical devices, and the sterilization process in particular.
Robust (ie. reliable) test systems for the efficiency of depletion, however, are still missing. Why? It is not easy to recreate a clinical load condition and the currently available models have weaknesses and are the subject of a lively debate among experts. It is true that no model can depict everything.
Take endoscope washer-disinfectors, for instance: Dummies, in conjunction with standardized artificial soils would have advantages in terms of comparability of the processes and, incidentally, help to standardize the dimensions of endoscopes. The endoscope manufacturers would have to present the dimensions and plus-minus tolerances of their products and deviations from the dummy would have to be justified professionally. This was the way in which trocar sizes and the inserted sliding shaft instruments were standardized in Germany, for safety reasons (DIN 58928-19/20). The background: it had happened repeatedly that the tolerances were so tight, that when using a trocar and an instrument from different manufacturers, the trocar was too narrow and could be pulled out along with the instrument; with obvious dangerous consequences for the course of the operation.
Today the dimensions (and the tolerances) and (channel) structure of endoscopes vary considerably with different manufacturers, which poses significant problems for WD-manufacturers, in terms of requirement profiles, they have to fullfil (regarding successful purging of channels and reliable cleaning). At least, the German "Validation Guideline for Endoscope WD" applies a division into three endoscope "families", each of which contains devices that share common structural features. For successful risk management, a grouping of various medical devices in accordance with their properties is useful and it is widely expected to be implemented in the revision of ISO 17664.
Back to clinical reality: What sort of contaminations can we determine anyway? We can detect bacterial colonization and rinse off/flush out residuals and test them for certain components. Microbiological tests on nutrient media are characterized by high sensitivity (few germs may suffice for colony forming units), as well as specificity (not everything grows on/in a bouillon). What we need, though, for our risk assessment, in addition to qualitative findings, are quantitative irrigation measurements on achievable depletion (eg. protein measurments), taking into account, that the recovery rate is basically unknown.

The goal would have to be the definition of treshold values and warning limits (relevant to the intended purpose of a given medical device) that would differ for micro- or macro-instruments and also with respect to the allocation of residues on the surface of a specific instrument. Bedpans may then have higher treshold values. These values would have to be in the non-visible range, as low as is technically feasible, since it is highly unlikely that we can obtain reliable clinical data with respect to anticipated rates of infection in case of a certain limit in contrast to another. As far as the percentage recovery rate of a (test) soil is concerned, this also requires an appropriate (with regard to soil) specimen.

No insight without sight!

No value without evaluation!

Not every step is a step forward!

Meaning, we must be willing to re-evaluate our findings time and again, to include into our assessment new findings due to determined data and due to the state of technology and science.

Considering the discussion about the ability to clean, the ”cleanability“ of medical devices, quality management comes to mind, with the important tasks of risk assessment, analysis and control. We shall not dwell on the question whether a certification of CSSD (according to EN ISO 13485) does actually improve said CSSD's capability of reprocessing ”critical“ complex structure and possibly thermolabile medical devices.

As far as this issue of FORUM is concerned: Cleaning is disinfection, of course, because it reduces the amount of contamination, that may just be microbiological in nature! And utilizing ultrasound, we have the opportunity to support cleaning of particularly inaccessible surface structures by an additional preparatory cleaning step. In some manufacturers' instructions for use this is even specifically requested, as part of a validated reprocessing method according to ISO 17664: 2004.

Cleaning requires acceptance criteria with practical relevance. In addition to a practical report we look at the various considerations for measuring depletion, from the test model to the test specimen. We deal with surfactants (tensides), whose foam behavior affects cleaning in a crucial way, because the depletion ”mechanics“ only work with liquids. And we look into the specifics of the term ”mild(ly) alkaline“. Loan instruments mean additional efforts for the reprocessing team, their quality management and risk analysis. We present a synopsis of some theses written for ”Fachkunde III“ (a specialised training course for heads of CSSDs).

Last but not least, an alternative to the traditional Bowie-Dick test has been available for a couple of years now. Lots of data (including some of our own) have shown electronic BD tesing to be at least equal to the colorimetric test, perhaps even superior, since it has shown to detect errors that the paper test could not detect. Here, we present a comparison between two electronic BD-test models.

From next year on, there will be bilingual FORUM issues for different international markets, with English being the common language, accompanied by another local language – dealing, as always, with questions of reprocessing processes and being a platform for presenting innovative products, but not an advertising brochure. We will start with the English-Spanish FORUM PanAmericano.

In addition, the autumn of 2016 will see the publication of our book, with the characteristic title ”Black Box Cleaning“.

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Cleaning is Dis-infection: on Depletion and Inactivation of Microorganisms

T.W. Fengler

"The less residues can be found on the instruments, the easier we can achieve sterility!" This was the message that the late Helmut Pahlke (at that time head of CSSD at the hospital Moabit, later Surgery Instruments AG Berlin) confronted us with since the 1990s. He also liked to demonstrate how to achieve amazing cleaning results with a cold pre-rinse without detergent. Logically, he applied this insight when advising various sterile supply departments in Germany by turning off the so-called "epidemics-programm" of the WD, in which the washing solution was discharged at 93 °C into the sewer (but protein residues remained on the instrument) and switching to "cool" pre-cleaning and warm cleaning (under 50 °C).

The reprocessing of medical devices is supposed to "rid" them of micro-organisms of any kind, particularly by cleaning (depletion), disinfection (inactivation by biozidal action) and sterilization measures (inactivation by pressurized steam or biocidal agents involving dry forms of bacteria, the spores).

But what really distinguishes cleaning and disinfection, if we look at it from the angle of the desired result, rather than the involved processes?

Disinfection accounts for a significant part of the antiseptic method of operation. According to the German Pharmacopoeia (DAB) "disinfection" means: "to transfer dead or living material into a state in which it can not infect. For disinfection chemical or physical methods can be used."

This definition fits the bill for cleaning, in as much as removed/depleted materials can definitely no longer infect.

Cleaning ensures that residues of any kind (particles, coatings, poisons) are minimized to a safe degree on or in the medical device. As a result of cleaning, the medical device must be substantially free of protein residues again, before being used on the next patient. But a depletion of microorganisms by about 2.5 to 9 orders of magnitude, which defines "cleaning", is quite ambiguous as a definition and quantification.

The wide range by itself shows, how unhelpful the application of depletion kinetics in log steps is when applied to the kinetics of cleaning, in particular because the initial amount of contamination, the load or bioburden is unknown[1].

Surely the important factor is the result, minimized residual contamination, and wether is has been reached – regardless of the initial contamination! So after proper cleaning, the instrument must be visually clean, and a residual amount, which is to be determined, shall not be exceeded.

Clinically relevant contamination indicators (e.g. as a carrier matrix for microorganisms such as bacteria, viruses, fungi, parasites) are

- proteins and their components
- mucus
- biofilm-capable substrates
- hemoglobin
- bone marrow
- pharmaceuticals (e.g. contrast agents)

While cleaning decontaminates by depletion, disinfection acts by inactivation of potentially pathogenic "remnants" (biocidal effect e.g. denaturation and precipitation). Achieving a "minimum value" of such residues is the ultimate goal. If it were possible to achieve a one hundred percent removal of adhesions, sterilization would no longer be needed.

Therefore, the sterilization process (if necessary according to Spaulding's Classification) must above all guarantee complete penetration of the sterilizing agent (saturated steam, ethylene oxide (EO), formaldehyde (FA), hydrogen peroxide, peracetic acid). The desired result for use on/in "critical" sterile areas of the body is then "sterility" and it is not provable. Sterility is subject to a scientific and organisational reserve: If the sub-processes were organized correctly (planned and implemented), it can be assumed that there is sterility. A review of the medical device ensemble in the sterile unit (STE) is costly and destructive (ie. the match has ignited, but now it is gone).

However, a sampling plan as a means of risk management is recommended in clini-

1 In rare instances where the initial bioburden was measured, the results showed very different values for the microbial load: «For example, the bioburden found on flexible gastrointestinal endoscopes after use has ranged from 10^5 colony forming units (CFU)/mL to 10^{10} CFU/mL, with the highest levels found in the suction channels. The average load on bronchoscopes before cleaning was 6.4×10^4 CFU/mL. Cleaning reduces the level of microbial contamination by 4–6 log. [Guideline for Disinfection and Sterilization in Healthcare Facilities, William A. Rutala, Ph.D., M.P.H., David J. Weber, M.D., M.P.H., and the Healthcare Infection Control Practices Advisory Committee (HICPAC), 2008 p.13]

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cal practice. Sterile supply or medical devices, which have been stored for 6 months are opened under sterile conditions and are microbiologically examined for growth in a highly specific and sensitive way.
This allows not only for a statistic to be built, but also to prove one's care efforts for one's own work (quality of production of processed items).
A disinfectant is bactericidal or bacteriostatic and/or sporicidal, virucidal, fungicidal, in short: it is biocidal, ie. germicidal. The requirements regarding safety and efficacy are different for surface-, hand- and medical device disinfectants.
Usually disinfection achieves a reduction of vegetative microorganisms and viruses of at least 5 orders of magnitude, so that (together with the minimum value that cleaning should achieve) a total reduction of at least 7,5 orders of magnitude can be expected. According to our guideline an overall reduction by 9 log steps should be achieved in the reprocessing of endoscopes, incidentally. The logarithmic approach describes the power, but we are interested in the result. Despite the momentum, it may be too little, if the depletion does not relate to an endpoint or result.
So what is cleaning, if not disinfectant action, a first step of dis-infection? The fact that this idea is not entirely new can be shown by a quote about the disinfection of cutting surgical instruments with soap spirit: "Since soap is a means for mechanical cleaning and mechanical cleaning is a disinfection method not to be neglected, I thought it desirable to also examine alcohol saponis kalinus quantitatively in this regard." [translated from German. Dr. Jaques H. Polak in Medizinische Wochenschrift 1901 (36)].
And it goes on: "The practical importance of cleaning with soap spirit becomes more clearly apparent since the awls [author's note: a tool to poke holes] were completely covered with dried pus and were treated for no longer than 30 seconds. In practice, the instruments are never so badly infected and one can ensure that the pus does not dry." Here, we witness an early attempt at a "worst case"-scenario, that strives to remain focused on the clinical tasks – which, unfortunately, does not apply to a number of test methods for cleanability of medical devices under different conditions practiced today.
The reprocessing of instruments has been a topic for more than 120 years. Even ophtalmic instruments, which have been focused on recently in terms of residue problems, were already the subject of experiments for reprocessing. As today, one was working with test soils, test specimens and test organisms. Meanwhile, the residue on dental handpieces has become the subject of investigations. Yet in the 1980s it was quite common to lay the drill in a bowl of disinfectant and corrosion inhibitor and to rely on the sole power of the disinfectant. Hygiene is indivisible, it must also work in dentistry or in the doctor's office.
Another look at the historical development shows, that, due to the lacking virucidal effect of phenol or its derivatives, it was predominantly replaced by aldehydes. That meant, however, that simultaneous "cleaning" with the disinfectant did no longer take place. Instead, rather the opposite process occurred, in which the organic residues present on the instruments after use were fixated by the chemical disinfection effect. For endoscopes in particular, this can have fatal consequences with regard to function and infectivity.
During automatic cleaning and disinfection the adhesion of remaining soil through heat must be avoided. Does that mean that depletion and inactivation are a contradiction? The process chain of cleaning involves more than just different cleaning methods. Upstream processes serve to prevent contamination or reduce the cleaning effort. The downstream processes include control of the cleaning success in quality assurance and, where appropriate, the environmentally friendly disposal of contaminants and cleaning agents.
Today it is clear: professional cleaning is essential to successful reprocessing and it has to precede biocidal disinfectants and/or sterilization processes. Meanwhile, it has been almost 20 years since the first descriptive standard series EN ISO 15883 for washer-disinfectors (1996) was published. This facilitates the discussion of "automated" cleaning, which nonetheless is always a partly manual task. Yet residue-"freeness" in terms of cleaning and cleanability needs to be duly appropriated. There is a lively discussion going on, about (technically and hygienically) sensible directives, limits and warning values for medical devices and whether they refer to certain areas and/or the instrument as a whole. How are such values to be assessed for a large as opposed to a small instrument? Which values are technically feasible, which values are clinically relevant? If, for example, the presence of contaminants can already be affirmed visually-tactile, then analytical examination in a laboratory and such a limit is of course superfluous - but that may differ, depending on the type of contamination (visible, difficult to see) and its localization (inside, outside).
Based on the specific quality management, sub-processes must be configured with the required parameters for the cleaning step to be considered technically correct and reprocessing as a whole successful. The sensitivity of the test methods employed needs to be taken into consideration, as studies on the comparison of different types of test proteins show.
At present there is no recognized or at least coordinated method for the definition of "cleanliness" with regard to tests with the same test soil, nor a uniform test for determining the effectiveness of cleaners, like there is for determining the efficacy of disinfectants.
We need to establish an evidence base through appropriate scenarios in laboratory test series. A corresponding "robust" test model will have to be developed, first and foremost by the WD-manufacturer, who must guarantee appropriate process safety as part of the placing of his product on the market; and then on the part of the medical device manufacturer, who then devises the corresponding validated methods for reprocessing, in accordance with EN ISO 17664, and describes them in the reprocessing instructions of his product's manual. ■

Report on ultrasound application in everyday practice

Hydromechanical cleaning through cavitation (backed up with detergents and disinfectants)

B. Amann

What does this entail?

Ultrasonography (ultrasound [US]) refers to the range of sound frequencies above/beyond (i.e. "ultra") those audible to humans. This range starts at around 16,000 –18,000 Hz (corresponding to 16–18 kHz). Through tensile and compressive forces ultrasound generates microscopically small vacuum bubbles in liquids which instantly implode again. These imploding small bubbles act like micro pneumatic hammers (jack hammers) which within the space of fractions of seconds dislodge soils from hard surfaces; these are then carried away by microjets (very small but strong negative pressure turbulences formed in the liquid). This physical hydromechanical phenomenon with its special form of turbulence is known as cavitation.

Against a background of more widespread use of filigree and complex instruments, increasingly more emphasis is placed on precleaning such instruments in an ultrasonic (US) bath. While in the past ultrasonic cleaning was the sole automated adjunct to manual cleaning, today ongoing innovations are being offered by certain manufacturers such as lifting and lowering mechanisms, automated closure, suction facilities, rinsing during sonication (see also on YouTube the MIELE publicity film Eindhoven Project with Bandelin, Elma, Steelco).

With the advent of ultra modern washers-disinfectors (WDs) and correspondingly optimized detergents, there was a widespread misconception that the outdated ultrasonic bath could now be phased out. In the meantime the opponents of that tried and tested cleaning method must ponder whether by professing such views they are failing to take account of the normative provisions.

The German KRINKO/BfArM Recommendation* (2012, p.1266) stipulates: "The decision as to how a specific medical device is to be reprocessed must be based on risk management pursuant to standard DIN EN ISO 14971. The requirements set out in DIN EN ISO 17664 must be observed", i.e. manufacturer's instructions. Now virtually all manufacturers issue instructions for precleaning in an ultrasonic bath. For example, here a citation from the manufacturer's instructions for "Cleaning, sterilization and care of KARL STORZ instruments", 2001, p.15: "The ultrasonic bath (with 35 kHz) is suitable for thorough and gentle cleaning of highly contaminated and delicate items. [...] Therefore all non-dismantable scissors and forceps, with or without an irrigation channel, sliding shaft instruments, suction devices, circular punches, coagulation instruments as well as microinstruments must be cleaned with ultrasound."

Hence anyone who does not use US to preclean e.g. their microinstruments or also their minimally invasive surgical (MIS) instruments is possibly acting contrary to these stipulations and requirements.

Since today the majority of surgical procedures are minimally invasive, partially minimally invasive or have a minimally invasive input, it is unclear how large Central Sterile Supply Departments (CSSDs) of reputable hospitals dispense with this essentially gentle ultrasonic method contrary to the manufacturer's instructions.

Advantages of US precleaning

US is able to reach hidden sites inaccessible to manual precleaning with a nylon brush. US is gentler than the most delicate hand! US cleans in seconds – faster than the best staff member. The occupational safety aspects must not be underestimated. Pretreatment in the US bath, including with an appropriate detergent and disinfectant, reduces to a minimum the risks posed to staff during subsequent manual precleaning (in Germany this is governed by the Technical Regulation for Biological Substances TRBA 250).

Other advantages:

- Compliance with legal, normative, regulatory requirements/directives
- Medical devices (MDs) treated with US look and feel cleaner
- US is gentler than manual methods for MDs (reduces the cost of repairs).
- US plays a major role in effective cleaning of problem instruments that have no flushing port and cannot be dismantled.

Example: Arthrex Scorpion® MIS instrument (Fig. 1) is a first generation MIS instrument that has no flushing port and

* *KRINKO/BfArM Recommendation: Recommendation for hygienic processing practices for medical devices, jointly compiled by the Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM)*

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Fig. 1: Arthrex Scorpion® MIS instrument is a first generation MIS device – a real challenge for the cleaning process

cannot be dismantled. But with three-minute US precleaning its protein load can be reduced by five powers of ten to < 50 µg residual protein, and this is further reduced in the WD to below the detection limit.

Evidence: Validation of the Scorpion® in the CSSD of Leopoldina Municipal Hospital of Schweinfurt (09/2014) identified a residual protein amount of 37 µg protein after three-minute US treatment. Following subsequent reprocessing in a WD no more residual protein was recovered.

Method: The cleaning action generated by means of US cavitation is much faster than that of all other, manual or automated, processes. Three minutes are generally enough. No WD is able at present to rival that performance despite the claims of ultra short processing times made by certain manufacturers.

Note: Anyone who fails to invest the Time prescribed by the Sinner circle to match its Mechanical, Temperature and Chemical components is wasting scarce resources in that these are prematurely allowed to run down the drain before they can generate their full effect.

Only very rarely is there a need for MDs precleaned with US to be recleaned prior to or after automated reprocessing in a WD. The time thus saved can be well invested for automated reprocessing. But US has its limitations when it comes to removal of burnt-in blood or tissue following diathermy (electrocauterization). There continues to be a need for manual precleaning of forceps or scissors limbs with burnt-in deposits. Manual preclearing of blade or needle electrodes is very onerous and can never be accomplished without damaging them in the long term. Single-use electrode needles or blades are recommended instead.

On precleaning instruments in a US bath, fat, blood, protein, synthetic or textile fibres, bone meal and bone fragments as well as foreign material such as drug and adhesive residues will be left behind in the US bath. As such, these will no longer lead to blockage of the nozzles of WDs or container tunnel washers, making it easier to clean them at fewer routine intervals. US pretreatment also benefits the microfilters increasingly fitted in WDs, e.g. for MIS loading trolleys or ophthalmological surgical instruments. This also reduces the cleaning intervals for fine and course filters fitted in the WD drain. And the risk of blockage of the narrow lumens of instruments through free particles when reprocessed in the WD is reduced the more such particles are dislodged and retained in the US bath.

Examples of such scenarios include the trays used in traumatology surgery/orthopaedics, gamma nails, total hip or knee replacement with high rate of bone residues. Only US precleaning will give the assurance that these MDs, most of which make stringent demands on the reprocessing procedure, will be optimally cleaned in the WD. That also applies to MDs that can only be cleaned manually or only with US (example: the TripleV flow sensor from CareFusion as well as endoscopic accessories). US reduces the cost of repairs since micro- and MIS instruments need no longer be manually cleaned (during which they are often twisted out of shape). And US reduces the expenditure incurred for detergents since the amount of detergent needed in a US bath is less than in a disinfectant bath thanks to the cavitation effect. Surfactants play a crucial role here since they not only improve the water flow properties (or those of demineralized water) by reducing the ionic bonding tension but also by binding fat- and water-soluble soils, thus preventing these substances from recontaminating the MDs in the US bath.

Based on our experiences no "sound shadowing" occurs, and this is really more a semantic neologism by analogy to "spray shadowing" in a WD. For example, even the instruments in the uppermost out of five trays will be impeccably clean although the transducers are all situated at the bottom of the US bath. As in the case of the spray pattern within the WD, it is thought that here too there is widespread deflection and redirection of the spray jets (Fig. 2 and 3). Perhaps sound is able to penetrate not just pipes and casing but also able to get around the corners?

In view of the complex manipulator systems as well as the delicate mini- and MIS instruments, we do not believe that the failure to exploit the benefits of ultrasound can be justified.

Needs-based procurement

When procuring ultrasonic equipment the size of the bath should be tailored to the needs of the respective institution. The detergent and disinfectant solutions are used up more quickly in smaller baths and must be replenished more often.

Simplified calculation of the bath size needed in approximate litres:
< 50 sterilization units (StU) /daily ➔ minimum bath size needed around 30–60 L
> 50–100 StU/daily ➔ around 60–100 L
> 100 or per 100 StU/daily ➔ around 1l/StU

For a load of more than three instrument trays automated lifting and lowering facilities should be used to relieve staff of

Figs. 2 and 3: «Sound shadowing»? Is not a problem in practice – even with up to five trays.

this task. This implies the legal need for automated closure of the bath, protecting against noise, aerosols and unpleasant odours from chemical substances. Suction facilities and optimum illumination should also be standard features. Several US baths of adequate size and performance guarantee versatility, unimpeded and reliable operation thanks to redundancy mechanisms.

Conclusion

The time saving achieved with US cavitation can be used for more meaningful tasks. For example, it reduces the extent of cleaning to be carried out by CSSD personnel (see Sinner circle where cleaning is the quotient of the Mechanical [water], Chemical and Temperature parameters). The working time, workload and potential hazards are reduced to a tolerable level. Misshapen instruments (repair costs) are rarely encountered. The sharp reduction in medical device residues already in the US bath prevents rust formation in the WDs or on the instruments. The enhanced activity of the chemical products producing visibly clean instruments helps to reduce detergent dosage in the WDs, while also measuring the conductivity. ■

Acceptance criteria for the cleaning of medical devices – ”borderline“ reflections

W. Michels

How to define ”clean“ and what degree of cleanliness is necessary is a very thorny question. There are no published clinical trials that show what defined residual soil quantities might impair subsequent disinfection or sterilisation processes. The same lack applies to the possible transmission of small volumes of residual soil during re-use of medical devices, to the tissues or blood circulation of patients that could trigger the most varied of undesirable reactions. Only glaring examples have been published, showing that such risks do indeed exist. Evidence of occurrence and individual documentation cannot therefore be used for risk evaluation and weighing up the pros and cons is not possible.

Our brief is to reach a common evaluation and to agree on a convention, to specify the cleaning results to be attained using acceptance criteria, bearing in mind ”best practice“ and taking into account the current state of technology. The following assumptions must apply here:

- Removal of soil and test-germ reduction are not usually correlated.
- Because test soils can only partially approach actual clinical circumstances, the cleaning of instruments soiled by actual use should be verified in the user-specific environment.
- Cleaning entails the removal of soils independently of the initial amount, in the range required for its subsequent treatment and proposed use i.e. to a specified residual amount.
- The specification of tolerated residual quantities cannot be done based on clinical data. Also because an analytical determination limit is not applicable, specification must be done according to the establishment of a suitable and surely achievable amount according to state of technology.
- The cleaner the medical device, the safer the subsequent process after cleaning and clinical re-use on patients. Therefore optimisation should always be striven for.
- Surfaces of medical devices that can be visually checked must always be visually clean after cleaning.
- Additional evaluations are required, especially for the areas of medical devices that are not visually accessible, recording chemical components or markers of soil after sample taking and independently of the risk assessment done with semi-quantitative or quantitative validated methods.
- The evaluation must take into account the dimensions of the tested surface, because only then is the comparative evaluation of different medical devices possible. For cleaning evaluation the data must be cited as µg/cm².

The standard ISO EN 15883 requires and recommends protein determination for the quantification of residual soil. Protein is certainly a constituent of most soil components and its quantification thoroughly encompasses the residual soil resulting from patient treatments or operations, and thus represents the most important monitor of cleaning (Zentr Steril 2001; 9 (1): 20–32). In ISO EN 15883-1 Appendix C the OPA, Biuret/BCA and the ninhydrin methods are listed and described. These days the ninhydrin method for protein quantification is regarded as unsuitable (Zentr Steril 2012; 20(6): 378–381). So the OPA and BCA remain as relatively robust methods even with sampling with 1% SDS solution (pH 11). It is reasonable to quote the residual amount of protein recorded as equivalent BSA (bovine serum albumin). Definite acceptance values have not been specified but this should be remedied in the next few years when the relevant section of the standard ISO TS 15883-5 is revised. The main basis for discussion about the specification of a benchmark for cleaned surfaces will be two particular publications. These are the test results of Alfa et al. (Am J Infect Control 1999; 27: 392–401), as well as those of Michels et al. (Zentr Steril 2013; 21: 212–215). Alfa et al. tested 30 flexible endoscope tubes cleaned routinely in hospitals in ZSVAs after use on patients. Michels et al. evaluated the performance test reports from validations of reprocessing processes in WDs in CSSDs, according to the German Guideline (Zentr Steril 2008; 16 – Supplement 2). In doing so, data from 3780 surgical instruments, 786 MIS instruments and 288 ophthalmological instruments was incorporated into the evaluation.

The basic question remains, whether because of the type of instruments and their materials, results obtained from flexible endoscopes can or should be transposed to any other type of medical device.

Looking more carefully at the Alfa et al. publication it becomes clear that there are methods used here that need critical ques-

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tioning. The endoscope tubes were merely subjected to manual cleaning with a brush and an enzymatic detergent, probably containing tensides. After rinsing once with water, sampling of the "cleaned" endoscope took place. It was then put in a reprocessing appliance, in which probably only disinfection followed. Compared with German practice, this is only counts as preparation for the subsequent automatic process of cleaning and disinfection (Bundesgesundheitsblatt –Gesundheitsforschung – Gesundheitsschutz 2012; 55: 1244–1310). Rinsing away the soiled detergent solution after brushing was done for the suction channel of the colonoscope and duodenoscope each time with a very small amount (25 ml) of tap water of unknown quality. This was before sampling, which consisted in renewed brushing with 10ml sterile, distilled water. The urgent question here, is whether sampling can be efficient with hydrophobic tubing material and hydrophobic soil constituents. Also whether very insoluble calcium precipitates have not already been formed because of the use of hard water. In fact, to prevent blocking of the auto-analyzer, the sample solution had to be centrifuged and only the supernatant were taken for analysis. This particulate matter in the eluate samples is very worrying and should have been the subject of specific analytical study. There is a dictum that surfaces to be tested must always be clean on visual inspection. Analogously surfaces that cannot be visually inspected (such as crevices and hollow spaces) must provide a transparent and particle-free solution after sampling with a fluid such as SDS.

In the Alfa et al. study the analysis and quantification took place with relatively low protein contents using a Bio-Rad Protein Assay, relying on the Bradford method. This method is much more interference-prone than the OPA or BCA methods, especially regarding tenside residues from previous cleaning cycles. Unfortunately, much more detailed information is required, especially about method validation and this casts doubt on the results. The results of this evaluation of manual (pre-)cleaning then, cannot become the basis for the specification of a benchmark or acceptance value for endoscopes after automatic cleaning and most certainly cannot be transposed for the surfaces of other medical devices.

The surfaces of the colonoscope suction channels had a maximum residual load of 1.19 µg protein/cm², those of the tested duodenoscope 2.26 µg/cm² and from the bronchoscope had 8.55 µg/cm². The median for the bronchoscopes was 6.36 µg/cm² and so obviously this is the basis of the suggested acceptance criterion, rounded up to 6.4 µg/cm². There are critical questions relating to sampling and determination method for these deviations of the maximum residual load and the quite limited number of bronchoscopes in comparison to duodenoscopes and colonscopes, (e.g. efficiency of sampling for each specific type of soil, interfering substances in specific soil components). The poor and worrying results for the bronchoscopes, never mind the other method criticisms, cannot become a blanket benchmark for acceptance criterion for all medical products. On the other hand the results (Zentr Steril 2013; 21: 212–215) leading to an acceptance criterion of < 3 µg protein/cm² in Germany, are of much greater relevance.

In Europe there are very few countries where acceptance criteria for tolerable residual protein come from cleaned instruments soiled by actual use. Apart from Germany, Austria and England are the only other countries. In Austria a value of 20 µg per instrument is taken, without reference to the size of the sampled surface. Such a low value can probably only be cited because the method used only allows a fraction of protein actually present to be recorded. Publications on method validation and detailed data are unfortunately not available. In England at the Conference of the Institute of Decontamination Science 2012 (Zentr Steril 2012; 20 (6): 378–381) the acceptable zone was considered to be between 1 and 2 µg/cm². Currently a fluorescence detection method has been established in England CSSD routines (www.synopticshealth.com), in which the instruments are sprayed with an OPA fluorescent reagent and then evaluated in a fluorescent light gauge. An acceptance criterion of 15 µg protein per instrument is applied (information from Wayne Spencer, Spencer Nickson Ltd., Selby, North Yorkshire, UK). The method is highly sensitive, but does not encompass crevices, joints or lumina (visual method) that actually constitute a priority here. Only surfaces which are easily to be cleaned are encompassed. ■

The influence of tensides on spray impact pressure

W. Michels

Over twenty years ago alkaline detergents without added tensides were used to reprocess surgical instruments. If detergents containing tensides were used, the problem of foam formation always cropped up. This was because at that time, detergent was always added to the incoming cold water feed, according to the disinfecting process recommended by the Epidemic Hygiene regulations in Germany, which had been taken up by some other countries. Only at a temperature of between 30 °C and 40 °C, above the cloud point, does foam break down and no longer compromise the mechanics of washing. The disadvantage of raising temperature is that the temperature at which blood denatures is quickly reached, leading to fixation of organic soil. Because of these cleaning problems, detergents containing tensides did not become established. But this changed with the introduction of the Vario process and the use of detergents in liquid form, which were added commencing from a temperature of 40 °C.

The term tenside comes from tensio meaning tension and refers to the characteristic reduction of surface tension between two phases. The main groups of tensides are anionic, cationic and non-ionic tensides. For use in detergents for automatic cleaning, usually only non-ionic tensides are suitable, as ionic tensides tend to produce a lot of foam.

It is well known that during alkaline cleaning, non-ionic tensides in detergents do definitely reduce foam produced by saponification of blood components, thus reducing the impairment of the mechanics of washing. But this type of foam formation can be pre-empted by thorough removal of blood brought in on instruments in a suitable pre-wash phase, making non-ionic tensides superfluous here.

The Task Force of the RKI made recommendations in 2001, regarding the prevention of iatrogenic transmission of vCJK pathogens, to improve the reduction of contamination and soil. Here detergents based on NaOH or KOH with the inclusion of tensides were recommended, but without giving any indication of the chemical category of tenside. A destabilising and inactivating effect on protein structure is expected from the non-utilisable anionic tensides, rather than from non-ionic tensides. The question remains to what extent the serviceable non-ionic tensides significantly support cleaning/the reduction of soil. We know from much practical experience with so-called neutral detergents that their contribution is not the last word on instrument cleaning. Laboratory trials have also shown that the pH value a detergent brings about in the cleaning solution is of more relevance than the effect of an added tenside. And where plastic components are to be cleaned, tensides can deliver a limited positive contribution to cleaning via improved wettability.

A user who knows their washer-disinfector inside out can actually hear changes when the intensity of the washing mechanics is affected. For example, the loud noise when washing with only water compared with the more or less obvious attenuation of noise in the presence of foam, or when detergents containing tensides are dispensed at the relevant dosage temperature. This acoustic perception allows us to conclude that by the reduction in surface tension, the wash sprays impacting the wash load and wash cabinet walls have become softer and less mechanically effective. This is an effect that is not measurable as pressure at the circulation pump head or statically at a nozzle. It is rather as if two different cars colliding at the same speed with a tree- an old Daimler and a modern car. The

Fig. 1: Pressure logger with open membrane

rigid Daimler will damage the tree much more than the modern "soft" car, which is constructed so that a greater part of the kinetic energy is transformed into deformation. The situation is similar for "hard" and "soft" wash sprays,

where "soft" sprays are subsequently reflected less and after impact their splashes have a considerably reduced effect. The resulting reflected sprays are then not particularly effective.

In order to quantify this, a pressure logger with the pressure-sensing membrane open, was positioned over a stationary wash spray so that the pressure membrane was directly impacted by the jet and was either 4 cm or 8 cm above the outlet of the nozzle opening. This is the usual gap size between nozzle and instrument to be reprocessed, so that the impulse pressure at that locus is measured. Recordings were carried out using fully-demineralised water without additives, an alkaline detergent with and without tensides and a neutral detergent. The evaluation shows a reduction of pressure impulse as shown in the

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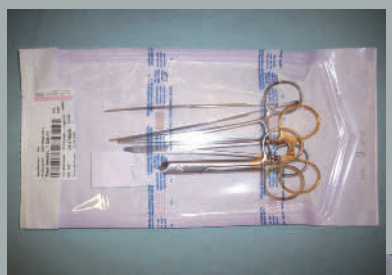
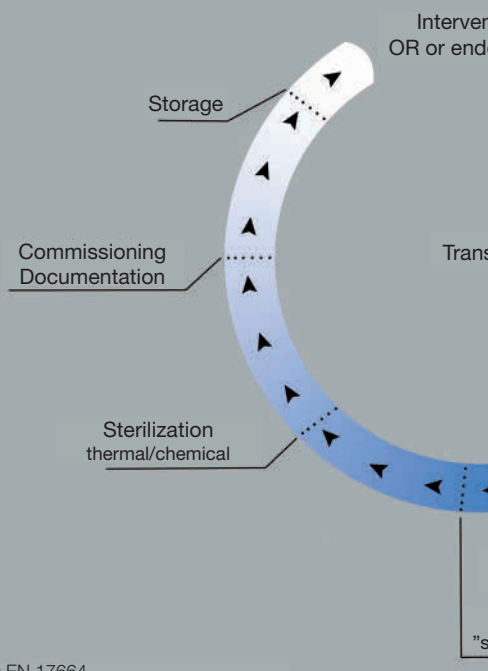
Reprocessing – a closer look



Quality cycle of instr



➔ ISO EN 17664

rument reprocessing

ntion
oscopy

Disassembly of medical devices

Removal of gross contamination

sport

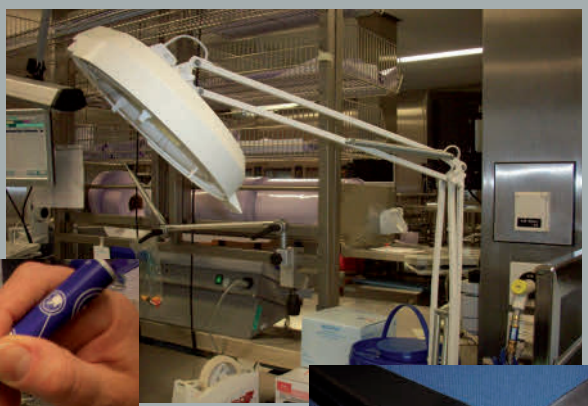
Cleaning
manual*/automated

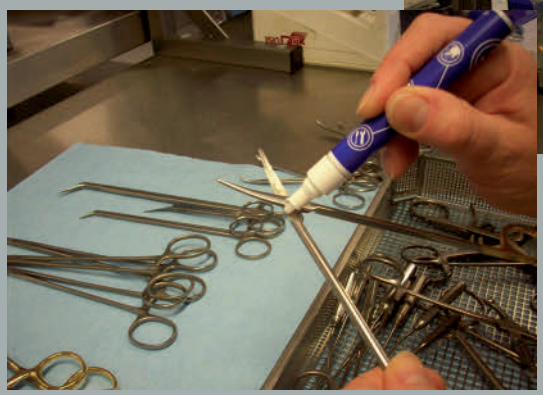
Disinfection
thermal/chemical*

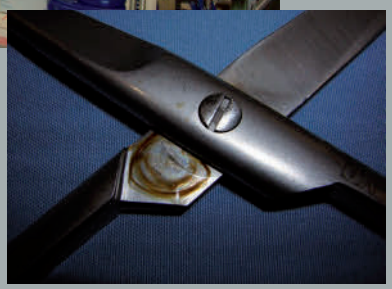
Inspection
Maintenance

Packaging
sterile barrier system“

* final rinsing and drying required







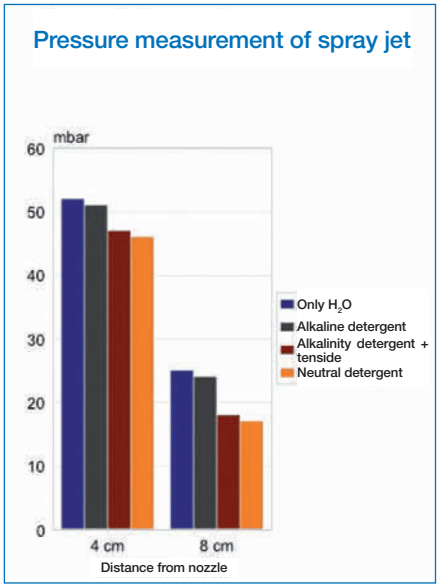


Fig. 2: Pressure measurement of spray jet

graph in Fig. 2, in the following order: water, alkaline detergent without tensides, then with tensides, neutral detergent. The measurements confirm the acoustic perception of quietening and the reduction of the mechanical effect associated with it, with negative consequences for cleaning power. Actually the reduction of the mechanical effectivity of reflected wash jets is not recorded with these measurements although they are also significant. But, in the still non-uniform wash situation of today's WDs, they may probably have even more influence than the reduction of pressure impulses of directly impacting jets (associated with quieter wash noises).

Non-ionic tensides are thought to prevent redeposition of dissolved soil suspended in the wash solution, but this has not yet been proven. In total, the amount of soil to be dissolved in the cleaning phase after the pre-wash is very low and is usually restricted to a few millilitres of blood. In this situation a pronounced capacity to carry soil does not seem to be particularly necessary attribute for a detergent. It can also be assumed that the negative charge present on dissolved soil and all the surfaces in the wash chamber, including the instruments- caused simply by the alkalinity- in itself prevents redeposition.

Automatic cleaning is a multifactorial event and has so far been investigated far too little. A lot of the mental pictures and notions about the mechanisms are taken from the area of dish-washing, which is significantly simpler than cleaning the multitude of instruments from various surgical disciplines. ■

A critical look at ”mildly-alkaline“ enzymatic detergents for automatic washer-disinfector processes

W. Michels

In the second half of the 1980s, when the Epidemic Hygiene regulation BGA or BSG programme was the routine programme for instrument reprocessing, exclusively alkaline detergents without tensides were used in the first process step, which included thermal disinfection. These detergents produced a pH of 11.0 to 11.5 at the then standard dose, depending on the quality of the softened water. Even at low blood adherence the washing pressure collapsed due to saponification of blood components and the creation of foam-active substances – and sometimes foam even poured out of the WD. These detergents were described as ”mildly alkaline“, which was certainly apt in comparison to commercial dishwasher detergents. But there was the problem of chloride-induced pitting corrosion, which was much more serious than it is today, as local tap water was used for the processes, often exclusively i.e. also for the final rinse, and only softened by the integrated WD ion exchanger. In those days the AKI urgently recommended the preventive use of fully-demineralised water for the final rinse (see 4th edition of the ”Red Brochure“), and for adequate corrosion protection, the use of a detergent for the washing-disinfection stage that produced a pH of at least 10.4.

With the introduction of the Vario Programme in 1994 and the separation of washing and thermal disinfection into two distinct process steps, alkaline detergents were employed for 5 minutes holding time, first of all at 45 °C then a little higher after it was determined that the compromising denaturation occurred only from 55 °C. Manufacturers of detergents quickly saw the chance that for the Vario process the conditions for tenside-based, enzymatic, neutral detergents could be suitably introduced. Furthermore, by using these higher dosed detergents a greater turnover would be possible. The users were also satisfied, because excellent material compatibility meant that now only a single detergent was needed for all types of loads. Extra care using different detergents and dosage applicators for sensitive materials e.g. aluminium containers, would no longer be required.

However it soon became obvious that even with a lengthened holding time in the cleaning phase, the cleaning performance for instrument reprocessing was very often not adequate. Following on from this, improvements were made and the pH of the detergent was raised, so that the detergent solution had a pH of about 10. Thus results could be attained that for the most part satisfied the requirements of the emerging performance tests. The swift and widespread use of these products now termed ”mildly-alkaline“ detergents, was supported by the Task Force vCJK at the RKI. In 2002 they favoured and recommended blanket use of a pH of more than 10 for non-denaturing temperatures of, for example 55 °C for validated automatic cleaning, because of the expected improved cleaning efficacy. Here the option of cleaning at 93 °C with a strongly alkaline detergent was also hinted at, without any exact facts being given. This is a very controversial subject, and this was probably intended to keep the door open for a possible use of the not really validatable Epidemic Hygiene regulation ”BGA“ process. A pH value of > 10 is still recommended in the appendix 7 of the 2012 KRINKO/BfArM recommendation, but does not keep open the option named in 2002.

But now we will look at the detergents mainly used today for instrument reprocessing, the mildly-alkaline, tenside-containing, enzymatic detergents.

It is certain that this alkalinity leaves any prion proteins it comes across chemically intact and with regard to material compatibility almost all reprocessable products can be treated with these detergents e.g. anodised aluminium or colour-coded titanium. They are thus almost universally deployable, which is pleasing to users who can keep chemical provision and programme design very simple. The cleaning performance is better than that of detergents that produce a pH <10 and tend towards neutral in the cleaning solution. But it must be pointed out that cleaning is still not optimal. An optimal situation for instruments suited to alkaline cleaning would be from pH 11.2 – 11.5 at a cleaning temperature of 55 °C (see ZentrSteril 2004; 12(6):384–387). At pH values above 11.5 however, the opposite effect takes over, because the high alkalinity facilitates denaturation and fixation i.e. a significant deterioration in cleaning.

This fixing effect can be very nicely visualised by using a soil applied to a template on stainless steel test objects using 75 µl reactivated, heparinised sheep’s blood and afterwards conditioned in a desiccator over saturated potassium carbonate solution. The test objects are then treated in the same way using the test set-up of the DIN

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Ad hoc Working group (Zentr Steril 2008; 16 (6): 424–435). One group is cleaned with an alkaline detergent solution at a pH of 11.3 (0.3% concentration), the other group with an alkaline detergent solution at a pH of > 12 (0.5% concentration), all for 5 minutes at 55 °C. Figure 1 shows the significantly greater residue at pH > 12 compared with the pH of 11.3 (Fig. 1).
The recommendation of KRINKO/BfArM unwittingly permits this fixation and so realises the opposite of what it actually intends: to minimise the risk of transmission of CJK/vCJK (insofar as this actually exists). According to the KRINKO/BfArM recommendation the holding time for cleaning at 55 °C and > pH 10 should be at least 10 minutes. This is also in the interests of users, as the mildly alkaline detergents generally require at least this length of time to have an adequate effect.
The topic of tensides as components of mildly alkaline detergents is already the subject of an article in this volume of FORUM. Anionic tensides could be very helpful for cleaning, but in WDs they tend to cause problematic foam formation. And where there is foam, dissolving and removal of soil by the cleaning solution is impaired. So in WDs almost always only non-ionic tensides are used, whose foaming behaviour is tolerable above the cloud point. But the reduction in surface tension of water caused by tensides also results in a certain reduction in washing pressure, in particular the extent and intensity of reflected sprays. For instruments with crevices that are oriented at a 90° angle to the main sprays, this is significantly lower. Cleaning is thus barely improved by tensides. But they do improve wettability, especially of plastics, as well as soil carrying capacity. But this is only of qualified significance, as cleaning temperature already ensures good wetting and the amount of soil in the cleaning solution is comparatively low.
Enzymes are proteins that act as catalysts to support and accelerate chemical reactions without themselves being used up. Some enzymes split substrates and thus make dirt easier to wash off and more soluble. Proteases split protein, lipases split fats and amylases split starch. Preferentially certain proteases are used in detergents for medical devices and not a mixture of several enzymes, as some of these, as proteins, could be digested by the proteases. Enzymes were first used in the middle of the last century in textile washing powder. During the washing of textiles, enzymes in the wash solution can target dirt from all sides of the fabric and the main wash lasts long enough for them to be effective. That is a completely different story to cleaning the hard surfaces of medical devices. Here the solution containing enzymes only reaches soil from one direction. Also the allowed holding time is really too brief. Moreover contact of the enzyme solution with soil lodged within crevice areas of instruments is extremely limited by spatial considerations and in fact only really the top layer is reached.

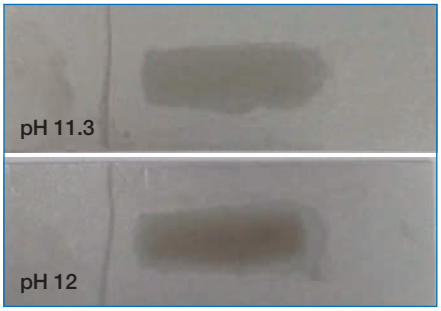

Fig. 1: The residue formation of soils containing protein increases with alkalinity (fixing effect)

The activity of enzymes is very dependent on temperature, pH value, time and further factors. The optimal conditions for activity often lie between very narrow temperature and pH limits. But conditions in the cleaning phase of processes for medical products are directed towards optimal effectivity of alkalinity rather than for enzyme activity. For certain detergents, the contribution of enzymes to the cleaning of medical devices has never really been experimentally proven. Attempts to determine the contribution led to rather questionable results and to speculation that the declaration of the presence of enzymes as ingredients was only intended to underline the characteristic of material compatibility or ecological compatibility. To put it mildly- this needs to be clarified by further research! ■

Dealing with Loan Instruments

A Synopsis of current Theses on the Topic*

A. Hartwig, R. Graeber, T.W. Fengler

"If you mention the term 'loan instrument', there is usually a lot of rolling of eyes. No one really knows how to improve it.", says ***Astrid Skottky*** in the preamble to her Fachkunde-III thesis (1) about the beginnings of her involvement with the subject. In fact, loan instruments (LI) are one of the topics that any employee of a CSSD in Germany could not avoid in recent years. They are extensively used, particularly in orthopedics and traumatology. Thus it is not surprising that this topic has repeatedly been chosen for FK-III theses.

LI are increasingly resorted to when medical devices/instruments needed for a particular operation are not available in the inventory of a hospital or are under repair, if the acquisition is expected not to be profitable (due to rare use) or in connection with trying out new surgical techniques. This procedure is a heavy burden for the CSSDs, because LI must be handled and reprocessed just as carefully as owned instruments. However, usually more than one complete reprocessing cycle is neccessary per patient use, because "these 'loan instruments/systems' must be processed before and also after use with validated procedures" (2).

The expended effort is therefore higher than for in-house instruments. In one example in our publication in FORUM-Journal No. 22 this effort amounted to 6.5 hours (for a loan system of 8 trays, previously unknown to the staff, from delivery to sterile provision) (3).

In addition, quality management (e.g. on the basis of EN ISO 13485) calls for a risk analysis (not only) before the use of new methods and techniques, which includes loan instruments. A. Carter, in a recent lecture at the in Munich University Hospital (3/16/12), pointed out (4):

- Dealing with LI often does not follow any regulated workflow.
- Each department has their own priorities and acts accordingly.
- Delays in the process are likely to occur, particularly in surgical planning and execution.
- Reprocessing is often carried out in a hurry and on steady besetting of the surgery department.
- The logistics of the LI are not stipulated.
- Proper procedures for dealing with LI is known only in everyone's own area, with cross-interfacing between departments being a rare exception.

This description sums up the circumstances, which are described as "Is"-conditions (the status quo) in the three theses summarized here. "Is" refers to the state before the respective optimization plans, that have been undertaken or planned within the context of these theses. The Deming wheel (or PDCA-cycle) may be called to mind here (Fig. 1).

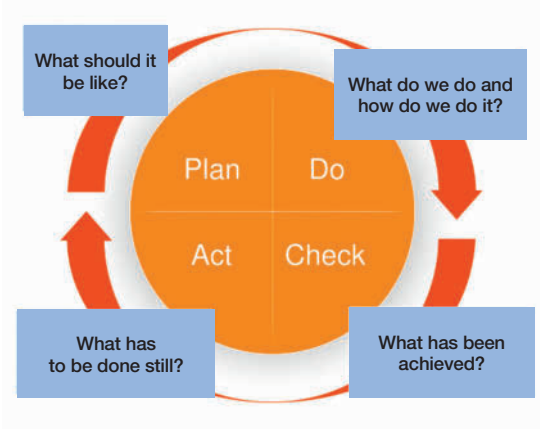

Fig. 1: PDCA (plan–do–check–act or plan–do–check–adjust) is an iterative four-step management method for the control and continuous improvement of processes and products.

Optimization plans include

1. recognition and detailed description of the problem
2. Shaping a task
3. Going for a solution.

This includes:

- Identification of all interested parties and joint action
- Structural and/or personnel measures

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* This article summarizes the main findings of three theses on the topic "loan instruments" (or ancillaries). These were written upon completion of the course "Fachkunde III", a specialised training course for heads of CSSDs at Brandenburgisches Bildungswerk für Medizin und Soziales (BBW) in Potsdam, Germany. The theses were filed in March 2014 and were all rated "very good" or "good".

– Restructuring of responsibilities
– Definition of responsibilities and workflows
– Creating administrative instructions or forms
– Documentation and action plan

Sometimes even small measures can be expedient, at other times major changes are required, that make neccessary the approval of many decision-makers, in order to be able to take that "big step" in the right direction. In any case, a CSSD obviously benefits from an expert with intimate knowledge of the specifics dedicating a lot of time and energy to a given problem, due to writing a thesis about it.

Renita Schlecht (University Hospital Carl Gustav Carus in Dresden) suggests a concept for the establishment of a local receiving department for LI at her clinic in her thesis, titled "Restructuring and Process Optimization in Dealing with Loan Instruments" (5).

Status quo: The acceptance of LI is carried out by the CSSD, but only for one department. Temporary storage takes place in an anteroom (where the crates are in the way, posing a potential source of accidents). From there, they are forwarded to the department, where the review and compilation of the trays is performed by a menber of surgical staff. They are then returned to CSSD, including a prefabricated data sheet and manufacturer's instructions. Documention is done and if necessary photos are taken; then follows reprocessing. Conversely, the other departments are directly supplied by the clinic logistics and store the LI themselves at their respective sites.

From this mixed approach arises a series of problems, starting with the lack of overview of the actual number of existing instruments and their respective classifications (A, B, C – noncritical, semi-critical, critical), or lost manufacturer's instructions, to confusion about the number of applications that the instruments are needed for and the available time slots for necessary processing and provision. In addition, due to the staffing situation qualified processing of LI cannot be guaranteed at all times, since for example not all employees are competent (and thus allowed) to carry out risk assessments.

The proposed solution:

– The appointment of one employee as fully responsible staff for LI, who would then perform all the neccessary tasks: acceptance of the crates, notification of the relevant departments, unpacking and possibly repositioning in tray baskets for processing, risk assessment and documentation, information processing, creation of standard operation procedures (SOP) and reprocessing of the LI.
– Reorganisation of an existing space as the central receiving department and interface for the LI of all departments; with all the necessary information about the presence of all instruments/accessories present at one place.

These two measures would undoubtedly contribute to a higher level of overview, a uniform procedure and a relief of all other departments concerned and especially all other employees of the CSSD. Not least, through new procedural instructions for the reprocessing of LI (created within the frame of the thesis) the processes for dealing with these medical devices are formulated in a clear, comprehensible and binding manner.

Tobias Leipnitz (Municipal Hospital Dresden-Friedrichstadt) designed a Concept for Process Optimization in Dealing with LI (6) in his thesis. Dealings with LI at the time of preparation of this thesis was characterized by "a lack of regulations" and "a fixed structure in writing". A number of unfavorable processes had evolved in his department: the LI were usually delivered far too late, sometimes no more than three hours before surgery. This led to all the employees involved being extremely stressed, which was further increased by continuous demands on the part of the surgery department.

Basic procedures could not be adhered to (e.g. sufficient cooling after sterilization) and if neither of the two heads of department was on duty then the acquisition of instruments had to remain incomplete. Should any accompanying documents be missing, there was likely to have been no time left to reorder these from the lender.

Little was known on how to proceed with the LI after the operation (repeated use? collection date?), which often led to unnecessary overtime (if, for instance, the trays had to be reopened and resorted after reprocessing and then sterilized again). There was therefore an enormous need for improvement, particularly in the areas of interdepartmental communication and time management.

The author, in cooperation with the CSSD management, designed two forms in order to solve these problems. The first, labelled "decontamination verification", fills a formal gap and is kept very simple. The second form, "registration loan trays", represents an attempt at initiating an exchange of information between the involved parties through pointed queries about certain data. Before that there was, for example, no way for the CSSD to know, who (which surgeon) had ordered the instruments in the first place and whom to consult in case of queries.

Using the new, one-sided form, which is sequentially processed, first by the orderer and then by CSSD, first and foremost an early order of LI and timely information to the CSSD can be achieved (delivery 24 hours in advance if possible, latest delivery 2 pm of the day before the operation). In addition, in this context responsibilities are clarified and codified (eg, acceptance and review of the delivery by surgical staff). The form also includes information about the retention of the LI after the first use, the completeness of the supplied documentation, the delivery time and whether CSSD was notified "on time/too late/not at all" – the latter no doubt with the intention of using such documentation to approach certain surgeons and raise awareness,should it be neccessary.

In addition, the author describes an optimized way of dealing with LI (using the standard forms) from initial delivery to final clearance, in such a detailed manner that the description may act as a template for a procedural instruction.

Apparently, a dialogue between the CSSD and the departments was set in motion by the author's preoccupation with his thesis, which led to a meeting of representatives of all parties involved, in which the CSSD could communicate their problems and needs associated with LI for the first time. On this occasion, the thesis' concept was presented. Moreover, the preliminary talks have gone so far that – according to the thesis' closing remarks – the implementation of the proposed concept was already a done deal at the time of submission of the thesis.

While a new set of procedural instructions was only one of several measures in the former two theses, they represent the central and in fact the only contents of Astrid

Skottkys final paper, The Work of creating the Service Instruction "Instrument Management" with the Procedural Instruction "Dealing with Loan Instruments" for the Clinic Magdeburg. Skottky had initially faced similar problems as Leipnitz. She referred to the dealing with LI as "not effectively regulated", especially in terms of concrete acceptance/delivery times, a lack of rules regarding "who ordered what, how and when", unclear storage and time capacites and lack of communication between users and the CSSD.

Her approach to create a set of authoritative process instructions for LI, led quickly to the conclusion that a unilateral venture of the CSSD would not be effective in view of the diverse group of stakeholders. Thus a project group was established, consisting, inter alia, of representatives of management, QM, hygiene, surgery, Medtech, nursing management. However, the author had to be patient at first, because the desire to talk was apparently so great that her real concern could not be addressed in detail until the third meeting of the group (before, it seems the new-found group used the meeting to agree on instructions for the procurement of medical devices, which was apparently also long overdue).

The total of seven meetings were documented by the author and offer a vivid insight into the complex process of opinion formation, also with regard to the interfaces between the departments. A lot of persuading had to be done, solutions were considered and discarded, and the feedback was not always fully euphoric, especially on the part of the chief physicians. A flowchart for "Provision, Processing and Use of Loan Instruments" was created, which would probably be sufficient by itself as the focal point for a thesis, followed by a tripartite dockets. The CSSD staff had to be trained to deal with the new documents and procedures and only then was the procedural instruction formulated, provided with a further flow chart and, after further training, implemented for a trial period.

This is undoubtedly the maximum solution to the problem, a large effort with a comprehensive result: a highly detailed regulation, which goes well beyond the concerns of the CSSD, deeply embedded in the quality management system of the hospital, surrounded by service instructions and arranged by the management, binding for all parties. It remains to be seen whether the daily production task of processing, integrating the different LI, thus is better met.

It should be noted that all three authors report to have found a listening ear for their plans and support and encouragement from their supervisors, be it the CSSD management or even the hospital management. This is good and important! The use of LI is not going to decrease, on the contrary, and the related problems will only become more pressing. Ultimately, operators should have a vital interest in neatly structured procedures in dealing with LI, for the benefit of their quality management and with regard to their own special responsibility: "It is the responsibility of the operator to properly implement the provisions of the Medical Devices Act and the Medical Devices Operator Ordinance. The responsibility applies to all medical devices over which physical control is exercised. This includes loan, lease or test devices." (Quality Task Group, Recommendation No. 81). ■

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Comparison of two electronic Bowie-Dick test systems for investigation of steam penetration in accordance with DIN EN ISO 11140-4

S. Kirschner, R. Streller, I. Kruse

In addition to the commercially available chemical indicators whose requirements are set out in the standard EN ISO 11140-4(1), alternative electronic test systems have been developed in recent years. EN ISO 11140-4 (1) is ideal as a guide to investigating such electronic systems since it gives details of all the relevant parameters and test criteria to be applied.
The aim of the test series described in this paper using the two most commonly employed electronic test systems was to identify any differences between them or weak points, while also taking account of the user friendliness of the software and of the entire system.
The tests revealed that both systems produced similar results and that the errors defined in EN ISO 11140-4(1) were reliably detected.
A Bowie-Dick test continues to be the only way to verify steam penetration in accordance with the normative provisions, but it is a very demanding procedure. This Bowie-Dick test was developed in the 1960s and is based on the use of chemical indicators that are inserted into a defined textile pack (test pack as per EN 285[3]) and are able to display steam penetration. Since this is the standard/reference test system, all other similar systems are designated as "alternative" systems.
EN ISO 17665-1 (2) stipulates that the steam penetration test be carried out daily before placing the steam sterilizer in operation.
The use of an electronic BD test system reduces the scope of documentation needed and is more environmentally friendly. This is important because legal requirements shifting the burden of proof to the user in the healthcare setting implies the need to maintain continuous and detailed documentation.
The main advantage conferred by an electronic system is its easy operation. The two systems tested were readily able to identify errors and independently evaluate the BD test. The user is given a clear-cut result of either "Passed" or "Failed". The reasons for any error will be displayed.
With electronic systems there is no risk of getting false results because of inappropriate storage or incorrect readout/evaluation by the user as is the case with chemical indicators.

Equipment, test sterilizer and test sequence

The test equipment comprised a 4 sterilization unit (StU) test sterilizer as per EN ISO 11140-4:2007 (1) from Lautenschläger, Type Central Certificate 3119, with steam generator ED72 and aeration unit. The special cycle sequences and programming method described in EN ISO 11140-4:2007 (1) are designed to reproducibly demonstrate faulty sterilization cycles.
Annexes B1, B2 and B3 of the aforementioned standard give precise details of three cycles with different evacuation phases, allowing for simulation of the cycles of different sterilizers.
The three cycles described in EN ISO 11140-4 (1) are illustrated in Fig. 1.

The test cycles and their settings

Errors were simulated with a textile test pack as described in EN 285 (3). Temperature sensors were placed at precisely defined positions within this textile pack.
In the event of a fault, an inert gas bubble is generated within the pack. This is signalled through a drop in temperatures within the pack.
The temperature reduction for an error is exactly defined in EN ISO 11140-4 (1) and must be within a narrow range, as illustrated in the exemplary curves in Fig. 2. There is no drop in temperature in the cycles that "Pass" the test.

PC and software

A personal computer with the appropriate software supplied by the data logger manufacturer and an interface to the data logger are needed to fully exploit the benefits of electronic system BD test systems.
The program Winlog.med V3.53 from ebro and the 3M software 4110 V2.0.1.1 were installed on the computer that used Windows 7 as operating system.

Test setup

Before starting each series of tests, the sterilizer was subjected to a vacuum test, and then heated while checking the quality of the demineralized water.
The mean conductivity at the inlet to the aeration unit incorporated into the sterilizer was 1 µs/cm.
As stipulated by DIN EN ISO 11140-4 (1), a textile pack test was then run to confirm that the sterilizer was functioning properly and the selected test cycles correctly exe-

Note by Publisher: *electronic systems measure one more parameter, i.e. the time. Colorimetric indicator systems are endpoint measurements and do not yield any time-synchronous information!*

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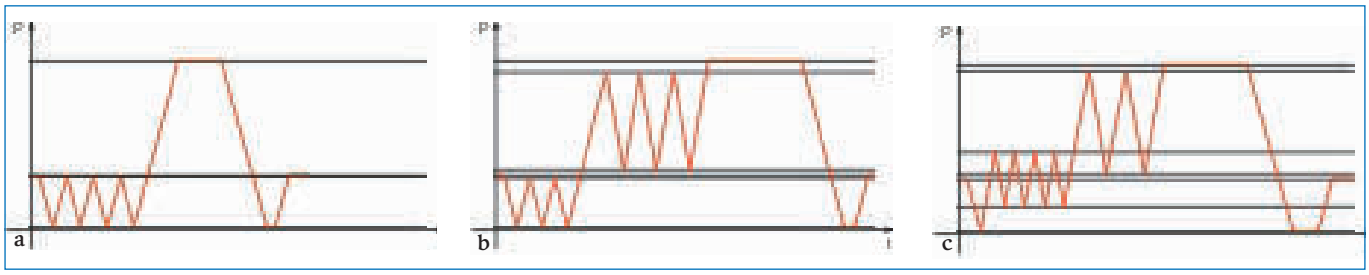

Fig. 1:
a) Annex B1: Evacuation by pressure change (vacuum)
b) Annex B2: Evacuation by transatmospheric pressure changes
c) Annex B3: Evacuation by pressure change (overpressure)

cuted. Next, three separate standard cycles were run, each with one of the devices being tested. After removal from the sterilization chamber, the test results were read using the manufacturer's software and the device was allowed to cool down to ambient temperature before running a new test.

Evaluation of the systems

Software

At initial PC program start-up, the user is registered as administrator and requested to enter the data for the user settings.

3M ETS System

The user administration scope of the 3M software is very limited and does not confer any rights to program functions.
The ETS system user interface is very confusing since all the already executed procedures and the various evaluation functions are displayed in tabulated form on the start-up screen.
Data recording is started on the ETS by directly activating a push-button on the device, i.e. without any software input, and optically confirmed. After removal of the logger, the result can also be read on the device, as indicated by various flashing signals that take time getting used to. Data transmission to the PC is started by pressing a button at the interface, and must also be done for electronic archival. After a short processing time, the test result is displayed on the screen.
The ETS software displays an overall result. Individual parameters are displayed but are not evaluated or inscribed.

ebro EBI 16 System

The ebro system is able to grant each staff member individual rights to various functions. Operation of the Winlog.med software is ergonomic and intuitive. All functions can be easily accessed from the ribbon menu bar, familiar from Windows, and are also described in detail in the Help file.
The software can also be used for other interconnected ebro loggers, e.g. EBI100-TP231, also for routine checks of other equipment e.g. washer-disinfectors (WDs), endoscope washer-disinfectors (EWDs) or bedpan washer-disinfectors.
Before the EBI 16 system is placed in the sterilization chamber it must be started by means of a programming template. The data can then be read out from the database entry generated. During the subsequent evaluation by Winlog.med all measured values are clearly displayed in graphic form for the user. A "Results" dialog is generated and a report produced. The measurement data are archived following an electronic signature. A choice of numerous formats is available for exporting the report.
The report generated by the EBI 16 cycle gives the overall result and detailed assessment of the various sections.

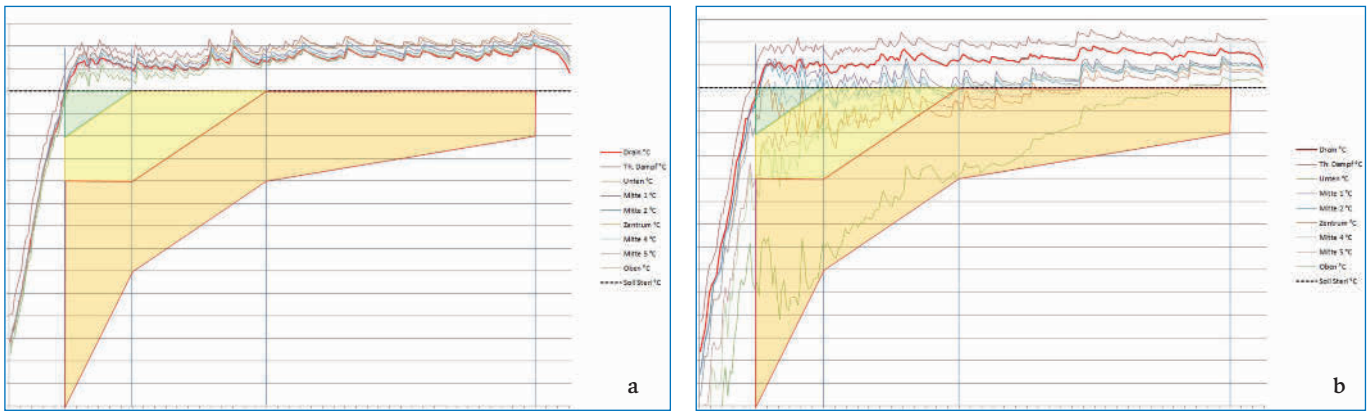

Fig. 2:
a) Temperature profile within the laundry pack during an accurate cycle (no temperature drop)
b) Temperature profile within the laundry pack during a cycle according to Annex B1 with a defined fault "deficient evacuation" (several temperatures stay within the faulty corridor during the whole holding time [orange field])

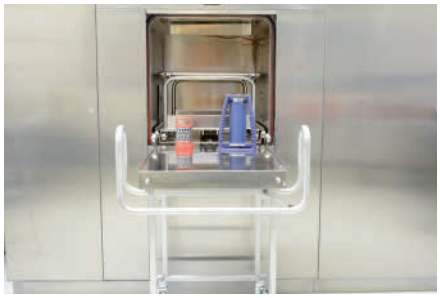

Abb. 3: Die Probanden im Test: links der EBI 16 und rechts das ETS

The 3M ETS (Fig. 3) is unwieldy to handle because of its enormous size and weight. It is difficult to fit into a 1 StU and cannot at all be used in a small sterilizer.
Because of its large mass, it takes more than two hours to cool down before it is ready for reuse. The device must cool down to 35 °C as specified by the manufacturer.
However, surprisingly the ETS can be started in certain circumstances even when the temperature is above 35 °C, but the software then displays the error message "Start temperature too high" when next evaluating the results.
This is annoying not only because of the device's limited service life of only 400 starts but also because of the time needed to repeat the test.
The ETS records data for only 3600 seconds.
After expiry of the useful life of two years or 400 cycles, the ETS can no longer be used and must be disposed of.
Based on a daily vacuum and BD test, this amounts to a useful life of around 10 months.
Segregation of the different components for disposal appears challenging or impossible, in particular removal of the polluting lithium battery because of the hermetically sealed casing.
The EBI16 logger (Fig.3) is small and easy to handle, hence it can cool down faster and is ready for reuse sooner. It can also be used in small sterilizers as those operated in office-based dental and medical practices.
The logger must be started as per a software template before it is inserted into the chamber, but a start time and the measuring frequency (e.g. BD test every 1 sec) can be specified. The EBI 16 temperature is verified and if it exceeds 35 °C an error message is generated on the screen alerting the user to the current temperature, while preventing a false start.
The EBI16 saves around 6900 measured values for a freely selectable measuring sequence and a preselectable start time.
The ebro service life is limited to 500 cycles, but that limit does not apply to measurements performed below 100 °C, hence the daily vacuum tests are not included in that count.
For the daily vacuum and BD test the useful life is around 24 months.
The client is able to replace the battery. Once the maximum number of 500 cycles has been reached, the EBI16 can be processed at the factory.
Neither of the two devices is designed exclusively as a BD test. Both systems are able to perform a vacuum test whose results can be evaluated per software and also have a log function for recording temperature- and pressure-related measurement data in general.

Conclusion

The most important conclusion that can be drawn from the test series are:
Both systems are able to reliably detect the errors specified in EN ISO 11140-4(1).
Both systems are suitable alternatives to the classic BD test.
The main differences between the two devices relate to handling (Table 1), price and environmental friendliness. For example, the components used to manufacture the 3M ETS cannot be segregated for disposal as the battery cannot be removed, see EU directive 2003/108/EC(4).
Winlog.med from ebro is not intended exclusively for EBI 16 but can also be used for all routine tests together with the associated data loggers e.g. EBI100-TP231, which are needed for automated reprocessing.
The Winlog.med software is essentially more comprehensive and appears to be more user friendly than the 3M software 4110. ■

Table 1: Comparison

Unit	EBI 16	ETS
Fault detection	Both systems detect the standard cycles reliably and reproducibly	
Application	Both systems can be used as BD test, as vacuum test and as data logger. EBI 16 can also be used in sterilisers < 1 StU	
Period of use	500 high temperature cycles (if used daily for BD and vacuum tests approx. 24 months), max. 2 years	400 cycles (if used daily for BD and vacuum tests approx. 10 months), max. 2 years
Cooling time	45 minutes, restart possible at temperatures below 35 °C	Restart possible after 2 hours, temperature must be below 35 °C
Service	Reprocessing of the system after 500 cycles, lower costs, battery change by user	No service, no battery change
Disposal	Reprocessible, dismountable, battery can be removed for disposal	Not dismountable
Software	Winlog med (EBI 16)	
Phase recognition	Cycle is reliably recognized	
Parameter evaluation Degree of dilution Other parameters	For the degree of dilution compulsory input of chamber volume Optional recording of temperature and pressure, residual air/degree of dilution, variance, fluctuation, lethality	Sterilizer data sheet with compulsory input (name, type, location, chamber volume) Pressure recording and evaluation is very detailed. Continuous recording of degree of dilution and residual air
Reports	Comprehensive reports and evaluation, export function to different formats (CSV, RTF, PDF, XLSand XLSX), also for the settings	Only one report sheet with process diagramm and result. Other evaluations are possible only via export functions (TXT, XLS).

Endoscope Surrogate Device as Specimen for Validation and Routine Monitoring of Endoscope WD

H. Pach

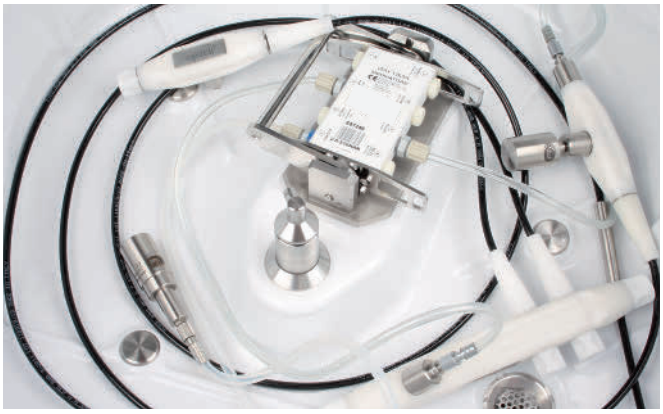

Fig. 1: Medivator with adapter and Ellab logger

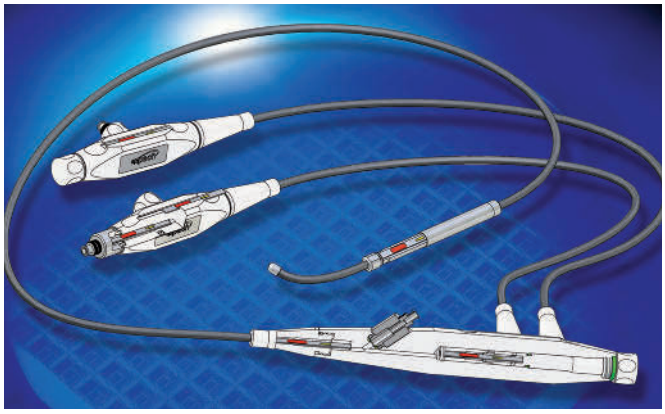

Fig. 2: The Endoscope Surrogate Devive spypach «spo-pro»

Millions of people each year receive an endoscopy of the bronchi, esophagus, stomach or colon. In the case of a lack of or insufficient cleaning or disinfection of the used, highly complex devices, patients could run the risk of contracting bacterial infections. One reason for the high rate of nosocomial infections is insufficient, non-standard and non-guideline-based reprocessing of endoscopes and their accessories. The risks associated with the reprocessing of medical devices are deemed "fully controllable", i.e. a risk to patients due to inadequate endoscope reprocessing is considered to be basically preventable.

For years, the law and the supervisory authorities have prescribed to the operator automated reprocessing and use of suitable, ie. validated reprocessing procedures. The verification of cleaning and disinfection performance by appropriate means takes a key role in this context. The goal is to prove reliable reproducibility of the processes according to the established specifications by sampling.

According to the German "Guideline for the Validation of Automated Cleaning and Disinfection processes in the Reprocessing of Thermolabile Endoscopes" (2011) the model specimen "2 mm tube" is used. There has been some controversy over the suitability of these tubes, in this magazine and elsewhere. The issues in question were, and still are, how significant such tests are, wether this tube model could simulate an endoscope adequately, and whether this was even intended by the authors of the guideline – which was apparently not the case. What's certain is that neither exterior cleaning is simulated with a tube, nor a leak test. Thus, the tube model does not match the validation standard EN ISO 15883 in any case. Also a simulation of trumpet valves and various adapter connection options are not reflected.

We need not delve deeper into these arguments for or against the suitability of the 2 mm tube, in order to conclude that there are ambiguities and inadequacies and assert that spypach's endoscope surrogate device was developed precisely with regard to such. The surrogate devices (dummies) correspond to real thermolabile, flexible gastroscopes or bronchoscopes from practice, with an operating component, a patient component with working or biopsy channel and two service components with a washing channel and leak tester.

They are simply placed in the endoscope WD to be tested in place of a real endoscope, with the possibility of placing both the endoscope as well as the indicators at precisely identical positions during a variety of tests on the same WD, which leads to a high degree of reproducibility. Exterior and interior cleaning can be checked with up to 12 critical measuring positions, such as in the flexible channel, on the outsides

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and in the connection between biopsy and irrigation channel.
With the endoscope dummy, a patented and standard-certified test and measurement system is available, which allows easy verification of cleaning and disinfection performance of endoscope WD. It is a reliable, reproducible system that is used by both validators as well as hygiene in hospitals, as an easy way of the self-test for routine monitoring according to EN ISO 15883. This way, maximum patient safety can be achieved, at low testing costs.
The dummies work regardless of the manufacturer of the WD or the indicators, ie. they can be used with all common WD (eg. Olympus, Steris, Soluscope, Belimed, BHT, Medivators, Steelco, Maquet Getinge etc.), with all common industrial test indicators (as eg. TOSI, SIMICON, DR.FRÜH Control, GKE, biocheck etc.) and also with all test soils that are to be carried out in Teflon tubes with different diameters. Thanks to extensive validation accessories, it is also possible to simulate, within a very short time, every conceivable available endoscope and to facilitate an exact verification: temperature, pressure, flow control, a clogged channel and leakage can be tested with positive and negative pressure at a number of measuring points. The leak test can easily and quickly be documented in the validation report. For all measuring instruments there is also a documentation software.
The devices can be used without problems in older pressure chamber machines, but also in single channel endoscope WD. Furthermore, the dummies are not only suitable for reproducible verification of internal cleaning of all channels, but also for external cleaning – which has been neglected in recent years, but is no less important. The test and measurement systems were tested according to standard 15883 and the Austrian ÖGSV-guidelines and include a verification opinion and an inspection certificate. ■

Last not Least: Stagnant Water on a Load Carrier

Right-angled surfaces without provisions for drainage on load carriers lead to stagnant water

The illustration shows design-related residual moisture: perfectly horizontal surfaces should be avoided when constructing load carriers, there should always be a certain inclination in pipes and no inaccessible "dirty corners". Elaborate designs will result from a dialogue between the manufacturer and the users. ■

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