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2003 **September** Vol. 11

ZENTRAL STERILISATION Suppl.2

International Journal of Sterile Supply

Medical Device Processing

Best of Forum 1999–2003

State of the Art/ Concepts for the Future (1999)

Evaluation of Automated Cleaning Performance (2000)

Verification of Performance Parameters (2002)

What Exactly Is It That Can Be Certified? (2003)

Chirurgie-Instrumenten-AG (CIA) Berlin
in Zusammenarbeit mit dem Brandenburgischen Bildungswerk für Medizin und Soziales e. V.

DGSV
Deutsche Gesellschaft für Sterilgutversorgung e.V.

mhp Verlag GmbH

EDITORIAL

Prof. Dr. Peter Heeg
Editor in Chief

Cleaning, disinfection and sterilisation have not always commanded the level of attention they are now being paid in the medical setting. Even when sterilisation, and somewhat later disinfection, became a trendy topic particularly in the aftermath of European standardisation and internationalisation of markets, few people initially showed any interest in cleaning. The rather helpless view expressed here was that ultimately everything would be sterilised in any case. But that cleaning is an indispensable prerequisite for effective disinfection and sterilisation and should not be disregarded when making efforts to improve quality assurance – by no means a completely novel insight – is something of which many people became aware only towards the end of the 1990s. T. Fengler and his colleagues from the Surgical Instruments Study Group (with its very apt German acronym "CIA") in Berlin must be thanked for being one of the first to not only address the myriad unresolved issues but, together with devoted specialists from universities and industry, to undertake concrete steps, too. In 1999 the first forum titled "State of the art – concepts for the future" was held in Düsseldorf in the course of the Medica exhibition. This topic was to set a trend, and was followed by similar events in 2000 (Düsseldorf) as well as in 2002 and 2003 (both in Berlin). The latter were organised in collaboration with Brandenburg Educational Institution for Medicine and Social Affairs under the auspices of the German Society for Sterile Supply (DGSV), thus attesting to the increasingly broader discussion base and the growing interest being elicited among specialists.

Designed along the lines of a "Best of ...", this present supplement summarises important contributions in order to give all participants and interested parties as comprehensive as possible a picture of the state of the art in the field of medical device processing. The main focus is initially on enhancement of cleaning efficacy and demonstrating proof of such. To begin with, this supplement serves to take stock of the current situation, and then goes on to concentrate on issues relating to monitoring and verification of processes. It presents basic processes such as surface analysis, radionuclide method or protein detection as well as practical procedural aspects such as how to select suitable process challenge devices or how to organise process documentation. A range of quality management issues is covered, the most important of which being just what it is that we should be able to certify (2003). Legal aspects are being attributed increasingly more importance in the wake of the amendment of the German Medical Devices Act in 2002 and following publication of the guideline of the Robert Koch Institute on processing medical devices, and these must be discussed in the light of medical, technical and organisational conditions and requirements.

Many questions will be answered in this supplement, but many will also remain unresolved and some problems will come to light only on focusing in greater detail on the matter. I hope that this synopsis of medical device processing will have a far-reaching impact and, in particular, will contribute in hospitals and other healthcare establishments to an accretion of knowledge and to promoting a greater understanding of the work carried out there. Ultimately, it is the personnel there we have to thank for good quality, i.e. safe and optimally functioning medical devices. At the same time, it is hoped that these contributions will serve as thought-provoking impulses for further developments and as a source of new ideas. The pace of innovation in medicine, as in quality management, is rapid and anyone who ceases trying to be better will soon prove to be not good enough. ◀

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FORUM


Th. W. Fengler


H. Pahlke


W. Michels

Forum „Medical Device Processing“ – Five Years Later

The "Forum" started in 1999 on the Medica Fair, Duesseldorf. Actually, it was about a year earlier, while we were running the first German Multicenter Study on organic material remaining on surface parts of medical devices. Six instrument designs with six samples each were investigated, in six CSSD with their different technical facilities and work process parameters, located in five different towns.

The "MRSA Study Part I" was completed and finally published in 2001 (Zentr Steril 2001; 9 (1): 20–32) . It showed that on about every third instrument proteinacious structures and/or components of blood could be found. For the first time the prevalence of proteinacious material on processed instruments was proven without answering the question of its clinical significance. This necessitates a different study design and was not our aim.

The completion of the first part of this study already was a highly demanding task, and we came in closer contact not only with hospitals but also with company research and development departments. This was the starting point for the idea to create a forum to talk about what we believe was neglected until then: cleaning as the most important step in the quality chain of sterile processing.

And then, we were three: Dr. W. Michels (Miele, Guetersloh), H. Pahlke (City Hospital Moabit, Berlin), and myself (Chirurgie-Instrumenten-AG [CLEANICAL] which means Surgical Work Group, Berlin). It was our wish to promote research in cleaning of medical devices deemed for so-called "sterile" use on human beings. In 1999, we covered three days with "State of the Arts/Future Concepts". The character of an open forum was chosen to suit the setting within a fair. However, we learned that visitors only participated for a while, and we never had the kind of compact audience which enables fruitful discussions.

"Evaluation of Automated Cleaning Performance" was the focus of the Forum in 2000, again at the Medica. Complaints about the selected day and the competitive situation with the Medica led us to the decision to finally move the location to the German capital Berlin.

Here, the first friday in February became a "jour fixe" and in 2002, we concentrated on the "Verification of Performance Parameters". Again at the same location, the Forum 2003 "What Can Be Certified?" related formal aspects to the verification of identified parameters of the stepwise process of sterile processing.

The next Forum 2004 will cover the topic "What is Possible, What is Necessary?", with new speakers, but old problems. And we will continue doing it for You and the common task of medical device processing.

Dr. Thomas W. Fengler, Editor

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Historical Developments in Hygiene, in Particular in Cleaning

T. Fengler (1999)

The instrument is the surgeon's extended hand. It dissects, grasps, holds, prises apart, binds, cauterises and penetrates bodily tissues. And in doing so, it can act as a vehicle for microorganisms and toxins. Its surface must be constructed such that it does not give rise to allergic, toxic or inflammatory reactions. In particular, diffusion of surface adhesions (biological materials, disinfectant residues) or material constituents (plasticizers from synthetic materials, metal ions, insulation particles) into bodily tissues must be kept to a minimum.

Throughout the ages it was necessary to practise "minimally invasive" surgery (MIS) if the patient was to survive – even before the advent of anaesthesia, haemostasis and antisepsis. Starting with trepanation of the skull (Early Stone Age 2000 B.C.) through Hippocrates ("What herbs do not cure, will be cured by iron" 460–366 B.C.), the "Caesarean" section, the Arabian medical expertise as described by Abu-L-Quasim or Avicenna, the Indian insights as portrayed in the Vedas, medicine has come a long way to the present-day hospital hygiene.

The Bible makes references to smoking and boiling (4th Book of Moses 31:21–24). In 450 BC water was stored in copper or silver vessels, to ensure its suitability for drinking. Aristotle advised Alexander the Great to boil water before using it as drinking water for his armies. Throughout the ages wine, vinegar and honey have been used for wound dressings. The first record of the role of hygiene in disease prevention is attributable to Galen v. Pergamon (129–199).

The surgeon's trade was practised by scarifiers, barbers (pulling teeth, splitting furuncles), judges (torture as proof of evidence during the Middle Ages, the need of reconvalescence before going on trial) and military commanders (amputations) and was hazardous at least as far as the patient's life was concerned. Only the advent of anaesthesia, haemostasis and hygiene (antisepsis, asepsis together with the discovery of antibiotics) made it possible to successfully conduct surgery as from the middle of the 19th century.

Patients with infectious diseases were placed in isolation for the first time in 1576, in the Julius Hospital, Wuerzburg. The book titled "Wundarztneyisches Zeughaus" (translation of the surgical armamentarium by Johannes Schultheiss = Schultetus) was published in Ulm in the 17th century. Around this time, Antoni van Leuwenhoeck was apparently the first person ever to observe bacteria using a microscope he had developed himself.

However, up till the 19th century only a tenuous link could be established between poor water, putrefied foodstuffs, inadequate hygiene (no sewage system) and epidemics (plague, dysentery, cholera). People believed in miasmas (disease-engendering vapours) and subscribed to the notion of the homeostatic equilibrium theory of health (blood, bile, phlegm and urine). Following the Industrial Revolution, increasingly more people lived together in cities. Inadequate sewage systems and cramped living conditions promoted the spread of infectious organisms. The word "pestilence" is derived from plague, with its infectious connotations.

During the Crimean War (1854-56), the American War of Independence (1861-65) and the Franco-Prussian War (1870-71) wound infections (gangrene, tetanus, sepsis) claimed a greater number of victims than did direct enemy fire. Following shot injuries, these deadly infections were contracted directly from the projectile penetrating the body tissue together with (contaminated) clothing particles, and thus opening up a portal of entry. Or (hours to days later) infection occurred at the site of the dressing via the amputation saw or another surgical instrument, which were used in quick succession for several patients – effective decontamination was not possible, or even known.

Despite all this, the sterilisation process was an established method already in 1860: by resorting to "preservation", foodstuffs for the soldiers were rendered imperishable during the American Civil War. Likewise, the autoclave with its safety valve was also known in principle (Henry, 1832).

Carbolic acid and phenol were introduced for wound disinfection (Lemair 1860). Joseph Lister pioneered the technique of disinfecting gauze with carbolic acid for use as dressing material (1867). This was later superseded by alcohol which is less damaging to the skin (Reinicke 1896). Fuerbringer recommended hand disinfection with 80 % alcohol.

Heat sterilisation with saturated steam is attributed to Louis Pasteur. In the course of his famous speech to the Science Academy in Paris (1878) he declared that, in his capacity of surgeon, he used only perfectly cleaned instruments, he always washed his hands with the utmost care and heated dressings, sponges and rinsing solutions to adequately high temperatures (110–150 °C) in order to kill all microbes. Neuber (1883) advocated boiling surgical clothing; the surgeons should take frequent baths and wash their arms and hands preoperatively. Redard had laundry sterilised thermally rather than chemically. And von Bergmann, his pupil Davidsohn, the latter's assistant Schimmelbusch, who spearheaded the aseptic movement in Europe, must also be mentioned. Kimmler described "Modern Surgical Dressing" (1897).

Lugol was the first person to use iodine solution (Paris 1829). Ignaz Semmelweis introduced the practice of hand disinfection with chlorinated water to reduce the mortality rate associated with puerperal fever

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("the deadly handshake" of students who went directly to the puerperal ward from the pathology department) (Budapest 1847). Max von Pettenkofer is known as the founder of hygiene.

Emil von Behring discovered "curative serum" (1890), leading to the introduction of the active vaccine against diphtheria (1913). Paul Ehrlich formulated the theory of antigen-antibody binding (1891), discovered the methylene blue stain for malaria and chemotherapeutics against infections (1910).

Rudolf Virchow (Pathologist, 1821–1902) pioneered social medicine and founded Moabit Hospital. Robert Koch promulgated the theory of infection, discovered the causative agents of anthrax, cholera and tuberculosis, and worked also at Moabit Hospital, among other places (1882). The Gram stain is a special stain with which cyan-violet Gram-positive cocci and burgundy-red Gram-negative rods can be identified. But this stain does not permit a distinction to be made between mycobacteria and treponemes (1884).

Gustav Adolf Neubauer was the first person to use a separate room as an operating theatre, this being an important landmark in the development of asepsis (1885). Carl Schimelbusch constructed a sterile supply container, attended to organising surgery and compiled the monograph "Guide to aseptic wound treatment" (Berlin 1892). Mathias Lautenschlaeger installed autoclaves in the first real central sterile supply department of a hospital (Charite Hospital, Berlin, 1890).

Alexander Fleming discovered by chance penicillin as a "contaminant" on bacterial cultures because of the formation of inhibitory zones (1929). From now on it was possible to treat the cause of bacterial infections, even if today microbial resistance and the development of new antibiotics are vying for the upper hand in an increasingly close race.

Remark:

The word "hygiene" derives from Hygieia, daughter of Asklepios. As the descendant of the god of healing, she personified health among the ancient Greeks. Asklepios or Aesculapius on Epidauros, was a son of Apollo; it is not certain who his mother was. He inherited his healing powers from his foster father, the centaur Cheiron. But these proved to be his downfall. He was not content to just heal the living, he wanted to reawaken the dead too. This was deemed dangerous by Zeus, father of the gods, and he killed him by lightning. ✦

What is Clean, What is Pure? Hygienic Instruments in Surgery and Endoscopy

T. Fengler (1999)

Cleaning is the most important step in sterile supply processing, but to date it cannot be quantified. It serves to prevent nosocomial infections. A prospective clinical observational study of the functional capabilities and decontamination of new, tubular instruments that could be dismantled was conducted for cases where laparoscopy was indicated (1). As tracer instruments, 3 trays were selected each with 100 OR cycles: straight scissors, obtuse straight/curved forceps, sharp straight insulated forceps, bipolar forceps. The parameters instrument handling, breakdowns, type of cleaning, visual condition before/after automated cleaning were documented for each instrument. Protein detection was carried out after elution with sodium dodecyl sulphate (SDS) as per the OPA method (ortho-phthialdehyde), in addition to erythrocyte testing with sticks. Based on these in vivo investigations, in vitro rests were carried out to investigate instrument design, surface roughness and any other parameters affecting the cleaning performance.

In vivo, visual inspection of the extent of contamination/cleanliness (1–3) showed significant correlations between the use of different cleaning techniques for the parameters design, ultrasound and pump performance of the washer-disinfectors. This permits inferences to be made as regards the suitability of the instrument design and cleaning sequences conducted during sterile supply processing. Electrosurgical deployment means that cleaning gets completely out of control. Residues were detected in 20% of the instruments used. In 5 out of 8 cases the sites concerned were the internal surfaces of tubular instruments which could not be visually accessed. The reuse profiles of instruments can be enhanced by dismantling them. This also assures a reliable cleaning outcome as it facilitates visual inspection and makes it possible to tailor stocks to the expected wear.

In vitro, robustness, reproducibility sensitivity and specificity of the OPA method were investigated using different experimental designs. Instrument design and roughness were shown to exert a significant influence on the recovery rate, something that must be borne in mind for clinical rinse tests because here the quantity of the baseline soil is not known. A high recovery rate of more than 90% is needed for results to be endowed with sufficient power.

As regards the instrument design, more attention must be paid to its amenability to cleaning and to its susceptibility to contamination. This has been attested to in in vivo investigations carried out by the Surgical Instruments Work-

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ing Group (CIA) at Moabit Hospital, Berlin. The reuse profiles of instruments can be enhanced by dismantling them. This also assures a reliable cleaning outcome as it provides for visual/tactile inspection of their "inner life". This approach also makes it possible to tailor instrument stocks to expected wear; however, the transmission of force between the surgeon's hand and the working end of the instrument on human tissue is adversely affected.

Selective clinical in vivo investigations, such as the Multicentre Residual Contamination Study of Processing (MRSA) conducted since autumn 1998 by the Working Group for Cleaning in Automated Processing (IRA) are needed to optimise processing safety and instrument design for instruments that can only be dismantled to a certain extent (arthroscopy, traumatology, neurosurgery, ENT) (2).

There is reason at present to claim that minute proteinaceous adhesions are of clinical relevance because many factors can adversely affect patient recovery. In the interest of a properly documented quality assurance system and of optimisation of the washer-disinfector configuration "validated" sterile supply processing must be verified, too. ✦

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Thermoelectric Verification of Washer-Disinfector Effectiveness

L. Jatzwauk (1999)

Test methods based on the use of screws or tubular sections contaminated with *Enterococcus faecium* ATCC 6057 to verify the effectiveness of disinfection processes operating above at 80 °C are endowed with only very limited power. After exposure to a temperature of 75 °C for just 1 minute, it is no longer possible to culture this test organism because it has a decimal reduction time (D value) of 1.28 minutes on exposure to moist heat at 68 °C. The fact that mechanical removal of these test organisms from the surface of screws can be achieved especially in defibrinated blood with reduction factors between 3 and 5 log levels is by no means representative of jointed or lumened instruments, and this imposes the need to interpret in relative terms the findings produced by biological indicators for assessment of disinfection efficacy.

The process parameters temperature and exposure time are the chief determinants of reliable microbicidal action. These are the only parameters that can be continually reproduced in the washer-disinfectors. Conversely, mechanical removal of biological soils/microorganisms (cleaning efficacy) is largely dependant on the machine type and load as well as on the changing mechanics mediated by the cleaning solution. Type tests for instrument washer-disinfectors have yielded experimental data for the requisite temperature and exposure times, or have at least postulated these (HBV, HCV). Therefore over the past 3 years, when conducting routine checks for these processes we measure only the disinfection temperatures and exposure times, while fully omitting microbiological tests in the machine, as recommended by the Robert Koch Institute. But while we do not include the cleaning performance in decontamination efficacy, we check the former by means of a simple, but difficult to remove, test soil (dried mustard).

We used temperature dataloggers manufactured by ebro Electronic to measure temperature. These wireless test instruments, measuring around 30 x 50 mm, are equipped with a PT 1000 sensor. Using special software, the loggers are programmed individually at the interface (and later evaluated in the same manner), with a measurement frequency of 10 seconds proving adequate. The logger has a storage capacity of around 3100 measurements. Resolution is given as 0.1 °C with a precision of ± 0.3 °C. The loggers are calibrated at the factory. They are placed between the instruments in the washer-disinfector and then subjected to disinfection. It is not necessary to provide for any cable fittings for measurements within the washer-disinfector. The loggers traverse the washer-disinfector or tunnel washers together with the instruments. Logger programming, measuring tasks during one or several instrument disinfection programmes and subsequent evaluation on a PC can be carried out at any location and at any time.

The temperature course within the cleaning chamber of an instrument washer-disinfector operated as per the specifications of the BGA (Former German Federal Health Office) /RKI programme is given in figure 1. The differences in temperature between the disinfection and cleaning phase (A), neutralisation and intermediate rinsing (B) as well as drying (C) can be easily discerned. Scan Data facilities mean that the associated temperature can be displayed for any desired point in time (shown here for the beginning of drying). One can note that practically no difference in temperature is detectable between the two dataloggers placed in the upper and lower tray between the instruments in the disinfection and cleaning phase. This is because the cleaning solution is heated together with the instruments. This can

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be detected only at the end of the drying phase and is attributable to the different positions of the loggers vis-à-vis the fan. The increase in the temperature-time graphic display during the disinfection phase, which is the chief determinant of antimicrobial action, shows temperatures of around 95 °C over a period of 14 minutes. Comparison, as practised hitherto, of the temperatures and exposure times actually reached during the disinfection phase with the aforementioned guide values or with the washer-disinfector manufacturer's specification represents one means of process control.

Still more accurate assessment is possible if the quantity of heat, exerting an influence, is calculated and assessed exactly on the basis of the time and temperature parameters measured. Using WINWERT software the efficacy of chemical disinfection can be calculated in the form of a process-specific F value, by comparing the verified disinfection process with a reference process. Such a process at 93 °C or at another temperature can be used as a reference process. WINWERT calculates F values as per the following formula:

$$F = t \times 10^{\frac{T-93.0}{z}}$$

F = F value

t = exposure time

T = disinfection temperature at respective point in time

z = exponent quantifying the effect of the temperature on antimicrobial action (mainly given as 10)

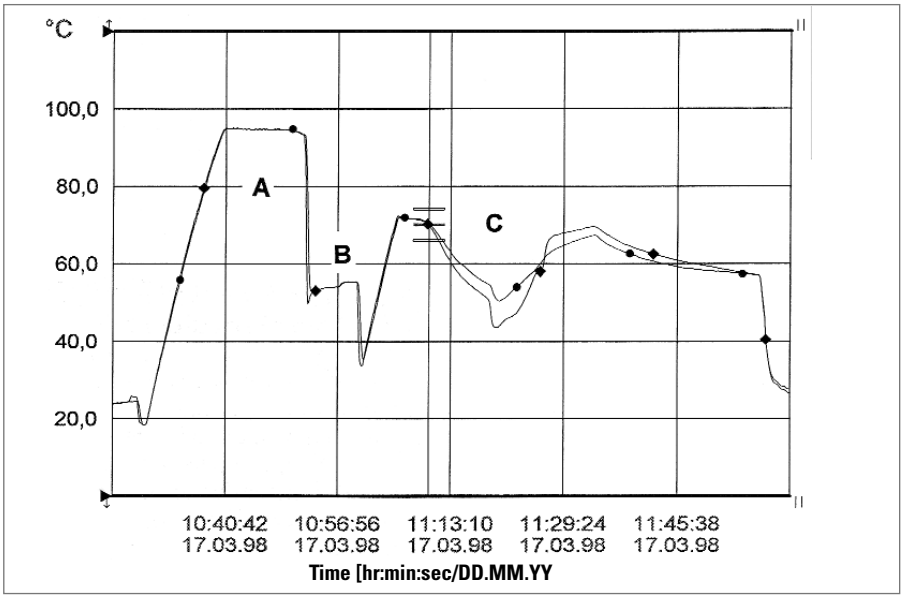

Fig. 1

$F_{93}^{10} = 1$ is used to denote an assumed disinfection process whose microbicidal action corresponds to a one-minute process at 93 °C. Using this evaluation process the heating phases as from 60 °C or fluctuating temperatures can be incorporated exactly into the antimicrobial action. The advantages of thermoelectrical verification of washer-disinfector effectiveness compared with microbiological testing reside in the speed of calculation, with the result being produced immediately after measurement. The known fluctuation range for biological test systems (resistance and number of test organisms, quality of transport and evaluation) is avoided. Likewise, an imbalanced time-temperature ratio (overkill) can also be detected, as can an inadequate heat effect.

The majority of washer-disinfectors tested in a hospital setting (stand-alone devices) were in operation prior to introducing thermoelectric testing at $F_{93}^{10} > 20$. Considerable temperature reductions and time saving were possible here. On the other hand, $F_{93}^{10} < 1$was noticed continually for 2 tunnel washers without the biological indicators used here ever having given any reason for complaints. ✦

Validation of Cleaning – the Radionuclide Method as a Quantitative Procedure for Spatial Resolution

K. Roth (1999)

Council Directive 93/ 42/ EEC of 14 June 1993 concerning medical devices states in Annex 1(13.6h):

"If the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of sterilisation of the device to be resterilised, and any restriction on the number of reuses...". Moreover, the German Medical Devices Act (MPG), stipulates that the reprocessing procedure must be validated.

Set against this background, a large series of investigations was carried out at the Test Centre for Medical Devices (PMP), in order to elucidate the possibilities and limitations in respect of processing of surgical instruments and to validate suitable methods. In the course of these investigations it was revealed that conventional test methods, often based on mi-

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crobiological procedures, are not enough to reliably verify all processing steps. Accordingly, it is not sufficient to merely check disinfection or sterilisation with the customary test organisms. The widespread belief that a good disinfection result correlates with good cleaning was repeatedly proven to be incorrect, which is why each processing step – cleaning, disinfection and sterilisation – has to be validated separately. In the course of these investigations we also examined to what extent single-use instruments were amenable to reprocessing and we compared them with reusable instruments used for similar indications.

To validate processing, we used the following methods: cleaning outcome was mainly checked with the radionuclide method, permitting quantitative results with spatial resolution. Technetium 99, a hard gamma emitter, was used as a test marker. Technetium was added to the test soil (blood) and the instrument was contaminated to simulate a worst-case scenario. Activity was measured before and after cleaning with a gamma camera and the quantity and location of residual contamination was determined on the basis of the data and images. This procedure constitutes an in vitro test method. In order to be able to get a picture of the cleaning quality of clinically used and reprocessed instruments, various surface analytical and mass spectroscopy investigations were carried out, supported by light and scanning electron microscopy (SEM) images.

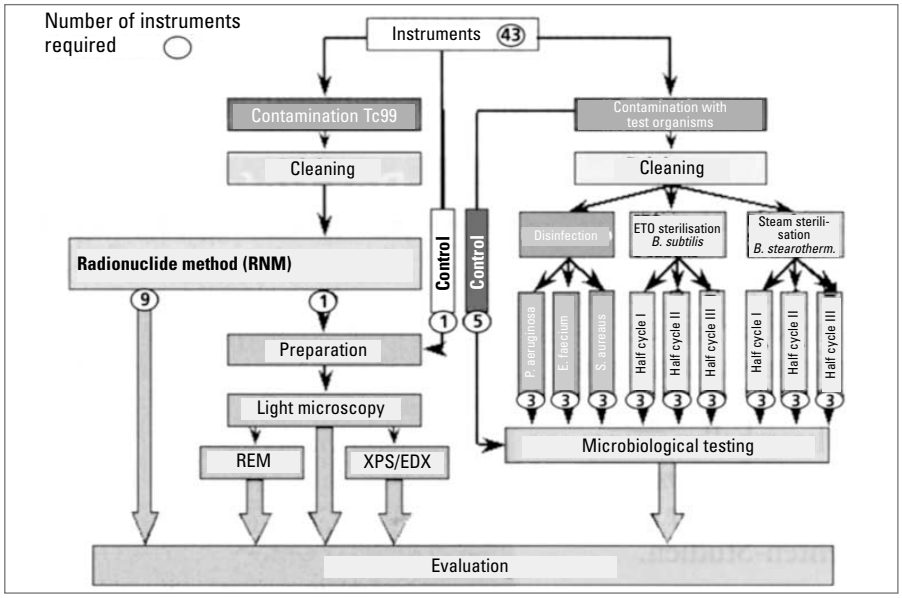

Fig. 1: Validation of processing

In addition to assessment of the cleaning result, these methods also provide information on the material behavioural profiles of instruments. However, the instruments have to be destroyed to obtain samples. Following successful validation of cleaning, the disinfection and sterilisation processes were verified using microbiological test methods, with a half cycle being run for sterilisation tests.

Based on examples, implementation of the test methods is demonstrated and validation of processing procedures described by way of example.

Depending on the statement of the problem, suitable methods of investigation are individually selected for validation of reprocessing procedures, so as to obtain a result endowed with the necessary power using as few investigations as possible. The flow chart (Fig. 1) shows a suitable test sequence that we used for validation of processing for single-use devices. ✦

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Medical Device Processing as a Quality Circuit... and Where One Can Go Wrong

T. Fengler, H. Pahlke (1999)*

Laws, standards and directives create the legal framework which must be observed when processing medical devices for sterile use on patients. Documentation and quality management then ensure that proof of this can be furnished at all times.

To begin with, a record must be kept of which medical device is being processed and of whether such a process can be carried out at all under the given circumstances. A comprehensive operating manual must be available.

Successful completion of the process steps must be recorded for each load. Functional testing, maintenance tasks and assembly of the trays/sets are a precondition for subsequent use in the OR and these must be documented, in particular in the case of high-frequency (HF) instruments, including accessories. Even after 30 years, it must be possible to identify the person who carried out testing (by means of signature or code).

Sterilisation, which is the final processing step, calls for the most comprehensive regulatory documentation. From the Bowie-Dick test through load assembly and inspection to microbiological testing involving spot checks conducted at different timepoints, everything has always been documented. If documentation is properly maintained, it must be possible to furnish proof of the entire processing circuit traversed by the instruments used for a surgical procedure. Only such detailed evidence can exonerate a hospital facing a liability claim.

The provisions of the Medical Devices Operator Ordinance decree that validated processes be used. This means that a process must be chosen which furnishes documentary proof of ongoing effectiveness and which must be used by each qualified staff member. Using a Quality Manual, similar to that used for accreditation purposes, each individual step and parameter ca10n be recorded. Such an approach prevents each staff member from devising his/her own system and thus making it impossible to have a validated process. This is particularly true for manual processing tasks, especially in the case of medical devices that cannot be subjected to automated processing. ✦

Optimisation of Process Sequences in Washer-Disinfectors in Situ

H. Pahlke, T. Fengler (2000)*

New washer-disinfectors are greeted with much enthusiasm in every CSSD, and it is hoped that they will make workloads lighter. But these expectations often fail to come to fruition, giving rise to great disappointment.

In most cases help is readily at hand. The problem will appear to have been overcome by selecting a higher detergent dosage setting, while at the same time prolonging the time. Using patience and a systematic approach, washer-disinfectors can, and must, be adapted to the locally prevailing conditions.

Since the washer-disinfectors are supplied with factory (default) settings, they cannot take account of the local water conditions nor of the detergents used in the respective hospital. Hence checking the water quality must come within the scope of commissioning for a new machine. As a first step here, it is enough to check the water hardness (analytical measures are called for if the problem persists). As regards the detergent, the lowest detergent dose specified by the manufacturer for the respective water hardness must be used to begin with. The water quality can be considerably enhanced by adding deionised (demineralised) water (lower dose with improved cleaning result).

Once these measures have been taken the entire process should be checked with a datalogger. The data now obtained will show the different times at which the cleaning solution is filled, the heating

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times, hold times for cleaning and thermal disinfection as well as the drainage times and drying phase. At the same time, one can identify at what temperature the water inlet is activated and the diverse cleaning and rinse cycles initiated. These parameters are paramount for an optimally set washer-disinfector.

It is not beneficial to make provision for a temperature of more than 40 °C for the water inlet when (pre-) cleaning surgical instruments. A lower temperature should be selected here. Only rarely should hot water supply be selected, since such a shortened heat-up time will also shorten the cleaning cycle: "cleaning is not a race!" Automated programmes that are thus shortened produce inferior cleaning results.

The cleaning temperature, time and detergent dosage must be tailored to the detergent itself. A higher temperature must be selected for some detergents, whereas others will produce excellent results if optimally dosed even at 45 °– 50 °C. "Too much is not enough": overdosage can counteract a successful cleaning outcome just as underdosage can. And anywhere there is foam, no particles or dissolved substances will be transported!

Five minutes are enough for the cleaning phase. One can shorten this period even further by subjecting the instruments to brief preliminary treatment in a suitable ultrasonic bath (see L. Jatzwauk, K. Roth) and/or hand shower (with spray protection). Provision must be made here for adequate intermediate rinsing to prevent entrainment of the cleaning chemicals.

The number of preliminary and final rinse phases must be set individually in line with the locally prevailing circumstances. If enough demineralised water is available, it should not be used only for the final rinse. To prevent entrainment of soils and/or cleaning chemicals provision must be made for adequate opening of the outlet valve. The time needed to drain the cleaning solution from the instruments must definitely be borne in mind for tubular instruments (MIS, ENT, trauma).

The same holds true for the drying phase. Here the temperature and time must be tailored to the contents of the load, i.e. checks must be made to see after what period of time the instruments are dry in order to avoid unnecessarily long drying times. It must also be borne in mind that excessively high temperatures can lead to alteration of certain materials.

The load time often depends on the type of pipes used within a particular establishment. It is not uncommon for longer filling times (up to 8 min per filling task) to result from old, calcified water pipes, and these can add up for several cleaning cycles. The load time can also be considerably prolonged by an inadmissible increase in pressure when adding deionised (demineralised) water. This thus gives rise to load times of 1.5 h and more, whereas an optimally set washer-disinfector would manage with a load time of 1 hour (incl. drying)!

Adopting a patient and systematic approach, most washer-disinfectors can be set such that the desired cleaning result is achieved without having to unnecessarily extend the load times and without higher dosage of chemical substances.

Any deviations in the cleaning programme can be detected later by using dataloggers, thus facilitating troubleshooting and subsequent redefinition of parameters (see above). Parameter definition can additionally provide proof of adequate disinfection performance, as outlined already in Forum 99 (see p. 10). ✦

Measuring Washer-Disinfector Cleaning Effectiveness with Instrument Process Challenge Devices

M. Pietsch (2000)

The instruments used in minimally invasive surgery (MIS) are amongst the most difficult to process. The German Society for Hospital Hygiene (DGKH) published an interim recommendation in 1998 for verifying the processing performance of the washer-disinfectors used to process MIS instruments. The aim here was to initiate a series of standardisation measures.

However, this document recommends only visual inspection as a means of checking the effectiveness of the cleaning process. But in view of the design of lumened instruments, visual inspection is only possible from the outside or, at most, by a few millimetres at both ends into the interior of the instrument. Only by resorting to the use of a narrow, rigid endoscope, such as that used in urology, can the internal surfaces also be inspected and qualitatively evaluated. But distinguishing between blood residues and rust marks can be a problem.

To establish an alternative quantifying process, initial tests for protein detection were conducted using the modified OPA method.

The shafts of original MIS instruments and process challenge devices designed by the DGKH were contaminated with solutions comprising sheep blood, mucin and mixtures of both components. After exposure in a washer-disinfector (Miele, Gütersloh, Germany), these shafts were removed either after cleaning or after

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cleaning and thermal disinfection and were then checked for residual protein contaminants. Already after the cleaning phase more than 90% of the shafts were declared to be free of protein. The average extinction value of positive instruments was reduced from 0.021 to 0.013 by the additional cleaning effect engendered during the disinfection phase on using a full programme; this value was thus within the detection limit for protein contaminants. Visual inspection of the internal shaft surfaces, which had been conducted in parallel, demonstrated that this residual contamination was below the threshold for visual detection. The DGKH process challenge device evinced the same behaviour as the original instruments and is thus suitable for such investigations. These data furnish proof that, on using appropriate process technology, proteins can be reliably eliminated already during the cleaning phase when subjecting MIS shaft instruments, which can be dismantled, to automated processing.

Nonetheless, despite of our results, a few instruments proved to be still contaminated in the protein detection test on a very low level. This could be due to the elution technique, cleaning method used in the washer-disinfector or to the contamination procedure.

In any case the data collected prove that quantitative verification of the cleaning performance yields additional information on the condition of an instrument and can thus improve hygienic safety prior to using the instrument. ✦

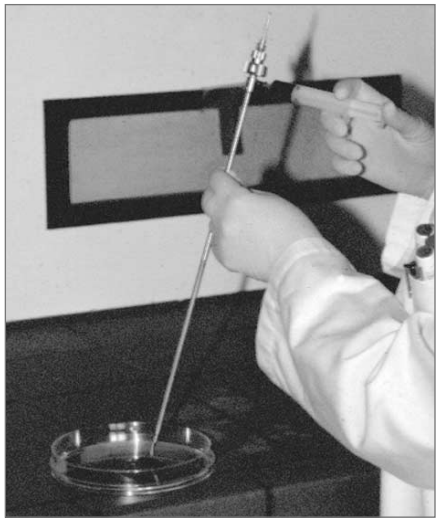

Fig. 1: Contamination of a DGKH process challenge device with a mixture of sheep blood and mucin

Quantitative Protein Monitoring with the Modified OPA Method Using the Eluate – Validation of the Method

H. Frister (2000)

Quantitative measurement of proteinaceous residual contaminants on and in surgical instruments is an important element of the quality assurance concept governing verification of cleaning efficacy. The method of choice for protein monitoring is the modified OPA method that is capable of measuring, quickly and with high analytical accuracy, proteins, peptides and free amino acids in sodium docecyl sulphate (SDS) eluate.

The measuring principle underlying quantitative measurement is a specific, stochiometric reaction between primary α- and β-terminal amino groups and orthophthal-dialdehyde (OPA) in the presence of N,N-dimethyl-2-mercaptoethyl-ammonium chloride as a thiol component. The isoindole derivates formed during this reaction are highly stable and can be measured photometrically at 340 nm. This method is characterised by the fact that it is easy to use and needs only short analysis times. Furthermore, it is a reliable and validated method which in respect of linearity, robustness, reproducibility and sensitivity provides for reliable protein monitoring results. Using this method it is therefore possible to photometrically detect substances right down to the picomol range, as has been clearly demonstrated for the most diverse substances such as for 19 free amino acids, various di-, tri- and tetra-peptides as well as proteins (globulins, albumin, and casein) of bovine and human origin.

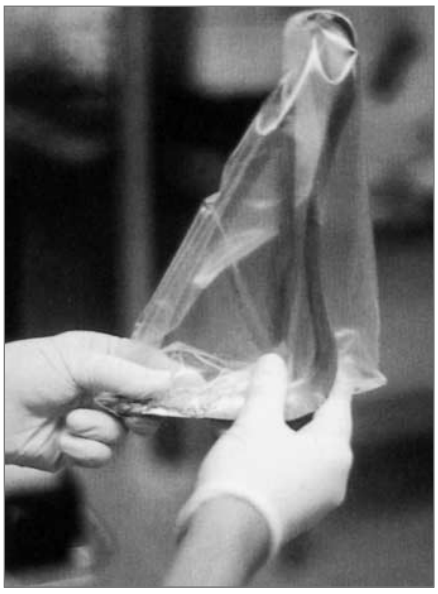

Fig. 1: Technique of rinsing of a speculum to obtain eluate after addition of 5 ml SDS

In view of the extremely low detection limit of the OPA method, the OPA reaction solution must be expertly produced and sample materials must be handled in a manner that rules out contamination, otherwise false positive results could be obtained. Another factor that can lead to false results is failure to effect photometric acquisition of blank or intrinsic extinction values for the various test matrices. Personnel should also be conversant with conductance of photometric measurements or be properly trained if this is not the case. ✦

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The Role of Water Quality in Cleaning Performance and Sterilisation

D. Steudten (2000)

The constituents of drinking water time and again lead to discolorations and deposits when cleaning and sterilising instruments. Using suitably treated water these problems can be avoided. This paper describes the well-established and traditional treatment methods based on reverse osmosis and ion exchange. Outlined in addition is a new electrochemical and continuous process for production of ultra pure water. This process is able to reliably produce water quality for both sterilising and cleaning instruments. There is excellent separation of silicic acid without any breakthrough. The system operates without any extra costs or regeneration chemicals and has thus a pioneering role in environmental friendliness and cost reduction.

The water quality is of paramount importance for successful instrument cleaning and sterilisation. Corrosion, deposits and discolorations can appear on the instruments. For example, compounds comprising the elements

- iron
- copper
- manganese
- magnesium
- silicon (encountered relatively often) can cause discolorations due to deposits

Corrosion can be caused by

- chlorides (pitting corrosion at contents > 120 mg/l)
- iron particles (extraneous rust, secondary corrosion).

At most, only traces of iron and manganese are found in German drinking water. The Drinking Water Treatment Regulation (TVO) permits only max. 0.1 mg/l iron and 0.05 mg/l manganese. An iron- and manganese-removal system must be connected downstream for any types of spring water which exceed these values. Here pressurised filter systems are used to precipitate and filter the iron and manganese by means of oxidation. Any residual traces are effortless retained in the ensuing treatment process in an ion exchanger.

Copper ions entering the water from the pipe material are easily removed thanks to their high affinity for the ion exchanger.

Chlorides are removed both by means of ion exchange and reverse osmosis. If their content in the raw water is higher (> 120 mg/l) the water used for cleaning must also be treated to prevent corrosion. Iron particles resulting from dissolved rust from the water pipes cannot be removed by means of ion exchange but this is by all means possible using reverse osmosis (RO). To protect the membrane, provision must be made for adequate particle separation (min. 5 µm) prior to reverse osmosis.

When cleaning, the instruments are rinsed with demineralised water mainly only in the last rinse cycle so as to preclude any adverse effects that could be mediated by the water constituents. Therefore mixed-bed ion exchangers are often used with the washer-disinfector for the last rinse cycle(s). In general, these function impeccably and are able to remove all dissolved minerals, including those that can give rise to deposits. RO systems fitted with membranes for demineralisation of the raw water are often used in cases with a high water consumption.

In many instances the quality of the purified water obtained suffices for cleaning, but not for sterilisation. Drinking water quality as specified by EN 285 cannot as a rule be obtained from reverse osmosis on its own. While the latter is capable, depending on the type of membrane and design, of separating 96-99.5% of minerals, the residual mineral content is often too high. Therefore a combination of RO systems and ion exchangers connected upstream is used.

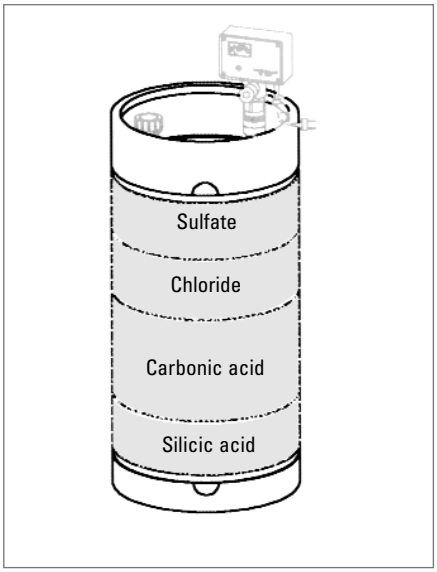

Fig. 1: Loading scheme of cartridge

When water is treated using reverse osmosis and mixed-bed ion exchangers, the requisite water quality can be effortlessly achieved and the aforementioned problems avoided since all the interfering constituents are removed to a level below their respective limit values. However, if the raw water used contains silicic acid (SiO_2), the ion exchangers must be operated in a particular manner to prevent silicate deposits. This holds true, too, even if a reverse osmosis facility is connected downstream. While in principle silicic acid is retained by an ion exchanger, it suffers the drawback that, as a weakly dissociated acid, it has only a low affinity for the exchanger resin and thus is only weakly

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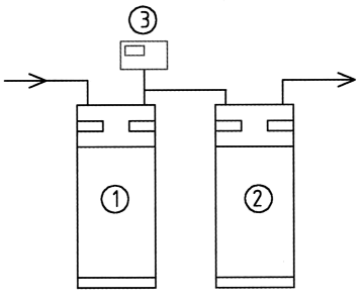
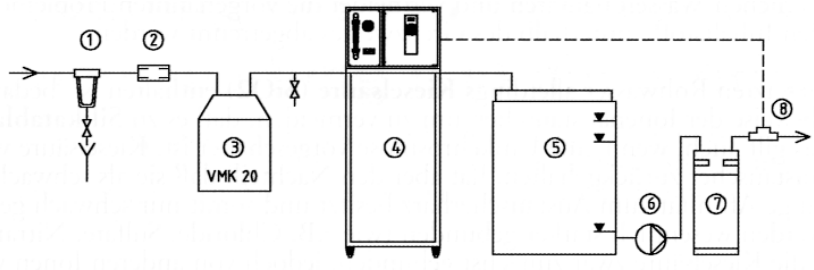


1: Mixed bed cartridge 1
2: Mixed bed cartridge 2
3: conductivity gauge

Fig. 2: Mixed bed ion exchanger connected in series



1: reverse flushing filter
2: separator
3: conductivity gauge
4: reverse osmosis system
5: storage unit
6: pressure increasing device
7: ion exchanger
8: conductivity gauge

Fig. 3: Typical installation of a reverse osmosis/ion exchanger combination

bound. Other anions are bound essentially much more strongly (e.g. chlorides, sulphates, nitrates, etc.).

Hence what happens is that the silicic acid is initially bound, only to be then displaced by other ions and deposited again in subsequent resins, from which it is displaced once again. Therefore a loaded ion exchanger has different loading zones (Fig. 1), depending on the degrees of affinity that the individual ions have for the resins and on the proportions of the latter compared with other ions.

So, if an ion exchanger is loaded, one first of all notices silicic acid breakthrough.

A major drawback here is that silicic acid is barely detectable on the basis of conductivity.

The amount of breakthrough is equal to the total anion content and hence a major load of silicic acid is discharged. Measurements conducted by us already many years ago with a cartridge operated in Hamburg revealed that even at 5 µS/cm it had contained a silicic acid content of more than 150 mg/l.

To easily obtain water that is free of silicic acid, it is recommended that two mixed-bed cartridges be connected in series and conductivity measured between the two cartridges (Fig. 2).

Once the conductivity value begins to rise in the first cartridge, it should be withdrawn and replaced by the second cartridge; a freshly regenerated cartridge then takes the place of the second cartridge. With this approach, silicic acid breakthrough will be intercepted by the second cartridge. But one must ensure that both cartridges are regenerated simultaneously at regular intervals regardless of the conductivity value displayed. One is also strongly advised against replacing cartridge 1 only in the presence of high conductivity. Reason: by virtue of the fact that cartridge 2 will have intercepted silicic acid breakthrough from preconnected cartridge 1, it will to an extent contain a certain amount of silicic acid when it is trans-

	Condensate	**Feedwater**
Vaporisation residues	≤1.0 mg/kg	≤10 mg/l
Silicon oxide SiO_2	≤0,1 mg/kg	≤1 mg/l
Iron	≤0.1 mg/kg	≤0.2 mg/l
Cadmium	≤1.0 mg/kg	≤0.2 mg/l
Lead	≤0.005 mg/kg	≤0.005 mg/l
Heavy metal traces apart from iron, cadmium, lead	≤0,1 mg/kg	≤0,1 mg/l
Chloride Cl	≤0.1 mg/kg	≤2 mg/l
Phosphate P_2O_5	≤0.1 mg/kg	≤0.5 mg/l
Conductivity at 20° C	≤3 µS/c	≤15 µS/cm
pH value	5 to 7	5 to 7
Colour	Colourless Clear No residues	Colourless Clear No residues
Hardness	≤0.02 nmol/l	≤0.02 nmol/l

Fig. 4: Contaminants in condensate and feedwater. Proposed maximum values for steam contaminants
Note: The use of feedwater or steam with constituents exceeding those values given in the table can greatly shorten the life span of the steriliser and can render the manufacturer's warranty or guarantee invalid.

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ferred to position 1. Anything that is now taken up additionally augments the content of this type of load.

At some point the entire resin layer will be loaded with silicic acid due to this displacement and this will not be picked up by conductivity measurements. One way to engage in selective monitoring is to examine the water regularly for silicic acid using a commercially available test kit. But this is a more laborious approach. Even if a combination of reverse osmosis/ion exchangers is used, the aforementioned applies as far as silicic acid is concerned. At most, the shelf live of the ion exchangers will be prolonged. If water consumption is high, mixed-bed ion exchangers alone become uneconomical due to the high regeneration costs.

Hence the combination reverse osmosis/ion exchangers is generally employed. Fig. 3 depicts a typical assembly of such a complete system. Pretreatment with reverse osmosis prolongs the service life of the ion exchangers by a factor of 10 to 20.

Other water constituents will not be discussed here, because these can gain access to purified water only if the cartridges are fully exhausted. This is because all other ions are preferentially taken up by the exchanger and give rise to a high conductivity on breakthrough. Measurement equipment will clearly draw the operator's attention to this state. In principle, sterilisation is also adversely affected by the same water constituents that interfere with cleaning. EN 285, table 1 lists the limit values for boiler feedwater (see Fig. 4). Here, too, the major hazard is posed by silicic acid. The other constituents can be easily reduced by means of reverse osmosis and ion exchangers to below their limit values.

A new method involving further treatment of the permeate of the reverse osmosis system is becoming increasingly more popular. This is known as electrodeionization (EDI). This method was initially developed by Forschungsinstitut Jülich (Jülich Research Institute) and then further developed by the license holders as marketable products and introduced under the name "EI Ion". This system comprises an ion exchanger cell with a very small volume of resin. The water to be treated is passed at a very high speed through this cell and conductivity is reduced to < 0.1 µS/cm. The resin is continuously regenerated during operation because of a connected electrical field. Hence only minute quantities of current are needed instead of regeneration chemicals. In its most simple layout, the cell consists of three chambers (Fig. 5).

The incoming water (RO system permeate with a conductivity value of

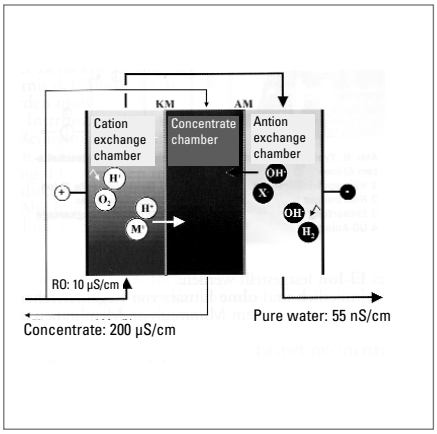

Fig. 5: Schematic view of the "Jülich cell"

≤ 30 S/cm) flows into a chamber, equipped with a cation exchanger, which is bordered by a cation exchanger membrane. In this chamber cations from the water stream are exchanged for protons (H^+ ions) from the ion exchanger resin. An anode with a plated surface is in direct contact with the resin bed. Here protons are electrochemically generated, maintaining the resin in a continually and partially charged state. Because of the electrical field, cations and protons migrate through the resin bed and the cation exchanger membrane (CM) into a concentrate compartment. The water exiting from the anode compartment is weakly acidic in line with the proportion of cations removed and the remaining anion content.

This next chamber through which the water flows is filled with anion exchanger resin and bordered by an anion exchanger membrane (AM). The hydroxyl ions needed for resin regeneration are produced on a stainless steel cathode. Here anions and hydroxyl ions move through the resin bed and through the anion exchanger membrane (AM) into the concentrate compartment. The salt load collected is continually removed from the concentrate compartment with a small quantity of permeate (10%). Depending on the design of the RO system, this amount of water is returned or filtered off with the RO system concentrate.

Two-stage cells are used to produce purified water, with the water produced from the first stage serving as feedwater

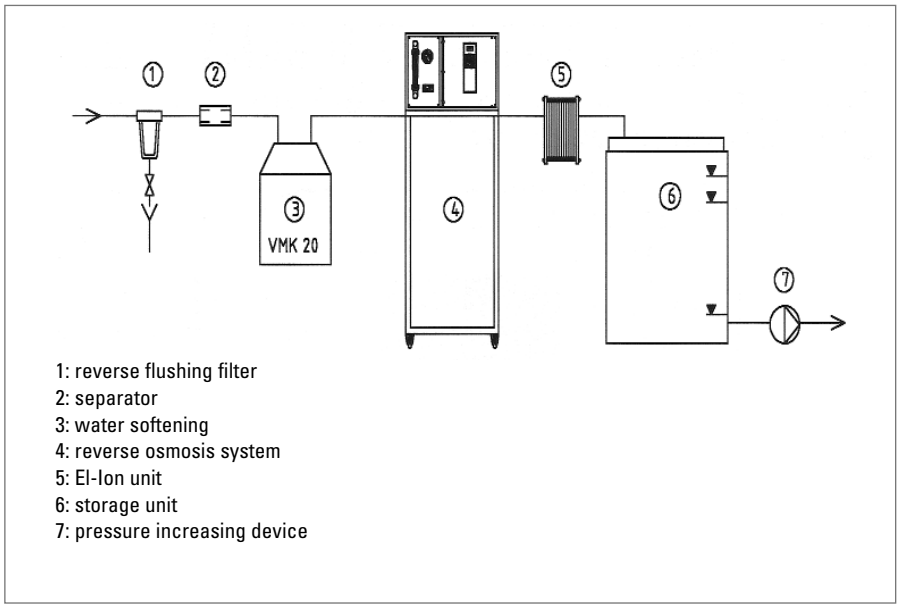

Fig. 6: Typical installation of a reverse osmosis system with integrated EI-Ion system

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for the second stage. This type of prototype cell has already been in continuous operation for more than 22,000 hours and has yielded stable values. With a total ion exchanger resin volume of 0.75 l, some 2.4 million litres of purified water have been produced with this cell or – calculated as NaCl equivalent – around 10 kg salt removed.

With an RO permeate baseline conductivity of 5–20 µS/cm, the first stage of the cell already produces a water quality in the range of 0.1 to 1µS/cm. This already suffices for most applications. Fully demineralised, ultra pure water with a theoretical limit conductivity of up to 0.055 µS/cm is then obtained after the second stage. A typical complete system with which these results can be obtained is depicted in Fig. 6.

At this juncture, the following El-Ion attributes are pointed out:

- The process operates continually and without the use of regeneration chemicals.
- The cell has a very basic design with a minimum of membranes and ion exchanger resins.
- Relatively thick resin chambers in the cm range with good flow properties (high flow speed with major substance exchange and little pressure loss).
- There is intermediate displacement in pH value as a result of single-resin beds instead of mixed-resin beds.
- This reduces the microbial count and silicates are separated.
- Direct electrode contact prevents microbial contamination of the resins.
- A German and an international patent application have been filed.
- There is no need for monitoring, replacement or dispatch of ion exchangers, with their attendant costs. ✦

Ultrasound – an Important but Hitherto Non-Standardised Factor in Instrument Processing

L. Jatzwauk (2000)

During test runs for the first destroyer of the British Marines in 1894, Sir John I. Thornycroft and Sydney W. Barnaby noticed strong vibrations originating from the propeller screw. These they believed were caused by large gas bubbles that were formed as the screw rotated and then imploded due to the water pressure. This phenomenon became known as cavitation. Later, targeted cavitation was no longer generated only by mechanical pressure but also by intensive sound waves in fluids. Alfred L. Loomis was the first chemist to detect in 1927 the unusual effects of intensive sound waves in liquids and thus founded what is known as sonochemistry. This discipline tended to be ignored and regained importance only in the 1980s when inexpensive and powerful ultrasound generators were introduced.

The term "ultrasound" denotes sound waves with frequencies above 16 kHz, i.e. 16 000 oscillations per second, and which are outside the human hearing range. Ultrasound waves compress and expand the liquid in an ultrasonic bath in an alternating pattern, giving rise to bubbles with a diameter of up to 100 micrometers in the presence of an adequate sound intensity. These grow and shrink in line with the compression and expansion phases, but continue to increase in volume until they have reached a critical size, only to then implode. Initially, the gas bubbles present in the liquid dissolve and attenuate implosion or the bubbles rise to the surface (degassing). Later, the bubbles contain hardly any more gas. When such bubbles implode (genuine cavitation) their contents are heated greatly, in some cases up to 5500 °C. However, these temperatures are maintained only for a little more than a microsecond; much too short for thermal disinfectant action, but adequate for gradual heating of the liquid in the ultrasonic bath. It is the transiently high temperatures that trigger the chemical reactions (sonochemistry) and light flashes (sonoluminesence).

If solid surfaces (e.g. instruments) are present in the liquid, bubble implosion will be targeted towards the surface such that a liquid jet is formed and crashes against the surface at a speed of around 400 kilometres per hour. And while the microcurrents and particle oscillations mediated by ultrasound exert a positive influence on the cleaning process, it is the cavitation on the surface of the instruments and not the ultrasound itself which is the chief determinant of cleaning, and thus the mechanism deliberately deployed by the equipment manufacturers.

Cavitation presupposes the presence of a minimal sound intensity, something that is not assured in every ultrasonic bath, nor at all locations in the ultrasonic bath and is generated only after a certain degassing time that depends on the liquid being used in the ultrasonic bath. Measurements have furnished proof that cavitation in an ultrasonic bath is not homogeneously distributed. The aluminium foil positioned vertically in an ultrasonic bath shows, at defined distances from the half of the ultrasound wavelength, characteristic perforated patterns as a re-

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sult of cavitation. In between, there is no evidence of activity. These perforated patterns are a logical corollary of the waves used in the ultrasonic baths and at whose pressure centres cavitation mainly takes place.

Since sonochemical reactions are also caused by cavitation, the kinetics of these reactions show an equal measure of heterogeneity when it comes to local distribution in the different ultrasonic baths. Points of minimal reaction velocities are generally found in the vicinity of the ultrasonic bath outlet because no sonotrodes are positioned there. In all ultrasonic baths cavitation results in an increase in the temperature of detergent and disinfectant solutions ranging from room temperature to above 50 °C, but because of the divergent use of frequencies seen in medical practice it is virtually impossible to standardise this. The cavitation used in the ultrasonic baths employed for processing medical instruments is not enough to effect morphologic disintegration of bacteria, viruses or fungi, as seen in laboratory ultrasound equipment. On the contrary, there have been more reports of bacterial multiplication in cleaning solutions in ultrasonic baths.

However, since the 1970s it has already been known that the microbicidal action of chemical disinfectants can be potentiated in ultrasonic baths. This effect has been proven for bacteria, enveloped and non-enveloped viruses, fungi and protozoa. It is manifested for different microorganisms, albeit not with the same intensity. Potentiation of the detergent and disinfectant action for medical instruments in ultrasonic baths holds out most interesting prospects of being able in future to process medical instruments quicker, while using lower doses of disinfectants. But this presupposes that sound intensity and cavitation can be measured and thus standardised.

Until matters have progressed thus far, any information relating to enhanced cleaning action and above all to potentiated disinfectant action is valid only for the respective type of ultrasonic bath specified in the expert opinion. This also applies for the following: information on the disinfectants and detergents, degassing time, the test load with instruments used and only for positions in the ultrasonic bath at which the germ carriers or bacterial suspensions had been placed. ✦

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Disinfection and Sterilisation Must Not Be Just a Matter of Belief – Machine-Independent Process Monitoring

A. Bosch (2002)

For as long as we have been performing disinfection and sterilisation of medical devices with the aid of heat, the manufacturers and operators of these machines have been looking for ways to control and document these processes. Up to the present day, these methods are generally not independent of the machine whose parameters are to be checked (logic control, integrated measurement equipment that is independent of the process).

One of the first control methods was based on biological indicators aimed at inactivating bacteria, which in itself was a logical approach as this was precisely the goal of the sterilisation process. It was known that bacteria could be killed when subjected to heat and moisture, but the exact interplay between these processes was not yet known at the beginning of the last century. To date, biological indicators continue to be used as a control method. Standard EN 285 (1996) still decrees that newly designed sterilisers must be tested with bacterial spores. This standard does not state that regular tests (every 3 months) must be carried out using biological indicators. Whether this stipulation is complied with or not depends on the respective regulations in force at national or local level. These tests are not suitable for verification purposes in an everyday setting due to the associated long incubation time (batch control).

A control method that now tends to be rarely used is the employment of a glass maximal thermometer that is sterilised as part of the sterilisation load (very imprecise). Efforts to control sterilisation processes have gained considerable momentum since the 1950s. Initially, indicator adhesive tapes were used; by undergoing a change in colour these indicated whether a product had been sterilised or not.

Bowie and Dick used this indicator adhesive tape as a prototype for designing their test pack. The adhesive tape is stuck onto a sheet of paper in the shape of a cross and in this manner placed as an indicator sheet in a laundry pack to furnish proof of whether good air removal/steam penetration has taken place. This test continues to be the world standard, albeit it must be stated that this indicator sheet has been improved in the meantime and has also been regulated in a standard. It provides information only on the location at which it is positioned.

But just what happens in everyday practice? After servicing or repairs, the engineer often takes just any Bowie & Dick test pack that he may find in the department and then proceeds to carry out the test. If the test result is unsatisfactory, the test will be repeated until it produces the desired result! We do not believe that this approach reflects the intent of the corresponding standards (DIN EN 285, 554).

The steriliser control system most commonly used in hospital sterilisation departments is chemical indicators. These enable the operator to control the process and release medical devices in a sterile state. But the quality of many commercially available chemical indicators varies considerably, as noted in the standard. Evaluation of processes to be checked with chemical indicators that undergo a change in colour in respect of time, temperature and moisture depends largely on the assessor's visual competence and accuracy. This matter is further compounded by the fact that a vast proportion of the male population is colour blind, thus calling into question the credibility of colour-based methods. Furthermore, it must be possible to continually document the test result, something that can be a problem in the case of colour indicators (indicator undergoes ageing process, as does the paper especially on exposure to light and because of different storage factors).

Disinfection und sterilisation processes are described in detail in standards. Standards and directives are generally based on physical measuring methods with definition of limit values. For disinfection and sterilisation it is mainly the temperature, pressure and time, set appropriately vis-à-vis each other, which produce the desired sterilisation result. This is based on experience of steam sterilisation gleaned over the past 150 years. (The historic background to this is given in the following German publication: "Die Geschichte der Hitzesterilisation und einige ihrer Standards", B. Knöller, mhp-Verlag, Wiesbaden, Germany; ISBN 3-88681-049-6).

The limit values applicable to a process that has not been properly executed are explicitly defined in standards. The processes are analysed on the basis of these criteria. Hence disinfection and sterilisation is no longer a matter of belief. It is now time to update control and documentation of these processes. The state of the art – in some instances dictated by developments in the foodstuffs industry – provides the mechanisms, with the help of dataloggers, for swift and simple control and documentation of these processes. For many decades now physical measuring systems (loggers) and test procedures have been available which could also have had their use in the field of medical device processing. The spore tests dating back more than 100 years which were used to check canned foods and then used to check sterility are one such example.

The deployment of dataloggers ushers in a novel approach to the monitoring of physical sterilisation parameters. In addition to temperature and pressure, the time during which the prescribed values are achieved is also acquisitioned.

In view of their greater power, precision and reproducibility, preference should be given if at all possible to physical methods over chemical or biological indicator systems.

For example, a sterilisation engineer checks a steriliser after repair (temperature, time, pressure and steam penetration) and passes on the results to the operator in the CSSD. This assures the operator that he can place the steriliser in operation again, pursuant to the pertinent provisions. He can refer to the process data in the event of any queries. ✦

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Sampling and Analytical Methods Used to Monitor Cleaning of Medical Products to be Sterilized

H. Frister and W. Michels (2002)*

The first step in the analytical monitoring of the evaluation of cleaning performance in practise is to find a suitable method of sampling. This must enable the highest possible recovery rate in the measurement area of defined cleanliness of any protein present in blood, mucus, etc. which may be present on the medical device.

To this end publications describe how instrument surfaces are wiped with a cotton swab dampened with water or detergent, or how surfaces are rinsed (eluted) with a detergent solution. The detergent of choice is 1% sodium dodecyl sulphate solution, the tenside described in the literature as performing best at denaturing proteins (in the sense of unwinding and dissolving them). Experiments using the swab method, in the simplified circumstances of stainless steel surfaces contaminated with defined amounts of heparinised sheep's blood (not reactivated), showed depending on the swabbing method and quantities used, recovery rates in part of plainly less than 80%. Here, the thinner the layer of contamination the worse was the recovery rate. On the other hand, using the SDS elution method and reactivated heparinised blood, the recovery rate was consistently greater than 80%. Here, the thinner the layer of contamination, the greater the recovery rate- this was using thin, but still visible layers of contaminant. Concerning greater amounts of contamination than tested, it became obvious that if the contamination has to be removed manually and is visibly obvious, it need not be quantified. There are also other experiments that demonstrate the particular suitability of SDS-solution.

The use of SDS solution to extract samples means that the protein analytical methods of Bradford, Eosin and Lowry cannot be implemented. This is because protein colour complexes do not form in this solution. SDS solution does not cause a fundamental problem when using the Biuret method or the more sensitive BCA method that is based on the Biuret method. Here it depends on the conception of the test kit. Saccharose does however interfere with the Biuret reaction, and falsifies the results. Mucus, which is a commonly found contaminant of medical products, contains saccharose. This means that the method is not suitable when quantitative measurements of such residual soil are required. However for semi-quantitative measurements on the spot in practise, it is quite sufficient. Practical test-kits are available on the market.

The modified OPA method is the method of choice in the laboratory for quantitative determination of proteinaceous residual soil such as blood, mucus etc. The principle of quantitative measurement is based on the specific stochiometric reaction between primary α- and ε-terminal amino groups with o-phthaldi-aldehyde (OPA), in the presence of N,N-dimethyl-2-mercaptoethyl-ammoniumchloride as the thiol component. The iso-indole derivatives thus formed have an astonishingly high stability and can be detected photometrically at 340nm. The method is a safe and valid one. Good results with regard to linearity, robustness, reproducibility and sensitivity are obtained.

The extremely low detection limit of the method means that when the modified OPA method is used in practise, the careful mixing of the OPA reagent as well as contamination-free handling of the sample material is essential; otherwise false positive results cannot be ruled out. False results can also stem from failing to record photometric measurements of blind values and intrinsic extinction values of the various investigated sample matrices. The personnel conducting the experiments should be familiar with the implementation of photometric measurements and trained to carry out the OPA method. ✦

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Centralisation as a Quality Measure

T. Fengler, H. Pahlke (2002)*

Rarely is a hospital able to provide all its sterile supplies without the help of an external supplier. Proof of sterility is regularly furnished here indirectly (!) by means of proper and continual documentation of a processing procedure that is deemed reliable, and which also includes spore tests, etc. Processes are deemed "reliable" in accordance with how they are rated in respect of the current stock of knowledge and the state of the art. This status is conferred by laws, standards and directives which, if not complied with, will surely result in the burden of proof being shifted in the event of a claim.

We are thus moving away from what was accepted as the norm in the past, where each operating theatre had ideally its own processing facilities in an adjacent room, "close to the action", and instead we are acquainting ourselves with ideas which make provision for monitoring of ordered sequences.

Without centralisation of uniform processes, it would be difficult to provide for their regular and uniform repetition (validation), because they involve tasks executed by many staff members, special equipment and automatic machines. Staff behave differently when each person member does their own thing in their own working area. But the technical equipment and facilities requiring high investments cannot be provided in infinite numbers and properly installed on the clean and unclean side.

It must be possible to verify all phases of medical device processing and these must comply with the quality standards stipulated by the hospital in conformance with the current stock of knowledge and the state of the art (see above). This starts already with procurement, correct positioning of the medical devices after use in the OR, avoidance of wet transportation, timely delivery of supplies to both the processing department and to the user (surgical staff, "client", in the OR).

For reorganisation purposes, it is important first of all to take an inventory and then compile a catalogue of measures. Do you know what instruments and other medical devices are still tucked away in various drawers? How are things when it comes to process sequences, setting the various process parameters, the level of staff training, organisation of work flow patterns?

Who is authorised to carry out repairs and order spare parts, and are the latter then registered as part of the inventory? These controlling endeavours would be greatly facilitated if each instrument had an unambiguous identification code, so that instrument cycles could be recorded, their extent of wear estimated and ordering of new supplies automated (traceability and tractability). This would make verification of performance parameters much easier where the medical devices are concerned.

At present, it is much easier to verify how processing procedures unfold (i.e. performance) thanks to the use of data-logging systems and process-step-control measures. This dispenses with the need for certain discussions, because figures (physical parameters) speak louder than words. Furthermore, these developments increase motivation because staff can view their performance in an objective light, relying on statistics rather than on visual inspection for assessment purposes.

Alas, controlling is often a novel territory whose ramifications have not yet found their way down to the basement, where processing is generally conducted in conditions characterised by poor lighting and visibility. How can an understanding of the relevant arguments then be achieved there? Therefore the solution often sought here is to turn to the external contractor because it is often beneficial to take away the decision-making powers from the known decision makers within the establishment, as regards matters that find a (broad) consensus.

The "arbiter" often becomes an active player if the reorganisational measures can be accepted. This gives rise to service contracts or subsidiaries together with services' experts.

An important requirement here is that personnel should be respected and that the expertise associated with all proposals be passed on to them. Time and again it comes to light that there is no time for staff training in the everyday hospital routine, so accordingly staff will have no understanding of the need for procedural and structural changes. "We've always done that in this way" is a claim often heard, with mention as to why. So in principle there are two options:

- In-/outsourcing
- Reorganisation of the services' area (Consulting, Management)

External services can be verified on the (new) basis of the contractually agreed target line, i.e. documentary proof must be provided of well-organised processes (parametric assessment) and reorganised structures (QM Manual), thus assuring the resultant quality of the CSSD. In some circles – see Medical Devices Act (MPG) – this is also known as validated processing. ✦

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Testing Washer-Disinfectors (WD) and Process Documentation

A. Brömmelhaus (2002)

Introduction

According to the regulations for the use of medical products, the entire procedure of processing medical products consisting in cleaning, disinfection and sterilisation must be carried out using validated methods, which can be documented (1). In the past sterilisation was the centre of general interest, and a series of guidelines and standards were produced on validation of processes. The cleaning and disinfection steps were discounted at first, although it is generally known that successful sterilisation can only be achieved if previous cleaning is adequate.

Because of the development of ever more complex and delicate instruments, cleaning and monitoring of cleaning results became increasingly the focus of interest. Thus cleaning methods were continually improved, and new baskets and inserts were developed for the safe processing of delicate instruments such as those used in MIS or Urology (Fig.1). Concomitantly methods such as the OPA-method for determining residual soil on instruments were developed, which allowed measurement of cleaning performance (2).

In Germany in practise even today WD appliances are routinely almost exclusively tested using microbiological methods. These methods do not differentiate between reduction of microbial count caused by rinsing and dilution or by killing, and certainly do not give evidence about the actual cleaning performance of the appliances. Decimation caused by the effect of temperature is a factor that can be far more simply and accurately monitored using thermoelectric measurements. The cleaning performance has then to be recorded independently.

Thermometric tests

Because of these factors the drafted norm prEN 15883 for thermal disinfection methods in WD appliances is not proposing the use of microbiological tests. Rather, the disinfecting performance of the appliances is to be periodically tested via thermometric measurements. The drafted norm sets A_0-values as the disinfection parameter. The A_0-value quotes the amount of heat necessary for successful disinfection, and is defined as the equivalent time in seconds at 80 °C at which the stipulated disinfection is attained. Disinfection is generally considered to be sufficient at an A_0- value of 600 secs. which can be obtained for example at 80 °C/10 mins. or at 90 °C/1 min. If particularly temperature-resistant germs are present such as the Hepatitis B virus, an A_0-value of 3000 secs. is recommended, which can be reached for example at 90 °C/5mins.

In order to test the disinfection performance of WD appliances, temperature measurements should be obtained from appliance-independent temperature loggers placed at various positions within the wash cabinet, and also directly on the wash load. These thermometric measurements should be carried out directly after commissioning a WD appliance, and also after programme alterations or servicing of such an appliance. How often such measurements are routinely conducted should be decided in the area of quality control. The drafted standard requires the appliances to be equipped with an entry port so that sensors can be fixed in various positions inside the cabinet. As an alternative, cable-free thermologgers can be used. These are put into the WD appliance along with the instruments. When the process is over, a temperature/time curve can be read off a PC and documented (3).

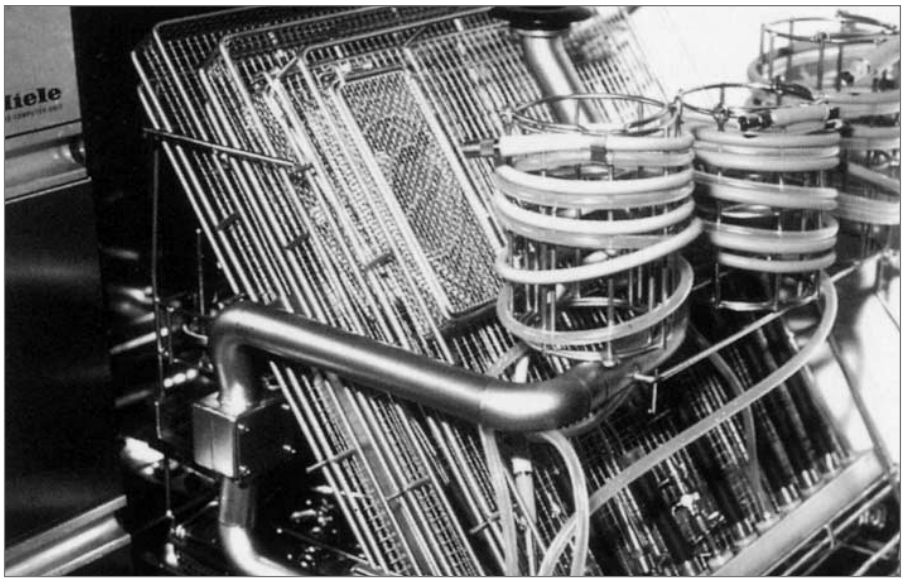

Fig. 1: Injector basket for MIS and urology – facilitates cleaning of delicate lumened instruments and considerably shortens the time required for reprocessing this kind of devices

Monitoring cleaning performance

Of course it is also necessary to conduct cleaning performance tests on the WD appliance as well as the aforementioned ther-

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mometric measurements. The drafted standard does not suggest the use of process challennge devices, as these cannot mimic the various geometrical shapes of instruments (4). The drafted standard directs the reader to an informal appendix on the subject of test contaminants, which lists a number of possible alternatives. A glance at this list throws up a few surprises. It includes contaminants that are used in microbiological tests in order to hinder the rinsing off of germs, for example semolina, egg-yolk or wallpaper paste. Materials such as these of course have little practical relevance, and may during tests lead to false conclusions about cleaning performance. The listed blood contaminants do have some practical relevance, but still cannot reflect competently the complexities of contamination found on actual instruments. These include various mixtures of blood, mucus, fat etc. that are not presently reflected by a standardised test soil.

The most important step in the practical monitoring of cleaning is therefore the visual checking of instruments for remaining soil after processing in WD appliances. For a more objective assessment of soil, and to monitor areas, which are hard or impossible to see, a recently developed and rapid protein-test kit can be used. Any possible residual protein on the instrument is eluted using a SDS-solution. The detection of protein in the eluate follows using the semi-quantitative Biuret method that has been modified to suit these specific circumstances. In this way the residual soil on a medical product can be determined on the spot and the cleaning performance for quality control of processing medical products can be randomly checked. Thus the appropriate performance of the processing method can be tested, weak points in the processing detected, and the cleanability of instruments can be determined.

Process documentation

As well as conducting periodic tests on the disinfecting and cleaning performance, the user must regularly ensure and document that his method parameters, which are necessary for the success of decontamination, always coincide with those used in the routine tests. Therefore the user of the WD appliance has to carry out a process/load documentation of parameters relevant to hygiene, such as cleaning and disinfecting temperature, holding time, detergent concentration etc. so that successful decontamination is comprehensibly guaranteed. The documentation can be printed out on paper or carried out electronically.

Using this approach of process/load documentation, the regular periodic performance checks via thermometric methods and monitoring of cleaning performance, the requirements of a validated decontamination are satisfied, and quality control is made possible. In this way a high level of safety is attained for the subsequent sterilisation and reuse of instruments on patients. ✦

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Validation Methodology for Automated Instrument Processing

L. Jatzwauk (2002)

The German Medical Devices Act requires that all users not only validate the sterilisation processes used, but additionally the preceding cleaning and disinfection processes, too. Similar recommendations are given in the amended sections on medical device processing in the Guideline for Hospital Hygiene and Infection Prevention of the Robert Koch Institute (RKI).

This demand for reliable instrument processing is legitimate. However, its implementation appears to be something of a problem because, unlike with steam sterilisation, it is not known to date by what means disinfection and, in particular, cleaning are to be validated. As regards medical device cleaning, there is a lack of scientifically corroborated data on just how clean a medical device must be after cleaning. Nor is it known to date what quantities of residual contamination have an adverse effect on sterilisation processes or could even directly damage the health of patients.

However, since the demand for validation of medical device processing enshrined in the Medical Devices Operator Ordinance must be properly and bindingly implemented, until such time as uniform standards and validation processes are in place, the solution is to avail of the existing control methods for automated disinfection as well as of individual specifications and methods for checking medical device cleaning.

Validation of automated washer-disinfectors means furnishing documentary

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proof that the processes used, bearing in mind the installation and operating conditions at the user's premises, i.e. reproducibly achieve the intended (specified) cleaning and disinfection efficacy

- when using defined detergents and/or disinfectants
- for the temperature and exposure times used
- for the specific mechanics of the cleaning solution
- for the respective quantity and type of load with particular instruments.

Appraisal of Technical Facilities

At the start of validation the available technical facilities must be appraised. Can the installed technical facilities, the washer-disinfector at all give the performance expected by the user? Appraisal of equipment at the time of commissioning is the responsibility of the supplier and/or installation firm. For revalidation, previous technical servicing/inspection can yield appropriate information.

The user should insist on obtaining protocolled information on machine programming (temperatures, exposure times, dosage quantities). The respective water quality (softened or demineralised water) as well as under certain circumstances the water pressure should be checked and documented. A check must be conducted to establish whether appropriate trays are available for the respective medical devices.

Specification and Appraisal of Disinfection Efficacy

Disinfection means restoring an apparatus, while taking account of its previous history, to a condition which when used can no longer act as a source of infection. Requirements for the disinfection efficacy are based on risk analysis. If an instrument is contaminated with hepatitis B/C viruses or if this cannot be ruled out, then this apparatus poses a risk of infection, disinfection processes that are effective against hepatitis viruses must be used and proof of a reduction of their titres by at least 4 log levels must be furnished. For thermal disinfection, pursuant to prEN ISO 15883-1 A_0 values of 3000 seconds at 80 °C or another corresponding time-temperature ratio must be selected (e.g. 5 min at 90 °C). If this is not possible, 600 seconds at 80 °C or equivalent A_0 value will suffice. These reduce the microbial count of defined bacteria and fungi as well as of heat-sensitive viruses by at least 5 log levels. The existing "BGA Requirements" (93 °C and 10 min) which continue to be valid can serve as a suitable specification for older washer-disinfectors (programme cards) that cannot, or only with considerable effort, be reprogrammed.

In our hospital the thermal disinfection performance is verified by means of thermoelectric measurement of disinfection temperatures and exposure times with dataloggers (ebro-Electronic, Ingolstadt, Germany). Calculation of A_0 (F) values for the disinfected supplies should take precedence over defined time-temperature plateaus, because by referring to temperatures during the heat-up phase it is possible to provide for energy- and time-saving operation. As opposed to the well-known biological indicators (*Enterococcus faecium* on screws or tubular sections) thermoelectric measurements enable one to reduce excessively large time-temperature ratios. The result is available immediately after finishing the measurements. Special attention must be paid to critical checkpoints in the device, i.e. respiratory tubes or, when low loads are used, the location directly between the rotors.

Chemothermal disinfection processes can be checked with the existing biological indicators using *Enterococcus faecium* in defibrinated blood or semolina on screws or tubular sections.

Specification and Appraisal of Cleaning Efficacy

The biological indicators used to verify the chemothermal disinfection efficacy, as recommended in the BGA guideline, do not produce reliable data on the cleaning of medical devices during processing procedures because neither the type of test soils nor the their germ carriers are representative of everyday practice. Myriad investigations have proved that there is no correlation between a reduction in the microbial count and the cleaning action (references can be obtained from the author). To date, no standards have been established or are generally recognised for verifying cleaning efficacy.

Again, risk analysis is one of the first steps taken in practice. The method used to verify cleaning efficacy of a processing procedure must be tailored to the instrument contamination encountered in a particular setting. The (potential) occurrence of coagulated (dried) blood on instruments is indicative of soils that are difficult to remove (surgical instruments). If blood-mediated soils can be essentially ruled out, cleaning will be less of a problem (wash receptacles, anaesthesia materials).

"Cleantest indicators" (PVP Hygienekontrolltechnik, Limbach-Oberfrona, Germany) has proved useful for verification of surface cleaning of medical devices that are easy to clean. These are stuck onto sites that are potentially difficult to clean. If residues of the coloured test contaminant can still be detected on completion of processing, this will point to fully inadequate cleaning efficacy as far as these instruments are concerned. This method is easy and inexpensive and can be affixed to medical devices of different designs.

Semi-quantitative findings on the cleaning performance of an instrument processing procedure are yielded by "TOSI indicators" (Biologische Analysensysteme GmbH, Lich, Germany) which are representative of difficult-to-remove test soils. Using suitable carriers, lumened instruments can also be simulated. This method can be recommended, too, for validation of cleaning processes difficult-to-remove contaminants.

Frequency of Validation of Disinfection and Cleaning Processes

The Guideline for Hospital Hygiene and Infection Prevention of the Robert Koch Institute recommends that the effectiveness of washer-disinfectors be verified every six months. To date, only the disinfectant action must be checked.

Based on risk analysis on site, this recommendation can be modified to meet the individual situation. Intricate instrument processing procedures entailing a greater risk of infection must be verified more frequently (flexible endoscopes: every 3 months) than relatively straightforward processes posing less risk of infection (washing receptacles, sliders: once yearly).

Additional verification of the cleaning efficacy appears warranted, in additional to the annual check, when commissioning new washer-disinfectors or changing the detergent and/or process control. It is always required in addition if visual soils can be detected on the instruments after processing. ✦

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Validation of Cleaning with Surface Analytical Methods

R. Reichl (2002)

The characteristic properties of boundary-surface and microstructure analytical- processes such as low information depth, high spatial resolution and pronounced detection sensitivity permit comprehensive – albeit selective – examination of the surfaces of materials:

Contamination analysis

- Element composition (qualitative and quantitative analysis)
- Chemical compounds (qualitative and quantitative analysis)
- Lateral distribution (element and compound distribution images)
- Layer thickness

Examination of the material surface following cleaning

- Alteration of element composition (qualitative and quantitative analysis)
- Alteration of chemical compounds (qualitative and quantitative analysis)
- Lateral distribution (element and compound distribution images)
- Material damage (corrosion)

Due to its typical trait of performing analysis in atomic dimensions, boundary surface research permits greater insights into processes unfolding in areas that remain inaccessible to human senses. Using this facility, it is thus possible to design and tailor to individual requirements – e.g. amenability to cleaning – new surfaces and materials going beyond the realm of conventional analysis.

Introduction

The difficulties encountered in trying to inactivate the insoluble scrape prion protein PrP^{Sc} using conventional sterilisation processes have led to the situation that reliable cleaning has now become the most important step of the entire chain when processing medical devices.

Strictly speaking, perfect cleaning means removal of all contaminants from the surface of the respective medical device, including all pathogens. But what actually happens in practice in many cases is a very different story.

Hence there is all the greater need for analytical methods that guarantee robust characterisation of medical device surfaces. However, as a rule it is possible to objectively assess cleanliness and the cleaning outcome on surfaces only by identifying and quantifying the residual contamination as well as by analysing the microstructure and the chemical composition of the material surface of the instrument or of the medical device to be sterilised. The composition of an initially contaminated and then cleaned surface is generally complex (Fig. 1).

In principle, different methods can be used to characterise a cleaned surface: particle count methods, contact angle measurements, UV-VIS spectroscopy, light microscopy, scanning electron microscopy, secondary ion mass spectrometry, X-ray photoelectron spectroscopy, radionuclide method, measurement and assessment of surfaces by means of evaporation rates, analysis of non-volatile residues, thermogravimetric methods, total organic carbon (TOC) analysis, phase formation analyses, gas chromatography/ mass spectrometry and Fourier's transformation infrared spectroscopy The correct choice of a method will as a rule depend on the requirements being addressed to the measurement results. The medical device must be destroyed to implement some of these methods.

Methods

Investigation and testing of the cleanliness of medical device surfaces were conducted at the Natural and Medical Sciences Institute at the University of Tuebingen (NMI) using boundary-surface and microstructure-analytical methods. To identify the medical device locations least amenable to cleaning the radionuclide method, conducted by SMP GmbH, was employed in the course of investigations of the cleaning behaviour.

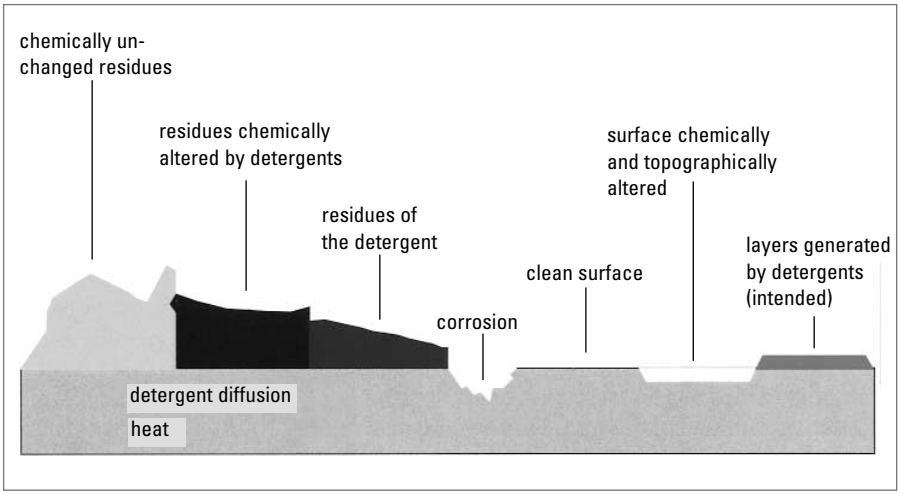

Fig. 1: Composition of an initially contaminated and then cleaned surface

However, it is not possible to carry out these procedures in a hospital setting. Rather, they serve to design instruments that lend themselves to cleaning, assuring safe processing from the moment of initial conception right through to parameter verification. Hence in terms of the procedure adopted, this approach is very similar to that used in sterilisation. Surface characterisation can be effected, inter alia, by means of light microscopy (LM), scanning electron microscopy (SEM) and X-ray photoelectron spectroscopy (XPS).

Light Microscopy (LM)

Light microscopy is employed already at the time of preparing samples for SEM and XPS. One important advantage of this method resides in the reproduction of colours in the light microscopy images.

Scanning Electron Microscopy (SEM)

In addition to magnification that can be as high as 100 000-fold, the main advantage conferred by SEM images is the enormous depth of focus. Even three-dimensional objects measuring several millimetres in diameter are depicted throughout in sharp focus.

X-Ray Photoelectron Spectroscopy (XPS)

Contaminants are often present as thin, topographically uniform layers, hence they cannot be identified with SEM. To identify such contaminants, the chemical composition of the surface is analysed with XPS, which also gives an insight into the provenance of the contaminants. By quantifying the contamination, it is possible to objectively assess the cleanliness of a surface. The adhesion mechanisms of specific contaminants can also be investigated in order to determine how materials respond to cleaning. XPS has proved to be a suitable analytical method in such circumstances.

Standard Surfaces

How clean is a surface that is recognised as being clean? What is definitely true is that in reality there is no such thing as an atomically clean surface. In a large industrial joint project carried out by NMI, a vast number of instrument surfaces that were deemed to be clean were subjected to XPS analysis. From the element concentrations thus obtained, mean values were calculated with their associated standard deviations. These XPS investigations formed the basis for definition of what is known as "standard surfaces". By means of qualitative and quantitative comparison with any arbitrary surface they permit objective and quantitative assessment of cleanliness. ✦

Masthead

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Central Service *is the official publication of the German Society for Sterile Supply e.V. (DGSV)*

Publisher
mhp-Verlag GmbH, Marktplatz 13, D-65183 Wiesbaden ✆ +49 (0) 611/505 93-31, Fax: -11, E-mail: info@mhp-verlag.de

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Rate Card
Rate card No. 11/2003

Printing
Druckerei Chmielorz GmbH, Ostring 13, D-65205 Wiesbaden-Nordenstadt

Paper
Terraprint mat "chlorine-free", 90 g/sq.m

Publication Schedule
Bimonthly: February, April, June, August, October, December

Subscription Rates
Single issue: € 8.70 (plus postage, tax included). Annual subscription rate (6 issues, postage and VAT included)Germany: € 52.59, Europe: € 60.30, World: (air mail) € 73.16.

Unless cancelled before August 31st of the current year, the subscription is automatically continued for another year. Subscription orders should be sent to the publisher.

ISSN 1612-0108

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Documentation, Quality Control and Verification of Performance Parameters for Medical Device Processing

R. Hussel (2002)

The Problem

In recent times there has been an increasing awareness of hospital infections, attributable in some cases to improper processing of reusable instruments (medical devices). These shortcomings now highlight the need for documentation of process sequences and verification of parameters, which is why a quality assurance system is to be introduced for sterile supplies. In Germany, this has already been determined in principle since the end of the 1980s (Code of Social Law). Only by adopting such an approach can the infection risk be minimised and proof furnished that all processing steps have been correctly adhered to.

Today, it is possible to organise a complete sterile supply management system by using computers with corresponding software and observing the prescribed sequences. In the meanwhile, similar standards (EN, ISO) governing sterile processing of reusable medical devices are in force in many countries. The demands addressed by such standards to the sterilisation department personnel are not low, especially if one bears in mind that even at present staff are under pressure to reduce costs and optimise the quality of the services rendered.

The Solution

In 1999 the Australian company Precision Medical was commissioned to develop a software system to meet these requirements. The order for this was awarded by Central Coast Health Service, a public hospital group (70 km to the north of Sydney). The key demand was to deliver a system that exactly met the needs of a central sterilisation department for medical devices; at the same time it should be easy to operate and comply with statutory provisions. The system "STS – Sterilizing Tracking System" was introduced in December 1999 and won a prize for the hospital, the "Baxter Innovation in Healthcare" Award.

Fig. 1: Scanning of packed devices with a portable computer

A key feature of the STS System involves the use of a portable computer with a barcode reader (Fig. 1). The main advantage of such a device is that manual data acquisition is dispensed with. A quick and correct means of data acquisition had been invented. All processing steps are documented by scanning a barcode label.

By scanning the barcode label for each processing step and using the extensive instrument register in the STS System, the following data are also concurrently registered:

- date, time and name of staff member entrusted with loading the machine
- which devices were used
- date, time and name of staff member entrusted with unloading the machine
- visual image of a test result
- parametric release by using a datalogger (temperature, pressure)
- date, time and name of staff member entrusted with distribution within the hospital
- documentation of costs (for internal accountancy purposes)
- sterile supply warehouse management for multiple storage sites in different hospitals
- date, time and name of staff member using the device on a patient
- proof of costs for complete operational cost control
- date, time and name of staff member entrusted with return to CSSD
- report on condition of supplies

In addition to documentation of sterile medical devices, the use of single-use medical devices can also be documented (Fig. 2). This is particularly important for control of implants and other invasive devices used for patients. Just as in the case of instruments, so here too instrument recall is possible at all times and the system is able to precisely locate the respective device.

The user has access to an extensive supply of statistical data thanks to automated documentation. These data are used to plan and optimise future instrument deployment, enhance new purchases, optimise equipment utilisation and control repair and servicing of instruments.

An inventory management system is also incorporated. An instrument register features all instruments, with operating instructions based on figures and videos. The system can also be used for training purposes. It can be adapted to different coding systems and languages. Trackability and traceability of single medical devices – not only of trays – become possible. ✦

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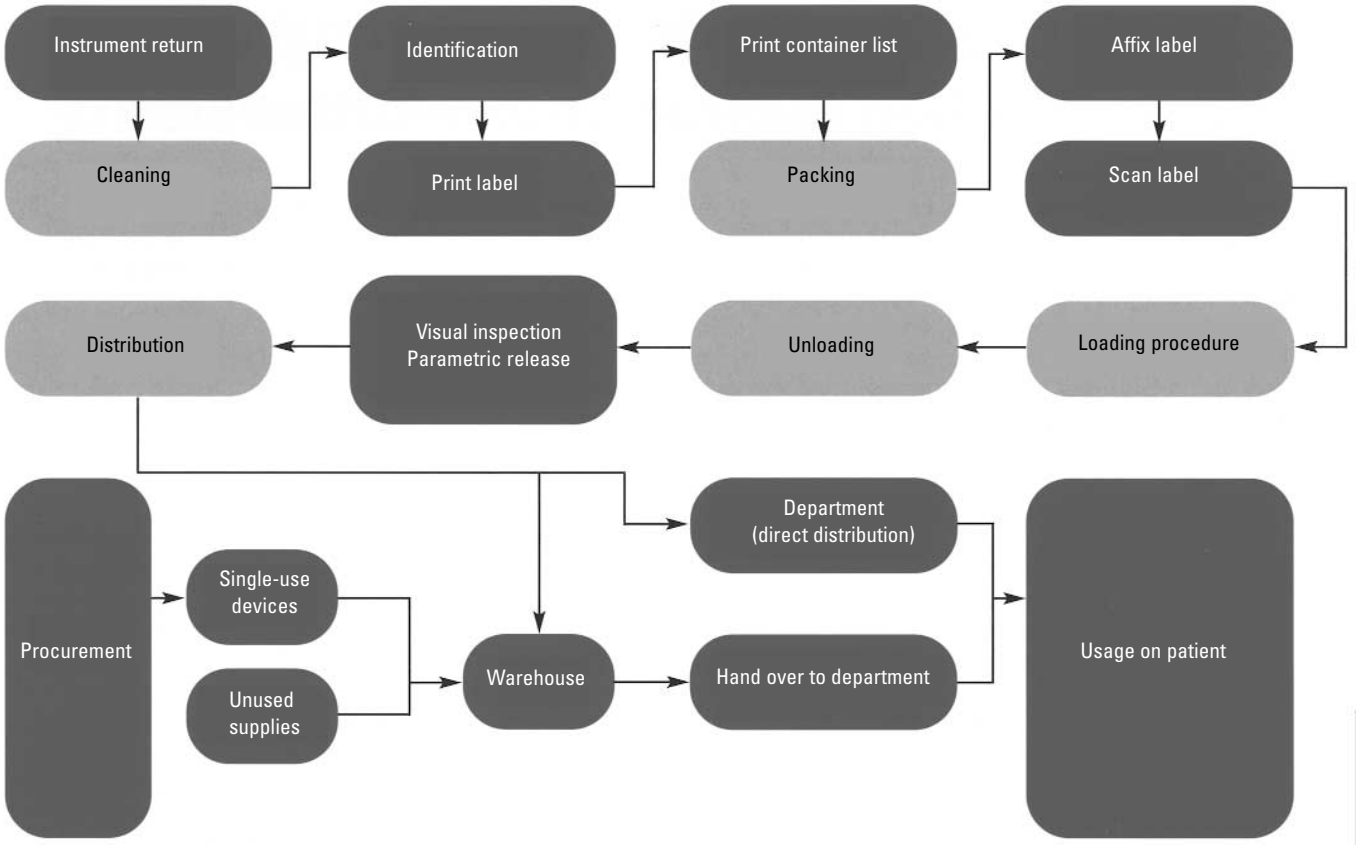

Fig. 2: Medical devices on the track – each one leaving individual traces which can be used for documentation purposes, economic considerations and in case of liability

Is All in Order with Sterilised Medical Devices?

T. Fengler, H. Pahlke (2002)*

Hygienic medical devices in the "cutting" disciplines

The surgeon bears responsibility for the surgical procedure, and also for the medical devices used in the course of such an intervention. The latter are governed by product liability legislation, which can also make liability infringements punishable crimes. They are also regulated, in particular, by the German Medical Devices Act (MPG), which has now been amended for the second time. It makes no difference whether the device concerned is a single-use or reusable instrument, in either case it must comply with pertinent legislation, regulations and directives as regards its functional capabilities and state of hygiene. Any deviation from these provisions means that the burden of proof is quickly shifted to the person conducting processing and in the event of any legal proceedings this person would have to have an expert confirm that the alternative procedure used was equivalent in terms of patient safety (see table 1). Here the legislator has deliberately not left clarification of the intended purpose of the medical device exclusively in the hands of the manufacturer ("power to define"), so that if a validated

procedure is used the hospital is authorised in principle to process single-use products – provided that this is worthwhile… The issue of whether the patient is to be informed that a processed device is being used is a controversial topic in Germany.

Special attention should be given to the guideline recently published by the Robert Koch Institute (RKI). This classifies medical devices into three categories in terms of their suitability for processing. For example, heat-sensitive cardiac catheters are assigned to Class III C (critical, with particularly stringent processing requirements); a kidney dish would belong to Class I A. A medical device is deemed critical if it comes into contact with body areas that are deemed "autologous" and sterile; in general this means that it penetrates the mucosal/skin barrier and mainly comes into contact with blood, something that happens when merely taking a blood sample.

The cleaning problems associated with sterile supply processing have become exacerbated since minimally invasive techniques became an established practice mainly for elective procedures (i.e. no vital indications). The instruments have become more delicate and more intricate; they are also more susceptible to malfunctioning and are not so easy to clean. But cleaning is the most important step in processing. However, neither sterility nor a successful cleaning outcome can be measured directly. Only the contrary outcome, i.e. contamination, can be detected – but unfortunately not always in the Central Sterile Supply Department (CSSD) before being used on the next patient. We have been able to demonstrate this in phase I of the first "multicentre study of cleaning during sterile processing" (known by its German acronym as "MRSA") to be conducted in Germany (1). In six centres we subjected various types of instruments (ranging from specula to trocars) from "cutting" disciplines (from gynaecology to traumatology) to three tests for residual protein contamination (haemoglobin, peptide and amine detection). It was possible to rinse off residues from one out of every two to three instruments, as reported in Forum 2000. Consideration must be given to the type of instrument to be used for a procedure: the less urgent a procedure, the longer the choice of instrument should be pondered. How come that a liposuction cannula or a Veres needle is not classified as a single-use device? Both are just as difficult to clean as the classic intramedullary reamer (fig. 1).

The necessity for an operation should be viewed in the context of the underlying clinical manifestation. Every surgical procedure entails a risk and this should not be increased by using potentially infectious medical devices. Nonetheless, it must be pointed out that the rate of postoperative infections has never been as low in the history of mankind as it is today (in industrialised countries).

Device appraisal (medical)

- Urgency of surgical procedure
- Vital indications (e.g. following an accident)
- Elective indication (e.g. gallbladder removal)
- Optional indication (e.g. liposuction)
- Suitability of the medical device
- Functional capabilities/ergonomics of medical device (in respect of selected surgical technique)
- Adequate provision of medical devices on trays/sets
- Availability on appointed OR day

Device appraisal (technical and logistic)

- Availability of functional, processable and processed medical devices on standardised trays
- Timely provision of medical devices calls for adequate stocks with suitably equipped trays/sets and qualified personnel in the Central Sterile Supply Department (CSSD)
- Provision and disposal of "single-use instruments"
- Amenability to cleaning as the decisive criterion when assessing possible reuse (risk analysis)
- Calculation as regards reuse/single use
- Central processing of medical devices is necessary because of reproducibility of work and process documentation, equipment installation/availability.

Table 1 Device appraisal is part of risk analysis

What can, what should "sterile" processing be able to deliver?

After surgery, the biologically contaminated (with blood, fat, mucous, possibly bone fragments, disinfectant or contrast media residues) instruments are transported in a dry state to the CSSD in sealed, protective containers. There they are dismantled for precleaning; hopefully an ultrasonic bath is also available. They should then be placed in a washer-disinfector/dryer such that spray shadowing is ruled out (figures 2 and 3).

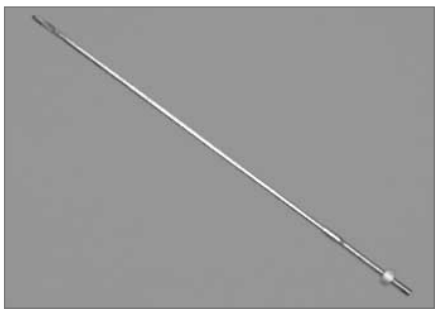

Fig. 1: Intramedullary reamer

Fig. 2: Spray shadowing

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It is here that the cleaning and (thermal) disinfection process is essentially carried out, under mainly reproducible conditions. Therefore preference should definitely be given to automated processes over manual procedures. This does not imply that manual cleaning is superfluous. Of the thousands of instruments processed daily, there are always some that have to be manually cleaned (personnel protection must be assured).

The (hopefully!) now dry instruments and equipment are then handled for the last time: for inspection of functioning and (visual) cleanliness, for packing and final steam sterilisation (in most cases, otherwise formaldehyde vapour, ethylene oxide, plasma sterilisation). All process steps must be documented in detail and verified by means of dataloggers wherever possible. Another task to be discharged by the processor is to ensure traceabiliy of any individual instrument (matrix or barcode), transponder) and to link this information to the patient's file. The medical device must not pose any risk to the patient. This to begin with implies how the device is handled by the surgeon and its safe functioning, but also refers to its hygienic safety, calling to mind the ongoing reports of diseases such as AIDS, BSE or of pathogens such as hepatitis viruses, staphylococci, streptococci and mycobacteria, the latter of which are encountered more commonly in a hospital setting.

Legally, reprocessing is viewed as a special form of medical device servicing. But this presupposes that the operating manual gives appropriate instructions for safe sterile supply processing rather than making references to outdated practices (e.g. metal wire brushes). The processor bears joint responsibility if he does not express any interest in the availability or observance of the operating manual. On the other hand, the manufacturer has a duty of product observation. For example, if it comes to light that certain devices are being handled in a manner that does not comply with the prescribed method, he must issue public warning instructions. If single-use devices are being processed the manufacturer must provide information on the associated hazards. If he neglects to do so, he would be held jointly responsible in the event of a liability claim. Processing does not at present come within the purview of European legislation, hence discussions at national level are important and effective. ✦

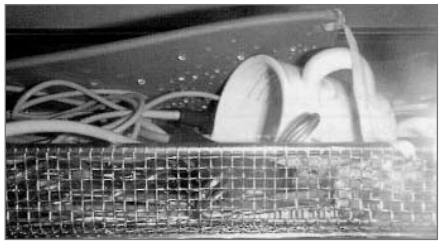

Fig. 3: Spray shadowing

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Experiences Gained from Reorganisation of Different CSSDs with "Inventory Protection"

T. Fengler, H. Pahlke (2002)*

In Germany, legislation and the recommendations of specialist committees give the impression that everything is in order in the German Central Sterile Supply Departments (CSSDs), and that all that is needed is a final brush up.

Right up to the present day medical devices continue to be processed in some settings whose facilities date back to the 1970s, at a time when dishwashers were modified to meet hospital requirements and the tray system magnified in enormous proportions to meet the processing needs. This alone reveals that what we have here are, in particular, structural problems, and not only the hospital management's presumed lack of interest in the CSSD but in addition a lack of financial resources. Of course, it is also easier to gain acceptance for the need for procurement of state-of-the-art medical therapy equipment than for a long overdue modernisation of the CSSD.

One solution would be to implement these modernisation measures with a minimum of expenditure. To that effect, the services of an external consultant would have to be enlisted, as such a person would not be influenced by locally prevailing circumstances and would be able to objectively approach the project and, for some time at least, to listen impartially to all parties concerned: ranging from the hospital management through nursing services to the hospital engineering services and workers' council.

To begin with, an inventory of the current situation from the CSSD viewpoint is taken – an angle that is unknown in many hospitals. This analysis highlights the interfaces to the 'clients': OR and wards. Here it will come to light for the first time that any changes in the CSSD, be it in respect of working patterns or merely reallocation of space, always have repercussions on other areas.

After more in-depth analysis, the possibilities for change will be revealed. This applies for work flow patterns just as it does for structural changes. Now the hospital is asked what type of changes are to be made. Everything, from a minimal solution (e.g. improvement of working patterns) to construction of a new building at a different location, must be jointly discussed, with meticulous appraisal of the issues involved. Of course, the ability to finance such a project is the key to the new CSSD; demand (internal and external) for processed medical devices must be assured in the long term.

Here a few examples: it is possible to increase the CSSD capacity and once again to assure provision with sterile supplies by

- optimising washer-disinfector programmes
- discontinuing the existing practice of wet transportation
- changing work flow patterns and
- introducing appropriate packaging.

In some cases analysis reveals that there are indeed too few instruments available. Only after taking a detailed inventory of existing stocks should the number of additional instruments needed be decided. This should not necessarily be carried out by an instrument manufacturer. Pooling and leasing are possible solutions here to reduce capital investment needed for other staff or technical measures.

In cases where structural alterations are necessary, all avenues must be explored to finance this project while incurring minimal costs. Already at the planning stage, a lot of money can be saved by involving the CSSD experts right from the outset, before support walls are constructed at the wrong sites. Once the hospital engineering services and the consultant have discussed the various possibilities and the expected difficulties, a very accurate blueprint of the reconversion project can already be drawn up, thus serving on the one hand to impose the necessary limitations on the architects and planning engineers, and on the other hand making it possible for the user to later execute meaningful work flow patterns in appropriate surroundings.

Consideration is given to the use of medical devices that have already been in service (equipment, instruments, accessories, parts) and which (in some cases after upgrading) meet the relevant requirements, particularly in the case of large equipment (ultrasound, washer-disinfector, steriliser). Equipment, which could by all means give a further ten years of service, is always becoming available as a result of modernisation, expansion or closure of other hospitals. In present times the hospitals' equipment park, which was abandoned due to changes in health policies, should also be used.

Nor is it possible to stock up only with new instruments. In many cases when inventories are taken in various hospitals one comes across instrument stores of considerable value. Often a telephone call is all that is needed to avail of the contents of this store at a reasonable price. Here, too, it is important to define priorities when procuring instruments. Often an inventory of trays brings to light the "greatest common multiple": gradually, everything requested by a surgeon has been added to the tray.

Removal of unused instruments calls for permission from the surgical department and involves an extra effort, which explains why often more than half of the instruments on a tray have not been used, but continue to be sterilised on each occasion. This prolongs the processing time (more trays must be kept available), increases the weight of the tray (often beyond the permitted limit of 10 kg) and in-

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dividual instruments are subjected to greater wear (with attendant repair and replacement costs).

Another possibility for restructuring is to combine the services of two or more hospitals as a single service company with a qualified partner for what is known as the "hotel services" of a hospital. Hospitals, too, are capable of begetting daughters! Working with a minimum shareholder from the infrastructural services' area, this joint business venture under the aegis of the hospital would pave the way for a professional partnership based on mutual trust.

The most important, and also legally stipulated, measure is that personnel qualification must be ensured in parallel; this is something that is often urgently needed but is not permitted by the hospital routine. Unfortunately, expertise on a level of that required by a sterilisation assistant is not assured on a large scale, despite the fact that such an investment could cut costs for the hospital in the long term.

Furthermore, a check must be carried out to elucidate and select just what tasks should be discharged by the CSSD: should an equipment park be maintained for automated processing of the receptacles used for washing on the wards – so as to make them available again to the same ward? Is this (personnel) investment justified? Must the washing tunnel for the hospital transport system be in the CSSD? Must all kidney dishes belonging to the oral care set (some 800 daily) be processed in the CSSD? Must each oral care set be sterile? Or are there no single-use baby bottles, kidney dishes, etc.?

Likewise, the medical devices and their manufacturing conditions must be queried. Must the CSSD really produce sterile wooden spatulas, bearing in mind that they are commercially available at half the price? Must all processing demands be met, or is it better to call for and impose a standard?

Cost-conscious sanitation often calls for an external expert who as an "honest broker" must also be able to get things done. This person is not part of the conflicting network of interests in the hospital hierarchy; he asks questions, proposes solutions, asks for instructions but, wisely, refrains from issuing any himself (acceptance, liability) and documents his work in a report that is handed over to the responsible parties. He will be judged by his performance and by the success of the measures involved. And, indeed, this is how the CSSD is appraised, which at the very least is the hospital's heart chamber. Everything must be done to assure its functions and performance – verification must take precedence here over the much-vaunted validation! ✦

Again: What is Clean, What is Pure?

T. Fengler, H. Pahlke, K. Roth, W. Michels (2003)*

Successful cleaning of surgical instruments is a basic prerequisite for successful disinfection and sterilisation. The verification methods currently employed, as outlined to an extent in the annex to draft standard prEN 15883-1, are described. A distinction must be made between methods conducted directly on the medical device, often necessitating destruction of the device, and those using the rinse solution (eluate), which do not involve device destruction and can be used for several comparative methods depending on the quality of the sample recovered. No reference is made to microbiological testing because the cleaning problems are more comprehensive, and also because considerable methodological problems arise due to a reduction of the microbial count in the suspension (see also Michels, page 19).

All methods involved here are indicating methods, i.e. they measure only constituents of any residual contamination from the last patient (e.g. peptide compounds, amino groups or haemoglobin); some require a test soil (e.g. radionuclide, sheep blood, bovine albumin, mucin). Elution tests using sample recovery presuppose that the recovery rate is known hence these can yield low values. Methods conducted directly on the instrument are not suitable for clinical routine because they mean that the medical device must be taken out of operation for a longer period of time or must be destroyed.

In addition to specialist knowledge of the diverse methods, the person(s) conducting such tests must therefore know just what is being attempted here in order to select the proper test method (e.g. type test, cleaning outcome in washer-disinfector, routine spot checks). The various methods must be validated; a multicentre study is also to be advocated (see our "MRSA" study part 1).

Until such a time as standardised process challenge devices and test soils are available as part of agreed test methods (i.e. before their development), it is important that the user in the CSSD can have recourse to a suitable method to verify the cleaning efficacy when processing reusable surgical instruments and that the role of spot checks as part of quality assurance is understood, Validation of sterile supply processing presupposes that each individual process step is validated.

Introduction

The German Medical Devices Act (MPG) and the Medical Devices Operator Ordinance call for validation of the process sequences used for instrument processing.

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Medical devices categorised as "Critical C" must be subjected to the most rigorous quality management demands (certification). It is well known that medical device cleaning is particularly important for successful sterilisation (Chan-Myers, DesCoteaux, Fengler, Marshburn, Nystroem, Rutala).

At present there is no calibrated measurement equipment to determine just what constitutes successful cleaning. The state of the art invoked in practice involves visual/tactile inspection of the cleaned and disinfected instruments. The degree of cleaning and hence the quality of that which is designated as "sterilised" on completion of the processing cycle will be based on this. Surface deposits – ranging from simple soils (e.g. blood-clogged cannula) to biofilms of mucous-producing bacteria (Exner, Rijnars, Riouful) – must not pose a danger to patients. But as opposed to endoscopy, it is only rarely possible here to definitively attribute occurrence of infection to a single cause (Chu, Coghill, Fengler, Ojajarvi, Rutala).

Using the methods described below for verification of cleaning, industry (manufacturers) and users now have at their disposal the first such methods (albeit of a limited nature) for checking the cleaning outcome during cleaning, thermal disinfection and drying in washer-disinfectors/dryers.

A distinction must be made, on the one hand, between measurement methods carried out directly on the instrument (e.g. element analysis) or additionally with a test soil on the instrument (e.g. radionuclide method) and, on the other hand, those performed (e.g. with photometry) using the rinsing solution after having rinsed off the instrument (e.g. with sodium dodecyl sulphate (SDS)) with a clinical or test soil.

Draft standard prEN ISO 15883-1 (first published in Oct. 1999, currently being revised, and to be put to a new vote), which specifies performance requirements for washer-disinfectors, also addresses the issue of verification of cleaning efficacy. Test soils are listed in annex B, albeit only those used in the past for microbiological testing with biological indicators. The aim here originally was to reduce the number of active microorganisms before actually verifying disinfection, rather than testing the cleaning success by microbial recovery. Apart from the investment required for reproducible preparation of suitable suspensions and from having to make the difficult choice of finding suitable microorganisms, this methodology does not directly check the cleaning dynamics, because the number of organisms is reduced during the entire process and their inactivation is in all probability not only due to cleaning (Michels, Fengler et al.).

The following therefore outlines the methods available for verification of cleaning efficacy. These include methods carried out with the eluate to test for residual contamination of a clinical origin (without knowing the magnitude of the baseline contamination). These are of much relevance in practice and are performed in the sterile supply department. However, these methods do not measure the reduction dynamics; a defined in vitro test soil must be used to that effect.

For quantification of these methods, in addition to the eluate method there are measuring methods that can be effected directly on the instrument surface (spot checks, entire surface). Instrument analyses or similar can be carried out with the eluate for type testing medical devices and for commissioning washer-disinfector/dryers. The former mean that the medical device must be taken out of operation for some time (or often permanently as it must be destroyed), which explains why they tend to be used for clinical, single-use "disposable" medical devices.

Methods

In addition to the distinction made between elution (rinse) and direct measurement methods, the type of sample recovery from the surface must also be borne in mind. Swab tests used to that effect have only a demonstrative function, as a defined sample recovery is hardly possible.

Directly on the medical device

All methods entailing measurements on the instrument mean that the instrument has to be taken out of operation, at least for some time, and must often be destroyed so that it can be examined. Hence, apart from optical methods (visual inspection, microscope) such methods are used for type tests (risk analysis, Medical Device Directory – MDD) and require the medical device to be dispatched to the laboratory (laboratory tests).

Visual/tactile inspection of the surface of the medical device

Today, the degree of contamination on instruments before cleaning and after automated processing in the washer-disinfector/dryer is mainly checked by means of visual/tactile inspection for cleanliness; this is documented. These findings can then be compared with analytical methods.

Radionuclide method

Here tracer proteins are chemically bound with a radionuclide. Technetium 99 is used as a tracer. This is a hard gamma emitter, with a short half life, which is added to a test soil (e.g. blood). The test instrument is contaminated in a process that simulates a worst-case scenario.

This is the only method that permits very accurate measurement of the reduction of the test soil, while concurrently measuring its distribution throughout the medical device before/after cleaning. It does not necessitate destruction of the device. Provision must be made for protection against radiation (Kirst, Schrimm). Temporal considerations must be observed because of the half-life requirements, for example sample dispatch is not possible (after application of the radioactive test contamination).

Activity is measured with a gamma camera before and after cleaning. The resultant difference serves as the basis for calculating the residual contamination using the time and half life.

Element Analysis

Here a defined section of the surface is examined to elucidate its element pattern. From this can be inferred which substances and substance mixtures were present; the element profile of a clean surface can also be filtered out using a series of tests, depending on the materials used. This makes provision for formulation of a highly sensitive standard (finger prints), which can then be referred to the degree of cleanliness required clinically – to be yet defined (Roth, Personal Notes).

Quantification of residual contamination is to be referred only to the surface examined, rather than to the medical device as a whole. Generally, it entails destruction of the device, and should therefore only be used for instruments that are no longer to be used (Reichl).

Qualitative Wipe Tests (wiping off a surface)

Colorimetric swap ninhydrin test

The swap must be moistened with sterile, distilled water and is used to wipe off the instrument surface to be examined.

The surface wiped off should not be less than 5 cm^2 but no bigger than 50 cm^2. No comparative measurements are expected here.

One drop (around 0.05 ml) of the ninhydrin solution is applied to the swab and left to dry in the air for 5 minutes. The appearance of a purple colour is indicative of protein/amino acid residues and no further treatment is required. If there is no change in colour, the swab is placed in a drying cabinet and heated for one hour to 110 °C (De Bruijn).

The appearance of a purple colour is supposed to be indicative of residual protein. The test sensitivity is sufficient to detect glycine at a concentration of 2 mg/m^2 (caution: do not allow the swab to come into contact with the skin – this leads to false positive results!) (De Bruijn).

Qualitative colorimetric Biuret test (Konicas Swab'N'Check)

The reagent solution is prepared from 2 components before the test. A defined quantity of reagent A is mixed with a drop of reagent B by mixing it in a test tube.

To carry out the biuret test, a defined surface is wiped off with a swab that has been moistened with 1 % sodium dodecyl solution (SDS). Using a blank test, one must rule out that the result obtained is not due to an intrinsic reaction of the cotton swab.

The size of the surface should be 10 cm^2 unless stated otherwise. This surface is wiped off twice in a longitudinal and traverse direction. Quantification of this method is not possible.

The swab is then "washed out" in the reagent solution using gentle movements. Following a 10-minute reaction time, the change in colour is compared to a colour chart. This chart ranges from green through grey and bright purple to dark purple (green: 0-25 mg protein content is interpreted as a positive result). Higher values are defined as protein contamination.

This method is based on what is known as the biuret reaction, showing reaction to proteins and peptides with at least 2 CO-NH groups. The reaction between carbamyl urea in alkaline solution with copper ions produces a change in colour between grey and purple depending on the quantity. According to the manufacturer's instructions, the detection limit for this method is up to 55 mg protein content (depending on the type of protein) and thus in a range that can no longer be seen with the naked eyed.

Rinse Methods (here: SDS elution)

Preliminary remark: a common feature of all rinse methods is that they rinse off "less than all" from the medical device surface – nonetheless, it should be borne in mind that this is being done after already having completed the cleaning cycle. Anything that can no longer be rinsed off can remain permanently on the instrument, but this is not necessarily the case. The greater the quantity of eluate, the harder it will be to conduct measurements due to the dilution factor. Particles – whether detectable or not – likewise shift the results in the direction of false negative results (Fengler). If the eluate quantity is too small for the surface to be rinsed off, the rinse effect is lost and the recovery rate is reduced. It should be above 90% and can be determined only with a defined test soil, for its composition.

For sample recovery, the instrument surface to be examined is rinsed off with a small volume (50 ml/10 ml) 1% SDS over a certain period (allowing breaks). To examine the entire surface of an instrument, this is placed in a PE bag, which is closed after addition of 5 ml SDS. The bag is gently moved to and fro, and repeatedly changed from one hand to the other to ensure that the SDS solution has reached all surfaces (see Frister, p. 12).

To examine internal channels of MIS instruments, the instruments are secured on a stand such that the distal end is standing in a glass beaker. A disposable syringe is connected to the other end by means of silicone tube sections. By withdrawing the syringe and emptying it, the instrument is flushed repeatedly with 5 ml 1% SDS in the beaker. In the case of trocar sleeves with a lateral opening (e.g. location of valve), this opening must be sealed first of all with paraffin film (parafilm) (Frister/Michels).

Semi-quantitative colorimetric haemoglobin stick test (Sangur)

This highly standardised "Sangur" test is used to measure haemoglobin and erythrocytes by means of the pseudoperoxydase reaction (on test strips to be immersed in the eluate).It is also suitable for conducting comparative semi-quantitative tests and provides information on blood contamination of the eluate. It was developed for urine diagnosis and is a suitable alternative in the presence of detergents such as SDS, albeit not for all disinfectants (see manufacturer's description, Boehringer, Mannheim, Germany). As regards the measurement precision, the degree of haemolysis is imprecise, as is the number of red blood cells still in the solution (particle error). Like all colorimetric methods entailing visual comparison of colours, this also has a range that can be interpreted by the investigator.

Colorimetric modified biuret test

This test measures peptides (Merck, Darmstadt, Germany). 1 ml of the recovered SDS solution is transferred with a pipette to a test tube. Now, 1 ml of reagent I is added and the preparation is left to stand at room temperature for 5 minutes. Then 2 drops of reagent II and 2 drops of reagent III are added. After mixing, preparation 2 is allowed to stand for 2 minutes and the change in colour is then assessed with the colour chart (Fengler et al. [9]).

The appearance of a purple colour complex is inversely proportional to the protein concentration, i.e. colourless means that more than 80 mg/ml protein equivalent is present as bovine albumin and a purple colour is indicative of markedly less or no protein. Appropriate dilution series can be used for more precise measurements.

Quantitative BCA method

The BCA method is based on the biuret method, but with enhanced sensitivity due to addition of bicinchonin acid in the complex. But it is more onerous to carry out than the simple biuret measurement. Here, too, mucous can be an interference factor when interpreting results (endoscopy, gynaecology, ENT).

Bradford method

This is a chemical/photometric method during which stains (Coomassie brilliant blue G-250 or eosin B [4'-5'-dibromo-2'-7'-dinitrofluorescein]) form protein-stain complexes in acidic solution, which can be detected at 595 nm or 540 nm.

Formation of protein-stain complexes is disrupted by salts, buffers and detergents. Nor are they formed in the presence of triton x 100 of sodium dodecyl sulphate.

UV absorption method

The concentration of uniform proteins is easiest determined by measuring UV absorption. The aromatic amino acids tyrosine and tryptophan absorb light at 275-280 nm. A calibration curve is drawn for the proteins to be measured.

If diverse and unknown proteins are involved, there will be no uniform pattern of

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absorption due to the different proportions of aromatic amino acids. Bovine albumin is often used as a reference protein. Interference is also attributable to other UV-active constituents such as nucleic acid and buffer substances.

Errors mediated by nucleic acids can be corrected by performing duplicate tests at 235 nm and 280 nm using the formula C protein = (E 235–E 280)/2.5 l (mg/ml). The effects of light scattering and turbidity cannot be compensated for; this holds true for all photometric methods based on Lambert-Beer law for homogeneous solutions.

Modified OPA method

This is a photometric method carried out in vitro in the laboratory. In the presence of N-N-dimethmy-2-mercaptoethylammonium chloride, free terminal amino groups of proteins react with o-phthialdehyde to form fluorescent 1-alkylthio-2-alkylisoindoles that can be detected at 340 nm. Chemical reaction takes place in SDS solution with tetraborate buffer pH 9.3. Proteins undergo denaturation, in respect of their folding, under these conditions.

Interference factors can arise from plasticizers in the synthetic materials used (check in advance!) as well as partial masking of the amino groups by glutardialdehyde residues. Attention must be paid to the effects of light scattering, i.e. any samples with particles must be discarded. But the following applies in principle: visual contaminants need not necessarily be quantified as they are obvious (Fengler, Frister, Michels, Orzechowski).

ATP method

This method is based on the production of light by the luciferin/luciferase reaction of glow-worms. All cells, organic substrates and enzymes producing adenosine triphosphate (ATP), can be measured in a particular concentration range by means of bioluminescence. This reaction gives rise to a continual light utilisation which is proportional to the ATP concentration. In the case of automated processing, this is a temperature-regulated process. Since ATP is very unstable, it is often reduced to non-measurable ADP and phosphor (P).

Discussion

Not every test soil is necessarily suitable for test purposes

To what extent the chosen test soil corresponds to the real contamination encountered during an operation is something that must still be validated in respect of its suitability as a test soil for a test method. If the instrument comes into contact during the operation not only with blood but additionally with other substances such as fat and other tissue constituents, detergents, solution residues, instruments are exposed to those substances at high frequency (HF), giving rise to thermally mediated adhesions.

The test soil must be applied to reflect the prevailing conditions. A soil that is never encountered in practice only serves to bring up false results, as it suggests that proof is being furnished that a surgical instrument is amenable to cleaning. Worst-case scenarios can go too far if used under semi- or non-critical conditions (e.g. external fixing device in traumatology).

Cleaning cannot be verified in the CSSD using electron beam microscopy or other "borderline" analyses, because this requires destruction of the instrument. But since instruments are needed for surgery, are available only in limited numbers and cannot be destroyed at will, also because of their high costs, such surface-analytical methods can be used only in limited cases for scientific investigations. This must be borne in mind when it comes to the common practice of demanding statistics when formulating standards.

If the baseline contamination is not known, as is the case in clinical sterile supply processing, it is only possible to measure the residual contamination by means of one of the indicator methods described here. At present, it is not possible to measure all contaminants, ranging from inorganic toxic substances, pyrogens, endo-and exotoxins to protein mixtures, carbohydrates and fats. Therefore, task definitions must be tailored to the capabilities inherent in the respective method used – for instance, the contaminants to be expected from instruments used in a bronchoscopic setting (while of a proteinaceous nature) will differ from those encountered in a traumatological bone operation.

There is at present only a limited number of standardised methods which have already been adequately tested in multicentre trials and laboratory tests for inspecting cleanliness. While the aforementioned methods, compared with earlier test soils (semolina, BAMS, Hucker Soil, egg yolk) tend to be of clinical relevance and can be standardised, they nonetheless only show the currently measurable components of a special type of contaminant.

If a suitably equipped laboratory is available, the eluate method with photometric measurement can be performed. This is likely to yield more accurate results than the wipe and test-strip methods. This also provides for optimisation of the cleaning process.

Different issues, different methods

Using different methods, it is possible to either detect the residual contamination content or by means of a test kit to measure the dynamics of a reduction process from the eluate or directly on the instrument surface. Quantitative methods presuppose that the baseline quantity and/or the ensuing contaminant quantity can be measured. All wipe tests permit only qualitative colorimetric methods which have limited quantitative power.

The basic cleaning performance of an automated process can be elucidated with a process challenge device (PCD) and a test soil, without having to resort to clinical investigations by means of spot checks. At present, there are no generally recognised and adequately validated PCDs, test soils and evaluation methods, only proposals for the test phase.

Microbiological testing with biological indicators must not be equated with testing the cleaning performance. The soils used here were formerly intended for reducing the recovery rate, so as to minimise the loss of microorganisms before commencing the actual test ("adhesive" for retention of test microorganisms).

Visual inspection is the simplest and presently most important method. It can be used only to a certain extent for jointed and lumened instruments, whose insides cannot be inspected. Nor is it always possible to distinguish between the deposits encountered. There is no method that can be conducted on site for quantitative measurement of all potential contaminants such as blood, fat, bone marrow, mucous, etc. Nonetheless, these are found together with protein (due to mucous and blood).

The standardisation committees (e.g. CEN/TC 102 WG 8) assume that soils originating from the patient are of a proteinaceous nature. Therefore protein analysis is the method of choice for determining cleaning efficacy for surgical instruments, while bearing in mind that an unknown baseline contaminant of differing composition is always encountered in the clini-

cal setting (differing levels of mucous, bone marrow).

In the Sangur test we have a simple, commonly used, semi-quantitative test for detection of haemoglobin and erythrocytes – which is thus very specific in respect of clinically relevant soils. But it does not appear to be sensitive enough, as revealed by our multicentre studies (Fengler et al. [7, 9]). When processing surgical instruments false results can also be obtained, e.g. due to the presence of various detergents in the disinfectants. The Sangur test was developed for urine analysis and is therefore easy to perform, even if it also put to other uses than those originally intended. Nonetheless, as a haemoglobin test it has proved to be a very specific in respect of human residual contamination (only blood) and is useful for general orientational purposes.

Interference factors can impinge on the results produced by all variants of the biuret test which measure cleaning efficacy by wiping off a more or less defined instrument surface with a cotton swab, which is then washed out in the test solution. This test method cannot be used if, for example, ammonium sulphate, glycerine or saccharose (mucous) are present. Nor is it possible to compare exact quantities because the result will depend on the size of the surface wiped off, the method of wiping and the amount of pressure exerted on the swab.

The ninhydrin method is a qualitative orientational test that originated in the United Kingdom and has been included in prEN 15883-1. But this is not suitable for evaluation of the cleaning result when processing surgical instruments. A drop of ninhydrin is added after wetting a cotton swab with sterile, distilled water and wiping off a surface > 5 cm^2. The appearance of a purple colour is indicative of residual protein. While this change in colour is supposed to indicate protein contamination, some cotton swabs do not change colour even in the presence of proteins. The change colour will also depend on the type of protein.

For all eluate methods based on rinsing, any residual contaminants present must first be dissolved. Detection is aimed at those substances to be found primarily together with proteins in surgical instruments. Residues of mucous or fat can produce errors for some methods, as can the presence of detergents, disinfectants or amines (e.g. plasticizers from synthetic materials).

Correct sample recovery that is able to recover at least three-quarters of the existing protein is an important precondition here. This is assured in most cases with SDS solution because this surfactant is particularly suitable in view of the denaturation in terms of protein folding. However, suitable plastic bags must be used to recover the rinse solution (eluate); this should not contain any substances that could falsify the respective method (plasticizers, see above).

Sample recovery is very difficult for some intricate filigree instrument designs, particularly from lumens. Visual inspection of such regions is not possible. By attempting recovery with defined protein soils, the power of eluate methods could be enhanced by defining the recovery rate with a test soil, for instance for the irrigation channels of dental hand pieces (De Bruijn).

What is important for tests of practical relevance that are carried out in the CSSD is the assurance that the instruments are available. This is the case where the recovery from the eluate is concerned, with the eluted instrument being clean in addition. Recovery from the eluate must not give rise to any chemical alteration of the instruments which could render them dangerous when put to use (value conservation). A spot check during sterile supply processing could thus constitute an application.

Attention must be paid to assuring absolutely clean handling. The detection limits of some methods (OPA, micro-BCA) is within the range of protein determination for a fingerprint.

As opposed to test-strip methods, photometric methods call for a suitable laboratory and for commensurate expertise as far as the methodology of eluate measurements are concerned. Hence with the majority of methods it is not possible to immediately measure the level of contamination on site in the CSSD as a batch control. Various biuret methods can be used as simple semi-quantitative tests for orientational purposes on site, but these are prone to a mucous-mediated error.

If a laboratory with a suitable photometer and quartz glass cuvettes are available, preference should be given to photometric methods. A clear (no turbidity) eluate that is free of particles is needed for correct measurements. Depending on the method, the correct wavelength must be observed for measurements. The extinction values of the measurement can then be converted into protein equivalents (BSA) to visualise the clinical residual contamination. It can be assumed that the cleaning result obtained after processing surgical instruments will never be 100%, which is why instruments have to be sterilised.

The radionuclide method can be performed without destroying the instrument, but cannot furnish proof of complete cleaning of an instrument that had been previously put to clinical use. Based on the clearly visible residual soils on previously marked, applied proteins weak points can be detected in the instruments in respect of processing and thus these can be compared with diverse cleaning methods. This gives the manufacturer the opportunity to propose a validated processing method to the user.

The radionuclide method is suitable for type testing new instruments or older complex instruments which have already been in operation and have lumens that cannot be visually inspected so as to be able to define a suitable process for the user – cleaning must then be defined in practice. Since the German Medical Devices Act (MPG) mandates that validated instrument processing be conducted, the manufacturer must also subsequently define the cleaning processes to be used in the CSSD for certain instruments that have been on the market for a long time (cannulas, bone marrow boring devices)

This method is particularly suitable for minimally invasive surgical instruments that cannot be dismantled in order to identify those surfaces that cannot, or cannot sufficiently, be reached by the cleaning solution. Since a radioactive marked test soil is needed here, such as human blood, this method differs from other methods only in respect of occupational health considerations. While the other methods focus on residual soils after use in surgery, the radionuclide method provides direct proof of the cleaning efficacy for a known test soil.

If eluate-based methods are to demonstrate cleaning efficacy, the question arises as to what extent the eluate contains all residual soils or whether proteins or other soils that have not yet been dissolved are still adhering to the instrument surface (and have not been dissolved).

Selective detection of pure fibrin deposits as a blood constituent cannot be effected with an SDS eluate alone because it is difficult to dissolve fibrin using SDS (elute once again). Elution with NaOH would be advisable here or the addition of 0.5% NaOH to the 1% SDS. But extreme caution is needed when handling NaOH

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	Surface analysis (on medical device)	Analysis of eluate (rinsing)	Radionuclide method (on medical device)
Site	Lab	Practical setting (hospital)	Lab
Investigation (of medical device)	Onerous	No implications for ongoing tests	Onerous (radiation protection)
Precision	High	High – but depends on recovery rate (< 100%)	High – depending on coupling rate of radionuclide on test substance
Test substance	Not necessary	Not necessary, but possible	Necessary
Medical device testing (type)	Medical device specimen	Medical devices or their samples Practical test possible on site in hospital	Medical device sample
Method (equipment)	Physical or chemical (div. physical measuring instruments, chemicals)	Physical or chemical (photometer, chemicals)	Physical, taking account of chemical properties
Test	Often involves destruction of sample device	Non-destructive, hence several analytical and comparative methods can be carried out on same sample device	Non-destructive; it may also be possible to use same device for further analytical and comparative methods
Investment	High	Usually low	High
Costs per sample	High	Low	Low

Table 1 Comparison of methods for detection of recontamination on surfaces of medical devices: direct measurement on specific device, often entailing its destruction, or indirect measurement of eluate (instrument not destroyed)

(occupational safety) and instrument alterations cannot be ruled out.

Detection of complete cleaning is possible only by destroying the instrument and performing analysis across its entire surface, something that is not realistic in terms of feasibility and clinical routine checks. This laboratory test is of interest only when applying for a marketing licence before placing the instrument on the market and for conducting investigations in the event of damage. Accordingly, all methods have advantages for specific task definitions as shown for the most important methods (no microbiological methods, as explained at the outset) in table 1.

Summary

Using the modified OPA method, which has been used for many years for analysis in dairy research, analyses endowed with sufficient power can be performed in the protein range, and this can be further enhanced with the addition of NaOH.

The radionuclide method is ideal for type testing, and does not necessitate destruction of the instrument. Here, too, a lot of experience has been gleaned over the years with radionuclide diagnostics. With a half life of 6 hours, technetium is suitable for practical use. But this method becomes more difficult when used for verifying the performance of washer-disinfectors/dryers in the CSSD.

It is urgently recommended that a method be developed to check cleaning of surgical instruments so as to be able to verify and document the performance of the cleaning step in sterile supply processing – only if this is accomplished will validation prove meaningful. Which of the methods described here might prove suitable for one or the other CSSD should be the focus of further investigations, to be conducted under scientific conditions. Due to the paucity of research investment, methodical validation, in particular, continues to be a problem. ✦

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Cleaning: What Is Verifiable?

K. Roth (2003)

With the coming into force of the German Medical Devices Act (MPG) and the Medical Devices Operator Ordinance new requirements apply for verification of the cleaning process and of the cleaning result. At present, the cleaning process is generally monitored with process challenge devices (PCDs) and dataloggers. But acquisition of these data alone does not yield any reliable information on the quality of cleaning since only some of those parameters that have subsequent implications for successful cleaning are recorded. By subjecting surgical instruments to type tests (ideally, before placing them on the market), the minimal requirements for the parameters can be defined, so as to ensure subsequent reliable cleaning. Compliance with these parameters must be verified and documented during the cleaning process.

Introduction

Among the various definitions and requirements for validation the following statement draws attention: "Validation serves to furnish documented proof, using a scientifically recognised test method, of the ongoing effectiveness when faced with the most challenging demands". This is a requirement that in most validation processes is observed only to a certain extent. Validation should target the worst-case scenario. This demand applies to both the extent of contamination and to the state of the washer-disinfector as well as the mechanism of action of the cleaning detergents. In most validated processes no special attention is paid to either the machine performance or to the effects generated by chemical detergents. In most cases only one programme cycle is defined, covering the parameters time, temperature and concentration of the detergent. Evaluation of the cleaning outcome is then left in practice to the user who faces problems, especially when it comes to evaluating instruments categorised by the Robert Koch Institute (RKI) as semicritical b and critical b. This is because only limited visual access is permitted to the critical sites. A validated process that takes account of all parameters of influence could be one solution to this dilemma and should also be vigorously advocated by the user.

Which Parameters Affect Successful Cleaning and Must They Be Defined?

Normally, time, temperature, mechanical and chemical factors are specified using what is known as Sinner circuit. While time and temperature can be recorded relatively easily by means of dataloggers, things are markedly more difficult when it comes to the mechanical and chemical aspects.

a) Mechanical Cleaning Performance

Often, the mechanical cleaning performance is monitored with PCDs that are intended to simulate intricate instrument designs. A specific test soil that had been applied must be removed during the cleaning process. The extent of residual contamination, which must be visually evaluated, constitutes the basis for any conclusions drawn as regards the cleaning performance. Using these types of PCDs, it is possible only to a certain extent to draw inferences on the cleaning effectiveness of the washer-disinfector, on the selected programme and on the chemical substances, but certain problems mediated by specific instrument constructions will not come to light.

If the water jet comes into contact with the surface of instruments of simple design and without joints or lumens, energy is released when the water droplet bursts, and this then produces a good cleaning result. A similar mechanism is observed in an ultrasonic bath where large amounts of energy are released on implosion of the vacuoles in the water. It is always assumed that the water jet or the ultrasound wave can optimally reach the surface. In the case of ultrasound, attention must also be paid to temperature, load and the level to which the bath is filled.

Things become more complicated for tubular or jointed instruments. Here the cleaning mechanisms must be selectively deployed at the intended site of action. In general suitable insertion carts are used to that effect, but the low cleaning pressure generated by the majority of washer-disinfectors is a problem in the case of tubular instruments. Our experiences demonstrate that, depending on the instrument design, satisfactory cleaning results are obtained only for cleaning pressure values that are markedly higher than one bar. Furthermore, in most machines flow through the instruments (patency) is not automatically checked. In the case of instruments that cannot be dismantled, it is best to check this manually with a hand pistol before the actual cleaning process. To achieve good external cleaning results, the instruments should also be placed in the washer-disinfectors in defined positions (that have been verified in advance). In particular, the jointed regions must be optimally positioned in respect to the water jet. The customary practice of placing the instruments on trays tends to prevent targeted cleaning, which is why ultrasonic precleaning is indicated in such cases.

To assure the mechanical cleaning performance, the following parameters must be validated, defined and finally verified: water temperature, cleaning time, cleaning pressure and assured access by cleaning

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solution to all critical sites of the medical devices placed in the washer-disinfector.

b) Effect of Cleaning Chemicals

In an age where vCJD poses a threat, detergents with pH > 10 are required because of their superior efficacy against prions. But the pH value is very much a function of the water quality! To what extent a pH > 10 really does protect against prions remains open. Besides, alkalinity can be achieved in different ways.

The foam generated by the chemical detergent is also another important aspect, because a large amount of foam can lead to a considerable reduction in the water pressure. The foam must be investigated in respect of blood contamination, something that unfortunately is possible in very few washer-disinfectors due to the absence of a transparent pane.

To be borne in mind additionally are the duration of action, dosage amount and dosage temperature. Compromises are often made in particular in the case of the duration of action in order to expedite the process cycle. But if one views this in the context of the total time needed for the entire processing procedure, it turns out to be negligible.

Attention should also be paid to how the chemical detergents are stored. For example, if an enzymatic detergent is stored in the machine in a canister, the action of the enzyme can be markedly reduced due to the effect of the heat generated in the machine, thus in turn producing poorer cleaning results.

To ensure successful chemical cleaning performance, the following parameters must be validated, defined and finally verified: type of chemical substances, application spectrum and duration of action, dosage amount and temperature, foam profile and water quality.

Who Must Supply Which Information?

Pursuant to the new standard EN/ISO 17664 the relevant information must be provided by the instrument manufacturer to the user. Non-specific terms such as alkaline or enzymatic detergents should be avoided, while specifying at least the exact procedure with information on the machine, chemicals and water quality to be used for validation. Only this approach will reassure the user that provision has been made for the appropriate and requisite cleaning performance of previously validated instruments. However, the user is responsible for verifying and documenting the relevant parameters.

European CLEANTEST Research Project

In a joint research project involving 8 companies processes are being developed to yield relevant data on the cleaning cycle. As a first step, the cleaning behaviour evinced by MIS instruments is investigated with the radionuclide method. If necessary, changes are made to the instrument design. The cleaning detergents are optimised, as is the washer-disinfector. In addition to data acquisition in the machine a logger-based monitoring system is used. Following successful validation, the instruments, machine and chemical substances are used for one year in a hospital setting. Spot checks conducted for diverse instruments while in use in the hospital as well as final boundary-surface analyses are intended as a means of demonstrating that a system validated under worst-case conditions will produce the desired success and guarantee parameter control during cleaning. ✦

Optimising Automatic Cleaning (in Washer-Disinfectors – WDs)

A. Brömmelhaus (2003)

The question of quality control and validation for instrument reprocessing is only a sensible one if reprocessing methods are optimised, and results are of adequate quality. As well as this of course, methods must be developed and established to assess objectively the success of the reprocessing.

Over 30 years ago the first automatic WDs for reprocessing surgical instruments and other medical products were developed, originating from the more and more common household and commercial dishwashing machines. During the first few years of the development of automatic WDs, personal safety, and therefore disinfection, was the centre of attention. In the last decade the focus of method development was on cleaning. This development was definitely partly facilitated by progress in medical technology. Surgical instrument structure became ever more complex (MIS instruments), so that cleaning requirements were also increasingly demanding. Therefore the appliances, and in particular the trays, were further developed, and optimal cleaning methods were introduced.

Despite this, in practice, one can still come across technical methods from the

early days of automated WDs. For example the so-called "BGA" process: Bundes-Gesundheits-Amt – German Federal Health Authority – with heating up to 93 °C, which renders cleaning more difficult, especially with respect to protein removal).

Sometimes MIS instruments or other instruments with a lumen are even reprocessed without a suitable insert basket. Obviously, such shortcomings in the reprocessing should be recognised and removed during quality certification. It is not really sensible to pursue quality control, if the quality delivered no longer reaches today's quite demanding standards.

The subject of optimising cleaning has become additionally explosive because of the current problem with prions. In the concluding report of the Robert Koch Institute (RKI) task force, it is advised that for general prophylaxis against prion transmission (via possibly contaminated instruments) a so-called "optimised" reprocessing method should be used, which has carefully chosen key parameters. Within these defined conditions it is presumed that the reduction of prions on the instruments is reached by simple washing. Therefore it is naturally necessary to optimise the method as much as possible with regard to protein reduction.

What constitutes optimised automatic reprocessing? The foundation is provided first by the current efficient automatic WDs, (which already conform to the requirements of the future standard prEN ISO15833-x). It continues with interfaces, process documentation, and optimised attaching systems, jets and rinse-cases for the various instruments. Cleaning can only be successful if the instruments are completely impacted by water.

Even using the most modern appliance technology, the best possible cleaning can only be carried out using optimised methods. This means that in the first step of method optimisation, techniques need to be developed to compare cleaning efficiencies. Because blood is the main contaminant when reprocessing instruments, the experiments conducted to optimise methods should use a suitable blood-contaminant. Protein analysis should be carried out in order to determine the residual contamination. The modified OPA method has proved to be the most useful here. Sodium dodecyl sulphate solution is used for elution, and the residual contamination is determined photometrically.

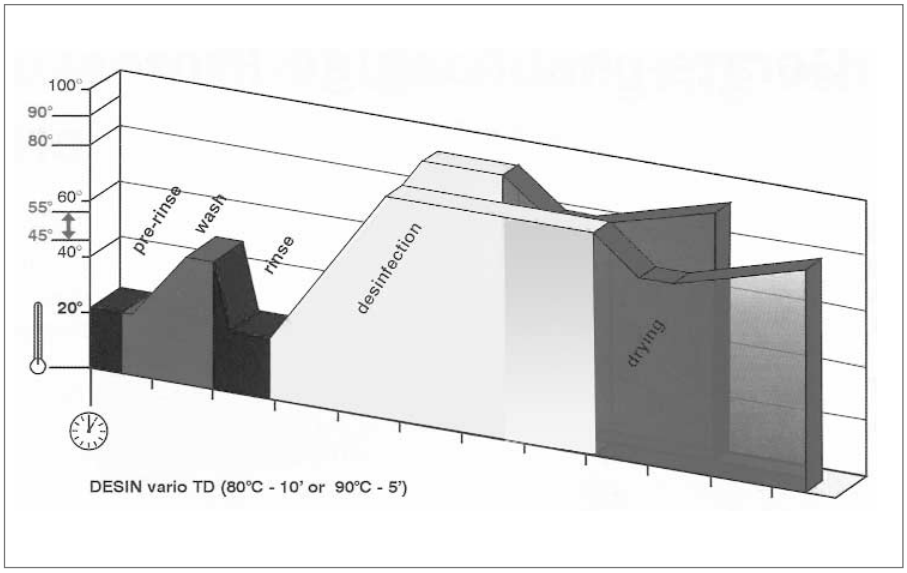

Fig. 1: Vario programme – superior to the BGA programme concerning its cleaning efficacy

An optimal process should be carried out according to the "VARIO" programme which was introduced about 10 years ago. The use of an alkaline detergent is necessary for the very best cleaning performance. The ideal pH value for removing blood is about pH 11.5. Most instruments can be reprocessed at this pH without coming to any harm. Gentle processing of rigid fibre-optics is even possible, if suitably composed detergents and appropriate baskets are used. Methods employing these pH values can also be used in the area of eye surgery. However it is necessary to make sure that an acid rinsing phase follows the cleaning phase. This ensures that the alkalinity is flushed out of or is neutralised in the narrow cannulae and handles. The pH value is checked at the end of the process, during routine and process verification.

Anodised metals are the only materials that can be damaged by such pH values, but this material is seldom used for surgical instruments. Cleaning should be carried out at 55 °C. Coagulation only occurs at higher temperatures. A temperature holding time of 5 minutes during cleaning has proved to be generally sufficient in practice. Lengthening the holding time does not significantly improve the cleaning performance. This is because protein removal under these conditions does not depend on a chemical reaction; cleaning depends on mechanical and physico-chemical factors, such as electrostatic and hydrophobic interactions.

It makes more sense to optimise the prerinse phase than to lengthen the cleaning phase, in order to prevent blood from causing heavy foam formation during the cleaning phase. Foam has a negative effect on the mechanics of cleaning and therefore on cleaning performance. It was recently shown that even so-called "low-foaming" alkaline detergents, some of which have been in use for some time, are not always able to compensate for foam formation, and may even make it worse when in combination with blood.

Thermal disinfection comprises the final stage of the method. The parameters of disinfection should be designed to conform to the A_0-value of the new standards for automatic WDs.

As well as these factors, there are others that play an important role in the cleaning result. For example water quality is a significant factor in reprocessing quality. This is not only important during rinsing, to produce a suitably spotless and material-friendly result, but also has a direct influence on cleaning performance. Because of the buffering effect of softened water, the pH value drops, which naturally has a direct negative effect on the cleaning performance. This means that in future, it would make sense to stipulate fully demin-

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eralised water as a requirement in the standardisation and quality control for cleaning machines.

When regarding this multitude of factors and their synergetic effects influencing cleaning, it becomes obvious that meaningful quality control and process verification of automatic cleaning can only be reached by a measurement of residual contamination. In addition to this, the geometry of the medical products to be reprocessed is of course extremely varied, and the contamination on the instruments may vary according to area of use and operator. The most important measure to ensure cleaning quality is therefore a thorough visual control of the cleaning results on all reprocessed instruments (100% inspection). Clearly, visual control is always subjective, and for many instruments only partially possible because of their geometry. Therefore these visual checks should be completed by protein analysis methods, both as random samples and for regular cleaning verification. These protein analysis methods should be designed to be simple, to be carried out on the spot, by the personnel operating the cleaning appliances. Any possible protein contamination needs to be easy to detect.

Recently just such a test has become available. This test kit determines the presence of protein. The first step is the elution of possible protein residues; the second is the semi-quantitative determination of possible protein presence using the modified Biuret test. A colour reaction gives information about the cleanliness of the instruments.

Optimising cleaning methods is only possible through knowledge of the complex processes occurring in automatic WDs. Through recognising and grasping the significance of the influence of possible synergetic effects it may be possible in the future to develop even more effective techniques. ✦

What Is the Role of Ultrasound in Instrument Processing?

L. Jatzwauk (2003)

Over the past few years ultrasonic baths have become an established feature of instrument cleaning in inpatient and outpatient departments in the health services. These baths are being operated in all central service departments as well as in half of the endoscopy suites. Current recommendations on processing medical devices view ultrasonic cleaning as suitable, especially for instruments that are difficult to clean as well as for stubborn soils. But on the other hand, the theoretical fundamentals underlying ultrasonic cleaning, as compared with those of washer-disinfectors or sterilisers, are virtually unknown to the personnel in central service departments and in endoscopy suites.

Therefore validation of the cleaning effect mediated by the ultrasonic bath is an indispensable requirement for effective instrument processing. This cleaning effect achieved in an ultrasonic bath of lower intensity is essentially attributable to cavitation. Measurement of cavitation effects in ultrasonic baths, of different sizes and manufacture, in health care establishments by means of an aluminium foil revealed major differences in the ultrasonic baths from various manufacturers. Furthermore, the addition of disinfectants and, in particular, degassing of the detergent/disinfectant solution greatly influences cavitation. The degassing times specified by the manufacturers are in most cases too short.

Current instrument processing recommendations make numerous references to ensuring proper loading of trays, while increasing ultrasonic shadowing. However, no further explanations are given for this. Nor is account taken of the fact that if stationary waves are present even in an empty ultrasonic bath cavitation will show regional differences. Despite loading with only a few instruments in only one location, divergent cleaning results are obtained for the instruments in accordance with their position in the bath and with the distance from the oscillators. The same holds true for decontamination effects in the germ carrier test.

Oscillating ultrasonic baths produce a uniform cleaning effect on the instruments. The decontamination action achieved with manual cleaning with a brush is infinitely superior to that of a much longer treatment in an ultrasonic bath.

Chemical disinfection processes are expedited in ultrasonic baths. This effect is not due to the presence of hard cavitation and its magnitude varies for different bacterial species and fungi. Therefore, the efficiency of ultrasound in instrument processing has to be investigated specifically. ✦

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Reorganisation Measures for Optimisation of Sterile Supply Logistics at Marien-Hospital Marl

H.-W. Krusius (2003)

Efforts to further improve upon an already well-functioning process are surely in the interest of all parties bearing responsibility for such matters. Each and every day, heavy sterile supply containers and trays must be repeatedly moved around in every hospital for the process chains associated with sterile supply logistics. In this respect, the provisions of occupational safety have to be borne in mind, i.e. weights above 10 kg must definitely be avoided!

Marien-Hospital was on the lookout for an intelligent, personnel-friendly solution, which should also cut down on procedures relating to repacking the sterile supplies as well as on those involving subsequent transportation, loading the steriliser and storage at the sites of use. In view of the existing structural layout of this 316-bed hospital, it was also necessary to work out precisely how to convey the sterile supplies to the transport point since there was no extra space available for a walk-in transfer area.

A logistical solution that involved having the sterile supplies transported outside the establishment arose with the amalgamation in 1997 of Marien-Hospital Marl with Gertrudis-Hospital, Westerholt, and when St. Sixtus-Hospital, Haltern, joined the Catholic Hospitals of Marl/Westerholt two years later. This was by no means an easy task for the "Hospital Trio", known as Krankenhaus GmbH, which had now more than 716 beds and a staff of around 1400, making it one of the biggest hospital establishments in the Recklinghausen district.

As a specialist for sterile logistics, the company Hupfer in Coesfeld, Germany, was able to come up with a system to meet these complex requirements, delivering this through initial-equipment/specialist distributor channels. It was possible to take account, to the user's satisfaction, of the prevailing structural conditions because the "Känguruh-System" could be customised to meet the specific requirements.

The Hupfer "Känguruh-System" consists, inter alia, of a closed transport trolley, into which the insertion rack is fitted. The sterile supplies are placed in this insertion rack, using height-adjustable tracks. To ensure that complete segregation between the clean and unclean area can be observed by the sterilisation team, under the supervision of the head of sterilisation and OR, the insertion rack is conveyed from the transport trolley and transferred to permanently mounted storage platforms exclusively with transfer trolleys so that the insertion rack itself never comes into contact with the ground. The transfer trolleys are also used to transport the fully loaded insertion rack to the steriliser, where it is parked so that the insertion rack can be used at the same time as a loading rack for the steriliser. Advantageous as far as disinfection and sterilisation are concerned is the fact that the entire system is made of stainless steel 18/10, material 1.4301. A hygiene expert opinion has also been issued for the "Känguruh-System".

The closed transport trolleys which move along the unclean floor of the hall are conveyed to a matching Hupfer pass-through cabinet. The two-way, electrical locking mechanism used for locking the cabinet doors ensures that the closed transport trolley can be loaded with the now already sterilised and loaded insertion rack only when the hall doors have been closed again. With their ingeniously conceived truck transportation system, the "Hospital Trio" are providing for optimal supply and delivery of sterile supplies between the respective establishments. It has been possible to make considerable savings by using this well-organised external transportation of sterile supplies in conjunction with a Hupfer "Känguruh-System" instead of conventional sterile supply transport trolleys, because in all cases the insertion racks are withdrawn at the site of use and the closed transport trolleys can be used immediately again for disposal of the used instruments and containers using other insertion racks that are already on standby. The last reconversion tasks were successfully completed in the newly constructed CSSD at Marl towards the end of 2000. ✦

Fig. 1: Removal of the sterile supply unit (StU) from the transport trolley

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Dosage and Selection of Detergents and Disinfectants

M. Mohr (2003)

Before one can think about dosage (dose quantity) of a detergent or disinfectant, one must first of all select these products. But when making this selection one should not disregard the technical information relating to dosage (powder or liquid product; maximal possible dose quantity).

Selecting detergents and disinfectants

The choice of detergent and disinfectant will depend on a number of factors, hence the following issues must be clarified:

- What medical devices are to be processed?
- Can these be subjected to thermal disinfection (93 °C) and also the thermal sterilisation (steam sterilisation)?
- What risk is posed by the materials to be processed?
- What technical facilities are available for processing and what processing methods are to be used?
- Is material compatibility assured, e.g. in respect of alkaline products?

The recommendations and memoranda of the Robert Koch Institute (RKI) will help to provide answers to these questions (see under References).

Risk assessment can be carried out for the medical devices to be processed by referring to the RKI recommendation "Hygiene Requirements for Processing Medical Devices" (1). According to this, devices are classified into uncritical, semicritical and critical, with examples of each category being given. A further distinction is made on the basis of the diverse processing requirements (A – no particular requirement; B – more stringent requirements; C – ultra stringent requirements) (table 1).

This recommendation also gives preliminary information on the chemical composition of potential detergents and disinfection, while also pointing out those substances that appear to be unsuitable

Classification of Medical Devices (examples)		
Uncritical	**Semicritical**	**Critical**
ECG electrodes	A) speculum	A) wound clamps
	B) gastroscopes	B) MIS trocars
		C) not suitable for steam sterilisation

Table 1: Classification of Medical Devices (examples)

	Heat resistant (suitable for steam sterilisation)		**Heat sensitive (not suitable for steam sterilisation)**		
Categories	Direct contact with CNS, etc. possible Semicritical A (e.g. speculum) Critical A (e.g. wound clamps) Critical B (e.g. MIS trocars)	No direct contact with CNS, etc. Semicritical A (e.g. speculum) Critical A (e.g. wound clamps)	No direct contact with CNS, etc. Semicritical B (e.g. gastroscope)	No direct contact with CNS, etc. Critical C	Direct contact with CNS, etc. Critical C
Non-fixing pre-treatment/precleaning	Yes	Yes	Yes	Yes	Yes
Cleaning/ disinfection	Automated cleaning/ disinfection Alkaline detergent	Manual cleaning/ disinfection Also neutral detergent	Manual cleaning/ disinfection Also neutral detergent	Automated cleaning/ disinfection Alkaline detergent	
Sterilisation	Steam sterilisation	Steam sterilisation	Suitable sterilisation or final disinfection, also with aldehydes	Suitable sterilisation	Clarify if reuse is permitted

Table 2: General Procedure for Processing Medical Devices (RKI)

Alkaline cleaning is recommended (e.g. using heated NaOH solution) since this is known to be highly efficacious for dissolution of protein and lipid residues in addition to its antimicrobial efficacy. However, the stability of the medical devices vis-à-vis alkaline products must definitely be borne in mind. Ultimately, what is decisive when choosing a product is evidence that a product or process is demonstrably able to assure the requisite cleaning performance.

The disinfectants specified in the list compiled by the German Society for Hygiene and Microbiology (DGHM) are intended for manual disinfection of medical devices and not for automated disinfection. Therefore the efficacy profile of such products when used in a washer-disinfector should be verified by consulting expert opinions issued by the respective manufacturer, bearing in mind the conditions encountered in automated processing.

The RKI memorandum "Variant Creutzfeldt-Jacob Disease" (vCJD) gives information on partially efficacious and non-efficacious agents for inactivation of prions, as well as recommendations for cleaning and disinfection when a risk of iatrogenic transmission of vCJD cannot be directly detected (2).

Automated cleaning/disinfection should be conducted in washer-disinfectors using a cleaning step in an alkaline milieu (> pH 10) for an increased, non-protein-fixing process temperature of e.g. 55 °C. The best results can be achieved by using detergents based on NaOH or KOH, while including surfactants, with an exposure time of 10 minutes. Depending on the detergent used, the temperature can be as high as 93 °C. This is possible in particular for highly alkaline detergents.

Table 2 (table 11 of aforementioned RKI memorandum) lists the general RKI requirements for processing and for chemical composition of products.

Special instructions for processing flexible endoscopes can be consulted in the "Hygiene requirements for processing flexible endoscopes and endoscopic accessories" (3).

Solutions made of surface, non-foaming substances (surfactants), enzymatic detergents or combinations of cleaning/disinfectant substances of demonstrated efficacy should be used for cleaning purposes. Alkaline cleaning is known to be highly efficacious for dissolution of protein and lipid residues in addition to its antimocrobial efficacy. To date, no unequivocal evidence has been produced to demonstrate the superiority of any individual substance compared with others. Approved disinfectants from the DGHM or RKI lists are used for manual processing. No such list is available for automated pro-

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cessing. Therefore only detergents and disinfectants whose suitability and efficacy have been proven and documented in expert opinions should be used.

In general all recommendations point out that fixing processes, e.g. aldehydes, should be avoided for cleaning. Preference should be given to automated processes, but manual processes continue to be possible. When choosing detergents and disinfectants, attention should of course be paid to ensure that they are compatible with the medical devices to be processed, as well as with any other products used for processing.

From the above information, one general recommendation can be inferred for selection of detergents and disinfectants. Table 3 (general table for selection of detergents and disinfectants) can be used as a general guide to processing medical devices.

Dosage of detergents and disinfectants

The manufacturer's instructions must be observed when conducting manual processing, both in respect of cleaning and disinfection. The correct detergent concentration, which assures a good cleaning result, should always be selected. There is no need to use a surfeit of detergent. For correct dosage, the adjuncts supplied such as dosing pump or dosing beaker should be used, also to assure proper documentation (error avoidance, validation, certification). The disinfectant concentration will depend on the required exposure time. But the exposure time selected should reflect the locally prevailing conditions. There is no point in providing a relatively highly concentrated disinfectant solution for e.g. 15-minute exposure time if the instruments are then left for one hour in the disinfectant solution.

For automated processing the detergents and disinfectants must be dosed by means of pumps designed for the specific machine, Attention must be paid here to ensure that dosage recommendations given by the detergent/disinfectant manufacturer are also in line with the programme cycles and dosage facilities available in the machine. In addition, the dosing pumps should be set and operated such that the required dose quantity is also conveyed to the cleaning solution. ✦

References

RKI Recommendations and Memoranda

1. Hygiene requirements for processing medical devices, Federal Gazette, 2001; 44: 1115–1126.
2. Variant Creutzfeldt-Jacob Disease (vCJD); Federal Gazette, 2002; 45: 376–394.
3. Hygiene requirements for processing flexible endoscopes and endoscopic accessories; Federal Gazette 2002; 45: 395–411.

	Heat resistant (suitable for steam sterilisation)		**Heat sensitive (not suitable for steam sterilisation)**		
	Direct contact with CNS, etc. possible Semicritical A (e.g. speculum) Critical A (e.g. wound clamps) Critical B (e.g. MIS trocars)	No direct contact with CNS, etc. Semicritical A (e.g. speculum) Critical A (e.g. wound clamps)	No direct contact with CNS, etc. Semicritical B (e.g. gastroscope)	No direct contact with CNS, etc. Critical C	Direct contact with CNS, etc. Critical C
1) Non-fixing pre-treatment/precleaning	Alkaline or neutral detergent	Neutral detergent or disinfectant cleaning (aldehydefree)	Neutral detergent or disinfectant cleaning (aldehydefree)	Alkaline or neutral detergent	
2) Cleaning/ disinfection	Automated cleaning/ disinfection Alkaline detergent	Manual cleaning/ disinfection Also neutral detergent	Manual cleaning/ disinfection Also neutral detergent	Automated cleaning/ disinfection Alkaline detergent	
3) Sterilisation	Steam sterilisation	Steam sterilisation	Suitable sterilisation or final disinfection, also with aldehydes <u>Gastroscopes:</u> Neutral detergent (with enzymes) + chemo-thermal disinfection (aldehyde-based or aldehyde-free)	Suitable sterilisation	Clarify if reuse is permitted

Table 3: General Recommendations for Selecting Detergents and Disinfectants

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Standards for Washer-Disinfector Appliances and Testing the Cleaning of Flexible Endoscopes

W. Michels, D. Heider*

The periodic performance testing of washer-disinfector appliances in German hospitals was, in the past, almost solely conducted using so-called bio-indicators (in accordance with the Guidelines of the German Federal Health Authority [BGA] on testing thermal disinfection methods in cleaning machines, 1980).

According to the commentary on the guidelines, the procedure should test disinfection, and not the literal washing away of germs by cleaning. If growth was determined, i.e. the disinfecting performance was insufficient, the customer service technician usually noted that although the parameters of thermal disinfection for loading the appliance had been complied with, the cleaning of the test items and test contamination was problematical. The microbiological testing technique is not sufficient, because it cannot differentiate between cleaning and disinfection performance.

The thermal kinetics of killing various microorganisms is generally well understood. Thus the destructive effect on a microbiologically contaminated load, of a defined temperature and holding time is also known. The European draft standard prEN ISO 15883-1 therefore intends, that to test the disinfection performance, it must be possible to measure the temperature and holding time at the load itself, at the inserts and at the internal chamber walls. These values are then compared with the stipulated specifications of the A_0-concept. Thus it is ensured that regulation and control (via the two temperature gauges at the reference point in the appliance) are such that the conditions are the same at all other points in the recirculation and in the chamber interior. The cleaning performance is tested and assessed independently of the disinfection performance. This results in a more objective and differentiated assessment of the disinfection performance as well as the cleaning performance. This is so even though the current testing of cleaning performance is rather dubious, because the testing methods have not been validated. At least thorough visual inspection of the processed instruments, and more objectively (in particular for instrument parts which cannot be inspected visually), random sampling by removing eluate and conducting a test to determine the presence of protein, can be carried out.

In order to obtain the greatest possible acceptance of the prEN ISO 15833, and also to allow those who do not yet want to utilise this new concept to retain the option of microbiological testing, the microbiological tests can be used additionally.

There is a consensus that microbiological control of disinfection performance is indispensable for the processing of flexible endoscopes in automatic washer-disinfectors, on account of the synergetic effect of temperature, contact time and chemistry.

However, there will always be a measure of washing-off and dilution via the cleaning and dilution steps involved, which is difficult to categorise. Moreover hygienists and microbiologists design these tests, so that the cleaning performance is also assessed microbiologically.

Of course, cleaning does contribute to the reduction of existing microorganisms; but it is questionable whether the surfaces to be cleaned are free of other unwanted substances to exactly the same extent. The relationship between the reduction of organisms and the removal of soil is not necessarily a simple linear one. Particularly after the removal of gross macroscopic soil (90–99%) the various adhesive properties and mechanisms of soil and microorganisms are relevant. These depend on the parameters of cleaning (mechanics, temperature, contact time, chemistry, water quality), surface structure and composition. The reduction of soil and that of microorganisms (or test germ applied as a marker) definitely have different kinetics. When testing cleaning of surgical instruments (by elution with 1% sodium dodecyl sulphate solution followed by chemical analysis for protein determination), we had always insisted on a recovery rate of possible protein of at least 80%.

But the following question arises: how many of the possibly existing microorganisms are recovered and detected by the microbiological test? In the HYGEA study, channels were flushed out with physiological salt solution and investigated for the presence of microorganisms. Especially here, the recovery rate is of particular significance. In microbiology one thinks in terms of logarithmic units, which can easily be misleading.

Of course it is insignificant whether a particular disinfection performance results in a reduction of 5.6×10^5 or 1.12×10^5, because in both cases we are dealing with a reduction of more than 99.999%. But if one starts with 5.6×10^5 germs, and only 1.12×10^5 are recovered, this has quite a different significance, because it is a recovery rate of only 20%. Therefore one cannot deduce a valid conclusion from it.

Because there are many studies that include similar experiments, but rather uncritically do not present a recovery value, (i.e. experiment lacks validation), we decided to go into the question of microbiological recovery.

Stainless steel and Teflon sheets were contaminated with various concentrations of *Bacillus subtilis* suspension. The suspension of spores was dried for 30 minutes. at room temperature, then it was suspended in sterile water by shaking vigorously for 15 minutes. The suspension thus obtained was diluted according to a predefined system, and plated out on CaSo jelly as in DAB 10. After incubating at 35 °C for two days, the colonies were counted. The population of the surviving germs was obtained by multiplication with the dilution factors.

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The recovery rate from contaminated stainless steel sheets was significantly higher than that from Teflon sheets. Using a high germ concentration of 10^7 the recovery rate for stainless steel was >90%, but only <10% for Teflon. At the low germ concentration of 10^4, the microbiological recovery rate for stainless steel was much lower (54%) and the rate for Teflon was equally lowered. The smaller the starting germ population, the smaller the microbiological recovery rate.

Further experiments are being conducted to discover more about the factors influencing recovery rate. These experiments confirm the strong adhesion of *Bacillus subtilis* to Teflon, which is described in the literature. They show that the recovered germ count is reduced by more than a whole $\log_{10}$ unit. The unfortunate dependence of the recovery rate on the initial germ count makes these microbiological experiments appear invalid.

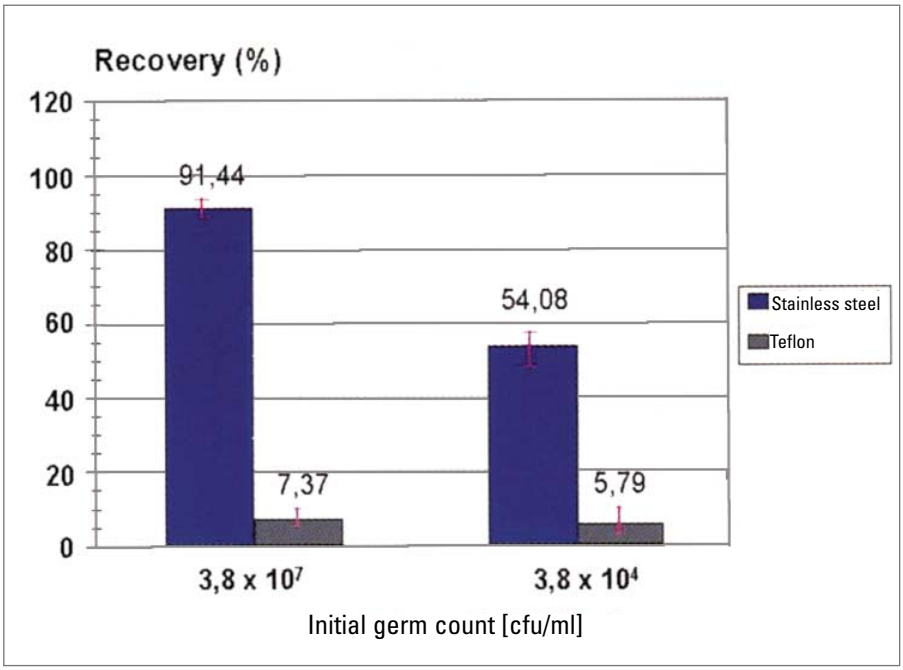

Fig. 1: Microbiological recovery of *Bacillus subtilis* after rinsing stainless steel and Teflon sheets

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In fact the opposite ought to be true: the lower the actual initial germ count, the better the recovery rate should be. These results are very thought-provoking, especially as the experiments were conducted without additional contamination. In conclusion, while microorganisms might be valid to examine disinfection dynamics, they are obviously not as helpful to evaluate cleaning efficiency. The ongoing discussions of this matter in the standard committees should acknowledge these facts, and these results should also be considered for the methodology of microbiological testing of surfaces with different affinity (materials), as for example in flexible endoscopes. ✦

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Assure Supply Sequences for Functional Medical Devices

V. Maute

The advent of the "Kenus System" marks the beginning of a new era in medical device management in the hospital. It is the first computerised control and management system to be used for a medical device in a hospital setting. Thanks to its simple operation, remarkable efficiency and comprehensive facilities, this system constitutes the ideal basis for a state-of-the-art quality management system and for meeting all business management requirements for accountancy and investment planning, because it makes provision for tracking a medical device once it has been registered and labelled.

The "Kenus Matrix" is the cornerstone of this system. This is a two-dimensional code affixed to the instrument, comprising an unambiguous identification number allotted by the hospital. This code can feature up to 3116 characters in minimal space. The information is encoded horizontally and vertically in the matrix. It offers a very high degree of security and

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virtually rules out substitution errors. The matrix can be easily affixed to any instrument, regardless of manufacturer, and thus provides for continual registration of the hospital's entire arsenal of instruments.

In addition, the matrix can be acquisitioned at the speed of seconds using a small, easily operated digital camera and transferred via a cable connection to the "Kenus Manager" software. The camera reads and inputs the data without any errors, thus preventing the type of errors encountered with manual entry of instrument identification numbers. This software is the most vital component of the system. The manager is a multifunctional SQL databank based on Windows and comprises administrative modules for batch documentation, tray management, repairs and reprocessing, placing orders, warehousing, documentation, validation of work sequences and planning surgical procedures. This system gives the hospital a complete overview and documentation right down to the individual instrument and thus complete transparency as far as costs are concerned The German Society for Sterile Supply (DGSV) awarded its Innovation Prize to this system in 2001. And so you will have each and every instrument under control! ✦

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