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Medical Device Reprocessing: Responsibility for Quality
Best of FORUM 12–15

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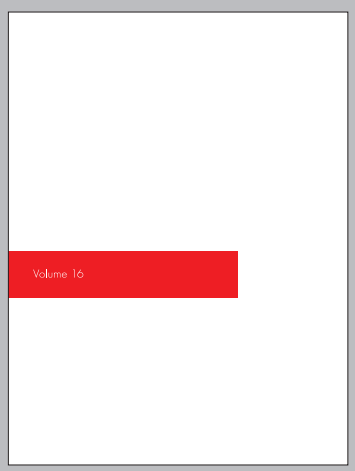
SURGICAL INSTRUMENTS' WORK GROUP



The «ABC» of medical device reprocessing is more than «critical»

There are countable and not countable events in the process of medical device reprocessing. A procedure description has to work for the practitioner, who has to implement it in a timely manner in his or her daily processing operations.

The requirements for usability of a given medical device need to be known and classified for the risk management: components, accessories, software. Is it an application under «critical» conditions? And how «critical» (i. e. invasive) is a medical device in its use: does it touch the skin or mucosa, does it open or penetrate body layers? Can it easily be cleaned and is the safe function still reliable afterwards?

The «ABC» of instrument design, may they be detachable or undetachable, foldable or purgable, is often more than «critical» for those who must deal with a suitable processing method, being the designated operator with responsibility for patients, staff and others. A clear assignment as to how non-critical, semi-critical or critical an application is, may not always be possible.

Recall the author of these lines' last «International FORUM Medical Devices & Processes« on February 27, 2010, which was held in a Berlin hospital with the theme: «Since when is processing easy? Clarification of the processes.» In fact, quite the opposite of clarification could, and still can be observed: in Europe, with the template for the new Medical Device Directive, and here in Germany with the new KRINKO recommendation of RKI and BfArM. The latter recommendation, more of a guideline really, has grown from 12 pages (2001) to currently 67 pages (2012), including other recommendations and addenda. It still has no glossary, but it does list hundreds of literature references, some of which are probably outdated by the time the document sees print.

Unfortunately, the ever-growing set of rules threatens to endanger the safety of processing by its sheer complexity. In an effort to clarify specific aspects the clarity of the whole process may get lost.

Why can't such documents (laws and regulations, recommendations and guidelines) – once they have grown so extensively, as is to be expected with consensus papers – be preceded by a set of procedure instructions of no more than one page? Why not retain the list of sources and literature, thus encouraging direct inquiries of interested readers? Why can't the changes in revised documents be indicated to the recipient?

At FORUM 2010, we noted that «*Processing should be simple and easy, that is the only way to ensure the reproducibility of constant quality of reprocessed medical devices. An analysis of the processes shows, however, that there is a colorful variety of requirements to be met:*

- *A diverse set of European rules, laws, partially obsolete standards and regulations, as well as recommendations and guidelines lay out the framework more or less clearly.*
- *The presence of suitable manuals, as well as their knowledge and compliance, cannot always be relied on.*
- *Various stages of the process with alternative approaches, partly manual or supported by automated steps, need to be structured through standard operating procedures and instructions.*
- *Instruments that are detachable to varying degrees – hundreds every day – have to be treated properly and professionally. This requires above all the knowledge of how they are to be cleaned and maintained.*
- *The existing hardware and equipment must be at the state of science and technology and be handled accordingly.*
- *Employees have to undergo training and further education «up to the limit of what is reasonable».*
- *Processing has to be described down to the substeps and be mastered describably. This is controlled and documented.*
- *Processing performance is documented.*»

We can leave it at that, even today, without changing the text. We then asked:

«*Isn't a bone marrow drill really »critical C«? And what about endoscopes, which are surgically inserted? The current classification may need to be supplemented with a category «critical B with unavoidable residual risk» as in the above examples. Both instruments are essential under certain circumstances, but certification will hardly improve the processing results.*»

In today's terminology these would be instruments with «increased» to «very high» reprocessing requirements. The focus is more on validated low-temperature processes now, and less on the formalism of certification: «External certification is not required, if the manufacturer of the medical device has given concrete information on the use of another specific sterilization process and the use of this process was validated in terms of its effectiveness on site.» (Citation from the new KRINKO recommendation)

More and more it is recognized that careful processing and the overall management of instruments as long-term investments is a key factor – especially under the conditions of required sterility. Reactions to this recognition may vary, a variety of partial observations makes it possible to achieve savings. In fact, hygiene standards are often also functional ones, as precision mechanical instruments suffer from soil.

To summarize: A review of every single instrument in the trays, baskets and containers requires a lot of experience in terms of processing (type and volume). Any sterilization process is a unique event, as regards individual loading patterns, the state of the hardware and steam quality. Given the range of very different medical devices that undergo daily sterilization processes (solid, porous, hollow) and therefore the number of design features that may cause problems, there can be no single PCD which identifies all possible errors. Rather, various PCDs may each represent specific product families, but must be used in combination to ensure safety for the whole range of sterilization materials.
Processing medical devices is therefore always a manual task, and the support of automated technology does not change the fact that appropriate technical and human resources and proper equipment for the execution largely determine the outcome of the process. Only partial steps can be mechanized and run automatically in a standardized manner. The careful use of water resources has undoubtedly become another issue that deserves increased attention.
«*Processing is a diverse and challenging work whose reproducible success depends on the consistent implementation of the available knowledge. Not everything that is possible here needs to be done, too. But that which is done should be justified and well documented.*»
That was the final judgement some years ago, at the FORUM 2010.
The ABC of medical devices must become an easy one, knowing that operators remain responsible for the quality of processing. Risk analysis and risk minimization are essential prerequisites to risk management – so that it does not get «critical» for the patient.

Dr. Thomas W. Fengler
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Content: Responsibility for Quality

Best of Vol. 12 – 15

Masthead

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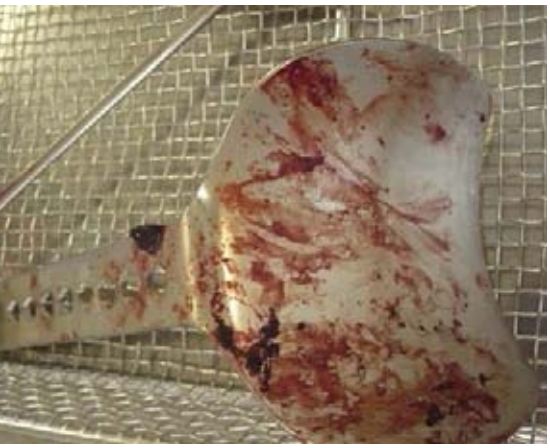
What it is all about: reprocessing at close inspection

Spitting was banned in public places to prevent the spread of tuberculosis
(For the promotion of public health you are urgently requested to refrain from spitting inside the station, on the platforms, on the stairs and in the carriages.)

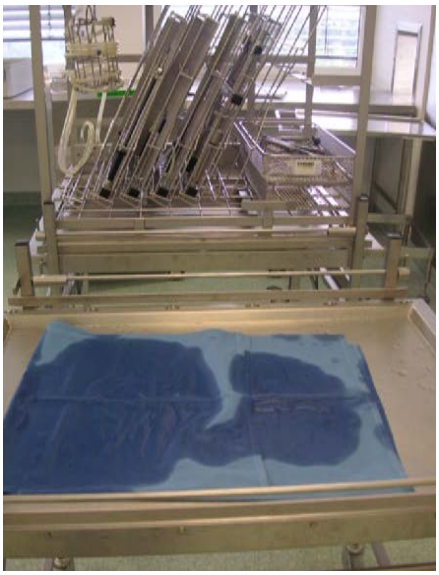
(An-) organic residues are hidden in instrument joints

Metal grit at a loading trolley may damage the rinsing pump and can harbour microorganisms



Prompt decontamination – blood residues on a surgical clamp should not be left to dry

Cleaning must «get to the point» – in this case a dental handpiece, whose channels must be rinsed to be freed from residues



Cleaning and disinfection do not happen «automatically» – microorganisms love humidity!

Cleaning results of diamond burs

A case study brought up for discussion

G. Schimanski

As a middle-ear surgeon I have recently begun to take cleaning results, especially those of diamond burs which we use in middle ear surgery, under the microscope.

The major manufacturers (e. g. Storz, Spiggle & Theis, Komet) do not usually offer single-use drills – only on special request, and then for 2 – 3 times the price of a reusable drill (well over 100 €/piece).

My recently launched REM- (reflection electron microscope) and EDX- (energy-dispersive X-ray spectroscopy) -screenings show alarming results, as can be seen in Figures 1 – 4. The existence of Ca(lcium), P(olonium) and O(xygen) are evidence that the diamond round burs in particular cannot be called «clean», regardless of the cleaning methods used.

I would love to discuss this topic with other experts. I am particularly interested in the question, which other components of the istrument surface of round burs/rose burs (e. g., tungsten, molybdenum, iron, nickel, chromium, carbon) are safe for further use in the middle ear after the first use.

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Fig. 1: Drills: diamond bur on the left, round/rose bur with A-toothing on the right, each new/unused

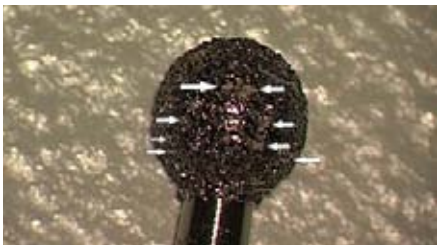

Fig. 2: Diamant 2 after mechanical cleaning (Komet cleaned with special brush, arrows point to osseous matter)

The microbiological screening of the diamond burs (8 – 10 pieces per group, used in a patient's ear) was performed according to European Pharmacopoeia (Ph. Eur. 5 initial volume 2005): direct inoculation method, i. e. test articles are inoculated with 10 ml Casein-peptone soymeal-peptone broth and incubated for a period of 14 days. On opacifikation under sterile conditions dissemination on a general purpose medium (e. g. Columbia-agar) and a selective medium (e. g. McConkey-agar) with following differentiation in case of colony growth. Cultivation had the following result:

- Group 1: not cleaned or sterilized; no groths on 3 burs, (although a turbid mud had settled, which was probably osseous matter). On 3 other burs detection of bacteria after enrichment: *Micrococcus* sp.
- Group 2: diamond burs used, not precleaned before transport to reprocessing unit: no detection of bacteria.
- Group 3: immediate mechanical cleaning and disinfection bath (immediately after operation) before transport to reprocessing unit: no detection of bacteria.

For a conclusive assessment on the reusability of burs, further investigations in order to detect RNA are neccessary and provided for. ◀

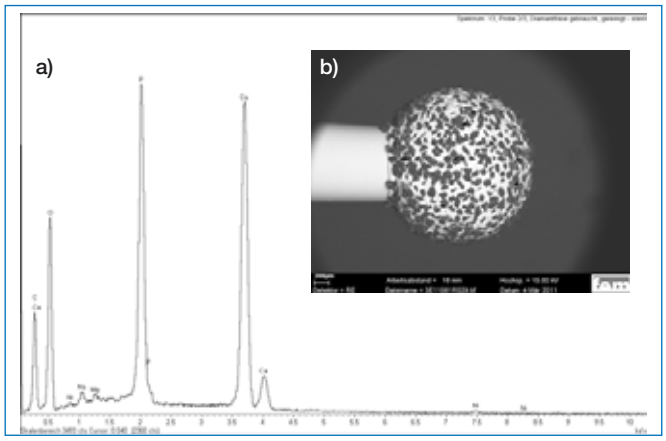

Fig. 3: a) Element analysis spectrum shows P- and Ca-peaks (calcium phosphate), indicating osseous matter.

b) Photograph of diamond bur (cleaned and sterilized): energy-dispersive X-ray spectroscopy (EDX): osseous matter in between the diamond splinters

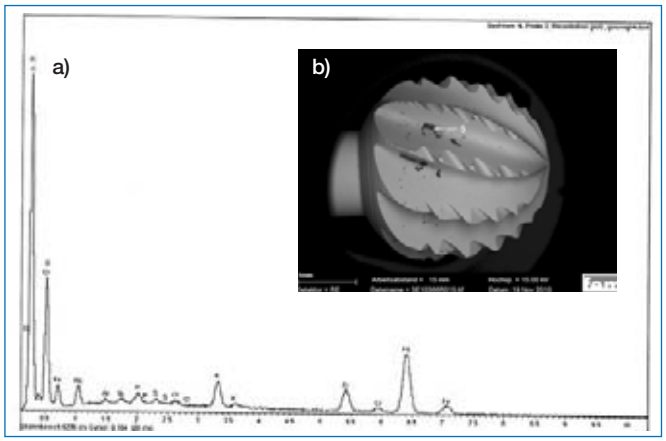

Fig. 4: a) Element analysis spectrum shows: K- and Pi-peaks (potassium chloride) indicating residues of cleaning agent (no P and Ca present)

b) Photograph of round/rose bur (large) with residues (mark 5)

Documentation of inadequately cleaned instruments – an essential component for evaluation of WD cleaning performance

«One glance around the lab and two at life»

L. Jatzwauk, A. Gräber

Introduction

In addition to the disinfectant action, cleaning is an essential component of the medical device reprocessing chain in washer-disinfectors. It guarantees the functional capability of instruments and has implications for the thermal disinfection process. While the viewpoint often expressed in everyday practice that «there is no such thing as sterile dirt» is not scientifically tenable, it is true that residual soils can markedly prolong the D-value (time during which the microorganisms present are reduced by one order of magnitude) of thermal and, in particular, chemothermal disinfection processes. Accordingly, EN ISO 17665-1 stipulates validation and management of the cleaning and disinfection processes used for medical devices in order to assure effective steam sterilization (1). In the recommendation by the Robert Koch Institute on «Hygiene in medical device reprocessing», «optical cleanliness» is cited as a criterion to be continually applied for effective cleaning processes (5). Only at greater intervals are analyses of residual proteins carried out for special instruments. The currently valid guideline compiled by the German Society of Hospital Hygiene (DGKH), German Society of Sterile Supply (DGSV) and the Working Group Instrument Preparation (AKI), «Guideline for validation and routine monitoring of automated cleaning and disinfection processes for heat-sensitive medical devices as well as advice on selecting washer-disinfectors», defines guide, alarm and limit values for protein detection following cleaning (2). These must be viewed as an orientational guide for process evaluation. This applies in particular to medical devices with channels or lumens that are not fully amenable to visual inspection. Part 5 of EN ISO 15883-5 (3) describes test soils and methods for verification of the cleaning performance. Since this part is merely a «Technical Specification», and despite the fact that the information given reflects the state of the art in science and technology, it does not have a binding, normative character. But it does serve as the basis for several instances of performance qualification of washer-disinfectors (WDs) in healthcare institutions.

Fig. 1a/b: Typical residual contamination after inadequate reprocessing

In addition to the nature of the soil, the amount of soil applied, the medical device used and the effectiveness of test soil recovery play a pivotal role in initial performance qualification and requalification of a WD.

It is all the more surprising that in the medical setting it is generally accepted, even for validated cleaning and disinfection processes, that a certain proportion of the instruments still harbour visible soils after cleaning and must be recleaned (Fig. 1). So widespread is this acceptance that this is not even registered as being a complication of the process. The explanation given for inadequate cleaning is that in medical institutions compared with industrial cleaning processes there are no exactly reproducible standard loads for a WD. The instruments to be reprocessed are those actually used for the respective patient clientele. In other cases, after being used certain (in some cases even a large number) instruments are precleaned manually or using ultrasound before they are decontaminated in a WD. This is based on the experience that these instruments could not be adequately cleaned otherwise using an automated decontamination process.

It is obvious that the spectrum and quantity of instruments that continue to har-

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bour soils after automated reprocessing constitutes an important quality criterion for the process. Unfortunately, that fact has not yet been taken account of in performance qualification; indeed, it has not at all been registered.

Method

Over a defined period of time (on one day each week) the staff in the packing zone of the Central Sterile Supply Department (CSSD) were instructed to make a note of all instruments that were visibly soiled after taking them out of the WD and had to be recleaned. The following details were to be noted:

1. Staff member who detected contamination
2. Instrument designation
3. WD or process in which residual soils were noted
4. Possible reason for contamination (as far as could be established)

Results

Conclusions that could be drawn from these notes on the effectiveness of the decontamination process:

1. Time and again it is a certain type of instruments that were found to be contaminated. One possible reason identified was inappropriate positioning of the instruments in the WD tray. Besides, the design of the instruments could also be responsible, something which did not at all provide for adequate cleaning. This should really have been checked by the instrument manufacturer pursuant to EN 17664 (4), but that was not done. Whether the poor instrument design or an incorrect loading pattern was responsible, should be checked at the time of the next, or unscheduled, performance qualification within the scope of validation. To that effect, it is not only Crile arterial clamps, but also those instruments listed above, which could not be properly cleaned, which must be contaminated and investigated.
2. It is always a certain WD that is unable to produce properly cleaned instruments. This is particularly worrying when the weekly number of such instruments increases. That is also one reason to carry out unscheduled performance qualification of the process.
3. It is the instruments of particular hospitals, departments or outpatient centres that are not properly cleaned. This is not due to inadequate decontamination. It is mainly due to prolonged storage of the used and contaminated instruments before they are reprocessed. But another reason could be unqualified precleaning of the instruments immediately after use.

Summary

It is paradoxical that evaluation of the cleaning performance of an automated decontamination process as conducted within the scope of validation is confined to analysis of residual proteins on defined instruments (Crile clamps) that had been contaminated in advance. Instruments that de facto have proven to be inadequately cleaned are not taken into account, despite the fact they had not been properly cleaned by the «validated process». If the user were to simply record that fact, it could give the «validation officer» important insights into weak links in the decontamination process, paving the way for testing in line with the everyday situation. On the other hand, these findings draw attention to instruments that are difficult to clean because of their design, and also highlight inappropriate workflow patterns (storing the instruments too long before reprocessing them). ◀

References can be obtained from the author

Cleaning technique in MIS injector trolley

W. Michels

Fig. 1: Properly loaded MIS injector trolley

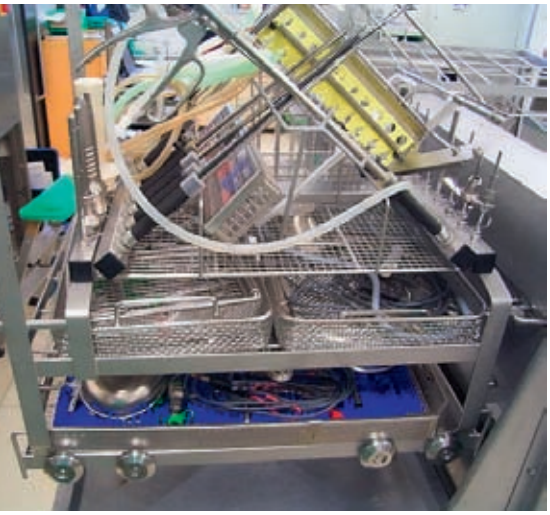

Fig. 2: Incorrectly loaded MIS injector trolley, e. g. spray shadowing due to silicone mat

The loading trolleys used for minimally invasive surgical (MIS) instruments often have no cleaning arm integrated into the trolley. Hence external cleaning of instruments or instrument components is performed by cleaning arms that are fitted into the bottom or top of the cleaning chamber. When loading the trolley, care must be taken to ensure that the instruments are not screened off, such that the cleaning jets of these cleaning arms will not be able to reach all outer instrument surfaces (spray shadowing).

Correct loading and uniform flow

Figure 1 illustrates a carefully loaded injector trolley, while Figure 2 shows a trolley that has been loaded without any care or thought.

The injector trolleys depicted here have two double rows of nozzles on the left and right sides of the trolley, with the outer row equipped in both cases with vertical screw fittings for nozzles, adapters and irrigation sleeves. The second row of nozzles is obliquely inclined towards the centre, so that longer instruments can be connected and positioned on racks. These rows of nozzles have silicone fittings to which nozzles, adapters and irrigation sleeves can be connected and also swiftly replaced during routine operations. The nozzle rows are soldered in the centre to the supply pipe of the loading trolley. The volume flow rate that would have to flow through a 2 m long tube with a 2 mm internal diameter to the various positions in a row of nozzles was calculated. In the middle region i. e. of the incoming pipe, this was calculated to be 1300 ml per minute and 1500 ml per minute at the terminal nozzles. Using the tube routed from the cleaning chamber and collecting the solution in a volumetric vessel, this was then verified. The measured values were essentially within the calculated range and differed from the calculations mainly in the case of the terminal connections. That was due to the fact that the nozzle pipes were closed at the ends with plastic caps that were not perfectly sealed, giving rise to pressure drops. The volumetric measurements were mainly in the range 1300 to 1400 ml per minute. Hence the volume flow rate can be standardized relatively well.

Avoidance of pressure decreases

Based on the Guideline compiled by the German Society of Hospital Hygiene (DGKH), German Society of Sterile Supply (DGSV) and Working Group Instrument Preparation (AKI), the cleaning pressure should be standardized such that deviations of more than ± 20 % from the average cleaning pressure will not arise during the active cleaning process steps. Therefore cleaning pressure deviations were investigated in line with different correct and incorrect connection settings in the loading trolley.

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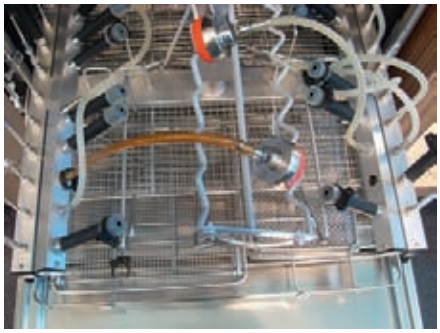

Fig. 3: Loading trolley with missing silicone fitting on right, front, and connected pressure loggers

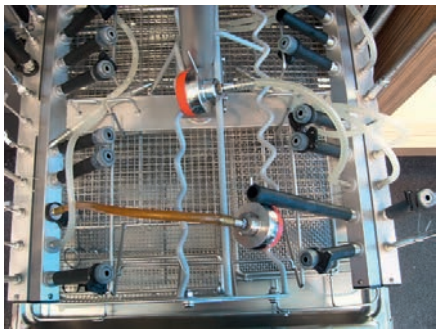

Fig. 4: Loading trolley fully equipped with flushing devices and with pressure loggers

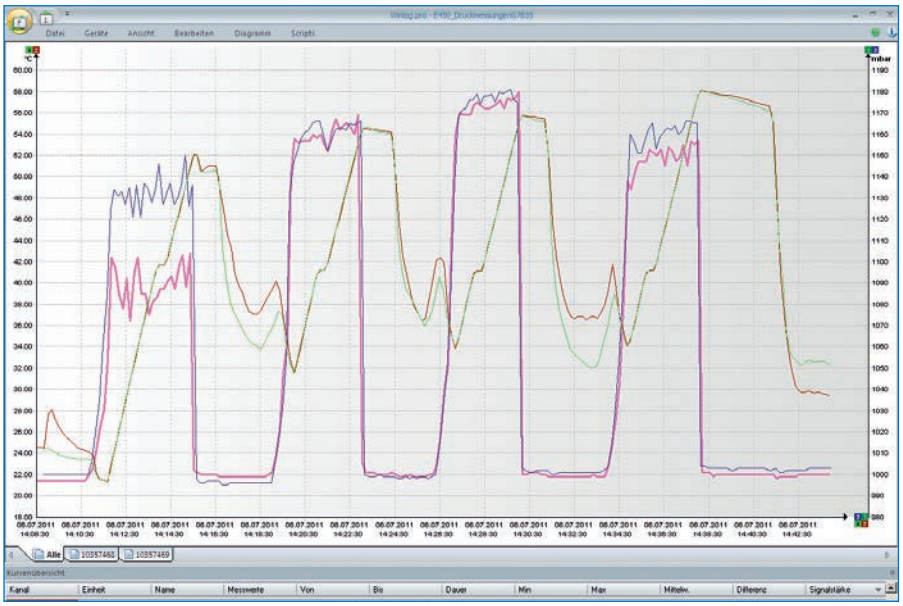

Fig. 5: Logger pressure measurements for four different connection configurations

Fig. 6: Dummy plugs in positions adjacent to the logger connections

Fig. 7: On the right, oblique nozzle row with unoccupied and unconnected silicone fittings

Based on the manufacturer's instructions in the case of the tubes with vertical screw fittings for flushing devices, all positions must always be occupied since otherwise, because of a 6 mm opening, this would lead to an inadmissibly large decrease in the water quantity, and consequently to a drop in pressure. In the case of the obliquely positioned tubes with silicone fittings, all positions need not be occupied because the silicone fittings are configured such that the cleaning water entry point is limited to a diameter of 3 mm. What happens in practice is that because of mechanical influences, it is quite possible that a silicone fitting may be damaged and missing. This would then give rise to an opening of 16 mm diameter, and further operation of the equipment under such conditions would possibly violate the intended use (see operating manual). Such a situation is illustrated In Figure 3.

Such a faulty situation was checked with pressure loggers, connected directly beside the large opening and a further logger, connected to the nozzle row directly opposite. This was then compared with a situation where all loading trolley ports are connected to irrigation flushing devices (Fig. 4).

In Figure 5 the first pressure peak (blue as well as purple curve) depicts the situation where a silicone fitting (Fig.3) is missing. The second peak shows the pressure values where nozzles are fully and correctly occupied (Fig. 4). Where a silicone fitting is missing, the cleaning pressure thus declines at the adjacent position (purple curve) by almost a half compared with the situation where all nozzles are completely occupied. The effects are significant even for the opposite row of nozzles (blue curve), where the pressure is somewhat more than 20 % less compared with the situation where all nozzles are completely occupied. As such, where a silicone fitting is missing, there is a drop in pressure at all connection positions in the loading trolleys and, accordingly, adequate cleaning results cannot be obtained.

As stated, the silicone fittings themselves standardize the cleaning pressure. Often the view is expressed that unoccupied positions should always be closed with blind screws. The situation where the positions adjacent to the pressure loggers were closed was simulated (Fig. 6).

The third pressure peak shows in Figure 5 the pressure conditions prevailing in this situation. While the pressure values are raised compared with the situation where all nozzles are completely occupied (Peak 2), that increase is not significant, i.e. less than 20 %.
The situation where silicone fittings were not occupied and not closed was also simulated (Fig. 7). The fourth peak shows the pressure conditions arising here. The pressure values hardly differ from those where all nozzles are completely occupied (Peak 2) For the cleaning pressure directly at the nozzle row concerned, the deviation continues to be less than 10 %, and no effect is discernible on the opposite nozzle row.

Conclusion

In the MIS injector trolley all vertical irrigation ports must always be fitted with flushing devices or blind screws. The silicone fittings in the obliquely positioned nozzle rows themselves standardize the cleaning pressure. Hence when these are connected to flushing devices to different degrees, or in some cases are not connected, they maintain the cleaning pressure in the range ± 20 % deviation from the situation where all ports are occupied.
If silicone fittings are defective or faulty or pipe end caps are faulty or missing, the loading trolley must no longer be used. These must be replaced immediately. ◀

INDUSTRY

With Miele «Robotvario» :

Reliable reprocessing for robotic instruments

Minimally invasive operations are being performed increasingly worldwide with robot-assisted instruments. To decontaminate long tubular instruments, Miele is now offering a demonstrably reliable and inexpensive solution that is not based on high cleaning pressure, but on a special enzymatic cleaning technique.
The «Robotvario» hardware consists of a compact and powerful washer-disinfector PG 8536, combined with the new special trolley E 428. This can accommodate six tubular instruments, with two connections ensuring the inner regions of the shaft and control housing are purged separately.
There is also a reprocessing programme which takes only just over one hour and does not require pre-rinsing. Instead, the instruments are first filled for half an hour with the detergent «Mucapur Robotvario», which enzymatically breaks down organic residues. «Mucapur Robotvario» has been developed by Merz Hygiene GmbH and, in terms of its active ingredient combination, it meets the special requirements governing cleaning of tubular instruments and is tailored to the special Miele cleaning technology.
If necessary, terminal instrument regions are next cleaned with a brush, before the tubular instruments are connected to the loading trolley E 428. The Miele special programme guarantees effective final cleaning, rinsing as well as thermal disinfection. This is confirmed by clinical trials and laboratory tests carried out at the WFK Institute for Applied Research in Krefeld. Both tests based on protein and haemoglobin reduction attest to the good performance of the «Robotvario» process.

Information: www.miele-professional.de

The new validation guideline – practical implementation in a CSSD in Germany

M. Lüttenberg

Elisabeth Hospital in Essen (613 beds) operates three washer-disinfectors (WD), two sealing devices and two steam sterilisers (6 StU) (each identical in construction) in its central sterile supply department (CSSD). Containers (70 %), sterilization sheets (10 %) and pouches (20 %) are used to package medical products. Gusseted Pouches are used, and these are sealed mechanically using the sealing devices.

Introduction

Validated preparation processes are required according to the European Medical Device Directive (MDD). Validation has become common practice for cleaning and disinfection and sterilisation processes. If one considers, however, that the packaging itself is the key reason why medical products remain sterile right up until use in the operating theatre, it becomes clear that the packaging process is a fundamental part of this instrument reprocessing chain. Only a reproducible, validated packaging process will ensure sterile medical products for clinical use. For this reason, the harmonised European EN ISO 11607 standard was published in 2006 which, in its second part, requires the validation of all packaging processes, regardless of whether they are automatic using sealing devices or manual, for instance during wrapping or when filling and closing a container.

Validation of the sealing process (automatic process)

Sealable pouches and reels must essentially be closed with a sealing device. Accordingly, the process is carried out automatically, which is why the validation process is relatively easy to implement in practice. The German Society for Sterile Supply (DGSV e. V.) therefore joined forces with the TÜV organisations to publish guidelines on the validation of sealing processes according to EN ISO 11607-2 in 2008. Checklists enable the validation process to be carried out. Essential requirements of course include sealing devices which monitor the critical process parameters temperature and contact pressure (the additional monitoring of speed/time is also recommended by the DGSV) and which alert the user in the event of any problems (Fig. 1). These devices must be confirmed by the manufacturer as being compliant with EN ISO 11607-2. Where older sealing devices are used, the manufacturer should be asked whether they already satisfy the standard's specifications. The packaging material must comply with the EN ISO 11607-1 standard. The manufacturer must provide a data sheet which lists the sealing temperatures (e. g. 170 to 200 °C).

Validation is carried out using checklists. Once the process has been validated, the sealing seams must be checked on a routine basis. The best way to do this is with either an ink test (Fig. 2) or a seal indicator (Fig. 3). We and many other hospitals have been carrying out validations of sealing processes for many years and, thanks to the automatic processes involved, everything has run without a hitch.

Validation of manual packaging processes (wrapping and container)

Standard operating procedures are required for the mandatory validation of manual processes. But are these enough? In response to this question, the DGSV has revised the existing guidelines and, at the DGSV Conference in 2011, published the «Guideline for Validating Packaging Processes according to EN ISO 11607-2». The «Sealing» section has been supplemented with a few very helpful sample standard operating procedures (SOP). New checklists for validating the «wrapping» and «filling and closing containers» processes were also included. Since these processes are entirely manual compared to the sealing process, the validation procedure is slightly unfamiliar and significantly more labour-intensive. This was however already noted during the planning stage. The entire team within our department needed to be given in-depth instruction in the contents of the guideline, its requirements and information on the practical aspects of carrying out the validation. Training courses and instructions were given to all employees on the various packaging techniques.

The first major obstacle was how to determine the number of validations and how to draw up a validation schedule. Countless documents, data sheets, product specifications and declarations of conformity have to be requested from the manufacturers of the packaging systems and their accessories. Experience has shown that this worked very well in most cases (PDF files from manufacturers). A lot of time was spent filling out the validation plan checklists. The installation qualification (IQ) was comparatively easy, since all that needed to be ensured was that all of the standard operating procedures were available. The guidelines include sample standard operating procedures (SOP) that were compared with our existing SOPs. The guidelines even provided examples for training employees.

The operational qualification (OQ) required the comprehensive documentation of all the containers and the accessories. The most critical packaging configurations for the containers and sets packed

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Fig. 1: Validatable heat sealer in action (here: hawo hm 3010 DC-V)

Fig. 2: Checking the quality criteria using the ink test (here: hawo InkTest)

Fig. 3: Checking the sealing seam with a seal indicator (here: hawo Seal Check)

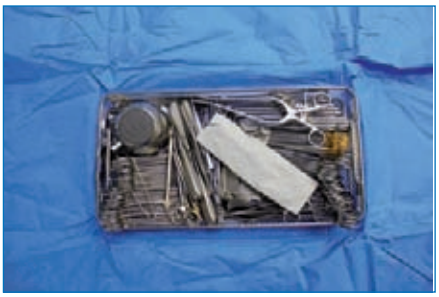
in sterilization sheets had to be defined. In this case, we followed the guideline's instructions and orientated our activities towards the heaviest and largest containers or sterilisation trays («worst-case scenarios»). Once these configurations had been defined, several employees who were unaware of the validation process and who were not under surveillance had to package 10 of these configurations in accordance with the standard instructions.

It became truly clear for the first time at this stage what effects the human factor has on the process. Differences in the quality of the finished packaging compared to the required quality criteria were found depending on the time of day and the employee responsible. It is essential that a constant level of performance is maintained in the department (e. g. through further training). Employees must always be deployed in accordance with their strengths. Only then can their performance be harnessed and documented.

The 10 «worst-case» packages were unpacked again and each step was documented with a photo. A corresponding series of photos was then incorporated into the «operational qualification» checklists. After a lot of work and training, there were no further obstacles to get in the way of the final stage – the performance qualification (PQ). A performance assessment must always be carried out after sterilisation. In accordance with the guideline, we removed a container or a sterilisation tray packaged in a sterilization sheet (it should be noted that the largest and heaviest container or sterilisation tray is always removed) during three different sterilisation cycles. These were then unpacked step by step, with each step being photographed (8 – 10 photos/see Fig. 4) and compared with the required quality criteria. The results were entered into the «performance qualification» checklists; everything was brought together in a validation report and the next repeat performance assessment was defined.

Summary

The «heat sealing of pouches and reels» validation generally runs smoothly, since it has been going on for a few years now and the process is comparatively automated. Things are significantly more difficult, however, with the validation of «folding and wrapping of sheets» and «filling and closing of reusable sterilization containers». Obviously, these processes are entirely manual activities. In these instances, humans and their varying performance levels on the day have a considerable influence. For practitioners, the implementation of the «Validation of packaging processes» guideline is undoubtedly a challenge, but one which has to be overcome. The DGSV guideline provides the resources required to do this. ◀



Figs. 4.1 to 4.3: Typical images of photographic documentation (containers) taken during the functional and performance assessment

Wrapping it up! – into sterile barrier systems and packaging systems

A. Hartwig, Th.W. Fengler

Packaging and sterilization belong together, since sterility can only be maintained with adequate sterile barrier and packaging systems. The selection of suitable systems is a focal point in the optimization of packaging processes and surrounding processes, in order to minimize complaints and failures to an unavoidable residual risk. As a result, in addition to the preservation of sterility of the medical devices until the time of use, unnecessary costs for complaints and errors can be saved (transport, materials, labour expenses in case of re-packaging and re-sterilization; in the worst case: the costs related to operation failure).

Several different systems for the packaging of medical devices due for sterilization are in use today. Each system has its own specification. It is therefore very important to include the relevant local or organizational conditions/requirements and particular needs into one's considerations when selecting a sterile barrier system and packaging system. If we, in this text, lean toward a given system, this must be seen within the scope of specific processes in a particular department for processing (CSSD) in regard to supply and disposal. The packaging systems must be adapted to the devices, the treatment processes, applications, as well as to the means and scope of transport and storage. «Sterile barrier system (SBS)» means medical devices being packed in a single sheet or container. It is – according to EN ISO 11607-1 – the minimal means of packaging, that is an acceptable microbial barrier, providing aseptic medical devices for an application (e. g., operation). Protective (outer) packaging might protect the sterile barrier system and together they form a packaging system.

Which sterile barrier systems and packaging systems have we worked with, in order to minimize complaints and error messages from users?

Which were the complaints or errors most frequently reported by the users?

There are very few complaints and error messages in regard to single or double packaging of medical devices in (paper-foil) header bags or hospital packaging reels. The paper-foil combination is typically used for individual devices or small sets. Trays are rarely in use with this system. Here, make sure that the medical device does not damage the packaging; the medical device unit (package including medical devices) should not weigh more than three kg (see example in Fig. 1).

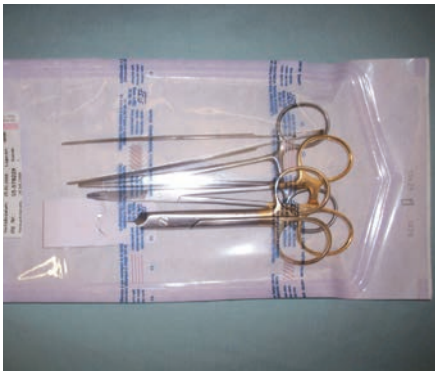


Fig. 1: Example of medical device unit in a paper-foil header bag (sterile barrier system), the medical devices being packed in a single layer

Most commonly, complaints and error messages were related to damaged sterilization sheets in the container or packages with two sterilization sheets. In cases of 2-layer packages with two sheets, the inner and outer sterilization sheets were both damaged (Figs. 2, 3).

The individual components of these packaging systems (Table 1) must be (or become) compatible. In our case, we replaced the component «instrument tray», because they were not suitable for the packaging with sterilization sheets, due to their construction and generation.

Imagine the tray from Fig. 3 wrapped in the sterilization sheet from Fig. 2: it should be noted that the sharp edges of the perforated frame will damage the sterilization sheet. In later generations of this tray the top edge is rounded off.

Similarly, the tray from Fig. 5, with its sharp struts, would damage the sterilization sheet in a way shown in Fig. 3.

We now only use trays without sharp edges for both the container system and the packaging system with two sheets. For the latter system we acquired another, compatible component for each medical device unit: they are now being placed in baskets, which protect the outer sterilization sheets (basket/tray system).

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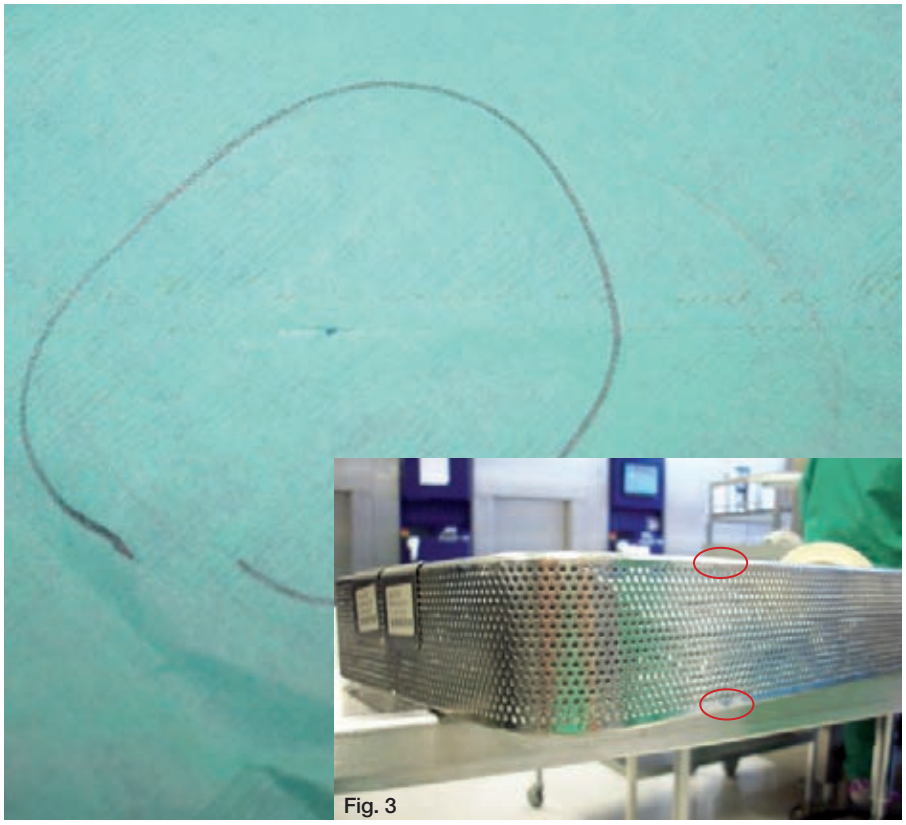

Fig. 2: Example of perforation by sharp edges of an instrument tray (as shown in inserted Fig. 3)

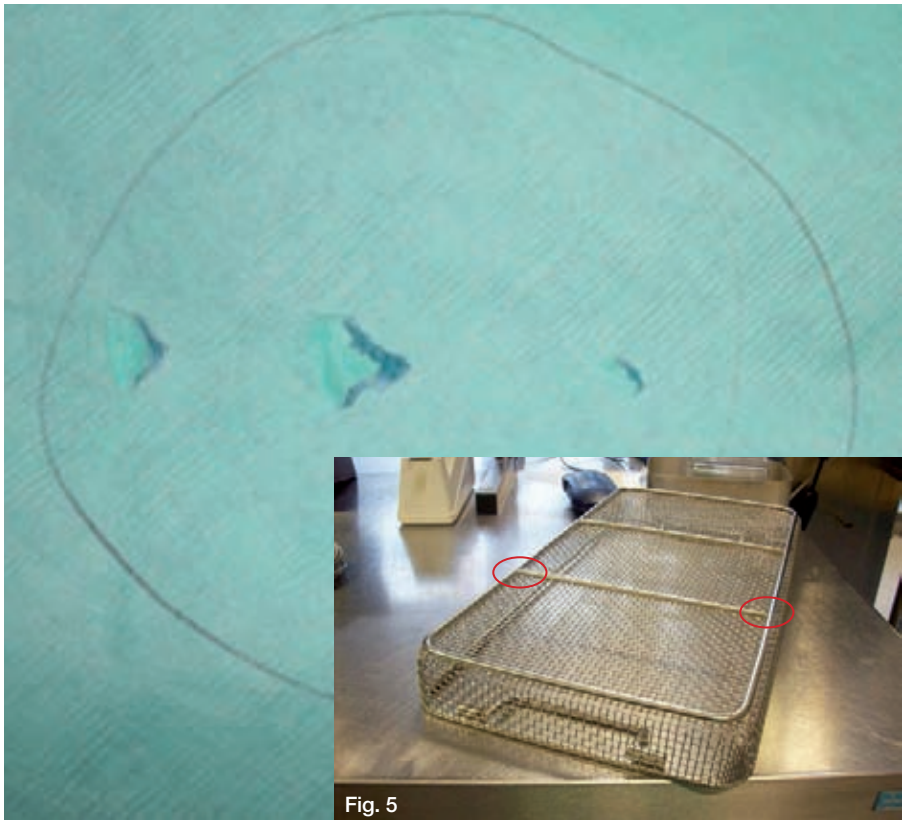

Fig. 4: Damage caused by dragging of sharp-edged struts (as shown in inserted Fig. 5)

For the packaging system with containers, one needs to ensure that the trays fit well into the container. If there is not enough space between the container wall and the sterilization sheet with the instrument tray, the sterilization sheet could become damaged when put into the container or during removal. There must be a minimum distance of 1 cm between the container lid and the sterilization sheet, so that the filter system can perform its function properly. A medical device unit packaged in a container system or in a basket/tray system should weigh – according to DIN 58953-9 – no more than 10 kg.

The trays, which we have taken out of the packaging processes were available for other functions, e. g. automatic cleaning/disinfection.

Our experiences and insights at a glance

The medical devices are still being packed in different packaging systems at our site: paper-foil-combinations, basket/tray system and container system. In order to reduce the number and frequency of complaints and error messages, packaging systems with containers and those with two sterilization sheets were optimized.

For containers, new trays that are suitable in regard to size and shape, and without any sharp edges, were introduced. The process of loading the containers has been revised in collaboration with the users, so that the minimum distance between container lid and sterilization sheet will be maintained. The packing lists have been updated accordingly. The container system is used for specific medical devices.

For the packaging system with two sheets, suitable instrument trays without sharp edges were procured, as well as fitting (size, shape) baskets, which complete the system and provide external protection.

Here is a list of noteworthy points about containers:

- Sufficient storage and transport capacities
- High costs for acquisition and processing utilization

Table 1: Contents of sterile barrier systems and packaging systems

	Sterile barrier system	Packaging system	With tray	Without tray
A	(paper-foil) header bags/ hospital packaging reels Single layer	Two layers: 1 inner bag, 1 outer bag		×
B	Container Single layer	Two layers: 1 inner sterilization sheet, 1 outer container	×	
C	Sterilization sheet Single layer	Two layers: 1 inner sheet, 1 outer sheet	×	

– Cost of maintenance, service and repair, as well as failure
– Effects of aluminum abrasion in the cleaning system (machine, cleaning and disinfection agents)
– Knowledge about and reduction of container (self-) weights
– Steam penetration and drying «only» through the filter surfaces

Unfortunately containers can only be stacked if they are from the same manufacturer and of the same design. There is a need for standardization here.
If more moisture than permitted remains in the container after sterilization (according to EN 285, for metal: 0.2 % of net weight), then this is is neither visible, nor tangible during release to the user or to storage, because the container is closed all around. But only dry packages are actually storable.

Table 2: Cost comparison for containers und basket/tray system in an example of one hospital

	Basket/tray system	Container system
Purchase costs	lower	higher
Follow-up costs	lower	higher
Repairs	low to none	higher
Maintenance	none	regularly
Cleaning/disinfection	No disassembly	Disassembly partly necessary
Weight	1.35 kg	≈ 2.5kg (depending on size)
Packaging system assembly for 1 average medical device unit	1 instrument tray 2 sterilization sheets 1 label with indicator 2 strips of sterile adhesive tape 1 basket	1 instrument tray 1 sterilization sheet 2 filters (depending on cont. brand) 1 strip of sterile adhesive tape 1 label 2 seals container labels
Sterilization	Steam penetration evenly from all sides.	Steam penetration through lid filter only
Release after sterilization	Visual assessment possible: undamaged? dry?	Assessment only partly possible

Advantages of the basket/tray system over container packaging:
– Acquisition and processing costs are lower
– No additional costs for maintenance, service, repair
– No aluminum abrasion, since baskets are made of stainless steel
– Very low weight of the baskets
– Steam penetration and drying from all sides
– Similar storage and transport capacities as containers

If more moisture than permitted remains after sterilization, this can be seen and felt during release, because the packaging sheets are visible all around through the baskets (Fig. 6).
Tray contents should be inspected periodically in any case, to see if all the instruments are really getting used all the time. For sterilization sheets, a suitable basket/tray system will have to be procured anyway.
A carefully matched basket/tray system is superior to the (previous) container system, but should only be introduced after a thorough review of the tray and instrument inventory, and tray reorganisation

where neccessary. The individual baskets, trays and associated packaging materials must be coordinated. A «colorful» mix will damage the packages, endangering the sterilization result and putting more strain on the daily work in the CSSD. Unfortunately, the currently prevailing financing practice of operators often favors the purchase of container systems, since they are considered to be investments (e. g. in case of construction of new hospital new buildings). ◀

Fig. 6: Residual moisture and possible damage can be assessed from all sides.

Fig. 7: Exemplary storage solution by Kögel for secure and safe transport of rigid scopes

Ink Test for checking the integrity of sealing seams

C. Wolf

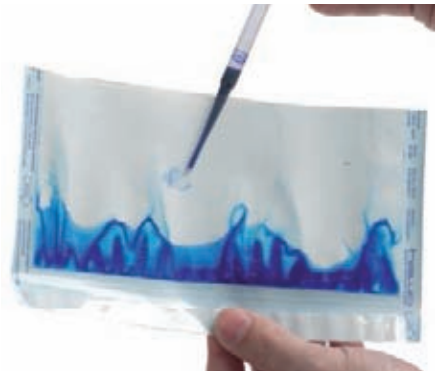

Fig. 1: Add the test dye penetrant to a sealed pouch or reel

According to the ISO 11607-2 standard, one of the most critical characteristics of a sterile barrier system is ensuring that the sterility of the medical device within is maintained. Validation of packaging processes is crucial for ensuring that the integrity of the sterile barrier system is achieved and maintained until the package is opened prior to use on a patient. For this reason, the international guideline for the validation of packaging processes was prepared. The guidelines can be downloaded in English, French and Spanish at www.hawo.com. For the first time, all practice relevant packaging systems have been covered in one set of guidelines, and it is clear that manual processes (wrapping in sheets and filling and closing of reusable containers) as well as mechanical packaging processes using a sealing device must be validated.

In the future, any packaging systems that cannot be validated will no longer be acceptable in practice (e. g. self-seal or taped pouches or bags). In addition to many checklists for validation, the guidelines also contain sample standard operating procedures (SOPs) for daily routine tests (e. g. of sealed seams). For daily routine monitoring of the integrity of self-produced sealed seams, the guidelines recommend the so-called dye penetration test (ink test). In comparison to the well-known Seal Check seal integrity indicator, this test can also be used effectively after sterilization. The ink test is especially well suited for checking sealed seams when gusseted pouches or reels are used. This test enables us to objectively determine at all times whether or not the sealed seam is intact, even in places where the foil is folded (see Fig. 2 and 3). Permeable sealed seams can lead to contamination during transport and storage of the medical device contained within. Furthermore, the dye penetration test as per ASTM F1929 is listed in ISO 11607-1 as a standardized test method for monitoring the integrity of sealed seams. The test should be carried out as follows:

1. Switch on sealing device and wait until operating temperature is reached; if possible, switch to test mode.
2. Seal an empty pouch or reel section (width at least 20 cm/length about 10 cm).
3. Cut open the pouch about 5 cm above the sealed seam (a reel section is already open at the top).
4. Use a pipette to drop about 2 ml of suitable test dye into the opened pouch or reel section just above the sealed seam (see Fig. 1).
5. After about 20 seconds, do a visual check to see if the sealed seam is intact.

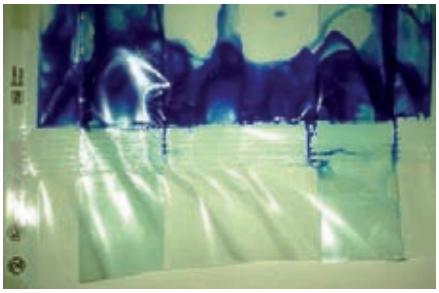

Fig. 2: Channels or defects can be localized using the dye penetrant (here: gusseted pouch, test with hawo InkTest)

Fig. 3: Perfect seal seam (here: gusseted pouch sealed using hawo sealing device, test with hawo InkTest)

6. The penetration of the test dye (see Fig. 2 and 3) reveals any flaws in the sealed seam such as channels, folds or missing spots.

Complete test kits containing test dye, pipettes and reference card for evaluating the test results are commercially available (e. g. hawo InkTest). ■

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Ethylene oxide low-temperature sterilization for industry and hospital

R. Salzbrunn

The most commonly used process for heat sensitive medical devices

Manufacturers and service providers worldwide are using ethylene oxide (EO) for sterilization of over 80 % of heat-sensitive, single-use or reusable medical devices in the industrial setting. Radiosterilization is used for the remainder.

The reactivity of EO ensures that, in turn, reactive groups within a cell will form compounds that then block the reproductive capacity of microorganisms.

According to EN 556-1 a medical device is designated as sterile if it is free of viable microorganisms after sterilization.

Other low-temperature sterilization processes are not being currently used in the industrial setting to place heat-sensitive medical devices on the market for the first time. This is because of the complex issue of product liability. This has no implications for reprocessing of used medical devices in medical institutions. The legislator does not permit any differences in the quality of new or reprocessed medical devices intended for use on a patient!

Fig. 1: Loading an EO sterilizer (closed system)

The limit values to be observed when using ethylene oxide are set out in the current national and international standards as well as in the conditions imposed by government agencies, the Employers' Liability Insurance Associations and the new Hazardous Substances Regulation (GefstoffV of December 2010 published with Federal Law Gazette [BGBL 1, p. 1643]). These include the Medical Devices Directive (MDD), the Hazardous Substances Regulation (GefstoffV), stipulating substitution, the associated Technical Regulation on Hazardous Substances (TRGS 513) as well as the Federal Emissions Act (BimschG) with the Technical Guidance to Air (TA Luft), the Occupational Safety Regulation (ArbStättV) and other conditions.

Modern EO sterilizers are fully automated machines that operate in accordance with the minimization principle from the Chemicals Act (ChemG) with a non-explosive gas mixture that is used in a hermetically sealed system for sterilization.

Thanks to monitoring of the room air at the installation site and highly efficient facilities for disposing of the active substance, no hazards are posed to persons or the environment.

Heat-sensitive bulk products as well as highly valuable electronic and optical equipment, implants and drug-coated catheters and stents are sealed in their terminal packaging for sterilization.

Ethylene oxide sterilization is deemed to be very useful, gentle and effective also for preservation and restoration of antique books, artworks made of wood, leather or wax. This form of preventive sterilization is used primarily to protect staff against any hazards arising when handling such items, e. g. because of fungi and spores.

A sterilization department must obtain authorization from the competent authority in order to be able to operate EO sterilizer. Conditions set out in the valid regulations, such as the Federal Emissions Act and the Technical Guidance to Air, are imposed in accordance with the capacity and size of the sterilizer. Regardless of the size of the sterilizer, having a sufficient number of expert personnel is one condition that applies. This expertise is imparted in approved training centres, where training is completed with an examination supervised by a representative of the competent authority.

Once the candidate has demonstrated that he/she has acquired the requisite expertise and is also in possession of a certificate issued by the occupational safety physician, a certificate of qualification is issued and the staff member is now authorized to operate an EO sterilizer in accordance with the manufacturer's instructions.

Modern, fully automated EO sterilizers can be started once loaded. An automatic logic controller executes the process steps pre-conditioning, exposure time, post-conditioning until the end of the interlocked desorption step. After comparing the associated documentation with the validated process, parametric release of the batch can be performed as per DIN EN ISO 11135-1 provided that no inadmissible deviations have been noted. The batch needs only a few hours for this, and this system does not involve degassing times that can last for days. This is important

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for productivity of a reprocessing department and for assuring rapid turnaround of those medical devices of which so few are kept in stock.
Validation of the sterilization process must be conducted before initiation of routine operations. This can be done by accredited laboratories. Testing can begin once the validation plan and a to-do list have been compiled.

Validation

Testing within the scope of installation qualification (IQ)
Once a sterilizer has been installed, a check must be carried out to ensure that all installation specifications and conditions have been observed.
Before commencing validation, all power units, pumps, heating elements, thermostats, control devices, sensors, water, compressed air, etc. must be tested to ensure they function properly.

Testing within the scope of operational qualification (OQ)
This involves testing the sequence of programme steps of which the sterilization process is composed.

Testing within the scope of performance qualification (PQ)
Testing is rounded off by demonstrating that the sterilizer is able to deactivate a particular number of microorganisms. To that effect, suitable test organisms are placed in a medical device, which is then sterilized and evaluated after sterilization. Furthermore, process challenge devices (PCDs) and loggers are used to verify the half-cycle time performance of equipment. In this way the process steps pre-conditioning, exposure time and post-conditioning are checked, while recording and saving details of all parameters that are vital for sterilization, such as pressure, time, temperature, relative humidity and active substance concentration.

Validation report
Once all tests have been carried out on the sterilizer, the microbiology results and residual gases evaluated, the validation report is issued by the accredited laboratory. This describes how reliably the sterilization process is operating and how successfully the process was executed. Recommendations are also given on operation, functional tests, documentation, safety measures and on compliance with the limit values.

Today, after taking medical devices out of the sterilizer they are ready for immediate use on a patient. This means that parametric release as per EN ISO 11135-1 has now become a routine task. There is no further need for time-consuming microbiology tests in routine operation.
In the case of industrial sterilization processes that are not fully automated, medical devices are often transferred to desorption rooms by personnel using personal protective equipment, where measures must be taken for several days to reduce the active substance (EO) from the devices and their packaging.
The sterilization process is then complete only once the medical device is ready to use and the limit values for residual gases for use as per EN ISO 10993-7 have been observed.
The sterilization technology developed and manufactured in Germany for fully automated ethylene oxide sterilizers is used worldwide and is synonymous with the state of the art. ■

The history of the «ebro thermologger» – from nobody to market leader

W. Klün

The first data logger I had heard about was from the USA, from the firm Gould Instruments. This was a 16-channel temperature recording system with a PDP-8 computer, a telex machine as well as a temperature amplifier. The data were recorded by means of a Philips-ECMA-34 digital cassette, and it took two hours back then just to load the operating software via punched tape. I could just about fit the entire equipment into the boot of my Ford Taunus Turnier car, with which I drove in 1974 throughout Europe to demonstrate this data logger to industry and to automobile manufacturers. By the way, at that time the price for this data logger was the unbelievable sum of 200,000 DM.

The first easy to handle data logger originated around 30 years ago from the United Kingdom and was called «Squirrel». The device was able to record temperatures and operated with an 8-bit computer. Its principle buyers were the major pharmaceutical manufacturers who had to monitor the warehouse and transport temperatures of drugs. Back then, data acquisition based on electronic data storage was a revolutionary concept because up till then the only such equipment known was dot printers and multi-channel recorders that were able to record the temperature values.

During the 80s ebro Electronic manufactured mainly plug-in power supply units and hand measuring devices for temperature, pH as well as for the relative humidity. In 1989 ebro, in cooperation with Willem Geu, its business partner of many years, developed the first battery-operated ebro temperature loggers known as «Temptimem«. That development was driven mainly by the rising demand from foodstuffs producers for battery-operated data loggers for monitoring temperature during transport and storage of frozen foodstuffs. A major client at that time was McDonald's, with its cold storage warehouses throughout Europe.

At almost the same time, in 1990, the foodstuffs industry was looking for a wireless temperature recording system for process monitoring of pasteurization and sterilization. Measuring the process temperature with wired thermocouples represented the state of the art back then. Placing the thermocouples in the foodstuffs to be pasteurized was an onerous, time-consuming and expensive task and, as such, its suitability for routine process monitoring was limited. In a word, that signalled the dawn of the first ebro thermologger called EBI 85. That logger was developed within the space of one year together with the engineering firm Franz Knopf in Offenburg, a member of the Stuttgart Transfer Centre. The EBI 85 was able to record temperatures in the range – 40 °C to + 85 °C and operated on the basis of the specially designed «Andropan» computer, because back then, while the personal computer (PC) with its DOS operating system was already known, it was not deemed to assure reliable operation and therefore could not be used as an evaluation system. In December 1992 the logger was finally certified by the Federal Institute of Metrology (Physikalisch-Technische Bundesanstalt – PTB) Berlin.

The temperature range of the EBI 85 data logger was eminently suited to monitoring pasteurization processes up to + 85 °C. However, the data logger was not yet up to monitoring sterilization processes. Hence, a new, more powerful data logger with a higher measuring and operating range had to be developed. Thanks to close cooperation with Texas Instruments, a manufacturer of electronic components, it was possible to develop in a short time a novel system of electronics that was suitable for use in sterilization processes. Texas Instruments developed for ebro the processors TSS 400 for a new data logger with a measuring range of up to + 125 °C.

Armed with the newly developed data logger EBI 125 it was now possible to measure and monitor all sterilization processes in the foodstuffs industry. The data logger was used for validation and routine monitoring of various pasteurization and sterilization processes for preserved meat, vegetables and fruit. Using data loggers it was now possible for the first time ever to conduct validation as well as daily routine checks of foodstuff production processes without having to rely on a validation system using wired thermocouples.

News of the successful EBI-125 data logger soon spread beyond the foodstuffs industry. Thanks to the universal measuring and operating range of -40 °C to +125 °C it was possible to use the data logger successfully in the pharmaceutical industry too. For example, it was possible to record sterilization temperatures as well as process temperatures for refrigerated transport and storage. This new data logger with its broad measuring range was ideal for myriad applications in the foodstuffs

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and pharmaceutical industry, and as such was well before its time.

Another milestone in the history of ebro-data logger was ebro-Software Winlog 2000, developed in 1998 and the first software in Europe that fully met the Food and Drug Administration Pharma Standard, FDA CFR 21 Part 11. The Technical Inspectorate TÜV Süd certified and validated in 1998 for the first time a logger system pursuant to that standard.

In 1999 I learned that it was not only the foodstuffs producers and pharmaceutical manufacturers who used autoclaves, but that these were also used in the Central Sterile Supply Departments (CSSDs) in hospitals. That year I therefore requested our sales manager Iven Kruse, to ask around at the Medica exhibition in Düsseldorf – by far the biggest exhibition in the field of medicine worldwide – whether anyone was interested in using our thermologgers for routine checks of CSSD processes. After an exhausting day at the exhibition, he informed me that nobody needed our thermologgers. That was because at that time only chemical or biological indicators were being used for routine checks of steam sterilization processes or of washer-disinfectors (WDs). In 1999 the requirement for validation of steam sterilization processes was largely unknown in the majority of hospitals despite the existence of validation standard EN 554, and this was implemented only at a very slow pace and hesitantly. At that time, validation of WD processes was inconceivable. The corresponding legal requirements and technical awareness were not yet in place to question processes. The CSSD placed its sole trust in machines and their processes.

While that was initially a cause for concern to me, it was also a challenge. I did not want to simply accept that view, wanting instead to find out whether there was not some way of introducing our thermologgers to the CSSD. I therefore decided to exhibit our products at the Medica. In cooperation with the firm H+P Sterilisatoren from Munich and in agreement with the company Dr. Herz, in 2000 I exhibited for the first time thermologgers on a very small exhibition stall measuring only 2 m^2 in the H+P booth in exhibition hall 12. Exhibition hall 12 was the correct hall and was visited by many CSSD employees but no one wanted to become acquainted with our thermologgers. I literally had to «drag» CSSD staff members to my small stall and demonstrate the new technology to them. But even that failed to elicit interest. While I was aware that there were no major differences between the processes used in the pharmaceutical and foodstuffs industries and CSSD processes, the users behaved differently. Bereft of legislation, standards and directives, it was virtually impossible to enable thermologgers to gain a foothold in the CSSD.

At the same time, my old friend, Albert Bosch, who at that time was still working for the company Getinge, recognized that in the data logger we had something very special for applications in the CSSD. He conducted various routine control measurements on a steam sterilizer at Aachen University, where he managed for the first time to convince a member of the service team of a steam sterilizer manufacturer that processes could be perfectly recorded with data loggers. Both were being ob-

served in the background by the, at that time, head of a CSSD, who enquired about the nature of the measuring device. Albert Bosch explained to him in detail how the data logger recorded temperature and pressure values in a steam sterilizer at intervals of seconds and, as such, was able to record precisely the different phases of the sterilization process – ranging from the evacuation phase through the equilibration time and the holding phase to the cooling phase. He demonstrated how data were evaluated on his PC, thus convincing the CSSD manager, who went on to place the first large order for data loggers.

That marked our entry into the CSSD setting with our thermologgers. Iven Kruse was appointed product manager for the medical and CSSD market and that same year became a member of the DIN NAMed NA063 committee as well as a member of the German Society of Sterile Supply (DGSV). The following year he became a member of the European Forum for Hospital Sterile supply (EFHSS), which would later become the World Forum for Hospital Sterile Supply (WFHSS). The following year Iven Kruse became an editor of «aseptica».

This was followed by several instances of fruitful cooperation with various consultants and manufacturers of steam sterilizers and washer-disinfectors (WDs). At this juncture, the excellent, long-term collaboration with Dr Thomas Fengler and his colleague Herr Helmut Pahlke († 2010) as well as Herr Toni Zanette from Tubingen University must be highlighted. At an early stage, they announced that thermologgers made it easier to carry out validation and also routine checks.

Support also came from Dr Jatzwauk at Dresden University, who used our thermologgers for the first time in 1998 for routine checks of WD processes with the, at that time, completely unknown determination of the A_0 value. That was then followed by publication of an article in the journal *Central Service* entitled «Thermal disinfection action of washer-disinfectors» (*Central Service* 2001; 9: 14–16). Dr Yushi Uetera from Tokyo University today a member of the advisory board of Central Service was able to appreciate the benefits of the ebro thermologger in faraway Japan. Many other manufacturers also became involved, of whom I would particularly like to mention the firm Miele which, with Dr Winfried Michels, always advised and actively supported ebro.

In 2002 the legal foundation was laid in Germany for medical device reprocessing with the Medical Devices Directive (MDD), the Medical Devices Operator Ordinance (MPBetreibV) as well as the recommendation compiled by the Robert Koch Institute (RKI) «Hygiene requirements for medical device reprocessing». These stipulated the use of validated processes to ensure that reprocessed medical devices would not pose any health risk to patients, users or third parties. Thanks to the standard prEN ISO 15883-1/-2/-3, which had not yet been published, as well as the guideline compiled by the German Society of Hospital Hygiene (DGSV), German Society of Sterile Supply (DGKH) and Working Group Instrument Preparation (AKI) the parameters for validation of automated cleaning and disinfection processes for heat-sensitive medical devices were defined. The standards EN 285/554 and DIN 58946-6, later ISO 17665, helped to define routine checks and validation for operation of large sterilizers in the healthcare sector. Due to new directives and laws, as well as to inspections by the competent supervisory bodies, CSSD personnel had to face up to new challenges.

That proved to be a turning point for the ebro team around Iven Kruse. He established contact with CSSD staff members as well as with all manufacturers of steam sterilizers and of washer-disinfectors. Temperature measurements were performed in WDs within the framework of routine monitoring as well as of validation to demonstrate that the temperature in the chamber and in the load was reached during the process. If the WDs were not equipped with any integrated temperature sensors, the temperatures in the load had to be recorded by means of additional data loggers. Evaluation of the data loggers showed the temperature curves in the entire process and provided for calculation of the A_0 value. The A_0 value had been successfully introduced by ISO 15883 and replaced the biological indicators as used for validation and routine checks of WD processes.

For medical devices that had been contaminated with heat-resistant viruses, e. g. hepatitis B viruses, an A_0 value of at least 3000 has been set. The use of biological indicators instead of the thermologgers was no longer justifiable (EN 15883-1, Section 6.8.1.). In steam sterilizers the pressure and temperature values of each batch were recorded by means of an integrated recording system. However, at that time many sterilizers did not yet have a recording system, hence the ebro thermologger was used here to monitor pressure and temperature. The software program Winlog.med was specially developed for users in the CSSD, to facilitate conduct of routine checks. Within the space of five years ebro Electronic GmbH went on to become the market leader for thermologgers in the CSSD throughout Europe. Many CSSD staff members spoke about «the ebro», a term that was now synonymous with a thermologger.

Despite our success, we had not yet managed to convince all validation personnel and major manufacturers about the benefits of our data loggers. What was missing was more flexible temperature sensors and, naturally, facilities for real-time measurements, as found in a validation system with thermocouples. But if one considers the enormous investment needed for calibration of thermocouple sensors as well as having to place them into a WD or steam sterilizer, something that can be done only via external connection ports, one quickly realises that a new radio logger would mean major cost savings.

The new innovative EBI 10 radio thermologger family from ebro Electronic made it possible with the EBI-10 radio technology to conduct routine checks and validation of WD and steam sterilization processes, using a wireless technique and in real time. The EBI 10 transmits by radio its measured data from the closed WD or steam sterilizer, while the responsible staff member can monitor the process live on a monitor and can immediately abort any malfunctioning process. That saves a lot of work and time. The EBI 10 (IP 68), which is absolutely impermeable to water and steam, has a temperature measuring range of – 80 °C to + 400 °C and a pressure measuring range of 1 mbar to 4000 mbar. The storage capacity is 100,000 measured values, enabling the processes to be recorded for up to ten hours at a measuring rate of 250 milliseconds. The temperature and pressure accuracy at h ± 0.1 °C

and ± 10 mbar, respectively, is very high and is documented in the accompanying ISO certificate.
The data loggers are operated with the special EBI-10 interface with an integrated antenna. It transmits radio signals at the worldwide approved frequency 2.4 GHz and complies with IEEE radio standard 802.15.4, which means that the logger can be used without any problem. At the same time, fast, flexible and steam-tight Pt-1000 temperature sensors were developed, which have the same response time (t_{90}) as thermocouples. Our EBI-10 system has been rounded off with the new validation software Winlog.validation, which complies with the requirements of ISO 15883 and ISO 17665.Our validation system was also successfully certified in 2008 by TÜV Süd.
In parallel, ebro developed for the CSSD an inexpensive electronic Bowie & Dick test (EBI 15) pursuant to ISO 11140-4. Armed with a modern electronic data recording facility, EBI 15 produces an unequivocal result («passed»/«failed»). The functional capability of EBI-15 logger was also verified by TÜV Süd as well as by the firm SMP as per EN ISO 11140-4.
Going from a Nobody to Market Leader for thermologgers in the CSSD was a long journey but it has continued to inspire us to the present day, and will continue to drive us towards finding solutions for greater reliability of processes in the CSSD. ◀

Validation – verification of countable and uncountable events of specific processes

M. Kempf, Th. W. Fengler

Validation: a Myth?

It would be a mistake to believe that only automatic processes can be validated and also that subsequently we would be cleaning «automatically». We wash with machine assistance. Validation is the verification of previously and separately defined specifications. In order to do this, we need definitions – preferably measurable parameters – and the right tools to carry out a review.

The work done in laboratories is a good example for the notion that there are but few processes, in which there isn't a good deal of «manual labour» and human interaction involved. The high quality standards required for laboratory analysis are met – despite a wealth of manual work steps «between the tubes». These steps are described accordingly by means of standard operating procedures (SOP), as prescribed in the Guideline for Manual Processing, which will be published soon.

Fig. 1: Measuring equipment of the validator: Data logger, conductivity meter, pH meter, balance

The term validation seems to be shrouded in myth. What are we talking about when we use the term validation? In the field of medical device reprocessing, we mean process validation, a documented procedure for the provision, recording and interpreting of the results that are needed to prove that a process consistently produces devices that meets the predetermined specifications (see EN ISO 17664 at 2:11; similarly in EN ISO 17665-1, 3.60).

Validation as Test Convention

In addition to substantive preconditions (i. e. specifications), a variety of test instruments is required; the results are documented in a highly structured protocol. The guidelines recommend a course of action for the validator, who needs to have sufficient knowledge and experience with the procedures and with validation. In relation to hygiene, however, the guidelines are merely an agreement, a convention.

Hence, the non-fulfillment of the so-called «acceptance criteria» is not automatically associated with infection and loss of function of the medical devices, to name but the most important targets of our quality management. They give the operator important information about the quality of his processes, so that he can take appropriate action; the shutdown of a machine certainly not being one, which is often used. Often the issue is water quality and consequently a need for tighter control until the problem is resolved («event-related»).

The lack of reliable correlation of whatever kind of test specimens (medical device simulators) are used as a «process challenging devices» (PCD), in connection with test soils or as indicators, make it hard to find a proper test model. All current specimen models and medical device simulators have their strengths and weaknesses – comparisons are particularly difficult.

Validation thus remains a review under special conditions, in contrast to the everyday verifications of the processor. Process efficiancy can only ever be reviewed up to a certain degree, as close as possible to the actual working conditions; but ultimately it represents less than what is meant by a «dress rehearsal».

Validation Responsibility of Manufacturers and Operators/Users

Who then is responsible for what, having just dealt with the how? The manufacturer is responsible for the marketing and commissioning of his products. He must perform a conformity assessment procedure (CE marking), and anything up from risk class II b and III has to be submitted to clinical trials. As part of their risk-analysis, manufacturers also check on the fulfillment of the conditions, under which validation is possible.

Risk assessment has to be performed according to the product's class, which requires a corresponding classification in the first place. The products must comply with harmonized standards or common technical specifications.

The manufacturer is responsible for ensuring that the operator/user is given information on validated reprocessing procedures for the product (preferably one for automatic and/or manual processes, or else a sufficient statement of reasons).

On purchasing a given medical device the operator takes over the responsibility for proper use. However, the manufacturer is required to continuously monitor the market («time related») so that he can intervene, should problems arise with the product – from misuse, over cleaning or functional problems to faults of reusability. An example of a medical device, the device

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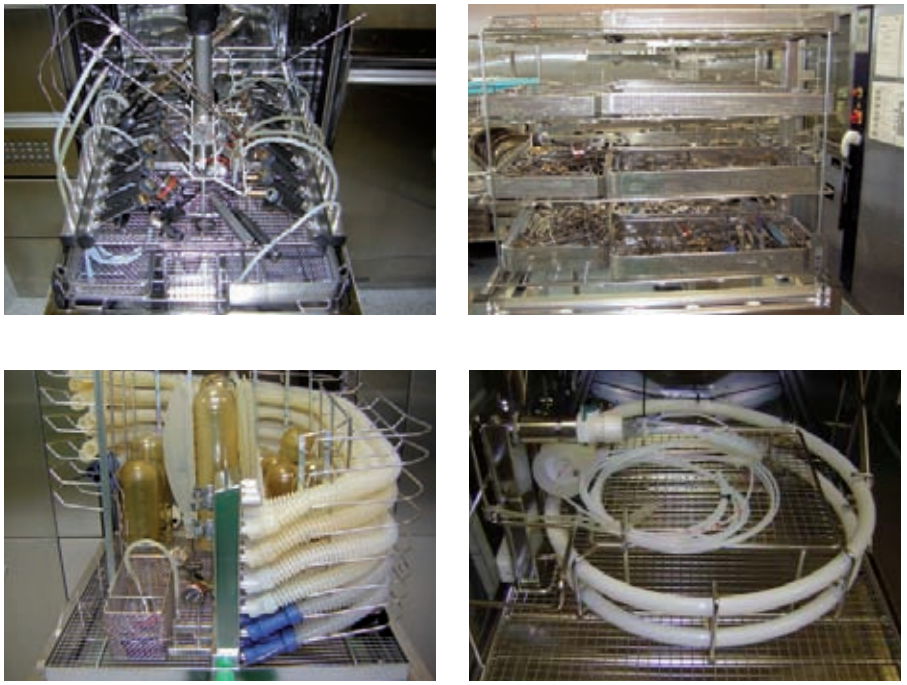

Fig. 2: Examples of WD processes
top left to right: MIS, instruments; bottom left to right: anesthesia, endoscopy

being a WD: «The manufacturer is responsible for conductance of the type test. It entails a risk analysis to delineate or evaluate the risks and furnish proof that the washer-disinfector complies with EN ISO 15883-1 and 4.» (Quoted from Appendix 1 of the «Guideline for the Validation of automatic cleaning and disinfection processes for flexible endoscopes»; *Central Service* 2011, 19, No. 3).

It is the operator's responsibility to have process validations and performance qualifications (PQ) performed. The operator is responsible for ensuring that routine tests be carried out periodically, as defined and documented in the validation and in further performance qualifications. He must also ensure that the staff responsible for processing have the necessary expertise. Things might get complicated due to the fact that the user at the patient is not the same as the processor, and in this context problems are often not adequately communicated.

The Practice of Validation/PQ

We may have all this in mind and be aware of it, when entering the clinic or doctor's office to find all sorts of differently-sized chambers for a high variety of batch configurations. Now is the time to arrange for reproducible test conditions, to make the appropriate tests and document the results.

Knowledge on the highly variable conditions (chamber size, loading, steam quality) suggests a precise and similar approach to each process validation.

The medical device simulators that are currently in use, and the quesition of which processes are actually being «challenged» by the PCD during process validation are a problem already mentioned. So we put into use what is described in the guidelines, simply and clearly. Deviations from the acceptance criteria are to be evaluated critically.

It is here, that the experienced validator differs from the one, who will, with his verdict of «Fail» or «Pass», claim a degree of process safety that can not be jusitified based on mere samples. The suitability of test systems remains a weighty quality issue in the production of sterile supply, and in process validation in particular. Take bioindicators: let us assume we believe the growth performance of a test microorganism (that may or may not survive a half cycle). What we do with the bioindicators, if there actually is growth after a few days? Should we confront the patient, who was operated with these instruments, now and let him know that he possibly has to deal with microorganisms, which would not be there at optimal processing conditions? What is the clinical relevance of such a test, then?

The verification of assumptions is the sterilizer manufacturer's task in his risk analysis before marketing the product. But during clinical performance qualification under user conditions we only review and document consistency with the predetermined processes and procedures. Here one must be able to rely on the general process safety. Again: the process-challenging use of indicators will bring about a false sense of security, since it may apply to the indicator, but not neccessarily to the medical device.

Quotations for Process Validation

A process validation begins with the preparation of a quotation. In the customer interview the customer specifies exactly which machines are due for process validation, and the number of processes to be validated. This is important so that required materials for the validation (e. g. Crile clamps, hygiene-kit for testing WD-E) can be ordered in sufficient numbers. Once the order has been placed by the customer, the validation starts on an agreed date. In the meantime the customer receives information about what is needed from his side, so that the validator does not arrive in vain.

In determining the date, it is important that the key people at the site are present on that day, i. e. the heads of the department in which the process validation is carried out and of the technical department or their designated representatives and other people who need to be involved professionally in order to ensure successful implementation.

Preliminary discussion

Process validation should always be preceded by a preliminary discussion, which is based on the communication prior to arrival. Here, technical and organizational issues are ironed out, so it is important that the said heads of the department are present. During the discussion, the questions of the respective standards and guidelines have to be dealt with.

The checklists that accompany the guidelines may be helpful for answering the individual questions. In order to keep the

preliminary discussion in a sensible time frame, it is an advantage if the customer has received the checklists prior to the discussion and has already filled them in, so that the required documents are already available at the meeting and do not have to be compiled there and then. If there are still open questions with the customers concerning the checklists of the guidelines and the standards, they can be answered now.

The the conduct of the validation is discussed the heads of the resp. departments. During validation of the various processes in the WD and sterilizers the batch configurations are set with the responsible employees.

Then the batch configuration for the steam sterilizer is established, based on the present tray lists. When compiling those, all departments need to be covered; it should also be checked if there are requests from the customer for a tray review. In compiling the batch configuration the existing batch carts must be taken into account, as well as those instruments, that are difficult to reprocess: MIS-, micro- and loan instruments, eye instruments (provided they are processed).

Most importantly, process validation will disrupt the clinical daily routine of sterile supply. This has to be made clear, not only to the contacts themselves, but also to the other affected departments (they need corresponding daily schedules). Medical devices needed for process validation are to be lent for that period from the respective departments. However, all this should already be taken care of by the customer, if he was properly instructed upon scheduling. As the operating theatre is usually most affected by process validations, it has to be necessarily involved in the planning.

After completion of the preliminary discussion, a suitable space in the department has to be made available to the validator to set up his equipment, including a workplace for the preparation of any additional material that is needed (eg. testkit for WD-E).

Process Validation

Before the start of the process validation the machines, accessories, and the utilized process chemicals must be identified, based on the available documents and the programs of the machines to be validated need to be chosen and documented.

Fig. 3: Examples of sterilization processes
top left to right: empty charge, BD test standard test package; bottom left to right: part load, full load

After the neccessary preparations are completed, the required batch configuration is set together with qualified members of staff. On this occasion validator and staff may, if needs be, optimize the configuration. The batches are compiled and then documented in writing and photographically.

Now process validation can commence, in accordance with the requirements of standards and guidelines. The test of processes includes tests of the parameters time, temperature and pressure with electronic data loggers.

Also the batch's individual sets' and trays' weight before and after sterilization will be determined. Moreover, using Crile clamps, cleaning performance can be quantified on the basis of a defined initial contamination, or an additional cleaning test for WD-E can be made respectively.

Should failures or faulty processes occur in the course of process validation, they have to be documented and reported to the head of department. If those disturbances can be rectified during the validation, the processes are to be repeated. If the fault persists, process validation has to be aborted. Any defects in the process flow should be discussed with the management so that they can take corrective action. Minutes should be taken.

Before the start of the test of the processes to be validated, the data loggers are programmed with the corresponding software. Afterwards the data loggers can be read out, the data received be reviewed and compared with the predefined process data of the machine.

Result-related consulting

Upon completion of the validation its results need to be discussed with the responsible people. The obtained results are explained and, if requested, the validator gives recommendations for corrective action. If all process parameters are met, the process(es) can be deemed as «Pass», meaning they are in accordance with the acceptance criteria of the guideline and in compliance with the relevant standards. Discrepancies in the process evaluation should be documented and assessed with respect to measures to be taken (proposal). Upon completion of the validation, a validation folder with all the data collected is created and delivered to the customer as a validation protocol.

Validation is not a secret and the result is not a myth, but a piece in the mosaic that is quality management. ◀

Action not reaction – experiences with inspections of Central Sterile Supply Departments since 2003

Th. W. Fengler, A. Hartwig

The reprocessing of medical devices is considered to be a «fully manageable risk» in terms of judiciary, a task that can be, and is required to be, performed error-free.

The responsibility remains with the operator

In order to ensure reprocessing at the state of technology and science, as required in Article 4 MPBetreibV, it is the operator's duty to keep himself informed.

Operator responsibility encompasses all operations of medical institutions, including reprocessing. The delegation of responsibilities for (parts of) this procedure by the operator to external service providers (outsourcing) is possible and is practiced to an increasing degree – aiming at shifting the task and liability to a third party. But ultimately the operator will not be exempt from responsibility (and liability) for the outcome, inasmuch as it is part of his organizational responsibilities to select a service provider and regularly monitor and evaluate their service.

The overall responsibility remains with him on the basis of the supply contract, which is laid down in the general contract. The patient, in particular, relies on the correct implementation of the contractual supply, especially since he is in a special «customer» relationship, so that his rights are worthy of special protection by the law. The well-documented realization of such care will affect the anticipated expert appraisal in case of liability claims. In this context it is worthwhile to look at the case law on the subject of physicians' liability, where the judge is virtually helpless without an expert.

State of play

The revision of the Infection Protection Act was passed in July 2011. In it it is laid upon the states to adopt or devise regulations for infection prevention of resistant pathogens in healthcare facilities until 03/31/2012. This should bring about a harmonization of the existing regulations of the German states (http://www. gesetze-im-internet.de/bundesrecht/ifsg/gesamt.pdf).

The Infection Protection Act calls for rules on the availability of hygiene specialists, the obligation to prepare hygiene plans and the establishment of a «Commission antiinfective agents, resistance and therapy» at the Robert Koch institute (RKI).

A total of 16 German states are responsible for the control of medical facilities on the basis of

1. EU regulations (e. g. Council Directive 93/42/EEC)
2. German Medical Device law (e. g. MPG, MPBetreibV)
3. subsidiary regulations (e. g. RKI recommendation)

Responsibility lies with the specialized departments of the government districts. Their employees have to be trained accordingly, while having diverse (not necessarily medical or technical) professional backgrounds. Insufficient staffing of the control authorities is a constant and fundamental problem; «inspection» is but one of their many tasks. 2000 hospitals and tens of thousands of medical practices must be monitored – and thus actually supported in their work on the patient. Due to the federal structure the application of a uniform set of criteria by the authorities is rather unlikely, although regularly called for and, of course, desirable. Think of closures and damage claims.

Another problem lies in often inadequate staffing of control authorities, as a statement of the Government of Niedersachsen from March 2011 shows: [www.landtag.niedersachsen.de/Drucksachen/Drucksachen.../16-3477.pdf]: «*For reasons of legal certainty, the businesses and facilities that are subject to monitoring, are to be treated equally, so that their exposure to government action does not lead to distortions of competition. A similar chance for companies to be monitored, could not be realised in Niedersachsen so far. In Niedersachsen, some 40,000 companies and institutions are subject to supervision by the competent authorities in accordance with the Medical Devices Act (MPG), which has to be dealt with by currently about ten staff member working in the medical devices surveillance. Even if each inspector could do one inspection every day, each company could be monitored only once every twenty-five years. An even approximately similar type and frequency of monitoring of the individual companies is therefore not possible with the currently existing staffing.*»

Requirements for the operation of a processing department

Different, duly justified defect reports regarding the reprocessing of medical devices have come up in the recent past (Bogenhausen, Fulda, Kassel), leading to uncertainty of both patients and employees and causing economic damage. Therefore, what is needed are defined require-

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ments that have to be met by a processing department for medical devices (CSSD):
hygiene
– premises
– hardware
– structure and organization
– interfaces
– procedures and processes
– documentation
– staff
– resources
– safety
– environmental sustainability

The equipment in the broadest sense should be «suitable» and «sufficient», with the first referring to the legal and normative requirements of the rules and «sufficient» meaning «in accordance with the scope of services»: structurally adequate and suitable premises of sufficient size, technically appropriate devices of sufficient capacity, appropriate and sufficient staffing (in terms of professional competence and number).
The current, ever-evolving state of science and technology must be considered. This concerns the organization of the entire work. It is a «lived», not only a formal quality management, that is being required. The SOPs (Standard Operating Procedures) are highly significant in this context, since they define the minimum requirements, on which the respective procedures are based.
Particular attention is put on the usability of the medical devices, which may sometimes only be used in combination:
– Instrument(s)
– accessories
– container or package.

Think of special instruments for implants (e. g. knee), which are often lending instruments and only present in an operator's inventory if needed and on a day-today basis. One recent clinical example is the Da-Vinci system, where instruments, which are approved for nine uses cannot be judged conclusively regarding the required reprocessing processes.
Here, problems and additional costs arise with regard to the validation, but also in terms of risk assessment after marketing. Not everyone is aware that the manufacturer as well as the operator have an obligation to perform market-monitoring. Special (near-)incidents have to be reported to BfArM. They may, and must, affect the risk assessment.
Adherence to the joint recommendation of RKI and BfArM is often part of the reason of judgement in administrative court decicisions, as it is mentioned in the Medical Devices Directive.
«*Proper reprocessing according to sentence 1 shall be presumed if the joint recommendation of the Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute and the Federal Institute for Drugs and Medical Devices on the requirements of hygiene in the processing of medical devices has been observed.*» (MPBetreibV Article 4 [2]).

Course of an inspection

Usually, the hospital receives notification that it is due for an inspection, within the frame of the existing laws. In preparation of the inspection a preliminary discussion between representatives of the concerned departments is to be recommended. During the inspection, a representative of each hospital management, hygiene, safety, facility management and processing department should be present.
Afterwards, one will normally receive a catalogue of failings and a deadline to answer the questions or to remedy the deficiencies. Typical questions have been collected by us over the years and are displaid in Table 1. Finally it depends on the quality of the existing (!) documentation.
Then follows the working off of tasks: evidence and statements must be sent to the authority in due time – or a delay must be requested (and substantiated). Responses to the control authority should address all concerns in an objective mode.
– Completed and planned work, or change (action plan)
– quality management
– comprehensible operating procedures
– full job and process descriptions
– special operating procedures (preparation of disinfectant solution)
– definition of interfaces to other departments, «clients» or «suppliers»
– communication with interface-contacts

Here is a quote from a letter from a health authority held by us:
«*The attached protocol (of the inspection) shows defects the non-removal of which can be an objective negligence, which, since the defects are known, would also be culpable (in case of damage). This could give reason for a damage claim against the organisation (…)*»
Reference is made to a complex set of rules, which is interpreted by the respective trained employees, acting «on behalf of»: the staff of the supervising authority as well as the CSSD staff.
Typical questions, collected by us over the years, can be seen in Table 1.
When the dust stirred up by the inspection has settled, if we look again at exactly what is being criticized, we might find that much of it is true, too!
The answer to the supervisory authority should be formulated objectively and address all concerns. Now is the time to work through the queue of tasks: documents and statements have to be delivered to the authority on time – or a (justified) postponement has to be asked for.
The following should be noted:
– Precise answers to the questions
– Development of a catalogue of measures
– Evidence of the statements as far as required
– Proof of the «lived» quality management

Selfimposed deadlines for the implementation of promised changes will usually be accepted and waited on by the authorities. Nevertheless, regular communication should be upheld with the designated contact person within the authority. Then it is likely to come to no further measures.
Admittedly, official action does sometimes lack
1. clarity regarding the responsibilities and what may – reasonably – be claimed. There are differences from district to district, from province to province, as is often criticized (and, incidentally, also by the authorities themselves),
2. definiteness of what is called for in a catalogue of failings regarding the procedure and the possibility for appeals (e. g. with suspensive effect)
3. a tangible entity which is responsible for moderation or even for compensation (like an Ombudsman) in regard to cancelled operations, patient uncertainty and possible «provider change» and additional costs incurred for construction and staffing measures. It does not make sense to take such matters to the administrative courts.

Table 1: Typical questions – comprised from inspections since 2003
T.W. Fengler, A. Hartwig, M. Kempf, H. Pahlke

		Yes	No	Partly	Failure
1.1	Responsibilities well-ordered and documented (e. g. competences, practical implementation)?	❑	❑	❑	
1.2	Qualification of staff sufficient («Fachkunde» = German formal expertise)?	❑	❑	❑	
1.3	Is the staff adequately trained with respect to the processes carried out?	❑	❑	❑	
1.4	Risk assessment and classification (non-critical ❑ / semi-critical A ❑ B ❑ / critical A ❑ B ❑ C ❑) i. O. ?	❑	❑	❑	
1.5	If «critical C»: certification available? If «YES», issued by:	❑	❑	❑	
1.6	Standard operating procedures (SOP) for all steps of reprocessing at hand?	❑	❑	❑	
1.7	Manufacturer's instructions complied with? Deviations substantiated?	❑	❑	❑	
1.8	Validations for all steps of machine-operated procedures obtained?	❑	❑	❑	
1.9	Documentation of clearance decisions available?	❑	❑	❑	
1.10	Quality control for all applied processes carried out?	❑	❑	❑	
1.11	Premises suitable for reprocessing and storage of medical devices/sterile supply?	❑	❑	❑	
2.1	Are there medical devices with a limited number of treatment cycles?	❑	❑	❑	
2.2	If «YES»: are these marked accordingly?	❑	❑	❑	
2.3	Manufacturer's instructions at hand?	❑	❑	❑	
2.4	Preparation organised (standard)?	❑	❑	❑	
2.5	Ultrasonic bath available?	❑	❑	❑	
2.6	Critical process steps identified and characterized in writing?	❑	❑	❑	
2.7	Is the drying of blood or tissue on devices prevented?	❑	❑	❑	
2.8	Regulations on vCJD/CJD at hand?	❑	❑	❑	
3.1	Operational instructions for precleaning, cleaning and disinfection at hand?	❑	❑	❑	
3.2.	Precleaning: manual: ❑ automated: ❑ Cleaning/disinfection: automated thermal: ❑ automated chemical: ❑ manual chemical: ❑ external: ❑				
3.3	Inner surfaces adequately taken into account (rinsing, brushing)?	❑	❑	❑	
3.4	Appropriate containers for transport available?	❑	❑	❑	
3.5	Exposure time/hold time observed according to the manufacturer's instructions?	❑	❑	❑	
3.6	Are detergent and disinfectant baths changed at the occurrence of visible pollution, or at least every working day?	❑	❑	❑	
3.7	Are disinfection procedures evidently bactericidal, fungicidal and virucidal?	❑	❑	❑	
3.8	Sufficient drying of the medical devices?	❑	❑	❑	
3.9	Visual test of medical devices for possible residual contamination?	❑	❑	❑	
3.10	Evidence of an effective process (e. g. TOSI washer test, thermologgers)?	❑	❑	❑	
3.11	Recontamination of the disinfected medical devices ruled out?	❑	❑	❑	

4.1	Specific maintainance for instrument's joints? (vs. complete spraying of instrument)	❑	❑	❑	
4.2	Packing lists at hand?	❑	❑	❑	
4.3	Required technical and functional tests performed prior to sterilization (laid down in work instructions)?	❑	❑	❑	
4.4	Is the packaging appropriate (conservation of function and sterility)?	❑	❑	❑	
5.1	Utilisation of effective and validated procedures for sterilization in terms of suitability for specific medical devices?	❑	❑	❑	
5.2.	Sterilisation: Steam* ❑ Hot air ❑ EO ❑ FO ❑ H_2O_2(Plasma) ❑ Gamma ❑ other ❑ ** Parameters given: e. g. for steam 134 °C, 5 mins*				
5.3	Performance records for different loads available?	❑	❑	❑	
5.4	Temperature-/pressure-/timeprofile determined and analyzed for each batch?	❑	❑	❑	
5.5	Proof of efficacy for each batch (e. g. helix test for steam)?	❑	❑	❑	
6.1	Is purpose indicated (if not immediately apparent)?	❑	❑	❑	
6.2	Routine batch marking performed?	❑	❑	❑	
6.3	Is an expiration date given?	❑	❑	❑	
7.1	Are the persons authorized for release named in writing (qualification)?	❑	❑	❑	
7.2	Are there standard instructions for the release procedure?	❑	❑	❑	
7.3	Are the criteria and procedure for «no release» described?	❑	❑	❑	
7.4	Release documented with date?	❑	❑	❑	
8.1	Access of unauthorized persons prevented?	❑	❑	❑	
8.2	Dust-free and condensation-free storage?	❑	❑	❑	
9.1	Daily sterilizer control (e. g. vacuum test at the start of work)?	❑	❑	❑	
9.2	Batch control for sterilizer (e. g. steam penetration, «Bowie-Dick»)?	❑	❑	❑	
9.3	Effectiveness of WD (e. g. TOSI test, microscopic inspection)?	❑	❑	❑	
9.4	Are random spot checks customary?	❑	❑	❑	

F1 = critical:
Conditions, practices or procedures, which may potentially or actually pose a direct threat to the welfare and safety of patients and staff. Critical objections are totally unacceptable. Immediate removal of defects is required.
Note: The existence of several serious complaints may amount to a critical state. Other critical errors are e. g. the lack of risk assessment according to RKI or contaminated medical products after processing.

F2 = serious:
Conditions, practices or procedures, which may potentially or actually pose an indirect threat to the welfare and safety of patients and staff. Elimination of a defect is immediately required.
Note: Numerous other complaints may result in the sum of a serious error. Serious defects include lack of validation of mechanical processes, structural deficiencies, lack of important procedures.

F3 = other complaints:
Faulty conditions, practices or procedures without evident effects on the welfare and safety of patients and staff go out. The remedial measures must be carried out within a narrow timeframe.
Note: The existence of several other complaints may indicate poor quality and result in the sum of a serious complaint. Additional other complaints include formal defects, missing or incomplete documentation of training, lack of authorization documents.

Finally, a catalog of measures to correct deficiencies is often about technical issues, which need to be given technical solutions (see table 1).

The project group «RKI-BfArM-recommendation » of the Workgroup Medical Devices (AG MP) states: «The nationwide implementation of Article 4 MPBetreibV was complicated, amongst others, by different interpretations of the requirements of the RKI/BfArM recommendation, leading to confusion among operators and users.»

Action not reaction

From a judgment by the Federal High Court (BGH): «*The Hygiene and sterilisation risk for the patient has to be minimised to the inevitable residual risk as defined by the state of science and technology.*»

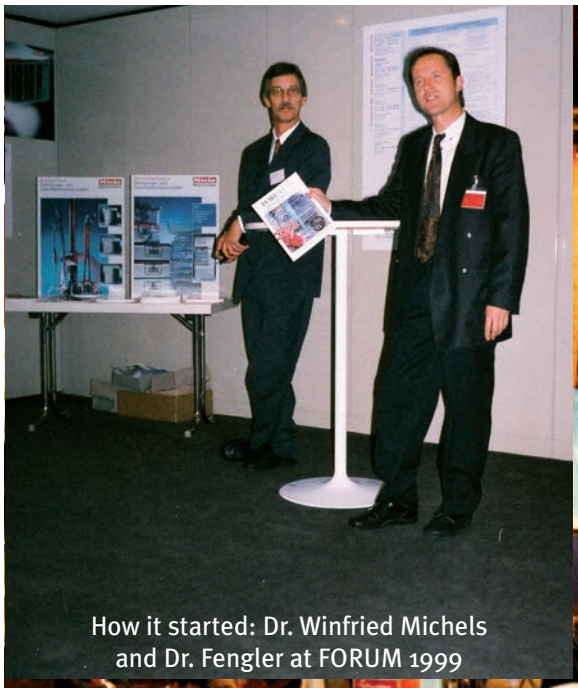
And: The work in a CSSD is – from a legal point of view – an activity «of a higher type». It follows the obligation for each employee to orient themselves on the state of science and technology and continue their training «to the limit of what is reasonable».

However, a catalogue of measures to remedy defects and failings is all about technical-professional issues (see Table 1). There ought to be a more reasonable form of conflict – among professionals – than disputes before the administrative court. For a constructive cooperation with the supervising authorities, as representatives of the executive branch, practical action is certainly a more rewarding strategy than mindless reactions. Structured working demands a structure, that is comprehensible to others! ◀

Fig. 1: Due for inspection? Don't lose your head! Asklepios, the «father of hygiene», at the Berlin Pergamon-Museum

Last not least: an institution from 1999 – 2010

Impressions from 11 years of FORUM congresses (dedicated to Helmut Pahlke)



How it started: Dr. Winfried Michels and Dr. Fengler at FORUM 1999

Hemut Pahlke 2009: his last FORUM lecture

Dr.Thomas W. Fengler at FORUM 2010

FORUM 2009 at KOSMOS: the panel discussion

Large Picture:Industry Exhibition and parts of the audience at medicallounge, 2008

HAWO. PERFECTLY VALIDATED SEALING PROCESSES

Being a part of the sterile goods packaging process, the sealing process also has to be validated in accordance with ISO 11607-2 – the new packaging guideline sets out what has to be done. hawo offers compatible heat sealers and testing systems.

HEAT SEALERS FOR HOSPITALS AND INDUSTRY

Rotary sealers are used to package instruments in hospitals and medical devices in the industrial sector. From the extremely compact and award-winning hd 680/hm 780 series to the particularly powerful pro-class hm 850/880 DC-V (see illustration) and hm 3010/20 DC-V models, virtually all hawo devices in this class feature intelligent monitoring, documentation technologies and intuitive device operation (IntelligentScan). All of the sealing devices marked with “V” (e.g. hm 850 DC-V) satisfy the requirements for process validation in accordance with ISO 11607-2 and have interfaces for connection to tracking systems.

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HEAT SEALERS FOR DOCTOR’S SURGERIES

For the secure sterile packaging of instuments in doctors’ and dentists’ practices, hawo offers the particular compact bar and rotary sealers. The top-of-the-range “ValiPak” hd 380 WSI-V model (see illustration) sets the standard in the clinical practice sector with a fully ISO 11607-2-validatable process and interface for connection to practice software.

TESTING SYSTEMS

hawo offers two testing systems for the routine monitoring of sealing seams.

> *Seal Check: The Seal Check med indicator strips for film pouches and reels made from paper / film and Seal Check HDPE (Tyvek®/ film) make faulty areas visible.*

> *hawo InkTest: The new dye penetration test for testing the seal integrity in accordance with ISO 11607-1 is distinguished by its simple handling and delivers objective results.*

Scan the QR code and download the guideline free of charge.

SBA Sterile Barrier Association

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