International FORUM

Medical Devices & Processes · Volume 22

Hands on ...

the medical device!

mhp Verlag GmbH

Chirurgie-Instrumenten Arbeitsgruppe (CLEANICAL®) Berlin

in cooperation with

Brandenburgisches Bildungswerk für Medizin und Soziales e. V.

under the auspices of

Deutsche Gesellschaft für Sterilgutversorgung e. V.

BBW

DGSV Deutsche Gesellschaft für Sterilgutversorgung e.V.

THE POUCHMAKER

hm 8000 AS/AS-V SealCut:

Pouchmaking machine for the automatic production of flat, gusseted and Tyvek® pouches.

NEW!

> ***Economical:*** *produces up to 5.000 pouches per hour from standard reels*
> ***Efficient:*** *ejects the finished pouches clearly sorted*
> ***Sustainable:*** *works on only 200 Watt (hawo GreenTek)*
> ***Validatable (AS-V):*** *fulfils the requirement of the ISO 11607-2 and the new ISO/TS 16775 guidance*

product video

TOP 100 Top-Innovator 2014

SBA Sterile Barrier Association

MADE IN GERMANY

Tyvek® is a reg. trademark of E.I. du Pont de Nemours

hawo

SealCut@hawo.com · www.pouchmaker.com

Content: Hands on ... the medical device!

2 Editorial

3 *T.W. Fengler*: 20 Years of FORUM in the Rearview Mirror

Cleaning

8 *B. Wallace*: The da Vinci® Surgical System: Validated Reprocessing Methods and Regulatory Compliance

12 *T.W. Fengler*: To be or to have: Can a complex medical device be clean? Or do we have reprocessing problems?

15 *K. Frösel*: Is the protein test really the test method of choice? Weak points of the protein test and alternative concepts

Packaging

18 *C. Wolf*: Create pouches easily yourself

Validation

20 *W. Michels*: Testing reference loads at validation and routine WD loading patterns

Transport

23 *A. Hartwig*: Time recording when using loaned instruments. From delivery to sterile presentation

26 *M. Kögel*: Decision criteria for selecting the «right» closed trolley system for an optimal reprocessing cycle

New Paths

29 *T.W. Fengler*: To explore new paths – an obituary. Wolfgang Klün (24.7.1945 – 4.6.2014), Managing Director of ebro Electronic 1994 – 2011

31 *R. Graeber*: The historic Kaiserin-Augusta-Hospital comes to new life

Best of Vol. 20 – 21

Masthead

Editor
Dr. med. Dipl.-Ing. Thomas W. Fengler

Publisher
mhp-Verlag GmbH, CEO Andreas Klein, Marktplatz 13, 65183 Wiesbaden, Germany. Tel.: +49 (0) 611/505 93-131, Fax: -11, E-mail: info@mhp-verlag.de

Editorial Staff
Dr. med. Gudrun Westermann, Tel.: +49 (0) 611/505 93-134, Fax: -11
E-mail: ZentrSteril@mhp-verlag.de

Script coordination
Ronald Graeber

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

Paper
Terraprint mat «chlorine free», 80 g/sqm

Publication in Preparation: In Vorbereitung:

Volume 23 of the series (in German)
FORUM Medical Devices & Processes

Cleaning is the physical way of disinfection
Reinigung ist die physikalische Form der Desinfektion

will be published in March 2015

Hands on … the medical device!

Tempora mutantur et nos mutamur in illis: «Times change, and we change with them». This is (according to Wikipedia) a latin adage in hexametric form that is proverbial since the 16th century. It seemed a fitting motto for our 20th anniversary edition of the International FORUM series. Times have certainly changed as far as the parameters of the reprocessing of medical devices are concerned. A review of the topics that we were concerned with 15 years ago clearly shows that we have come a long way (p. 3).

Apprehension requires comprehension, so that we can convey something to the addressed person. Clear thinking and clear phrasing in short sentences are important tools. For the daily work in the reprocessing of medical devices, there is a wide range of such tools: we use various sources of information, from oral work instructions to the European regulation of the Medical Device Directive (currently under revision). We do this more or less mechanically or automatically, e.g. with algorithms of search engines. An algorithm is a list of unambiguous instructions for to solve a problem or a class of problems. Algorithms consist of a finite number of well-defined steps. Similarly, we use tools in order to achieve the goal of reprocessing, i.e. producing sterile medical devices and making them available to the next patient. The patient may then experience these instruments in quite a direct and injuring way, even if not necessarily consciously: during surgery or endoscopy.

Times are changing, also with regard to the technical possibilities of reprocessing. Complex medical devices are reprocessed in compliance with elaborate process steps, supported manually and mechanically, but not automatically! The adjustment of the processes to the specific requirements of the respective medical device is becoming ever more important. The classic dichotomy of methods, «manually» versus «automatic», needs to be called into question, as Brian Wallace impressively illustrates by example of the da Vinci instruments (p. 8). Another aspect is the sometimes doubtable practice of validation, if the challenging load for testing is not taken from real clinical practice but is just a fake as is shown in the analysis of validation protocols by Winfried Michels (p. 20).

In this volume, we look at novelties (p. 18). And we question the status quo once again. Reprocessing is always at least partly a manual task, since a load carrier will be loaded manually, instruments having been manually disassembled previously and cables untangled by hand. Precleaning often is indispensable. There are of course hydromechanically supportive washer-disinfectors with a similar process flow, but on different load configurations. The quality of the result however depends not only on the performance of the process, but also on the competence and the skills of the employees who load the machine and operate it (p. 12).

The «hydro-mechanical» depletion of microorganisms by cleaning is a physical process. And «cleanability» is a decisive criterion for the reuseability of medical devices, for functional and hygienic reasons. According to the German Pharmacopoeia (DAB) disinfection means: «putting dead or living matter in a state in which it can not infect.» Chemical or physical processes may be used for disinfection. Thus, cleaning is actually a disinfectant action. Times are changing, our understanding is developing, and we need to go new ways (p. 29).

Clinical evidence of residues was first proven in our publication on protein traces. At that time the SDS-OPA-method was introduced to «cleanical» (clean and clinical) purposes [Fengler et al.: Are processed surgical instruments free of proteins? Results of the clinical multicenter residual contamination study of processing (MRSA)]. Statistics weren't as bad at that time for the clinical circumstances given (n > 200 total, not group-related). Medical devices, our objects for clinical consideration were showing evidence of remanents after elution!

Since 2001 there is clinical evidence (for a sample of six German hospitals) that after cleaning rinseable proteins remain on two out of to three typical medical devices (6 different design). Thus, the discussion on contamination still is based on the amount of residues that can be rinsed off from outer or inner instrument surfaces, endoscopes or tubes. What remains debatable is the way of tracing and the clinical value of warning values (p. 15).

Nowadays, for sure, we verify our processing behaviour, more than ever before (p. 23). And the standard operating procedure to be executed only partly consists of automated processing steps, but still it echoes «Hands on … the medical device!» Welcome aboard!

Dr. med. Dipl. Ing. Thomas W. Fengler
Cleanical Investigation & Application
www.cleanical.de

20 Years of FORUM in the Rearview Mirror

T.W. Fengler

We got the chance to organise an event of our own by the failure of another. In 1999, the Interhospital fair was discontinued. The companies Olympus and Miele Professional asked us to organise for the Medica a series of lectures on medical device reprocessing, which could also be broadcast to the stands. The FORUM was born.

Medical devices were then called «instruments» or they were «accessories», the CSSD was the «Central Sterile Supply Department», even though it was often neither central, nor was the «Supply» always «sterile». Supply had to be fast, above all, but a separate department was not always evident.

A first recommendation of the recently-founded Robert Koch Institute (RKI) on hygiene in reprocessing was under way. It was the time when «reprocessing» was readily equated with «sterilization» and the «BGA-program» of the former (until 1994) Federal Health Office (for epidemic diseases) was still often mistakenly used as the default program for medical device cleaning and subsequent thermal disinfection. But at over 90 °C proteinaceous residues on the instruments were not easily removed and the fine mechanical movements often became sluggish or impossible. Fortunately, the cleaning-«machines» could be programmed by punched cards, so that we made the appropriate corrections and could in some cases considerably enhance the cleaning result. Helmut Pahlke compiled the results of physical parameter readings, which were then published and demonstrated the importance of time-synchronous monitoring of the process steps. The concept of «validation» was born [1].

Meanwhile, the «International FORUM Medical Devices & Processes» has been around for 15 years and has produced 22 volumes of journals, with more than 100,000 copies distributed. The organisation and secretariat is the responsibility of the Surgical Instruments Working Group Berlin, founded some 20 years ago. In the following we – i.e. the FORUM as the working group's platform for discussion – will take a journey through the articles and topics of 15 years, always with a regard to what is «history» and what we must yet achieve.

1st FORUM: State of the Art. Concepts for the Future. (1999)

The first three-day FORUM-convention took place during the MEDICA in Dusseldorf, the lectures were broadcast to the stands of Olympus and Miele. The first thing to do was to describe the basic requirements for reusable medical devices (especially the surgical instruments) and the processes related to reprocessing them: the setup and function of the instruments and the possible effects of the reprocessing processes. How to optimize instruments by aid of new materials and composite options? The special conditions of endoscope reprocessing – specifically the new, and yet uncommon possibility of automated reprocessing with chemo-thermal disinfection – were discussed.

The increasing use of potent disinfectants outshone the basic cleaning process, which was perhaps considered to be too mundane to receive proper scientific attention. Strictly speaking, this overestimation of disinfection could be felt until the 90s of last century, if one thinks of the insertion of dental drills in disinfecting corrosion-inhibitors solutions or the insertion of endoscopes in a disinfectant solution.

But while cleaning includes transport kinetics, disinfection is mere inactivation of microorganisms which occurs physically, chemically or biologically: they remain (sticking) where they are, but are biologically inactive. Which means that the medical device is still unclean and its function remains impaired, unless the disinfectant solution has a rinsing effect. But then it must stay on the instrument for as long as the disinfection effect takes to be completed. Whether to bathe or rinse (out) the medical device, that remains the question!

So cleaning is a transport process, but what is clean, what is pure? There is a method for protein determination, which comes from cheese research and is therefore well understood: the modified OPA method as the key to quantitative protein-monitoring, a non-destructive method on the rinse solution [2, 3]. The catch here is: What percentage can I rinse of, how much remains on the surface? The determination of the recovery rate is a necessary calibration process for the evaluation of the results.

Back in 1999, we asked in the Editorial, if there could be an indicator system that allows the cleaning performance to be measured and verified – not based on some logarithmic reduction factor. Rather an unknown initial amount has to be reduced to an acceptable amount of residual contamination. But just which amount could be considered clinically safe, that remains a topical subject in the professional debate – even 15 years later!

Dr. med. Dipl. Ing. T.W. Fengler, CLEANICAL® GmbH, Im AUGUSTA-Hospital, Scharnhorststr. 3, 10115 Berlin, Germany
E-mail: info@cleanical.de

Hygiene specialists as well as manufacturers, surgeons as well as reprocessors as the clinical users, they all require an understanding of the physical, chemical and biological processes that have to run reproducibly in the course of a reprocessing cycle. Detergent mechanisms and disinfection processes must be considered alongside hydromechanical rinsing processes, in order to gain a practical understanding of, for example, the clinical application of full injector baskets for MIS, in which to flush cannulated cavities.

Thermoelectric parameter monitoring, and thus efficacy testing as part of validations, constitutes a clinic-relevant test method for washer-disinfectors and secures compliance of determinable process parameters. «Sterile supply» reprocessing is to be regarded as a quality cycle, typical errors are to be described in order to learn to avoid them. On the occasion of the FORUM 99 the «Interessengruppe Reinigung bei der (maschinellen) Aufbereitung (IRA)» («Interest Group Cleaning in (automated) Reprocessing») was presented, which was about to conduct the first clinical study on actual residual contamination: Multicenter Residual Contamination Study on Reprocessing (MRSA) [4].

Also, the only method to date that has «insight» was introduced, being able to identify «hot spots» on instruments' internal surfaces using a radioactively marked test soil: the radionuclide method, with which the validation of cleaning processes is possible (spatially resolving, quantitative method).

Sterilization should lead to sterility, which mostly takes place in hospitals and other medical facilities with a steam sterilization process as the final step of hygienic instrument reprocessing. On the unwrapped set at the operating table one might then see possible problems with instrument reprocessing: discoloration, corrosion, malfunctions or residual contamination. The instrument is the critical factor for the quality of cleaning – the Achilles heel is the water quality. Its importance for the cleaning performance and subsequent sterilization cannot be overestimated.

Finally, reprocessing was put into the context of hospital hygiene as a whole, being just one aspect amongst many in the concept of quality assurance that have to be constantly monitored.

2nd FORUM: Testing the Performance in Automatic Cleaning (2000)

The optimization of the cleaning of instruments for minimally invasive surgical technique was in the centre of the discussion at this second FORUM event at Medica in Dusseldorf.

But to be fair, first we had to take stock: hygiene, in the sense of practiced prevention, is different in the case of flexible endoscopes than it is for surgical instruments. What about dentistry, what about implants, that might have to be processed multiple times in order to be used in a patient? Can ophthalmic instruments and traumatological instruments be compared?

The focal point of the one-day event was the first Multicenter Residual Contamination Study on Reprocessing (MRSA) [3]: presentation of design and results. It was important to describe the used methods, which had to be «robust» with respect to the reproducibility of the results. In addition to clinically used hemoglobin sticks this was achieved through quantitative protein-monitoring with the modified OPA method on the eluate (rinse-off solution) and the modified biuret method. Obviously, such a sample of six of about 2000 German hospitals could only be a first step, further cleaning studies would have to follow.

The weak point of all rinse-off (non-destructive) testing methods is the incomplete amount of matter that can be detached from the medical device surface under the given conditions and, using a more or less long steeping step, be rinsed off into a few milliliter of eluate. The so-called «recovery rate» always has to be also measured by means of a zero sample. In addition to studies on the cleanability of different instrument surfaces, automated cleaning methods were presented, some cleaning «machines» as well as the ultrasound-assisted mobilization of contaminants in a basin (i.e. without rinsing and drainage of contaminated water). This process is difficult to verify – which means that validation is of little relevance.

The presentations and discussions displayed a serious effort, to find a suitable method for the evaluation of cleaning and disinfection performance of WD, among other things in terms of checking the cleaning of tube shafts of modular instruments for minimally invasive surgery. Suitable samples were also needed for quantitative measuring (e.g. a microporous borosilicate-sinter test specimen). After all, the measurement will have to be relevant for a given medical device in clinical use! There is always the risk that test specimens and test systems in medical device and process simulation have little to do with the clinical reality. Defining the requirements, from water quality to those specifics known only to the manufacturer, came to be one of the tasks of the «FORUM Instruments Reprocessing», as it was called at that time. Therefore, some issues are raised again and again.

3rd FORUM: Verification of Performance Parameters (2002)

Consequently, we (the Surgical Instruments Working Group Berlin) used the following year to think about the verification of (identified and measurable) parameters as a basis for meaningful validation of the «reprocessing of medical devices», as it was called now. The event was postponed for three months, due to the move to Berlin, and took place in the Heart Center of Virchow Clinic, Charité, in early 2002.

«Disinfection and sterilization need not be a matter of faith», was the title of one presentation, in view of thermal disinfection and the synchronous determination of the sterilization parameters of pressure and temperature. Process documentation was enriched with new process data, especially by the still unfamiliar data logger measurements; the end-point determinations with chemical and biological indicators were found to be inferior and were suddenly leap-frogged.

Another important topic was the newly released 11-page hygiene recommendation of the Robert Koch-Institute, which introduced the medical device categories «non-critical, semi-critical, critical A, B, C». Some reprocessing methods proved to be quite «critical» themselves in the daily routine and a residual contamination determination has to be submitted to corresponding criticism of methods: What can be determined, using which tools, under laboratory conditions and what in the clinical reprocessing routine?

Taking samples and analytical methods for cleaning control for sterilized medical devices were on the agenda, as well as the question of alternative methods for the verification of instrument cleaning.

And there was the novelty of an instrument tracking system, which was used in Australia.
«Pantha rei, everything is in flux» – whether the cleaning chemicals in conjunction with machines and instruments or the reorganization of various «grandfathering» sterile supply departments.

4th FORUM: What can Actually be Certified? (2003)

The formal process of quality assurance had now reached the domaine of the reprocessing of medical devices. But what lies behind this part of the conformity assessment process? Certification («certe» from lat. = certain, secure and «facere» = to make) refers to a process by which compliance with certain requirements is demonstrated. This can apply to facilities, but in any case device-independent process monitoring becomes necessary. Think of the still popular color indicators for monitoring the sterilization process. Logistics and traceability have to be organized in a sensible way for certification. The identifiability of events in the reprocessing cycle is of central importance in all processes and process steps, whether it be monthly reports, duty rosters, dosage questions in cleaning/disinfection processes, packing methods or ethylene oxide sterilization of thermolabile medical devices, most common in the industry. Professional certification consultation on the act of getting certified (and its effects on the routine operation) helps to save unnecessary costs and time.
The presentation of innovative methods for cleaning has always been a focus of the FORUM! That year e. g. optimizing «automatic» cleaning (this term was used at the time) in the WD by the VARIO method, which had been around for 10 years, characterized in particular by multiphase wash up at temperatures below protein precipitation (45–55 °C) instead of disinfecting cleaning at about 90 °C, as is still common – and wrong. Pulsed ultrasound for the cleaning of hollow instruments was also new. In the laboratory, one can examine what ultrasound does in instrument reprocessing under certain conditions. But what can we know under practical conditions, where it is often not even clear how many instruments have already passed through the basin and when the cleaning solution was changed?
«What is clean, what is pure» we asked, given the fact that a first worldwide descriptive standard for WD had been proposed as a basis for discussion (the series 15883 part 1). What was still difficult to bring in line were the measurable parameters and the formal requirements in the context of a routine operation, that has to move thousands of individual instruments (and parts) each day, with the aim to provide them again, sterile, for the next patient.

5th FORUM: What is Necessary, what is Possible? (2004)

This convention – again at the Charité, Virchow Clinic – focused on the practical aspects of medical device reprocessing. This is matched by a complex set of rules of European directives, national laws and regulations, as well as guidelines, standards and recommendations. Some guidelines are really recommendations (currently: VDI directive 5700), another recommendation may obtain a law-like character, because it is mentioned in a regulation (KRINKO). The user is expected to know his way around here.
But what is possible, what is necessary? For endoscopy, for example, more is unresolved than is resolved in the sphere of (mostly manual) reprocessing. And what to expect in the processing department as a whole? Whether it's the «metering and control technology» at work or the cleaning chemicals of automated cleaning and disinfection processes: the procedural differences are significant.
There were some interesting findings pertaining to blood pollution and its impact on sterility: How much blood affects the sterilization process? Especially low-temperature methods showed weaknesses here. So concrete statements in terms of the interplay of chemistry and mechanics in WD were welcome. One of the reasons for glass doors in WD is the possibility of observation of foaming (which is ineffective for cleaning), besides overturned bowls that fill up or blocked spray arms. Geometry (of the load and load carrier) is crucial for the proper interaction of chemicals and spray mechanics. So is the flushing of cavities with sufficient pressure. Based on these prerequisites, one could begin to think about a validated reprocessing method for ophthalmic instruments, including batch control with data loggers (according to the then current draft standard prEN ISO 15883-1).

6th FORUM: Instrument Management (2005)

The legal bases of reprocessing and the control activities of the authorities increasingly moved into the focus of the FORUM, since the RKI recommendation of 2001 had delivered a manageable framework. At that time the simple term «re-validation» was used (now «Performance Requalification or assessment»; see relevant guidelines). An important tool: data logger and software suitable for routine checks and validation. After the validation, consequences should be drawn instead of abusing the validation protocol as an alibi! This applies in particular to the selected test loads, an issue that remains topical until today. Back then the suitability of test screws «on semolina» had yet to be confirmed, today it is about Crile clamps or «Sunday» batches instead of clinically relevant mixed loading.
Appropriate and trained staff and appropriate management may well be able to reduce in the CSSD, e.g. damage and repair costs of rigid endoscopes during handling and processing in surgical practice. But no one will know, unless appropriate statistics are being kept, when using an instrument management system for traceability, where the relevant data can be retrieved. We also had to learn that not every system is set up accordingly, so as to prepare and provide the data in a user-friendly form.

7th FORUM: CSSD Regulations: Claims and Contradictions (2006)

As in the year before we held the FORUM in a convention hotel and we changed the name once more, into «Medical Devices & Processes», so as to do justice to the fact that a medical device needs to be seen in connection with its «intended use». The main topic were the rules and regulations themselves, with their claims and the existing contradictions. It was in this context, that we voiced our opinion on the RKI recommendation «Infection Prevention in Dentistry», which more or less defines its own hygiene. Here one should perhaps look at functional and hygienic aspects of implant dentistry and ask oneself the question where the difference to surgery and surgical endoscopy is supposed to be. Hygiene is indivisible! Special requirements of a given surgical operating field belong into the Annex of a hygiene recommendation, and nowhere else.

Increasingly – partly due to the expansion of the private hospital chains – efficiency gains and quality improvements in the supply of hospitals with medical devices and the associated issues of quality and profitability are becoming aspects of working in the reprocessing department. What are the building blocks for effective instrument management? This includes an algorithm, with which complexity and content of a medical device unit can be calculated with regard to reprocessing.
Which processes can be regulated and how and where are the boundaries of process optimization? Do we know the requirements for process chemicals according to prEN ISO 15883-1, and what's new for enhancing the cleaning efficiency even in inaccessible surface areas? Finally, we would like to know what verification, validation and routine monitoring in the CSSD with data loggers is good for.

8th FORUM: Prevention (2007)
We looked at a sample from Frankfurt of hygiene prevention in practice between the desired and actual state, that had its sight on outpatient surgeons. Of course, training and careful selection of the available staff are important, but they require control in terms of implementation. Having validations, on the other hand, is the operator's contribution to the prevention process. The correct choice of instruments for an operational use of medical devices from the viewpoint of prevention of infection was considered from different angles. Process control in the surgical area, on the transport routes and in the processing department have measurable impact on hospital infections – if the relevant parameters are documented, which is rarely the case. The new packaging standard DIN EN ISO 11607, part 1: «Requirements for materials, sterile barrier systems and packaging systems» was presented and the validation of the sealing process according to DIN EN ISO 11607, part 2, was explained. Interestingly, the classification of medical devices with regard to the reprocessing conditions in 7 groups for compliance with standards was welcoming the classification («the 'critical' ABC of the RKI for Medical Devices») of the hygiene recommendation of the Robert Koch Institute.
Preventing discolorations of instruments and implants was another topic, as well as evaluating a relatively new low-temperature sterilization method and its application profile in the hospital.
For the first time, a surgeon came to speak of his views on the quality of instruments for surgical operations. He urgently made clear that functionality can not be separated from the sphere of hygiene. The success of surgery depends on reliable medical devices!

9th FORUM: Process Control: National – International. In practice. (2008)
That year we had several foreign speakers whose lectures brought a special atmosphere to the event. Apparently one can easily lose sight of the fact that – on a global scale – medical devices are usually processed manually, with only few machines to help. This is done for financial reasons as well as for reasons of availability. Process control in such cases is staff control, which should begin with training! Endoscopy units need special process controls, and the significance of reviews of process and outcome quality of automatic endoscope reprocessing is rather specific. A particularly sensitive issue is the classification of medical devices in the «Critical ABC of RKI»: «Critical C» implies the formal commitment to certification, which does not guarantee that the ongoing processes necessarily improve. Terms of quality management were explained.
One can, of course, also reprocess in deviation of recommendations and guidelines, if the corresponding performance records are in order. The irony: at that time there was only one accredited («notified») body, that could have issued a certificate for such formalisms – for an estimated 2,000 German hospitals.
The assessment of hygienic reprocessing from the perspective of a surveillance authority also requires as much expertise on the part of the inspector as it does for the employee on the operator side, whether in a hospital or in a medical practice. However, a hospital has more human and financial resources to respond to the vulnerability analysis of the authority. Sometimes it is easier for an external service provider to initiate processes and to organize, optimize and control procedures.
And again dentistry-related issues were present, in particular on the issue of reprocessing of handpieces and turbines, where a final (microorganism-containing?) drop is likely to remain in the channel.
Test soils and methods – more or less related to blood – are presented in the ISO TS 15883-5. After two unsuccessful votes in 1999 and 2002 the relevant Annex of the standard series 15883 part 1 – 4 had been removed, by now it has been agreed upon and it is globally applicable. The Annex exists as a technical specification since 2005. Real-time monitoring during routine checks and validations in the CSSD, the monitoring of steam quality as «the fourth parameter of steam sterilization» and optimization of process steps were other topics.
Medical devices are a major investment and they need a manual for appropriate utilisation – including reprocessing. How has ISO 17664 helped in the respect?

10th FORUM: Users and Experts (2009)
10 years of FORUM were celebrated in a dignified place at Kosmos Berlin. «Experiences at your fingertips» were described and the concept of the International FORUM Workshop CLEANICAL® in different countries around the world was presented. For the first time three final assignments for Specialist Training Course III for CSSD managers were presented to the public – a novelty. One of them described a proper medical device disposal practice already in the operating room. The other two studies dealt with experiences with tray reorganisation and quality management in the field of tension between OR and CSSD objectives.
In one of his last lectures H. Pahlke asked: What is the use of certification according to EN ISO 13485 in the CSSD/physician practice? Clinical reality should serve as a measure of any rule – if only ...! What is actually measureable in the validation of cleaning processes? And what use is the cleaning standard DIN EN ISO 15883?
Sterilization assistant, surgical notes on reprocessing, availability, and communication between the parties involved, as well as a treatment on steam sterilization as a proven method in a changed environment completed this anniversary event.

11th FORUM: Processing – Simple Please! (2010)
The last time we met for a FORUM congress at DRK-Hospital Westend, the lectures appeared on CD-ROM this time (and later in an international volume of the FORUM-Journal in summarized form). Like

all the presentations of all volumes of FORUM you can find the lectures on our website, online at www.cleanical.de/media/pdf/vortragsuebersicht_FORUM_2010.html

12. FORUM: Le meilleur sur une période de 10 ans/Lo mejor de los 10 años últimos

The best entries from 10 years FORUM were published in a Spanish-French Supplement of the journal *Central Service*. What initially looks like a linguistic exercise, had its meaning in the context of our International FORUM Workshop® CLEANICAL, especially in Latin America, apart from a number of German-Chinese meetings at the Medical Lounge Berlin.

After the end of the conventions there was no need to stick to the February deadline for the journal. Since then we publish simultaneously with the big annual conventions of the hygienists and reprocessors in April and October in German, as well as for the Medical Devices Fair in November in English in a separate volume. Here are the topics of the journals, all of which can be downloaded from www.cleanical.com/forum-cleanical.html

FORUM-Journal 13 – 19 (2011 – 2013)

- Betreiber aufgepasst – Können wir Verantwortung delegieren? (2011)
- QualitätsLEIDfaden Aufbereitung MP (2012)
- Unvermeidliches Rest-Risiko Aufbereitung (2012)
- Medical Device Reprocessing: Responsibility for Quality. Best of FORUM 12–15 (2012)
- Alles geregelt? Aufbereitung ist immer auch manuell (2013)
- Medizinprodukte-Aufbereitung: Begreifen und Begriffe (2013)
- Medical Device Processing: Manual Skills and Residual Risks. Best of FORUM 17–18 (2013)

FORUM 20: Anniversary Volume (2014)

20 years Surgical Instruments Workgroup Berlin, 15 years of FORUM and 20 volumes of journals, number 20 having the guiding-theme «Only Clean Medical Devices are Safe.»

The headline on this FORUM volume referred to the discussion of the recent years. «Safe» is more than hygiene, it's functionality, availability, reliability and much more – think of capable staff.

The current debate may be described as follows:

- Central documents from the rules and regulations will be revised in the coming years:
  - A new EU directive (to replace the 93/42) will specify the control of medical devices, particularly class 3, provide for inspections of manufacturers and will probably also monitor the Notified Bodies in terms of qualification. He who can describe how he reprocesses disposable instruments, can also actually do it and the manufacturer of single-use devices is even encouraged in certain circumstances, to rectify and add to his instructions for use a reprocessing guide according to ISO 17664: 2004 (in order to make the disposable product reusable).
  - The new KRINKO 2012 on hygiene in reprocessing disappointed a lot of users, since it has grown sixfold, due to the integration of additional recommendations that were separate before. Its 67 pages contain a variety of information, but it was not possible to match these parts to each other, probably so as not to endanger the expert consensus. An inflated and unfinished «many-people-work» – without a table of contents, without a glossary.
  - A revision of ISO 17664: 2004 takes place under ISO Secretariat. Among other things, the greater involvement of validation as part of risk management provokes discussions.
  - ISO 15883 is growing (now to 7 parts) and even the load carrier – our standardization proposal of 2009 – may finally be included.
  - On the occasion of the publication of the guideline for manual processing a heated debate about «limits» ensued. In fairness, our current limits are really hardly more than conventions, due to a lack of intense research.
- Terms of quality management have made their way into the reprocessing departments, that are increasingly treated as production facilities for sterilized medical devices. Think of the work and process descriptions in particular. The possibilities and limitations of cleaning and disinfection are now described in detail. Hence, not only the process of steam sterilization, but other process steps such as cleaning and packaging are being validated and thus subjected to random checks, too.
- The Communication between the involved parties has become more professional: the same technical resources will be used and gray areas will be candidly admitted, once they are identified. Especially in Germany, it is not only the sovereignty of the Laender that allows for a wider scope for the permitted (and approved) processing and operating conditions, but it is being recognized that there must be some leeway, if we want to continue to successfully and comprehensively reprocess in 2000 German hospitals. ■

References

1. H. Pahlke, Th. W. Fengler: Verification of BD Test in the CSSD. ZentrSteril 2001; 9 (5): 350–352.
2. Frister et al. Probengewinnung und analytische Verfahren zur Reinigungskontrolle bei zu sterilisierenden Medizinprodukten. FORUM 2002: 13
3. Frister et al. Quantitatives Proteinmonitoring mit der modifizierten OPA-Methode am Eluat: Validierung der Verfahren. FORUM 2000: 20
4. Fengler TW et al: Are Processed Surgical Instruments free of Protein? Results of the Clinical Multi-Centre Residual Contamination Study of Processing (MRSA). Zentr Steril 2001; 9 (1): 27–32

The da Vinci® Surgical System: Validated Reprocessing Methods and Regulatory Compliance

B. Wallace

Advanced tools for minimally invasive surgery (MIS), like the da Vinci Robotic Surgical System are widely used throughout the world. Because of markedly improved patient outcomes (see examples of supporting evidence below), the use of MIS tools and da Vinci systems have quickly replaced open surgical procedures and, in some markets, serve as the predominate surgical solution for patients requiring common procedures such as prostatectomy and hysterectomy. This article will provide background on the da Vinci Surgical system, and dispel any misconceptions (1) that this device has questionable clinical utility or that it does not meet international regulatory requirements. We will also describe the procedure for reprocessing EndoWrist® instruments used with the da Vinci system, and provide evidence for their safe use in accordance with international standards for the reprocessing of medical devices (2).

Intuitive Surgical, Inc. (ISI) received FDA clearance for its first da Vinci surgical system in 2000. Since then, advancements to the da Vinci robotic platform and EndoWrist instrumentation have been made to improve and expand robotic surgical options to patients and physicians. Since its start, ISI has been dedicated to providing the benefits of minimally invasive surgery to patients; since that time over 2 million da Vinci surgical procedures have been performed.

More than 8000 peer reviewed articles have been published on robotic surgery using the da Vinci system. In these articles, the clinical benefits of da Vinci surgery have been extensively described through high level of evidence publications. The evidence of the clinical benefits of da Vinci prostatectomy and cancer related da Vinci hysterectomy is presented below as examples. In both of these examples, studies prove unequivocal clinical benefits and patient outcomes compared to open surgery.

da Vinci Prostatectomy

- Improved cancer control through lower positive margin rates (3, 4, 5)
- Faster return of erectile function (6, 7)
- More patients have full return of urinary continence within 6 months (5, 6, 7)
- Patients experience shorter hospital stays (5, 6, 7, 8, 9)
- Less blood loss (5 – 12)
- Lower risk of complications (5, 7, 12)
- Lower risk of infection (12)
- Less pain (10)
- Faster recovery (11) and return to normal activity (9)

da Vinci Cancer Hysterectomy

- Better chance of living cancer-free at 2-year follow up (13)
- Fewer complications (13 – 19)
- Less blood loss (13 – 20)
- Less pain (19, 20)
- Shorter hospital stays (one day in many cases) (13 – 17, 19, 20)
- Faster recovery and return to normal activity (18)

The majority of EndoWrist instruments are reusable up to a regulated number of use lives, which is controlled by an integrated circuit device contained within the housing of each instrument. When the last instrument life has been recorded on the device, the surgical system will no longer allow that instrument to be used. The majority of EndoWrist instruments have 10 rated use lives, however, some instruments are rated for between 5 and 30 lives, depending on the indication for use and design of the instrument.

ISI provides reprocessing instructions which are compliant to ISO 17664 (21) standards and which describe the validated cleaning and sterilization methods for EndoWrist instruments, endoscopes and accessories. For the purpose of this article, the automated method for cleaning EndoWrist instruments is described, since this method is most commonly used in Europe. The validated cleaning method requires simple manual pre-cleaning steps followed by processing in an automated washer disinfector. A manual process is also validated, which requires the use of an ultrasonic bath. A flowchart describing a high-level overview of the validated automated cleaning method for EndoWrist instruments is shown in Figure 1.

Unlike simple or laparoscopic surgical devices that are exposed fully to soil within the surgical field during use, Endowrist instruments have distinct limited regions of the device that are either in direct patient contact, indirect patient contact or patient non-contact, based on the design and use of the instrument during surgery. The regions of the instrument are shown in Figure 2.

During a da Vinci procedure, the abdominal cavity is insufflated with approximately 1 bar of pressure to create an open sur-

Brian Wallace, PhD, Director, Device Reprocessing and Sterilization, Intuitive Surgical, Inc. Sunnyvale, California, USA
E-mail: Brian.Wallace@intusurg.com

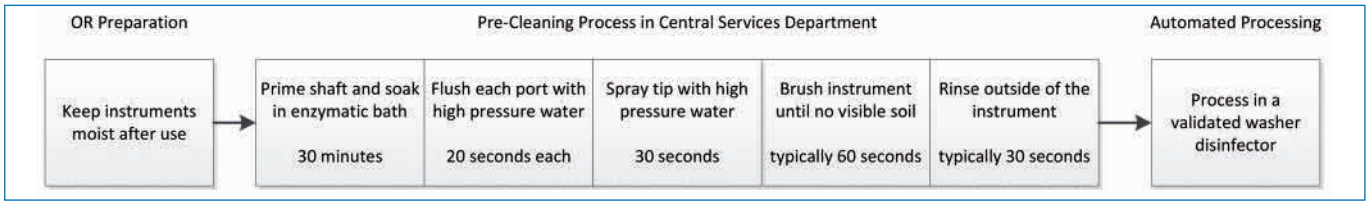


Fig. 1: Flowchart showing the main steps of the da Vinci S and Si 8mm EndoWrist instrument automated cleaning process, including the simple pre-cleaning steps.

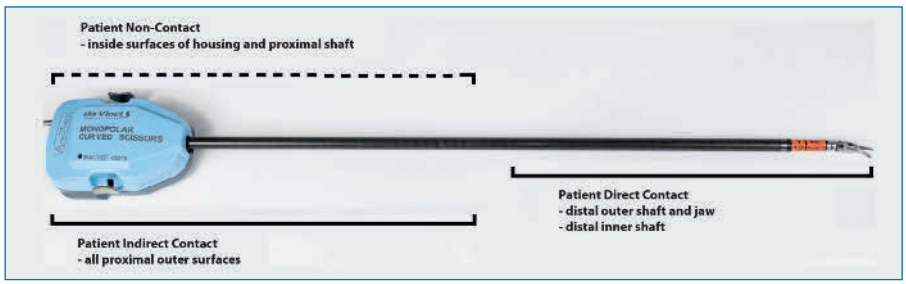


Fig. 2: Picture of an EndoWrist instrument showing the different regions of the instrument divided into direct patient contact, indirect patient contact and the patient non-contact regions.

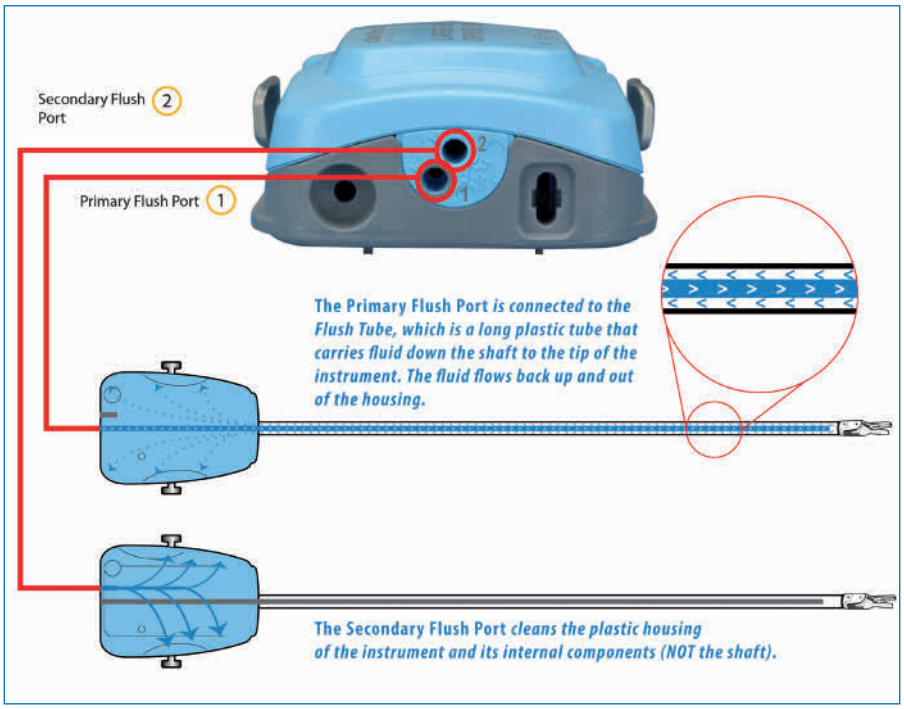


Fig. 3: Mechanism within the EndoWrist instrument designed to flush the internal components.

gical field. Consequently, blood may enter the distal inner shaft during a procedure by riding along the cables as they move. However, fluid ingress is limited by the distal shaft seal through which the control cables pass. Any blood which does enter the inner shaft is removed during reprocessing by a flush tube that originates on the back of the housing and terminates close to the end of the distal inner shaft. Figure 3 shows the flushing design of the EndoWrist instrument which allows for proper cleaning of the internal surfaces of the instrument.

Through proper training and execution of the validated cleaning method from ISI, the central services staff can achieve excellent cleaning results (both in type testing and performance qualifications according to ISO 15883). EndoWrist instrument cleaning efficacy is evaluated by visual examination of the external surfaces and quantitative residual protein testing of extracts of the patient contact areas including the distal tip and inner shaft. Acceptable cleaning results are routinely achieved, even at levels below the 100 µg limit set by the KRINKO Guidelines (22) in Germany. In some cases, the results of performance qualification tests at hospitals in Germany are below the limit of detection for the protein test methodology. Figure 4 shows a sampling of performance qualification results at European hospitals. The residual protein results are a combination of testing both the distal tip and the distal inner shaft. Methods for conducting intact and destructive EndoWrist instrument tests, as well as the results of round-robin testing at various recognized hygiene laboratories has been published (23, 24) by the da Vinci Working Group.

In addition to the quantitative endpoint testing conducted in support of ISO 15883 washer disinfector validations, visual examinations of the components of the distal inner shaft of EndoWrist instruments were conducted on instruments from German hospitals at the end of clinical life. Figure 5 illustrates the cleanliness of the distal components of disassembled instruments after 10 cycles of clinical use and reprocessing.

Da Vinci systems and devices are approved (or cleared) for sale or CE marked in 54 countries, including the European Union. Da Vinci systems are affixed with the CE Mark in accordance with Council Directive 93/42/EEC concerning medical devices (commonly referred to as the Medical Devices Directive). Furthermore, conformity to the Medical Device Directive and the underlying DS/ISO 13485:2012 Quality System is

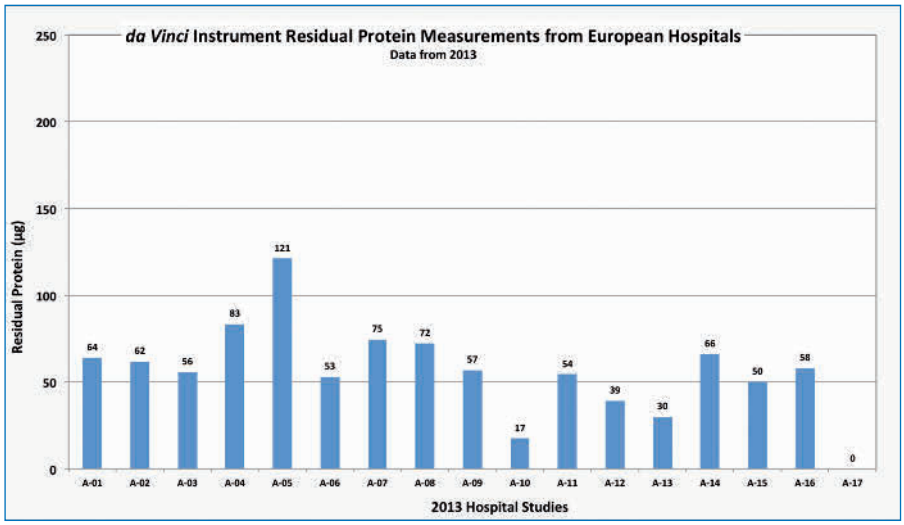


Fig. 4: A sampling of residual protein results from performance qualifications at hospitals in Europe on clinically-used EndoWrist instruments demonstrating reproducible results.

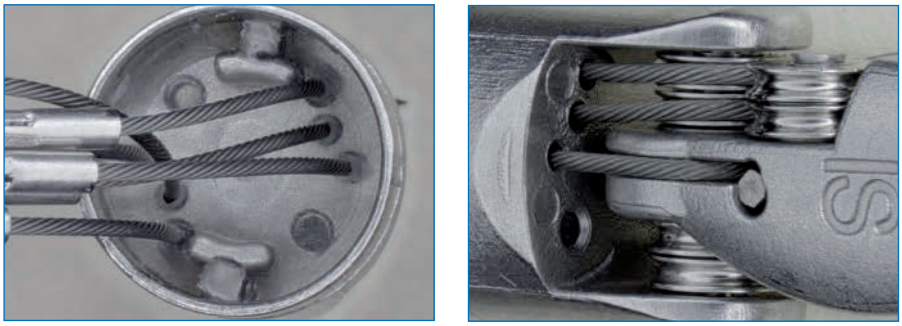


Fig. 5: Examples of photographic evidence showing the cleanliness of the distal components of EndoWrist instruments after 10 cycles of clinical use and reprocessing.

re-assessed by the Notified Body Pre-Safe/DGM (Notified Body Number 0543) on a periodic basis. Annual surveillance audits are conducted by DGM which include inspection of Technical Files, as well as post-market surveillance data. ISI holds and maintains certificates of compliance to DS/ISO 13485:2012 and Annex II of the Medical Device Directive as well as many other quality system certificates and licenses issued by worldwide regulatory agencies. Intuitive Surgical has conducted validations of the reprocessing methods related to EndoWrist instruments, including cleaning, disinfection and sterilization in accordance with regulatory guidelines and requirements worldwide. These requirements are described in the product labeling and ISI Instructions for Use.

In summary, the da Vinci surgical system is in wide use in more than 50 countries in the world where trained surgeons are providing the clear clinical benefits of minimally-invasive da Vinci surgery to patients. Furthermore, EndoWrist surgical instruments and their corresponding reprocessing instructions are designed and validated to provide safe and effective medical devices for use in surgery in full compliance with the local laws and regulations where the da Vinci system is approved for use. On a global basis Intuitive Surgical is not aware of any incident in which a health complaint was proven to be associated with protein residues or other types of contamination in a da Vinci instrument due to improper device reprocessing. ■

References

1. Fengler TW. DaVinci-Instrumente zum mehrmaligen Einsatz: Einmal, mehrfach oder keinmal verwendbar? FORUM Medizinprodukte & Prozesse (2014) 20:28.
2. BS EN ISO 15883-1: 2009 Washer-disinfectors Part 1: General requirements, terms and definitions and tests.
3. Weerakoon M, et al. Predictors of positive surgical margins at open and robot-assisted laparoscopic radical prostatectomy: a single surgeon series. J Robotic Surg (2011) DOI 10.1007/s11701-011-0313-4.
4. Coronato EE, et al. A multi-institutional comparison of radical retropubic prostatectomy, radical perineal prostatectomy, and robot-assisted laparoscopic prostatectomy for treatment of localized prostate cancer. J Robotic Surg (2009) 3:175–178.
5. Health Information and Quality Authority (HIQA), reporting to the Minister of Health-Ireland. Health technology assessment of robot-assisted surgery in selected surgical procedures, 21 September 2011.
6. Rocco B, et al. Robotic vs open prostatectomy in a laparoscopically naive centre: a matched-pair analysis. BJU Int. 2009 Oct;104(7):991-5. Epub 2009 May 5.
7. Ficarra V, et al. A prospective, non-randomized trial comparing robot-assisted laparoscopic and retropubic radical prostatectomy in one European institution. BJU Int. 2009 Aug;104(4):534-9. Epub 2009 Mar 5.
8. Ho C, et al. Robot-Assisted Surgery Compared with Open Surgery and Laparoscopic Surgery: Clinical Effectiveness and Economic Analyses [Internet]. Ottawa: Canadian Agency for Drugs and Technologies in Health (CADTH); 2011 (Technology report no. 137).
9. Hohwu L, et al. Open retropubic prostatectomy versus robot-assisted laparoscopic prostatectomy: A comparison of length of sick leave. Scand. J. Urol. Nephrol. Apr 7 2009:1–6.
10. Menon M, et al. Prospective comparison of radical retropubic prostatectomy and robot-assisted anatomic prostatectomy: the Vattikuti Urology Institute experience. Urology. 2002 Nov;60(5):864–68.
11. Miller J, et al. Prospective evaluation of short-term impact and recovery of health related quality of life in men undergoing robotic assisted laparoscopic radical prostatectomy versus open radical prostatectomy. J Urol. 2007 Sep;178(3 Pt 1):854-8; discussion 859. Epub 2007 Jul 16.
12. Carlsson S, et al. Surgery-related complications in 1253 robot-assisted and 485 open retropubic radical prostatectomies at the Karolinska University Hospital, Sweden. Urology. 2010 May;75(5):1092–97.
13. Lau S, et al. From McGill University: At two-year post-op follow-up. Outcomes and cost comparisons after introducing a robotics program for endometrial cancer surgery. Obstet Gynecol. 2012 Apr;119(4):717–24.

14. Paley PJ, et al. Surgical outcomes in gynecologic oncology in the era of robotics: analysis of first 1000 cases. Am J Obstet Gynecol. 2011 Jun;204(6):551.e1-9. Epub 2011 Mar 16.
15. Estape R, et al. Robotic-assisted total laparoscopic hysterectomy and staging for the treatment of endometrial cancer: a comparison with conventional laparoscopy and abdominal approaches. J Robotic Surg 2009 DOI 10.1007/s11701-011-0290-7.
16. DeNardis SA, et al. Robotically assisted laparoscopic hysterectomy versus total abdominal hysterectomy and lymphadenectomy for endometrial cancer. Gynecologic Oncology 2008;111:412–417.
17. Boggess JF, et al. A comparative study of 3 surgical methods for hysterectomy with staging for endometrial cancer. Am J Obstet Gynecol 2008.
18. Bell MC, et al. Comparison of outcomes and cost for endometrial cancer staging via traditional laparotomy, standard laparoscopy, and robotic techniques. Gynecologic Oncology III 2008:407–411.
19. Halliday D, et al. Robotic radical hysterectomy: comparison of outcomes and cost. J Robotic Surg (2010) 4:211–216 DOI 10.1007/s11701-010-0205-z.
20. Magrina JF, et al. Robotic surgery for endometrial cancer: comparison of perioperative outcomes and recurrence with laparoscopy, vaginal/laparoscopy and laparotomy. Eur J Gynaecol Oncol. 2011;32(5):476–80.
21. BS EN ISO 17664:2004 – Sterilization of medical devices – Information to be provided by the manufacturer for the reprocessing of resterilizable medical devices.
22. Regulation concerning the construction, operation and use of medical products. Recommendations of the Committee for Hospital Hygiene and Infection Prevention (KRINKO) at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM) (Federal Health Gazette 2012-55:1244–1310. DOI 10.1007/s00103-012-1548-6).
23. Wehrl M and Michels W. A method for testing the cleaning of MIS robotic instruments. Central Ser (2013) 3: 202–207.
24. Wehrl M, et al. Round robin tests conducted by the working group DaVinci («AG DaVinci») to establish a method for testing the cleaning of MIS robotic instruments. Central Service (2014) 3:173–179.

To be or to have: Can a complex medical device *be* clean? Or do we *have* reprocessing problems?

T.W. Fengler

Clean medical devices?

As 20 years ago we explained to infection control experts the problems encountered when cleaning lumened instruments, they pointed out that industry was responsible for such problems and that they, in their capacity of infection control specialists, could account only for disinfection efficacy testing.

In the meantime one notes that increasingly congresses are addressing topics dealing exclusively with the question: «Is that clean?» From research into prions, and the problems resulting from «misfolded» proteins we know that visually clean is not actually clean and protein residues are critical (regardless of the low clinical relevance of prion infections, as evidenced so far).

Cleaning medical devices calls for manifold technical skills:

- The manufacturer must keep track of his medical devices through the process involved when placing them on the healthcare market and through market observation (risk assessment and monitoring).
- The manufacturer must have qualified his medical devices for reprocessing, and specify validable manual and automated processes.
- The operator, responsible for operation of the premises where the medical device is used, must at the time of procurement and application ensure that the device will not present any danger to the patient, employee or third, not directly involved, parties. The onus to do so is enshrined in the patient contract.
- The user must understand the medical device, which also implies the ability to reprocess if it has been declared for reuse.
- The regional supervisory authorities must have concerted policies for expert response to shortcomings and deviations from standard practice. The aim here is to bring about improvements and preserve health in the broader sense of quality assurance in the healthcare sector.

This, of course, involves a trade-off since every treatment entails risks. Patients consent to undergo medical procedures, e. g. endoscopy and even more so surgery, only because they believe that such a more or less invasive surgical or endoscopic therapeutic procedure will contribute to their health or «convalescence». That is also why the patient is willing to undergo surgery.

Infection control specialists like to talk about the «800,000 healthcare-associated (nosocomial) infections» occurring each year in German hospitals, thus suggesting that these could have been prevented. That is true only to an extent:

- Hospitals bring together sick people and a very specific type of microorganisms.
- Often, treatment regimens weaken the immune system (surgery, chemotherapy)
- Every person has «their» own microorganisms to which they «grant asylum». On admission to hospital patients come into contact with many new microorganisms of a different nature. These take the patient's immune system by surprise and can give rise to infection.
- In line with demographic changes, increasing more elderly, immunocompromised persons are being admitted to hospital

The medical device is just one of the many other risk factors implicated in healthcare-associated infections. Such potential sources of infection include the surgeon's orofacial mask, which becomes moistened through breathing and speaking, draughty air conditioning systems or the billowing gowns of staff as they hurriedly move around. And, of course, not to be forgotten is inadequate hand hygiene, which is possibly the main cause of infection, as demonstrated by Semmelweis in the 19th century, something that, as is well known, provoked a hostile reaction.

Surgery was carried out with the bare hands 150 years ago. Indeed, back then the conventional practice was to allow a caesarean section wound to repair itself from within the abdomen without a suture by relying on the ensuing «therapeutic purulence». One third of women died from bacterial infections. These infections could have been diagnosed had the microscope, already available for centuries, been used to investigate them. It was the knowledge, and not the tools, which was missing.

Nonetheless: we must take account of the fact that it is sick, not healthy, persons who are admitted to hospital and that the ability of establishments to meet hygiene and technical demands differs greatly.

The role of complex medical devices

The manufacturer qualifies a process for manual and automated reprocessing of his medical devices (see EN ISO 17664). The operator, in general, and the user, in particular, must employ a validated process for reprocessing all his products. That presupposes that the process qualified

Dr. med. Dipl. Ing. T.W. Fengler, CLEANICAL® GmbH, Im AUGUSTA-Hospital, Scharnhorststr. 3, 10115 Berlin, Germany
E-mail: info@cleanical.de

by the manufacturer for reprocessing his devices is available in the specific hospital, and can be executed there in line with validation so that the device can be reused on a patient.

Hence at times expensive medical device systems are purchased without the procurement department having given any thought as to how they could be reprocessed. In the past that was clearly demonstrated in particular in the case of robotic systems, where the manipulators can only be cleaned when observing the correct sequence and configuration of manual pre-cleaning steps and using appropriate loading trolleys in a high-performance washer-disinfector (in compliance with the validation specifications set out in the operating manual at the time of placing the devices on the market).The manual steps are of paramount importance in determining the outcome. While robots represent enormous progress in terms of surgical precision, the absence of facilities to reprocess them is tantamount to regress.

What is the use of an operating manual if I am not able to implement the process steps in my reprocessing department? The operator uses different criteria when purchasing medical devices. In such cases, investment in a surgical robot is often more important than purchasing an appropriate washer-disinfector or making provision for the workforce required.

The user or operator of the surgical department must be able to perform surgery successfully, which is where most money is made. And the reprocessor must act fast to ensure that instruments are available once again in the operating room (OR).

An effective infection control policy must be the cornerstone of a successful prevention strategy. Trust is not enough: control is what is needed! Medical personnel must be convinced of the merits of the proposed measures, as they will then be more likely to comply with them.

How do we improve medical device reprocessing?

We improve medical device reprocessing by understanding the issues involved and having a structural approach as well as clear definitions. What are the benefits of the current raft of regulatory guidelines? These include European directives, national legislative acts and regulations, more or less clear guidelines issued in the nature of recommendations (VDI 5700). In Germany, for example, there are the recommendations that go beyond the scope of the Medical Devices Operator Ordinance and have more the nature of directives (KRINKO 2012).

The purpose of standards and guidelines is to set out regulations to facilitate management of medical devices. Standards are intended, in particular, for manufacturers; they use constructs that endeavour to promote consensus among manufacturers so that all of them will base their practices on the same prerequisites, aim and targets. While everyone understands what a connector and socket, or the track gauge of a railway, is supposed to mean, matters are different when it comes to the reprocessing instructions to be provided by the medical device manufacturer, which are often less clear. In any case, it takes years to reach a consensus here.

As per its Wikipedia definition, the term «standard» was originally understood to mean a royal decree, which, as such, was considered to be legally binding. But the age of «royal standards» is now long gone and today infection control specialists are «kings without a kingdom».

But who is responsible for research if not the university chairs/professorships? Unfortunately, reprocessing procedures are all too rarely the focus of structured research projects? But reprocessing encompasses challenging scientific topics that are of some relevance to the healthcare industry.

The chemical and physical interactions taking place in cleaning processes are anything but trivial. When conducting laboratory tests and investigations, depending on the test substance used the actual relevance in the everyday clinical setting must be evaluated as objectively as possible. For example, in the case of cement, semolina, egg yolk or lipstick, blood, mucus, etc.: all substances are of very different composition and can be standardized only to an extent.

In the case of non-destructive analysis of a test object, it is not just the quality and

Fig. 1: Free access to the baskets, spray arm rotating freely

Fig. 2: Control of water distribution through a glass pane

Fig. 3: Thorough flushing by complete connection, parameter control by data loggers

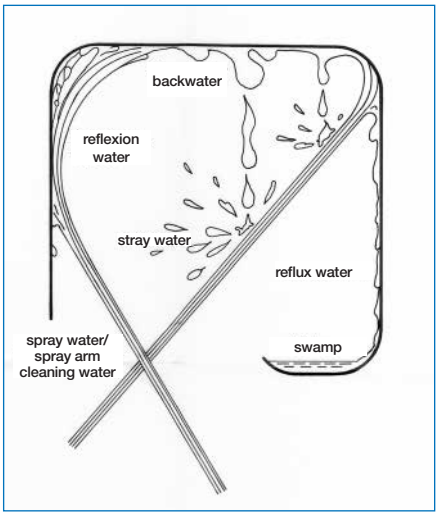


Fig. 4: Description of the hydromechanical force exerted by the water inside a WD chamber (cited from Koller W: Reinigung und Desinfektion von Essgeschirr, Instrumenten und Ausscheidungsbehältern im Krankenhaus. Wien, 1981.)

quantity of the results that matter, but also an understanding of what and how much of the test object remains (recovery rate, composition of residues, possibly different from those that can be detached and dissolved (transferred to a solution) during sampling/elution and then determined. Very different test models must be used in research and development (R&D). For example in the case of medical device R&D, account must be taken of the clinical residual contamination encountered across all application fields, from urology to bone surgery, from dentistry to endoscopy. Only then can medical device simulators challenge the (reprocessing) processes.

With regard to reprocessing practices, more attention must be paid to the multifaceted influences at play here, while not losing track of reality:

- ***Since in reality, the devices encountered are always more complex than the models, the common practice must be to use objective testing of the reprocessed medical devices after actual use.***
- ***Meaningful limit values for residues whose clinical relevance must be verified. In cases of doubt, one can refer to the efficacy of subsequent processes and long-term use in terms of functionality and service life. The focus here is less on infection control (hygiene) and more on achieving acceptance values based on the state of the art, which can be continually optimized.***
- ***Insights into retention of residues in line with the medical device geometry (design, product families) aimed at achieving the optimum residue-free condition for hygiene and durability reasons***
- ***Investigation and continuous monitoring of hydromechanical factors in the respective chamber and load configuration***

In that respect, I draw attention to our description of the hydromechanical processes in an attempt to find definitions:

- spray water
- spray arm cleaning water
- collision water
- reflexion water
- waste water
- atomized water
- flushing water
- branching water
- backwater
- swamp water (Figures 1–4)

Until such time as we have defined the terms it will be difficult to describe research objectives such that new procedures can be explained. Hence the importance of global harmonized standards (EN ISO).

We are working more and more with complex medical devices since, by the latest, the introduction of «keyhole access» in abdominal surgery. Puncturing endoscopy is used for surgery, e. g. arthroscopy.

Annex C of ISO 17664 Revision (manufacturer's reprocessing information) sets out for the first time a system of cataloguing an estimated number of seven medical device groups, classified on the basis of the validation requirements to be met when placing the devices on the market and in terms of reprocessing demands.

Nevertheless: certain medical devices will not be, and will prove impossible to, clean in the future too. We demonstrated that 15 years ago during a clinical multi-centre study, where it was possible to rinse off protein residues from between one and two thirds of cleaned (undisinfected) medical devices of varying design (SDS/OPA method). Unfortunately as regards that method, owning to the test design used then, we do not know exactly what type of residues persisted on the instrument surfaces (1)! We therefore continue to live with this widespread lack of knowledge of the dynamics of processes:

- Mechanical/physical: rheology (flow, resistance, adhesion and cohesion forces, viscosity), pressure, pulse variables, pulse frequency, temperature, time
- Chemical: composition of substances, adhesion forces, solubility (as a function of hydrolysis, ionic charges, etc.), analytical test methods
- Biological: biocides, composition and inflammatory effects of residual soils or of chemically altered substances,
- Thermodynamics: steam sterilization, condensation

Perhaps we are not living too badly after all, as borne out by the current findings of reprocessing in 2000 hospitals. But neither are we able to impute postoperative infections to a single source. It would be virtually impossible to carry out such a study; nor would it be easy to do so in the case of endoscopy, as demonstrated by the publication by Spach et al. from the 1980s. However, there is reason to believe that endoscopy was implicated in the transmission of tuberculosis in isolated cases.

Process safety cannot thus be explained, it must be based as a whole on the organizational safety of the processes, their purpose, feasibility, standardizability and quality management. After all in legal terms reprocessing is considered to be «fully controllable», hence commensurate demands must be made on quality and documentation. Are we able to meet these demands? ■

Acknowledgement

I would like to thank Dr. W. Michels for his valuable suggestions.

References

1. Fengler ThW, Pahlke H, Michels et al.: Are processed surgical instruments free of protein? Results of the clinical multi-centre residual contamination study of processing (MRSA). Central Service 2001 9 (1): 20–32.

Is the protein test really the test method of choice?

Weak points of the protein test and alternative concepts

K. Frösel

The Guideline for validation of manual cleaning and manual chemical disinfection of medical devices as well as the supplement to the Guideline for validation and routine monitoring of automated cleaning and disinfection of heat-resistant medical devices as well as advice on selecting washer-disinfectors, compiled by the German Society for Hospital Hygiene (DGKH), German Society of Sterile Supply (DGSV) and Working Group Instrument Preparation (AKI), both of which were published last year, contain significant changes with regard to the acceptable residual protein load. Whether these have set new standards for the acceptable residual protein load must still be clarified.

The crucial question here is whether the method recommended for protein determination is suitable. Two factors must be taken into account to that effect:

First, the sensitivity of the method used in determining the protein load in the irrigation solution, bearing in mind that detection limits in the range 3–10 µg/ml appear realistic when using the currently recommended methods (modified OPA method, biuret/BCA method).

Second, it is of course particularly important that the greatest possible amount of residual protein can be removed from the test instrument and transferred to the irrigation solution. Failure to detect any residual protein that cannot be easily removed would result in underestimation of the actual residual protein load on the instrument. Besides, any residual protein soils located in poorly accessible parts of an instrument have an adverse effect on the subsequent disinfection step (detraction of the disinfectant action on microorganisms embedded in and beneath the residual protein soils) as well as on the sterilization cycle (reduced efficacy of the sterilant against microorganisms embedded in and beneath the residual protein soils). But a high residual protein recovery rate is an insdispensable prerequiste for the effective detection of remnants especially required at such poorly accessible areas.

Factors that impact on recovery

Hence the next issue is to identify the factors that impact on the recovery rate. In that respect, at least the following aspects must be borne in mind during elution:

First, this is the composition of the cleaning solution used; the method currently recommended in the guidelines (1 % SDS solution, set to pH 11) appears to be very suitable, as also attested to in everyday practice.

However, the efficiency of recovery is also affected by the volume of the rinse solution and the duration of rinsing. In that regard, elution with as small as possible an amount, or 2–5 ml, of SDS solution as recommended in the guidelines, appears to be somewhat counterproductive. Moreover, no specifications are given as regards the duration of rinsing.

Since the relevant publications addressing the currently recommended methods do not feature any tests for determining the specific recovery rate, other sources must be consulted (e. g. AAMI TIR 30: 2011, A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices).

Medical Device Services, which is a German test laboratory accredited and certified pursuant to Section 15(5) of the German Medical Devices Act (MPG) and EN ISO/IEC 17025, has been carrying out validations of reprocessing processes, also including complex instruments, for almost 20 years now. Based on the experiences and results obtained from internal validations regarding removal of protein soils from medical devices, there is reason to believe that the elution conditions described above are not sufficient in most cases.

It must also be pointed out that the detection limits of the protein test do not generally permit the use of conventional methods to determine the specific recovery rate, e. g. repeated rinsing of the same instrument.

If nothing else, the deficiencies of this method have meant that not only in Germany determination of the protein load has been restricted to particular parts of an instrument. But the crucial question here is on what basis such instrument parts can be selected at all? That difficulty stems from the fact that instruments can become contaminated not only during application but also by subsequent processes prior to reprocessing. Therefore, all instrument parts are susceptible to contamination and as a consequence require extended consideration during the investigations – as is currently the case in other countries. Therefore a targeted selection of certain relevant instrument parts to demonstrate an acceptable safety level appears questionable.

Klaus Frösel, Medical Device Services – Dr. ROSSBERGER GmbH (www.mdservices.de), Lilienthalstr. 4, 82205 Gilching, Germany
E-mail: kf@mdservices.de

Alternatives to the protein test

The quest for alternative methods is thus justified:

In AAMI TIR 30 consideration is given to, apart from the protein test, in particular the total organic carbon (TOC) and haemoglobin test, which, however, do not have any markedly better detection limit in routine practices. Hence the preconditions for proper determination of specific recovery rates are missing. Besides, the current FDA practice of taking account of at least two of these factors does not appear to be particularly helpful since even the combination of two factors of low sensitivity does not essentially enhance detection of the same parameter.

On the other hand, a very different approach can be taken by using microbiological detection methods in accordance with ASTM E 2314 [Standard Test Method for Determination of Effectiveness of Cleaning Processes for Reusable Medical Instruments Using a Microbiologic Method (Simulated Use Test); 2003, reapproved 2008], since in this case a good microbial recovery rate is assured thanks to the use of membrane filtration regardless of the irrigation volume used, which can be as large as needed for good recovery. In that case, the sensitivity of the detection method is virtually independent of the rinsing volume. And the high sensitivity of the test method also allows for the use of conventional methods to determine the specific recovery rate, e. g. repeated rinsing of the same instrument. For these microbiological detection methods a large count of suitable test organisms (generally *Bacillus atrophaeus* spores) is embedded into application oriented soils with a high protein content and their elimination, as well as removal of the surrounding contamination, is confirmed on the basis of the microbial recovery rate. The suitability and high sensitivity of this method have been confirmed repeatedly by comparing the results obtained with those of conventional methods, which have also been reported in studies for instruments with comparable geometries. Furthermore, these have been corroborated on the basis of practical observations (visible contamination after reprocessing once or repeatedly) as well as based on product returns. However, this method requires a microbiology laboratory and is generally not feasible at the user's premises.

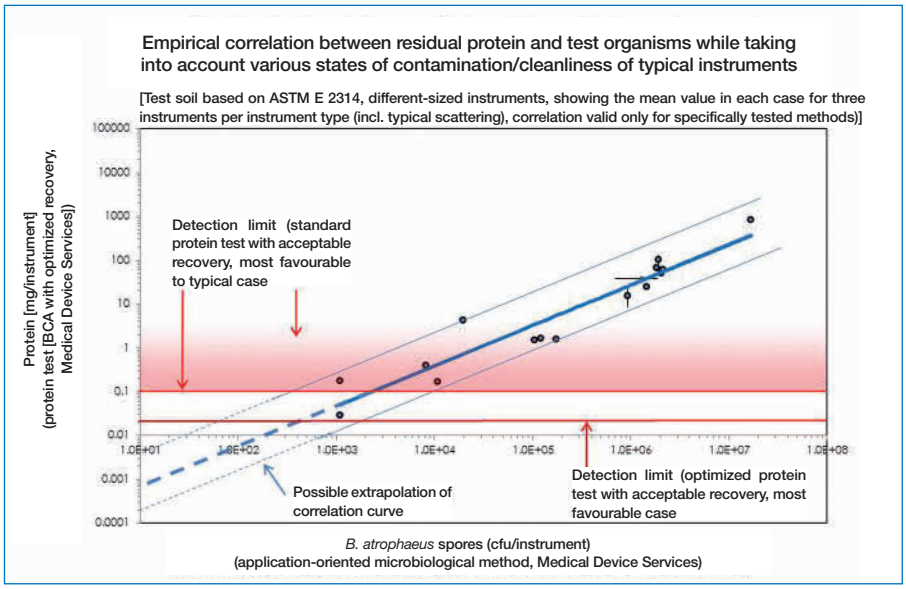


Fig. 1: Empirical correlation between residual protein and test organisms (application-oriented microbiological method, Medical Device Services)

For a long time now there has also been another method available aimed at overcoming the recovery problem: after the introduction of radioactive marker substances into soils any residual contaminants can be directly localized. However, the amounts of marker substances as well as the detection methods used only permit reduction rates in the range of two orders of magnitude, which are not enough to identify a correlation with the residual protein amounts to be now taken into account. Besides, radioactive marker substances can likewise only be used in special settings, and definitely not at the user's premises.

Conclusion

Microbiological methods, which should actually be preferably used because of their sensitivity, are not suitable for routine use at the user's premises. Therefore the following concept appears beneficial:

- Protein determination continues to be employed as a routine method at the user's premises. However, to that effect – while taking account of the specific characteristics of the instruments (size, shape, etc.), and also intending to achieve the highest possible recovery rate – realistic specifications should be formulated for both methodological aspects and the acceptable residual protein load. The current specifications are suggestive of a safety level that in many cases is unlikely to be assured.
  The results obtained for protein determination (as a selective marker) of course only serve as a general pointer to the fact that the cleaning cycle had no serious flaws.
- Hence it is all the more important that a highly sensitive method be used for validation of reprocessing to be performed by the manufacturer. In this regard microbiological methods, with suitable soils, have stood the test of time and have – to a statistically representative extent – proved to be the method of choice. For instruments produced with attention to hygienic problems reduction rates of at least five orders of magnitude can fundamentally be achieved, while bearing in mind that the cleaning dynamics cannot be viewed exclusively in logarithmic reduction terms. Here it is decisive what the user deems to be an unobjectionable residual value when finally inspecting the medical device.
  The correlation test results available to the author also confirm that on achieving a reduction rate of at least five orders of magnitude it can be assumed that the residual protein load is sufficiently low.

Outlook

Of particular interest with regard to validation to be conducted by the manufacturer is the fact that certain microbiological tests enable indirect evidence of the residual protein load and that this indirect procedure with consideration of an effective recovery is markedly more sensitive than the protein test.

The tests performed by Medical Device Services for the purpose of internal method validation using instruments of different sizes and complexity have identified a linear correlation between the reduction of test organisms and the residual protein load, with very good reproducibility in respect of the same instruments. This is in any case acceptable when taking into account the broad spectrum of typical instruments and the nature of the test method of interest. Therefore by application of extrapolation, the residual protein loads can even be estimated in ranges that are markedly beyond the sensitivity range of a protein test whose irrigation volume was tailored to an acceptable recovery rate (Fig. 1).

Meanwhile Medical Device Services successfully developed an optimized protein test which establishes a reasonable weighting between recovery and limit of detection. For more information on this please contact the author. ■

References available from the author

Create pouches easily yourself

C. Wolf

Fig. 1: Automatic pouchmaking machine SealCut hm 8000 AS/AS-V with optional sorting module

Fig. 2: Hans Wolf, CEO, and Christian Wolf, CEO, receiving the «Top Innovator 2014» award from Ranga Yogeshwar

The filling and heat sealing of pouches and reels is a particularly safe and reliable packaging system that is an indispensable part of the reprocessing of medical devices. Producing pouches yourself from standard reels is a common practice that offers a superlative degree of flexibility. The in-house production of suitable pouches, however, is generally a manual process and is therefore associated with considerable time and staffing commitments. The user also needs to have the relevant experience to cut the right pouch for the instrument being packaged. The wrong pouch size can increase process costs.

hawo has developed a solution for this: a fully automatic pouchmaking machine known as SealCut (hm 8000 AS-V) for the production of pouches from standard reels (Fig. 1).

The machine processes reels compliant with EN 868 both with and without gussets, as well as Tyvek®[1] reels.

Cost-effective production

The pouches are produced completely automatically in the desired quantity and length while users are able to focus on more important jobs. Up to six reels of film can be stored on the roll holder. Depending on what is loaded onto the machine, it can then produce up to 5,000 pouches an hour.[2]

On an optional sorting module, sorting chutes can be positioned into which the SealCut then sorts and ejects the produced pouches.

The required number of pouches in the required length, the complete configuration and all SealCut settings can be programmed conveniently via the control panel or also using the unique hawo IntelligentScan-system. This scanning system allows custom-designed scan lists to be created via which staff names, materials to be sealed or instrument sizes can be read into the SealCut device. Entire formulas can be created as a barcode. With a scan, the machine knows how many pouches of what length at what temperature to produce. With hawo SizeMatic-technology, the user can even configure the ideal pouch size with just one scan of the instrument length. The new SizeMatic-technology then calculates the ideal pouch length automatically. The safety distances required as standard are complied with. As a result, the user can produce precisely-dimensioned pouches. Pouches that are too long or too short are therefore finally a thing of the past.

1 Tyvek® is a registered trademark of E.I. du Pont Nemours

2 With 6 film rolls, sealing time 1.5 s, 100 mm pouch length in economic mode

Christian Wolf, CEO hawo GmbH,
www.hawo.com
E-mail: info@hawo.com

The sorted, produced pouches can be conveniently removed, processed further and labelled. An optional printer will provide a label automatically. All the relevant information such as the date of production, the expiry date, the batch number, the name of the packer and the name of the medical device can be printed on the label.
In seal-only mode, the SealCut can also be used as a common sealing device for closing the fourth side of the pouch.

Process that supports validation

The SealCut hm 8000 AS-V satisfies the requirements of EN ISO 11607-2 and the new international ISO/TS 16775 guidance. In accordance with the standard, the device monitors critical process parameters such as the sealing temperature, contact pressure and sealing time. If any deviations occur, the process is stopped and the user is alarmed. For routine checks, the machine has a seal check function that can also be activated via the control panel or via the IntelligentScan scanning system. The critical parameters defined with validation are displayed following the test seal.
SealCut can also be connected to batch documentation systems using standard RS 232, USB and Ethernet interfaces.

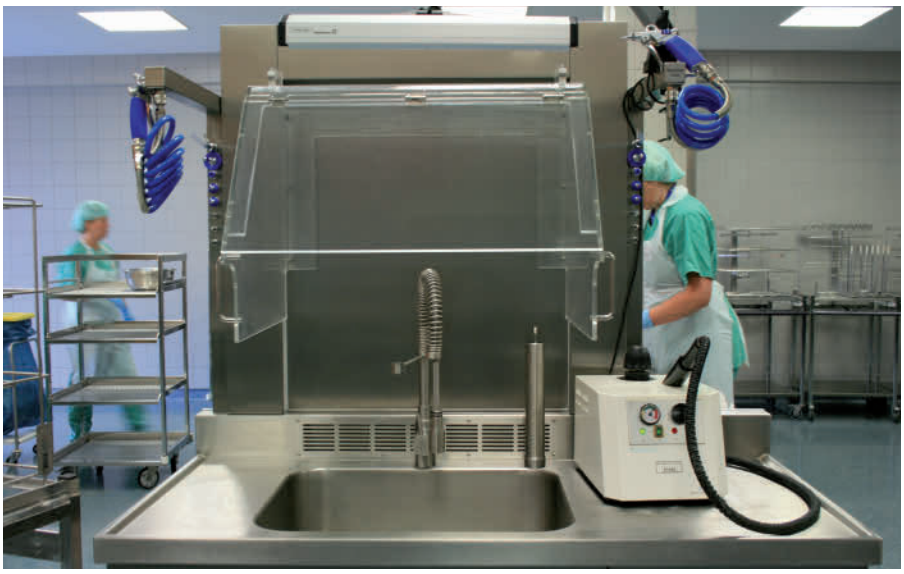
Sustainable technology

Its footprint of 740 mm has been achieved thanks to a compact design and even its energy consumption of just 200 Watt has been kept astonishingly low. The use of wear parts has also been reduced to a minimum (hawo GreenTek).
The new SealCut from hawo once again highlights the company's impressive flair for innovation (Fig. 2).

More information/video:
www.hawo.com/en/hawoTV
hawo GmbH, Obere Au 2 – 4, 74847 Obrigheim, Germany; Ph: +49 6261 97700; E-mail: SealCut@hawo.com, Internet: www.hawo.com

Auxiliary devices for reprocessing

Cleaning is the first disinfection measure!



Adequate workplace for pre-cleaning

Faucet for manual pre-cleaning – with splash guard and personal protective equipment

Correct connection of hollow instruments (here: Veress canula), unused sockets are closed

Illuminated maginfier for packaging

Waste disposal close at hand

Testing reference loads at validation and routine WD loading patterns

W. Michels

The «Guideline of DGKH, DGSV and AKI for Validation and Routine Monitoring of Automated Cleaning and Disinfection Processes for Heat-Resistant Medical Devices as Well as Advice on Selecting Washer-Disinfectors» requires that each process of the WD be tested with typical everyday loads.
Only thus can it be ensured that validation results are realisable during routine reprocessing. For the performance test the reference load must use instruments soiled by everyday typical soil caused by actual use. Any local conditions in the operating theatre, during disposal, as well as possible pretreatments that could influence cleaning should be taken into account.
When looking at validation reports, many of the photo documents of loads lead to the justified suspicion that the tested load is definitely not an everyday typical reference load. This is because the load carriers are only very sparely stocked with medical devices to be reprocessed. Figures 1 and 2 show examples of such «underloaded» carriers.
It is understandable that the CSSD have not got much time to conduct performance tests so that either these tests are planned for times when there is a reduced theatre schedule, or the schedule is reduced to make room for the tests. Thus the necessary numbers of medical devices needed to put together a suitable reference load simply are not available. Here there are conflicting interests and the silent compromise is under-loading.
It does not follow that test results are necessarily better for underloaded carriers than for those of an actual routine load. This could be the case, but the opposite effect is also possible. To clean all geometrical parts of medical devices, not only direct wash jets are crucial but also reflected jets. This is especially applicable for instruments with joints whose crevices are bounded by surfaces at an awkward 90° angle to the wash jets coming from below and/or from above. These are much better reached by various reflected wash jets. Therefore there should be a certain density of instruments in the sieve baskets, only achieved with a balanced load. If the load is too densely packed however, there is the danger of items screening each other from the reach of the wash jets (missed areas/rinse shadow), resulting in inadequate cleaning results. This aspect is often underestimated as relevant to result quality and not taken into account. Thus the performance test is a suitable aid to document loading effectivity.
Looking through validation reports or reports of repeated performance tests, in about 60 % of all cases loads can be found

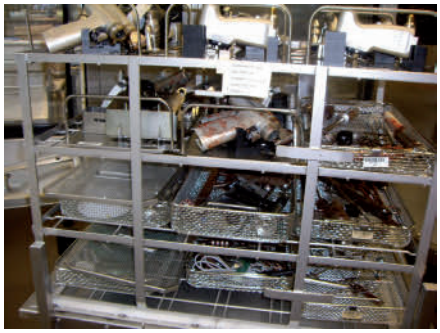


Fig. 3: A reference load that credibly represents a routine load

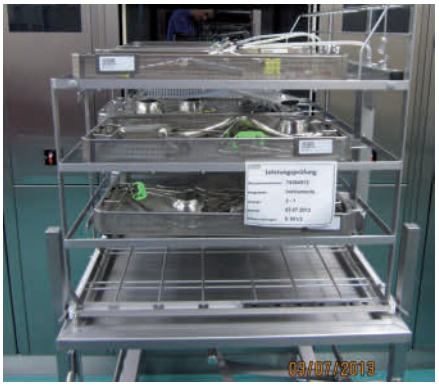
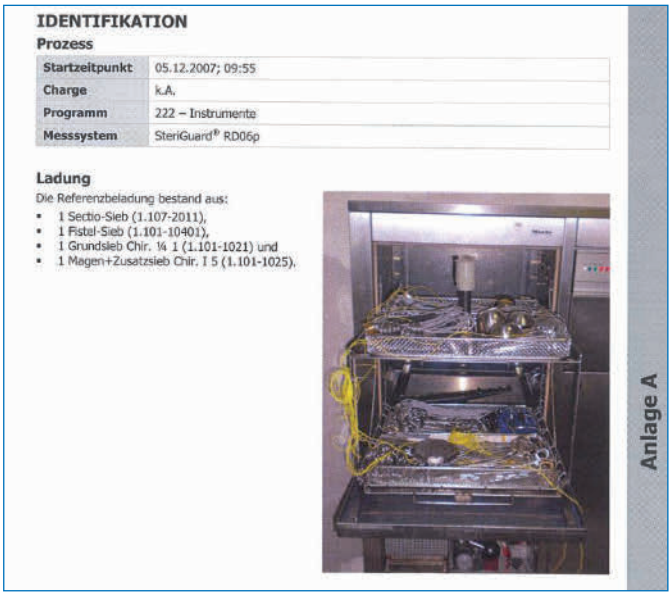
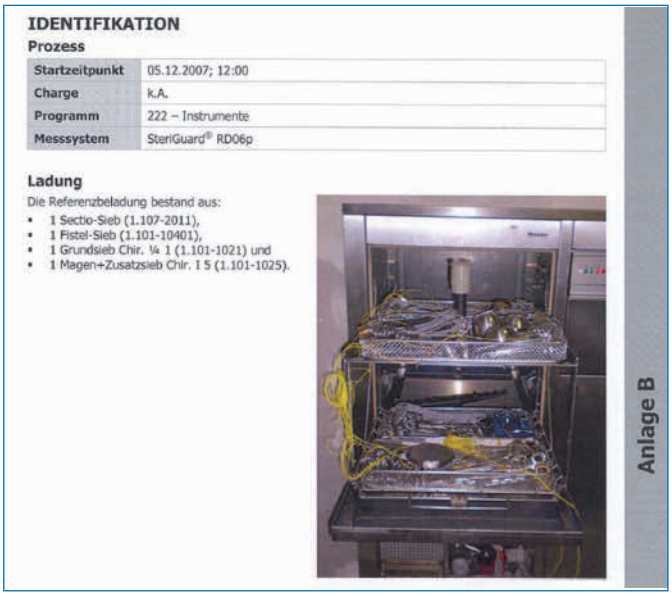


Fig. 1 and 2: Reference loads tested at validation with obvious underloading compared with actual routine loads

Dr. Winfried Michels, c/o Miele Professional, Carl-Miele Str. 29, 33332 Gütersloh; Germany
E-mail: winfried.michels@miele.de





that do not properly represent reference loads because they are underloaded. However, about 20 % of loads in the reports we looked through may represent actual credible reference loads, as for example Fig. 3. For a further 20 % however this is doubtful. What is the cause of this? Because of low availability of instruments soiled by actual clinical use (as opposed to routine loads) the test or reference load is reduced or it is simply not possible to assemble the three test loads necessary for validation (for repeated performance qualification just 2 loads). It also became apparent that at least one tester resorted to crude dishonesty. This author saw one test report from a testing laboratory, where all three tested loads A, B and C were absolutely identical. Both the documentation of the sieve baskets and the photos were identical. The fact that the cables were lying in identical positions in the sieve was the final proof that all three cases were in fact the same load. Evidently the reference load had only been photographed once and copied for the two other loads (Figs. 4 – 6). For a validator given the job, making the journey and then finding an inadequate situation, it is quite understandable that they would rather not make a fuss and start an argument. The job is then done

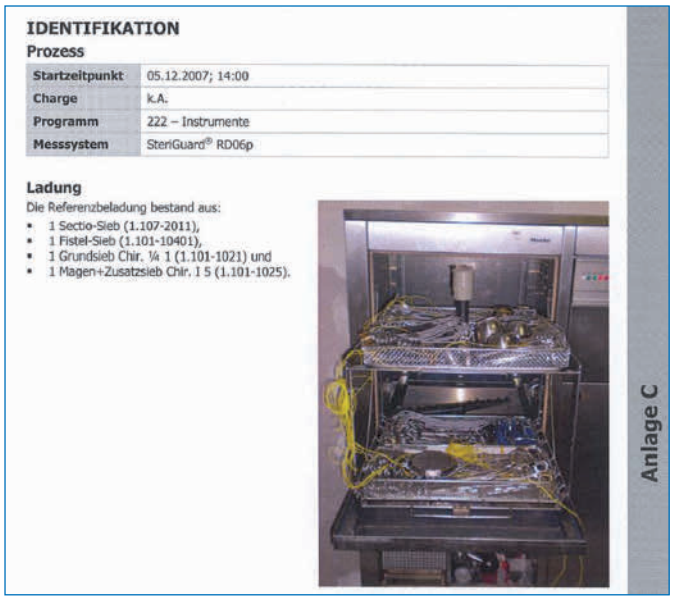


Fig. 4, 5 and 6: Faking of three test loads by copying («copy and paste»)

Fig. 7 and 8: Sieve baskets/loaded carriers encountered routinely

somehow, with compromises having far-reaching consequences.
It is understandable that the procedure of the validation job should take place as amicably as possible so that the client is equally satisfied with the test result and the validation performance. No validator carrying out the possibly regular check as a regular job wants to face a conflict. The employee makes the journey and discovers the inadequate situation regarding the test load. But he feels forced to complete the job somehow. So as a service provider he sometimes makes compromises which are not beneficial to the actual point of the validation. Of course the same can apply to other problems on site, when (travel) costs are calculated without the job (validation) being done, for example appliances turn out to be defective or in need of service.

For the performance test there is rarely a responsible CSSD person motivated enough to see to it that a really typical workday load is tested. Actually it is essential that the reference load to be tested is determined between the expert department (CSSD) and the validator. For the performance test the motivation of all concerned is focused on obtaining a «positive» report, in which the fulfilment of the acceptance criteria is certified and a «pass» is obtained. But validation is not something that is «passed» but stands as proof of a test which is certified independently of the result.
When putting together a test load, meticulously trying to prevent overloading and the creation of rinse shadows, avoiding testing problematic instruments, or excluding cases where an unacceptable result is likely and/or ignoring instruments that can't be easily sampled (e. g. medullary drills), is not constructive. It is quite common to come across a routine load that very probably would not have had adequate cleaning results and for this very reason is badly in need of testing as Figures 7 and 8 show.
It is important that in the future everyone involved makes more of an effort to put together reference loads for realistic performance tests, despite organisational problems and difficulties with capacity, so that the test loads approach more closely those routinely encountered. Only then can the results of the performance test reflect the assumed results in everyday operation. ■

Different load carriers and different configurations of loads may lead to different qualities of cleaning results (see our draft proposal for ISO 15883 in the German mirror committee of DIN 2009) (top: Miele, Steelco, Getinge [left to right], bottom: Getinge, Belimed, Webeco [left to right])

Time recording when using loaned instruments

From delivery to sterile presentation

A. Hartwig

Loaned instruments (LIs) are being used increasingly when, for example, the medical devices/instruments needed for a particular operation are not part of the respective medical establishment's inventory and their purchase may not be cost-effective, or they are used for the purpose of trying out novel surgical techniques.

While that approach has economic and scientific benefits for the medical institution on the whole, it represents a considerable additional burden for the Reprocessing Unit for Medical Devices (RUMED).

This comes into play in particular when the LIs are supplied for the very first time to the medical institution since, first of all, all relevant data must be entered, recorded and documented. If the registered LIs are supplied on a regular basis to the RUMED, it will be easier to manage them when they are delivered to the department.

In both cases more than one entire reprocessing cycle must be carried out each time the LIs are used for a patient. As such, the efforts undertaken are greater than for the establishment's own complement of instruments.

Within the framework of a quality management (QM) and staffing analysis carried out for a medical establishment, we recorded the time investment for managing LIs supplied for the very first time to that institution, while itemizing the subprocesses from delivery/receipt until sterile presentation.

In our example the extra time needed to deal with LIs was not less than 6.5 hours. For greater transparency, we opted for an ideal situation where each work step was performed immediately after the preceding step (i. e. without any breaks, interruptions, waiting time, etc.); we also rounded seconds up or down to the nearest minute.

We will now start by citing an extract from our QM standard for management of LIs: «*In principle, LIs must be handled and reprocessed with the same care as the establishment's own instruments. LIs must be delivered at least 24 hours before they are used for a patient. The leasing firm must be requested to supply a delivery note, packing lists, reprocessing instructions and operating instructions. In general, LIs must undergo an entire reprocessing cycle as per the manufacturer's instructions before they are used for a patient. Conduct of a test sterilization cycle is recommended; this serves to verify the drying results. Reprocessing is carried out in accordance with the risk classification system used for in-house instruments, using validated processes*».

Fig. 1: Delivery of loaned instruments in transport crates

Time sequence from delivery/receipt to sterile presentation based on the example of 'unknown' loaned instruments

08:00 to 08:05: receipt of delivery (5 minutes)

In its capacity of user, the operating room (OR) has ordered the LIs from a leasing firm. The leasing firm entrusts a transport company with direct delivery of the LIs to the RUMED. The RUMED accepts the delivery, checks the delivery note and signs the receipt. This calls for interdepartmental cooperation! The competencies are set out clearly in advance (QM). Who is responsible for what? All subsequent activities are executed by the RUMED personnel as illustrated in this example.

08:05 to 08:25: delivery of LIs (20 minutes)

In general a delivery consists of several transport boxes/crates (Fig. 1). The boxes contain the LIs and industrially sterilized implants. The content of each box is not recognizable from the outside. Therefore the seals must be removed first of all (two seals per crate). Next one crate is opened after the other and arranged in terms of their contents. The sterile implants are left in the crates and are set aside separately. The LIs are taken out of the crates. Caution! Sometimes individual instruments are placed between the implants!

08:25 to 08:30: delivery of LIs (5 minutes)

The LIs are placed on a RUMED trolley (cart) after removal from the crates.

08:25 to 08:30: delivery of LIs, documentation (5 minutes)

Delivery of the LIs is documented on the 'LIs' QM form. The following data are recorded: number of implant crates, number

Antje Hartwig, CLEANICAL® GmbH
Im AUGUSTA-Hospital, Scharnhorststr. 3,
10115 Berlin, Germany
E-mail: info@cleanical.de

of LI crates, and number of LI trays from the crates, number of individual instruments and completeness of the documents supplied.

08:30 to 08:35: receipt of LIs, transport (5 minutes)
The LIs are transported on the RUMED trolley to the RUMED office, while taking the necessary hygiene precautions. The transport crates with the sterile implants are transported to the OR, while taking the necessary hygiene precautions.

08:35 to 09:05: receipt of LIs (30 minutes)
It takes 15 minutes to enter data on the LIs into the IT documentation system in the RUMED office. Each individual tray features a barcode label. The individual instruments are assigned a cumulative label in this example. A further 15 minutes are needed to photograph all trays. The photos are assigned to the respective tray as recorded in the IT documentation system and then saved to ensure that the LIs can be properly packed.

09:05 to 09:10: weighing the LIs (5 minutes)
The trays must be weighed (validated processes; Fig. 2). One tray should not exceed 12.5 kg (thus validated in this RUMED). The weights are recorded in the packing list.

09:10 to 09:12: transport and receipt of LIs to the washer-disinfector (WD) (2 minutes)
The LIs are transported on the RUMED trolley from the RUMED office to the unclean area of the RUMED, while taking the necessary precautions.

09:12 to 09:27: cleaning/disinfection of LIs in WD (15 minutes)
The trays are registered in the unclean area by scanning them into the IT documentation system (3 minutes). Next, the LIs on plastic trays are transferred to stainless steel/wire mesh trays (Figs. 3, 4). The plastic trays are cleaned and disinfected separately in the WD (in accordance with the manufacturer's instructions).

09:27 to 09:51: cleaning/disinfection of LIs (24 minutes)
The trays with the LIs may be pre-treated in an ultrasonic bath before automated cleaning/disinfection (note the manufacturer's instructions!). Sonication takes at most 3 minutes. Only one tray may be placed in the ultrasonic bath for each sonication cycle. Around 24 minutes should be calculated from an average of eight LIs trays from one loaned system (8 times 'tray in/tray out').

09:51 to 09:59: cleaning/disinfection of LIs, intermediate rinse (8 minutes)
The deposits resulting from ultrasonic treatment and the processing chemicals from the ultrasonic bath must be thoroughly removed and hollow cavities flushed. Some instruments must be brushed before thorough intermediate rinse.

09:59 to 10:04: cleaning/disinfection of LIs, load batch (loading) trolleys (5 minutes)
After receipt, pre-treatment and intermediate rinse, the trays containing instruments that have no hollow cavities are placed on the WD loading trolleys. Instruments with hollow cavities and lumens must be connected on a special WD loading trolley, while using the appropriate connectors (internal flushing). This takes 1 to 5 minutes depending on the task.

10:04 to 10:05: cleaning/disinfection of LIs load WD and batch documentation (1 minute)

Fig. 2: Weighing the loaned instruments

Scan: employee code, WD task, all trays. The data are transferred to the IT documentation system and documented. Then the loading trolley is wheeled into the WD, the WD is closed and the process started.
10:05 to 11:35: automated cleaning/disinfection, process (90 minutes)
In this example the process cycle time is 90 minutes per batch.

11:35 to 11:36: WD release (1 minute)
Open WD, wheel out loading trolley and scan again: employee code, WD task, all trays. This procedure is repeated for each IT workstation to assure continuous documentation from receipt to presentation of the sterilized medical devices, and is also done for LIs.

11:36 to 12:16: packing (40 minutes)
After release of automated cleaning and disinfection, the WD loading trolleys are transported to the packing station and all instruments are removed for packing. The empty loading trolleys are transported back to the unclean area (return conveyor belt). The packing task starts by scanning again: employee code, packing task, and all trays one after the other. When a tray

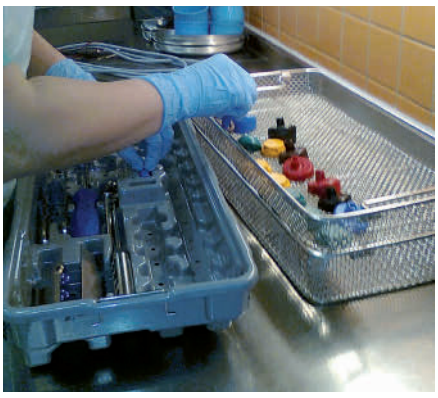


Fig. 3: Unpacking the loaned instruments

Fig. 4: Plastic tray is not suitable for reprocessing loaned instruments

Fig. 5: Storage place for the loaned instruments' roller containers and transport crates

is scanned, the corresponding packing list and/or packing photo is displayed on the screen. The LIs are packed in accordance with the saved lists and/or photos. After scanning, the scanner is placed on the workstation. The data are transferred to the IT documentation system and documented.

All trays (in this example 1 system with 8 trays) are managed as follows:

- Inspect for cleanliness and dryness
- If necessary, assemble dismantled instruments
- Functional test
- Instrument maintenance/care
- Check for completeness
- Wrap trays in two sheets of wrapping paper
- Seal packaging with sterile adhesive tape
- Label tray by affixing a label
- When finished, place tray in a sterilization basket
- Place basket with tray on the sterilizer loading trolley
- Individual instruments are shrink-wrapped in a sterile barrier system in addition to protective packaging.

Once the packing process is complete, a barcode label is affixed to each tray and also to the individual instruments

12:16 to 12:18: sterilization of LIs, loading (2 minutes)

The sterilization task starts again with scanning: employee code, sterilizer task, for all trays one after the other. The batch (load) content is displayed on the screen, it is checked, the loading trolleys are wheeled into the sterilizer and the latter is started. When loading the sterilizer, attention must be paid to the load configuration used at the time of validation.

12:18 to 13.48: sterilization of LIs, process (90 minutes)

In this example the (sterilization) process cycle time is 90 minutes per load.

13:48 to 14:18: cooling down (30 minutes)

Before release, the sterile supplies are allowed to cool down on the sterilizer outfeed conveyor belt in the sterile supplies' store.

14:18 to 14:28: release of sterilized LIs (10 minutes)

Supplies are released in accordance with the procedural directives. All trays are checked:

- Packing items dry?
- Packaging items and seals intact?
- Labels present?
- Have indicators changed colour?
- Have the process parameters temperature, pressure, time been observed?

Next comes documentation in the IT documentation system as well as electronic batch release. Scan: employee code, release task, for all trays.

14:28 to 14:33: consignment of LIs, verification storage, presentation (5 minutes)

For consignment, the scanned batch content is checked again against the trays on the loading trolley to ensure that all trays have been fully recorded. Then the sterilized trays are stored in the sterile supplies warehouse until the time of the scheduled operation or they are taken directly to the OR; this is done by loading the case cart for the OR and placing it in front of the operating room (theatre).

Returning the LIs

Following the surgical procedure, the LIs must once again be subjected to an entire reprocessing cycle (around 4 hours) regardless of whether they continue to remain in the medical establishment or are returned to the leasing firm.

If the LIs are returned to the leasing firm after an operation, following complete reprocessing (i. e. after sterilization and cooling down!) they are packed again in the leasing firm's trays, transport crates and roll containers, and checked for completeness (in accordance with the delivery note). A form attesting to reprocessing must be filled out and enclosed with the returned items. The internal documentation must be completed, the packed transport crates and roll containers must be made available for collection, and collection arranged in accordance with the respective establishment's procedures (approx. 1 hour).

Summary

An unknown loaned system as described in this example containing eight instrument trays takes at least 6.5 hours to process from delivery/receipt (08:00) to sterile presentation (14:33).

Following the surgical procedure, the LIs are returned from the OR, reprocessed and returned, with all this taking around 5 hours.

In total – including pre- and postsurgical reprocessing – the time invested for management of loaned instruments for a surgical procedure is thus around 11.5 hours.

For known LIs, the 30 minutes invested in recording data at the administration workstation in the RUMED office (generating labels, photographing, entering data into the IT documentation system, weighing) can be dispensed with.

The time needed for organizing the storage space must also be taken into account when managing LIs. The empty transport crates, trays and roller containers belonging to the leasing firms must also be stored somewhere. Not many RUMEDs have enough space for these additional storage needs (Fig. 5).

More than one loaned system is delivered some working days, and not just from one leasing firm! Besides, many loaned systems are composed of more than eight trays. ■

Decision criteria for selecting the «right» closed trolley system for an optimal reprocessing cycle

M. Kögel

Users/reprocessors in clinical practice face a major challenge in choosing the «right» closed structure trolley system for the optimization of the reprocessing cycle, due to the complexity of this topic and the many detailed points to be considered. The following deliberations outline the main issues in this context and summarize the most important criteria in the form of a checklist. The selection process of the right (hospital-specific) logistics system is thereby objectified and proceedings with potential suppliers in this area become much easier.
In today's hospital environment, the «right» logistics systems become increasingly important. With their help internal hospital processes are optimized, which facilitates the daily routines in the hospital in general. The target within the reprocessing cycle lies in the achievement of a closed process chain, taking into account the highest standards of hygiene.
Especially in the process step of sterilization and the associated interfaces, it becomes increasingly important to quickly transport the reprocessed/sterilized medical devices in a sheltered environment from the (internal or external) reprocessing site to the operating theatre without recontamination. The protected transport of contaminated medical devices from the application site to the reprocessing site is equally important.
In order to determine the optimal logistics system, designed for a particular hospital, there is a number of considerations to be made prior to the purchase decision.
Besides a wide range of different market suppliers, who differ in reliability, quality and price levels, the first choice to be made is between the two basic trolley design variants «stainless steel and aluminum».
Transport systems made of stainless steel are characterized by a significantly higher temperature and chemical resistance compared to aluminum products. Thus stainless steel trolleys can be reprocessed more intensely and at much higher temperatures than a comparable aluminum version. Transport systems made of aluminum, however, as provided for example by Kögel, are characterized by their significantly lower weight. Aluminum trolley systems are lighter by a factor of 1.5 – 2.5 than a comparable steel version. They enable a more agile transport behavior, which provides a significant relief in daily clinical routine, especially when fully loaded. The corresponding weight savings do not just bring about ergonomic benefits, but also reduce the transport costs between external reprocessors and the hospital. The ergonomic advantages simplify the daily handling of the transport systems and support the hospital operator in obtaining the performance and good health of his employees. An important point in favour for the aluminum version is the price, which is usually lower than it is for a comparable steel version.

Fig. 1: Closed transport trolley system with flexible and fixed inner frame manufactured by Kögel

In addition to defining the outer material used, an aptitude test for the transport system is important, for transport between external reprocessor and hospital or only for internal transport. For optimal protection of the cargo, the castors and the locking systematics need to be determined accordingly. Furthermore, it should be specified whether a logistics system is required with removable or fixed inner frame. Flexible inner frames in the form of a car-in-car or a shuttle system are very well suited for case-specific delivery of the various operational areas, ensuring a process-optimized and, above all, hygienic delivery of the processed instruments into the surgical area.

At the same time the subsequent collection of the contaminated instruments is also greatly simplified. The following checklist summarizes the main options in the choice of the required transport system and thereby facilitates the internal specifications of the clinic, with or without subsequent tender, as well as the discussions with potential suppliers. ■

Mathias Kögel, Kögel GmbH, Hagenfeldstr. 4, 75038 Oberderdingen, Germany
E-mail: m.koegel@mk-koegel.de.

Checklist: Choosing the right trolley system

Question	Variants	Comment
Topic 1: Capacity		
How should the trolley be used?	• internal and/or • external transport	
What material design is preferred?	• stainless steel • aluminum	
What is the corpus stability? (torsional stiffness) Can the trolley e.g. easily be opened and closed at max. loading and on uneven terrain?		
What are the special requirements regarding the cleanability of the trolley?	• wipe disinfection • tunnel washer suitability • sterilisability	
In how far have sharp edges and undercuts been avoided by the manufacturer in order to improve handling safety and cleanability?	• design of the trolley's and door's interior sides (seamless construction) • surrounding door seal for max. dust proofing and reduced recontamination	
Which missed areas/rinse shadows are to be expected? (In the interior, on the doors or between the body and the doors)		
Is residue-free drying ensured within the trolley?		
Required dimensions/capacity of the trolley? Are containers/baskets in DIN or ISO dimensions stored/transported? Is a combined storage/a combined transport of DIN and ISO containers required?	• 3 STE* • 6 STE* or • 9 STE* * STE = Sterilguteinheit, being a rectangular form of 60 × 30 × 30 cm and a total volume of 54 liters	
Are there plans to use the trolley as a case trolley in the OT?		
Which loading weight per compartment is needed for the trolley?		
Topic 2: Reprocessing Requirements		
Which pH values are currently used as part of the cleaning process?		
What cleaning agents are currently used for reprocessing?		
Is tunnel washer suitability of the trolley necessary?		
Are the trolley or (if applicable) the inside cart to be sterilized?		
Topic 3: Detailed design		
Were measures taken to improve the water flow from the trolley roof?		
Is the trolley rainwaterproof? (important for external reprocessing)		
How much noise does moving the loaded trolley create?		

What locking sytematics are required?	• easy twist lock hole for seal • lockable lock • 2-point central locking	
Is a movable inner frame required?	• Shuttle Car-to-Car System • transfer trolley (movable in one or in two directions) • unloading platform • solid inner frame	
Is a circumferential door seal for optimized dirt protection required?		
Are circumferential wall guards or bumper guards necessary?		
Should the inner rack be adjustable in height? If so, with which spacing?		
Should the mobile inner frame be able to be moved along and/or across?		
Is a pull-out stop function for the transported containers required?		
What are the specific requirements for the coupling mechanism between transfer trolley and cabinet trolley for removal of the slide-in rack to provide for a maximum of handling safety?		
What kind of castors is required?	• 2 steering castors and 2 fixed castors • special abrasion resistance • central braking • fixable castors specifically for the use in a train or in combination with pass-through cabinets • sterilizable castors • antistatic castor design • positioning of the castors (parallel arrangement or crossover position for simple turning during standstill)	
Is train operation required/provided for?		
Required opening width and lockability of the doors?	• 255° and/or • 270°	
Is individual color coding required e.g. for identification of case trolleys?		
Which uneven grounds must normally be crossed?		
Topic 4: Required accessories for rationalization/facilitation of processes:		
Which accessory equipment should be included for the clinical routine?	• tow-bar and drawbar • add. friction damped tow-bar for swerve-free train operation • A4 label frame • A5 label frame • clipboard • earth cable • central brake • wheel brake • directional lock • vertical or horizontal push handle (on one or both sides) • height of handle position • support grids • wire baskets • support plate (possibly with holes) • containers • gallery on the roof of the transport system as an additional storage area • additional coding e.g. within the bumper strip	

To explore new paths – an obituary

Wolfgang Klün (24.7.1945 – 4.6.2014), Managing Director of ebro Electronic 1994 – 2011

T.W. Fengler

Can business partners be friends? This question came to my mind when I learned of his death. Wolfgang Klün has in his time as CEO of ebro Electronic contributed significantly to the improvement of the reprocessing of medical devices, by promoting the introduction of data loggers for process monitoring during reprocessing. Under his leadership, ebro Electronic developed into a leading company in the field of metrology for CSSD, food industry and pharmaceutical industry. It is thanks to him that ebro data loggers have become indispensable today for German CSSDs.

In FORUM Volume 16 (2012), Wolfgang Klün reflected on his life's achievements under the title «The history of the ebro thermo logger», and told to some extent his own story.* We would like to once again call to memory some of the most important stations.

Klün worked in the sale of data loggers since the mid-nineteen-seventies, when these devices were still far from being handy (but rather filling the boot of a car). They cost a small fortune and were used for example in automotive manufacturing. Klün observed several innovations in data loggers (miniaturization, temperature resistance, electronic data storage) as well as the development of the company ebro, from a producer of television lights and power devices, into a driver of innovation (1989 first battery-powered temperature logger TEMPTIMEM).

It was the birth of the first ebro thermologger. The first applications for the new technology were temperature monitoring for refrigerated goods, and from 1990, process monitoring during pasteurization (with the data logger EBI 85) or sterilization of food (with the EBI 125, with a range of up to +125 °C). Using data loggers it was now possible for the first time to carry out validations and the daily routine monitoring for food manufacturing processes, without having to rely on a validation system with wired thermocouples. This facilitated the handling while avoiding cable tangle. While new applications for the EBI 125 were explored in the pharmaceutical industry, Wolfgang Klün took over the management of ebro Electronic. In 1998 ebro developed the software Winlog 2000, the first software in Europe that fully met the FDA-standard.

The technical inspectorate TÜV Süd certified and validated in 1998 for the first time a logger system pursuant to this standard. From 1999 Klün began with the development of a new application area for data loggers in the CSSD, as only chemical or biological indicators were used for routine checks of processes in steam sterilizers or WD. «Live»-monitoring of physical parameters instead of endpoint determination by a color change! «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», said Klün upon looking back. «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.»

So it was perhaps no surprise that ebro was quite unsuccessful at the Medica exhibition in 2000. But the right mix of tenacity, strategic skill and chance made the

business idea of thermologgers for process validation succeed at last.

A first major delivery to the CSSD of Aachen University helped to make routine clinical monitoring of reprocessing processes by the data logger a subject of discussion. This was followed by collaborations with various consultants and manufacturers of autoclaves and WD. In 2001/2002 the legal basis for medical device reprocessing in Germany was laid down with the introduction of the MPG (Medical Devices Act), the Medical Devices Operator Ordinance (MPBetreibV) and

* Klün, W: The history of the «ebro thermologger» – from nobody to market leader. In: FORUM Medical Devices & Processes Vol. 16: 20–23.

Dr. med. Dipl. Ing. T.W. Fengler, CLEANICAL® GmbH, Im AUGUSTA-Hospital, Scharnhorststr. 3, 10115 Berlin; E-mail: info@cleanical.de

the «Hygiene requirements»-guideline of Robert Koch-Institute (RKI), respectively. The requirement for a «suitable validated method», in particular, was tailor-made for the benefits of the data logger over static chemical or even delayed biological indicators. The A_0-value concept was introduced successfullly through ISO 15883 and replaced biological indicators completely.

At that time many sterilizers had no recording system, so that the ebro thermologgers were used there, too, for pressure and temperature monitoring. The software solution Winlog.med was specifically designed for the users in the CSSD, to create the possibility of a simple routine check. Within five years, ebro Electronic GmbH became the market leader for thermologgers for CSSDs all over Europe. «Many CSSD staff members spoke about 'the ebro', a term that was now synonymous with a thermologger.», as Klün remarked later.

This was followed by further development and innovation: flexible temperature sensors and wireless real-time measurement (radio thermologger), the expansion of the measuring ranges (the EBI 10 temperature ranges from –80 °C to +400 °C and has a pressure range from 1 mbar to 4000 mbar), a validation software that meets the requirements of ISO 15883 and ISO 17665 as well as an inexpensive electronic Bowie-Dick test (EBI 15) according to ISO 11140-4.

When Wolfgang retired in 2011, ebro Electronic was a completely different company, with a global orientation and over 100 distributors worldwide. Intensive business contacts with China and various lecture tours since 2005 enriched our consulting work on a personal level and demonstrated his predictive vision. He offered his experience and opinions, said out loud what he was thinking. No ifs and buts – always authentic, whether he was happy, serious or angry (which he could never keep up for long).

Life-affirming as he was, he allowed to others, he certainly demanded a lot, but also offered a lot. I gladly remember the business meetings, for example, on the Danube, to which he invited us from Berlin. Those who knew Wolfgang Klün appreciated his positive attitude, he radiated warmth, made one feel comfortable.

His openness and transparency and the way in which he conducted business was unusual and characteristic of his work. For him, the customer was always at the center of attention. I can remember him saying on several occasions: «Impossible is nothing». It was not just a slogan, it was his credo. He was a real heavyweight, who had threatened «to go to his knees» for some time, in the truest sense of the word; he had difficulties walking. But when he did fall, it was differently than expected, and now he is gone.

To explore new paths. ■

The historic Kaiserin-Augusta-Hospital comes to new life

R. Graeber

The FORUM booklet that you hold in your hands is the first Best-of-volume that we have completed at our new place of work, because CLEANICAL Berlin has moved and now resides at the new top address of the Berlin medical-technology landscape: Since October 2013 KARL STORZ uses the renovated and modernized former Kaiserin-Augusta-Hospital (Empress Augusta hospital) as its new Berlin corporate site. The historic charm of the building, built in 1868, has been preserved as part of the renovation and skillfully enhanced with contemporary elements. Then as now, medicine and its use for the benefit of patients are at the center of the building use. The medical history is thus preserved and continued into the future in an altered form.

It is an interesting and varied history, that highlights some of the great subjects in German history since the founding of the German Empire. It begins, as so often, with a war: The foundation of the former hospital in 1868 is traceable back to an initiative of the Queen of Prussia and later German empress Marie Luise Augusta Katharina, the wife of Wilhelm I, who was particularly committed to the promotion of charitable institutions. The house was built to designs by the architect and building inspector Hermann Blankenstein (who has planned many important public buildings in Berlin), for the Berlin Frauen-Lazareth-Verein (women's military hospital club), which was under Augusta's protectorate. The building stood on land provided by the War Department. Founded in the war of 1866, the Lazareth-Verein continued their activities even after the end of the war. During the Franco-German war, the Hospital admitted numerous german and french wounded – an effort for which the matron of the hospital, Countess Rittenberg, later received the War Commemorative Medal for non-combatants, and the Cross of Merit of France. So while it was initially focused on the care and treatment of war wounded, the scope did soon broaden to encompass the «promotion of general health care.»

The foundation of the house falls into that first heyday of Berlin between 1870 and the First World War, when Berlin enjoyed a worldwide reputation as a «health city», which attracted the most prestigious international practitioners, and in the center of which stood the Charité with its 1,500 beds. But unlike the latter, which had originally been founded as a plague house, been used as a shelter for the homeless temporarily, and finally became a hospital of the poor and «helpless» (i.e. acutely ill), the Augusta Hospital served as a small hospital (85 beds) for the high society early on. Inpatient treatment of non-acute illnesses was at that time still a novelty, many private clinics were only just emerging. Close contacts with nearby Charité (it is only a 5 minute walk) existed from the beginning, including some overlapping in staff: Oscar Fraentzel, for instance, was directing physician at Augusta Hospital from

Fig. 1: Former Augusta-Hospital, as it looks now

Ronald Graeber, CLEANICAL® GmbH
Im AUGUSTA-Hospital, Scharnhorststr. 3,
10115 Berlin, Germany
E-mail: info@cleanical.de

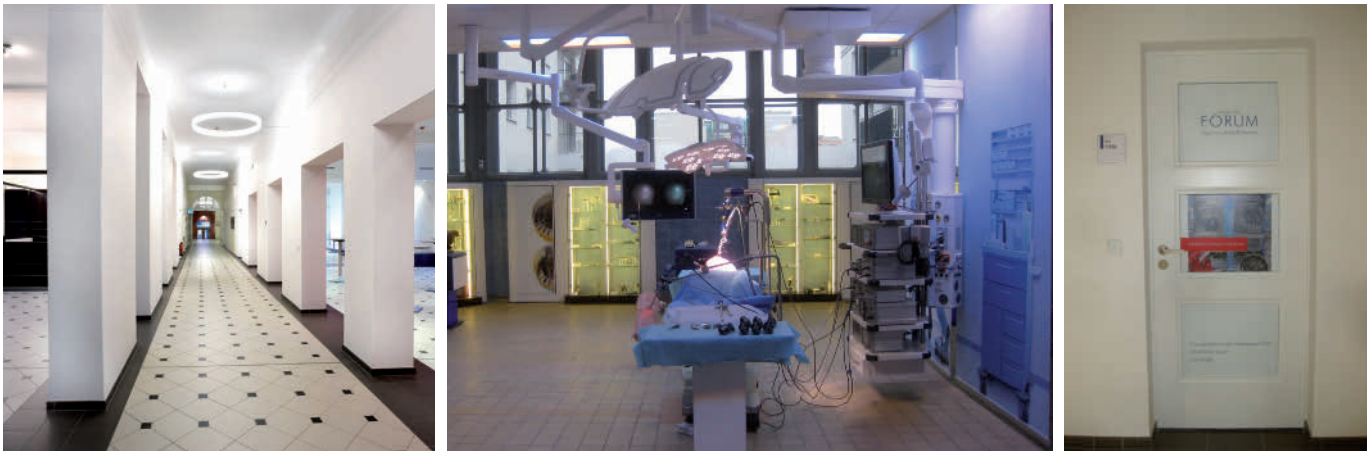


Fig. 2: Modern MedTech in a historic setting – an inspiring contrast.

1869 to 1873 and directing physician at the Charité from 1870.

In 1871, Ernst Küster took charge of the surgical department of the Augusta Hospital, began to realize his ideas of antisepsis and asepsis in wound treatment and thus became a pioneer of Lister's ideas («antiseptic method») in Germany. Empress Augusta herself repeatedly denied the appointment of Küster to foreign chairs in order to keep him in Berlin and at the Augusta Hospital.

After the First World War, the sisterhood of the German Red Cross took over the hospital and remained there until 1945. During that time the building was extended with another central wing, additional floors and side wings and successively took on the current U-shape.

By 1935, the department of internal medicine of Augusta-Hospital was dedicated to the treatment of digestive diseases and digestive tract disorders under the leadership of chief physician Schlayer. Schlayer and his assistant medical examiner Joachim Prüfer were among the major sponsors of creating the profession of «dietician».

During the Second World War the building was severely damaged, and then only repaired, but not historically reconstructed. The hospital as such was dissolved by the Soviet occupation forces. The Berlin Red Cross nurses lost several important partners due to the division of Germany, because the Municipal Hospital in Ruedersdorf, too, was now in the Soviet occupation zone, later in the GDR. While at first some sisters still lived and worked in the East and could reasonably freely visit their mother houses in West Berlin, this came to an end with the construction of the Berlin Wall in August 1961. Not before 1998, a memorial to the nurses of the hospital was re-erected on Invalidenfriedhof (invalids cemetary), just opposite the house. The building of the Augusta Hospital was given to the Charité as a substitute for their Radiotherapy Clinic, occupied by the Soviet headquarters. The Charité set up their orthopedic clinic there, with 50 beds initially, which remained there until 1982. Reconstruction and expansion of the house went on for decades and were not completed in 1963. It was not until 1959 that the clinic was united with the polyclinic under one roof and the number of beds rose to 155.

Since 1982 the Charité were using the old hospital only as an administrative building, until use ended altogether in 1995.

After a prolonged vacancy KARL STORZ purchased the building in 2010. After a construction period of almost two years, the house now shines in new splendor: on 8,000 m^2 premises were created, in which the company brings together several departments and offices, that were scattered across Berlin, its subsidiaries and affiliated companies (including ourselves). It will be used for sales activities, repair services and the development of clinical software, in order to take advantage of shorter routes and improved interfaces. In addition, the house will serve as a venue for training courses and thus is open to medical professionals and organizers of training events as a meeting place where to hold lectures, watch live surgery broadcasts and conduct endoscopic training with innovative equipment.

Fortunately, the owners have spared no effort in conservation and so aspects of history are ubiquitous when walking through the building. From the bullet holes in parts of the facade, over the ironwork in the stairwells and on the elevators to the conserved devout verses on the bathroom walls (Fig 3): Put your trust in the Lord/He gladly helps us; Rejoice, ye righteous:/the Lord helps his servants. ■

Fig. 3: Edifying words behind glas: «Rejoice, ye righteous: the Lord helps his servants.»

“Cleanliness at Work” –

with quality products from KARL STORZ

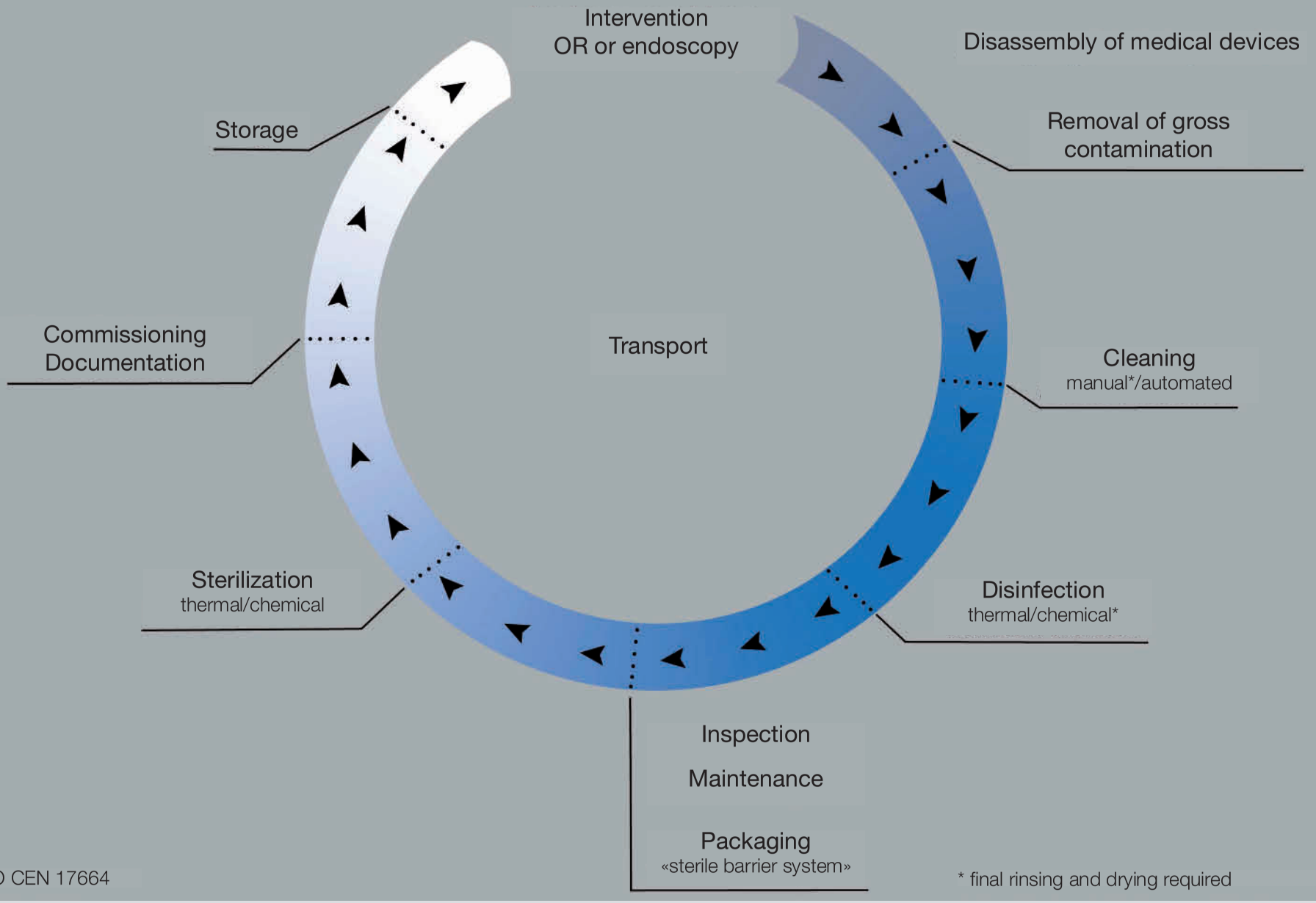
More information on “Hygienic OR Products“ from KARL STORZ at www.karlstorz.com

STORZ
KARL STORZ — ENDOSKOPE
THE DIAMOND STANDARD

KS 79 02/2014/A-D

KARL STORZ GmbH & Co. KG, Mittelstraße 8, 78532 Tuttlingen/Germany, Phone: +49 (0)7461 708-0, Fax: +49 (0)7461 708-105, E-Mail: info@karlstorz.com
KARL STORZ Endoscopy America, Inc, 2151 E. Grand Avenue, El Segundo, CA 90245-5017, USA, Phone: +1 424 218-8100, Fax: +1 800 321-1304, E-Mail: info@ksea.com
KARL STORZ Endoscopia Latino-America, 815 N. W. 57 Av., Suite No. 480, Miami, FL 33126-2042, USA, Phone: +1 305 262-8980, Fax: +1 305 262-89 86, E-Mail: info@ksela.com
KARL STORZ Endoscopy Canada Ltd., 7171 Millcreek Drive, Mississauga, ON L5N 3R3, Canada, Phone: +1 905 816-4500, Fax: +1 905 858-4599, E-Mail: info@karlstorz.ca
www.karlstorz.com

Quality cycle of instrument reprocessing



→ ISO CEN 17664

* final rinsing and drying required