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For the Users‘ Benefit

Three leaders in innovation have been collaborating for 30 years in the field of flexible endoscope processing

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Hope Exchange Programme 2017

S. Kauertz

HOPE is the acronym of the European Hospital and Healthcare Federation, which was founded in 1966. It is an association of European hospitals. HOPE promotes improvements in the health of citizens throughout Europe. HOPE takes part in various scientific health-related projects that are partly funded by the European Union.

This year I was lucky enough to take part in the HOPE EXCHANGE PROGRAMME 2017.

This is a European exchange programme for professionals working in the management sector of the healthcare field. The programme has been in existence since 1986. This year there were about 200 participants from all over Europe. The programme consists of a 4-week stay in a European country. It seeks to transfer knowledge among European countries and help participants gain an understanding of the various healthcare and hospital systems in Europe. The idea is to swap ideas and forge contacts.

I was lucky enough to be given a placement in Sweden and got to know an unbelievably patient-orientated system. The patients receive only what they actually require.Local care is not quite so easily accessed as in Germany, but the Swedes don't complain about travelling 300 km to a suitable hospital.

Of course emergency care is more rapidly accessed. Swedes also have a different set of expectations concerning their health than Germans do. A Swede is happy if he or she visits the doctor with a problem only to be told everything is alright. In Germany, patients are more likely to want a pill for their problem or at least further tests.

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Fig. 1: Dirty reprocessing room in a 350-bed clinic

Fig. 2: Pass-through endoscope cleaning and disinfection machines help prevent cross-contamination

Fig. 3: Modern endoscope storage in special drying cabinets

Fig. 4: Dirty reprocessing area in a small clinic

Fig. 5: Unsuitable endoscope storage

During my stay I was able to visit several endoscopy departments and realised that of course in Sweden they also have hygiene guidelines. However, their implementation quality varies quite widely. Of course I was particularly interested in the reprocessing of endoscopes, and I came across ultra-modern ones as well as departments I would describe as "antediluvian". To give you an impression of what state-of-the-art reprocessing looks like, I photographed the dirty side of the reprocessing room in a hospital (Fig. 1 and 2) that deals with about 5000 endoscopes annually.

Storage of endoscopes in Olympus drying cupboards (Fig. 3)

However I had a very different experience visiting a private hospital that only carries out planned investigations and does not deal with emergencies. An impression is given by Figs. 4 and 5.

At this hospital the assisting personnel did not know the dosage of the pre-cleaning solution, nor was a leakage test performed during reprocessing. Endoscopes were stored in a wooden cupboard. The personnel in the department had no specific training for working in endoscopy. However, I was assured that they did know that endoscopes should be stored more optimally and that a new cupboard had already been ordered.

The nurses had just come back from a congress promoting a method of cleaning where foam balls of different diameters are pulled through the endoscopes - this instead of brushing them. This new method was apparently based on the most recent research. I was astonished, as the vendor was a German firm and I had never heard of this method, nor can I believe it is efficacious. In the

Fig. 6: Modern reprocessing in the CSSD

Fig. 7: Packed surgical supply carts in the CSSD

Fig. 8: Surgical container storage in the CSSD

meantime I contacted the firm in question to find out what scientific findings are the basis of this method and why the foam balls are not on the market in Germany. So far I have had no reply.

So it is apparent that even in Sweden not everything is optimal, but I must reiterate that this was a private hospital, of which there are only a few in Sweden, as the Swedish Hospital also views the concept very critically. During my exchange I was also able to get to know the CSSD of a 350-bed hospital, which was optimally organised.

Reprocessing was conducted using ultra-modern equipment. (Fig. 6)

Here all types of instruments were reprocessed and complete surgical trolleys were packed. Everything needed for a particular operation was put in the trolley including gloves, gowns etc. so that the operating theatre itself did not need a store room storeroom. (Fig. 7)

There were special parking spaces for the packed trolleys and signs hung from the ceiling showing the operation the trolley was packed for. Each speciality had a different colour.

The instrument storage box store seemed gigantic to me and more suitable for a 1000-bed hospital. (Fig. 8) The boxes themselves were also colour-coded colour-coded according to the speciality departments.

The CSSD storage room was organised on rails to save space. Each cabinet section could be pushed automatically to the right and left, so that space could be optimally utilised. (Fig. 9)

There are 20 of these cabinets that can be moved individually on rails, allowing for free movement among them. Up to now I have seen this in use only in archives. Throughout the entire CSSD, dust suction devices were attached to the ceilings, as is now the norm in modern operating theatres. They are the grey hemispheres seen on the right of the ceiling lights in Fig. 9.
Furthermore trolleys with spare supplies for the operating theatres of the various speciality departments were packed here. (Fig. 10)

There are packing lists stored in the computer for each trolley and these can be printed out as necessary.
The CSSD personnel have a large screen where they can see the status of each operation in each operating theatre and so always know what needs delivering to a particular operating theatre at a given time. (Fig. 11)

Overall I must say it is an excellent method of organisation, providing maximum relief to the personnel working in surgical preparation.
Ten members of the staff ten members of staff work in this department from 7:30 to 17:00. Outside these times the on-call staff take over to ensure prompt reprocessing.
The staff in the CSSD are mainly nurses, particularly male nurses who formerly worked in operating theatres. In Sweden there is not yet a special job profile for personnel in the CSSD.

My conclusion:

The sojourn in Sweden was very worthwhile. I got to know a very staff-orientated health system, where the pay is no better than in Germany, but working conditions are generally a dream. My other colleagues from Scotland, Spain, Holland and Italy all shared my opinion – we had been in paradise for 4 weeks.

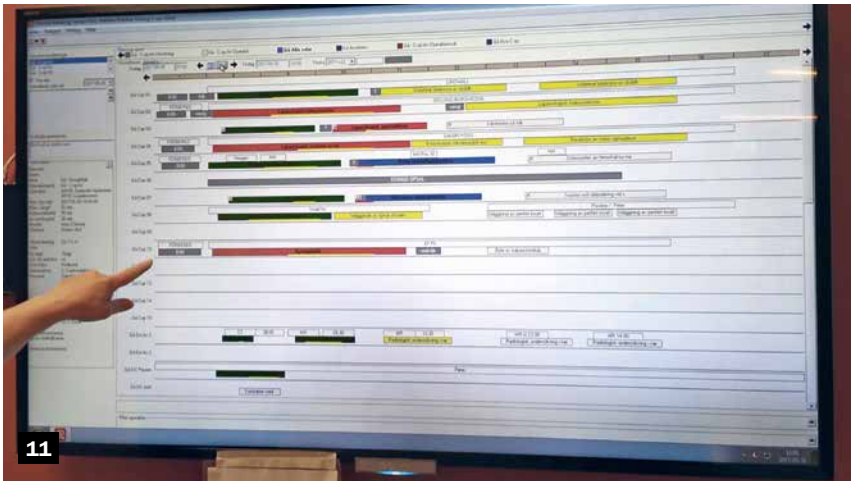

Fig. 9: CSSD storage; optimal use of space

Fig. 10: Replacement supply carts, which are loaded in the CSSD

Fig. 11: Overview of in-progress and planned surgeries

A formula for success: three leaders in innovation + one partnership = 30 years of success

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When Ecolab, Miele Professional and Olympus agreed 30 years ago to work together in the field of flexible endoscope reprocessing, the three companies made a far-sighted strategic decision. It led to the development of a partnership that continues to set new standards in hygiene for hospital endoscopy departments and endoscopic medical practices by constantly optimizing the all-important aspects of patient and user safety as well as the development of efficient processes.

Leveraging synergies is the goal of every partnership. Achieving this goal requires the partners to use those synergies in a way that enables each to complement the others. The protagonists of the partnership in the success story here started out strong in this regard, and today they continue to bring together the expertise of their three companies, leaders in three very different fields. Ecolab provides guidelines and ideas for the prevention of infections. Its work is based on highly effective cleaning and disinfecting products, for use in areas from hospital wards to operating rooms to central sterile processing departments.

> It started with a converted dishwasher and the glutaraldehyde (GA) disinfection process.

Miele Professional contributes its knowledge about high-performance, durable mechanical technology. Such technology is based on resource-conserving production processes and leads the way with regard to sustainability and innovation.

Olympus, the third member of the group, is known in the medical technology world for top quality and innovation in endoscopic equipment. Both characteristics are basic prerequisites for ensuring that the circuit from a clean endoscope to an unclean one and back functions optimally and without interruption.

The three companies started in 1987 with a converted dishwasher and the glutaraldehyde (GA) disinfection process. 17 years later, the innovative peracetic acid (PAA) process was introduced in addition to the classic GA process.

Perfectly coordinated systems

That represents an important innovation in mechanical endoscope reprocessing, because it makes it possible to lower the temperature to 32 °C in the disinfection step, meaning the endoscopic materials are exposed to less stress.

Today, users can work with the fourth generation of this under-table machine, and with systems that are perfectly coordinated with only another. Highlights of the ETD4 include its cleaning chemistry, the quality of the mechanical reprocessing and the exceptional user-friendliness and high degree of process reliability.

The latter is possible because all relevant reprocessing parameters are monitored. Flow control ensures that blockages are reliably recognized and that all channels of the endoscope are rinsed out. Thanks to RFID chips installed in the endoscopes, reliable tracking of reprocessing to the patient has now become the gold standard in endoscopy.

The high point of the partnership to date: the ETD Double

In the ETD Double, clinics and specialty practices have access to a pass-through endoscope reprocessing machine. This makes possible strict separation of the clean and unclean sides. It is thus a member of the newest generation of cleaning and disinfection equipment and is the logical next step in the ETD systems. Special attention is paid to the disinfection tests in the machine. Only real endoscopes are used, never "dummies."

Many innovations are aimed at maximum efficiency along with greater user convenience. The best example is in the handling. Baskets are loaded and endoscope channels are connected at the work table, so the processes are comfortable and take place entirely outside of the machine. This means that operators can already fill the next baskets while the machine is still running. No additional connections are needed inside the machine. Thus idling is also reduced to a minimum.

Moreover, connection of the various ports of the endoscopes to the relevant adapters is both simple and safe, thanks to colour and mechanical coding. Up to seven endoscope channels can be connected simultaneously; ready-to-use adapter sets are available for Olympus endoscopes and for compatible equipment from other manufacturers. Rapid-connection technology also saves additional working time.

Figure 1: Ease of operations and handling, yesterday and today. Here's how an ETD2 was loaded in 2001.

To 30 more years

All components that are used undergo rigorous testing and further development so that the benefits are available in all systems. The progress that is made affects processing chemistry as well as the technology of the entire range of automated equipment.

For example, the introduction of peracetic acid (PAA) can be considered another milestone in the partnership. PAA is especially efficient, acts on a broad spectrum of microorganisms and meets all relevant European standards.

In addition to shorter processing steps, another benefit of PAA is that it is neutral and thus particularly gentle on materials, which has a positive effect on the life span of the endoscopes undergoing reprocessing.

Figure 2: Today, an ETD Double has completely different components; the working steps are no longer comparable.

Figure 3: There are also big changes in the operating elements. The comparison shows the programming of an ETD2 in 2001 with a supplemental module for documentation using a hand scanner...

From generations 1 to 4 of ETD to the introduction of PAA or of ETD Double in endoscopic departments, users' positive reactions and the associated commercial successes consistently show that Ecolab, Miele Professional

> Ever more efficient cleaning processes make an important contribution to patient and user safety.

and Olympus are, thanks to ever more efficient cleaning processes, making an important contribution to patient and user safety in mechanical endoscope reprocessing.

From this perspective, the partnership certainly seems very well prepared for new challenges in endoscope reprocessing and for another 30 years of successful work together in the hygiene field. |

Figure 4: ... and the programming of a current ETD Double using a touch screen.

Visual routine control of sterilization containers

J. Schnurbusch

The question about visual checks of sterilization containers is always a hot topic in the processing of surgical instruments. Therefore, systems were taken randomly with different lifetimes from a process to verify them on their microbial integrity. In this process, the sterilization containers are strictly checked visually at each packing process. The results show that there were observed no growth of microorganisms during the tests. So, a visual inspection of the critical areas to evaluate the functionality of a sterilization container seems to be sufficient.

Problem

Again and again the question arises in practice, like container systems can be checked even after years of use regarding their functionality. This is discussed at conferences and in the literature, a variety of test methods are used to test especially the tightness and the sterility integrity. In most cases, these tests are limited to testing the tightness of the system and are difficult to do or limited applicable in practice. The applicability is mainly complicated, when using different types of container systems in a CSSD. An exclusively visual inspection of the components of a container system for assessing the functions will also be challenged. The question is whether visual inspections are actually sufficient, or if reliable test methods in daily routine must be worked out for container systems.

Investigation concept

Because of this, we have tried a differentiated approach at the University Hospital Basel. For containers in accordance with EN 868-8: 2009 maintenance steps are indicated. These maintenance steps are generally limited to visual inspections of critical areas or parts. In addition, manufacturers recommend to perform these checks before each reuse, so at each packing process. In certain defect images a repair or replacement of the affected parts is necessary.

To clarify the question of whether these suggested visual inspections are sufficient for guaranteeing the functionality, we have developed a random study.

In total 6 containers of different ages were taken under a random procedure from the CSSD process. The University Hospital of Basel is using 2 containers of different development generations. This made it possible for us to easy identify differently aged systems. So we have taken container, which had already a real lifetime of 5-9 years.

These containers were then sent to the Institute of Microbiology and Hospital Hygiene at the University of Anhalt, with the aim to show the effectiveness of the sterility integrity during a storage period of 4 weeks. This test is usually used by manufacturers of containers to simulate a shelf life in a highly contaminated environment. This test is also known as the so called Aerosol test and was developed by Prof. Junghannß et al. Therefore, it seemed reasonable to us, to use this already practically relevant and accepted test procedure for the investigation.

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Process description of using the tested containers

Description of the reprocessing cycle

The University Hospital of Basel decided several years ago that containers are to be used for sterile packaging of instruments where possible. This is due to the simple and safe handling, the robustness of the material and not least for ecological reasons. In the packaging of individual instruments or bulky materials other packaging materials such as pouches or nonwoven are used. The containers are used for the supply and disposal alike. They are reprocessed about 200-250 times per year.

Picture 1: Critical areas, which should be tested during visual inspection

Cleaning and disinfection

The cleaning and disinfection of the container is carried out exclusively by machine. Generally we are using a multi chamber washer and disinfector but partially we are using s single-chamber W&D as well.

A mildly alkaline solution with a ph value of about 10 is used. The A0 value for the reprocessing of the container is at least 600, wherein the used process is significantly higher.

Routine visual controls during packing

Since the used containers are equipped with a lifetime barrier system, the visual control is limited to a secure fit and the integrity of the barrier. The container itself is visually inspected for defects, such as a non-planar upper edge (rim) or other deformations. If the container rim is misused as storage for instrument trays, the top edge of the bottom can show small notches after a period of time. This notch with appropriate depth may degrade the performance of the gasket. Even such containers were used for the testing procedure.

With the container lids, the gasket and the closure requires special attention. Especially with the slightly recessed gasket must be checked visually. However, the surfaces must be inspected for very fine hairline cracks or other material changes.

In total, the visual routine inspection shall include in each packing process the following steps:

- Secure fit of the microbial barrier
- Gasket is fitting completely on the bottom
- Closure mechanism is working and without defects
- No surface changes, or if yes, evaluation of surface changes
- No cracks
- Container not deformed
- Rim of the bottom without any defects

Sterilization

The containers are steam sterilized at 134 ° C and stacked together. Thereafter, a parametric release of the sterilized material is performed.

Storage and transport

Picture 2 shows the storage after the sterilization. The containers are stored until use or transport to the operating theater in this way.

Picture 2: Storage conditions of the sterilized items

Laboratory testing

Testing description

The test material comprises 6 containers, as described in the table below. The containers were filled with an assortment of surgical instruments.

Size of container	Type of loading	Age in real years	Age in real cycles	Description in test
60 × 30 × 16	Surgical instruments	5	approx. 1,000	01 – 06
60 × 30 × 16	Surgical instruments	5	approx. 1,000	02 – 06
60 × 30 × 16	Surgical instruments	8	> 1,600	03 – 06
30 × 30 × 16	Surgical instruments	5	approx. 1,000	04 – 06
30 × 30 × 16	Surgical instruments	>5	> 1,000	05 – 06
30 × 30 × 16	Surgical instruments	>5	> 1,000	06 – 06

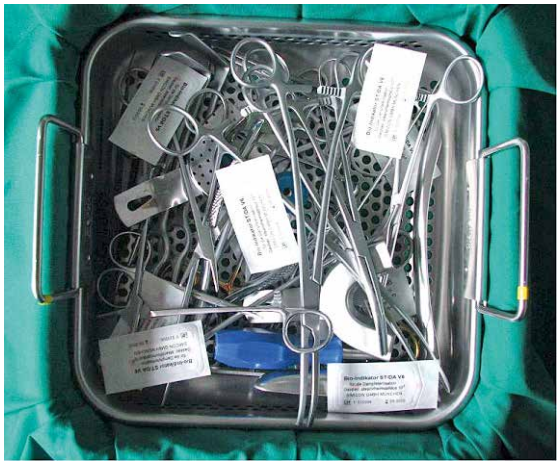
Table 1: Listing of the tested containers

Experimental design

The fitness of the containers for sterilization and storage was tested. According to that, they were tested to integrity and functionality following the intended use. Every container was fitted with 10 biological indicators in accordance to the standards EN 866-1, EN 866-3, EN ISO 11138-1 und EN ISO 11138-3, based on the organism Geobacillus Stearothermophilus. The spores used had a spore density of 1.8 x 106 CFU / biological indicator with a D121°C value of 2.3 +/-0.2 min.

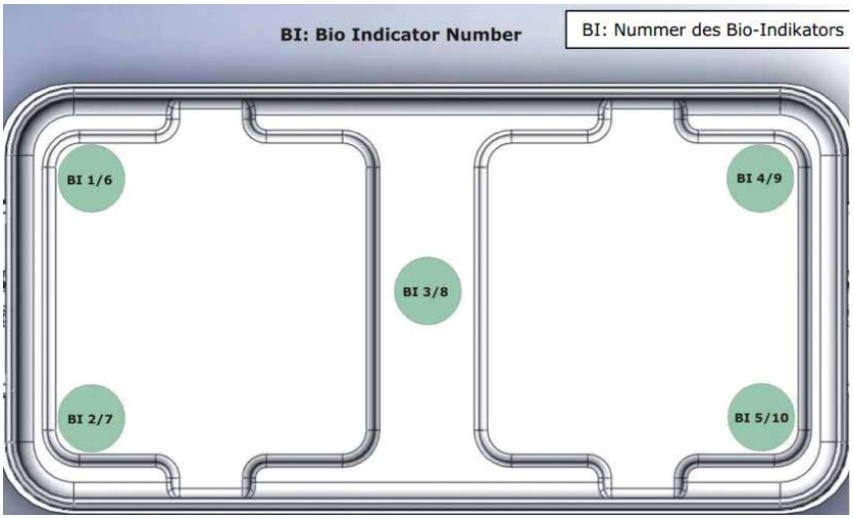
The containers were filled with baskets containing general surgical instruments and each fitted with 10 biological indicators. Pictures 3 and 4 are showing the loading of the baskets for each size. Pictures 5 and 6 are showing the placement of the biological indicators in the containers.

Picture 3: Loading for 60x30 Container

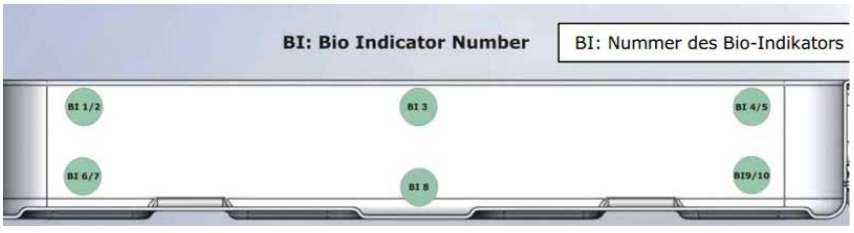


Picture 4: Loading for 30x30 Container

Picture 5: Positioning of bio indicators (view from above)



Picture 6: Positioning of bio indicators (side view)



The containers were then steam sterilized with 134 °C, 2-bar, 5 minutes.

After the sterilization all containers were sprayed with Bacillus subtilis (109cfu/ml) spore solution in an unventilated room. The room was also sprayed with this solution. The containers were stored in the same room for four weeks. During this period the aerosol with the Bacillus subtilis spore solution was again sprayed in the room.

Evaluation and result

The containers were opened after four weeks and the biological indicators were removed under sterile conditions and incubated in a spore suspension for seven days at 55 °C ± 1 °C.

In addition, 10 contact samples per container were taken from the interior of the container (nutrient medium: casein tryptic soy peptone agar with disinhibitory agent). The samples were incubated for seven days at 36 °C ± 1 °C.

No growth of bacteria or fungi was observed on the samples.

Contact samples were taken twice during the storage period and immediately before opening the container outside the sterile barrier as a positive control for the presence of Bacillus subtilis and other bacteria and fungi. Indicators from the same production batch as the indicators used for the test were used as the positive control of the biological indicators. Growth was confirmed with all positive indicators.

Table 2 shows the evaluation after 4 weeks for each container.

Conclusion

The positive result of the shortened shelf life test in a highly contaminated environment shows that the arbitrarily selected container with a usage period from 5 to 8 years are still an effective packaging system for sterility integrity and no bacteriological disturbances inside the container have occurred. As routine checks, only visual controls in each packing process find application. This is an indication that the performed visual inspections of critical areas during each packing process may be sufficient to check the container for their safe functionality. Therefore, it's all the more important, to precisely do those visual inspections to send critical container for repair or to replace parts accordingly. Additional tests of containers with respect to the functionality of the gaskets and the integrity of the container system appear to be unnecessary even after years of use, according to the present study.

Literature:

Überprüfung von Sterilisier-Containersystemen: Prof. Dr. U. Junghannß, S. Winterfeld, Hochschule Anhalt, Köthen; L. Gabele, U. Kulow, Aesculap AG & Co. KG, Tuttlingen; Zentralsterilisation 7 (1999), 154-162.
DIN EN ISO 11607-1
DIN EN ISO 11607-2
DIN EN ISO 17665
ANSI/AAMI ST33
United States Pharmacopeia, Current Edition
AAMI CDV2/ST77
DIN EN 868-8

Description in test	Spore Strip No.										10 impression preparation samples										Negative growth control	
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**1**	**2+3**
01-06	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	growth	growth
02-06	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	growth	growth
03-06	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	growth	growth
04-06	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	growth	growth
05-06	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	growth	growth
06-06	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	growth	growth
0 = no growth																						
growth = heavy growth																						

Augsburg Hospital uses pass-through appliances to reprocess flexible endoscopes

C. Roth

In large medical institutes all over Europe there is an obvious trend towards using pass-through appliances for cleaning and disinfection of flexible endoscopes.
The Endoscopy Centre at the Augsburg Hospital is no exception here. The endoscopy department is part of the 3rd Medical Clinic, which specialises in Gastroenterology and Infectiology.
This centre is one of the largest endoscopy centres in the whole of Germany, carrying out, for example, over 18,000 interventions in 2014. Recently, the reprocessing of the required endoscopes has been carried out using two new Olympus pass-through appliances. The report describes the experience of staff using these appliances, type ETD Double, since they were introduced.

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At first glance, the main distinctive feature is that the new automatic endoscope washer-disinfectors (WDEs) are six foot high, and thus effectively separate the dirty from the clean side.
Further inspection reveals new and different loading and unloading technology, particularly in comparison to the smaller appliances reminiscent of dishwashers and washing machines. But the WDEs type ETD Double have another novel feature- just one of these appliances can reprocess three endoscopes simultaneously.
According to Rita Hieber, the head Endoscopy Nurse at the 3rd Medical Clinic at the Augsburg Hospital, it was partly the increase in throughput of endoscopes that made it easier to plump for this solution. "Large"

Fig. 1: The new ETD Double from Olympus at the Centre for Endoscopy of the Augsburg Hospital: large capacity and hygiene security thanks to parallel reprocessing of three endoscopes per WDE

Fig. 2: Rita Hieber, head specialist Endoscopy nurse at the 3rd Medical Clinic of the Augsburg Hospital

is certainly a suitable term for Rita Hieber's employer. This tertiary care hospital in Augsburg consists of 26 clinics and institutes. "We assist doctors from seven of these clinics in the Endoscopy centre of the 3rd Medical Clinic", she explained.

Out of the aforementioned 18,000 interventions in 2014, 6,150 were oesophago-gastro-duodenoscopies and over 3,700 were colonoscopies. In addition there were 1,150 ERCPs, 40 enteroscopies and 870 bronchoscopies, not to forget 730 flexible endosonographs and more than 4,200 sonographs. These numbers are reflected in reprocessing. According to Rita Hieber, because several endoscopes can be used per patient per day, on average 60 flexible endoscopes are cleaned, disinfected and made available in pristine condition for their next deployment, every single day.

Figs. 3–6: Top left: After a successful training phase using the practice basket with an adaptor plate for endoscopes, all the work steps in loading and unloading the ETD Double are easily performed
Top right:
The pass-through principle with strict separation of clean and dirty sides
Bottom left: The display with A and B user levels, is operated by touchscreen and users find this reduces their workload considerably
Bottom right: The high performance pumps of the ETD Double along with the use of peracetic acid combine to produce excellent cleaning and disinfecting results (Photos: Olympus, Soenne)

More than 30 years of experience with WDEs

Since the Augsburg Hospital was opened in 1982 the technical facilities have been significantly improved.
To begin with, reprocessing was carried out manually, then developments led initially to the introduction of semi-automatic appliances and wall-mounted models with pipe systems. According to Rita Hieber, staff from Olympus in Augsburg were always on hand during this process of automisation. "We could always rely on the quality of the appliances, whether for semi-automatic appliances, or in more recent years, the fully automatic WDEs".
When I asked her about the new set-up, she said the decision-making process for pass-through appliances had been significantly advanced by planned conversion work on the hospital building. But the hospital management and those responsible in the department had been considering this technology for some time. After all, said Rita Hieber, the separation of the clean from the dirty side is recommended in the Robert Koch Institute Guidelines. The commercial regulatory authority of the administrative region Schwaben in Bavaria is in agreement with this view for consultancy and building regulations.
Modifications like those made in the Endoscopy Department at Augsburg are being made at the moment at many similar health institutions all over Europe. It is ever more common for the central sterile services department (CSSD) working as an internal or external service, to guarantee the cleaning, disinfection, care, sorting, sterilisation and provision of medical products.
As a manufacturer of flexible as well as rigid endoscopes and the necessary endotherapy equipment for interventions, Olympus knows the users‘ requirements and since the introduction of the pass-through appliances of type ETD Double, they provide the system solution wanted by many hospitals, from a single source.

Augsburg Centre for Endoscopy- also innovating in reprocessing

Professor Dr. Helmut Messmann, Head of the Endoscopy Centre and Head of Department at the 3rd Medical Clinic, along with his team of doctors and nursing staff, has made it his motto to integrate relevant progress for patients in the individual specialities gastroenterology, hepatology and rheumatology as fast as possible into the hospital routine. The same applies whenever possible to medical technology. The Endoscopy Department of the Augsburg Hospital cooperates closely with Olympus by intense activity in further training as well as the development of new Endoscopy techniques, for example endoscopic submucosal dissection. That is why the company has partnered the architects and the planning office since 2010, even before the first plans for the departmental refurbishment had been drawn up.
This is a fact that Rita Hieber views positively and sums up in one sentence: "If one manufacturer makes the flexible endoscopes as well as the reprocessing appliances, then compatibility is guaranteed. " There was a lot to be done before the new pass-through appliances could be put into service.
The ETD Double required a detailed project plan and more bespoke work than any previous solutions. This comprised in particular the installation of afferent media in the form of various types of water along the ceiling, the installation of drainage under the flooring as well as an adequate supply of pressurised air.

Simple operation, improved documentation, more safety and ergonomics

Such a complex system demands a thorough introduction and training phase. Rita Hieber explained that this was completed in several steps.
First of all, the management team of nurses from the Augsburg Hospital travelled to the manufacturer in Hamburg to be introduced to the material at their Training Centre. After this initial phase, the team were given a cleaning basket including an adapter plate for the endoscopes, so that the on-site staff in Augsburg could practise using them. Rita Hieber sees this practice phase as an important step, because the connecting mechanism for the endoscope in the appliance is newly configured compared to the previous device. She would recommend it to other hospitals and doctors' surgeries, if they are considering switching to the pass-through principle. The training phase included learning how to produce provoked faults. This was helpful for the training in error recognition and its correction. Also careful and proper handling had to be learned.
"In particular my younger colleagues, who have grown

up with Smart phones and Touch screens loved the ease of handling. And because the display is mainly self-explanatory, we oldies also manage quite well", says Rita Hieber contentedly. The easy operation continues even in the time after the official Start. So after obtaining validation results as well as consulting and testing with Hospital Hygiene, the first endoscopes soiled through actual use were successfully reprocessed. First of all, gastroscopes and colonoscopes were reprocessed. Then more than six months after its introduction, use was extended to the reprocessing of duodenoscopes with an Albarra channel, bronchoscopes and endosonography appliances.

> By separating the clean from the dirty side, recontamination of the reprocessed endoscopes by not yet processed appliances is ruled out.

Furthermore, the staff have become accustomed to working with the individual programmes. Documentation of reprocessing takes place automatically. This last aspect is a huge improvement. Until recently documentation was stored in patient files in paper form. But in future, documentation will be available in the so-called Netbox, in the electronic patient file in the hospital information system. In the new reprocessing complex progress has also been made from the point of view of patient safety. By separating the clean and dirty sides, recontamination of the reprocessed endoscopes by not yet processed appliances is ruled out.
In particular the ergonomical aspects of the new appliances provide many advantages. Loading the appliance, which takes place outside of the ETD Double, is significantly more efficient and simpler than it was previously.

Peracetic acid is key

After the first few months of operation further advantages have become apparent thanks to the changeover. This is mainly because three endoscopes can be reprocessed simultaneously.
Cleaning performance and the associated greater throughput compared to hitherto, as well as the short cleaning times per reprocessing cycle, are very positive. It is immediately apparent, looking through a glass window on the ETD Double, that there is a high throughput of liquid. The monitoring of individual channels is also very precise. There is a precise protocol of quantity, concentration, temperature and length of individual steps. Rita Hieber also approves of the display, which permanently shows current information in a way that can be easily comprehended and which is later stored in the protocol. This proves helpful for later checks and analyses of the finished processes. In addition, the security of the cleaning process is improved by new canisters that have RFID (radio frequency ID) coding. The appliance recognises automatically whether the date of expiry of the chemical being used is exceeded or not. Rita Hieber thinks the reason for peracetic acid's ascendancy in this area has several reasons. She considers it as excellent, both from the point of view of improving air quality in the room, as well as improving staff safety. She adds "In this case I can confirm the difference to the previous system for my own breathing, because for many years we used aldehydes and I always had a cough."
Furthermore, the broader spectrum of efficacy and the lower risk of protein fixation in the reprocessing procedure are important arguments for the hospital, when choosing the modern type of endoscope reprocessing. Rita Hieber thinks it is not a coincidence that in France, disinfection with peracetic acid is a standard procedure to ensure staff safety. The new throughput control built into the appliances also sets a benchmark. Rita Hieber notices that it brings operators peace of mind to know that all channels are checked and monitored in every reprocessing step. This guarantees that all the necessary components of the endoscopes are reached by the cleaning and disinfecting solution. The new connecting technology with individual channel connections and channel separation, do however require a thorough and intensive training course - a pathway Rita Hieber and her colleagues have successfully negotiated. It will be fascinating to see if the new system becomes established in other large hospitals.
The successful switch and the day-to-day operation showcased in this example (which can also be attributed to the successful partnership between manufacturer and hospital), shows the great innovation potential of the ETD Double through-put appliance. |

How reliable are the alternative Bowie & Dick test systems? On the informational value of electronic and chemical indicators

S. Kirschner, R. Streller

There is a wide range of chemical Bowie-Dick test systems and recently also electronic versions to be found in the highly competitive market place.
But how reliable are they and what informational value do the commonest chemical B&D tests have compared with an electronic system? The aim of the study is to establish how well qualitatively the systems determine effective steam penetration according to the Standard DIN EN ISO 11140-4(1).

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The everyday monitoring of a steam steriliser using the B&D test is still the only way to ensure effective removal of air and effective steam penetration, thus flawless sterilisation. This is clearly regulated by paragraph 12.1.6 of the DIN EN ISO 17665-1(2).

Overview of B&D test variants:

1. The Standard Test Pack

The textile pack, also known as a laundry pack, which corresponds to the original test developed in the 1960s, requires professionally trained personnel. Because it is time-consuming, it is mainly only used for validation.

2. Alternative systems according to **DIN EN ISO 11140-4(1)**

a. Chemical Indicators
For this type of monitoring test strips impregnated with chemicals, test sheets in a test pack or a helix attached to the end of a narrow tube are used. Process steam and temperature cause a colour change of the chemicals on the test sheets.

To rule out erroneous reading of the change in colour when using this alternative test method, the impact time of 210 ±5 seconds must be strictly adhered to. Particular storage conditions and length of storage life must also be carefully heeded. At the end of the B&D test the test strips are appraised visually by the operator and evaluated. Archiving of the sheets as evidence is virtually impossible, as the colouration alters with time.

b. Electronic systems
Appendix B of the Standard DIN EN ISO 11140-4 describes a number of defined test cycles in great detail. Thus a basis is created for electronic logging of all criteria and parameters relevant to the process. Modern electronic systems precisely monitor all the data gathered in this way such as temperature, pressure and time.
Thus they provide a clear and up-to-date evaluation of sterilisation cycles. Their use is also very simple and user-friendly. The operator receives an unambiguous "Pass" or "Fail" result at evaluation, possible causes of faults are also often given. Many electronic systems are tested and certified for effectivity by an independent test laboratory, as for example the EBI 16. (Fig. 1)

Fig. 1: The EBI 16 was tested by an external laboratory according to DIN EN ISO 11140-4(1)

Validation is possible here, in contrast to the alternative chemical system, because the human factor does not affect the evaluation. There are both stand-alone and integrated electronic systems available on the market. The former can be put in the centre of the chamber as described in DIN EN 285(3). For integrated systems this is usually not possible. Permanent and uncritical documentation of the test results is given by all the systems.

Causes of faults

The DIN EN 285(3) refers in Appendix 17.1 to possible causes of a failed BD test:
- ineffective elimination of air
- a leak during elimination of air
- non-condensable gases in introduced steam

Reliable sterilisation is only guaranteed by sufficient

elimination of air and good steam quality. But of course a failed BD test can have other causes. It is often difficult to evaluate the colour change of the test object properly, because not all areas show clear colouration; some systems "pass" the cycle even after a very short impact time or at temperatures that are actually too low. Lastly, wrong use or positioning in the chamber can also be fault criteria. An expert inspection of the entire process allows for possible exclusion of causes.

Test design and sequence

The 4STE is used- a test steriliser made by Lautenschläger of the type CentraCert 3119 with a steam generator ED72 and a gas release facility. Because of the particular design and programming of the cycles described in the appendices B1, B2 and B3 of the DIN EN ISO 11140-4(1) all the sterilisation cycles defined there, whether faulty or error-free, reproducibly be replicated. First of all this was tested with a laundry pack. (Fig. 2)

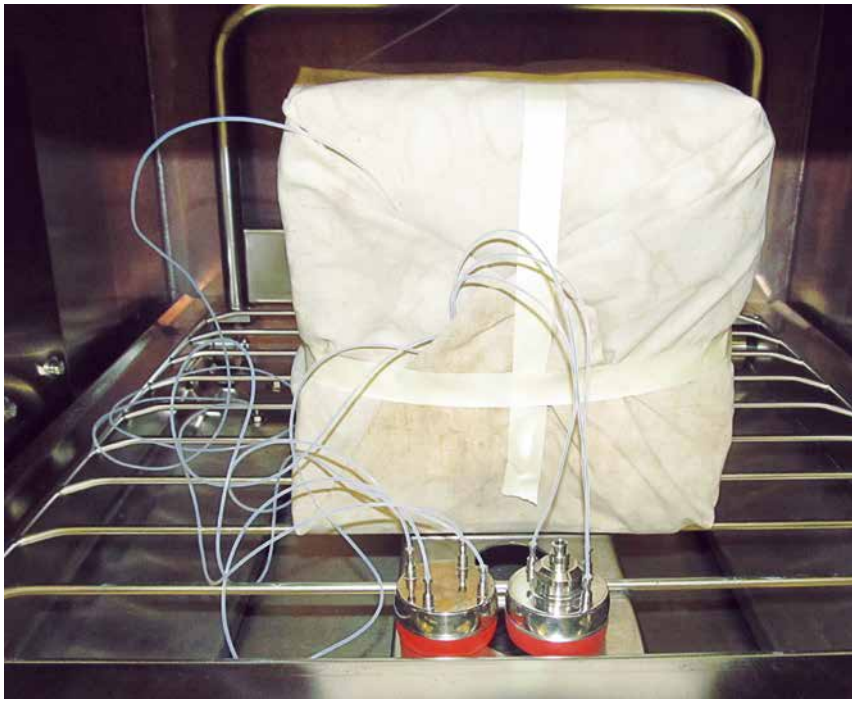
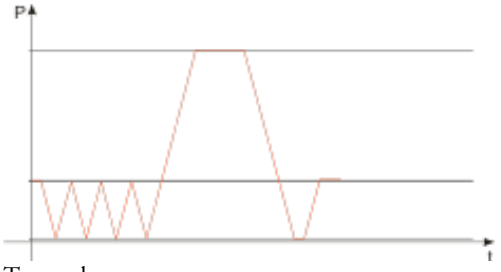


Fig 2: Standard test pack

The three cycles according to DIN EN ISO 11140-4(1)

Appendix B1

Elimination of air by pressure change in a vacuum

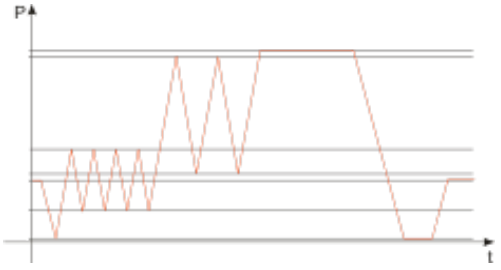


Test cycles:

B1 –Pass / OK
B1 - Leak in evacuation (Error 1)
B1 - deficient elimination of air (Error 2)
B1 - Air injection during heating (Error 3)

Appendix B2

Elimination of air via transatmospheric pressure change

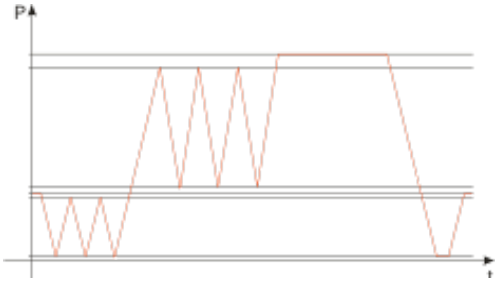


Test cycles:

B2 –Pass / OK
B2 - Deficient elimination of air (Error 2)

Appendix B3

Elimination of air via pressure change at overpressure



Test cycles:

B3 –Pass / OK
B3 - Injection of air during heating (Error 3)

To ensure reproducibility all the tests were conducted three times.

Systems/equipment/devices under test

Various chemical systems were tested
Paper test pack: BD-Test 3M 1301,
BD-Test Browne STE2352AB,
Hollow body system: Melacontrol,
GKE Chemo-D-BDS-1-C-H-EU,
GKE Chemo-D-BDS-1-C-P-EU
as well as the electronic test system EBI 16 by ebro.

The test objects were placed in the centre of the chamber. (Fig. 3a+3b)

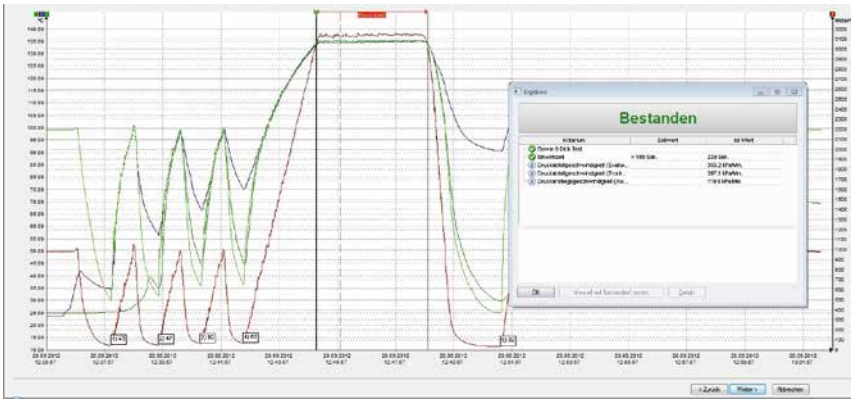
Fig. 3a: Arrangement of 3M, GKE and EBI 16 in the chamber ready for the test

First results and findings

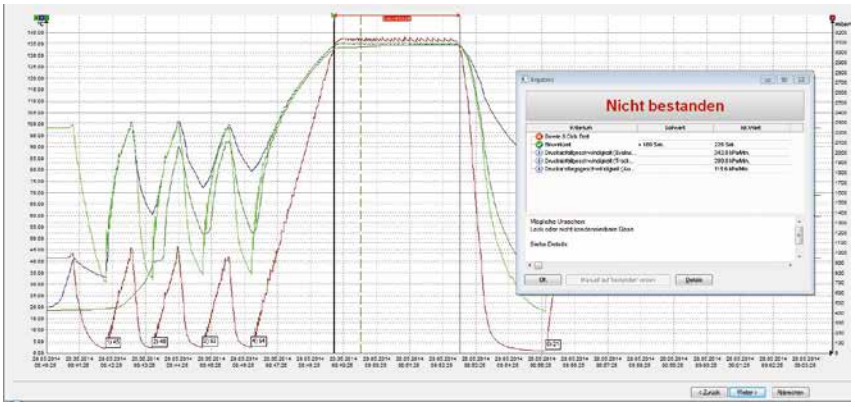
Evaluation takes place after each and every cycle. Here it was noticed that it is sometimes very hard to properly interpret the colour change in the chemical tests. The lighting in the room, or rather having homogeneous lighting is vital for confident recognition. Here, electronic systems offer the advantage of more certainty due to a clear "Pass" or "Fail".

Fig. 3b: Arrangement of Browne, Melacontrol and EBI16 in the chamber for the test

Results of the electronic evaluation using the EBI 16:



Passed with detailed result of the evaluated process parameter.



Failed with detailed result of the evaluated process parameter. Possible causes of fail are also shown

A closer look at the chemical test systems reveals very different results. Some recognise all errors consistently, but unfortunately often only some of the pre-set error scenarios. The only system to provide thorough and coherent recognition was the test pack BD Test 3M 1301.

The electronic BD test EBI 16 recognised and evaluated all standardised cycles correctly.

Impact time as error source

The impact time is also of great importance for the colour change of the chemical indicators. The standards indicate 210 seconds ±5 seconds.
To show the differences in results for a deviation in time, all error cycles were repeated with a foreshortened impact time of 180 seconds as well as a lengthened one of 240 seconds.

There were more frequent errors recognised for the foreshortened impact time. For longer impact times the accuracy drops (Table 1). The systems recognise fewer or different errors.

For the GKE Steri-Record the violet and the blue test objects correspond to DIN EN ISO 11140-4(1), the latter additionally corresponds to DIN EN 867-5(4), the standard for hollow body tests. In the evaluation of an error cycle both systems deliver very different results, which is confusing: the blue system shows an obvious error whereas the violet system has a complete colour change. (Fig. 4) From the table it can also be seen that for the electronic system EBI 16, the impact time has no influence on the result. Because of the different technical implementation of electronic tests, the adherence to the impact time is evaluated differently depending on the measurement system. However, an exact measurement and evaluation of the exposition time is usually possible.

Plateau time 210 seconds in line with the standard

System		Cycle B1				Cycle B2		Cycle B3	
		OK	Error 1	Error 2	Error 3	OK	Error 2	OK	Error 3
Electronic	EBI 16	√	√	√	√	√	√	√	√
Paper	BD test 3M 1301	√	√	√	√	√	√	√	√
	BD test Browne STE2352AB	√	x	x	x	√	x	√	x
Helix	Melacontrol	√	x	x	x	√	x	√	x
	GKE Chemo D BDS 1 C H EU	√	√	√	√	√	√	√	√
	GKE Chemo D BDS 1 C P EU	√	√	x	x	√	x	√	x

Plateau time shortened by 180 seconds

System		Cycle B1				Cycle B2		Cycle B3	
		OK	Error 1	Error 2	Error 3	OK	Error 2	OK	Error 3
Electronic	EBI 16	√	√	√	√	√	√	√	√
Paper	BD test 3M 1301	√	√	x	√	√	x	√	x
	BD test Browne STE2352AB	√	x	x	x	√	x	√	x
Helix	Melacontrol	√	x	x	x	√	x	√	x
	GKE Chemo D BDS 1 C H EU	√	√	√	x	√	√	√	x
	GKE Chemo D BDS 1 C P EU	√	√	x	x	√	x	√	x

Cycle correctly recognised √

Cycle incorrectly recognised x

Table 1: Result overview

Summary

All the systems tested here claim to be in compliance with DIN EN ISO 11140-4(1) according to their printout and data specification. But the results are very different, from conforming with the standard to more or less useless.

DIN EN ISO 11140-4 & DIN EN 867-5

DIN EN ISO 11140-4

Cycle in accordance to annex B.2 "Fail" cycle – modified air removal stage

Fig. 4: GKE

Operators of such systems must find out for themselves, whether the claims of the manufacturer are suitable for the particular appliance and its load within the process, as DIN EN ISO 17665-1(2) clearly stipulates. It does seem most sensible and realistic for an operator to choose a system certified by an independent test laboratory and to trust that. After all, the proper functioning of a reprocessing process is today's basis for the safety of all of us as the patients of tomorrow.

Literature source

(1) DIN EN ISO 11140-4:2007
Sterilisation of health care products- chemical indicators- Part 4: Class 2 indicators as an alternative to the Bowie and Dicktype test for detection of steam penetration (ISO 11140-4:2007); German version

(2) DIN EN ISO 17665-1:2006
Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 17665-1:2006); German version

(3) DIN EN 285:2006+A2:2009
Sterilisation- Steam sterilisers- Large sterilisers; German version

(4) DIN EN 867-5:2001-11
Non-biological systems for use in large sterilisers- part 5: Determination of indicator systems and test objects for the performance test of small sterilisers of type B and type S.

Manual dosing aids in the area of environmental hygiene or manual instrument reprocessing

A. Papadopoulos

There are many dosing aids from the simple measuring spoon, measuring cup to dosing pumps. But exact dosing can usually only be attained by using a dosing device. This prevents over- or under-dosing. Microprocessor controlled dosing devices for preparation of disinfectant solutions feature extremely high dosing accuracy in the adjustment range of 0.25 – 10.0% but with very simple handling. High reliability as well as high accuracy of repeatability is of major importance. The disinfectant is dosed into the through-flow of water in a proportional volume. Supply of concentrate usually occurs via a 5-10 litre container, which can be attached to the stainless steel console on the right or left of the device.

System separation according to DIN EN 1717 offers protection against flow back of disinfectant into the drinking water circulation. Dosing devices such as the ones made by Ecolab are tested by the Federal Institute for Materials Testing (BAM), Berlin, according to the guidelines of the BAM and RKI for disinfectant dosing appliances. The safe operation and robust construction of the stainless steel housing guarantees reliability and longevity. The high level of safety is ensured by:

- Visual control display for dosing operation, operation dysfunction, lack of product or water
- Suction lance with out of product alarm
- Flow rate volume limit by volume regulator
- Automatic stoppage of the device in the case of a power cut, product or water deficiency as well as lack of product flow
- System separation according to DIN EN 1717

The time interval between installation and the first service or between two consecutive services may not exceed 12 months. Servicing of the device, which may be carried out strictly only by trained personnel, usually comprises:

- Testing of concentration
- Testing safety provisions
- Testing leak tightness of all components carrying disinfectant and water
- Checking for damage to electric wires and all components,
- System separation

As a part of servicing it is advisable to conduct microbiological routine tests on disinfectant dosing devices. The drinking water used to produce disinfectant solutions (e.g. in disinfectant dosing devices), is not sterile and can contain pathogens able to cause nosocomial infections. The main pathogens here are Acinetobacter species and Pseudomonas aeruginosa. To recognise possible bacterial contamination and the associated risks in good time, routine microbiological tests are advisable.

Fig. 1: Decentralised dosing device

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The potential pathogens mentioned above are normally reliably killed by the disinfectant. In addition the use of suitable components in the dosing device [1] and regular servicing with testing and replacement of critical water-carrying components reduce possible contamination.

Nevertheless over longer periods or through irregular use of the dosing device or through wrong operation and stagnation, a biofilm can form and so an increase in hygiene-relevant pathogens can occur. These are not always completely inactivated by the disinfectant.

This is why leading hygiene experts from the Robert Koch Institute (RKI) [2], the Commission for Hospital Hygiene and Prevention of Infection (KRINKO) [3], the Society for Applied Hygiene (VAH) [4] as well as the Advisory Centre for Hygiene (BZH) [5] recommend microbiological testing of the disinfectant solution at least annually.

If there are conspicuous findings, then individual components of the disinfectant dosing device e.g. the drain cock or the control panel or other frequently touched or critical areas should also be microbiologically tested for pathogens relevant to hygiene. In principle it is the operator's responsibility to test and ensure the flawless and hygienically safe operation of the disinfectant dosing device.

Through regular servicing, the use of original spare parts and regular microbiological testing of the dosing appli-

Table 1: Specifications for routine dosage testing of decentralised disinfectant-dosing appliances (N/A = not applicable)

	BAM / RKI /KRINKO 2004 [1]	DGHM 2005 [3]	VAH 2013 [2]
Interval	Annually and – Before commissioning – After changing disinfectant	N/A	Bi-annually and situationally according to KRINKO
Range	all devices	N/A	all devices
Type of implementation	Put disinfectant and water into two separate containers; determine concentration e.g. by volumetric measurement	N/A	N/A
Critical value	-0 %/+10 %	N/A	Note manufacturers' instructions

Table 2: Specifications for the routine microbiological monitoring of decentralised disinfectant dosing appliances

	BAM / RKI /KRINKO 2004 [1]	DGHM 2005 [3]	VAH 2013 [2]
Interval	N/A	Annually	Bi-annually
Range	–	Random sampling or all	All
Type of Implementation	–	– Discard first litre – Save next litre – 100ml disinfectant solution + 100ml inhibitor – Stand for 30 min – Membrane filtration – Incubation of filter on blood agar (24-48 h) – Germ count determination	– Removal of the minimum amount stipulated by the manufacturer into a sterile container – Mixing of part of it with inhibitor in a second container
Testing for	–	Any growth in 100ml	Minimal range: coliform, Pseudomonas aeruginosa, Acinetobacter
Critical value	–	Individual evaluation	0 CFU/ 100ml for the above named bacteria

ance and disinfectant solution, possible risks that can lead to nosocomial infections can be recognised early and eliminated. This serves to protect the operator and patients and gives the operator legal security. No coliform bacteria, no Acinetobacter species and no P. Aeruginosa may be shown to be present at the microbiological test. For sample taking it is vital to use professional and standardised methods and to use a suitable neutraliser. Also the following work on the samples must take place in a suitable microbiological laboratory (ideally with its own section for disinfectant testing) conducted using suitable methods and standardised conditions. |

Fig. 2: Decentralized dosing device

Sources:

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[5] Deutsches Beratungszentrum für Hygiene: Überprüfung von Desinfektionslösungen aus dezentralen Dosiergeräten , BZH-Newsletter 12/2012 (Testing disinfectant solutions from decentralised dosing appliances)
[6] Testung von Desinfektionsmittellösungen aus dezentralen Desinfektionsmittel-Dosiergeräten – Vorschlag für eine praxisnahe Methode zur Routinetestung, Johannes Tatzel, Brigitte Bauer, Thomas Regnath, Matthias Trautmann, Hyg Med 2015; 40- 10 (Testing disinfectant solutions from decentralised disinfectant dosing appliances – Suggestion for a practical method for routine monitoring)

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