Das Fachmagazin für Krankenhaus- und Praxishygiene

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28. Jahrgang 2022 | Heft 1

Bilingual

Hygienische Besonderheiten in einer Akutgeriatrie

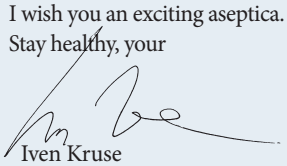
Special hygiene considerations in an acute geriatric clinic

Editorial

Dear readers,

the aseptica, your specialist magazine for hospital and practice hygiene, is not a political magazine, but the current situation in the Ukraine cannot leave us untouched. The suffering of the Ukrainian population as a result of the Russian war of aggression is extreme great and demands our solidarity. The willingness to help in taking in refugees from the war zones and the willingness to donate urgently needed relief supplies are unbroken even after several weeks and are met by a grateful Ukrainian people - I would like to thank you for that.

In the first issue of 2022 in the "Latest News" section, Dr. Kluge Senior Vice President Unit Professional of the Miele Group in an interview about 4 years of Miele & Steelco with the question "what was the most important milestones and moments of this time".
In the "Clinic & Hygiene" focus, Ms. Konschake considered with the manual preparation of beds in hospitals and Dr. Holz, Dr. van den Abeelen, Mr. Kiesel and Ms. Kemnitz-Frahm with the hygienic features in acute geriatrics.
For validators and AEMP management, the article by Mr. Koster, Mr. Wenzel and Dr. van Doornmalen the use of the new NKG sensor for the parametric release of the steam sterilization by measuring the parameters temperature, steam composition and time.
What is meant by the term calibration and why is the calibration of data loggers so important for use in validation? Mr. Streller, Mr. Glaser and Mr. Kruse address with the topic of calibration.
I am particularly pleased to be able to introduce you the company Veolia Water Technologie, a new aseptica partner. The Veolia Group is a leading company in the field of environmental technologies with sustainable solutions in resource management.
The 16th Congress for Hospital Hygiene of the DGKH (www.krankenhaushygiene.de) will take place from May 1st to 5th as a face-to-face event in the Hotel Berlin Central District (formerly the Maritim Hotel) in Berlin.
I wish you an exciting aseptica.
Stay healthy, your



Iven Kruse

Report

More suicide attempts among adolescents in Germany during second COVID lockdown

There was a nearly 3-fold increase in suicide attempts among adolescents aged 12 to 17 years in Germany during the second COVID-19-related lockdown compared with 2017 to 2019, researchers at Essen University Hospital concluded, using data from one-fifth of German pediatric intensive care units. The suicide attempts had mostly involved drug intoxications. Compared with the corresponding periods in 2017 to 2019, the rate of suicide attempts among adolescents in the 1st lockdown was reduced by 32%. The retrospective cohort study of suicide attempts in the 1st lockdown included data from 1,444 admissions to 37 German pediatric intensive care units, representing 21.5% of German pediatric ICU capacity. According to the researchers, pediatric intensive care units are particularly affected by changes in this area because they are often involved in stabilizing patients' vital signs and monitoring them after self-harm and suicide attempts.

Source: aertzeblatt.de

Contents

Miele Group wrap-up – 4 years of Miele & Steelco

An interview with Dr. Christian Kluge, Senior Vice President Business Unit Professional

Miele and Steelco announced in 2017 that they were going to join forces. Steelco has been a wholly owned part of the Miele Group since 2021. How satisfied are you with developments?

Let me start with our motives: By joining forces, we can offer our clients in hospitals, surgeries, the pharmaceutical industry and other branches better and more comprehensive services at very competitive prices. The customer segments and the product ranges of both firms complement each other to a great degree. And there was huge potential to further strengthen each other. Four years down the line, these expectations have been fully vindicated.

It is quite reasonable to expect a character clash between Eastern Westphalia and Northern Italy. How could integration be successful?

Common values are a sound foundation. There were demands relating to long-term customer relationships, the reliability and longevity of our products on both sides – a common understanding under the umbrella of our 'Immer Besser' motto. And, indeed, cultures have to grow together – and we deliberately set aside enough time for this, in an atmosphere of great mutual respect. Today, we are pleased at the level of trust and confidence on both sides and the blend of talents.

What were the key milestones and moments during this period?

Early on in the process, the main milestones were drawing up a joint market strategy and, in 2017, the first joint trade shows, including Medica in Düsseldorf. Worth mentioning, too, are the first products which we each built for the other partner respectively, for example our large-chamber decontamination unit with its patented Pulse Power Cleaning. We have now reached the point where we are working on many aspects of the value creation chain in close union. Through all these efforts we have taken sales to new important heights – Steelco turnover has more than doubled since 2017 while Miele Professional has also grown well during the same period.

Fig. 1: Dr. Christian Kluge, Senior Vice President Business Unit Professional, Miele & Cie. KG.

I would like to highlight one very recent milestone, reached at the end of 2021: The successful realignment of our Miele production plant in Bürmoos, Austria. Key products from this plant were rendered obsolete by the acquisition. The team there has succeeded in giving the plant a new and important role, thereby creating a sustainable economic basis. Miele Bürmoos now focuses on baskets, components and load carriers – for both Miele and Steelco. This is a crucial success factor in our line of business, as indicated by more than 750 model versions alone.

Fig. 2: Miele

Would you briefly outline what has changed in Sales and Service over this period?

There has been an increasing focus on the deployment of the two brands and sales activities. This involved bringing together the planning and equipping of central sterile supply departments (CSSD) at Steelco (project business) whilst Miele was given responsibility for the medical product business in surgeries and dental practices (transactional business). Sales in the project and the transactional business fields differ considerably, in particular in terms of order complexity, order values and the number of transactions. Hence, it makes sense to specialise.

In addition to this, we have merged after-sales service for both brands in many countries so that a service infrastructure guarantees the good and fast availability of spare parts to Steelco customer as well.

On the Miele side, we also introduced specialisation to the sales team in 2020, differentiating between Medical/Laboratory/Dental on the one side and HoReCa/Care/Self Service on the other. This alignment with sales channels helps us to serve our clients better.

What is special in your mind about the transactional business?

Our customers, for instance from medical and dental practices, expect advice, delivery and service on site without extended waits. Proximity to customers is very important to us in this respect. For this reason, we maintain high-performance sales and service structures offering blanket geographical coverage. This is the case both in direct sales through our Miele subsidiaries and via our trading partners. Order volumes commonly reach four- or five-digit figures in euros. Clients are given individual and comprehensive advice which also includes service concepts, matching process chemicals, the routine use of process challenge devices and process documentation solutions.

In what ways does the project business differ?

These tend to be larger and in part highly customised orders clinched via a tendering process – typically equipping CSSDs. This business is conducted via Steelco in around 15 countries through our own sales subsidiaries and in more than 100 further countries through dealers. This does not require a blanket sales organisation. This approach to sales generally involves serving an entire country from one single location. As no two projects are ever the same, Steelco provides support with planning, installation and capacity calculations. In the projects sector, order volumes often reach six-, seven- or even eight-digit figures in euros.

Professional has been around in its current form since 2020 – what has changed?

The establishment of the Business Unit Professional was part of bigger organisational changes at Miele with the aim of bolstering our focus on individual business fields. Professional is the only business unit to be run consistently as a 'firm within a firm': From development right through to Sales and Service, all core functions are under the same leadership. This enables a greater degree of focus on these complex business deals, greater speed and a more client-centric approach. And we

have changed a lot within the business unit, from specialisation in sales through to boosting the customer perspective in product management.

Which corporate units does Professional comprise?

Alongside solutions for cleaning, disinfection and sterilisation, we also offer various solutions in the fields of laundry and dishwashing technology as well as air purifiers. The products originate from seven production plants, of which five belong to the Professional business unit – two in Germany, one in Austria and two Steelco plants in Italy. The global Professional sales and service network covering Miele and Steelco also counts as part of our business unit. Furthermore, our remit includes companies and startups offering specific customer-specific solutions. I would like to draw particular attention to Bloomest, a company planning and installing turnkey launderettes, and AppWash providing digital solutions for shared washing machines.

In the past two years, the world has been in the thrall of the Covid pandemic. How has this influenced the Miele Group?

In the early days of Corona, our biggest priority was to continue serving our customers, in particular providing service to critical infrastructures, whilst at the same time ensuring safe working conditions for our employees. Luckily, we were successful in both respects. More specifically, our branch was also faced with issues regarding infection control. The aim was to issue clear recommendations based on scientific insights – for example on the A0 value required to deactivate the Corona virus or efficacy criteria for air purification.

As everywhere else, the pandemic was also a catalyst at Miele in driving digitalisation. Online meetings have now become the norm. The Miele Group and, indeed, we in Professional have succeeded in mastering the enormous volatility in demand (and in the supply chain) and in growing year-on-year.

Would you hazard commenting on future prospects?

For Professional, we are only just seeing the power and dynamics we are able to unleash with our new organisation and strategy. Lots more will happen, for example in the field of digitalisation. Individual building blocks will increasingly join up and grow into integrated solutions and eco systems. Miele is also making very positive progress in the domestic appliance sector and is moving into new business fields, for example outdoor cooking. The domestic and Professional business fields have common roots, in particular with respect to their focus on quality and our keen pioneering spirit. Both find expression in our – joint – Purpose Statement: 'Miele – Creators of Quality'.

Fig. 3: Steelco

The manual processing of patient beds in the hospital – A smiley face as a motivational tool

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For patients, the hospital bed is an important component during their hospital stay and in the process of their recovery. In this bed, wound dressings, small rinses, food intake, excretion of excrement, contact with the outside world and much more takes place until recovery. Every patient may demand and expect a clean and hygienically proper bed, so that he/she is not already burdened with pathogenic microbes on the day of admission.

Used patient beds are microbially contaminated depending on the patient clientele and can therefore be a source of nosocomial infections.

Consequently, hygienically correct processing of the bed is an important aspect in the infection prevention regime. Patient beds can be processed either automated in a washer disinfector for beds with a chemo-thermal process or manual by wipe cleaning and disinfection.

The topic of hygienically reasonable bed processing is still particularly important to the cost-benefit discussion, as in terms of the hospital administration there are still considerable streamlining reserves to be mobilized. The subject of manual processing of patient beds in the wiping process is particularly relevant and poses major challenges for hospital staff.

Fig.1: Contaminated frame of a hospital bed with blood..

Hospital beds are not easily accessible everywhere in their construction and design, which makes cleaning difficult and very time-consuming (Fig.1). When purchasing beds for patient care, the professional groups of nursing, cleaning and hygiene specialists should be involved in order to evaluate the handling and disinfection resistance of surfaces.

The success of a manual processing of patient beds is strongly dependent on the conscientiousness of all employees involved in the processing process.

A routine success check should be carried out and documented by the hygiene specialist or the hygiene officer at regular intervals. To check the quality of the results, a system for the determination of residues of fluroscidal agents can be used.

This is an optical implementation control (quality control) of cleaning measures by means of UV light (Fig.2).

To determine successful cleaning and disinfection measures, a risk analysis is carried out and a standardized process is required.
Based on three patient groups, the risk of infection is distinguished:

1. Patients without colonization or infection, patients without colonization burden with multidrug-resistant pathogens (MRE) (e.g. outpatient procedures, rehabilitation facilities)
2. Patients at risk of infection or MRE-Last (e.g. acute care hospitals, early rehabilitation facilities)
3. Patients with a high risk of colonization or infection (e.g neonatology, intensive care units, hematology and oncology)

Daily bed disinfection without changing patients

The patient bed and the bedside cabinet are disinfected daily by the cleaning staff. In addition, visible contamination is removed by the nursing staff during the care of the patients by a wipe procedure. The product used for disinfection must be adapted to the pathogen, but must meet

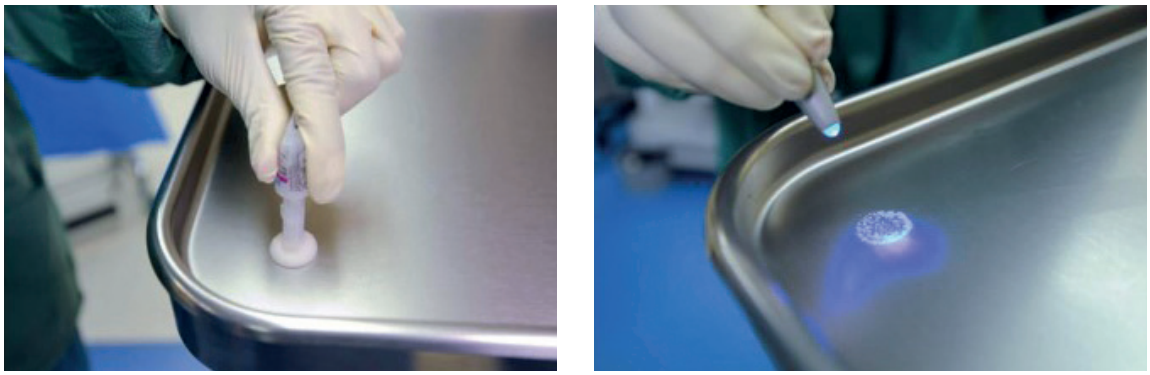


Fig.2: Control after cleaning measures have been carried out by UV light.

the minimum requirement bactericidal, yeasticidal and limited virucidal. The proof of efficacy is carried out according to EN standards or VAH / DVV methods and the products are in VAH list or DVV of the IHO database and mapped in the hygiene plan. The hygiene plan is binding both for the staff of the medical institution and for the staff of external companies. The staff observes basic hygiene during disinfection: hygienic hand disinfection, wear disposable gloves and a protective apron.

For patients without multidrug-resistant pathogens or infections, there is no routine change of bed linen, only in case of visible contamination.

Bed disinfection after discharge, relocation or final disinfection Practical Experience: time spent on bed disinfection

An important part of the work process of proper processing of patient beds are employee consultations. Cleaning staff without training had prepared the patient's bed within ten minutes, but insufficiently.
It takes 25 minutes for the straff to thoroughly process a patient bed. Only trained personnel should be used in the processing team. The commissioned personnel wears personal protective equipment (PPE). The disinfection must be adapted to the pathogen and the exposure time must be observed, in the case of concentrates, the correct dosage must also be observed. Products with broad efficacy and short exposure times are helpful for praxis to ensure rapid availability of disinfected beds.
The entire bed (including mattress topper, bed mechanism, bed frame, chassis) is wiped from top to bottom (Fig.3).

The bed linen is disposed of in the usual sorting system. Pillows and blankets are given to the laundry. The laundry bags must only be filled in such a way that they are still easy to close (two-thirds filling). It must be ensured that no foreign objects (secretion bags, drains, etc.) get into the laundry bag. In case of moisture penetration, the cloth bag is additionally placed in a plastic bag according to the specifications of the laundry. Infectiously contaminated laundry must be disposed of in a laundry bag intended for infection laundry. The laundry is processed in external companies according to a certified procedure. Defective mattress covers must be replaced, if this is not possible, the mattress must be disposed. After finishing the cleaning activity, the PPE is removed, hygienic hand disinfection and the patient bed is upgraded with fresh linen (Fig.4).

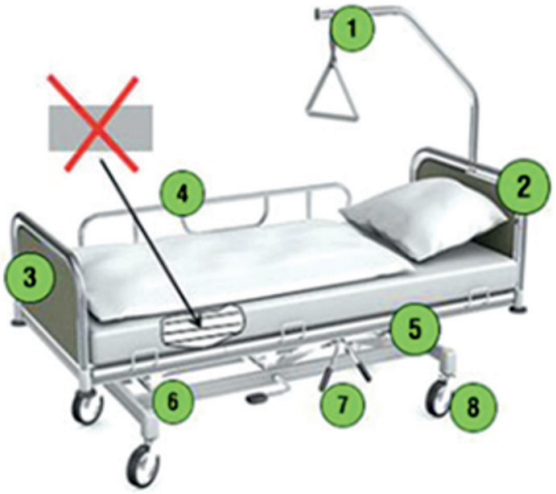


Fig. 3: Sequence of the work steps in bed preparation.

Fig.4: Prepared hospital bed and bedside cabinet.

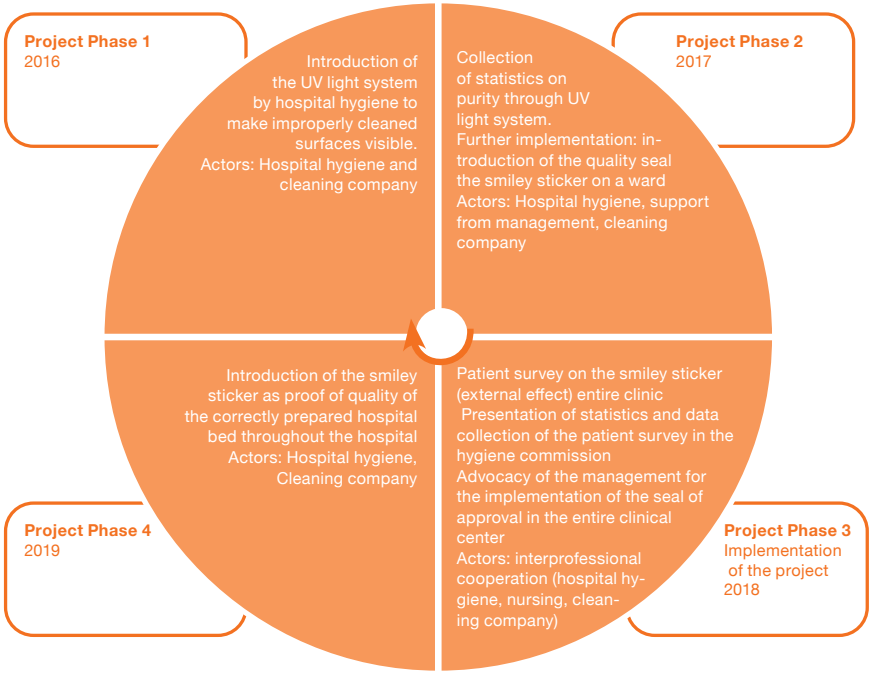
Maintenance / inspection of patient beds

Patient beds are medical devices and must comply with legal requirements for safety.

From practice to practice

The smiley project (Fig.5, Fig.6) for the decentralized patient bed processing of the Johanniter GmbH branch in Stendal (Germany).

The background to the project was insufficient results for cleaning and final disinfection of patient beds by the cleaning staff.



Objectives of the project:

- Increased attention to correctly disinfected surfaces at the patient's bedside.
- Recognition and motivation for the cleaning staff, increased performance
- Processed bed place immediately recognizable, can be occupied immediately, inquiries of maintenance is omitted, identification by signature of the executor of processing
- Correct disinfection for more patient safety, image enhancement, less indirect or direct transmission of MRE and other pathogens

Conclusion:

The hygienically flawless bed processing in the medical sector serves both cleanliness and infection prevention and is an important key in patient and personnel protection.

The decentralized treatment (in the patient room) can thus easily replace a cost-intensive bed centre and offers the necessary security in everyday hospital life in the interprofessional team.

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Special hygiene considerations in an acute geriatric clinic

Hubert Holz, Lothar van den Abeelen, Markus Kiesel, Hanna Kemnitz-Frahm

Marienhaus Klinikum Mainz (MKM) is categorised as a Level II hospital under the German system and has 602 beds and around 1500 employees. It treats 50,000 inpatients and outpatients a year at its 19 clinics and 10 centres. Although the acute geriatric clinic was set up at MKM 15 years ago, since 2021 our department has been located in a completely new ward on the fourth floor of the Marienhaus Klinikum. We have 59 standard beds and 11 beds for optional services. Our goal is to help our patients retain, regain or improve their level of independence in carrying out daily tasks as much as we can; to minimise or, where possible, avoid the need for care altogether; and to maintain the very best possible quality of life for each patient. Treating our patients as individuals is at the forefront of everything we do.

The ward is divided into units and each unit has a ward round trolley, some of which are equipped with a PC workstation, a unit trolley, which acts like a mobile nurse's station, and a care trolley. The geriatric department is home to a small optional services area with 11 beds. This area includes a communal lounge, a balcony and a cosy coffee corner.

The multi-professional team working in the acute geriatric clinic is made up of all the various occupational groups involved in patient care, from medics and nurses to physiotherapists, occupational therapists, psychotherapists and even social services professionals. The hallmark of this team is its interdisciplinary and collaborative approach to its work. Having this type of organisation calls for lots of frank discussions and clear agreements with each other in the interest of finding the best way of working together – and these processes need to be jointly re-evaluated on a regular basis. Besides the everyday communication that goes on between employees and the handovers they conduct, the clinic also holds well-structured team meetings. These meetings not only ensure the team is focussed on delivering multi-disciplinary and multi-professional patient care, they also underline the importance of making sure the department structure is allowed to evolve in the context of continuous improvement.

Hygiene in a geriatric trauma centre – Special considerations in an acute geriatric clinic

Before it opened, many MKM staff were worried that the new geriatric department would act as a gateway for multi-resistant germs and that the number of problem germs would increase considerably. Partly in the interests of quelling this fear, there was close cooperation between the future therapeutic team and the hospital's hygiene team right from the planning and preparation phase for the new acute geriatric clinic.

Multi-resistant pathogens in geriatric care

If we look at the data on multi-resistant pathogens contained in the Pathogen-KISS module of the Krankenhaus-Infektions-Surveillance-System (KISS, the hospital infection surveillance system) of the German National Reference Center for Surveillance of Nosocomial Infections (NRZ), we can see that there is indeed a higher than

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Fig. 1: Coffee corner in the MKM acute geriatric clinic. (Photo credit: Hanna Kemnitz-Frahm)

Fig. 2: Communal area for patients in the MKM acute geriatric clinic. (Photo credit: Hanna Kemnitz-Frahm)

average prevalence of the most common multi-resistant pathogens found on geriatric wards[1]:

- Methicillin-resistant Staphylococcus aureus (MRSA) have a significantly higher prevalence on admission, although nosocomial incidence densities are the same as elsewhere.
- It's a different picture for vancomycin-resistant enterococci (VRE) and multi-resistant Gram-negative bacteria that are resistant to three of the four classes of antibiotics (3MRGN). For these pathogens, not only the prevalence, but also the nosocomial incidence densities are higher on geriatric wards than the average of all wards.
- In contrast, we can see that with multi-resistant Gram-negative bacteria that are resistant to all four of the four classes of antibiotics (4MRGN), and which are therefore the most serious of the multi-resistant problem germs, there is not only a comparable level of prevalence, but there is also a trend towards a slightly lower incidence density of nosocomial cases.

So, there is actually no basis for the claim that a geriatric department will automatically be some sort of "bacterial incubator". On the contrary, we interpret this data to mean that our patients, who frequently have multi-morbidity and a history of contact with a variety of healthcare settings, are more likely to bring a multi-resistant pathogen into the hospital with them, but that our specialist departments are able to deal with these bacteria well or even better than other departments. This applies in particular to the classic problem germs of MRSA and 4MRGN. In our view, the higher incidence densities of nosocomial cases of VRE and 3MRGN can be explained by the much longer hospital stays experienced by our patients (13.6 days on geriatric wards compared to 5.1 days on all wards) as well as their increased susceptibility to infection[6] by colonisation pathogens.

Multi-resistant pathogens and screening in the acute geriatric clinic at MKM

To keep a close eye on how these pathogens are developing in the MKM acute geriatric clinic, the ward is also taking part in the Pathogen-KISS module of the NRZ. And now the general picture described earlier comes into even sharper focus. In the MKM acute geriatric clinic there were no nosocomial MRSA cases whatsoever, nosocomial VRE cases are very much the exception and 4MRGN are rarely seen pathogens brought into the hospital from the outside. How is this possible? From the very start, patients have been universally screened for MRSA on admission to the MKM acute geriatric clinic, so the MRSA status of every single patient, regardless of any risk factors they may have, is always known. In the past, MRSA screening was conducted not only when patients were first admitted to the clinic from outside the hospital, but also whenever in-patients were moved there from a different area of the hospital. However, once the MRSA full screening programme had been introduced in all MKM departments by the end of 2017, this approach was no longer followed. The acute geriatric clinic was a pioneer in this regard and a driving force behind the campaign to totally eradicate nosocomial MRSA cases throughout MKM[2]. There is also an intensive admission screening programme in response to the presence of VRE and MRGN, but no universal full screening programme for these pathogens. That said, if easily defined risk criteria are present (patient transferred from another hospital / facility; patient being weaned from / dependent on a ventilator; dialysis or oncology patient; interventions in or treatment of the patient's gastrointestinal tract), specific tests are run to identify these pathogens in the MKM acute geriatric clinic. The rate of positive tests is very high for patients transferred from other clinics and those on ventilation and dialysis in particular[3, 4]. So what happens with patients in the acute geriatric clinic if a multi-resistant pathogen of this type is found? Well, that is a complex issue.

The main treatment process in specialist geriatric departments is known as "complex geriatric treatment". It is aimed specifically at older patients suffering from multiple illnesses who have a functional impairment but who cannot (yet) participate in normal follow-up treatment. The decision as to whether complex treatment can be pro-

vided will be taken by a specialist geriatric doctor together with the geriatric team during the first few days after the patient is admitted.

Standardised geriatric assessments will be performed at the start, and sometimes the end, of the patient's stay and will cover aspects such as:
· Mobility, risk of falling
· Cognition
· Emotion
· Capacity to help oneself
· Care situation
· Nutrition, pain, difficulties with swallowing

In order to plan our patients' treatment, we hold weekly team meetings attended by all the occupational groups involved in patient care. This is where we plan courses of treatment, discuss any action that needs to be taken at the moment and talk about new treatment goals for the upcoming period. During a patient's stay, their treatment will be based on their existing medical issues as well as the results of their geriatric assessments. They will be offered targeted treatments, in line with their particular limitations and treatment goals, by physiotherapists, occupational therapists, speech therapists and, if necessary, psychologists. The nursing procedures are performed according to a special concept called "activating therapeutic care". Therefore, keeping patients in strict isolation may be diametrically opposed to the treatment goals that acute geriatric medicine is striving to meet. So whenever a case of a multi-resistant pathogen is identified, especially in the acute geriatric clinic, the hospital's hygiene team discusses the case with the treatment team in a "hygiene consultation".[5] In this meeting, hygiene specialists and the treatment team can decide between them whether the individual patients with a VRE or 3MRGN infection really need to be isolated or whether they can be accommodated normally (good compliance, no acute infections with multi-resistant pathogens).[3, 4]
If MRSA is detected, patient isolation and eradication attempts will always be initiated in MKM, but we will also highlight any ways in which those affected can still play an active part in their treatments. It is only where there is evidence of 4MRGN that therapeutic options are limited, although even in these cases we will offer as many options as possible, depending on the pathogen and where it has been located.

The acute geriatric clinic as a high-risk area

Generally speaking, the MKM acute geriatric clinic is classed as a high-risk hygiene area. This classification is due to patients having multi-morbidity as well as the phenomenon of immunosenescence, in which the immune system ages and the body's natural defences become less effective.[6]

Outbreak prevention and management

This predisposition to acquire pathogens and shed them over a prolonged period also necessitates targeted concepts for managing other, non-multi-resistant infectious agents, especially in relation to preventing nosocomial infections and outbreaks. In the preventive and proactive phase[7], detecting infectious diseases early is paramount, with treatment and containment measures being introduced where there is even a suspicion of infection. This might include a new episode of diarrhoea or emesis, a new fever or an unexplained respiratory infection. If illness is confirmed, the case is critically assessed to determine whether it makes sense to isolate the patient. In our experience, where norovirus infections and influenza are detected, neighbouring patients will almost always develop the illness too,

Fig. 3: Therapy area for patients in the MKM acute geriatric clinic. (Photo credit: Markus Kiesel)

Black rooms	Symptomatic patients with (a suspected) infection
Grey rooms	Asymptomatic contacts during the incubation time and previously sick patients who have recovered (NB: no mixing of the two groups)
White rooms	Can be used freely. Black rooms become white rooms again once the previously sick patients have been discharged or moved and the rooms have undergone final disinfection

Tab. 1 Isolation according to the "Dresden model". (Source: According to Prof. Lutz Jatzwauk[8])

even if isolation measures are put in place immediately. This is presumably because the patient will have been shedding infectious virus particles during the pre-clinical phase of their illness. Neighbouring patients will therefore also need to be isolated initially until the end of the incubation time. The patient should also remain in their current treatment unit so they cannot spread pathogens around several treatment areas. Once there are two or more cases, then we enter the reactive phase[7]. At MKM this means we immediately convene an Outbreak Management Team (OMT) made up of members of the hospital's hygiene team and senior staff from the various occupational groups. The OMT meets on site every working day, reviews the barrier measures, trains staff and evaluates how things are progressing. Even once the patients are through the acute phase of their illness, there is still a need for further measures because the patients may continue shedding infectious pathogens for a prolonged period of time (safeguarding phase[7]). This applies to noroviruses, rotaviruses and respiratory syncytial virus, for example. In one case, on a weekend a patient was moved into the same room as another long-term in-patient whose clinical phase of a norovirus infection had ended three weeks earlier. This contact then triggered a norovirus outbreak. So at MKM we follow Prof. Jatzwauk's "Dresden model"[8] for problem pathogens (which are usually viral) such as these. If patients have recovered from this type of illness, they nevertheless remain in a single room (or grouped with other patients who have also recovered) for the rest of their stay. This is known as a "grey room". Only after the patient has been discharged and a final disinfection has been carried out can the room be used freely again as a "white room". MKM has seen very good results from applying this concept and has significantly reduced the number of outbreaks experienced in its acute geriatric clinic.

Recording infections

Since, as we mentioned earlier, geriatric patients are more susceptible to infection, a hospital's infection surveillance concept should take any acute geriatric department into account. At MKM, all geriatric areas are monitored from the start by recording nosocomial urinary tract infections whether they are associated with transurethral indwelling catheters or not. In previous years, there was a slight increase in the infection rate for patients in the acute geriatric clinic who had transurethral indwelling catheters fitted. And this was because MKM had introduced its "delirium-sensitive hospital" concept.

Delirium can have very serious consequences for a patient: it can cause lasting cognitive impairment, lead to a dependency on care or exacerbate existing needs, and it also increases mortality[9]. It is therefore important to take steps to identify patients who are at risk of delirium and then act to prevent it.

One of the methods for preventing delirium at MKM involves removing the transurethral indwelling catheter (which, after all, is a foreign object) as quickly as possible during the early post-operative phase, in a bid to stop post-operative delirium developing. But with our patients it is a real balancing act to find exactly the right moment to do this. In the beginning, new transurethral indwelling catheters occasionally had to be reinserted because of urinary retention. Inserting catheters multiple times like this increased the risk of infection, which we were able to show in the infection surveillance records. The more experience we gained, the better we were able to solve this problem and bring the infection rates back down too. However, sometimes it is still necessary to reinsert a catheter, although this is now rare. Even so, we deem this to be an acceptable risk, as the consequences of post-operative delirium are much more serious and more difficult to control than a potential urinary tract infection. The latter can be largely prevented by following proper hygiene measures and practising careful catheter care or can be cured with specific treatments.

Clostridioides difficile infections (CDI) in the acute geriatric clinic

Over the last 20 years, the issue of CDI has evolved from an exception to one of the most urgent problems in hospital hygiene[10]. If we take a look at the KISS data again, we can see that the incidence density of nosocomial cases is over twice as high on geriatric wards as it is on average on all wards. That said, it is rare to see a serious CDI[1].

The picture at MKM is a similar one: CDI occurs frequently in the acute geriatric clinic, due to the fact that antibiotic treatments are often vital, medically appropriate and indicated. However, CDI is always detected very early on thanks to our incredibly vigilant staff and it is usually treated with antibiotics even before microbiological confirmation of CDI is received. Unlike in other clinical departments at MKM, in the acute geriatric clinic we do not treat a CDI with metronidazole to begin with; instead, we start with oral vancomycin right away. Administering this potent treatment at an early stage speeds up recovery and very often avoids serious infection. The surveillance results from the Pathogen-KISS module relating to acute geriatrics are further confirmation of this.

The challenge of disinfection

One final aspect we want to highlight is disinfection measures. Once again, there are special considerations that must be taken into account in our acute geriatric clinic.

Where **hand hygiene** is concerned, the acute geriatric clinic has more patients who are unable to disinfect their hands themselves, or who are capable, but only when they are given extra guidance and reminded of what to do. It is important to have team members who are patient and have been made aware of this particular issue, so they can guide those they are treating in the direction of good hand hygiene time and time again.

The literature often describes **device disinfection and reprocessing** as a problem area. At MKM too, we have long wrestled with the issue of which devices it is appropriate to use from a hygiene point of view on patients who are often confined to their beds for a prolonged period of time (e.g. razors and shavers or nail care tools). But there are also pitfalls when it comes to reprocessing pressure-reducing aids, toilet seats, booster seats, walking aids and mobilisation devices: inaccessible corners, a lack of material compatibility, rapid wear and uneven or damaged surfaces can all impair reprocessing. That is why we regularly conduct unannounced inspections on all these devices and others besides. And even though everyone involved always holds their breath when these tests are carried out (hygiene specialists included!), the results are always flawless – not always a given, as we can see from other departments and the literature.

Surface disinfection as one aspect of barrier measures is of course an established standard in all clinical areas. But in the acute geriatric clinic this is also extended to "public" areas such as social rooms, visiting rooms and group treatment rooms (as well as any exercise equipment, like mats and balls, that are shared amongst the group, after patients have hygienically disinfected their hands). Plus there are some other very special areas in our clinic that require surface disinfection. The MKM acute geriatric clinic is on the fourth floor of the hospital and has its very own "bus stop" on site.[11] This stop was donated by the Mainzer Stadtwerke public utility company and effectively prevents patients who have a strong urge to move from getting away from the clinic. The bus stop also offers patients a place of refuge, since it is a familiar sight in the unfamiliar hospital setting. And because patients often sit here to calm themselves down, it too is subject to regular surface disinfection as part of routine cleaning work.

Fig. 4: Bus stop 4C for patients in the MKM acute geriatric clinic. (Photo credit: Markus Kiesel)

Fig. 5: A sample from the exhibition "Den Faden verlieren – Kunst trifft Demenz" ["Losing your thread – Where art meets dementia"]. (Photo credit: Marie-Luise Anten-Dittmar[12])

Pictures brighten up the corridors in all the wards at MKM. These might be high-quality photographs of Mainz and the surrounding area or perhaps art prints. But what is really special about the acute geriatric clinic is that it has a permanent art exhibition on the subject of dementia displayed on its walls. These are works made of fabric, thread and wood, which were created by artist Marie-Luise Anten-Dittmar together with patients who have dementia. The works are displayed along with quotes about their illness from those involved in the project[12].

When decisions were being made around this project, there were concerns about whether it would be possible to hang these works of art in the corridors of an acute hospital. Of course, the hospital's hygiene team supported the ward when it came to these issues: from our perspective, there was no risk of infection from a work of art hanging on a wall. And so the very moving exhibition "Den Faden verlieren – Kunst trifft Demenz" ["Losing your thread – Where art meets dementia"] can now be viewed in the MKM acute geriatric clinic on a permanent basis.

Conclusion

Generally speaking, the hygiene requirements and regulations that apply in an acute geriatric unit are no different to those in other clinical areas. That said, in this area more than any other, the requirements must be adapted to the specific situation on site, to the individual needs of patients, and to the conditions necessary for effective complex geriatric treatment – and all that without compromising hygienic safety.

This called for the acute geriatrics therapeutic team and the hospital's hygiene team to work closely together in a spirit of trust. In the 15 years since the acute geriatric clinic has been up and running at MKM, this collaborative approach has really proved its worth and is appreciated by both sides. This successful partnership has also led to a number of projects and insights (such as the MRSA full screening programme and the Dresden model) finding their way into the clinical routine throughout MKM.

So in this way, the acute geriatric clinic is not only creating medical added value for the ageing population of its Rhine-Main catchment area, it is also improving the quality of treatments and increasing patient safety in all departments throughout MKM.

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New preparation system for the nitrous oxide sedation

From early 2022 onwards, Miele will be offering a space-saving solution for the reprocessing of the hoses and accessories used in nitrous oxide sedation:
A new system which accommodates up to five hoses. The hoses are connected using adapters to the injector nozzles in the slightly inclined holder and routed past the other inserts. This ensures reliable cleaning and drying of all internal and external surfaces, leaving sufficient space for lumened items, e.g. transmission instruments, and further instruments in the same cycle.

Hence, this approach does not interfere with general reprocessing.

Fig. 1: A 105/1 upper basket with new reprocessing system for APWD 325 nitrous oxide sedation components.

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Parametric release with measurements of steam sterilisation parameters: temperature, steam composition and time

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Summary

Background: With the current methods specified in standards, not all the steam sterilisation conditions as specified in standards can be guaranteed in every steam sterilisation process ran.
Aim: Find an easy way to implement a method to monitor steam sterilisation in every steam sterilisation process, as specified in the standards.
Method: Identify a method that can be used in every steam sterilisation process to determine the steam sterilisation conditions in the sterilizer chamber. Apply this method in the practice of a Central Sterile Supply Department.
Conclusion: With the identified method the steam sterilisation conditions can be determined in every steam sterilisation process. The method is evidence based and easy to implement in the workflow of a Central Sterile Supply Department (CSSD).

Introduction

Before use in surgery invasive medical instruments have to be sterilized. The most applied method of sterilization in health care facilities is steam sterilisation. Steam sterilisation conditions are detailed in the literature[1, 2, 3] and include the temperature, steam composition and time. Unfortunately the steam composition is not quantitatively specified in the literature. This is resolved in standards[4, 5] by detailing the amount of Non Condensing Gases (NCG) in the steam with 3.5 ml NCGs in 100 ml condensate[4] which equals 3.5 % $V_{NCGs}/V_{100\ ml\ condensate.}$

The origin from this amount of NCGs comes from the early period of standard development in the 1960s. At that time no methods were available to measure the steam composition or NCGs in the steam sterilizer chamber. Therefore a method was developed to measure the 'steam quality' in the steam supply line near to the sterilizer chamber. This method is described in the standard[4] but has several disadvantages. One of the disadvantages is presented in a note of the 13.3.1 in the standard EN285:2015+A1:2021[4]: "This method does not necessarily express the true content of NCG in steam. The limiting value was defined experimentally in the 1960s in relation to the sensitivity of air detectors commonly used in the UK at that time. Repeated measurements give an idea of the true picture of NCGs in the steam supply". A second disadvantage is that the thermodynamic conditions in the steam supply line differ from the thermodynamic conditions inside a sterilizer chamber. For example, in the steam supply the pressure is higher than in the chamber and relative to the steam in the steam supply line, the steam is not moving in the sterilizer chamber. Especially not in the holding phase, the actual steam sterilisation period of a process. A third disadvantage is that these steam measurements are taken at an arbitrary moment in time while it is known that the steam composition in steam supply (line), and therefore in the chamber, vary over the day. The variation in NCGs in steam makes that every steam sterilization process is an unique event.[6, 7, 8] This makes it also necessary to monitor or more precise, to determine the steam composition of the NCG amount in every process in the sterilizer chamber.

In some countries it is suggested to use the measured temperature and a theoretical temperature calculated out of the pressure to determine the steam composition. This is not a valid method.[9, 10, 11] With use of physical laws this can be and is written out and available on the internet. For example on the website of the Dutch sterilisation association SVN.[12]

In the here reported study a method has been identified with which the NCGs in every process are quantitatively measured in the chamber of a steam sterilizer and in each process. With the identified method the steam composition can be determined. Together with the temperature and the time of the holding phase the steam sterilisation conditions as specified in the literature[3] and standards[4] can be determined in every steam sterilisation process. This increases the safety of sterilisation for patients and staff drastically.

Method

Several methods to determine composition of the steam in the steam sterilisation chamber were identified. Methods with chemical and biological indicators were found not suitable, for example because they depend on subjective human interpretation of colour changes or were not accurate enough.[13] Also transferring the results to a subjective quantitative result appeared challenging.

Three methods were identified that make use of the physical properties of present gases. E.g., water in vapor state can condense in the pressure and temperature range of steam sterilization, while the so called non condensing gases cannot condense in these ranges. The two further studied methods were the 3M ETS (3M™, Neuss, Germany)[14] and the SolidToo NCG-sensor (SolidToo B.V., Veldhoven, the Netherlands).[15]

The SolidToo NCG sensor was chosen because of the easiness of use. E.g., the NCG sensors are calibrated, provide quantitative results for the actual steam sterilisation conditions temperature, steam composition (or NCG amount) and time, do not need human interpretation or handling, and, in each process the steam sterilisation conditions (temperature, NCGs and time of the holding phase) are measured in the sterilizer chamber and reported in an Every Load Monitoring (ELM) protocol. On the website of the NCG sensor the working principle is further described[15] and the calibration method of the NCG-sensor is specified in the literature.[16] An additional advantage is that this method is retrofittable on all steam sterilizers with a port to introduce probes into the steam sterilizer chamber[4], in daily practice often referred to as validation port.

On the four new steam sterilizer of the Onze Lieve Vrouwe Gasthuis (OLVG) location west (Amsterdam, the Netherlands) NCG-sensors were installed. The sterilizers have passed a Performance Qualification according EN285:2015+A1:2021[4] and ISO17665:2006[10] with a good result before going into production.

After identifying the criteria to meet had to be worked out. The steam sterilisation parameters temperature, steam composition and time are the sterilization parameter.[3] According to the literature the pressure is not a steam sterilisation parameter. When using the EN285:2015+A1:2021[4] the criteria for the steam sterilisation become:

- The steam penetration capacity of a process has to be sufficient for the loads that are processed.
- In every process the steam sterilisation parameters for the holding phase have to be defined, e.g. a 134 °C steam sterilisation process:

$$\begin{cases} 134\,°C \leq T \leq 137\,°C \\ \square \quad \square \quad NCG \leq 3.5\,\% \; {}^{V_{NCGs}}/_{V_{100\,ml\,condensate}} \\ \square \quad \square \quad t \geq 180\,s \end{cases} \quad (1)$$

- After the process has ended the load has to be dry.

The pressure is not a sterilization parameter. It is a parameter to control the process. However it is mentioned in the standard and therefore it was monitored and judged in the NCG-software. Out of the pressure the theoretical temperature was calculated and judged to the temperature bands specified in the standard.[4]

Because these criteria cannot be measured on all locations in every steam sterilisation process that is ran, the conditions should be measured as good as possible during Performance Qualification (PQ).[4, 10] As a consequence it is necessary that during the PQ the combinations of the sterilizer, process, load, loading pattern (including position[17, 18]) and sterile barrier that would be used in the daily production, are measured and confirmed that the sterilization criteria are met. Once this is established, it is necessary to ensure that similar conditions are present in each process with the qualified combinations. In the standard[4] accuracies for measurements are specified, e.g., the accuracy for temperature an accuracy of 0.5 K (or °C) is specified. To ensure to comply with this standard[4] that would mean that the indicated value of the temperature has to be within:

$$\begin{array}{ccccc} 134 + 0.5\,°C & \leq & T & \leq & 137 - 0.5\,°C \\ \square & \square & \Leftrightarrow & \square & \square \\ 134.5\,°C & \leq & T & \leq & 136.5\,°C \end{array} . \quad (2)$$

This means also that when the temperature indication indicate:

$$\begin{cases} 133.5\,°C \leq T < 134.5\,°C \\ \square \quad \square \; and \; \square \quad \square \\ 136.5\,°C < T \leq 137.5\,°C \end{cases} , \quad (3)$$

the specifications in the standard[4] are met within the accuracies of the standard[4].

When the temperature is in the range:

$$\begin{cases} T & < & 133.5\,°C \\ \square & or & \square \\ T & > & 137.5\,°C \end{cases}, \quad (4)$$

the temperature does certainly not meet the standards. In Figure 1 the equations the temperature criteria are graphically presented.

The steam composition is a steam sterilisation parameter according to the literature and the standards.[3, 4, 5, 10] Steam exists out of water in the gas state (also reported as the Water Vapour Fraction (WVF)[7]) and the NCGs, hence:

$$100\,\%\,GAS\,(steam) = X\,\%\,WVF + Y\,\%\,NCGs. \quad (5)$$

Therefore it is also possible to measure and determine the NCGs in the steam to qualify the steam composition.

In the EN285:2015+A1:2021[4] a method to measure the NCGs is specified. When the accuracies of the methods are used, the criteria for the NCGs (expressed in $V_{NCGs}/V_{100\ ml\ condensate}$) can be calculated. This is written out in reference[16] and demonstrates that the 3.5 % are certainly not met when:

$$NCGs \geq 4.3\,\%. \quad (6)$$

When the NCG value is:

$$2.8\,\% \leq NCGs \leq 4.3\,\%, \quad (7)$$

the standard is met but the value is within the allowed accuracies of the standard.[4]

When the value:

$$NCGs < 2.8\,\%. \quad (8)$$

The criteria for NCGs is certainly met.

In Figure 1 the equations the NCG criteria are graphically presented.

Results

In this study the results of the NCG-sensor-configuration on the four steam sterilisers (OLVG1 to OLVG4) located in the CSSD of the OLVG hospital (Amsterdam, the Netherlands) in the period from 11 October 2021 to 09 December 2021 are reported. In Table 1 a summary of the processes ran in this period on these sterilizers is presented. The table shows that the number of fail processes vary from 0 (OLVG4) to 20 % (OLVG3). This was not expected because the steam sterilizers are from the same brand and the same type, they were new, have passed the Performance Qualification according EN285:2015+A1:2021[4] and ISO17665:2006[10]. The brand and type of the steam sterilizers are not detailed because it does not add information for the reader of this study.

Results per sterilizer and per process type are presented in Table 2. The results in this table indicate that the result of a steam penetration test (Bowie and Dick test) has no relation with the results of the production processes, 134 °C standard process

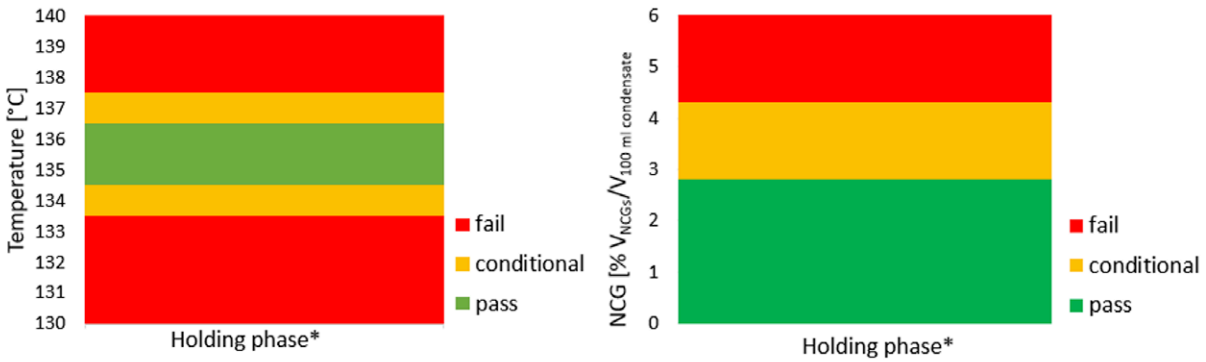

Fig. 1: Graphical presentation of criteria for 134 °C steam sterilization process with accuracies for temperature and NCGs. in the holding phase in the chamber according to the standard.[4] To guarantee steam sterilisation conditions according to the standard[4] the trace of the temperature and of NCGs have to lay in the green area. When one or both go through the orange area the process is still a pass but is in the accuracies of the standard.[4] When one or both traces go through the red areas the process does not comply with the criteria in the standard[4] and is qualified as a fail process.

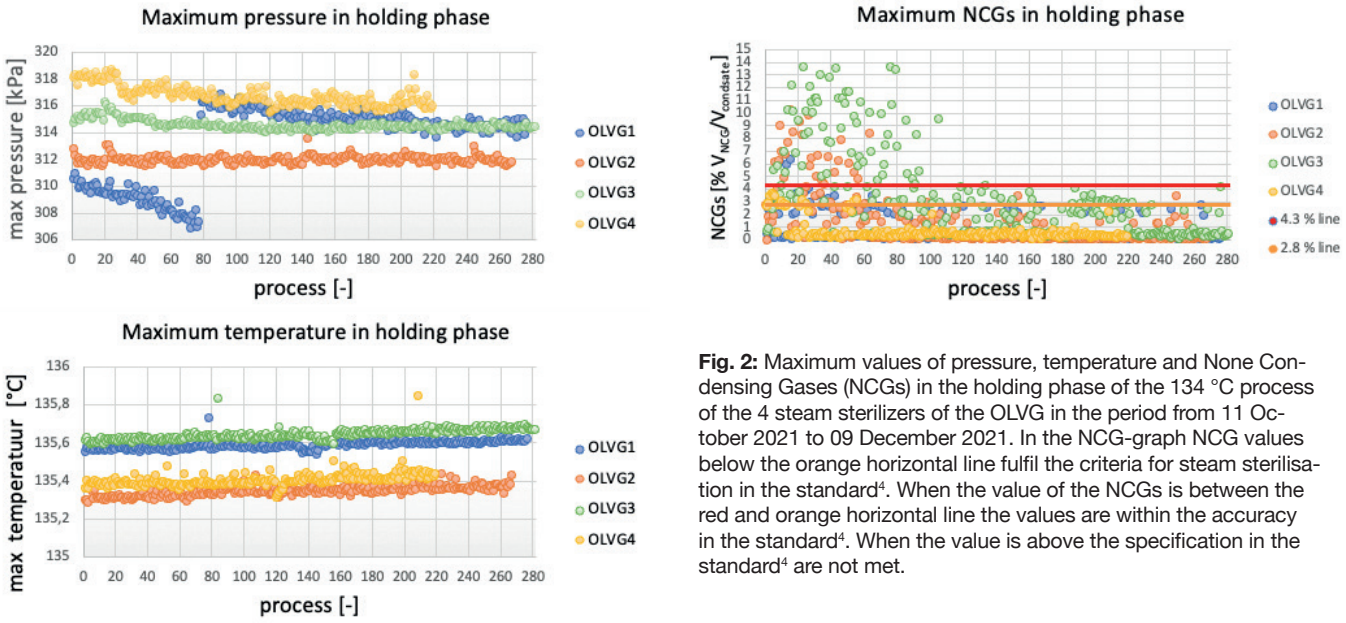

Fig. 2: Maximum values of pressure, temperature and None Condensing Gases (NCGs) in the holding phase of the 134 °C process of the 4 steam sterilizers of the OLVG in the period from 11 October 2021 to 09 December 2021. In the NCG-graph NCG values below the orange horizontal line fulfil the criteria for steam sterilisation in the standard[4]. When the value of the NCGs is between the red and orange horizontal line the values are within the accuracy in the standard[4]. When the value is above the specification in the standard[4] are not met.

In Figure 2 the maximum pressure, temperature, NCGs in the holding phase from the 4 steam sterilizers are presented. As mentioned above, the pressure is not a sterilization parameter but is mentioned in the standard[4]. In the pressure values of OLVG1 a 'step' or shift in pressure is made at process number 80. When it was investigated what happened it appeared that the pressure control sensor was re-calibrated. However, this step does not occur in the temperatures of this sterilizer. This is another indication that with measuring steam pressure the composition of steam cannot be determined.

A closer look to the pressure and temperature values may indicate a small drift in these measurements. The observed drifts are well within the specifications of the standard[4]. The most interesting graph in this Figure 2 is the graph with the results of the NCGs in each process. An important results is that in each process the amount of NCGs is different. Further it is interesting that in the first approximately 80 to 90 production processes the variation of the NCGs is larger than after this period. Especially for the sterilizer OLVG3. The results indicate that until the 80-90th process the steam supply for the sterilizers was not the same as after these 80-90 processes.

Approximately at the same time that the step in the pressure of the OLVG3 steam sterilizer occurred, the quality of the steam became better. NCGs values went down. From that moment onwards almost no fail processes have been observed.

	OLVG1		OLVG2		OLVG3		OLVG4	
Processes	[-]	[%]	[-]	[%]	[-]	[%]	[-]	[%]
Total	338	100	326	100	345	100	283	100
Pass	249	74	273	84	197	57	265	94
Conditional	85	25	25	8	77	22	16	6
Fail	3	1	27	8	69	20	0	0
Unidentified	0	0	0	0	1	0	0	0
Fragmented	0	0	0	0	0	0	0	0
Aborted	1	0	1	0	1	0	2	1

Tab. 1: Summary of the processes and their results in the period from 11-10-2021 to 09-12-2021 of the sterilizer OLVG1 to OLVG4. The processes include the air leakage test (vacuum leakage test), steam penetration test and 134 °C standard process. The differences in the number of fails between steam sterilizers demonstrate that every steam sterilizer is a unique device.

Discussion

Although the sterilizers OLVG1 to OLVG4 are similar sterilizers the results of process differ drastically. This demonstrates that every steam sterilizer is a unique device. Furthermore this stresses the necessity to measure and judge the steam sterilisation parameters, temperature, steam composition (or NCGs) during holding time in each process.
The fact that no relation has been found between the results of steam penetration tests and the actual production processes makes it doubtful if a steam penetration test provides additional information.

The reason why the NCGs are measured in the supply line is because in the 1960s no methods where available to measure NCGs in the sterilizer chamber. The NCGs or steam composition in the steam sterilizer is essential, as reported in the literature[7, 8] and again demonstrated in this study.

in this study applied method with the NCG-sensor the pressure was reported, even though it is not steam sterilisation parameter. The pressure is used to control the sterilizer process. The advantage to report the pressure is that it makes it easy to recognise the sterilisation process and its phases. However, it is advised to not use the pressure in the judgement of a steam sterilisation process.

In the Figure 2, a step can be observed in the pressure of the steam sterilizer OLVG 1 It is not yet clear where the drift comes from, from the sensors of the steriliser or from the independent pressure and temperature measurements of the NCG-sensor system. It has to be remarked that this kind of trend information on sensors in steam sterilizers is not found in the literature by the authors. However, these result demonstrate again that Every Load Monitoring of the steam sterilisation parameters is essential to guarantee steam sterilization conditions.

		OLVG1						OLVG2					
Program	**Result**	**proc**	**t**	**p**	**T**	**dT**	**NCG**	**proc**	**t**	**p**	**T**	**dT**	**NCG**
Vacuum leak test	Pass	7						6					
	Cond	0						0					
	Fail	0						0					
Steam penetration	Pass	43						45					
	Cond	11	0	0	0	11	2	7	0	0	0	3	4
	Fail	0	0	0	0	0	0	0	0	0	0	0	0
134 °C standard	Pass	199						222					
	Cond	74	0	1	0	76	16	18	0	0	0	0	18
	Fail	3	0	0	0	0	3	27	0	0	0	0	27
		OLVG3						**OLVG4**					
Program	**Result**	**proc**	**t**	**p**	**T**	**dT**	**NCG**	**proc**	**t**	**p**	**T**	**dT**	**NCG**
Vacuum leak test	Pass	8						9					
	Cond	0						1					
	Fail	0						0					
Steam penetration	Pass	27						52					
	Cond	21	0	0	15	1	8	0	0	0	0	0	0
	Fail	6	0	0	0	0	6	0	0	0	0	0	0
134 °C standard	Pass	162						204					
	Cond	56	0	0	0	0	56	15	0	0	0	0	15
	Fail	63	0	0	0	0	63	0	0	0	0	0	0

Tab. 2: Summary of the processes. In which 'Proc' stands for the number of processes and 'Cond' for conditional. Conditional means that the process is a pass according to the standards, but is in the accuracy band of a parameter. The parameters are judged in the holding phase . The 't' represents the time, of the holding phase, 'p' the pressure, 'T' the temperature, 'dT' the temperature band per scan and calculated out of the measured temperature and the theoretical temperature calculated out of the pressure and the NCG, the None Condensing Gases.

Possibly at the same time that the pressure step occurred the steam quality became better (Figure 2). Possibly during work on the steam sterilizers the steam supply was improved as well. No records of this improvement has been found but the results of the NCG sensors indicate the improvement. That this can happen is also reported in the literature[23] and should be monitored with every load monitoring of the steam sterilisation parameter in each process.

Conclusion

To ensure steam sterilisation condition it is essential that the steam sterilisation parameters are monitored in every steam sterilisation process. A robust method to do that has been identified in the NCG-sensor. This method is retrofittable on every steam sterilizer and easy to implement in the workflow of a CSSD.

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What is meant by calibration …

... And why is the calibration of the data logger so important?

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For many years, the processes in the Reprocessing Unit for MEdical Devices (RUMED) have been subject to metrological controls, for example during routine controls and during validation. The requirements for the construction, conversion and operation of a RUMED include the failure concept to bridge planned and unexpected operational disruptions. In the event of a failure of the server, PC or software for documenting the process data, suitable independent data loggers are used for process documentation. For the validation of the processes in the washer-disinfector or steam sterilizer, independent data loggers have long been established among validators. The question arises, how valid is the recorded data? Does the data logger or the measuring device itself have to be checked, checked and calibrated periodically? The use of calibrated measuring devices / data loggers is regulated in the following standards: Standards DIN EN ISO 17665-1[2], DIN EN ISO 15883-1[3], DIN EN 13060[4], DIN EN 285[5] and the German standards[6], guidelines[7] and guidelines[8] The calibration status must be proven in accordance with the requirements of the quality management system.

What does the term calibration mean?

The International Dictionary of Metrology describes calibration as "an activity which, under specified conditions, in a first step establishes a relationship between the quantity values provided by standards with their measurement uncertainties and the corresponding indications with their associated measurement uncertainties, and in a second step uses this information to establish a relationship by means of which a measurement result is obtained from an indication". This means that measurement deviations are documented during calibration. The measurement deviation [e] is the deviation of the measured value [X] in the process from the true value [Xw] of the measurand. If the measurement deviation [e] is subtracted from the measured value [X], an exact result [Xw] is obtained.

e=X-Xw

Fig. 1: ebro data logger EBI 12 TP 237

A brief explanation of the terms in aseptica is therefore useful:
Calibration is a measuring process to determine and document the deviation of a measuring device compared to another, mostly more accurate, higher-quality measuring device (normal). Calibration includes taking into account the deviation determined when using the measuring device.
Adjustment or adjustment is the setting of a measuring device or its display as precisely as possible through professional intervention.
Verification, usually the calibration, is the confirmation that specified requirements have been met (e.g. comparative measurement)
A comparison standard is, for example, an accurate measuring device that is used for a measurement or is used to calibrate other measuring devices. National or international standards are at the top of the calibration hierarchy.
Measurement uncertainty or standard deviation limits a range of values within which the true value of the measured variable lies (tolerances, temperature distribution).
Tolerance is the specified, permitted measurement deviation of the measuring device.
Some of the definitions of these terms are also contained in EN ISO 11139: 20181.

What are the different types of calibrations?

Accredited calibration, e.g. DAkkS
The accredited calibration procedures and documents are the benchmark for all industrial calibration tasks. The appearance and content of the certificates are determined by the state accreditation body and are stored in the quality assurance manual of the laboratory. DAkkS certificates are approved as binding evidence in court cases in Germany, for example.

ISO calibration:
ISO calibrations are used in all areas in which test equipment monitoring and calibration are required, but no DAkkS calibrations are required.

Normative requirements for calibration:
The standards DIN EN ISO 17665-1[2], DIN EN ISO 15883-1[3], DIN EN 13060[4], DIN EN 285[5] and the German standards[6], guidelines[7] and guidelines[8] describe the calibration. All measuring chains of the machine, for the control as well as for the recording and the independent test devices and data loggers are

Fig. 2: DAkkS accreditation certificate Xylem Analytics Germany GmbH.

Fig. 3: Types of calibration.

considered in these documents and must be calibrated. The maximum permissible measurement deviation of the measuring chains is identical for both the sterilizers and the WD machines. An accuracy of 0.5 K (± 0.25 K) is required for temperature measurement. This also applies to the independent measurement chain / data logger that is used, for example, for process validation tasks. This means that data loggers that are used for validation or routine control must show a maximum deviation of ± 0.25 K. If the independent data logger or the measuring device is used to test and calibrate the machine measurement chains, a significantly higher accuracy of 0.2 K (± 0.1 K) according to the cited standards must be maintained. The DIN EN ISO 15883-1[3] washer-disinfectors - Part 1: General requirements, section 6.2.3 describes calibration as follows: "6.2.3.1 The calibration must be carried out in accordance with the instructions of the measuring device manufacturer using a validated procedure; a working or reference standard is to be used that can be traced back to a national standard."

"6.2.3.2 The device must have a valid test certificate and the calibration data must include a temperature within the disinfection temperature range." The WD guideline describes: "So that the calibration values do not always have to be added manually for each release according to physical parameters (temperature / pressure), an adjustment is always recommended, especially if the deviations are significant. Calibration and adjustment are instruments of quality management and quality assurance. Therefore they are not automatically part of the maintenance. The user is therefore not responsible for calibrating the measuring equipment and machines. The monitoring is regulated by the QM manual. "The section 14.2 in the DIN EN 285 Sterilization - Steam Sterilizers - Large Sterilizers, describes the calibration for the machine: "All measuring chains of the sterilizer must be calibrated. Before carrying out any test, the calibration status of all test measuring devices must be verified."And in section 23.3.2.4 for the test equipment: "The calibration of every test measuring system must be carried out using a working standard or reference standard that can be traced back to a national standard or primary standard."

How often does a data logger have to be calibrated?

The intervals for the calibration depend on the manufacturer and the device. The calibration interval for data loggers is usually annually, please ask the manufacturer of the data logger for this. The creation of a risk assessment can deviate from the manufacturer's information, but the use of calibrated measuring devices must meet the requirements of the quality management system and is the responsibility of the operator or validator. Calibration intervals can be extended or shortened by evaluating external influences. Ideally, the operator or validator maintains a test equipment monitoring database which, in addition to the data logger / measuring device and the calibration cycle, also contains the respective calibration provider and any existing works contracts. Since test equipment monitoring is not available with every validator or in the RUMED, the ebro® data loggers of the EBI 10, EBI 11, EBI 12 series use the calibration date, which is displayed in the evaluation software in the routine or validation report.

Why is a calibrated data logger so important?

A temperature sensor drift of the data logger or the built-in WD machine sensor of only 1 ° C results in a result change of 25% when calculating the A0 value in the WD.

That means, if the measuring system of the WD or the data logger measures 1 ° C too low, instead of the expected result of e.g. A0 value of 3500 only a result of A0 value 2780 is recorded or displayed. In this case, the disinfection effect A0 value is less than 3000 and is not permissible, which means the machine would have to be repaired and the validation of the processes must be repeated. In the event of an incorrect measurement in the sterilizer, a deviation in the measuring system has a particularly negative effect on the equilibration time, the sterilization temperature and also on the holding time. Deviations of more than 0.5K are not acceptable for the validation of sterilization processes.

These errors can be identified through the routine checks of the physical process parameters and the associated verification of the measurement results on the basis of the validation results.

Use of the calibrated data logger:

A validator uses calibrated data loggers with the accuracy required by the standards. To ensure that the data loggers maintain the required accuracy, the validator regularly compares and verifies the calibration of the data logger, e.g. by comparing all sensors of the data logger in a known process in the washer-disinfector or sterilizer. The maximum deviation of all temperature sensors must not exceed ± 0.25 K. The calibration of the WD or sterilizer sensors is also part of the validation. For this reason, the validator uses data loggers with increased accuracy during validation. The validator compares his measurement results with the measurement results of the machines and thus carries out a calibration. If deviations occur, these are documented in the validation report. If the deviations are outside the specification, the validation cannot be assessed as a "pass". The operator must inform the service department in the event of deviations and commission repairs or adjustments and calibration.

Conclusion

Routine checks with calibrated data loggers can detect errors in the RUMED at an early stage and counteract misinterpretations, malfunctions or machine failures. In addition, data loggers are an indispensable tool in the event of an accident or malfunction, they serve for process reliability and ultimately also for patient safety. In order to be able to guarantee a correct validation of the complex processes in the WD or sterilizer according to the standard, only normative and calibrated equipment should be used.


KALIBRIERZERTIFIKAT
CERTIFICATE OF CALIBRATION
CERTIFICAT DE CALIBRATION

Fig. 4: ebro-®ISO calibration certificate

Contents of an ISO calibration certificate:

- Clear identification of the measuring equipment
- Description and identification of measuring equipment
- Calibration date
- Calibration results obtained after adjustment or repair
- Identification of the calibration procedure
- Normal that was used to ensure traceability
- Environmental conditions
- Specification of the uncertainties when calibrating the measuring equipment
- Identification of the person (s) who carried out the confirmation

In the calibration laboratory of Xylem Brand -ebro-®, DAkkS calibrations in the accredited area as well as ISO calibrations can be carried out for temperature, relative humidity and pressure values. ebro® offers you highly precise calibration services through our trained service technicians and through DAkkS accreditation. We recommend that you have your data loggers calibrated annually to ensure the accuracy of your measurements. On request, we will be happy to include you in the calibration reminder service, which is free of charge for you. So you don't miss the right time to calibrate your data loggers. The registration form for the ebro® calibration reminder service can be found at https://www.ebro.com/fileadmin/pics/PDFS/07_033_Kalibrierdienstflyer_XAGS_160718_mipdf. Since October 18th 2021, the ebro® data loggers will be calibrated in the new service center in Weilheim.

https://www.ebro.com/fileadmin/pics/PDFS/Service/Service-Form_Validation_and_Process_Loggers_EN_v17.pdf

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New aseptica partner Veolia Water Technologies

The Veolia Group is the leading company in environmental technologies and the global benchmark for sustainable solutions in resource management. With Veolia Water Technologies, the group has expertise in water and wastewater treatment that can look back on more than 130 years of history in Germany. With strong brands such as Berkefeld, ELGA Labwater or EVALED, Veolia Water Technologies has been a reliable partner for planning, delivery and service of water treatment solutions in hospitals, therapeutic facilities, laboratories and industry for many years.

We are the specialists for water

Whether for the technical building equipment in hospitals, the ultra-pure water requirements in clinical and analytical laboratories or for the sensitive requirements in the manufacture of medical pharmaceutical products, Veolia Water Technologies offers comprehensive turnkey solutions for municipalities and industry.

The core competencies include:

- Central sterile supply department (CSSD) / reprocessing unit for medical devices (AEMP)
- Ventilation for sensitive environments and clean rooms
- Pure and ultra-pure water for laboratories
- Cooling water treatment
- Heating water treatment incl. local/district heating
- Swimming pool water incl. therapy and exercise pools
- Complex drinking and waste water solutions

In addition to the 350 employees at the company headquarters in Celle, Lower Saxony, more than 30 sales engineers and 50 technicians are working around the clock in Germany, providing critical infrastructure throughout the country with know-how and comprehensive services.

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Safe and standard-compliant water treatment is a prerequisite for the hygienic operation of CSSDs or AEMPs. In addition to the appropriate system technology, Veolia Water Technologies also provides a comprehensive range of training, services and additional service solutions, such as the digital service from Hubgrade, which allows the essential parameters of the water treatment to be permanently monitored, documented and analyzed online - across all our locations and on any terminal device.

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Publisher:

Office, das Büro der aseptica
Bernd Vieregge
Frieda-Nadig-Straße 53
33332 Gütersloh, Germany
E-mail: info@aseptica.com

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COLLET Concepts Communication
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E-mail: info@aseptica.com
Website: www.aseptica.com
Stefan Collet, Sandra Acikportali

In co-operation with:
Ecolab Deutschland GmbH
Ecolab-Allee 1 | 40789 Monheim am Rhein, Germany;
Miele & Cie. KG
P.O. box | 33325 Gütersloh, Germany;
Dentsply Sirona Deutschland GmbH
Fabrikstraße 31 | 64625 Bensheim, Germany;
Xylem Analytics Germany Sales GmbH & Co. KG
Ebro
Peringerstraße 10 | 85055 Ingolstadt, Germany;
Innovations Medical Vertriebs GmbH
Badstraße 11 | 78532 Tuttlingen, Germany

Veolia Water Technologies Deutschland GmbH
Lückenweg 5 | 29227 Celle

Title image: adobe stock
Circulation: 6500
Publication schedule: three times a year
Printed on chlorine-free bleached paper

ISSN 1439-9016

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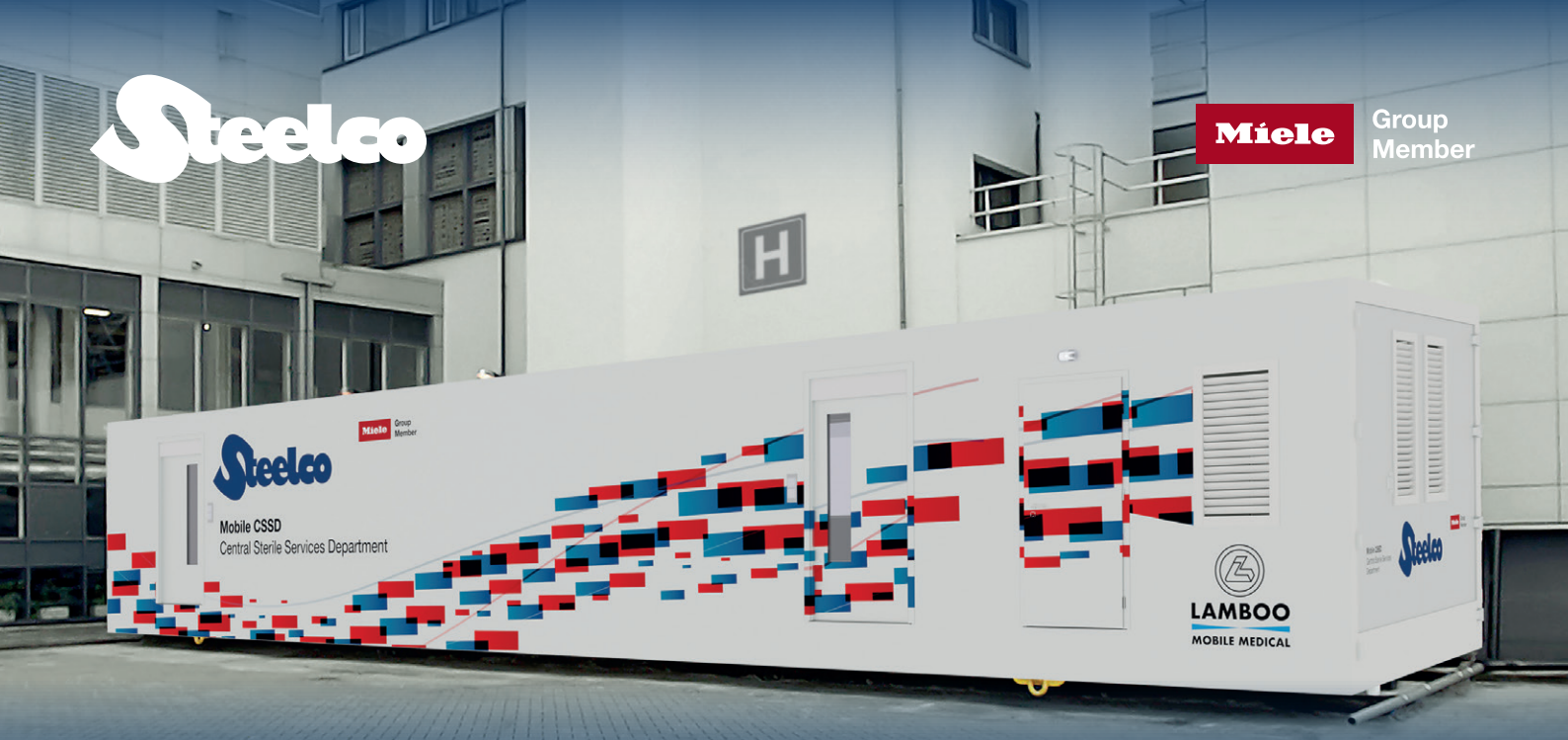

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