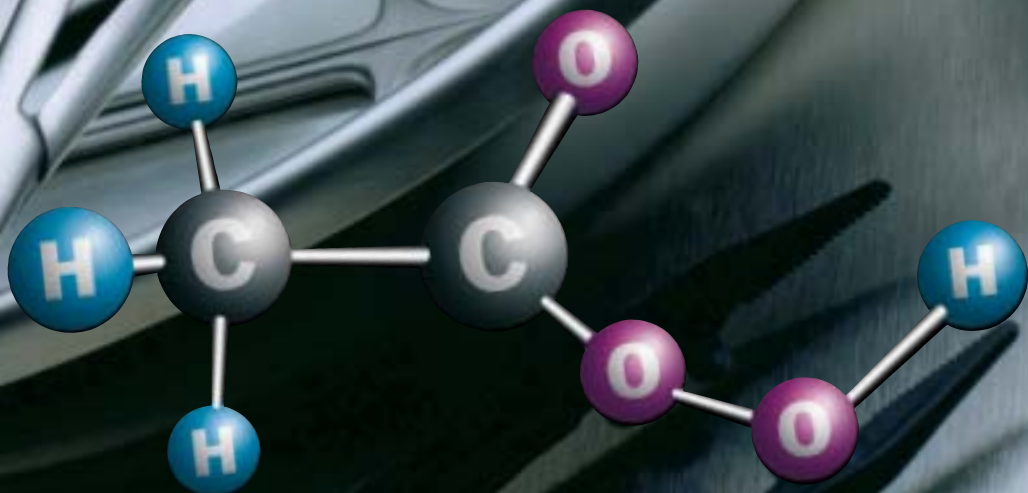


aseptica

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TITEL TOPIC

**More than 100 years of
Peracetic Acid**



Dear Readers,

You have in your hands the first English-language »aseptica«. The German issue has appeared over the last 11 years with increasing success. Let me say a few words concerning the history of this publication. »aseptica – the modern specialist journal for hygiene and disinfection« (extract – November 1994). Under this title, a new specialist journal came onto the market to link up with Medica 1994, and whose purpose was to provide information for those personnel responsible for hygiene management in Germany on current developments and standards accomplished in practical hygiene matters such as, for example, in the preparation of surgical instruments. Since then, 10 years have gone by and the »aseptica« today is established on the specialist publications market as an important journal both in Germany, as well as beyond its borders into predominantly German-speaking countries. No wonder that since 1997 »aseptica« has self-confidently been proclaiming itself as the »specialist journal for hygiene in hospital and medical practice«.

Of course, since 1994, this specialist journal has undergone several transformations – the external image has changed over the years, and for many years the »aseptica« pages on the internet under www.aseptica.com have also been well visited, but up to now have only been in the German language. In previous years, »aseptica« has constantly put forward suggestions for tackling the latest subjects in order to promote discussion of problem areas in preparation techniques and procedures. We believe that we can be of help to you by presenting you with a wide variety of subjects in which you are confronted with these problematic questions day-in, day-out. An international exchange of information has long been taking place, not only in industry, science and standards committees, but also among users. Internationally there still continue to exist very varied conditions in hospitals and medical practices. Account is taken of this circumstance in the first English-language edition of »aseptica«. We are convinced that we can offer important information to users in non-German speaking countries in the form of selected contributions submitted in recent years. It is therefore our aim in the future to provide an international »aseptica« edition for MEDICA on a regular basis.

The editorial staff will be pleased to receive your feedback. Only in this way can we succeed in further developing the »aseptica« also for you. We now wish you an interesting read.

With all good wishes



Reinhild Portmann

Content

Data logger: yes! But which data logger ist the right one for a particular application?	p. 3
New data logger software for routine monitoring and validating	p. 5
OXIVARIO – an automatic reprocessing method using an oxidative additive	p. 6
An experiment: alkaline release of active oxygen from hydrogen peroxide	p. 8
Approaches for Preventing, Removing and Killing Biofilms	p. 9
7. International FORUM 2006	p. 11
Orthovario – a novel oxidative process also suitable for aluminium.	p. 12
Preliminary experience with a new modular mobile unit	p. 13
More than 100 years of Peracetic Acid	p. 14
Report on the German medicaltechnical market	p. 20
»Washing wiht any water« – Water softening, properties and effects in machne preparation	p. 24

Data logger: yes! But which data logger is the right one for a particular application?

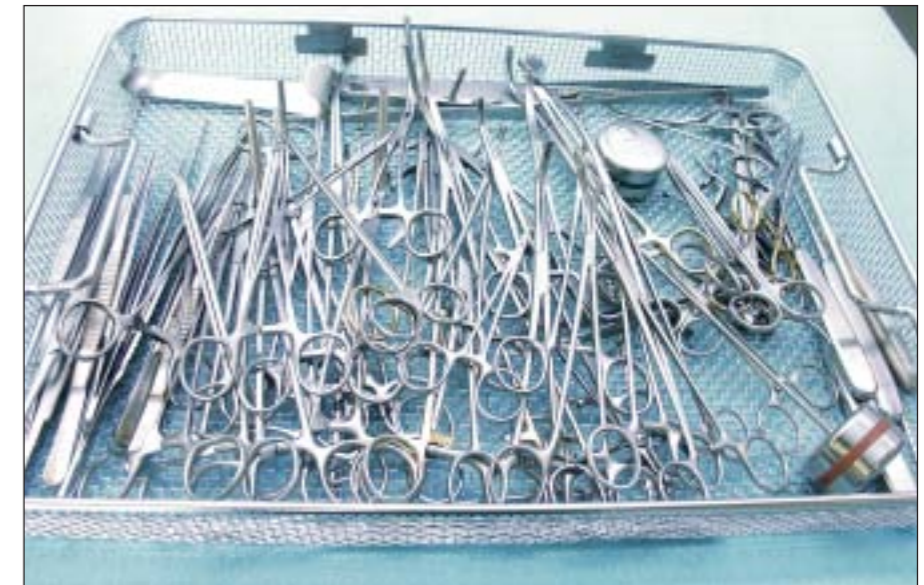
H. Pahlke, Th. W. Fengler

There are many opportunities for using a data logger in a hospital. Every process with temperature and pressure parameters can be subject to an appliance-independent check-up. Because of the flexible programming of the recording interval from 1 second up to 8 hours, the time course of any process can be taken into account. For example when checking a sterilisation process, the interval between recordings can be set to 1 second, whereas for monitoring refrigerators used to store blood conserves, a 15 minute interval can be set. For the user it is also relevant which data logger he or she uses for which check-up. The following is a user's guide to data loggers.

First of all one should consider which data logger should be used for routine monitoring or for validation, and whether it is possible to use just one logger for both purposes.

Routine monitoring of WDDs

To start with there is the simplest data logger EBI-125 A with an internal Pt1000 sensor, which can register temperature without an external sensor. This data logger can also be ordered with a securing eyelet (EBI 125 A OE). This is especially good in the case of monitoring WDDs, because it can be put into the sieve basket along with the instruments to be reprocessed. Here, because of the relatively great mass, the temperature recording is somewhat sluggish, as is typical for a temperature curve from a process load (instruments). The Ao value resulting from the temperature curve gives a safe evaluation of the disinfection performance.



Pressure-temperature data logger EBI-125 A PD3 with flexible temperature sensors, diameter < 2mm.

On the other hand, when recording in cavities that need to be reached by the washing solution, data loggers are suitable that have fine, flexible sensors with a diameter of 1.6mm, such as for example EBI 125 A-EM 500 F 1.6 that can be inserted into the instruments.

An optimal set consists of 3 simple data loggers EBI 125 A, 1 data logger with flexible temperature sensors EBI 125 A-EM 500 F 1.6, a selection appliance and the software Winlog 2000P.

Validating WDDs according to pr EN DIN 15883

The use of data loggers to validate WDDs according to pr EN DIN 15883 requires temperature sensors with a diameter less than 2mm. These are necessary for validating a process, because here recordings must be made not only at several positions in the wash-load area, but also on the wash chamber walls, in the sump and in the

drainage area. To reduce the number of data loggers one should stick to a data logger (EBI 125 A-EM 500 F 1.6 2K) with two temperature sensors. Of course data loggers with flexible 1.6mm temperature sensors can also be used to validate steam sterilisers, according to DIN 58946-6. An optimal set consists of six data loggers with flexible temperature sensor EBI 125 A-EM 500 F 1.6 2K, as well as an interface and the software Winlog 2000 P.

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Pressure-temperature data logger EBI-125 A PD3 with flexible temperature sensors, diameter < 2mm.

Routine monitoring of steam sterilisers

For checking and routine monitoring of sterilisers, at least one data logger is required which is equipped with temperature and pressure sensors, such as EBI 125 A-PT AK 5N. If a data logger is used to monitor the load, it is sufficient to use a logger equipped with a rigid temperature sensor and a pressure sensor. If the data logger is positioned among the items being sterilised, it can provide exact information about the course of pressure and temperature in that load. Because temperature is dependent on pressure, it is possible in addition to the simple pressure recording also to calculate the theoretical temperature, using the software Winlog 2000 P. This then supports the temperature recording.

Of course this data logger (EBI 125 A-PT AK 5N) can also be used to check the parameters in WDDs. In a WDD for example, the pressure channel can be faded out should it not be required, using the software Winlog 2000 P. An optimal set then, consists of a pressure-temperature data logger EBI 125 A-PT AK 5N, a

thermal insulation box, as well as an interface and the software Winlog 2000 P.

Validating steam sterilisers according to DIN 58946-6

If temperature sensors are to be introduced into sterilisable product packaging to validate the course of the process, they should have a diameter of less than 2mm, as required by the standard DIN EN 554. Because of its flexibility, the sensor can be positioned more or less anywhere amongst the items to be sterilised. Furthermore the sensors are suitable for temperature recordings in cavities, as for example in hoses- these latter pose considerable problems for sterilisation.

An optimal set consists of 5 data loggers with flexible temperature sensors EBI 125 A-EM 500 F 1.6 2K, 1 pressure-temperature data logger EBI 125 A-PT 3, 6 thermal isolation boxes, as well as an interface and the software Winlog 2000 P.

A data logger can also be used to conduct a check-up on a low-temperature formaldehyde gas steriliser. Because the sterilisation process occurs in a vacuum at temperatures between +50°C and +65°C,

it is important to monitor these parameters. However no evidence about gas sterilisation itself can be deduced. The use of loggers here is identical with that in an autoclave, where the recording interval should be set so that recording can take place during the entire time taken by the process.

There are further uses for loggers outside the CSSD. To check the disinfection performance of bedpan washers, data loggers can be fixed to a bedpan with clips, at say three positions. Here data loggers with or without temperature sensors can be used. If there is a wash device for urine bottles built in as an integral part of the appliance, then it is suitable to use a „dummy« bottle, with a flexible temperature sensor inserted right up to the top of the bottle. The Ao value can then be calculated from the temperature curve. An Ao value of at least 60 should be attained.

Temperature data loggers can also be used to document storage temperatures in a sterile store and in used goods stores (indicators!) or to monitor temperature in working areas. Furthermore one could plan to use a data logger in the food preparation area. As well as the monitoring of refrigerators and cold rooms (although these have built-in monitoring systems) the temperature insulation of the tray system can be monitored. The flexible sensor is introduced into the food and the data logger documents the temperature curve from the kitchen all the way to the patient.

Furthermore for chemical-thermal reprocessing of crockery, the temperature of the washing solution of a washer-disinfector can be monitored whether it is a single appliance or a conveyer belt system. In laboratories, blood banks and in the operating theatre various appliances can be monitored by data loggers, for example incubators, refrigerators, freezers or warm cupboards.

Because of the various uses of data loggers, it is sensible to draw up a checklist of those processes in the building that should be monitored and documented. Then using the checklist, the necessary data loggers can be obtained. ■

New data logger software for routine monitoring and validating Winlog.med and Winlog.med Validation

S. Neumann, I. Kruse

ebro Electronic, in Ingolstadt, has developed Winlog.med, a new software solution especially for the routine monitoring and validating of washing and sterilising processes in the CSSD using data loggers. For washer-disinfector appliances, the evaluation by the new software is made according to the standards pr DIN EN 15883-1,2,3 and according to the guideline draft of the DGKH and DGSV. For steam sterilisers the evaluation is made according to DIN EN 285, DIN EN 554, DIN 58946-6 and DIN EN13060.

CSSD application

Winlog.med is available in two versions:

- Standard version Winlog.med: for daily routine monitoring. It is simple to use, so that even untrained personnel can easily learn how to use it.
- Winlog.med Validation: this software was developed for annual monitoring. Winlog.med and Winlog.med Validation analyse completely automatically the data from data loggers used for daily routine monitoring, as well as the annual validation of washer-disinfectors, bedpan washers and steam sterilisers. The software recognises and independently checks the relevant stages of cleaning or sterilisation, conducts all necessary analyses automatically, and delivers a fast and accurate assessment of the process (passed/not passed).



Routine monitoring

For daily routine monitoring of WDs and bedpan washers, the disinfection parameters Ao value 60, 600, 3000 and the temperature curve are especially relevant. For the routine monitoring of steam sterilisers the pressure/temperature/time curves are documented. The values are automatically determined and graphically represented using the standard version Winlog.med.

Validation

For the validation of WDs, bedpan washers and steam sterilisers, Winlog.med Validation is suitable.

In addition to the features provided by the standard version, this software includes „mapping«, i.e. the number and position of the data loggers are defined in the software in three dimensions. This means that the exact position of the logger within the appliance is fed into a three-dimensional model of the WD or steam steriliser. Here each logger series number, channel and position is stored. The appliance to be monitored is selected beforehand from a data bank.

Winlog.med Validation provides automatically the following information from the data logger about the validation of the WD:

- WD data: model, inventory number, appliance number, programme, data logger load, previous monitoring.
- Name of person carrying out the monitoring (obtained from the electronic signature of the user, entered by the user before using the appliance)
- Position of sensor, type and series number of sensor
- Chosen programme
- Calculated and required Ao value
- Release of load (yes/no)

The automatic report generation for steam sterilisers works in exactly the same way as

it does for WDs, but for steam sterilisers different information is relevant:

- Steam steriliser data: model, inventory number, appliance number, programme, data logger load, previous monitoring.
- Name of person carrying out the monitoring (obtained from the electronic signature of the user, entered by the user before using the appliance)
- Position of sensor, type and series number of sensor
- Chosen programme
- Residual air
- Minimum pressure at vacuum
- Compensation time, holding time



- Attained sterilisation temperature
- Temperature range
- Theoretical temperature
- FO value
- Release of load (yes/no)

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The software marks each of these values as OK / not OK. A click of the mouse shows the relevant value or curve. The protocol is initially shown on the screen, but can be stored or printed out.

Summary

The new Winlog.med and Winlog.med Validation software from ebro Electronic provide the CSSD user with the possibility of automating and therefore simplifying routine

work with data loggers. Because Winlog.med and Winlog.med Validation were developed especially for cleaning and sterilising processes in the CSSD, they encompass exactly those features necessary in these areas. ■

OXIVARIO – an automatic reprocessing method using an oxidative additive

R. Portmann, A. Schläger

The reprocessing of surgical instruments presents CSSD personnel with the daily problem of how to reprocess instruments thoroughly, avoiding any remaining residues. This problem is classified as critical by the Robert Koch Institute, and not just since the new variant of Creutzfeld Jacob disease appeared. In the Nov. 2003 edition of aseptica, we presented the first tests and results of a new reprocessing method that uses an oxidative additive. Meanwhile we have collected further results from tests on the Oxivario process: the radionuclide method reveals the improved instrument cleaning performance, and a REFA study confirms that time is saved in the CSSD.

Ten years ago Miele set a new standard for instrument reprocessing with the introduction of the Vario-TD process for washer-disinfector appliances. The new Oxivario process, that uses the additive hydrogen peroxide, is a further development of the Vario-TD process. It provides the user with a high performance reprocessing procedure especially suitable for instruments classified as critical by the Robert Koch Institute.

The Oxivario process uses an additional second wash stage, taking place after the

cold pre-rinse and first wash stage. This second wash stage takes five minutes at a temperature of 55°C, and hydrogen peroxide solution is added to the alkaline wash solution. Thus any remaining protein on the instruments is oxidised and dissolved. Even fibrin, that causes the particularly stubborn adhesion of blood on and in instruments, is completely removed. This was shown by chemical protein analysis and infrared spectroscopic experiments on contaminated test objects. Even coagulated deposits found on high frequency instruments are degraded, and almost all are converted into water-soluble compounds. This process is suitable for reprocessing surgical instruments, including those used for minimally invasive surgery and even for optics.

It is true that a similar cleaning effect can be attained using strongly alkaline detergents containing active chlorine. But the instruments are attacked chemically due to the strong alkalinity and the chloride



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released. Corrosion of this sort does not occur with the new process using hydrogen peroxide. Thus an optimal cleaning effect is attained, while at the same time materials from which these expensive instruments are made are reprocessed very gently. However after cleaning, the instrument joints need more attention than previously. After reprocessing they are so clean that metal surfaces stick, and the joints become stiffer after a while. They have to be lubricated using medical instrument oil.

Radionuclide method furnishes experimental proof of improved cleaning performance

A recent experiment was conducted by SMP GmbH, a test laboratory in Tübingen, to determine the residual contamination on reprocessed instruments using the radionuclide method. It was shown that the addition of hydrogen peroxide during the alkaline cleaning stage of the Oxivario reprocessing programme led to clearly improved cleaning performance. Here cleaning behaviour was investigated for instruments with hidden surfaces, i.e. the fissures of jointed instruments.

For these experiments the joint areas of arterial clamps were contaminated with a defined amount of radioactively marked coagulable sheep's blood. Afterwards the clamps were opened, laid in mesh trays and reprocessed in a Miele washer-disinfector. Forty clamps were cleaned at a time, either using the Oxivario process with addition of hydrogen peroxide in the relevant process step, or using the same process without the addition of peroxide. After reprocessing, the arterial clamps were tested with the gamma camera. Here the gamma camera measures radioactivity, and thus residual

radioactively marked sheep's blood is reliably determined. In this way the remaining residual soil was quantitatively measured and evaluated.

The results obtained from the cycles without addition of hydrogen peroxide were considerably lower. For the instruments cleaned with this procedure, more than five percent showed residual contamination over the limiting value. Instruments cleaned using the full Oxivario process with addition of peroxide, all showed values beneath the limiting value, at a level indicating successful cleaning. Thus the standardised cleaning performance is confirmed at a very high level. Even areas that are hard to reach due to their construction, such as joint surfaces, are thoroughly cleaned. One can only really speak of a proper prevention of transmission of prions, as required by the Task Force vCJD (variant Creutzfeld Jacob Disease) at the Robert Koch Institute, when cleaning conditions produce considerably more than 99% completely clean instruments. This is why the Oxivario process is being tested for effectivity on prions (pathogens causing the Creutzfeld Jacob disease) at the Neuropathology Institute at the Großhadern Clinic in Munich.

REFA study- Oxivario process saves time in instrument reprocessing

A recent REFA study conducted in the district hospital of Grevenbroich in North-Rhine Westphalia shows that the Oxivario cleaning process not only cleans more thoroughly than previous methods, but also saves considerable time in the central sterilising service department. Here each process stage of the reprocessing was recorded. A protocol was kept from just before the removal of the container of used theatre

instruments from the transport trolley, right up to the visual control after automatic cleaning. The time taken for the cleaning and disinfection of three different mesh trays of contaminated instruments was investigated. The reprocessing took place in a G 7828 Miele washer-disinfector. For this study the instrument reprocessing took place once using the Oxivario process, and once using the Vario TD cleaning programme. For both processes the mesh trays were filled, emptied, checked and where necessary manually cleaned by one and the same employee at the Grevenbroich hospital.

The process analysis of the REFA study shows that the Oxivario process offers considerable time saving compared with the Vario TD process. Although the programme running time of the Oxivario process is in total a little longer, manual after-cleaning is completely unnecessary, because of the markedly better automatic cleaning results. When using the automatic reprocessing programme Vario TD, the instrument sets had to be checked visually, where necessary laid in hydrogen peroxide, rinsed, cleaned a second time and dried by a CSSD employee. These additional jobs are not necessary with the Oxivario programme.

The REFA study shows that the Oxivario process saves 23% or 24 % on time taken depending on the instrument set, compared with the Vario TD process. Thus the Oxivario reprocessing programme contributes to a positive balance of cost and performance in the central sterilisation service department. In addition to the cost factor, personnel are spared manual cleaning steps and thus are less at risk of injury and contagion. ■

An experiment: alkaline release of active oxygen from hydrogen peroxide

W. Michels

The OXIVARIO programme makes use of the release of oxygen from hydrogen peroxide in the second alkaline cleaning stage. Initially oxygen radicals are formed (Latin: status nascendi) before molecular oxygen (O₂) is formed. These radicals are chemically very active (active oxygen) and have a strong oxidising effect. Thus organic material is partly broken down and polymers are transformed into shorter and more polar fragments that are more soluble.

Hydrogen peroxide has a natural tendency to break down into water and oxygen when warmed. At room temperature the rate of decay is immeasurably small. As temperature rises, the rate of decay increases, although at a hydrogen peroxide concentration of 0,1% in the wash solution at 55 °C, it is still too slow to exert a thorough and optimal effect during a cleaning time of 5 minutes.

Alkalinity catalyses the decay of hydrogen peroxide. This effect is utilised in the OXIVARIO programme.

Hydrogen peroxide solutions have an acid pH value. Solutions with over 30 % hydrogen peroxide have a pH value of 2-4, a 6 % solution approximately pH 5. The acidity of hydrogen peroxide has to be compensated for with alkalinity. Additionally a sufficiently high pH must be reached

to catalyse the decay. An ordinary alkaline detergent that has a pH of 11.2 at a concentration of 0.5 % only reaches a pH of 10.4 when 0.35 % hydrogen peroxide is added (approximately 30 %).

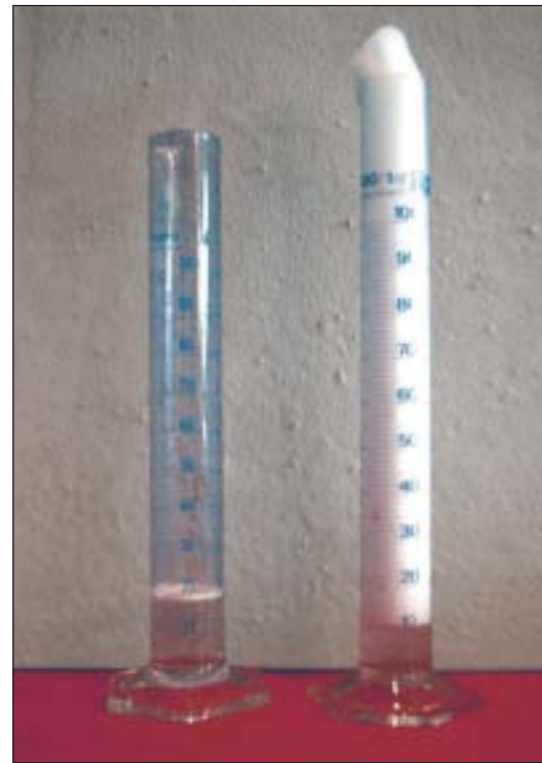
The following experiment demonstrates visibly that active oxygen release requires a sufficient pH value:

10ml of a 30 % hydrogen peroxide solution is pipetted into each of two graduated cylinders. 2-3ml of a 1 % SDS (Sodium dodecyl sulphate) solution (alternatively 1ml of an ordinary hand-wash solution) are added to each cylinder. 5ml of a liquid alkaline detergent (pH about 12.5 in concentrated form) is added to the left hand cylinder, and 10ml detergent to the right hand cylinder.

It is immediately noticeable that tiny oxygen bubbles form in the right hand cylinder, that rise, causing foam formation in the tenside. The foam rises slowly up the graduated cylinder reaching the top after about 15 minutes. Heat can be felt at the base of the full cylinder. Very little has happened in the left hand measuring cylinder. The solution is not warm, and there is at the most, a thin foam layer about 1mm thick on top of the solution. If the pH of the two solutions is ascertained they show a difference. The left hand cylinder has a pH of less than 11, the right hand cylinder a little more than 11.

Significance for practical applications:

In order to utilise the oxidising potential of hydrogen peroxide in the automatic washing-disinfecting process OXIVARIO effec-



Visualisation of the release of active oxygen by foam formation, on the right with sufficient alkalinity.

tively, it is necessary to choose a finely balanced combination of alkaline detergents, but also to strike just the right balance in the dosage and relative concentrations. If other detergents or different concentration relationships are used, the good results from the OXIVARIO process proven by experiments, will not be attained in practice. In some circumstances most of the hydrogen peroxide would be hardly or not at all utilised, and simply rinsed away with the waste water. Up to now it has seemed that „anything goes“ in the area of cleaning and process chemical use. However in future everyone should stick to the conditions for use which are used in the effectiveness proofs. ■

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Approaches for Preventing, Removing and Killing Biofilms

B. Meyer

Biofilms not only pose a significant hygienic risk in the food industry, but also lead to economic losses by causing the technical failure of water systems, cooling towers, heat exchangers, chain lubrication systems and other systems. Biofilms also contribute to an increased risk of infection through growth on implants, venous or urinary catheters or other medical devices. The growth of biofilms near the seriously ill, namely in overflowing wash basins or drains, can cause infections if biofilm organisms are spread by aerosols (e.g. by a stream of water that directly enters the drain). Not of least importance, biofilms in the human oral cavity can impair health by promoting the formation of cavities. Therefore, possibilities for preventing, removing or killing biofilms are being sought out in nearly all areas of hygiene.

All of the pertinent experiments confirm that microorganisms that live in biofilms are more difficult to kill with biocides than free-living microorganisms of the same species. This is the result of microorganisms developing a more resistant phenotype when attaching to surfaces or forming biofilms. The expression »resistance« is confusing, since this property cannot be inherited. Therefore, the reduced sensitivity to biocides in this case should be called »phenotypic adaptation«. Apart from this phenotypic adaptation, the effect of biocides on biofilm organisms can be limited by the slower penetration of the biocides into the biofilm matrix, the extracellular polymeric substance (EPS) and by a chemical reaction with the EPS.

Because of the many different influencing factors such as the surface material, the

presence of nutrients and oxygen, the microbial species, flow velocity of the surrounding liquid, etc., biofilms exhibit a broad variability. Therefore, results that have been obtained with a certain biofilm type are not necessarily directly transferable to other biofilms. Each biofilm is fundamentally different. The literature describes many attempts at defining standard conditions for biofilm production. However, so far a specific model that is representative of biofilms in general and that could be used in tests with disinfectants is unavailable.

Regular disinfection to prevent biofilm formation

A possible strategy for the prevention of biofilms is regular disinfection before biofilm formation begins. However, the first phase of biofilm formation, the attachment of microbes to a surface, is a relatively quick process and lasts no more than a few hours. It is primarily in this first phase of biofilm formation that phenotypic adaptation occurs. Therefore, in a permanently moist environment and with many areas of application (e.g., in the food industry) it is hardly possible to prevent this first step of biofilm formation. In water systems regular disinfection may even lead to an increased number of free-living microbes in the water. This can be the result of an increased detachment of microbes from the wall or an increased availability of nutrients due to the oxidative splitting of organic polymers by disinfectants.

Removing and killing existing biofilms

To kill and/or remove biofilm organisms an active agent must penetrate the EPS and gain access to the cell. Since the chemical composition of the EPS can vary greatly from biofilm to biofilm, nonspecific mechanisms are preferred. Oxidizing substances

such as active chlorine or peracetic acid are commonly used. In water treatment it was possible to show that active chlorine was more effective in eliminating Legionella biofilms than non-oxidizing biocides such as quaternary ammonium compounds or biguanides. Other authors have also reported the relatively poor effectiveness of biguanides against semiartificial biofilms. However, it has also been reported that active chlorine concentrations of up to 1,000 ppm were required to clearly reduce the number of biofilm organisms, while merely 10 ppm proved sufficient for the same free-living microbes. Nevertheless, active chlorine often is seen as the first choice to combat biofilms. This may be due to the fact that active chlorine, in addition to killing microorganisms, also can remove the EPS from surfaces which makes it more difficult for the microbes to once again attach themselves to these surfaces. Ozone, an even stronger oxidizing agent, has been successfully used to kill and remove biofilms in nutrient-poor water systems.

The situation appears to be different in the disinfection of open surfaces as opposed to water systems. For example, peracetic acid was more effective than active chlorine in killing biofilms composed of Listeria and Pseudomonas on stainless steel. The differences between the two active agents were especially clear when testing under an organic load (here 5% milk) in order to simulate conditions encountered in practice. This can be traced to the fact that active

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chlorine fundamentally exhibits a higher protein effect than peracetic acid.

Other authors came to the same conclusion when testing relatively young biofilms of *Staphylococcus aureus*, *Proteus mirabilis* and *Pseudomonas aeruginosa* on stainless steel. According to information provided by the manufacturer, different disinfectants were tested under »clean« (0.03 % protein load) und »dirty« (1 % protein load) conditions. The evaluation of the active agents according to these results can be seen in Table 1. However, this evaluation only considers the killing of biofilm organisms and not the removal of EPS in which active chlorine possibly may have some advantages. Removal of the microbes and the EPS is important in practice in order to reduce the attachment of new microbes and a renewed biofilm formation. In most cases good precleaning or a good cleaning result with the disinfectant used is a precondition for a successful disinfection. Therefore, the ideal agent for a given problem can best be determined under practice conditions.

Electrical fields, catalyst-modified surfaces and ultrasound have been used to improve biofilm removal and increase the effectiveness of biocides against biofilms. However, such systems are limited to small surfaces or objects and, except for the case of ultrasonic cleaning of simple medical instruments, hardly have found use in practice.

Enzymes and detergents have likewise been used as synergists to increase the effectiveness of disinfectants. However, the specific mechanism of action makes it difficult to find enzymes that are effective against all

Table 1: Evaluation of agents acting against biofilms

Effectivity	Active agent
Strongest	Per-acids Jodophores Biguanides Active chlorine Amphoteric tensides
weakest	Quaternary ammonia compounds

the different biofilm types. Formulations that contain several different enzymes are likely necessary to achieve success. Fundamentally, proteases and carbohydrate-splitting enzymes can be useful.

The removal of biofilms during cleaning is significantly affected by the mechanical force that is applied to a surface. The use of an automatic cleaning machine or high-pressure cleaning notably increases biofilm removal when compared with the use of cleaning gels or low-pressure cleaning with disinfection. However, high-pressure cleaning can cause more hygiene problems than it solves: The resulting aerosols can lead to a widespread dissemination of the biofilm organisms into the surroundings. Other means of exerting mechanical force on large surfaces, such as foam that slowly trickles down onto vertical surfaces or turbulent flow in closed systems, are preferable. Each mechanical effect not only improves cleaning, but also leads to an improved killing of microbes during disinfection. It has been shown that the effectiveness of peracetic acid in a closed system increased by 99.7% during the transition from laminar to turbulent flow. This increase was not solely attributable to an improved removal of microbes.

Possibilities of preventing biofilm formation without killing microbes

In many technical processes microbes do not pose a problem as long as they do not form a biofilm. In other areas at least disinfection would be easier if the attachment of microbes could be prevented. Many attempts were made to find materials for surfaces that do not promote biofilm formation or even suppress it. For example, water samples from different water reservoirs made of different materials were examined: Independently of the water quality, biofilms developed on certain materials (bituminous paint, chlorinated rubber) while other materials remained biofilm-free (polymethylmethacrylate). Presumably, the leaching out of organic material from the surfaces or an accumulation of organic material on certain materials led to increased growth in nutrient-poor systems. In any case the type of surface material plays a decisive role in biofilm formation.

Likewise, the microbe content of water from different hoses also was examined: Water in contact with PVC or rubber generally had a higher microbe count than water in contact with glass or Teflon. Although these data only reflect the number of free-living microbes, they can indirectly provide information about biofilm formation on the material in question. Different materials were evaluated generally for biofilm formation and specifically with regard to *Legionella*. The results are shown in Table 2.

It follows from these results that hardly any material exists that facilitate absolutely no biofilm formation. Such assessments also must be carefully considered, because they can vary depending on the microbial species involved and the boundary conditions. It was discovered that the polyester seal for a culture medium supported the strongest biofilm formation if materials were tested in nutrient bouillon. In contrast this same surface in a nutrient-poor medium exhibited hardly any biofilm growth. On the other hand, nylon only weakly supported biofilm formation in nutrient bouillon, but exhibited a clear surface coating with a biofilm in a nutrient-poor medium. Therefore, it has so far been nearly impossible to predict which materials will least support biofilm formation under practice conditions. However, some general predictions should be possible if the boundary conditions, such as the nutrient supply and temperature of a system, can be held constant.

Table 2: Evaluation of various materials relevant to encouragement of biofilm formation

Encouragement of biofilm growth	Substance
weak	Glass Stainless steel Polypropylene Chlorinated-PVC Non-plastified PVC Steel Polyethylene Ethylene-propylene
strong	latex

Many attempts have been made to inhibit biofilm formation with a permanent microbicidal finishing of the surfaces, especially in medicine. Biofilm formation on implants is a frequent reason for rejection reactions. A few authors have reported about biofilm suppression on such medical devices through finishing with silver. However, an advantage under practice conditions could not yet be confirmed. Implants treated with silver oxide could not suppress biofilm formation in vitro. On the other hand, negative clinical effects in vivo could be reduced by using devices coated with silver/chlorhexidine or chlorhexidine/chloroxylenol. However, the infection rate could not be reduced with chlorhexidine-coated venous catheters. Since each biocide must chemically interact with the microbial cell, biofilm formation finally can only be influenced by the slow leaching out of such substances from the surfaces. However, it was possible to show that the infection rate in silicon implants could be reduced by using covalent, namely tightly bound quaternary ammonium compounds. However, it did not follow from these investigations whether this effect required a slow release of the biocides into the surroundings. However, a slow release of the biocide also can be assumed in this case,

because the coated material likewise reduced an artificial contamination in vivo. So far none of these coatings has found broad practical use. Among other reasons, this may be due to the contradictory reports concerning the clinical advantages made by different authors. In other areas of application, such as the food industry, a possible transmission of active agents to food and a possibly only time-limited effect limited the use of such coatings. The ecological advantages for microbes in biofilm formation have been thoroughly discussed in the literature. They are summarized in Table 3.

- Generation of its own microniche
- Symbiosis of various species in food chains
- Protection from desiccation
- Improved nutrient uptake from fluids flowing past
- Adsorption of nutrients via the EPS
- Excretion and possibly storage of carbon compounds in the absence of other growth factors

An inhibition of biofilm formation through withdrawing carbon sources is virtually impossible since many microorganisms can grow in extremely low concentra-

tions. Even water systems with highly purified water support biofilm formation. Another approach involves adding growth factors which causes biofilm formation to be minimized since it is no longer advantageous for microbes. Nitrogen or sources of phosphorus are frequently a minimal factor for the growth of microbes. However, until now such considerations have hardly found any practical application.

Conclusions

There are fundamentally three strategies available for combating a biofilm formation:

- Timely disinfection before a biofilm develops
- Disinfection of existing biofilms with »hard« biocides
- Inhibiting the attachment of microbes by selecting suitable materials or minimizing the advantage of biofilm formation for the microbes

None of these strategies is suitable for every biofilm problem. The solution possibly involves finding the right strategy or the right mix of all strategies for each biofilm problem.

References are available from the author. ■

7. International FORUM 2006

Medical Devices and Processes 24. February 2006 in Berlin, Hotel Esplanade

Program:

- A. Albrecht:** *Regulatory Affairs in the CSSD – objectives and contradictions*
- W. Mohr:** *Requirements for Processing Chemicals following prEN 15883-1*
- W. Michels:** *Cleaning Efficiency – Orthovario*
- S. Schnekenburger:** *Quality and Economies – crucial for an efficient Instrument Management*

- I. Kruse:** *Verification, Validation and Routine Control in the CSSD*
- H. Pahlke:** *CSSD – what kind of Process what kind of Regulation?*
- K. Roth:** *One year of Experiences with the Guideline for Validation*
- A. Schorer:** *Process Optimisation for sterile Loads*
- Th. W. Fengler, R. Graeber:** *Medical Technologies Market in Germany – Medical Devices for the World*

Organizer:

Chirurgie-Instrumenten-AG (CIA - »Clinical Investigation & Application«) Berlin
In Cooperation with Internationalen Forum für Implantologie Mainz
Brandenburgisches Bildungswerk für Medizin und Soziales e.V.

Under the patronage of the German Society for Sterilisation Services (DGSV) e.V.

Orthovario – a novel oxidative process also suitable for aluminum

W. Michels, M. Pieper

The Oxivario cleaning and disinfection process provides the user with a mechanical process to adequately clean instruments with exceptional cleaning demands or particularly stubborn organic residues. The process, however, is not suitable for many titanium alloys, particularly color-coded implants. It is also unsuitable for aluminum because of alkalinity. This results in some limitations, particularly for orthopedic instruments, which require very high levels of cleanness. Now, however, the Orthovario process enables oxidative treatment for aluminum.

When the Oxivario process was used for stainless steel instruments, we began to examine more closely the material changes occurring in color-coded implants and aluminum materials. There we found that oxidative processes generally produce rapid color changes in color-coded implants and that this result is less associated with the pH level at the oxidative cleaning stage.

Our studies of the stability of color anodized layers uncovered a very interesting effect. Sheet metals with sensitive blue anodized layers were stirred for one hour at 55 °C in beakers containing a 0.35 % hydrogen peroxide solution set to different pH levels with an automated alkaline cleaning medium. The sheet metals exhibited varying amounts of corrosion, but this

could not be clearly illustrated photographically on the sheet metals themselves. It was much better illustrated in coloring pigments added to the solution.

Figure 1 shows the solutions in a sequence from left to right at pH 8.0 - 9.0 - 10.0 - 11.0. As alkalinity increases, so does the attack on the materials, and while a pH 8 or pH 9 shows little increase in pigments in the solution, a sharp increase is noted at pH 10. Surprisingly, at pH 11 this no longer occurred and the solution remained colorless. On the other hand we know that at a temperature of 55°C the release of active oxygen starts only above the pH 10 level and this must be the factor stabilizing the anodized layer, which is a layer of aluminum oxide.

Therefore the anodization attack in the Oxivario process must be attributed mainly to the alkaline initial cleaning stage. This finding led to the development of the Orthovario process in which the process stages are retained in the same sequence as that of Oxivario. The difference lies first in the fact that the cleaning medium used in both cleaning stages is a special tensid cleaner suitable for an oxidative process, thereby inducing a pH level in the first cleaning stage that is aluminum-tolerant. Then, in the second oxidative cleaning stage, the pH level is set to approx. 10.0 to 10.5 through appropriate addition of an alkaline cleaner in the presence of hydrogen peroxide. The alkalinity is also substantially more gentle here compared with the Oxivario process and is

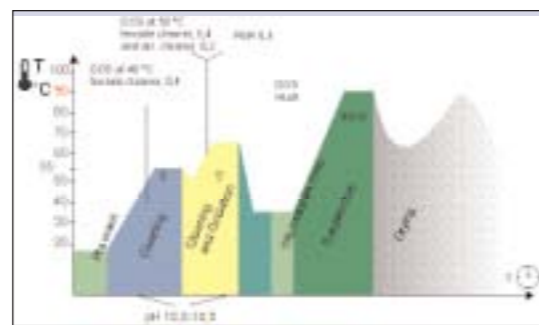
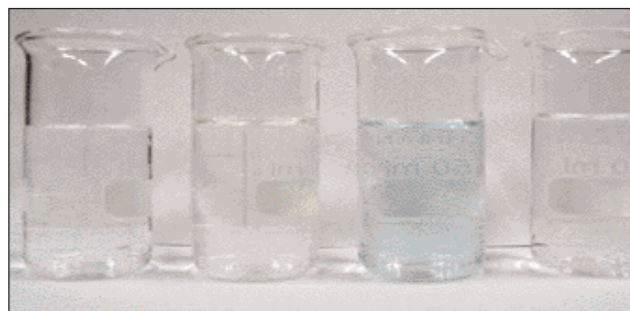


Figure 2 graphically illustrates the temperature/time curve of the Orthovario process.

no long capable of releasing active oxygen in an effective manner at 55°C. Release occurs therefore by raising the temperature appropriately to 65°C.

Orthovario has good material tolerance for colorless anodized layers – compact aluminum oxide layers by which the aluminum is protected. There are still some limitations with color anodizing. The quality of color anodized layers can be very variable, and if the quality is marginal the pigments can be washed off only very slowly even if no detectable chemical attack occurs on the anodized layer. The latest improvements should result in good tolerability in this area also. Now the active oxygen that stabilizes the anodized layer in the Orthovario process enables aluminum medical products also to be cleaned in the oxidative cleaning stage at a pH greater than 10. ■

Figure 1



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Preliminary experience with a new modular mobile unit

Anja Hairson-Klein

We have been testing a modular mobile unit, which can hold four washing modules, in our hospital for about a year.

The increased demands for the preparation of instrument systems in the orthopaedics and trauma modalities require suitable mobile units that are large enough and designed to hold instrument trays and specially designed instruments (cannulated instruments and implants). It is often not possible to use a multilevel cart, which would usually be used for standard mesh trays.

The modular cart is a two-level system and can hold four removable washing modules, two on each level. The modular cart in our sterile supply department was fitted with three modules with a spray system (two on top and one on the lower level). They all have four rows of equally spaced nozzles above the mesh tray and the mesh trays with instruments are sprayed from above with particular intensity. The intensity of the spray means that even the reflected spray has a high mechanical impact and can thoroughly cover the contents of the mesh tray.

In the lower level there is a spray module and also a module with washing equipment for cannulated instruments that are difficult to clean. Eight removable washing sleeves pointing diagonally upwards are available for instruments with channels larger than 5 mm.

Multiple test runs with bone drills have shown excellent cleaning results in the oxivario and the orthovario program, without requiring brushing and rinsing of the internal lumens. The result of the cleaning process is checked

by a careful visual inspection and also by the Biuret/BCA method. Drying takes approximately one hour. The lumen module for instruments from the urology department, such as obdurator, has also been successful in our sterile supply department.

Small components with lumens were inserted in small stands and placed on a standard mesh tray with the basic instruments of the instrument set.

The ability to replace the insertion modules provides optimum efficiency for use in other modalities. We frequently only have a limited number of mesh trays available for specific procedures.

Many perforated baskets in the various modalities are different in height and length from the standard DIN basket, allowing the modular cart to be used simultaneously for different modalities.

Compliance with the specified loading configuration of our validated processes prevents utilisation of the full capacity of a common multilevel mobile unit. The resulting waiting times mean that it is longer before the perforated basket is available for use again. Optimum use of the available capacity is another aspect for optimising preparation times and also supply of the operating theatres. The new modular cart meets a need, resolves well-known cleaning problems and makes it unnecessary to pre-clean or post-clean instruments for the above modalities.

However, there are still some preparation problems: under the RKI (Robert Koch Institute) recommendations and EN 17664 instrument manufacturers are required to supply clear directions for preparation by at least



one machine procedure that can be validated. The users and RDG manufacturers must work together to resolve various problems, particularly difficulties with the storage tray design that affect cleaning and disinfection by machine. Directions and recommendations for procedures that are not used in Germany require the operator to provide proof that the procedure in actual use is equivalent or better. Here we would like to ensure legal security for employees in the sterile supply department and economical solutions for practical implementation.

We can only achieve our common goal of the best possible care for our patients and their safety when we work together. The new modular cart is certainly a contribution to this goal. ■

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More than 100 years of Peracetic Acid

An old active substance with a bright future

H. Biering

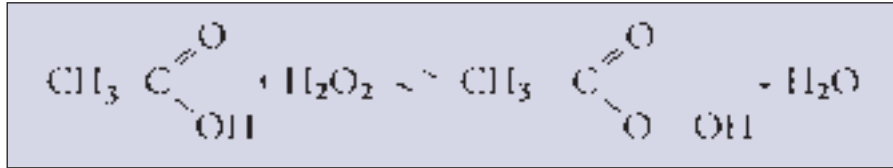
The antimicrobial action of peracetic acid (PAA) has been known for over a hundred years. In 1902 the American Chemical Journal published an article by Freer and Novy [1] entitled «On the formation, decomposition and germicidal action of benzoylacetyl and diacetyl peroxides,» in which, for the first time, the germicidal and sporicidal properties of PAA and perbenzoic acid were described. Following this publication, nearly 50 years passed before this active substance was «rediscovered». The reasons for this long period of neglect are perhaps to be found in reports of the spontaneous decomposition of highly-concentrated PAA, uncontrolled corrosion problems, and in an inadequate understanding of how to stabilise PAA solutions.

At the annual conference of the American Bacteriological Association in 1949 a report was given on comparative experiments on the effectiveness of various agents against spores of Bacillus thermoacidurans. The authors showed that, compared with all 23 substances tested, including those chlorine containing compounds, PAA is the most effective germicide [2].

The first practical application of PAA in the disinfection of facilities for breeding germ-free experimental animals began a short time later [3].

The breakthrough, leading to the widespread application of PAA as an antimicrobial substance, came in the 60s of the last

Figure 1: Equilibrium formula of peracetic acid



century as a result of fundamental experiments conducted by the working group around Sprössig and Mücke in Erfurt, Germany, and the Ticháček-Havel group in Prague, into the stability of PAA in solution, its analytical determination, its efficacy spectrum against different types of germs, and its corrosive behaviour.

Today many thousands of tons of PAA are used annually in Europe in CIP (cleaning in place) systems for disinfection in the food industry, in breweries and dairies, to disinfect cooling and industrial water systems, as well as in ion-exchange columns for water purification.

In the medical field PAA is principally used in the reprocessing of surgical and heat-sensitive instruments, in disinfecting hemodialysis instruments, as well as for laundering hospital linen in accordance with the German RKI-listed procedure.

The chemistry of Peracetic Acid

Pure PAA is a colourless, strongly smelling, corrosive liquid which is prone to spontaneous decomposition when heated. For this reason PAA is made available commercially exclusively in the form of an aqueous or aqueous-alcohol solution in concentrations of < 40 % or in the form of PAA-generating systems in which PAA is produced on site in an aqueous solution.

In the large majority of cases PAA is delivered to the customer in liquid form, as so-called «equilibrium PAA,» in concentrations of 5 %, 10 % and 15 %. Production is effected by the reaction of acetic acid with hydrogen peroxide, in the course of which, after a certain time, an equilibrium in the

components of the system have been achieved (figure 1). The ratio of the components acetic acid and hydrogen peroxide may differ for the same level of PAA concentration. This ratio, however, has a considerable effect on the behaviour of PAA in different technical applications, such as its corrosive properties with regard to metals, tolerance of plastics, the stability of the concentrate and the dilute solutions produced from it.

In addition, it is possible to improve stability during storage by adding the appropriate stabilisers.

In any case, a or more or less rapid decomposition of PAA takes place, which may be accelerated by external influences such as higher temperatures. For this reason most producers of concentrated equilibrium PAA indicate a stable storage period of some 12 to 24 months.

An alternative method of producing PAA consists in its generation at the point of use, by chemical reaction of an active oxygen containing compound with an acetyl-group donor. The chemical reaction takes place in water and produces a ready-to-use PAA solution.

Either liquid hydrogen peroxide or solid perborates or percarbonates can be used as the active-oxygen vehicle.

Substances are used as acetyl group donors in which the acetyl group is linked by oxygen or nitrogen atoms (figure 2). This type of compound was originally developed for use in the washing process as a «bleaching activator» in order, in low concentrations, to strengthen the bleaching effect when washing at 90 °C, or, in higher concentrations, to reduce the water temper-

Figure 2: Examples for acetyl group donor compounds
 TAED Tetraacetyl-ethylene-diamine
 TAGK Tetraacetyl-glycoluril
 DDU N,N'-Diacetyl-N,N'-dimethyl urea
 DADUT 1,5-Diacetyl-2,4-dioxohexahydro-1,3,5-triazine
 ACL Acetyl-caprolactam

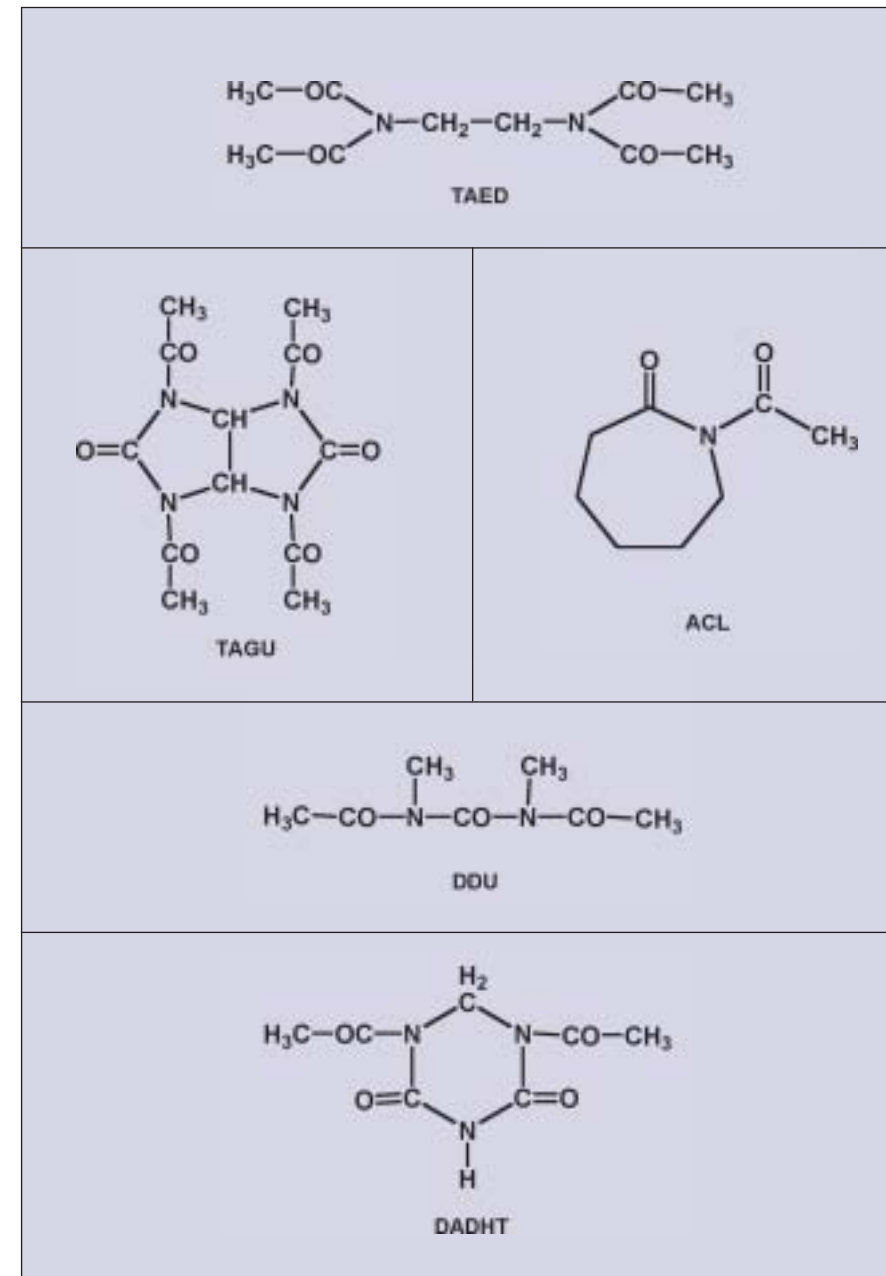
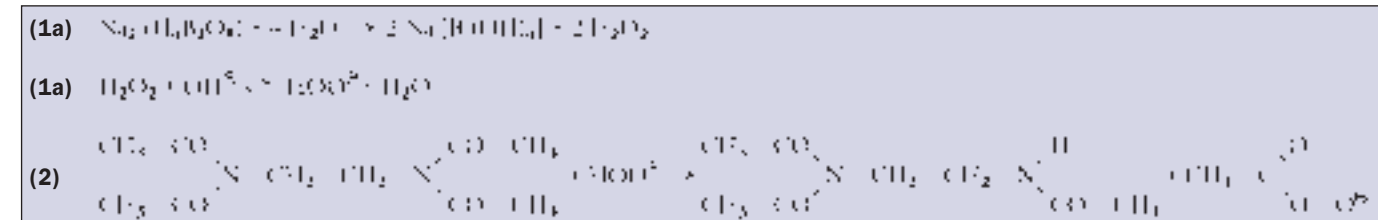


Figure 3: Reaction scheme of the generation of PAA from sodium perborate and TAED



ature to 60 °C with the equivalent bleaching effect as at 90 °C.

Today, for uses in the medical field, combinations hydrogen peroxide / acetyl caprolactam are principally used in the acid pH range, and sodium perborate / TAED in the slightly alkaline pH range.

The products on the basis of sodium perborate / TAED are mixtures of solids which are to be dissolved in water. Depending on the proportion of water to solid, the concentration of PAA in the solution can be varied to suit the requirements of the application. When a perborate / TAED mixture is dissolved in water the first stage is the formation of hydrogen peroxide which then reacts with TAED (figure 3). The reactive agent was discovered to be hydroperoxy-anion which is formed in the alkaline environment of hydrogen peroxide, which accounts for the pH dependency of the reaction [4].

In a product based on hydrogen peroxide / acetyl caprolactam currently available on the European market, two liquid components are to be combined and mixed together. The maximum PAA concentration is predetermined by the quantities of the original components in the solution, and hence cannot be varied (figure 4). In both processes, the PAA concentration required for effective disinfection is obtained about 15 minutes after mixing.

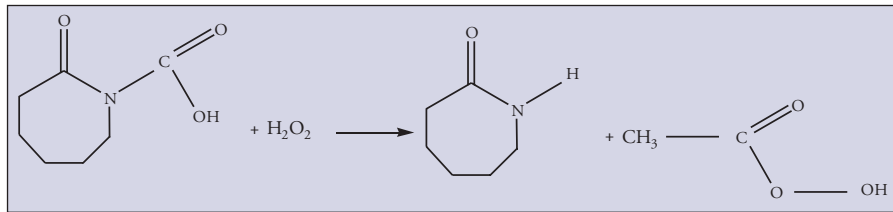
Analytical determination of Peracetic Acid

A PAA solution is a dynamic system made up of various components. Besides the equilibrium reaction described in figure 1, there also takes place the decomposition of PAA into acetic acid, oxygen and water. The stability of a PAA solution is affected by such factors as the pH value, the temperature, the hardness of the water, heavy metal ions, serum and other forms of impu-

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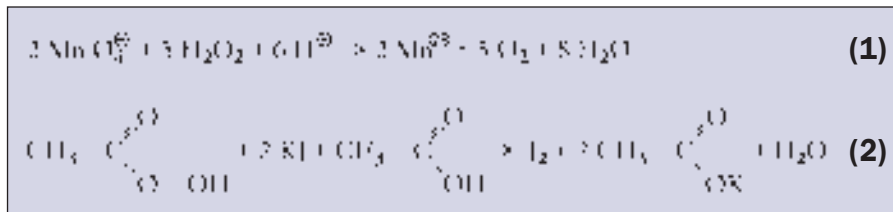
Figure 4: Reaction scheme of the generation of PAA from hydrogen peroxide and acetylcaprolactam



rities [5]. The possibility to control the PAA concentration is crucial in assessing the effectiveness of disinfecting procedures, especially in the final disinfection of heat-sensitive instruments. In dilute solutions, PAA and hydrogen peroxide can be determined by a two-stage volumetric analysis [6]. Firstly the hydrogen peroxide content is detected with 0.1 n potassium permanganate in an acetic sulphur solution (see figure 5.1). In the second step potassium iodide is added to the mixture and reacts with PAA, forming iodine (see figure 5.2). The quantity of iodine as equivalent to the content of PAA is detected with 0.1n sodium sulphate. The advantage of this method lies in the determination of hydrogen peroxide and PAA from one sample. To be able to conduct this test successfully requires the appropriate analytical experience, especially in the visual recognition of the end point of titration. Misinterpretation can lead to substantial divergences in results.

It is particularly the amount of PAA in the solution used which is of interest for applications in the medical field. The determination can be simplified into a one-stage process by means of a modification to the method described above. In doing so, use is made of the different reaction rates of PAA and hydrogen peroxide in the act of generating of iodine from potassium iodide. The use of sludge and a rapid titration until first discoloration is observed are the necessary preconditions to avoid a distortion of the

Figure 5: Reaction scheme of the two-step titration for the determination of PAA and hydrogen peroxide



result in the parallel but slower reaction rate of hydrogen peroxide and potassium iodide.

Both methods require certain chemicals and titration equipment which are often not available at the point of use. The usual procedure of taking a sample for subsequent examination in an analytical laboratory produces false results in most cases as the decomposition of PAA continues during transport thus making it impossible to achieve a reliable determination of the PAA concentration at the time the sample was taken.

This problem can be solved by means of a method of chemical transformation which fixes the PAA content at the moment the sample is taken. A reaction which produces this result is the oxidation of methyl-p-tolysulphide by PAA into the corresponding sulphoxide (figure 6). As the product of the transformation does not change during the transport or the storage of the sample, the true PAA concentration at the time the sample was taken can be determined at a later time by means of HPLC [7]. This method is especially suitable for optimisation of CIP processes in breweries and the food industry or in the case of inspections on users' premises by external authorities. The amount of effort and the financial expense involved make this method impractical for everyday use.

In the medical field, test strips provide a sufficiently accurate alternative. These are obtainable commercially for concentrations < 100 ppm and can be used, for example, to

determine the concentration of PAA remaining in rinse water following the disinfecting of the water cycle in hemodialysis devices.

For higher concentrations of PAA, such as those used in the reprocessing of surgical instruments, test strips which are specially designed for the product are necessary. In the development of this type of test strip the following steps are to be taken:

- Determination of the minimum effective PAA concentration for each germ in a range of bacteria, fungi and viruses in conformity with the appropriate test method and exposure time.
- Definition of the minimum effective concentration of PAA against the complete range of bacteria, fungi and viruses to be targeted plus a safety margin.
- The development of a test strip that allows unambiguous detection of the defined minimum effective concentration.

Figure 7 shows the range of colour gradations between effective and ineffective PAA concentrations for test strips which have been developed in conformity with this procedure as a disinfectant for instruments.

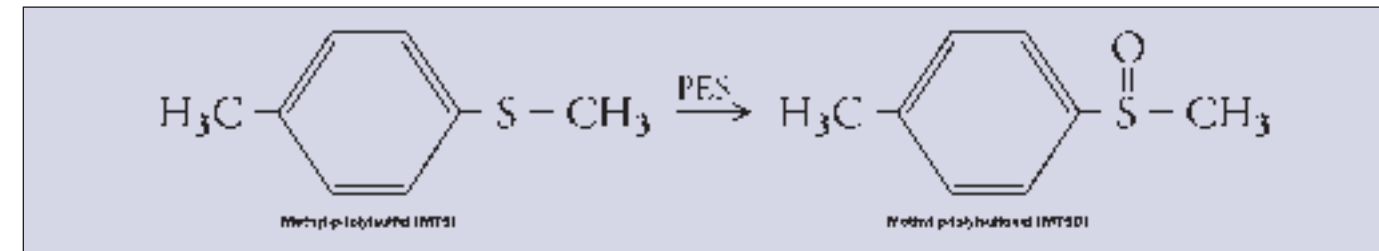
Antimicrobial activity of Peracetic Acid

On the basis of its chemical properties, PAA is to be classified in the group of microbicide reactive substances. Members of group the reactive substances, to which the aldehydes also belong, achieve their effects against germs by chemical reaction with parts of the cell or cell membrane. In this process these substances display an unspecific action mechanism and the chances that resistance can build up are slight.

PAA acts biocidally or inactivally against a wide range of bacteria, including microbacteria and bacterial spores, fungi and viruses, including unenveloped viruses like the polio virus and the Hepatitis A virus [8,9].

Because of its high chemical reactivity PAA may also react with other organic materials. Depending on the organic load, this leads to a reduction in effectiveness. Reactive substances all display a deviation due to proteins to a greater or lesser extent. Comparative studies on the effectiveness of PES and active chlorine against a spectrum of bacteria, with and without protein soiling, show that, in the case of active chlo-

Figure 6: Reaction scheme for the PAA analysis with methyl-p-tolylsulphide



rine, a substantial extension of the exposure time is necessary to ensure the complete elimination of the test organisms [10].

Reactive substances differ in the way in which they react chemically with proteins. Whereas PES at pH >5 and active chlorine destroy the protein molecules an oxidation reaction, the reaction of proteins with aldehydes or PAA at pH <4 leads to the formation of higher molecular compounds, for example of precipitates. As a result of inadequate cleaning, these reaction products or precipitates may be deposited as residues on the surfaces, which can lead to hygiene problems in, for example, the processing of flexible endoscopes in those channels which are particularly difficult to reach. The pH-dependency of the action is of particular interest in the use of PAA in the medical field for the reprocessing of instruments. The positive effect of pH-value adjustments in relation to the odour, the inhalation toxicity, the material compatibility of metals and plastics in many cases runs contrary to its microbicidal effectiveness.

Table 1 shows that PAA is most effective in an acidic solution with a pH < 3 [11]. If the concentration remains constant, the sporidical effect diminishes with rising pH-values until it becomes practically ineffective at pH 8. This pH effect can, however, be offset by varying other parameters such as the degree of concentration, or the temperature. Hence, for example, complete spore effectiveness is reached in alkaline solution at pH 10 to 11 when disinfecting hospital linen in accordance with the German RKI process at a concentration of 100 ppm PAA and a temperature of 60 °C [12].

A considerable boost in effectiveness can be achieved simply by a moderate increase in temperature. This is particularly evident with micro-organisms which are especially difficult to eliminate, like the mould fungus,

Aspergillus niger. As table 2 shows, an increase in temperature of 20°C, to 35°C, with considerably lower PAA concentrations, allows a level of effectiveness of > 4 -log-steps to be reached. Moreover, experiments were conducted at 30°C and 35°C with a pH-value of 8 which, as presented above, reduced effectiveness but improved other characteristics, such as material tolerance, very considerably. Even under these conditions effectiveness is reached at levels as low as 675 ppm at 35 °C. In contrast, a concentration of 1800 ppm is necessary at 20 °C, even at pH 3, a level which boosts the efficacy.

The mechanism of action against microorganisms has long been a matter for speculation. In the last ten years various working groups have published investigations

pH	2	4	5	7	8
log reduction	4	3	2	1	<1

Table 1: Effect of pH on the survival of bacterial spores (*Bacillus subtilis*) exposed to 300 ppm PAA at room temperature

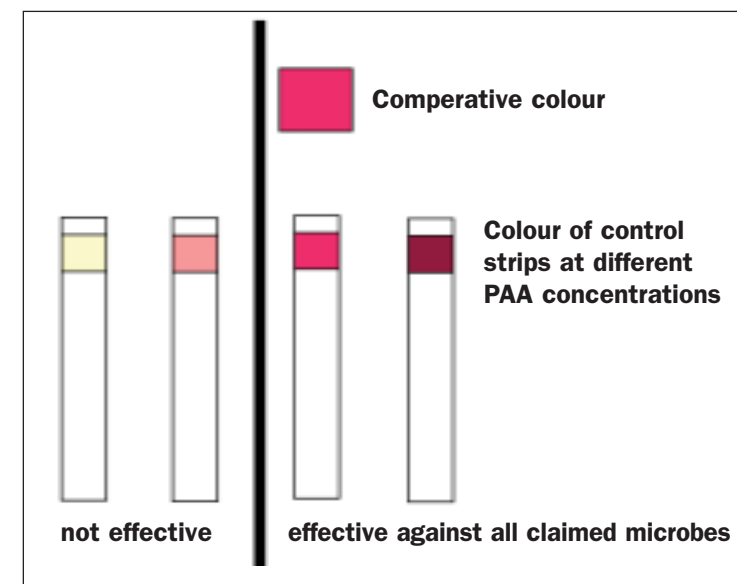


Figure 7: Colour stages of PAA control strip

[13,14,15], that have made a data-based discussion possible. In spite of these findings, we must recognise that there is still no full explanation of the mechanism of action of PAA. It has been demonstrated that radicals are formed which react with functional groups of proteins and cause them irreversible damage. Besides the proven formation of hydroxyl radicals, the formation of organic radicals is being discussed. In any case, the result of the chemical reaction is the irreversible disruption of the chemiosmotic function of the cell membrane.

The Toxicology of Peracetic Acid

Three issues must be borne in mind in the toxicological assessment of PAA when evalu-

ating its use as a disinfectant. Firstly the danger arising from undiluted products, secondly the toxicological properties of solutions of PAA-based products, and third the toxicological assessment of residues on the surfaces of disinfected instruments [16].

The toxicological properties of PAA have been investigated in numerous studies [17]. Generally speaking, the toxicological potential of PAA depends on the degree of concentration of the solution in use.

PAA solutions with a higher than 5 % concentration are to be categorised as corrosive. As PAA in commercial products is to be found in concentrations between 5 % and 15 %, safety procedures must be followed when handling the undiluted product. For example, any chance of contact with the skin or eyes is to be eliminated by the wearing of protective gloves and protective glasses. PAA solutions in concentrations of 0.3 % to 5 % are classified as irritant. Also for these levels of concentration the wearing of protective gloves and protective glasses is recommended. On the other hand, PAA solutions in concentrations up to a maximum of 0.35 %, as generally used in the medical field, are no longer to be regarded as corrosive or irritant.

In the event of oral intake, toxicity also depends on the level of concentration. While PAA solutions with a concentration of up to 1 % are not to be classified as acutely toxic, more highly concentrated PAA solutions cause marked toxic reactions after swallowing.

The corrosive or irritant effect of PAA is determined by two mechanisms. These are, on the one hand, the acidity of PAA, and, on the other, its strongly oxidising properties. The irritant effect of PAA caused by its acidity can be reduced by a corresponding adjustment to the pH value. In addition, the adjustment to a higher pH value can bring about a reduction in the evaporation of PAA from solutions.

When disinfectants are correctly used, only minute residues are to be expected on the equipment to be treated. In this connection PAA has the additional advantage it decomposes into acetic acid and oxygen, so that any possible residues are further reduced. What is especially important for the toxicological evaluation of these minute

pH-value	PAA [ppm]	20 °C	30 °C	35 °C
pH 8	450	not carried out	< 3,0	3,6
	675	not carried out	3,8	> 4,0
pH 3	900	< 3,0	not carried out	not carried out
	1800	4,2	not carried out	not carried out

Table 2: Effect of temperature on the fungicidal activity of PAA to *Aspergillus niger* at a exposure time of 5 min

quantities is the question of whether allergic or mutagenic effects may be caused. Experiments conducted into this question have been able to show that no allergic or mutagenic risk is to be expected from PAA.

Peracetic Acid and the Environment

The evaluation of the environmental behaviour of chemical substances is primarily based on the results of investigations into two sets of questions:

1. What happens with such a material in the environment, i.e. most importantly, how easily can it be degraded, and, directly arising from this, what levels of concentration are to be expected in the relevant areas of the environment, such as rivers, and
2. What is the effect of the substance on organisms in the environment?

With regard to the first set of questions, PAA possesses the great advantage that its decomposition already takes place during use or, at the latest, in the waste water, and in the process its toxicity and biocidal action are removed. The acetic acid which remains is easily biodegradable [17], so that it in biological waste water treatment, a rapid and total biological degradation takes place, which ensures that no significant quantities reach surface water, such as rivers. In the end, a total biological degradation is guaranteed, so that no residues remain in the environment.

In spite of its antimicrobial action, PAA under normal conditions has no effect on the growth and decomposition process of the water treatment bacteria. It has been possible to show in water treatment plant simulation experiments that in concentrations of up to 100 mg / l, PAA caused no reduction in effectiveness of the plant's performance. A reduction in the performance of the laboratory plant was first recorded at and above the unrealistically high concentration of 130 mg/l. As

the laboratory water treatment plants, in comparison to commercial plants, are generally more prone to disruption, the maximum concentration level, set at 100 mg/l for PAA, may be regarded as conservative.

The data concerning the ecotoxicity of PAA are well-established. In common with other biocidal substances, PAA displays a relatively high acute aquatic toxicity (there is a variety of published test data for all organisms). For algae and daphnias (water fleas) the standard is EC 0 (i.e. the highest experimentally determined concentration at which no toxic effect is observed) below 1mg/l. For fish, most data suggest an LC 0 (the highest non-lethal concentration) in the region of 1 mg/l.

The very slight toxic effect of PAA on water treatment plant bacteria, together with its chemical instability and the ease with which it decomposes biologically, guarantee that aquatic organisms are not exposed by PAA under normal circumstances. Thus it is to be anticipated that the use of PES does not pose any problems for the environment.

Material compatibility of Peracetic Acid

The compatibility of metals and plastics with PAA, as with all acid / alkali based systems, is highly dependent on the pH value of the solution used. This fact is frequently neglected in discussing the material compatibility of PAA in the reprocessing of medical equipment, and especially of flexible endoscopes. The good compatibility of one PAA-based disinfectant with medical instruments cannot be automatically extended to all PAA-based products, and conversely the damage caused by one product can not be generally extended to all products which contain this substance.

The importance of the pH value may be shown by the comparison of the effects on materials of sulphuric acid and its salts. It is generally understood that sulphuric acid has a strongly corrosive effect and produces signifi-

Material	pH-value / PAA concentration		
	110 ppm / pH 6,4	250 ppm / pH 5,4	500 ppm / pH 4,6
Aluminium 99,5	0	0	0
Chrome-nickel steel 1.4301, 1.2201	0	0	0
tinned iron	0	0	0
galvanised iron	0,05	0,2	0,5
iron steel 37 / 2	0,7	1,1	1,6
cooper	0,05	0,1	0,5

Table 3: Effect of pH and PAA concentration on corrosive behaviours detected by weight lost in g/m²/h at room temperature according to DIN 50905

cant alterations in materials, while its salts, such as sodium sulphate, have only a minimal effect on materials.

The corrosive effect of PAA at differing pH-values is shown in table 3. In the case of some metals, such as aluminium or stainless steel, no corrosion was observed under experimental conditions, whereas the corrosive effects in the case zinc-coated iron or copper between pH 4.6 and pH 6.4 show a difference of a factor of ten. An analogous corrosion effect has been demonstrated for copper alloys and nickel. Anodised aluminium becomes discoloured in both alkaline and acid solutions. There is only a narrow pH range in which a sufficient degree of stability on anodised aluminium can be obtained.

PAA-based products have been successfully used for decades in the manual cleaning and disinfection of surgical instruments. They are used in a slight alkaline environment, combining good material compatibility with an outstanding cleansing performance. In contrast, the disinfection of stainless steel instruments with PAA in acidic solutions is not recommended as an extended period of contact leads to pitting corrosion.

A whole range of plastics, such as polyethylene, polypropylene and rigid PVC, are compatible with PAA solutions. Certain components of plastics, such as plasticizers, may be changed by PAA by oxidation, which can lead to brittleness and a reduction in the life of the plastic. The same applies to sealing materials and adhesives.

To avoid or minimise changes in materials as a result of the use of PAA, it is important to choose an appropriate disinfectant, compatible to the area of application and its conditions. Optimal products of this kind are

already commercialised for disinfection procedures in the medical field for the manual or automated reprocessing of flexible endoscopes or for the disinfection and cleaning of surgical instruments. Any deviation from these optimum products and systems of application may however lead to substantial material damage.

Summary

Following a period of 60 years after the discovery of the microbicidal action of PAA in which only a few practical applications uses were publicised, the work of various groups on the spectrum of its microbicidal efficacy, on its toxicology, ecology and the safe production of concentrated and dilute PES solutions and their handling, on the analytical determination of the active components as well as on the interaction with various materials, has led to the opening up of a wide variety of new areas of commercial application.

These comprise, for example, the disinfecting of foodstuffs, such as fruit and vegetables, applications in the food and food-processing industries, such as breweries and dairies, the removal of biofilms in various areas, as well as applications in the medical field in disinfecting hemodialysis instruments or in the processing of endoscopes and surgical instruments.

As a reactive substance, PAA is effective as a microbicidal substance over a wide spectrum of germs including mycobacteria, spores and enveloped viruses. Its microbicidal effectiveness and application behaviours are, to a very great extent, dependent on the pH level. Limitations in application with regard to material compatibility and toxicology have been largely overcome by the optimisation of commercialised products. In this light, this »old« substance, after a history more than 100 years,

continues to be a microbiologically effective substance with a bright potential for development of fresh and innovative applications. ■

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Report on the German medical-technical market

Dr. T.W. Fengler, R. Graeber

The global medicaltechnical market

The health market is one of the most attractive international markets and demonstrates a low dependence on economic trends. The global medical device market is in a growth phase with an estimated annual growth rate of 5%. The entire volume of the current global market for medical devices is an estimated € 184 billion. International mega-trends indicate continual growth in the future medical device market. This can be accounted for by rising health consciousness in the general population (prophylactic perspective), with the accompanying rise in readiness to spend money on the health sector; demographic trends (increase in proportion of elderly people in the industrial nations), rising world population- and therefore a greater variety of illnesses and time spent ill, medicaltechnical progress, globalisation (great need to catch up in emerging and developing worlds) and new marketing methods e.g. internet.

The current economic position of the German market

The German medical device market, with a volume of about € 19 billion (plus about € 5 billion for dentures), constitutes the third largest single market after the USA and Japan. From this about € 7 billion is for in-patient treatment, about € 12 billion for outpatients.

The German medicaltechnical field is known to be innovative, relatively resistant to crises and exceptionally wealth creating. The number of employees has risen constantly over the last few years (2004: + 2.8%) to 90,000 today. There are about 1,200 businesses. Highly qualified personnel are in great demand, especially for research and development. The German personnel market can hardly match these requirements. In 2004 the German MedTech businesses were again able to increase their total revenue, by 8.1% to € 13.6 billion. Exports in 2004 constituted € 7.9 billion. This is 1.3% of Germany's total export volume, although only 0.5% of all employees work in this sector. The USA is the biggest single purchaser of German medicaltechnical devices. In 2004 the foreign revenue grew by 15.8% to € 7.9 billion. The internal revenue decreased somewhat (-1% at € 5.7 billion). The export quota was 58%. It can be presumed that the significance of the external market will continue to rise over the next few years.

The reasons for the stagnation of the home market are mainly to be found in the Public Health Reforms. These are theoretically completed, but refinancing, implementing statutory measures, and their consequences for the industry (as for the health service in general) are not yet calculable. It is however certain that pressure will contin-

ue to be brought to bear on manufacturers for cost reduction. It is quite likely that people will take advantage of the fact that medical devices, making up about 10% of the entire health care budget, offer an extraordinary saving potential. So for example, minimal invasive surgery, using technically very complicated instruments, considerably shortens the hospital stay, turning patients back into premium payers. The professional associations have been pointing out relationships such as these for years. The manufacturers would also benefit by emphasising this sort of potential as a selling point for their devices.

Imports

The growth of the medical device market at about 4.2% in Germany, is somewhat less than both the European and worldwide markets. The import of medical devices, services and refinements constitutes about 1% of the total German import volume. The import market is growing steadily, although less vigorously, and in 2002 reached € 5 billion for the first time.

The most important supply countries are North America and the EU. The most important import categories are X-ray machines, needles, catheters and cannulae, ultrasound diagnostic instruments, endoscopes, artificial joints, transfusion and infusion appliances, heart pacemakers, medical syringes, hearing aids, monitoring

equipment and systems, artificial body parts and organs (including eyes), MRT appliances and dental instruments.

Investments

Readiness to invest in the German MedTech market is waning. This affects investment in research and development (R&D), which forms 6-7% of revenue compared to 1999 figures, when investment was still at an average of 10%. US medicaltechnical firms invest an average of 13% of their revenue in R&D.

Foreign investment in German firms is deteriorating. Fusions and take-overs dropped by 35% in the last few years, compared to an international rate of only -8%. The German market seems to be unattractive to many foreign investors because of a high degree of regulation, lack of transparency in technology assessment processes and the paucity of market-economic stimulants.

A receding readiness to invest can be observed, not least in the in-patient sector, due to the prevailing uncertain conditions in public health politics. Many hospitals refrain from making expensive new purchases, making do instead with repair and servicing of their larger appliances. In German hospitals, for X-ray and radiotherapy machines and R/F systems (radio fluoroscopy appliances) 10-year-old machines are the norm rather than the exception. The German trade associations for these sectors estimate the stagnation of investment at about € 12-15 billion.

Market share disposable products

In particular providers of disposable articles, such as scalpels, bandaging material and catheters, observe an alteration in demand, reduced acceptance of previous price levels, and an increased tendency of customers to seek out cheap foreign providers. Enhancing the sophistication of these products does not pay off, particularly since a higher price in this area isn't usually justified by better service or a greater measure of innovation. It is therefore necessary to provide systematic customer relationship management bringing customer loyalty related to specific performance (e.g. clustering of sales packages).

An exception in this area is wound management for chronic wounds. The introduction of DRGs (diagnosis related groups) and the endeavour to keep the hospital stay as short as possible have led to an increased demand for modern bandaging material. Strong growth is to be expected in moist medicated and antiseptic bandages, as well as for replacement skin (»tissue engineering«) and hybrid products with integrated collagen or silver.

Market share long-life one-use products and auxiliary products

Long-life one-use products are used over a long period, but only once in or on a particular patient e.g. implants and prostheses as well as auxiliary products such as walking supports (crutches, sticks), wheelchairs and hearing aids.

The auxiliary area was the biggest loser in the health reforms of 2004, with an expenditure cut of 12.1% in the first quarter (despite a rising number of cases), after introduction of the Statutory Health Insurance Modernisation Act. (GMG or Gesetz zur Modernisierung der Gesetzlichen Krankenversicherung) The public health insurance funds' rigorous price reduction policy led to a price collapse of up to 40%. Auxiliary products with the best growth in the last few years were articles for the care of stoma and incontinence. For the first time, in the first half of 2004, this area posted a deficit of 1.5%. This can be explained by the reduction in the number of people consulting specialists since the introduction of a medical surcharge due when visiting a doctor, and the uncertainty of doctors who write prescriptions concerning the new regulations.

The situation for implantable long-life one-use products is quite different. Because of their high specialisation and sophistication these products are subject to much less price pressure. If people do complain about price decay in this area, it is usually due to purchasing associations who order goods for hospitals. The market for long-life one-use products tends to be a growth market, with good prospects for foreign firms as well. The following areas have strong growth and good perspectives: dental implants, cardiology, administering systems and self-testing equipment for diabetics.

Investment products

Where acquiring products for repeated use on various patients requires investment, two categories exist- technologically sophisticated investment products (such as operating robots, appliances for endoscopy or imaging methods) and OT investment products (reprocessible surgical instruments).

The pressure to optimise costs is relatively low for this part of the market. Even more than long-life one-use products, investment products require a lot of attention- from installation to servicing and repair, personnel training and reprocessing of surgical instruments. Because of these services and the alternative high cost of changing a system, providing new attachments and replacement supplies, strong customer loyalty prevails, and the price takes second place to the service. Despite the great importance of service, according to the estimates of German manufacturers, this criterion is taken advantage of only partly or not at all. There is an opening for small firms here, which could differentiate to meet demand, as long as they can offer product-accompanying services. The same idea applies to the criterion »reliability of suppliers«.

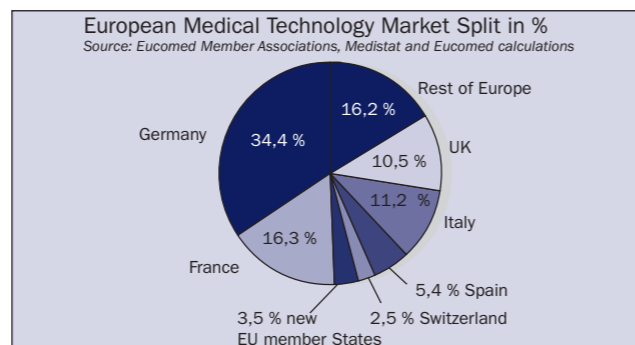
The whole share of the market for investment products offers small to medium sized businesses good prospects for success. But in the area of large electromedical appliances where the market is in the hands of one or two big concerns, only suppliers of single parts or semi-finished products are required. Multinational firms such as Siemens Medical Solutions or Dräger Medical constitute only 2% of German medicaltechnical firms, but take 48% of the revenue.

Imaging systems constitute more than half of the entire market for electro-medical appliances, with a worldwide market volume of just € 10 billion. At the moment the growth rate of Positron Emissions Tomographs (PET) is in double figures. Other growth segments are dialysis and blood replacement (an annual increase in the number of dialysis patients of 6-7% is expected), orthopaedics, especially vertebral surgery, reconstructive joint replacement and osteosynthesis. Here the manufacturers of investment products (surgical instruments, OT equipment) will benefit just as much as those of long-life one-use products (implants).

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Fig. 1 Share of the medical device market Europe 2003¹



Technologies with positive futures

A strong market potential in the future is expected in the following areas²:

- Cardiology products to treat beating hearts
- Microsystem technology (minimally invasive methods e.g. capsule endoscopes or controllable catheters)
- Biotechnology (e.g. tissue culture, biological cartilage reconstruction)
- New materials and coatings (also medication coatings on implants)
- Imaging systems
- Telemedicine (cardiology and diabetes)
- Nanotechnology
- Coated and biocompatible micro-products for vascular surgery (stents, artificial vascular prostheses)
Products for plastic surgery in ophthalmics, liposuction, aesthetic surgery.

Innovations

The most important criterion for a good market position is the innovation potential of the relevant product. Over 50% of the revenue in this sector is obtained from products that are not yet two years old. Admittedly not every product is based on new technology, but modifications of components or designs, or a software update can result in a »new« product.

Well over half of all German inventions originate in small or medium sized businesses that specialise in problem solving. Because of the pressure for cost reduction as well as rising investment and development costs, the business with an innovative product has better chances than ever before to conquer new parts of the market or market niches. This is even more likely when the product doesn't just promise better therapy but also additional saving potential.

The closer doctors, scientists and engineers from medicaltechnical businesses can work together in the early research phase, the greater the degree of innovation, and the greater the guarantee that there is a need for the new product, and therefore a market. The research departments of successful businesses tend to use the »Lead-User-Process« where one tries to identify and gain the cooperation of particularly forward-thinking users. Another approach is »customer immersion« where engineers spend some time in the OT as observers, to determine the

needs of the surgeons, who may themselves be oblivious to possible improvements. In the critical phase of development of a prototype the »co-invention team« is useful, where doctors and engineers hold intensive meetings.

Problem area: state regulations and Statutory Health Insurance reimbursement

Access to the German medical device market is only possible after wading through a complex set of rules, which can greatly hinder market entry. First of all, quality control in registration is affected, which may require complicated clinical studies. Secondly, cost reimbursement via Statutory Health Insurance, i.e. inclusion in the Uniform Assessment Standard or the Financial Aid Register. Particularly if a new treatment procedure is considerably more expensive than that already in use, a correspondingly greater therapeutic value has to be proven.

Waiting times and costs occurring here damage especially those products with a high innovation potential. Until the invested capital is recouped, years may pass, during which the product loses its unique character. During the waiting period, costs for performing studies, making reports, for personnel and marketing accumulate, so that the original investment cost is rarely wholly recouped, rendering the original investment cost insignificant in comparison. About 90% of the costs for a complex innovative product originate after the prototype phase!

Various marketing methods

Registered doctors in practices and those in hospitals are the main purchasers of medical products. Both groups have altered their purchasing habits because of the need to cut costs. Independent purchasing advisors are often hired. Most of the buying is done via the Internet.

Technically equipping a doctor or a dentist's practice, is becoming more and more a question of cost and cost-effectiveness (profitability). The purchase of technical equipment and medical devices accounts for an increasing share of the total cost for setting up a doctor's or a dentist's practice, since these days ever larger medicaltechnical appliances are used in practices. The average

financial volume for doctors' practices is between € 45,000 (psychologists) and € 280,000 (internists). For dentists it is as much as € 327,000, where 63% is for the technical equipment. In doctors' practices the head receptionist generally buys disposable products (in 54% of practices), but sometimes shares the responsibility with the doctor (14%). Only seldom (10%) does the doctor make all the purchases.

Purchasing associations and clinic associations

Those in the know predict that unless part of a purchasing association, no hospital of the future will survive. There are various forms of association. The highest level of buying and logistic efficiency is reached by a so-called GPO structure (Group Purchasing Organisation). Product range, standardisation, price bargaining, and delivery management are all dealt with by one organisation.

German hospitals have joined together to form about a dozen associations to bargain for more value for money. Other businesses (e.g. Medical Columbus AG) have specialised in handling orders on the net, make available data e.g. product catalogues, deal with electronic accounts, or make themselves available banded together as a procurement platform e.g. Medicforma and Global Healthcare Exchange (GHX).

The results of a questionnaire given to the members of the professional association BVMed showed that price pressure, which such buying associations cause, is seen as the greatest obstacle in the sector. Even for small orders purchasing pools would seldom accept the list price. What is more, purchasing pools tended not to obtain the optimum for the patient, but the most economic solution for the hospital. The fact that Germany has by now the lowest prices, has apparently given some purchasing pools the idea of exporting medical products abroad as wholesalers themselves.

The patient

In the future the patient himself will be increasingly the potential buyer of many products, and will need to be taken into consideration, because one can presume the patient will increasingly be paying his own health costs. At the moment German

patients pay about 12% of health outgoings out of their own pockets. In the past manufacturers in the medicaltechnical sector did not need to consider the purchasing behaviour of the final customer. This was because the health insurance groups were positioned between them. But recently new ways of thinking are becoming apparent. A forward pointing strategy with regard to this new market can be compared with the automobile industry. A business offers its innovative product to a patient as »special equipment« for his treatment e.g. a telemedical heart pacemaker, which collects data itself and sends it to the manufacturer's service centre for evaluation. If the therapy is successful, and is cost-effective, then the product may be elevated to the »fitted as standard« category i.e. be taken up into the Uniform Assessment Standard (Einheitlicher Bewertungsmaßstab=EBM).

Marketing instruments

The choice of suitable marketing methods requires employers to make strategic decisions, which strongly depend on whether one is dealing with short- or long-lived one-use products or investment goods, and how much explanation the product needs. Particularly for innovative medical products, the specific clinical use worked out with a medical partner is of great relevance because there is a need to justify and explain the use of a product from a medicaltechnical point of view. Here it may help to provide scientific publications and conference speakers in addition to the usual marketing measures.

Internet marketing

As well as the classic marketing methods i.e. advertisements in specialist journals, exhibition stands at trade shows and of course the interaction with customers, the internet has developed into a vital medium in the last few years, whether as an information source for one's own market research, for advertising or for doing business selling products- although up until recently only to a small degree. While in the beginning primarily large businesses made use of e-business solutions, medium-sized businesses are now active in this area.

The number of patients who privately obtain information from the Internet about

treatment methods (mainly for pharmaceutical products) is growing continually and is supported by a growing number of health sites. In 2003 alone growth was as much as one million. The probability is rising that potential customers come across medical-technology for technically supported therapy methods that could be useful to them. Businesses whose products, in the loosest sense, are interesting for the patient himself, that is the manufacturers of (long-life) one-use goods and auxiliary products, should make their web-sites easy for the lay-man to understand.

Further potential customers are doctors and the hospital buying associations. According to new surveys the proportion of doctors who regularly use the Internet to obtain information and to supplement their education rose from 18.8% in 1999 to 73.7% in 2003.

E-commerce

Here business is the centre of attention. It can occur in online-shops or on the web pages of e-commerce providers, who provide for several businesses. Experts think e-commerce for sales in the health market will gain relevance. Therefore firms should start early to standardise procurement procedures and to make everything electronic. This means standardising article numbers and names, functional interfaces, removal of media breaks, and integration into the logistics concept. ■

This up to the minute article is based on a metastudy done for the Swiss Business Hub- Germany, Stuttgart, in cooperation with OSEC, Zürich:

Fengler/Graeber: Germany's medical market. Opportunity and risk for Swiss firms. Berlin, Stuttgart, Zürich, Dec. 2004.

The complete branch report is available for 130.00 Swiss francs from OSEC, Stampfenbachstr. 85, CH-8035 Zürich.
1 Source: Eucomed Medical Technology Brief 2004. Online www.eucomed.org
2 Source: Bastiaan M. de Ruiter: Area report- »Medical technology in Germany«. Investruit Healthcare (publisher), Bonn, 2003, p. 89.

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Published by:

medienfabrik Gütersloh GmbH
Carl-Bertelsmann-Str. 33
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ISDN: 0 52 41/2 34 80-64
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Implementing, layout and printing:

medienfabrik Gütersloh GmbH
Guido Klinker, Sandra Daut

Edition: 9,500

Frequency:

Printed quarterly
Printed on paper processed chlorinefree

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ISSN 1439-9016

»Washing with any water«

Water softening, properties and effects in machine preparation

W. Michels

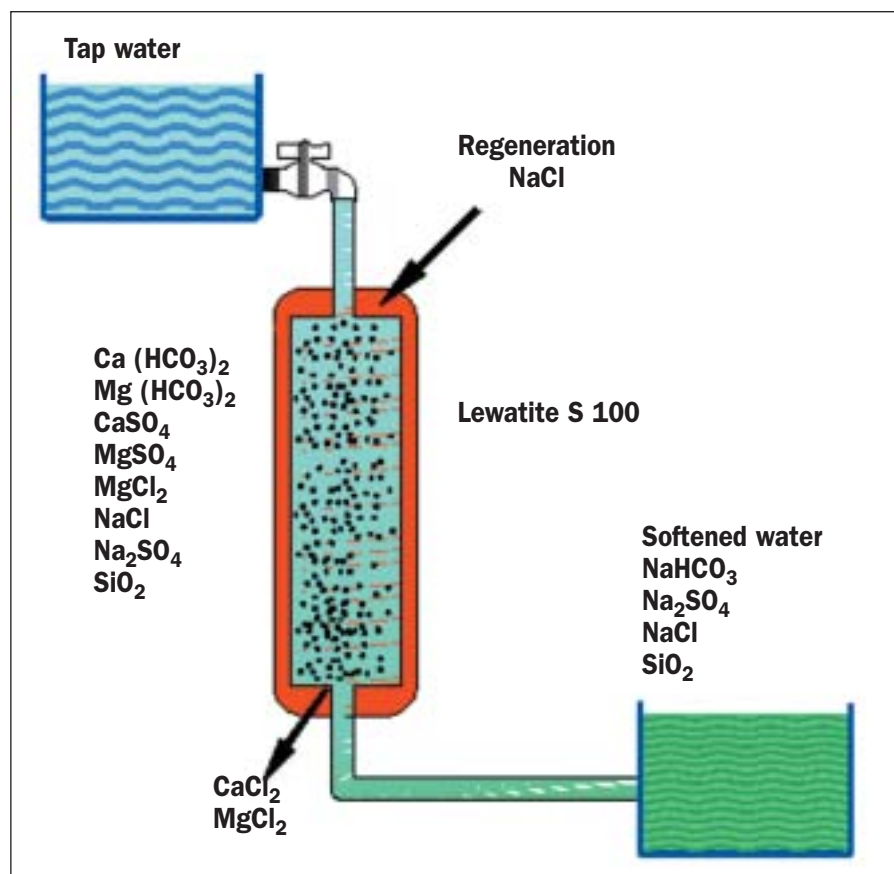
Water is used as a solvent in washing and purification processes. It is used in association with moving components or with kinetic energy first to remove large or easily removed contaminants or for pre-washing or prerinsing. In the main wash or cleaning, water is added to chemicals that work at a higher temperature in order to effect fine cleaning. After that it is rinsed without additives in order to make the instruments free of dissolved contaminants and to rinse off additives.

Tap water, which serves for drinking and general use, is also used for preparation of surgical instruments, but has a variable content of other constituents depending upon the ground over which it has flowed. The water must therefore be conditioned before use to an extent that differs from place to place. In automatic washers and disinfection machines for preparation of surgical instruments, conditioning takes place:

- to avoid deposition of water contents such as chalk on the rinsing parts and cleaning parts by hard water and
- to avoid corrosion of instruments and to achieve residue free results
- by complete desalting.

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Principle of water softening and regeneration with ion exchanger.

Water hardness

Water hardness is caused by dissolved calcium and magnesium salts. Temporary and permanent hardness can be distinguished. Temporary hardness forms as hydrogen carbonate salts, because these change on heating into carbonate, which is generally called chalk deposit or scale. They are thus precipitated from the water, hence the designation »temporary«. Calcium and magnesium compounds such as sulphate, chloride and others are not affected and remain, and therefore permanent. The measure of water hardness, both temporary and permanent as total hardness, is the German degree of hardness,

abbreviated as °dH. 1 °dH corresponds to 10 mg calcium oxide per litre of water or 17.7 mg calcium carbonate per litre of water. Magnesium compounds are regarded as equivalent to calcium compounds. Since 1975 water hardness has been expressed in millimolecular weight, abbreviated as mmol. 1 °dH = 0.178 mmol calcium per litre. Water hardness is divided into four hardness grades:

Hardness grade	1	2	3	4
Mmol/l	Up to 1.3	1.3-2.5	2.5-3.8	Over 3.8
°dH	Up to 7.5	7.5-15	15-21	Over 21

Water softening

The salts dissolved in water, including calcium hydrogen carbonate, split (dissociate) into two oppositely charged parts (ions): the positively charged ions are called cations, and the negatively charged ions are called anions. In contrast to calcium hydrogen carbonate, which in water dissociates into Ca²⁺ and HCO₃⁻ and is dissolved, calcium carbonate has a much lower solubility.

Heating causes hydrogen carbonate to form carbonate and thus chalk deposits, or so called scale.

To avoid chalk deposits on the rinsing head, the rinse space and also the heating elements, the water that is used is softened. In smaller washing machines, such as automatic cleaning and disinfection machines, this is achieved by a softener integrated into the machine, but in larger machines the water must be softened on the supply side. The general recommendation is to wash with water that has a maximum of 4°dH or less. This is particularly true for temperature related washing phases. In the final rinse phase, the final wash phase, completely desalted water should be used to yield completely residue free preparation results.

For softening water, the calcium and magnesium compounds are converted into the corresponding sodium compounds by exchange of the calcium and magnesium cations. Sodium hydrogen carbonate and sodium carbonate are very soluble and thus do not precipitate on heating or form residues.

For this exchange of calcium and magnesium for sodium ions, only these cations, ion exchangers (cation exchangers) are used. The ion exchanger consists of a filling of resin spheres about 0.5 mm in diameter, that are microporous in addition, allowing water to flow over and through the spheres

The resin contains on its surface a large number of bound sulfonic acid groups with negative charges. In the regenerated state it can bind a correspondingly large number of sodium ions. These are exchanged by flow over and around the resin of water containing calcium ions; this results in the sodium salts being present as hydrogen carbonate, sulphate,

chloride etc. in the water. The capacity of ion exchanger integrated into large space washing machine is very high, and may exceed 20,000 hard litres. That is the number of litres that is able to reduce the hardness by 1 °dH, so that for 10 °dH the capacity is something over 2000 litres. Depending upon the initial hardness, the resulting softened water has a low residual hardness.

Regeneration

When the softener is exhausted, that is the ion exchanger no longer has enough sodium ions, it must be regenerated. This is achieved using a special regeneration salt, sodium chloride (cooking salt).

The large excess of sodium ions causes release of the calcium/magnesium ions, which are then rinsed out as calcium or magnesium chloride, the ion exchange resin is thus reloaded with sodium ions. This requires that the salt solution has sufficient contact time. For the regeneration of the large space softener, only coarse salt is recommended, since this dissolves somewhat more slowly and does not flow too quickly through the softener resin without effective

saturation. Today, there are also instrument integrated softeners as so-called monoblock softeners that do not need a periodic regeneration programme after softening a certain amount of water depending on the hardness, but carries it out during the cycle. The capacity is sufficient to ensure that a complete programme can run with one regeneration with a hardness of up to 60 °dH. With soft water, for example 8 °dH the automatic regeneration occurs after every third cycle. The salt for this is in a prefilled container for the ion exchanger and must periodically be filled again. The process of regeneration must be carried out according to the instructions and awareness is required that using excessive amounts of salt in the washing space or forgetting to close the salt container may endanger surgical instruments through chloride induced corrosion.

If the water is softened centrally for washing and disinfection automatic machines, the water must not be injected. Injection is only recommended for protecting the piping against corrosion.

The medium usually also contains silicate, which can lead to instrument discoloration.

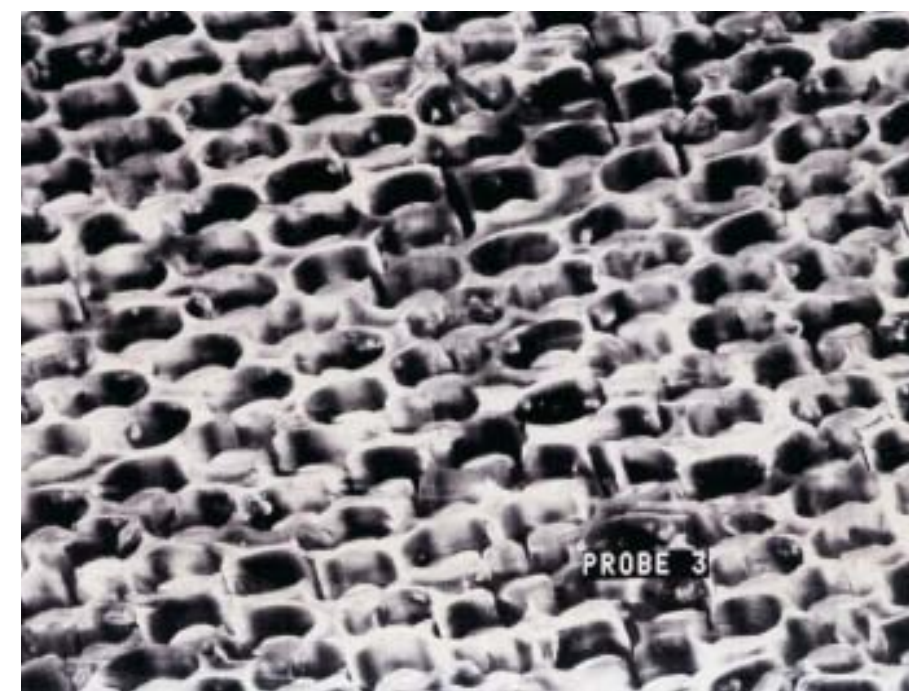


Photo: glass corrosion of the end fibre bundles of a scope after 50 cycles with softened water at 93 °C for 10 minutes.

Properties of softened water

After softening of water, not only is formation of deposits prevented but other alterations in properties can be seen. The total salt content of the water is unaltered. Measurement of the conductivity reveals slightly higher values, due to the somewhat higher mobility of the smaller sodium ions compared with the calcium/magnesium ions in water. The steam residue, as another measure of water quality, is also somewhat higher, since one calcium with an atomic weight of 40.08 or magnesium with 24.31 is replaced by two sodiums of mass 23.99 each, thus giving a total of 47.98. In the large space softener, there also a slight increase in bio-organic material, since micro-organisms are able to multiply on the ion exchange material. In the monoblock softeners this is not the case, since the regular resalting and regeneration has a lethal effect. An important property of softened water is its increased pH value. If this is in the range of 7.2 to 7.4 for drinking and normal water, then it will be 7.4 to 8.0 afterwards. The sodium hydrogen carbonate generated in softening is more alkaline than calcium or magnesium hydrogen carbonate. Addition of heating of softened water depending on the temperature and the time in the cleaning and/or disinfectant and/or final rinse phase causes a further increase in pH value. From two molecules sodium hydrogen carbonate, water and carbon dioxide split off and lead to sodium carbonate (soda) according to the equation:



Because of this alkalinity of the water, the rinsing of alkaline cleaning material from the instruments after the cleaning rinse phase is made more difficult. In order to achieve efficient rinsing nonetheless, a neutralisation step is needed with a phosphoric acid or citric acid containing product. This is especially important in silica containing cleaners, that if there is delay in the final rinse phase, small silica residues may remain on the instruments at the end of the process, yellow/brown silicate discoloration may result. These are often seen first on the walls and the door of the machine.

The effect of water alkalinity leads for some materials even to attacks on the material. This is greater than if highly alkaline cleaner that contain silicates as a corrosion protection component is used.

This material attack is recognised with anodised aluminium (containers); it leads to a variable, piebald appearance with a white powder that can be rubbed off.



Aluminium corrosion after 100 runs of a chemothermal Programmes at 60 °C. Left: with mildly alkaline cleaner in softened water. Right: no addition, softened water alone.

With discoloration, the colour comes out after a few cycles if rinsed with softened water at high temperatures. This can only be completely avoided if completely desalted water is used for the higher temperature phases of the preparation programme (1).

With optical light guides (rigid endoscopes) too, use of softened water at high temperatures can lead to interference in light transmission because the rinsing water enters into the open end of the light fibre bundle (see Photograph, p. 15). In the Vario-Programme with completely desalted water in the final rinse with thermal disinfection, this corrosion is eliminated (2).

Severe material attack by hydrolysis is also seen with polycarbonate if softened water is used at high temperature in the final rinse phase.

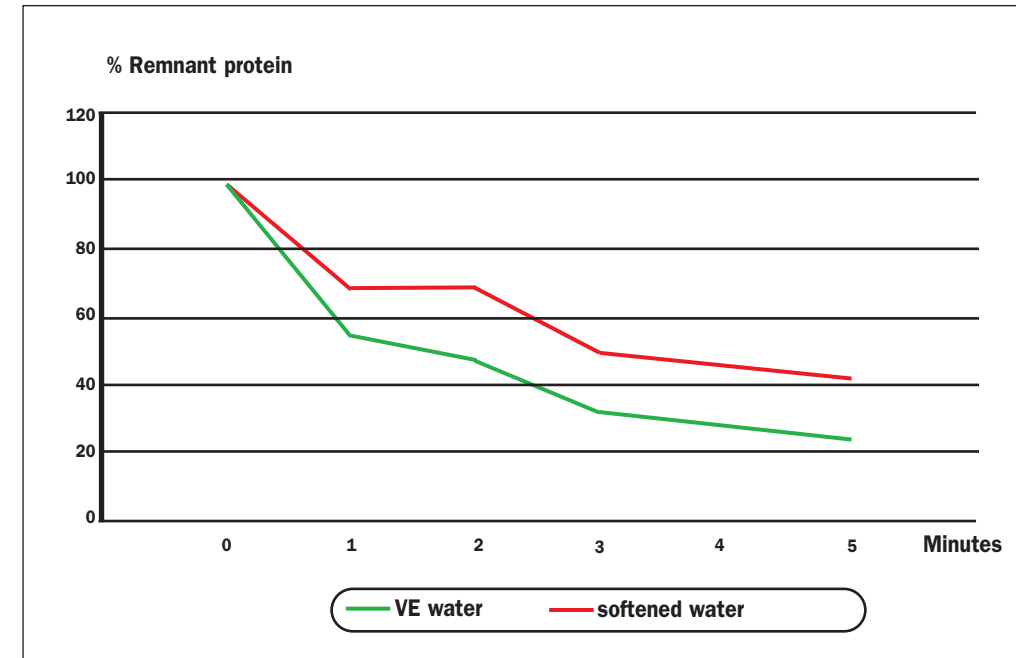
The material quickly becomes milky and turbid.

Effect of softened water on wash performance

The pH value increase in softened water does not have a positive effect on the performance of alkaline cleaning material. In the region of pH up to 11.5, higher alkalinity improves cleaning performance.

In comparison with isothermic elution of the sintered, microporous borosilicate test bodies contaminated with protamine sulphate reactivated heparinised sheep's blood with 0.3 % of an alkaline cleaning material at 45 °C results with softened water showed poorer contamination removal compared with use of completely desalted water (3), see Figure p 17. Elution of the contamination with 0.2 % cleaner with completely desalted water is better than softened water with 0.3 % cleaner. In view of this, the demand for more precise cleaning medium dosing must be considered.

In measurements of pH values of softened water that has added cleaner, the pH is lower than given in the data sheet of the cleaner with fully desalted water. The measurement of the resulting pH value of a 0.3 % cleaner solution in completely desalted water with added sodium carbonate (soda) in amounts in the hardness grade 1 to 4 showed no pH value change. With addition of sodium hydrogen carbonate, however, there was a pH fall (Table). This fall through the buffering effect of sodium bicarbonate is responsible for the reduced cleaning performance. Thus the cleaning performance is significantly dependent on the regional water quality and in generally attempting to improve standardisation of cleaning in instrument preparation, use of fully desalted water is recommended. This offers the optimal chance for cleaning.



Water quality and vCJD problems

The report of the RKI shown on the internet, and which will be published in April »Variant Creutzfeldt-Jakob disease (vCJD)« The recommendations for routine are aimed at general prevention during

Further remarks are worth making concerning this publication. Destruction of proteins by hydrolysis, even if only partial, is only achieved at pH values significantly higher than 12, and with increased temperature. But, as regards destabilisation of

mg NaHCO ₃ /l + 0,3% Cleaner	Corresponding hardness value before softening	Resulting pH
85	1	11,5
165	2	11,3
250	3	11,1
350	4	11,0

instrument preparation even for risks of iatrogenic transmission of vCJD, The cleaning should be carried out using a cleaning material at a pH value of at least 10. This improves cleaning performance compared with lower pH values; based on the effect of softened water, however, mild alkaline cleaners may undershoot the intended pH value because of this buffering effect. There is no recommendation for using fully desalted water in the cleaning phase.

prion particles, the lasting effect is very questionable.

With electrostatic charges at a pH around 10 to 12, transient destabilisation can be seen, but it is without effect and reversible and does not inactivate prion proteins. Moreover, the recommendation of a working time of 10 minutes is only relevant under conditions of hydrolysis and permanent damage of prion proteins, but not for cleaning or destabilisation. During cleaning, based

on studies it can be said that if things that are not clean after five minutes, they are not clearly better after ten minutes. This allows the isothermic cleaning curves to be compared. If non-alkaline at pH values > 12 and with a temperature of 95 °C is used, the Vario-Programme should be preferred. A temperature of 55 °C is recommended (5). A prewash is always required since the preparation results are very dependent on the contamination introduced with the instruments and their effect on the cleaning process (6). ■

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