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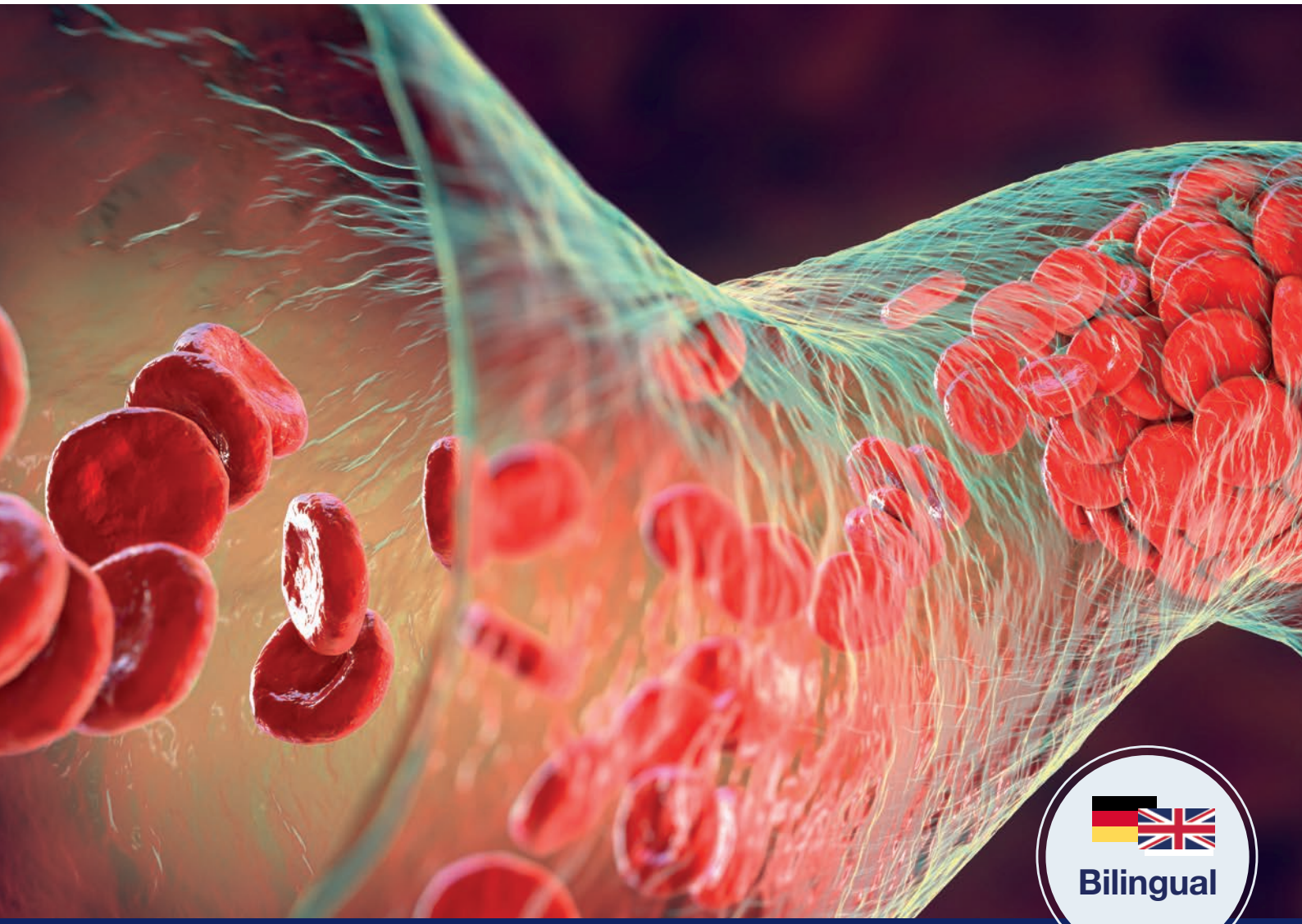


Bilingual

## Leistungsfähigkeit manueller Reinigungsmittel zur Entfernung von Fibrin – eine Marktübersicht

## The fibrin removal capabilities of manual cleaning agents – an overview of the market

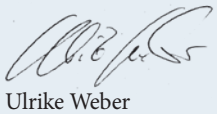
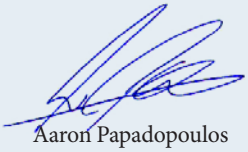
# Editorial

**Dear readers,**

Aaron Papadopoulos and Ulrike Weber would like to welcome you to the third edition of aseptica on behalf of the editorial team. Please make yourself comfortable and sit back. For your own safety, we request that you read each article slowly and page for page, and take a break between individual articles. The use of your phone is not permitted while reading. You may, of course, leave your smartphone or notepad switched on. We would like you to dispel any heavy thoughts or lock them securely away.

With this most recent issue, we wish to take you on a journey with exciting articles on the subjects of hygiene, hospitals and technology. We start with the 'second part of the ISO 17664 standard and the information to be provided by the manufacturers' of medical products, an article written by Ms. Nehr-Werner.
The next article, penned by Drs. Brill, Kampe and Wehrl, provides an interesting market overview on the capacity of detergents used in manual processes to remove fibrin. We present a study comparing alkaline with pH-neutral and enzymatic products.
Another focus of this edition is sedation using nitrous oxide. Dr. med Mathers throws light on the subject in a detailed examination, and the reprocessing of nitrous oxide tubing and accessories in dental practices is described in a further article by Dr. Weber.
The 'Technology & Hygiene' category features current topics from the field of automated processing. Mr. Bühler reports on a recently published recommendation on the validation of da Vinci instruments; Mr. Hoppe and Dr. Weber describe the latest design features on washer-disinfectors. In addition to this, there is more from the series entitled 'Surface changes on instruments – Correct evaluation and analysis'. We also present Dr. von Rheinbaben as our new crew member. Your journey is brought to a close with 3 questions to Ms. Nehr-Werner on the subject of corrosion and pitting on instruments.

With this last issue for 2021, we would like to wish you a pleasant Advent season, a Merry Christmas and a Happy 2022 on behalf of the entire editorial team.
Stay healthy!

Ulrike Weber Aaron Papadopoulos

# Contents



# Report

**Gun violence increases significantly during pandemic**

Evidently, gun violence is another phenomenon that grew even bigger in the USA during the COVID-19 pandemic. In the first year of the pandemic, the number of offences, injuries and fatalities rose by almost a third compared to the year before. These are the findings of a study by “Scientific Reports”. An initial indication of the problem can be gleaned from the surge in gun purchases: between March and June of last year alone, the FBI scrutinised 13.7 million gun purchase applications, an increase of 42 % on the previous year. This translated directly into an increase in violent acts: in the summer months of last year, the number of offences was more than 45 % higher than in the preceding years.
The team of scientists headed by Paddy Ssentongo at the “Penn State Center for Neural Engineering in Hershey/Pennsylvania” attributes the increase to the lockdown and to social distancing measures. The scientists claim that even though these measures are crucially important for containing the spread of COVID-19, society needs to be aware of the unintended social and economic stress factors that could potentially lead to gun violence. Other studies have also highlighted a substantial increase in depressive symptoms among the population.

Source: aertzeblatt.de

# ISO 17664-2 – Processing of health care products

*Information to be provided by the medical device manufacturer for the processing of medical devices – Part 2: Non-critical medical devices*

*Stella Nehr-Werner*

Standard ISO 17664-2 was published at the beginning of this year. It is a standard aimed at medical device manufacturers and contains requirements for reprocessing instructions. Part 2 deals with non-critical medical devices that are either only intended to come into contact with unbroken skin or are not intended to come into contact with the patient at all. The standard does not deal with the reprocessing instructions themselves. Rather, it explains the requirements involved so that manufacturers are able to create reprocessing instructions for the medical devices concerned.

## Demarcation from Part 1:

The boundary between Part 1 and Part 2 is clearly demarcated and defined by the scope specified for each part of the standard. Part 1 clearly includes all medical devices that are reprocessable, semi-critical or critical, i.e. those that come into direct contact with the patient and have to be cleaned, disinfected and/or sterilised. This also applies to medical devices that are supplied unsterile and have to undergo processing before coming into contact with a patient for the first time.[1] Part 2 of the standard covers all non-critical medical devices that only come into contact with unbroken skin or do not come into contact with the patient at all. The demarcation between the two parts can be clearly illustrated by means of an example (see Figure 1). Annex E of ISO 17664-2 contains further examples to assist with demarcation.[2]

## Structure of the standard

Firstly, Part 2 is clearly demarcated from Part 1 under "Scope". This also clarifies what is not included in the standard and describes the target audience. As stated there, the standard merely lays down requirements concerning the information that the medical device manufacturer must provide in relation to reprocessing; it does not specify the actual reprocessing instructions themselves. The target audience is always the manufacturer of the medical device that is to undergo reprocessing, not the operator of the device. At this point, special attention should be drawn to Section 3 of the standard, which covers the specialist terminology used as defined in ISO 11139. When it comes to digesting all the existing standards that relate to the reprocessing of medical devices, consistent use of the terminology makes life much easier, as does having the terms all defined in one place at a general level.


**Fig. 1:** Panoramic X-ray machine from Dentsply Sirona:
The handles, temple supports and surfaces of the X-ray machine are covered by Part 2. The occlusal bite block is covered by Part 1.

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The manufacturer is required to demonstrate that all the processes they describe are effective and compatible with the material. These processes have to be validated. To make the validation process easier, product families can be created and the processes established according to the level of risk involved. This enables the manufacturer to group together medical devices with identical or similar properties and characteristics. The important thing here is to consider the worst-case scenario. From the perspective of reprocessing, this means that the medical device must also be considered in conjunction with the greatest challenges it poses for reprocessing – not only those that stem from the design but also from the parts that are most likely to lead to contamination and cross-contamination (i.e. points of contact with the patient). In turn, this reveals the minimum requirements.

When providing the necessary information, the manufacturer must consider the following points:

1. All information and methods must be tailored for the medical device and the intended use. If additional aids, special techniques or methods are required for reprocessing, these must be specified in the instructions. All methods must be validated.
2. In addition, national standards and nationally applicable guidelines must be considered when providing the instructions.

As a minimum, the reprocessing instructions must meet the following requirements:

1. At least one validated reprocessing method must be specified.
2. The specified method must be appropriate to the market. This means that it must be capable of being performed in the country concerned.
3. All steps must be described in detail, including any accessories to be used and the specifications for process parameters.

If reprocessing is subject to any restrictions or other limiting factors, these must be communicated to the operator. These include, for example, processes that may affect the service life or any limit that applies to the number of reprocessing cycles in general, as well as any incompatibilities as regards certain substances.

Reprocessing begins with preparation of the medical device. The manufacturer must state whether the medical device has to be prepared for reprocessing and, if so, how. Among other things, this includes disassembly, which must be carried out in accordance with the manufacturer's instructions and may call for special tools or accessories. The manufacturer may find Annex A helpful when describing this step.

In the case of the cleaning process step, a distinction is drawn between manual and automated cleaning. At least one method must be described and validated. The following – among other things – must be described for both the manual and automated methods: the parameters and chemicals to be used, the contact times and any accessories (such as adapters, connectors or other aids). The manufacturer must clearly draw attention to any limitations or other influencing factors of the process that could have a detrimental effect on the medical device or even the success of reprocessing. In addition, step-by-step instructions are required in each case. If automated processes are selected, a machine conforming to the ISO 15883 series of standards must be used. Once again, Annex A provides valuable tips for drawing up the information.

Both manual and automated processes are again mentioned under "Disinfection". The manufacturer must describe at least one process and this must also be validated. Attention must be drawn to the limitations associated with the process, e.g. material incompatibilities relating to heat or chemicals. In addition, the manufacturer must specify any aids or accessories that are required to carry out the process.

Even the drying stage has to be described as a process step in its own right. However, this can sometimes be integrated into the previous step as part of automated reprocessing.

A medical device check/inspection is an important step that must be carried out before the device is reused or put into storage. During this step, maintenance products may also need to be applied (e.g. application of oil) or the medical device may have to undergo calibration prior to use. Whatever the situation, the operator must

always be told in detail what steps are necessary to end up with a medical device that is free of faults and in full working order.

To cover transportation and storage, the manufacturer must finish off by specifying the relevant conditions.

Part 2 of the standard concludes with the section entitled "Presentation of the information", which instructs the manufacturer to make the above information available generally. The information can be provided electronically but must – as a minimum – be issued in writing on request.

## How does the user benefit from this?

In general, ISO 17664-2 is a standard for medical device manufacturers. However, users also benefit from having the reprocessing information presented in a standardised format. Knowing that manufacturers have to validate all specified processes and that certain information is required as a minimum makes day-to-day tasks easier for users. In addition, the inclusion of limitations helps them to understand which factors affect the service life and which substances are incompatible with the device.

## Conclusion

Ideally, the manufacturer should supply the reprocessing instructions together with the medical device. This is not only necessary for semi-critical or critical medical devices but now also applies to non-critical medical devices as of this year. Information in a standardised format is expected from the manufacturer along with safe, validated processes that are effective and compatible with the material.

Literature references

1. DIN EN ISO 17664-1:2021 – Aufbereitung von Produkten für die Gesundheitsfürsorge – Vom Medizinprodukt-Hersteller bereitzustellende Informationen für die Aufbereitung von Medizinprodukten - Teil 1: Kritische und semi-kritische Medizinprodukte (ISO 17664-1:2021); Deutsche Fassung EN ISO 17664-1:2021.
2. ISO 17664-2:2021(E) – Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices —Part 2: Non-critical medical devices

# The fibrin removal capabilities of manual cleaning agents – an overview of the market

*Florian H. H. Brill, Andreas Kampe, Markus Wehrl*

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In the context of reprocessing reusable medical devices, cleaning is a crucial step for success. Only when contamination (e.g. blood) is removed successfully can the subsequent disinfection and – where applicable – sterilisation steps be performed efficiently enough to make the medical device safe for the next patient. Together with the other three parameters of the Sinner's circle, the performance capabilities of the cleaning agent play a crucial role in helping the cleaning step to achieve its aim. Cleaning agents for reprocessing medical devices are actually categorised as Class 1 medical devices in their own right. However, no official standard or other binding guidelines have yet been produced for assessing the performance capabilities or effectiveness of these cleaning agents and using the results as a basis for drawing up recommendations for use. Therefore, unlike disinfectants (for example), cleaning agents cannot be independently assessed by users to determine whether they are suitable for their applications and the claims emanating from various manufacturers are all based on different foundations. For this reason, the Deutsche Gesellschaft für Krankenhaushygiene e.V. (German Society for Hospital Hygiene, or DGKH for short), set up a working group (WG) more than 10 years ago: the Working Group for Testing Detergents. This work bore its first fruit in 2018, when a testing method was published for the comparative evaluation of cleaning agents for manual instrument reprocessing (Wehrl et al. 2018[1]). The method is a standardised approach for testing the removal of fibrin (the most stubborn constituent of blood) from stainless steel surfaces. In the interest of standardisability, the mechanical component of cleaning is largely excluded from the method.

Following its publication, one of the objectives of the Working Group for Testing Detergents was to investigate how effective various types of cleaning agent were at removing fibrin in order to gain an overview of the market and verify the practicability of the testing method. For this reason, they selected a set of cleaning agents for manual instrument reprocessing that were customary in the market. The efficacy of these agents was then investigated at two independent test laboratories using the method described in Wehrl et al. 2018.

## Material and methods

In order to carry out the effectiveness tests, one alkaline cleaning agent, two enzymatic cleaning agents and one neutral cleaning agent were selected. Water of standardised hardness (WSH) was used for control purposes. The test method described by Wehrl et al. 2018 was used and three independent experiments were performed at each laboratory. This involved applying reactivated sheep blood to small stainless steel plates (80 x 12 mm with a grain size of 80). The process challenge devices were incubated for one hour in a desiccator at 100 % relative humidity. To dehaemoglobinise the blood soiling, four wash steps were performed (10 min, 10 min, 15 min, overnight) using fresh demineralised water (DI water) for each one. Once the process challenge devices had finished drying at room temperature inside tightly sealed plastic cans filled with silica gel, they were ready for use.

Without using any mechanical action, the standardised fibrin stainless steel PCDs were brought into contact with the cleaning agents in the concentration specified by the manufacturer for activation times ranging from 5 to 30 minutes. At the end of the contact time, cleaning agent and detached soiling residues were removed using a standardised rinsing process (brief immersion in demineralised water). After that, the fibrin residues were recovered and dissolved. For this, the PCDs were trans-

ferred to glass tubes containing a 1 % SDS solution (pH 11). This was followed by thermal solubilisation of the fibrin residues in autoclaves at 121 °C for 20 minutes. The modified OPA method (ISO 15883-5[2]) was used to quantify the residual fibrin/protein content so that it could be used as a measure of the residual contamination.

## Results

The results are shown in Figures 1 to 5. The results reveal that WSH was able to reduce the fibrin soiling only slightly, by less than 20 % (Fig. 1). As expected, the alkaline cleaning agent started acting quickly, reducing the fibrin contamination by approximately 40 % after 10 min (Fig. 2). The neutral cleaning agent achieved a similar effect after 15 mm (Fig. 3). The first enzymatic cleaning agent (Fig. 4) eliminated the fibrin almost completely (residual fibrin content <10 %) but took 20 min to do so. The second enzymatic cleaning agent (Fig. 5) managed to reduce the fibrin content by approximately 50 % after 20 min.

## Conclusions for practice and outlook

The results reveal that different cleaning agents achieve different removal kinetics in relation to fibrin. The test method appears to be able to differentiate between them in this regard. The data also shows that the performance capabilities can vary. When selecting a cleaning agent, it is important for the user to consider the performance capabilities (among other aspects) on the basis of objective data. Of course, it is also important to take account of other factors that contribute to the cleaning results, such as the remaining 3 parameters of the Sinner's circle. Furthermore, it is necessary to factor in the chemical nature or chemical composition of the relevant soiling that is typically encountered in practice (e.g. the proportion of soiling containing lipids or carbohydrates).

In the future, evaluating the effectiveness of chemical cleaning agents is going to be a crucial step for assuring the quality of reprocessing processes. Fibrin (among other things) should definitely be taken into account as part of this. Other constituents of blood, such as haemoglobin, are extremely water-soluble and so do not pose enough of a challenge for a chemical cleaning process.

The developed test method has proven its practicability and it is now a question of defining effectiveness requirements to enable the testing of cleaning agent effectiveness. Following on from this, further work may be required so that other types of soiling and cleaning agents for automatic cleaning can be incorporated into the tests. The work described above represents an important initial step in this regard.

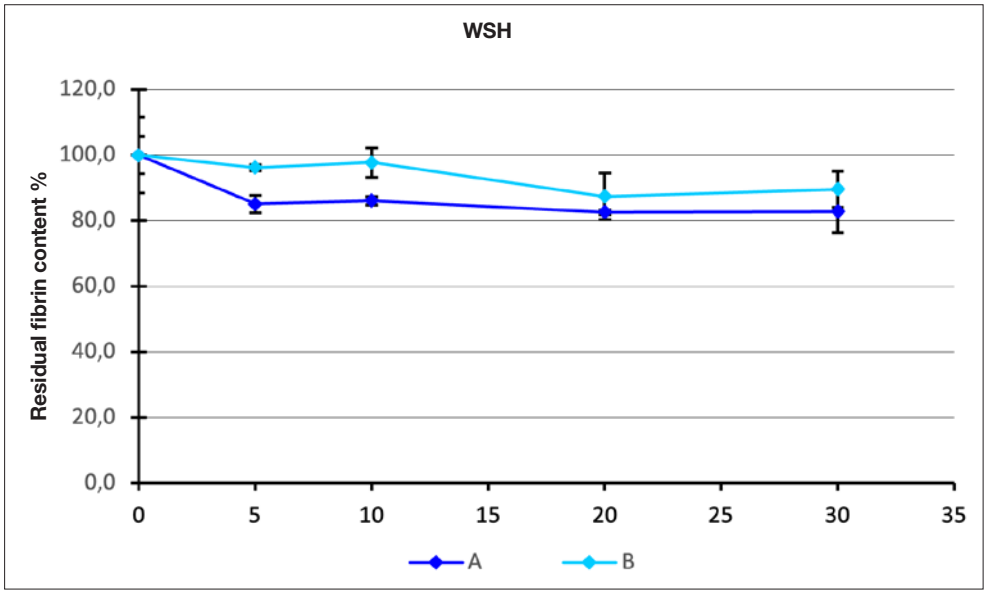


**Fig. 1:** Fibrin removal kinetics for fibrin PCDs using water of standardised hardness (WSH) for a period of 0 to 30 min at 25 °C. A, B: both labs; the figure shows the arithmetic means (n=3) for the residual fibrin content as a percentage of the initial quantity (untreated control sample) together with the respective standard deviations.

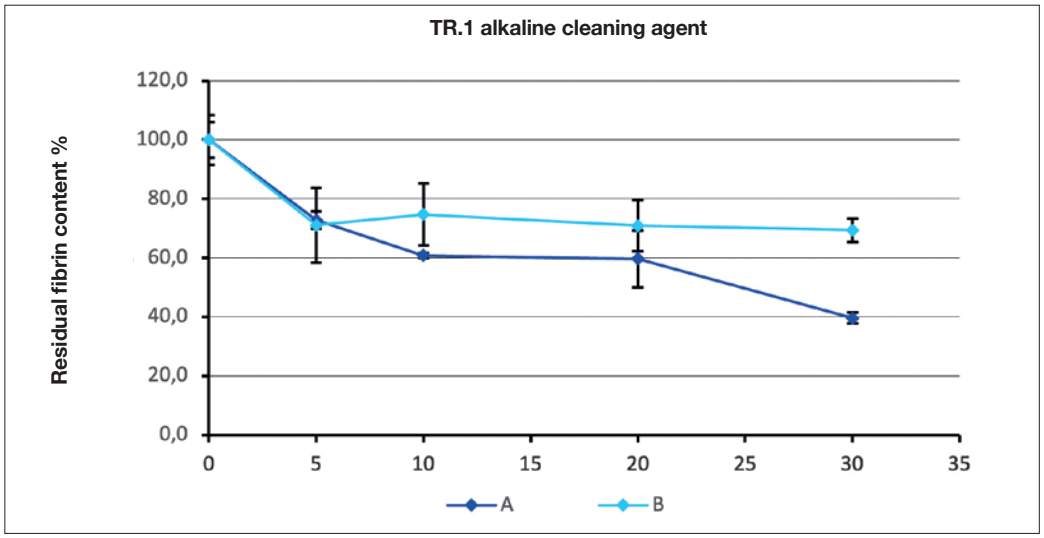


**Fig. 2:** Fibrin removal kinetics for fibrin PCDs using an alkaline cleaning agent (test cleaning agent TR.1) for medical devices for a period of 0 to 30 min at 25 °C. A, B: both labs; the figure shows the arithmetic means (n=3) for the residual fibrin content as a percentage of the initial quantity (untreated control sample) together with the respective standard deviations.

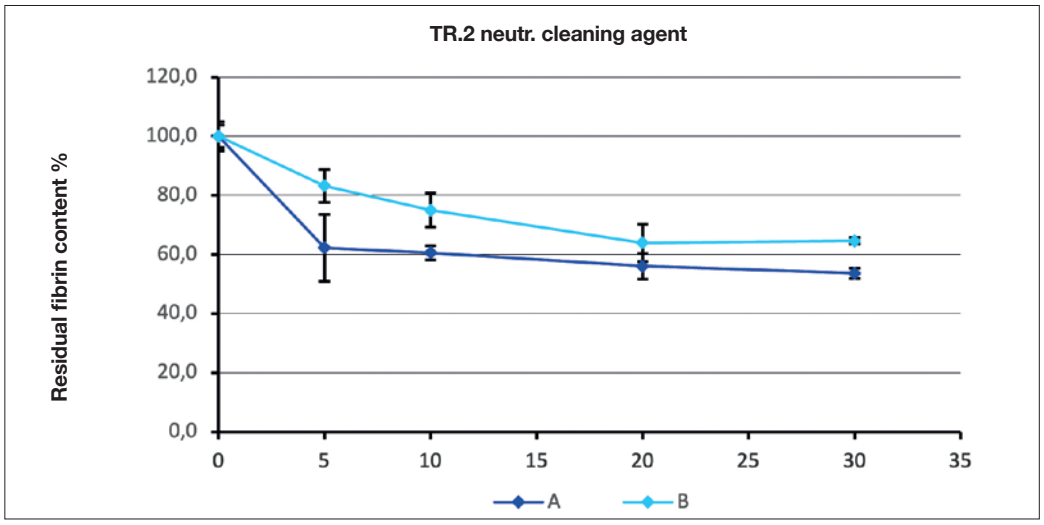


**Fig. 3:** Fibrin removal kinetics for fibrin PCDs using a neutral cleaning agent (test cleaning agent TR.2) for medical devices for a period of 0 to 30 min at 25 °C. A, B: both labs; the figure shows the arithmetic means (n=3) for the residual fibrin content as a percentage of the initial quantity (untreated control sample) together with the respective standard deviations.

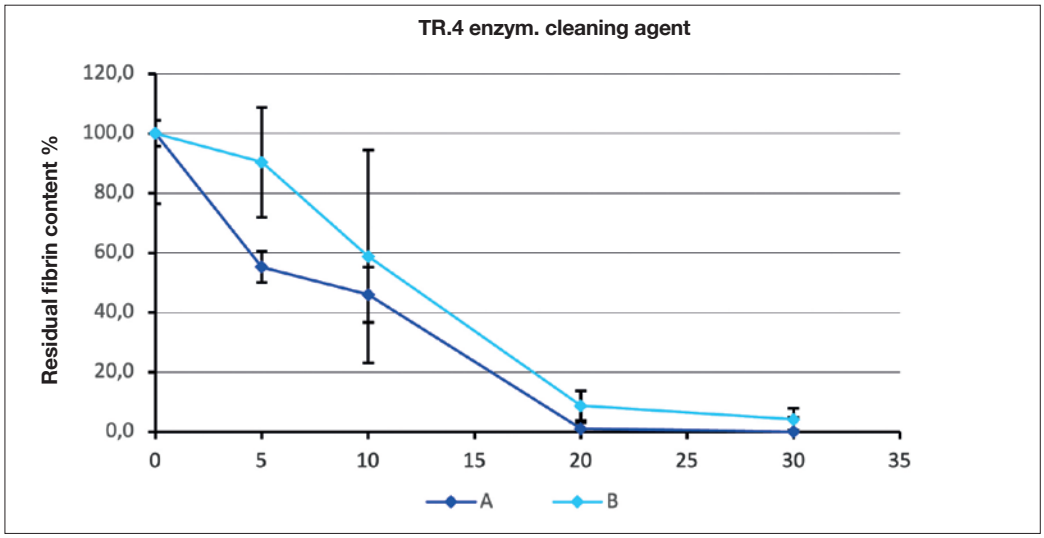


**Fig. 4:** Fibrin removal kinetics for fibrin PCDs using the first enzymatic cleaning agent (test cleaning agent TR.4) for medical devices for a period of 0 to 30 min at 25 °C. A, B: both labs; the figure shows the arithmetic means (n=3) for the residual fibrin content as a percentage of the initial quantity (untreated control sample) together with the respective standard deviations.

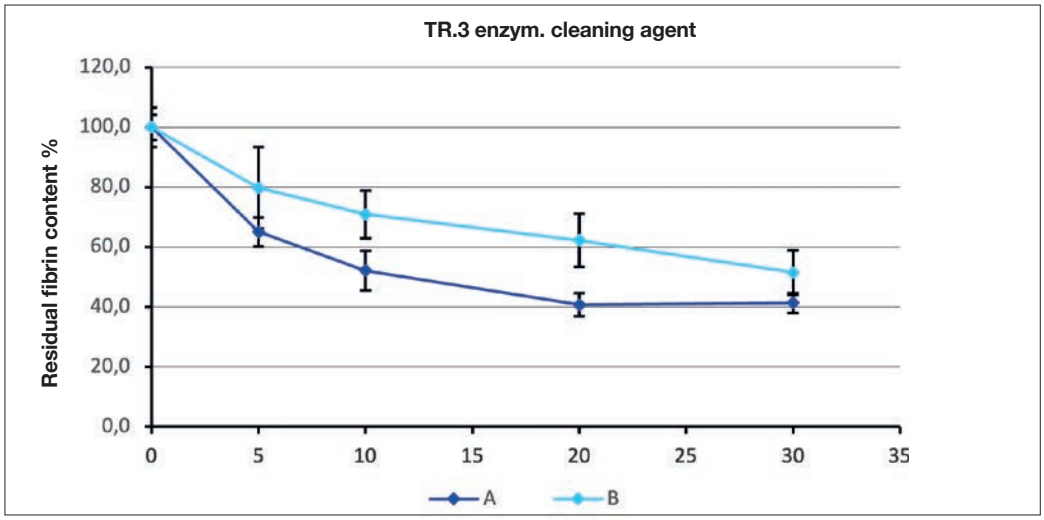


**Fig. 5:** Fibrin removal kinetics for fibrin PCDs using the second enzymatic cleaning agent (test cleaning agent TR.3) for medical devices for a period of 0 to 30 min at 25 °C. A, B: both labs; the figure shows the arithmetic means (n=3) for the residual fibrin content as a percentage of the initial quantity (untreated control sample) together with the respective standard deviations.

Literature references

1. M. Wehrl, U. Rosenberg, F.H.H. Brill, H. Gabriel, A. Kampe, W. Michels, K. Roth, L. Schnieder, P. Frey, J. Köhnlein, O. Riebe, A. Hartung, R. Bloß, G. Kirmse, M.-T. Linner, D. Martini, M. Tschoerner, U. Weber, S. Krüger, H. Martiny, J. Gebel: Prüfmethode für die vergleichende Bewertung von Instrumentenreinigern zur manuellen Aufbereitung von chirurgischen Instrumenten auf der Basis von Fibrin (Test method for comparative evaluation of instrument detergents for manual reprocessing of surgical instruments on the basis of fibrin). ZentrSteril 2018; 26(6): 366–381.
2. DIN EN ISO 15883-5:2020-06 – draft. Washer-disinfectors – Part 5: Performance requirements and test method criteria for demonstrating cleaning efficacy (ISO/DIS 15883-5:2019). Beuth Verlag, Berlin.

# Sedation with nitrous oxide

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Sedation by the inhalation of nitrous oxide is well suited to reducing anxiety in a wide range of patients. In many parts of the world, it is the standard process within the dental industry and, increasingly, is now also being adopted by other specialist fields, such as paediatrics, surgery, urology, emergency medicine, and so on.[1,2] The many advantages of nitrous oxide sedation easily outweigh the disadvantages, of which there are almost none of any relevance. Due to its widespread use within the dental industry, this overview will be confined to its usage within this field.

The use of nitrous oxide is classed as "minimal sedation", i.e. the patient remains conscious and responsive at all times.[3] In Germany, it is the anaesthetist that provides the dentist and dental team with the training they need in conformity with the rules and regulations. This takes two days, which is shorter than the training for more invasive methods, such as intravenous sedation.[4] Dental nitrous oxide sedation is an established standard process that has been in use for decades and enjoys a high level of acceptance among dentists and patients alike (Fig. 1).


**Fig. 1:** Nitrous oxide machines (medical devices from Biewer medical).

**Fig. 2**: Karl Wilhelm Scheele (1742–1786).

In recent times, it has become an increasingly widespread practice in Germany to combine the use of oral/enteral sedation with sedation by the inhalation of nitrous oxide. The advantages are that patients are more deeply sedated and easier to manage, although they often show signs of amnesia.[5] However, there are some important distinctive features, meaning that the dentists and their assistants require special training.[4]

## Sedation by the inhalation of nitrous oxide/oxygen

Historically, the use of nitrous oxide as a clinical anaesthetic stems from the pioneering work carried out by a dentist called Horace Wells in Boston (USA) in around 1850[6]. However, nitrous oxide was actually discovered much earlier than this by a German-Swedish pharmaceutical chemist called Karl Wilhelm Scheele (Fig. 2)[7]. This drug is well suited to patients with low to moderate anxiety. The exact mechanism of action (i.e. how the drug works) has still not been definitively explained, although we do know that nitrous oxide acts on the opiate receptors and on the benzodiazepine receptors in the central nervous system (CNS). Neurobiologists attribute its anxiolytic and analgesic effects to these mechanisms.[8,9]

## Physical properties, pharmacokinetics and pharmacodynamics of nitrous oxide ($N_2O$)

At room temperature and atmospheric pressure, $N_2O$ is a colourless and non-flammable gas. It has a faint, sweet odour that most patients describe as pleasant. This gas

**Fig. 3:** Patient undergoing treatment while under nitrous oxide sedation (institute for dental sedation).

does not irritate the respiratory system and has no effect on the respiratory control centre, i.e. unlike other sedatives, it cannot cause respiratory insufficiency. Nitrous oxide is supplied in liquid form inside steel canisters. The pressure above the liquid phase is always 50 bar. The pressure only drops below 50 bar once the liquid has fully vaporised and at this point the canister must be replaced.

Oxygen is always mixed with the nitrous oxide and all commercial machines ensure a generous oxygen percentage of at least 30 % thanks to a feature known as the "nitrous oxide lock". When you consider – by way of a comparison – that normal room air contains only 21 % oxygen, this means that optimum oxygenation is always ensured whenever inhalation sedation is used. Oxygen remains gaseous inside the pressure cylinder and is supplied in full canisters at a pressure of 200 bar. The pressure drops as the gas is extracted from the cylinder.

The anxiolytic and sedative effects of nitrous oxide correlate with the depression of the CNS and, in turn, this is dependent on the concentration of nitrous oxide inhaled. Continuous inhalation of the gas results in equilibrium being established between the brain and other types of tissue (muscle, fat, etc.). Due to its poor solubility in blood plasma, nitrous oxide only experiences minimal losses while travelling between the lungs and CNS. As a result, it has a rapid sedative effect that works within minutes.[10] Conversely, the gas also leaves the body very quickly if the supply is interrupted.

One of the key factors behind its widespread and safe use in dental practice is that this anaesthetic gas has only a mild effect. In the case of dental treatment, nitrous oxide concentrations usually range between 30 % and 50 %.[11] In order to achieve general anaesthesia, it has been calculated that you would a nitrous oxide concentration of 105 % – a figure far in excess of the maximum possible concentration of 70 % that modern nitrous oxide machines are capable of delivering as a result of the "nitrous oxide lock".[12] Due to the pharmacological properties of nitrous oxide, patients sedated with this gas remain responsive and cooperative at all times (Fig. 3).

With its low level of solubility in blood and mild effect, $N_2O$ is the ideal sedative. CNS depression can be quickly and easily titrated (i.e. adjusted) within minutes via the concentration of nitrous oxide inhaled. The ability to communicate continuously with the patient allows medical personnel to ascertain the depth of sedation on an ongoing basis and, where applicable, whether the nitrous oxide titration should be increased or decreased.

## Complications of nitrous oxide sedation

All modern machines ensure a minimum oxygen concentration of 30 %, thereby reliably ruling out the risk of hypoxia. The cardiovascular and respiratory systems are barely affected by $N_2O/O_2$ sedation, and no significant changes in vital bodily functions are observable in clinical settings. The kidneys and liver are not affected by nitrous oxide either.

## Practical applications

From a technical perspective, nitrous oxide sedation is very easy to initiate. First of all, a device check must be carried out and an adequate supply of nitrous oxide and oxygen must be ensured. The patient's vital signs are measured and a pulse oximeter is connected to enable continuous monitoring. The patient inhales the set gas mixture from the reservoir bag on the machine. Adults inhale approximately 6 litres per minute. If the flow is too low (i.e. not enough gas is being fed into the reservoir bag), the bag collapses. Conversely, if the quantity of gas being fed into the bag exceeds the quantity being exhaled by the patient, the bag inflates (Fig. 4). When the reservoir bag is 80 % full, it means that the flow is correct, i.e. that the patient is inhaling the quantity set by the user. Once the flow has been set correctly, nitrous oxide titration commences with an initial composition of 20 % nitrous oxide and 80 % oxygen. Depending on the clinical effect on the patient, the concentration is then increased by 10 % every minute until the patient is in a comfortable state. Patients generally need a nitrous oxide concentration of up to 50 % to become sufficiently sedated and feel at ease, although a small number require a concentration of up to 70 %.[13] At the other end of the scale, there are also a few patients who need less than 20 % nitrous oxide to feel pleasantly relaxed.
The depth of sedation can be changed from one minute to the next. Consequently, the user constantly has the option of administering higher nitrous oxide concentrations for more invasive phases of the treatment and lower concentrations for less invasive stages.


**Fig. 4:** Filled reservoir bag (Institute for dental sedation).

Each patient experiences nitrous oxide sedation in their own way but many describe a floating sensation and feeling of relaxation, sometimes accompanied by tingling in the hands, feet and around the mouth. Nitrous oxide reduces the perception of pain, with the result that the patient barely feels injections, if at all.[14] However, a local anaesthetic must always be administered because reliable anaesthetisation is not the reason why nitrous oxide sedation is used in dentistry.

There is no toxic overdose level for nitrous oxide but excessive concentrations do lead to subjective malaise, dysphoria, perspiration, nausea or the inability to respond adequately when spoken to. In such cases, the concentration is gradually reduced until the patient's condition improves again, which usually happens within the space of a few minutes.

At the end of treatment, the nitrous oxide supply is shut off and the patient continues to inhale pure oxygen for three minutes. Depression of the CNS is quickly reversed and the patient can be sent home unaccompanied once they have regained all normal bodily functions. It is also possible to drive after being sedated with nitrous oxide alone.

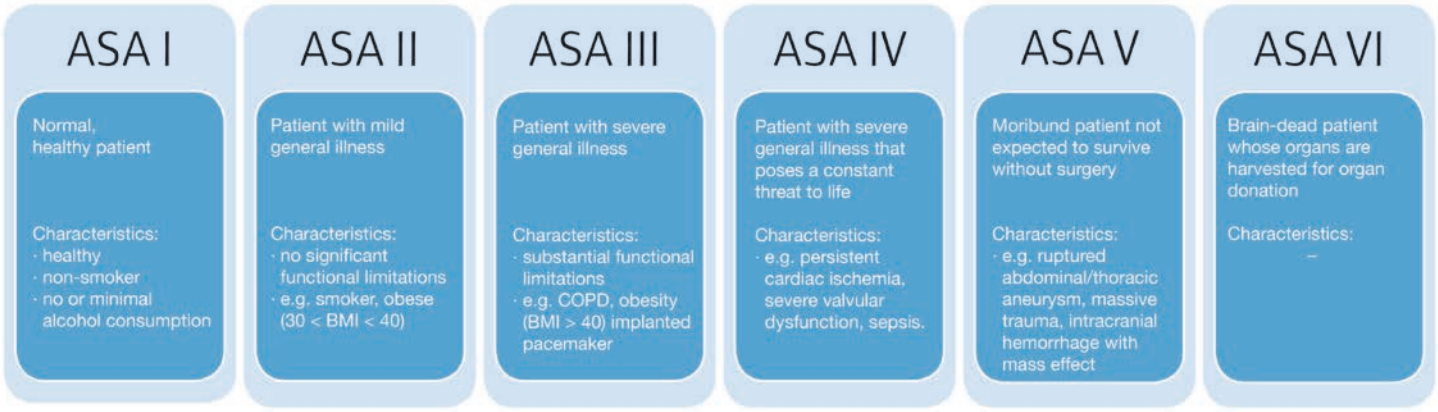


**Fig. 5:** ASA classification system (institute for dental sedation).

## Diffusion hypoxia

Whenever someone has been sedated with nitrous oxide, 100 % oxygen must always be administered by inhalation for three minutes at the end. This prevents nitrous oxide that is exiting via the alveoli from starving the oxygen supply (a condition known as diffusion hypoxia). The phenomenon of diffusion hypoxia was described within the field of anaesthesiology in the 1950s but has not proven reproducible in dental studies since then.[15, 16] Nevertheless, to ensure the highest possible standard of safety, patients sedated with nitrous oxide at the dentist are always given 100 % pure oxygen at the end of their dental treatment. In this way, the risk of diffusion hypoxia can be reliably ruled out.

Occasionally, patients have to spend slightly longer than three minutes inhaling pure oxygen until the sedation wears off completely. This is a familiar phenomenon and is no cause for concern on the part of the dentist or the patient. Particularly in the case of longer procedures, the patient may take slightly longer to regain their normal responsiveness. Sometimes, the patient may need to spend some time recovering after the procedure until they feel confident enough to leave the practice.[17, 18] In this case, it is important to take account of the patient's individual experience.

## Safety aspects

The ASA (American Society of Anesthesiologists) classification system is used worldwide to assess physical and mental health (Fig. 5). Once the patient's medical history has been taken and they have been examined, the dentist assigns them to an ASA class. Only patients assigned to classes 1 and 2 are suitable for dental sedation with nitrous oxide.

In addition to patient-related risks, technical machine faults must also be ruled out. As well as undergoing manufacturer-specific maintenance, the machine must also be checked against a checklist prior to each use to ensure it is functioning perfectly. Machines are also designed with safety in mind. For instance, colour coding is applied to identify the gas and gas-specific connections are used in accordance with DIN standards to prevent gas supply mix-ups. Reference has already been made to the machine's internal "nitrous oxide lock", which reliably prevents a hypoxic gas mixture from being administered.

## Health risks for personnel

Although nitrous oxide is not acutely toxic, the German Social Accident Insurance Institutions still lay down rules to limit the level of room air contamination for personnel.[19] For this reason, exhaled or excess nitrous oxide is removed with an extraction system. A tight-fitting nasal mask helps to minimise leaks. On the machine, the gas supply (flow) must match the patient's respiratory minute volume. Excessively high flow rates lead to overpressure in the system, causing the excess gas to escape into the ambient air.

Patients should be asked not to speak to prevent them from exhaling the nitrous oxide mixture in uncontrolled ways. In addition to using technical equipment to limit room air contamination, the effectiveness of simple actions – such as the low-tech measure of opening the window in between two patients – should not be underestimated.

## Misuse

Nitrous oxide induces feelings of euphoria and is therefore also misused. The potential for dependency is lower than for other drugs but it can serve as a gateway drug. Chronic misuse is typically associated with the middle and upper classes, and dental personnel – including dentists – are particularly at risk.[20] In addition to the extensive psychosocial consequences of having an addictive disorder, long-term use of nitrous oxide over many years can also lead to polyneuropathy, which may also prevent the sufferer from performing finer movements of the hands.[21]

## Summary

Over recent decades, further advances have been made in the area of nitrous oxide and new applications have been discovered. Originally used in operating theatres as an additional gas for general anaesthesia, nitrous oxide now tends to be employed as a sedative by specially qualified doctors and dentists. Its high level of safety, combined with high rates of satisfaction among patients and dentists, means that use of nitrous oxide is likely to continue moving on an upward trajectory.


Literature references

1. Fiorillo, L., Conscious Sedation in Dentistry. Medicina (Kaunas), 2019. 55(12).
2. Collins, M., Nitrous Oxide Utility in Labor and Birth: A Multipurpose Modality. J Perinat Neonatal Nurs, 2017. 31(2): p. 137–144.
3. Ogle, O.E. and M.B. Hertz, Anxiety control in the dental patient. Dent Clin North Am, 2012. 56(1): p. 1–16, vii.
4. Berufsverband Deutscher Oralchirurgen & Deutschen Gesellschaft für dentale Sedierung: Empfehlungen zur Sedierung in der Zahn-, Mund- und Kieferheilkunde. Anforderungen an einen Rahmenlehrplan und die apparative und bauliche Ausstattung. Bundeszahnärztekammer, 2018.
5. Sivaramakrishnan, G. and K. Sridharan, Nitrous Oxide and Midazolam Sedation: A Systematic Review and Meta-Analysis. Anesth Prog, 2017. 64(2): p. 59–65.
6. Gillman, M.A., Mini-Review: A Brief History of Nitrous Oxide (N2O) Use in Neuropsychiatry. Curr Drug Res Rev, 2019. 11(1): p. 12–20.
7. Grainge, C., Breath of life: the evolution of oxygen therapy. J R Soc Med, 2004. 97(10): p. 489–93.
8. Cahill, F.J., et al., Antagonism of nitrous oxide antinociception in mice by intrathecally administered antisera to endogenous opioid peptides. J Biomed Sci, 2000. 7(4): p. 299–303.
9. Quock, R.M., et al., Benzodiazepine receptor mediation of behavioral effects of nitrous oxide in mice. Psychopharmacology (Berl), 1992. 107(2–3): p. 310–4.
10. Kety, S.S., M.H. Harmel, and et al., The solubility of nitrous oxide in blood and brain. J Biol Chem, 1948. 173(2): p. 487–96.
11. Hallonsten, A.L., Sedation by the use of inhalation agents in dental care. Acta Anaesthesiol Scand Suppl, 1988. 88: p. 31–5.
12. Hornbein, T.F., et al., The minimum alveolar concentration of nitrous oxide in man. Anesth Analg, 1982. 61(7): p. 553–6.
13. Kharouba, J., et al., Effectiveness and Safety of Nitrous Oxide as a Sedative Agent at 60% and 70% Compared to 50% Concentration in Pediatric Dentistry Setting. J Clin Pediatr Dent, 2020. 44(1): p. 60–65.
14. Benedetti, C., et al., Effect of nitrous oxide concentration on event-related potentials during painful tooth stimulation. Anesthesiology, 1982. 56(5): p. 360–4.
15. Fink, B.R., Diffusion anoxia in clinical anesthesia. Acta Anaesthesiol, 1954. 5(1): p. 42–6.
16. Quarnstrom, F.C., et al., Clinical study of diffusion hypoxia after nitrous oxide analgesia. Anesth Prog, 1991. 38(1): p. 21–3.
17. Guideline for Monitoring and Management of Pediatric Patients Before, During, and After Sedation for Diagnostic and Therapeutic Procedures: Update 2016. Pediatr Dent, 2016. 38(5): p. 77–106.
18. Coulthard, P., Conscious sedation guidance. Evid Based Dent, 2006. 7(4): p. 90–1.
19. Wegscheider, W., Naujoks, G., Wahl, G., Mohr, B., Lachgassedierung: Inhalative Exposition des Zahnarztpersonals. BGW Forschung, 2017. BGW 55-82-001.
20. Sandoval, V.A., Nitrous oxide: a serious look at laughing gas. Tex Dent J, 1993. 110(5): p. 13–6.
21. Chiew Angela, L., et al., Just "nanging" around – harmful nitrous oxide use. A retrospective case series and review of internet searches, social media posts and the coroner's database. Intern Med J, 2021.

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# Recommendation, validation of reprocessing procedure for da Vinci instruments (IG WiG Publication)

*Klaus Bühler*

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Robotic-assisted surgery has now arrived in many hospitals. The da Vinci surgical system is a surgical assistance system designed to enable operations to be performed using a minimally invasive approach. With its state-of-the-art technology, the da Vinci operation system can calibrate and filter the surgeon's hand movements, and seamlessly convert these into precise instrument movements. The da Vinci EndoWrist instruments can be moved with more degrees of freedom than the human hand, thus offering better access to the site of the operation. A complex configuration of these instruments is required to make this possible. The da Vinci instruments with seven degrees of freedom cannot be dismantled for reprocessing, but are constructed in such a way as to allow straightforward reprocessing anyway. Internal rinsing channels allow efficient cleaning of the inside surfaces of the instrument shafts and the casings. However, due to the product design, operators and validators are sometimes unsure how best to validate the reprocessing procedure. A working group at the Swiss IG WiG (Interessengemeinschaft Wiederaufbereitung im Gesundheitswesen [interest group for reprocessing in healthcare]) therefore looked at this question and put together a recommendation, with the aim of creating an approach for validating the reprocessing procedure for da Vinci instruments. The group of experts, led by the manufacturer Intuitive, worked with specialists from cleaning and disinfection device (CDD) manufacturers, validation agencies and users with practical experience, to draw up process validation instructions for da Vinci instruments from the point of view of the operator and the validator. There was a particular focus on the analytical checking of the cleaning performance by means of quantitative residual protein determination with regard to the da Vinci instruments. Due to the product design of the da Vinci instruments, a special procedure was required to extract the residual proteins from the instrument shaft and instrument tip. The detailed process description for the protein extraction allows easy and efficient practical application. A flow diagram and checklists for the operator and validator describe the individual steps and provide assistance during performance qualification. Preparatory measures required for the instruments prior to the protein test have also been described, as well as the handling of possible transportation to an external laboratory. Possible error sources are also highlighted, to ensure smooth validation. The IG WiG working group is pleased to note the frequent use of this recommendation. Download is available from the IG WiG website (www.igwig.ch).

# Automated processing of nitrous oxide hoses and accessories in dental practice

*Ulrike Weber*

After use, nitrous oxide hoses and the associated noise pieces have to undergo processing in accordance with the respective manufacturer's recommendations. Within this context, priority should be given to automated processing. The (lumened) design and associated need for connection to the washer-disinfector's wash circuit pose particular challenges.

The hoses are more than 80 cm long and, depending on the system, can be routed individually or in pairs. They have an adapter on the end so that they can be attached to the nose piece or unit tower. The part that comes into contact with the mucous membranes (the nose cap) is available as either a disposable or reprocessable product.

## Requirements for processing

Firstly, the length and number of hoses present a challenge and have an impact on the process. An associated issue is that some of the wash water gets captured during the wash cycle, thereby reducing the volume available to the other components of the wash mechanism (e.g. spray arm, circulation pump). However, it is essential to have a programme sequence (including the applicable amount of water in each case) that is balanced and tailored for the relevant load items (load configuration) to ensure a consistent wash pressure. If the load items capture too much water for the respective wash mechanism, this water ceases to be available to the circulation pump, in turn reducing the pressure and generating foam.

Secondly, the positioning of the hoses is crucial for successful processing. If they are positioned incorrectly, water pockets will form (sagging hoses). As a result, wash water will be carried over to the next wash step and too much residual water will be captured in the final wash step. Having a vertical filling system with a rising column of water and carefully controlling the passage of wash water through the hoses ensure that the process is reproducible.

Given what we already know about the processing of anaesthetic hoses and materials, it is possible to infer requirement criteria for the processing of nitrous oxide hoses and accessories. To avoid the need for a separate programme on the washer-disinfector, the load items should also be capable of withstanding thermal disinfection and the use of standard process chemicals.

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## Contaminants

Mucous membranes and contaminants transferred during handling (by touching items after they have undergone treatment) are of relevance here. The gas itself is volatile and does not impose any increased requirements as far as reprocessing is concerned.

## Special requirements for registered practices

User surveys carried out with registered practices have revealed that the optimum approach is to integrate reprocessing of the hose systems into existing load carriers and configurations (no storage space for an additional basket and more ergonomic because basket does not have to be changed).

## Summary

The following aspects pose particular challenges for the reprocessing of nitrous oxide hoses and accessories within the dental sector:

- Load items that capture too much water during processing
- Load items that form water pockets if positioned incorrectly, leading to carry-over
- Scalable quantity of hoses requiring adaptation
- Ideally, there should be no separate basket
- Ideally, there should be no separate programme

# Accurately assessing and analysing surface changes


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In practice, changes occur over time on the surface of a wide variety of medical devices, the cause of which can be traced to chemical, thermal and/or physical influences. The causes of these surface changes can normally be traced back to the reprocessing process, provided they were not caused during use. Should surface changes occur, a systematic sequence of steps must be followed for rectification and prevention.

- Locate the type, origin, and cause
- Assess the risks
- If necessary, follow the manufacturer's recommendations for prevention
- Determine avoidance measures and conduct a new performance qualification if necessary

The example surface changes that most commonly affect metallic instruments made from stainless steel and/or products made from plastic or rubber are based on the system described above.

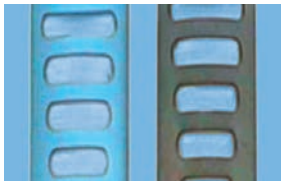
## Metal - Discoloration – Caused by Oxidation

A shiny, gray-black passive chromium oxide layer is only formed in the case of hardenable non-stainless steels, frequently initially identifiable with cutting instruments (e.g., scissors), but also in the case of non-cutting instruments (e.g., forceps, thumb forceps).
In the case of titanium materials (pure titanium or alloys) surface discoloration may be formed with uniform varying coloration (e.g., gray, blue, violet, red, golden yellow, green) or with blotchy multicolor discoloration.

## Type of surface change

Retractors with discolored black shaft in hardened Cr-steel with the handle and blade remaining bright, made from non-hardenable CrNI steel.

Clamp in detail: Lock and ring area.



Section – titan valves: Lefthand valve – brand new. Righthand valve – washer disinfector cleaned.

The change in color is generally even. However it can also occur in patches.

## Origin and causes

In the case of the above stainless steels, the passive layer is formed during automated reprocessing as a result of the neutralizer carried during the final rinsing and/or by other as-yet unidentified factors forming passive layers. Passive layers may be transparent (is usual) to black in the case of stainless steels, depending on the composition, density, and thickness. The tendency to form gray-black chromium oxide passive layers depends, in particular, on the ratio of chromium content/carbon content, alongside the influences of the material composition referred to above. In practice, this means that the higher the carbon content, the faster a gray-black discoloration may become visible.
In the case of titanium materials, damp heat and/or cleaning chemicals used in the various reprocessing stages may lead to oxidation of the surface and hence to discoloration of the surface.
Titanium oxide deposits may be transparent or multicolored/colored depending on the composition, density, and thickness.

## Recommendation for removal

Repair of the damage by the user is not recommended due to the properties of the deposit but may be carried out by the manufacturer or a qualified repair service if necessary. In both cases, appropriate surface treatment is required (mechanical in the case of steel). In the case of stainless steels, removing the deposit with a basic cleaning agent has no effect on account of significantly increased resistance to corrosion.

## Preventive measures

In the case of stainless steels, ensure exact dosing of the neutralizer. Exclude carry over of the neutralizer with a thorough rinsing. In the case of titanium materials, surface changes are hardly or not at all avoidable, since they are caused by the prevailing environmental conditions that are unavoidable during processing (temperature, process chemicals, humidity).

## Assessment of potential risks

No corrosion – aesthetic effect.
If, in the case of titanium materials, any identification/coding function lost as a result of discolorations, e.g. color coding of the blade width in the case of valves (see picture), does not present a safety risk, color changes due to the formation of different properties of oxide layers is completely unproblematic. That is to say, there are no restrictions with regard to biocompatibility, hygiene, function or lifetime. Discoloration may make visual inspection difficult (such as detecting dirt residues).


References

1. Working Group Instrument Reprocessing (AKI), red brochure on reprocessing of instruments to retain value, 11th edition 2017.

# Modern design features – Mechanism used in washer-disinfectors

*Markus Hoppe, Ulrike Weber*

You are no doubt already familiar with the parameters of the Sinner's circle and how it can be influenced via the time (extension), chemistry (higher or lower concentration, particular characteristics of the respective chemical compositions) and temperature (within the respective optimum range for the items undergoing reprocessing and the process chemicals). In the context of washer-disinfectors, the mechanism is generally expressed in terms of the wash pressure or spray arm speed. Particularly when it comes to modern washer-disinfectors, there is a clear focus on these parameters, as can be seen from the spray arm design and internal rinsing option for connected lumened instruments.

These two design features – the spray arm and Power Pulse Cleaning – will now be explored in greater detail below. Both examples involve moving or accelerating water as a cleaning medium, which is made available for the cleaning process so that the effects listed in Table 1 can be achieved.[1]

## Spray arms

Items that undergo processing in a washer-disinfector differ with regard to their design and material properties. Typical items are surgical instruments (both with and without hollow bodies), shoes, instrument trays (with and without lids), washbowls, containers and baby bottles – to name but a few examples. The spray arms feature nozzles and are used to clean the outside of all kinds of load items while also ensuring that gaps and joints get cleaned internally as a result of turbulence and reflections.

The main machine spray arms are generally positioned at the top and bottom of the washer-disinfector (Figures 1 and 2). Depending on the size of the chamber, basket spray arms may also be present on one or more levels (Fig. 3).

In modern machine designs, the spray arms feature differently shaped nozzles, nozzle outlets that are offset in relation to each other on both sides of the arm and special nozzle geometries with different tasks (e.g. directional nozzles for rotary movement). This makes it possible to achieve uniform spray coverage inside the washer-disinfector chamber and allows the cleaning energy distributed via the spray arms to be applied evenly to the load items.

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| Process | Effect |
|---|---|
| Removal of dirt | - Movement generates shear forces<br>- Wetting ability facilitates the penetration of hollow spaces<br>- Negative charging of solids in water (zeta potential) causes the dirt particles and load items to repel one another<br>- Water-soluble constituents get dissolved<br>- Dirt constituents disintegrate or are removed through a chemical reaction with water |
| Transportation of dirt | - The motion of the water keeps solid dirt constituents in suspension<br>- Repulsive forces maintain the suspension<br>- Dissolved substances are transported away |

**Tab 1:** Effects of water in the cleaning process[1].

**Fig. 1:** Example of upper spray arm.

**Fig. 2:** Example of lower spray arm.

**Fig. 3:** Basket spray arm example A 207/1.

## Power Pulse Cleaning

Load items with an inner lumen and minimally invasive surgical (MIS) instruments require extra-special care during cleaning due to their delicate and complex structure. The majority of the contamination deposited on the instrument consists of blood, secretions and residual tissue, which can spread throughout the interior via the shaft tube. The application of overpressure during the medical procedure and the adhesive tension of the soiling facilitate the spread of contamination in the inner lumen of instruments. If the instrument does not undergo processing immediately after the procedure or if the instrument manufacturer's instructions (e.g. rinse thoroughly straight after the medical procedure) are not followed, this contamination may set, thereby blocking the narrow inner lumen of the instrument.

MIS instruments are placed on load carriers with adapters so that they can be connected to the washer-disinfector via an injector nozzle. As a result, they become part of the wash water circulation route.

Remaining virtually constant within a range of approximately 150–600 hPa, the wash pressure transmits the energy to the inner surface of the instruments and soiling is removed mechanically. The wash pressure depends on the type of washer-disinfector, the programme (including the circulation pump speed), the amount of water and the load carrier (including which modules and components are used; see example in Fig. 3).
In a hollow body, the flow velocity decreases towards the edge. This is illustrated by the bisectional view in Fig. 5. The reduction in velocity is dependent on various factors, including the diameter of the lumen and the wash pressure.

With Power Pulse Cleaning (available on the Steelco PWD 8626 and PWD 8628 washer-disinfectors), the wash water that gets fed through the lumened instruments is interspersed with pressure pulses (medical grade compressed air) (Fig. 6). The compressed air inlet pressure is adjustable so that the right balance can be struck for the specific load in terms of ensuring the desired cleaning performance while also respecting the material compatibility of sensitive lumen instruments.

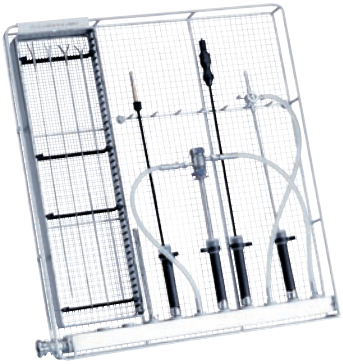

**Fig. 4:** Example of a MIS module.

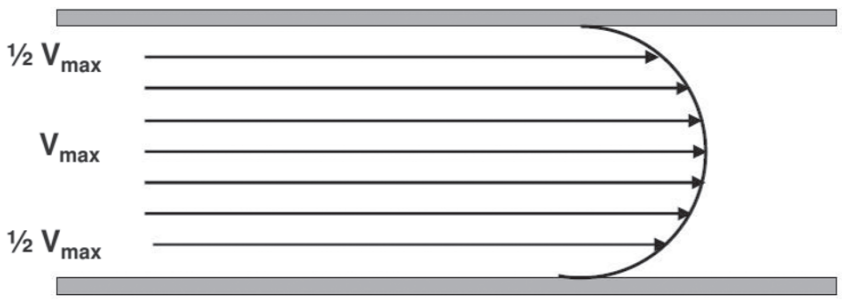


**Fig. 5:** Graphical representation of the velocity inside a lumened instrument and at the walls[2].

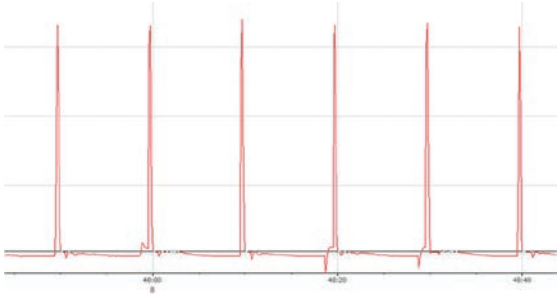

**Fig. 6:** Chronology of pressure pulses.

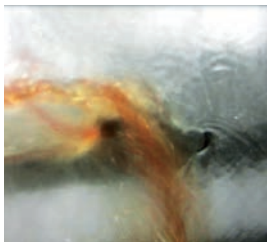

**Fig. 7:** First pulse during the cold pre-wash stage of the washer-disinfector process: effect of pulse illustrated by a lumened instrument contaminated with sheep blood, removal of blood soiling is clearly visible.

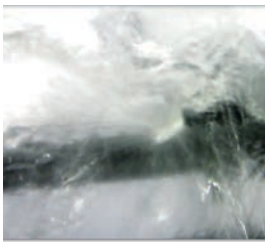

**Fig. 8:** Second pulse during the cold pre-wash stage of the washer-disinfector process: effect of pulse illustrated by a lumened instrument contaminated with sheep blood, blood soiling is already no longer visible.

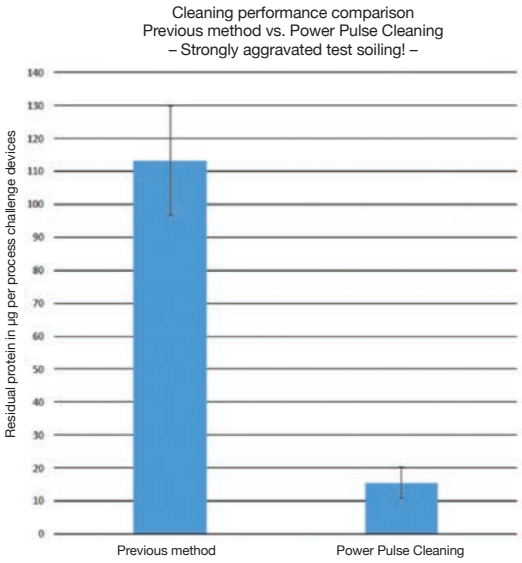


**Fig. 9:** Cleaning results from laboratory tests.

The blasts of compressed air generate a pressure pulse in the wash water within the inner lumen, thereby briefly increasing the pressure and flow rate of the wash water as it passes through the hollow spaces being cleaned. In this way, a portion of the wash water is accelerated without completely interrupting the flow of water. As a result, the flow velocity also increases at the instrument walls (see Fig. 5).

No new pressure pulse is triggered until the higher fluid pressure generated by a previous pressure pulse has decreased again.

This principle allows the wash water to be accelerated significantly. The velocity at the walls of the instruments, the resulting shear force and the associated mechanical action generated for the cleaning performance likewise increase.

Power Pulse Cleaning works by relying on a special compressed air/water pulse profile. The hallmark of the system is that a continuous flow of water (internal rinsing) is accelerated by regularly feeding in blasts of compressed air; see Figures 7 and 8.

In order for the pressure pulses to be generated in the wash water, the lumened instruments have to be firmly connected and securely seated in the relevant module in the washer-disinfector load carrier.

The cleaning performance has been verified on multiple occasions with protein analysis methods using special MIS instruments that underwent reprocessing without pre-cleaning (Fig. 9).

Using pulses to accelerate the wash water has resulted in an innovative method – one that introduces a new way of increasing the mechanical action to achieve the desired cleaning performance.

The method provides operators and manufacturers of medical devices with options for optimising reprocessing practice in various respects (e.g. shorter cleaning processes, reprocessing of instruments with a critical design, elimination of manual pre-cleaning).

Literature references

1 Koller, W. (2008): Grundlagen der Reinigung und Reinigungsverfahren für medizinisch relevante Bereiche. p. 321–334. In: Wallhäußers. Praxis der Sterilisation, Desinfektion, Antiseptik und Konservierung. Qualitätssicherung der Hygiene in Industrie, Pharmazie und Medizin. Edited by Axel Kramer and Ojan Assadian. Thieme Verlag.

2 Guarda, L (2019): Innovation in washing technology – Power Pulse Cleaning; presentation at the WFHSS congress.

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# "Three questions for ..."

## *Stella Nehr-Werner about surface changes on instruments/corrosion*

*1. What are the risks associated with instrument corrosion?*

Instruments that have succumbed to corrosion ultimately pose a risk to patients because once a surface has become damaged in this way, reprocessing can no longer be carried out safely and reliably. An instrument with a corroded surface can no longer be restored to the condition expected of a clean, disinfected or sterile medical device. Furthermore, the instrument may crack or rupture, or become impaired in some other way, making it unsafe to use.

**Fig. 1:** Dental handpiece coupling with rust.

**Fig. 2:** Original dental handpiece coupling.

*2. What kinds of things accelerate surface changes and should, therefore, be avoided in the case of instruments?*

All sorts of surface changes can occur – from fretting corrosion and discolouration caused by using the wrong chemicals right through to pitting corrosion, to name but a few. You should never sit back and do nothing if instrument surfaces start to exhibit noticeable changes. Instead, the affected instruments should be removed from the instrument cycle immediately and the precise cause investigated to prevent any further spread and to stop all the instruments from becoming affected. In a worst-case scenario, surface changes can also impinge upon the actual reprocessing machines. In such an event, the problem can often only be remedied by carrying out very costly and time-consuming repair work or replacing the entire machine.

*3. What are the key things to watch out for when removing corrosion?*

The most frequent causes of corrosion are chlorides (which cause pitting corrosion) and abrasion (which causes fretting corrosion damage). In both cases, the surface undergoes changes, thereby becoming a target for phenomena such as rust formation. Improper repair work could compromise the functional capabilities or safety of the instrument. Therefore, you should leave the removal of corrosion to specialists. However, in my view, the focus should be much more on prevention. Some causes of surface changes can be prevented altogether by ensuring instruments are used correctly and pre-treated properly as per the manufacturer's instructions – either during the operation itself or in the treatment environment – and making sure they are not left for too long before being cleaned. In addition, the manufacturer's instructions must always be observed during reprocessing itself. The manufacturer is required to validate all the reprocessing processes described in its reprocessing instructions in accordance with DIN EN ISO 17664-1. This means testing them from the perspective of material compatibility and effectiveness. As a result, the operator is provided with comprehensive information about the processes that should be used – including details of which chemicals are to be used (e.g. cleaning agents or disinfectants) – the level of water quality required during the reprocessing steps and everything they need to know about caring for the instrument correctly. Following these instructions does not just ensure that the instruments are reprocessed correctly and effectively but, ultimately, that they also retain their value.

**PD Dr. Friedrich v. Rheinbaben**

# New advisory body member

PD Dr Friedrich von Rheinbaben studied microbiology and virology at the Universities of Bonn and Gießen. In 1987, he made the move to industry and established the Virology department at Henkel KGaA before going on to work for ECOLAB. By the end of his tenure there, he had amassed more than 25 years of experience in R&D at the two major companies. Since 2012, he has been working for the HygCen Group.

PD Dr. von Rheinbaben qualified as a professor at Witten/Herdecke University in the field of hygiene and microbiology/virology. He holds several lectureships at Witten/Herdecke University in Germany (Faculty of Health) and Danube University Krems in Austria (Faculty of Health and Medicine).

In addition to authoring and co-authoring several textbooks and numerous articles on hygiene and infection prevention, PD Dr. von Rheinbaben advises industrial companies on matters of technical and industrial hygiene.

# 16th Annual Congress of the DGKH in Berlin

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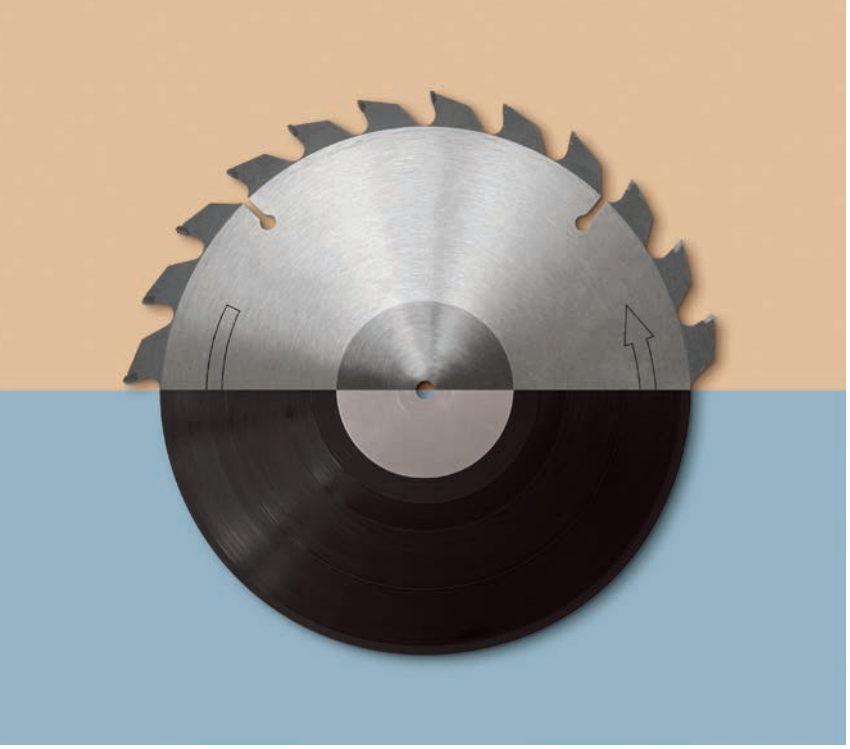

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