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Original Article

Presentation of an in vitro validated practical wipe disinfection procedure for quality assurance of manual reprocessing of transvaginal ultrasound probes.

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Summary

Introduction: Transvaginal ultrasound probes (TVUP) must be reprocessed after each use to reduce the risk of infection. According to the recommendations of the German Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices, proper reprocessing is assumed if TVUP are reprocessed mechanically as semi-critical medical devices (category A). In addition, since 2020, the validation of manual wipe disinfection has been questioned by the Working Group on Medical Devices (AGMP) of the German Central Authority of the Länder for Health Protection with regard to Medicinal Products and Medical Devices (ZLG). Gynaecological operators are now faced with the challenge of having to change their reprocessing procedures while facing enormous time and cost pressure. We therefore present a laboratory-validated method for manual wipe disinfection based on the adoption of a Phase 2/Stage 2 test procedure.

Materials and methods: Three representative TVUP and the ready-to-use surface and instrument disinfectant Mikrobac® Virucidal Tissues were used. The probes were each highly contaminated with *Enterococcus hirae*, *Staphylococcus aureus*, *Candida albicans*, and polyomavirus SV40 at two critical and difficult-to-access areas. The entire probe surface was manually disinfected with three pre-soaked wipes in a standardised manner. Residual organisms were then recovered from the previously contaminated surfaces and the reduction was determined in comparison to untreated controls.

Results: At both contaminated areas of all three probes, wipe disinfection achieved mean reduction factors (RF) of ≥ 5 lg for *E. hirae* and *S. aureus*, and ≥ 4 lg for *C. albicans* and SV40, corresponding to an inactivation of ≥ 99.999% and ≥ 99.99%, respectively.

Keywords
- semi-critical items
- TVUP
- contamination
- manual reprocessing
- validated procedure
- quality assurance

Discussion: Using the example of two critical surface areas on three probe types, manual wipe disinfection of TVUP proved to be standardizable with sufficient bactericidal efficacy against Gram-positive pathogens, yeasticidal efficacy and virucidal efficacy against SV40. By defining wiping time and procedure as well as number of wipes a valid manual wipe disinfection method is given which can facilitate the validation process for operators. Hygienically safe reprocessing and documentation by trained personnel are feasible.

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Conflict of interest:
This study was conducted by Dr. Brill und Partner GmbH on behalf of BODE Chemie GmbH, a company of the HARTMANN GROUP. All authors declare that there is no conflict of interest as defined by the guidelines of the International Committee of Medical Journal editors (ICMJE).

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Introduction

Examinations using transvaginal ultrasound probes (TVUP) are among the standard services in gynaecological and obstetrical practice. In order to prevent the risk of infection through contaminated TVUP for patients, these must be properly reprocessed after each use. Various studies and reviews show that there is a real risk of infection from TVUP and that the prevalence of contamination is up to 14% [1–3], which underlines the importance of adequate reprocessing [2, 4–6]. The most clinically relevant pathogens that can be transmitted if probes are not adequately reprocessed include human papilloma viruses (HPV), fungi, chlamydia, Streptococci, Staphylococci, and faecal bacteria [4, 5, 7–9]. Consequently, the reprocessing should be carried out using disinfectants with proven efficacy against bacteria, yeast, fungi, and viruses (bactericidal, yeasticidal, fungicidal, and virucidal). However, the risk of infection can arise not only from the probes themselves, but also from contaminated ultrasound gel or coatings [1, 10, 11]. Equipment parts that are often neglected during reprocessing, such as the handle, also harbour a risk of cross-contamination if they are not disinfected as well [12, 13].

In Germany, proper reprocessing of a medical device is legally presumed according to the German Medical Devices Operator Ordinance (MPBetreibV) if the joint recommendation of the Commission for Hospital Hygiene and Infection Prevention (KRINKO) at the Robert Koch Institute and the Federal Institute for Drugs and Medical Devices (BfArM) on the requirements for hygiene in the reprocessing of medical devices is fullfilled [14]. Since TVUP can theoretically come into contact with mucous membranes despite the usual use of protective covers, e.g. in the event of tearing or incorrect handling, they are generally classified as semi-critical medical devices of category A. The KRINKO and BfArM recommendations of 2012 do not require any special form of reprocessing for this category, which includes both manual and mechanical reprocessing if it can be validated [15]. In the recommendation of the German Society for Ultrasound in Medicine (DEGUM), which considers mechanical procedures and immersion disinfection to be particularly effective, the simple wipe disinfection of rigid endoscopic probes is only regarded as insufficient if no disinfectant is specifically applied to cavities and joints [11]. In contrast, the Quality Committee of the German Society for Sterile Supply (DGSV e.V.) is in favour of classifying TVUP as semi-critical medical devices of category B [16]. This would require mechanical reprocessing. At the end of 2020, the Robert Koch Institute (RKI) confirmed its assessment that the validation of manual wipe disinfection is currently not possible [17]. The Supreme State Authorities responsible for medical devices and the Federal Institute for Drugs and Medical Devices (BfArM) endorsed this technical assessment in a statement published in October 2021 [18]. Strictly speaking, manual wipe disinfection, which is preferred by many facilities for reasons of practicality, as well as time and cost efficiency, does not currently meet the legal requirements, even if it is more of a „soft law“ without the adaptation of the KRINKO recommendation [19]. In order to be fully legally compliant, operators of TVUP are now under pressure to adapt their reprocessing methods to the recommended procedures.

A guideline-compliant validation of their manual procedure implemented on site [20], which is not entirely excluded on the basis of the recommendations, is hardly feasible for most operators. However, simple and effective manual disinfection procedures with short exposure times are still crucial for the rapid reprocessing of probes – especially for facilities with high patient volumes – and are also suitable as a decentralised solution for mobile or transportable medical devices.

The only (partially) automated methods currently available in Germany are devices based on the disinfection of the probe (without the handle and the cable) by UV-C light or H_2O_2 [4, 21, 22]. However, these are associated with high acquisition costs and also require manual pre-disinfection [4]. Alternatively, according to KRINKO, manual immersion disinfection can be carried out (also after manual pre-cleaning), but this method is time-consuming, involves inhalation hazards for the staff and greater wear of the transducer membrane, and poses the risk of liquid penetrating into sensitive parts of the device [4, 23, 24]. Practice has also shown that many of the medical products available on the market are not suitable for mechanical reprocessing in a washer-disinfector [23]. In order to facilitate the situation for gynaecological practices and hospitals in the future, work is currently being done on the improvement and development of fully automated mechanical processes, but these are not yet available. The German Society of Hospital Hygiene (DGKH) therefore advises operators to consider the options for reprocessing before acquiring critical medical devices [20].

We asked ourselves whether wipe disinfection of TVUP can be validated in the laboratory and whether the formal problem of the inadequate standardisability of manual procedures could be solved, contributing to gynaecological facilities being able to reprocess their TVUP easily and effectively as well as in a legally compliant manner. The aim of our study was therefore to go beyond normal wipe disinfection, as it is usually practiced on surfaces using a cloth, and to establish a practical, valid procedure for manual reprocessing of semi-critical TVUP based on the adaptation of a Phase 2/Stage 2 test method [25].

Material and methods

Transvaginal ultrasound probes

Three different representative TVUP were used to validate manual wipe disinfection: V5-9, EC4-9 and E3-12A (all Samsung Medison Co. Ltd., Seoul, South Korea).

Wipe disinfection

The ready-to-use surface and instrument reprocessing product Mikrobac® Virucidal Tissues (MVT; BODE Chemie GmbH, Hamburg, Germany) was tested undiluted at room temperature.

The manual wipe disinfection of the TVUP was performed using three MVT wipes for each probe. Additionally, a swab was used in a standardised manner (**Table 1)** after contamination of the probes with pathogen-containing inoculum or control fluids. The time required and consequently the thoroughness of the standardised wipe disinfection go well beyond a „brief wiping over“, but are more suited to the conditions than mechanical reprocessing or immersion disinfection. All tests were performed with surrogate microorganisms for clinically relevant pathogens according to EN 16615 (except *P. aeruginosa*) [26]. It is important to emphasise that the test

organisms were applied into the cavities of the TVUP with very high titers to match the conditions of a high-level contamination that is possible in practice. Residual pathogens were recovered from the probes after 2 minutes of exposure following the completion of the wipe disinfection procedure.

Virus testing

The test was carried out with polyomavirus SV40 strain 777 (provided by Professor A. Sauerbrei, University of Jena, Germany), with which the inoculum was produced after propagation in CV-1 cells with the addition of 0.03% bovine serum albumin (BSA) and 0.03% mucin. SV40 is suitable as a surrogate virus for HPV due to its properties and should therefore be considered in the scope of testing [23].

To contaminate the probes, 25 µL of inoculum were pipetted directly into the transducer on the top of the scan head and another 25 µL were distributed with a pipette tip over approximately 1 cm^2 of the scan head surface (**Figure 1**) and dried at room temperature for approximately 60 to 120 min.

The manual wipe disinfection tests were carried out after drying without storage time. To detect virus residues and to inactivate possible disinfectant residues, the two inoculated areas were wiped with a FLOQSwab soaked in culture medium. The swab was transferred to a 5 mL serum-free medium and the wiping was repeated twice with new dry FLOQSwabs. After resuspension, the eluate was diluted 1:10 in an ice-cold maintenance medium and inoculated onto the cell culture. The disinfectant was sufficiently neutralised in the process, so that no further neutralization step was required.

Virus controls were titrated before (VC before) and after drying (VC t0). For VC before, 50 µL of virus inoculum was added to 4,950 µL of serum-free medium. For VC t0 (reference for calculating the reduction factor), the transducer and scan head were each contaminated with 25 µL and the residual virus was recovered without prior manual disinfection.

Table 1: Standardised manual wipe disinfection with Mikrobac Virucidal Tissues

Step	Consumption MVT	Purpose	Procedure	Time required [seconds]
1	Wipe 1	Wipe disinfection of probe shaft and scan head	Distribute disinfectant liquid by wiping. Start at the handle, move up the tube to the scan top. Repeat the wiping 10 process several times.	10
			Additional wiping of the scan head. Repeat the wiping process several times.	10
2	Wipe 2	Wipe disinfection of probe shaft and scan head	Distribute disinfectant liquid by wiping. Start at the handle, move up the tube to the scan top. Repeat the wiping 10 process several times.	10
			Additional wiping of the scan head. Repeat the wiping process several times.	10
3	Wipe 3	Disinfection of the transducer	Press the wipe directly onto the transducer so that it fills it completely. Collect the overflow and soak the sampling swab (Heinz Herenz) in it. Disinfect the cavity with the soaked swab by rubbing for 10 seconds.	10
4		Reaction time	After the wiping process is complete.	120

MVT: Mikrobac® Virucidal Tissues

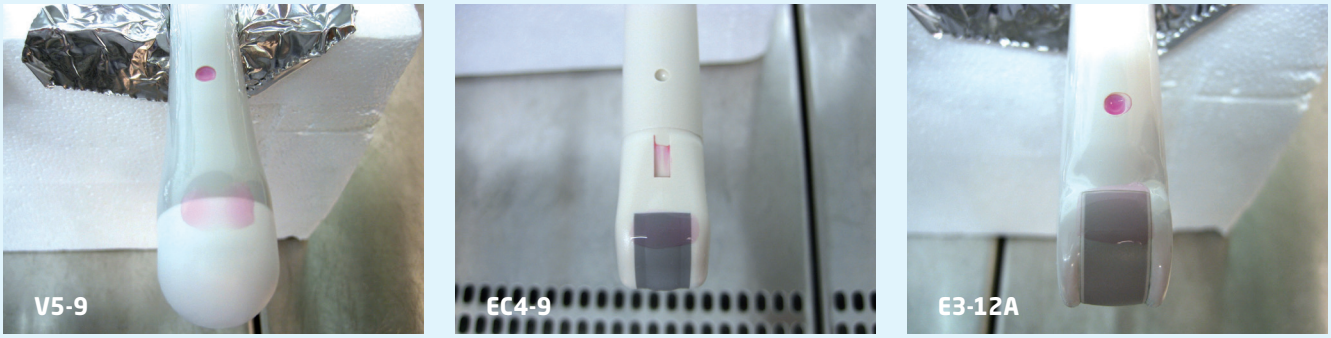

Fig. 1: Areas of transvaginal ultrasound probes contaminated with SV40 in the tests. The viruses were grown in the cell culture system using phenol red as a pH indicator, resulting in a red coloration of the harvested virus pool.

Verification of disinfectant efficacy

The probe transducer and scan head were contaminated with medium analogous to virus inoculum, but virus-free, and were disinfected manually with MVT after drying. Virus residues were collected as described previously. After adding 50 µL of test virus suspension to the eluate, it was incubated on ice for 60 minutes, before virus titration.

Determination of cytotoxicity

These tests are required to determine the lower detection threshold for non-inactivated SV40. For this purpose, the probe and scan head were inoculated with 25 µL serum-free medium. After drying and wipe disinfection, the eluate obtained as described was diluted 1:10.

Further controls

A 0.7% formaldehyde solution (v/v) according to EN 14476 [27] was used as a reference for the test validation. Furthermore, a cell control (medium only) was performed.

Testing with bacteria and yeasts

The test suspension was prepared with *Staphylococcus aureus* (ATCC 6538), *Enterococcus hirae* (ATCC 10541) and *Candida albicans* (ATCC 10231) and reached 1.0-3.0 × 10^9 colony-forming units (cfu)/mL (bacteria) and 1.0-3.0 × 10^8 cfu/mL (yeast). 0.03% BSA and 0.03% mucin were added to the inoculum. The bacterial analysis was adapted based on existing procedures [26, 28]. Prior to the start of the test, the probes were pre-disinfected with an H_2O_2-based solution and rinsed with sterile distilled water.

For contamination, a FLOQSwab soaked in inoculum for 5 seconds was pressed onto the probe transducer and scan head (approximately 2 cm of surface diameter each), resulting in an initial cell count of approximately 10^6–10^7 cfu/mL (bacteria) and 10^5–10^6 cfu/mL (yeast) per area. Contaminants were dried at room temperature for approximately 15 min and tests for manual wipe disinfection were then carried out with no storage time.

After the manual wipe disinfection, the contaminated areas were treated with a FLOQSwab soaked in neutralizing rinse solution (according to [26]) in order to recover the test organisms and inactivate disinfectant residues. The reference was a contaminated but untreated positive control.

Three test runs were carried out, each with three parallel tests. Since the reduction of test organisms was based on untreated controls, correction factors for cell number were not included in the assessment of the efficacy of disinfection procedures.

Calculation of infectivity, cytotoxicity and disinfection efficacy

The infectivity of the viruses was determined using the endpoint dilution method according to the guideline of the German Association for the Control of Viral Diseases (DVV) eV [29]. The cytotoxic effect was assessed after 18–21 days using an inverted microscope. The infectious dose (tissue culture infection dose) was calculated as $TCID_{50}$/ mL according to the Spearman-Karber method.

The disinfecting efficacy of MVT was evaluated by calculating the virus titer reduction of evaporated virus inoculum after treatment with the manual disinfection procedure compared to the virus control (VC t0) without treatment, and the difference was expressed as the reduction factor (RF). A virus-inactivating effect exists if the titer within the recommended exposure time is reduced by ≥ 4 lg steps (= inactivation of ≥ 99.99%) [29].

For bacteria and yeasts, CFU were calculated according to EN 16615 [26]. The efficacy criteria defined for this disinfection process were the achievement of a mean reduction factor of ≥5 lg for bacteria and ≥4 lg for yeasts and at least 3 lg for a single reduction for each test run consisting of 3 parallel tests.

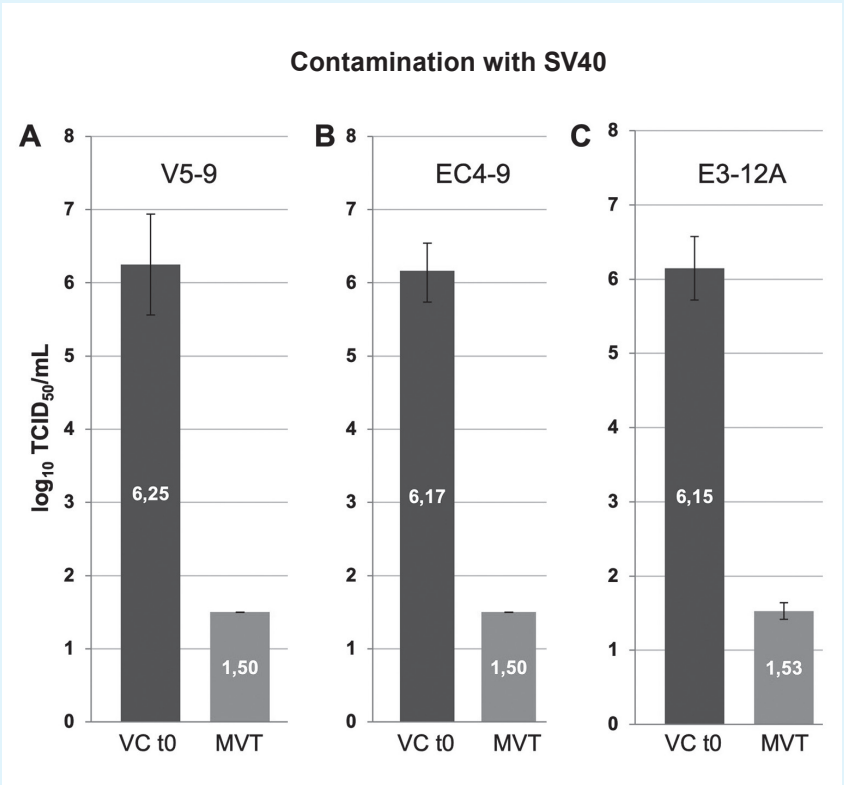

Fig. 2: Wipe disinfection with MVT of ultrasound probes V5-9 (A), EC4-9 (B) and E3-12A (C) contaminated with SV40. For each probe, 9 parallel tests were performed. Mean values and 2-fold standard deviations of virus control after evaporation (VC t0) and recovered viruses after MVT wipe disinfection (MVT) are shown. MVT: Mikrobac® Virucidal Tissues; TCID50: tissue culture infection dose 50; VC: virus control.

Results

Virucidal efficacy of the process

The preliminary tests to evaluate the virus recovery of SV40 did not show a significant reduction in virus titer for any of the three probes after drying, hence recovery was considered to be successful. After drying, the titer of VC t0 confirmed that a reduction of 4 lg levels could be demonstrated for the

disinfectant testing according to guideline [29].

A possible cytotoxic effect of MVT could also be ruled out by cytotoxicity analysis according to the guidelines [29]. In addition, the reference tests with formaldehyde showed that the virus inoculum produced was suitable for virucidal testing.

For the virucidal test, both contamination areas (cavity, scan head) of the probes were evaluated together and the results were averaged. As shown in **Figure 2**, manual wipe disinfection with MVT was able to sufficiently inactivate SV40 on all three probes. In three independent test runs with three parallels per probe, mean RFs of ≥ 4.75 lg (V5-9), 4.67 lg (EC4-9) and 4.62 lg (E3-12A) were obtained. This corresponds to an inactivation of ≥ 99.99% in each case. Thus, for the tested ultrasonic probes V5-9, EC4-9 and E3-12A, enough RF was detected in the tests and the manual disinfection procedure was evaluated as sufficiently virucidal against SV40.

Bactericidal and yeasticidal efficacy of the procedure

To determine bactericidal and yeasticidal efficacy, the scan head and cavity were evaluated separately for all three probes and thus the efficacy of the disinfection process was considered separately depending on the surface condition of the probes.

For both the scan head and the cavity, the recovered cell count from the untreated positive controls was > 6 lg levels (bacteria) and > 5 lg levels (yeasts), respectively, which was sufficient to test the efficacy of the wipe disinfection (RF calculation based on the CFU count of the positive controls). The bactericidal and yeasticidal efficacy was investigated with all test organisms in three test runs with three parallel tests each.

Ultrasonic probe V5-9

The results of manual wipe disinfection with MVT compared to the positive controls are shown in **Figure 3**. Wipe disinfection with MVT produced com-

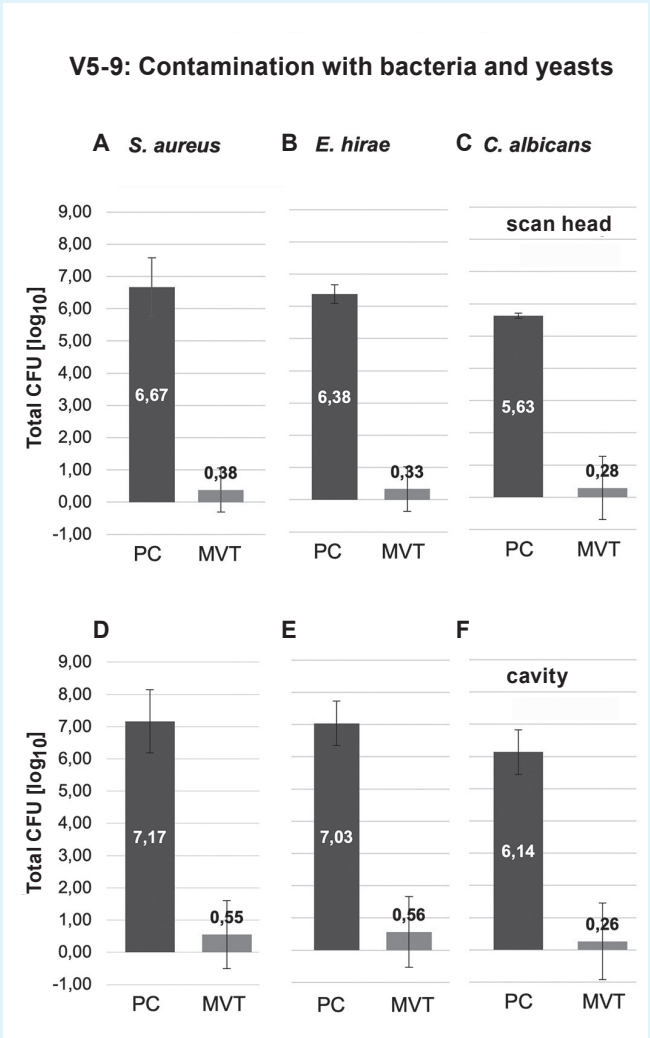

Fig. 3: Wipe disinfection with MVT of with *S. aureus* (A, D), *E. hirae* (B, E) and *C. albicans* (C, F) contaminated ultrasound probe V5-9 in 9 parallel tests. Mean values and 2-fold standard deviations of the contamination of the scan head (AC) and the transducer (D-E) are shown. CFU: colony-forming units; MVT: Mikrobac® Virucidal Tissues; PC: positive control.

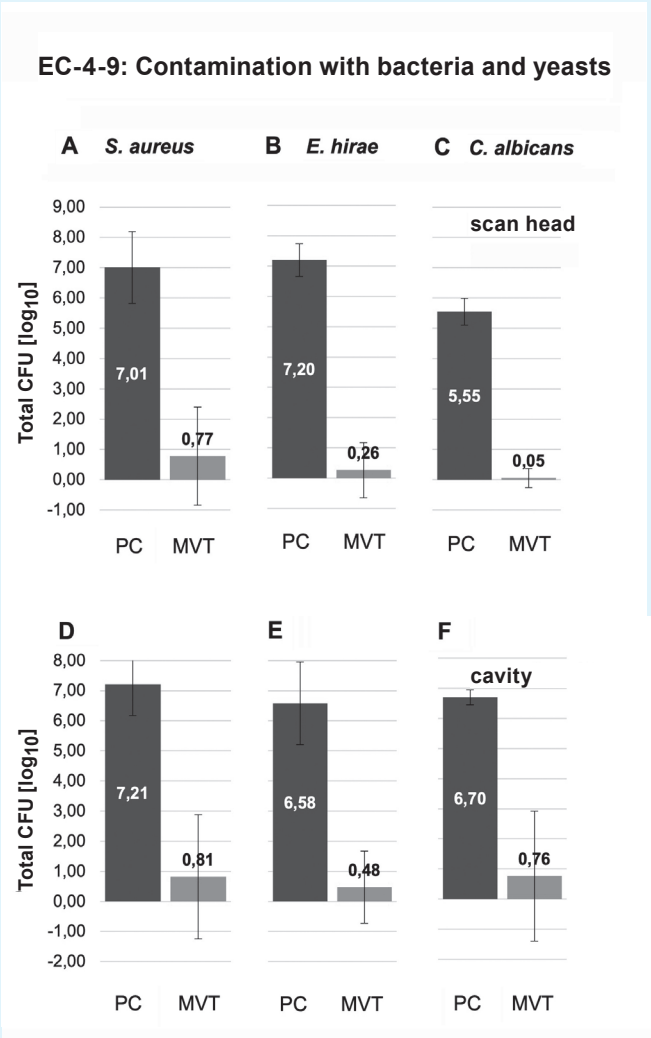

Fig. 4: Wipe disinfection with MVT of with *S. aureus* (A, D), *E. hirae* (B, E) and *C. albicans* (C, F) contaminated ultrasound probe EC4-9 in 9 parallel tests. Mean values and 2-fold standard deviations of the contamination of the scan head (AC) and the transducer (D-E) are shown. CFU: colony-forming units; MVT: Mikrobac® Virucidal Tissues; PC: positive control.

parable results for both the scan head and the cavity. The mean reduction at the scan head was 6.29 lg for *S. aureus*, 6.05 lg for *E. hirae* and 5.35 lg for *C. albicans*. A comparably high reduction was achieved in the cavity, 6.62 lg for *S. aureus*, *E. hirae* 6.47 lg and *C. albicans* 5.88 lg.

Ultrasonic probe EC4-9

Figure 4 shows the results of manual wipe disinfection with MVT compared to the positive control for the EC4-9 ultrasound probe. In this case, bactericidal testing for *S. aureus* and *E. hirae* for both contamination areas had a mean RF of 6.24 lg and 6.94 lg at the scan head and of 6.4 lg and 6.1 lg in the cavity. For *C. albicans*, a mean RF of 5.5 and 5.94 lg was obtained in the scan head and transducer, respectively.

Ultrasonic probe E3-12A

Similar results were also obtained for the E3-12A ultrasound probe (**Figure 5**). Thus, the mean RF at both contamination areas was 6.04 and 7.41 lg, respectively, for *S. aureus* and 6.28 and 7.17 lg, respectively, for *E. hirae*. A single positive control (scan head) achieved a cell count of only 5.70 lg levels for *S. aureus* in one test run instead of the targeted 6 lg levels. *C. albicans* was reduced to 6.36 lg at the scan head and 6.58 lg in the cavity.

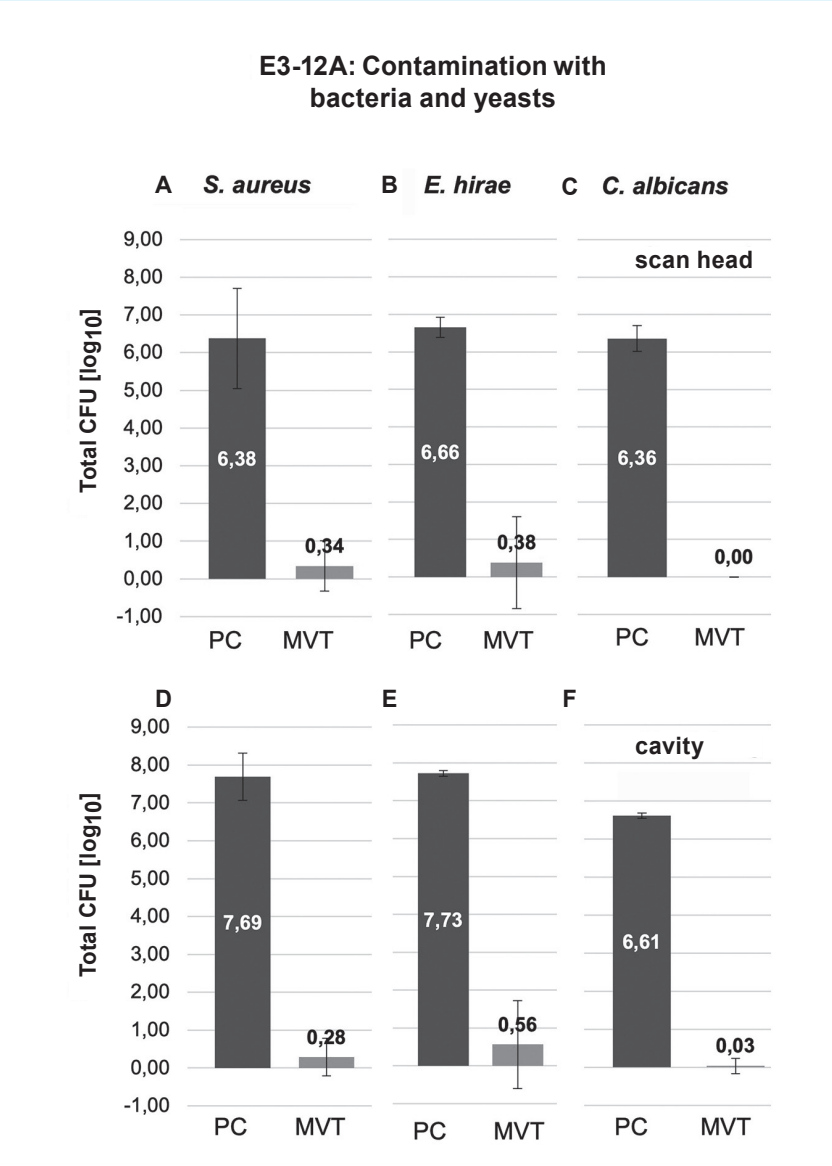

Fig. 5: Wipe disinfection with MVT of ultrasound probe E3-12A contaminated with *S. aureus* (A, D), *E. hirae* (B, E) and *C. albicans* (C, F) in 9 parallel tests. Mean values and 2-fold standard deviations of the contamination of the scan head (AC) and the transducer (D-E) are shown. CFU: colony-forming units; MVT: Mikrobac® Virucidal Tissues; PC: positive control.

Discussion

In our study, we found that the success of manual reprocessing of TVUP depends not only on the disinfectant used and its spectrum of efficacy, but also on the type of reprocessing. Even if the efficacy of the product is proven according to valid standards and test methods, manual wipe disinfection on a complex surface such as the TVUP represents a further challenge in practice. To ensure reprocessing, a sufficient amount of disinfectant liquid must be applied as well as mechanical force by wiping. This was achieved in this study by using three wipes with a wiping time of ten seconds per wipe. Due to the repetitive, rotating movement during the wiping process, it can be assumed that the probe was sufficiently wetted with disinfectant and that sufficient force was applied. Cavities were treated separately with a swab soaked in disinfectant to reliably disinfect areas that were difficult to access and therefore not sufficiently wetted during wiping.

In our laboratory test, we were able to show that wipe disinfection with MVT can be standardised even on complex surfaces of different TVUP and is effective against SV40 viruses as well as Gram-positive bacteria and yeasts.

Overall, sufficient bactericidal, yeasticidal and virucidal efficacy was demonstrated on an average of two contamination areas each from three different probes, which met the requirements for the reduction of relevant test germs [25–27, 29]. The process steps were adapted for the reprocessing of probes as complex surfaces and went beyond the usual wipe disinfection with only one wipe. Relevant parameters such as wiping time, number of wipes required and other steps necessary for the disinfection result were determined (see **Table 1**). This is based on the Guideline for validation of manual cleaning and manual disinfection of medical devices [20].

The primary goal of the reprocessing of TVUP is the prevention of clinically relevant infections as defined by the Infection Protection Act. In order to be able to carry out a risk assessment,

the first question is to what extent the classification of TVUP as semicritical is actually proportionate.

Since the probe itself is to be operated only with a protective cover and thus does not come into direct contact with mucous membranes, it could be argued that, strictly speaking, it is not a semi-critical medical device. However, this would only be the case if tearing of the probe covers can be virtually ruled out and the handling of the protective covers does not involve any risk of cross-contamination (e.g. when putting it on). However, to date there is no normative basis for the quality and testing of these probe covers.

Various studies have shown that the use of gloves or probe covers is associated with a risk of perforation or contamination (which varies depending on the study) [30–32]. Even though the tear strength of commercial probe covers has obviously been improved [33], a risk of contamination remains [24, 34], especially when using protective covers that are not individually wrapped. Furthermore, a survey published in 2016 by the European Society of Radiology (ESR) revealed that 11% of European users do not clean endocavity probes after each use and an equally high proportion do not always use protective covers [35]. These results indicate an urgent need to increase users' awareness of the risk of infection from TVUP. There are also important hygiene-related differences in the selection of protective covers. Many operators use protective covers that are provided in a cardboard box without individual packaging. When a protective cover is picked, several covers in the box can become contaminated. The risk of cross-contamination could be minimised by having the covers in individual packages.

A survey conducted in 2017 regarding Munich hospitals showed that there were considerable deficiencies in compliance with the KRINKO-BfArM recommendation and that the reprocessing of the TVUP was carried out exclusively manually and without standardization of wipe disinfection by non-expert personnel. No traceable validation took place [36]. Although it is unclear to what extent the 14 hospitals concerned are representative for Germany, the results indicate that a lack of expertise could be one of the main problems in the proper reprocessing of TVUP. Sartoretti et al. made it clear that adequate hygiene training can significantly improve the success of manual wipe disinfection. Although the sample size of 36 probes was relatively small, the median number of CFU was significantly reduced from 53 before hygiene training to 0 afterwards [37]. In contrast, Schmitz et al. compared automated UV-C treatment with Antigermix AS1 and manual wipe disinfection with ready-to-use disinfectant wipes and described both methods as similarly effective. While nosocomial pathogens were completely removed with both methods, environmental germs or organisms of the normal flora were still found after disinfection in 34.2% (UV- C) and 40.5% (manual; $p > 0.05$) of cases [22]. This indicates that expertise is also required for automatic reprocessing to avoid recontamination after the disinfection process. When considering the entire automated reprocessing operation, this also includes manual steps that can only be partially validated and depend on the thoroughness of the person performing the procedure, for example, pre-disinfection (removal of ultrasound gel, organic contamination and disposable protective cover). Cleaning aims to remove organic residues from the patient, including blood, mucus or secretions, to ensure that the subsequent disinfection kills all remaining pathogens/microorganisms in a controlled manner. If organic contaminants are not adequately removed, biofilms may form, allowing pathogens to survive the disinfection [38, 39]. The process described here starts after pre-cleaning, where residual ultrasound gel and other contaminants are usually removed in advance using a dry cloth. Even though cleaning was not explicitly considered in this study, generally speaking a cleaning effect also occurs during the mechanical wiping process. Thus, each wiping cycle served both cleaning and disinfection purposes with the aim of removing microbial contamination. To evaluate the cleaning effect in practice, this method would have to be adapted using a suitable simulated contamination load.

Büscher et al. further compared the automated reprocessing of TVUP using H_2O_2 (Trophon EPR) with manual wipe disinfection. In this study, clinically relevant germs were removed significantly better with the automated (91.4% success) than with the manual method (78.8% success) [12]. However, the article does not indicate to what degree the performance quality of the manual method was recorded. The fact that the authors strongly emphasise the role of transducers as a source of cross-contamination indicates an insufficient standardization of the manual method, especially regarding the neglect of the transducers. Thus, it could be argued that although the success of wipe disinfection - as emphasised previously - does in fact depend very much on the person carrying out the process, this also applies to the manual steps of automated procedures. So far, no validatable procedure has been described for the manually performed reprocessing steps. Our results, however, demonstrate that manual reprocessing can also be standardised and validated and should therefore not be regarded as insufficient per se. In addition, advantages such as low costs and ease of transportation enable simple and decentralised integration of manual wipe disinfection into everyday practice. In consequence, this can presumably also improve compliance. Even if the responsibility for the correct execution and documentation of the manual reprocessing lies with the operator, the described method can provide assistance by means of the protocol (**Table 1**) to ensure a consistent quality of the wiping disinfection process. In addition, regular monitoring by swabbing allows the microbiological status of the reprocessed surfaces to be determined so that corrective measures can be taken if necessary.

In principle, the manufacturers of ultrasound probes are obliged to describe at least one suitable reprocessing method. In the past, however, this was often not sufficiently complied with, and the naming of disinfectants was oriented more towards material compatibility than efficacy against pathogens [40]. There has been a paradigm shift in this regard in recent years [41], so that the situation has now improved, and the spectrum of activity is taken into account. Nevertheless, the operators are not released from the obligation to check the meaningfulness of the information and to carry out their own risk assessment and validation, as well as to use a suitable reprocessing method. The presentation of our prac-

tical application for the reprocessing of TVUP can help to facilitate this process. Since this study focuses on demonstrating reduction in critical and hard-to-reach areas, the method shown involves the manual wipe disinfection of complex surfaces and hard-to-reach areas such as joints and cavities, as well as different material transitions of representative TVUP.

This enables the user to implement a methodical strategy within the framework of the currently valid recommendations.

The method presented can be used to validate the process on site after a risk assessment by the operator and enables hygienically safe reprocessing and documentation of the same by trained personnel.

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