Recommendation of the Committee for Hygiene, Construction and Technology

Requirements for the environmental conditions and their control in Reprocessing Units for Medical Devices (RUMEDs)

Part 2

DGSV e.V. FA HBT
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Preface

Already in 2018, the Committee for Hygiene, Construction and Technology (FA HBT) of the German Society of Sterile Supply (DGSV) discussed this topic in detail and initiated tests, based on which a recommendation was issued. That recommendation has now been expanded to include additional tests and revised.

Introduction

The aim of this publication is to present information on the state of the art and experience with respect to hospital hygiene, microbiology and audits. This information lays the groundwork for the formulation of requirements for the environmental conditions and their control and for bringing the current publication into line with the state of the art. The requirements for the air quality (microbiological, physical), its control and occupational safety and health aspects will not be addressed.

The information is intended for the economic operators of Reprocessing Units for Medical Devices (RUMEDs), RUMED management, hospital infection control officers and staff and the supervisory authorities.

Are there specifications in place for the environmental conditions in a RUMED?

Pursuant to the *KRINKO/BfArM Recommendation* [1], "Contamination of the environment must be avoided as far as possible when reprocessing medical devices."

Attention is also drawn to the *KRINKO Recommendation* "Hygiene requirements for cleaning and disinfection of surfaces": [6]: "For assessment of the inanimate environment (all surfaces surrounding the patients and personnel), the following must be viewed as potential infection risks: the ubiquitous presence of microorganisms and persistence and infectiousness of pathogens (in the inanimate environment) and their transmission pathways as well as the infectious dose …". Reliance on identification of visible soils alone is not an appropriate criterion for assessment of the contamination levels of inanimate surfaces […]. For example, no longer visible soils harbouring blood may contain a hepatitis B viral load of 10^2–10^3 infectious particles […]".

"Following cleaning and disinfection processes, recontamination of surfaces occurs within a few hours depending on use […]; initial recontamination is predominantly with apathogenic environmental microorganisms […]."

There are legal regulations stipulating the need for a quality management (QM) system. In Germany, for example, this is enshrined in the German Code of Social Law (SGB V Section 135a).

The *KRINKO/BfArM Recommendation* [1] stipulates that a QM system must also be in place regardless of the nature of the medical devices reprocessed or the RUMED size.

Standard DIN EN ISO 17665-1, Section 7.10 c, regulating steam sterilization calls for control of the environment in which a product (medical device) is manufactured, assembled and packed. Environmental control tests may be conducted at regular intervals in areas that could impact the microbial burden on the device.

Standard DIN EN ISO 13485 regulating QM systems calls for requirements for the work environment as well as for monitoring, control and formulation of requirements for the microbial and particulate cleanliness of sterile products and for measures to ensure compliance with such regulations. "If the working environment conditions could adversely affect the product quality, the organization must document the requirements addressed to the working environment and processes for monitoring and management of the working environment."

There are no specific guidelines for RUMEDs, as opposed to drugs (Good Manufacturing Practise – GMP) [2]. Similarly, the first recommendation did not contain any specific reference values but did make suggestions for formulating in-house reference values. These specifications are laborious and were not applied in practice. The Committee for Hygiene, Construction and Technology therefore decided to formulate reference values based on more extensive test series.

For medical devices that are disinfected but not sterile when used, stringent requirements are addressed to the environment and handling to prevent recontamination. These measures must be applied to the reprocessing processes and subsequent processes such as packaging, transport and storage.

What areas are considered?

All surfaces in a RUMED – whether animate (people) or inanimate (room, equipment, work materials) – are contaminated but are not equally important for the reprocessing quality of medical devices.

Since the bioburden on the medical devices being reprocessed is higher in the cleaning and disinfection zone (C+D zone) than that of the surround-

[1] KRINKO/BfArM Recommendation: Recommendation for hygienic processing practices for medical devices, jointly compiled by the Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM)

ing environment, there is no relevant risk of the environmental bioburden negatively impacting the reprocessing process.

However, the risk assessment is different for medical devices being further reprocessed in the packing zone and sterilization zone as they have only a low microbial count. Contamination of surfaces and packaging materials in a RUMED must be kept to a minimum, as must the recontamination of medical devices after cleaning and disinfection.

Control of environmental surfaces

Control procedures

In various areas of technical hygiene targets have been defined on the basis of different concepts which can be referred to by way of comparison.

The introduction of any type of undesirable extraneous materials, i.e. including visible particles such as e.g. skin scales, hair, dust or of invisible particles into patients must be avoided. One approach is to visually inspect medical devices immediately before the packing process; this is useful in particular for detection of residual soils. Since this is not suitable for identification of contamination with microorganisms, special control measures are needed.

Such methods entail pre- and post-measurement tests or testing based on the use of test soils to demonstrate the efficacy of cleaning and disinfection.

Another target could be to focus on the optical state of environmental surfaces or of reprocessed medical devices prior to packaging, while also using microscopic methods for particle detection. These give no insights into the actual state, instead focus on whether the applied processes were properly executed under the specific conditions and thus achieve a target state. For practical reasons, this method cannot be used in establishments offering 24-hour service.

Structured observation of the conduct of cleaning/disinfection as well as observation of workflow patterns aimed at avoidance of the introduction of particles through windows and doors or materials could also contribute to control and protection of environmental conditions. The intervals and scope must be defined for the target variables in the infection control policy.

ATP bioluminescence methods are commonly employed for measurement of cleanliness but these are difficult to standardize since residues of disinfectants, cleaning utensils, etc. could lead to false results. Besides, there is no linear correlation with culture-based tests. [Dancer 2014, Watanabe 2014]

The KRINKO Recommendation "Hygiene requirements for cleaning and disinfection of surfaces" defines the aim of disinfection as not being "the elimination of environmental pathogens but defined reduction of the number of pathogenic or facultative pathogenic microorganisms." Tests carried out for the purpose of defining threshold values for routine checks found that in settings with healthcare-associated infection (HAI) pathogen counts >1 CFU per cm², bacteria such as MRSA, VRE, *Clostridium difficile, S. aureus* (MRSA+ MSSA) were detected more often on hand-touch surfaces. The absence of *S. aureus* (MSSA and MRSA) appears to be the best indicator of cleanliness, whereas coagulase-negative *staphylococci* serve as indicators of hand contact [Dancer 2014].

Nor are there in general any binding guidelines for medical devices that should harbour only a low microbial count when used (disinfected medical devices). Based on the requirements of the European and US American pharmacopoeias, the absence *S. aureus* and *Pseudomonas aeruginosa* on medical devices that come into contact with the mucous membranes of the nose, oropharynx or vagina may be required [14].

Accordingly, the target here would be the ability to demonstrate the presence or absence of "undesirable" microorganisms through contact plating or swabbing tests.

Suitable indicator organisms in der RUMED would be microorganisms that indicate inadequate decontamination of surfaces or point to recontamination with skin or mucosal flora or are able to demonstrate a direct health risk from reprocessed medical devices.

Another frequently applied concept has been the total microbial counts. That has been regulated by GMP standards for manufacture of drugs of varying degrees of purity.

Likewise, total microbial counts are defined as target variables in the foodstuffs industry and for control of room ventilation systems (based on VDI 6022). These definitions are based on epidemiology data and empirical values, are largely dependent on the nutrient media used and set different reference values e.g. 5 colony forming units (CFUs)/contact plate for class B clean room, 25 CFU/contact plate for class C clean room, 4–10 CFU for surfaces coming into contact with foodstuffs. Swabbing or contact plating methods can be used for sampling. The contact plating methods for measuring the aerobic mesophilic microbial counts are described in DIN 10113-3 and the semi-quantitative swabbing method in DIN 10113-2.

Efforts have also been made to define a threshold value for the definition of cleanliness with regard to cleaning and disinfection processes in order to prevent healthcare-associated infections (HAIs). For high-touch surfaces the benchmark could be in the range 2.5–5 CFU per cm². It has been demonstrated that detection of higher CFUs was associated with an increasing probability of contamination with *Staphylococcus aureus* and MRSA. However, to date that threshold value has not been adopted for routine checks [Dancer 2014] and would also apply to surfaces involved in direct patient care.

From the requirements governing medical device reprocessing, which in general stipulate that infection risks to the patient, user and third parties be kept to a minimum or which in some cases call for control of environmental conditions, it can be inferred that the target here is to reduce the total microbial counts to a minimum.

Conduct of tests for definition of reference values

In the following, the targeted acceptable level of contamination was defined on the basis of serial testing since there are no universally applicable threshold values for "clean or unclean surfaces".

A series of tests were carried out in accordance with the criteria, outlined below, in five representative RUMEDs with spatial separation of the C+D and the packing zone and which had in place a QM system. The test results were evaluated in four different microbiology laboratories. At least 40 contact plating tests were run for each series.

Sites for microbiology tests

1. Critical surfaces
   a. Hand-touch surfaces in the packing and sterilization zone

b. Worktops in the packing zone and storage surfaces in the packing and sterilization zone

2. Non-critical surfaces
   a. Surfaces not coming into contact with reprocessed medical devices

Documentation - Sampling

- Date, time, room, surface,
- In workflow
- Person taking sample: infection control staff/officer, external sampler

Test materials

- Rodac plates (Replicate Organism Detection and Counting)
- Size: 25 cm², round, rigid, with lid
- Trypticase soybean agar (TSA agar) with neutralizer (for neutralization of any surface disinfectant residues on nutrient media which could lead to false results because of persistent bactericidal action on the nutrient media).
- Principle: Bacteria on the test surface continue to adhere to the contact plate when the plate is pressed onto the nutrient medium (nutrient agar surface) where they multiply in the laboratory under incubation conditions and over a period of 48 hours. As such, bacterial, or also fungal, colonies which can be counted are grown (quantitative evaluation) and their species identified (qualitative evaluation).

Method

- Label the underside with waterproof pen.
- With disinfected hands, remove the lid of the Rodac plate without touching the nutrient medium.
- Applying gentle pressure, press the nutrient medium evenly to the test surface for around 5–10 seconds without destroying the nutrient medium and without generating friction motion.
- Then replace and fit the lid immediately without contaminating the nutrient medium.
- Never sample the same surface twice.

Evaluation criteria

1. CFU count per Rodac plate
2. Differentiation at species level: Gram-negative rods, *S. aureus*, *enterococci*, *streptococci* including quantitative specification in CFU/25 cm²
3. Differentiation of spore-forming from vegetative microorganisms
4. Differentiation of other microorganisms as needed for further evaluation (e.g. coagulase-negative *staphylococci*, *micrococci*, moulds, *Candida* spp.).

Results

Each RUMED was responsible for selecting the test sites but this was done in accordance with the aforementioned criteria. In two test series only critical surfaces were included.

The qualitative evaluation results of the contact plating tests are presented in Table 1, showing an expected microbial spectrum. Hardly any potential pathogens were detected. The most relevant pathogen was *Staphylococcus aureus*, with detection not limited to hand-touch sites. In addition, a small number of bacteria belonging to the mucosal flora were identified. Small numbers of moulds and, with one exception also humidophilic microorganisms belonging to various species (Table 1, blue marking) were detected in all series of tests of non-critical surfaces.

Summary quantitative evaluation was performed taking account of all surfaces. Spore-forming bacteria are presented separately since the use of sporocidal methods for surface disinfection is neither prescribed in the standards nor commonly applied. Quantitative evaluation was done for each series, while calculating the median, mean and standard deviation for vegetative and spore-forming microorganisms. The results were evaluated for all surfaces as well as separately for only the critical surfaces. Due to the high microbial variance on the surfaces, which is expected and can be tolerated in the operational state, the standard deviation is correspondingly high and the mean is greatly

RUMED 1-3 series		RUMED 1 check after 3 months		RUMED 2		RUMED 3		RUMED 4		RUMED 5	
Pathogen group / ward	Total	Pathogen group/ ward	Total	Pathogen group/ ward	Total	Pathogen group/ ward	Total	Pathogen group/ ward	Total	Pathogen group/ ward	Total
Total	715	Total	95	Total	30	Total	64	Total	61	Total	61
CNS	263	CNS	39	KNS	7	KNS	31	KNS	36	KNS	32
Micrococci	223	*Micrococci*	21	*Micrococci*	5	*Micrococci*	17	*Micrococci*	12	*Micrococci*	13
Spore-forming bacteria	133	Spore-forming bacteria	19	Spore-forming bacteria	0	Spore-forming bacteria	2	Spore-forming bacteria	0	Spore-forming bacteria	1
No pathogens detected	24	No pathogens detected	4	No pathogens detected	12	No pathogens detected	14	No pathogens detected	12	No pathogens detected	5
Moulds	20	Moulds	3	Moulds	0	Moulds	0	Moulds	1	Moulds	4
Corynebacteria	16	Corynebacteria	5	Corynebacteria	4					Corynebacteria	4
S. aureus	8	*Acinetobacter*	2	*Paracoccus*	1					*Neisseria*	1
of which MRSA	1	*Candida*	2	*Microbacterium*	1					*Rizobacter*	1
Lactobacteria	7									*Brevibacterium*	2
Moraxella-Branhamella	6									*Streptomyes*	1
Pseudomonas	3										
Other non-fermenters	3										
Rothia mucilaginosa	2										
***Acinetobacter* spp.**	1										
Arthrobacter	1										
***Aspergillus* spp.**	1										
***Brevibacterium* spp.**	1										
***Burkholderia* spp.**	1										
Kytococcus schroeteri	1										
Other *Enterobacteriaceae*	1										

Table 1: Microbial spectrum

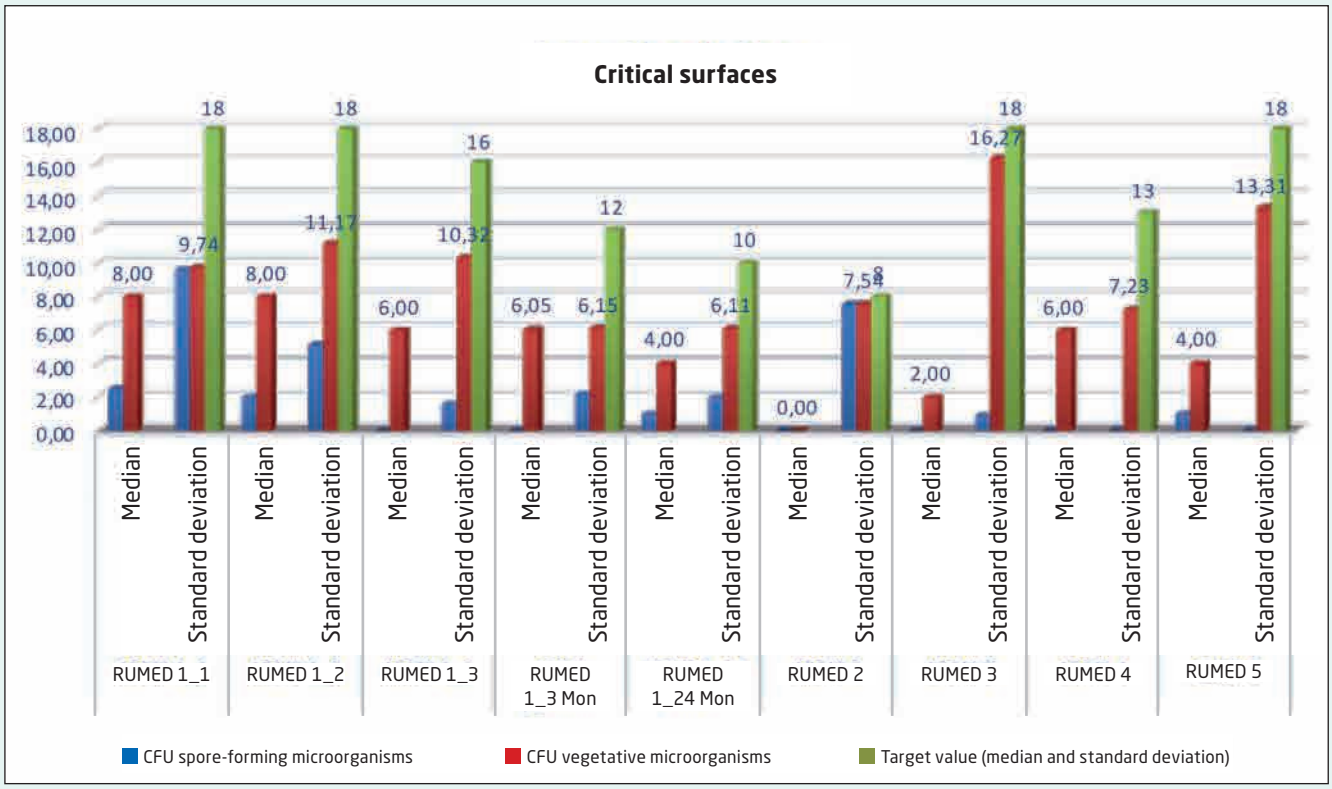

Fig. 1: Evaluation of all critical surfaces

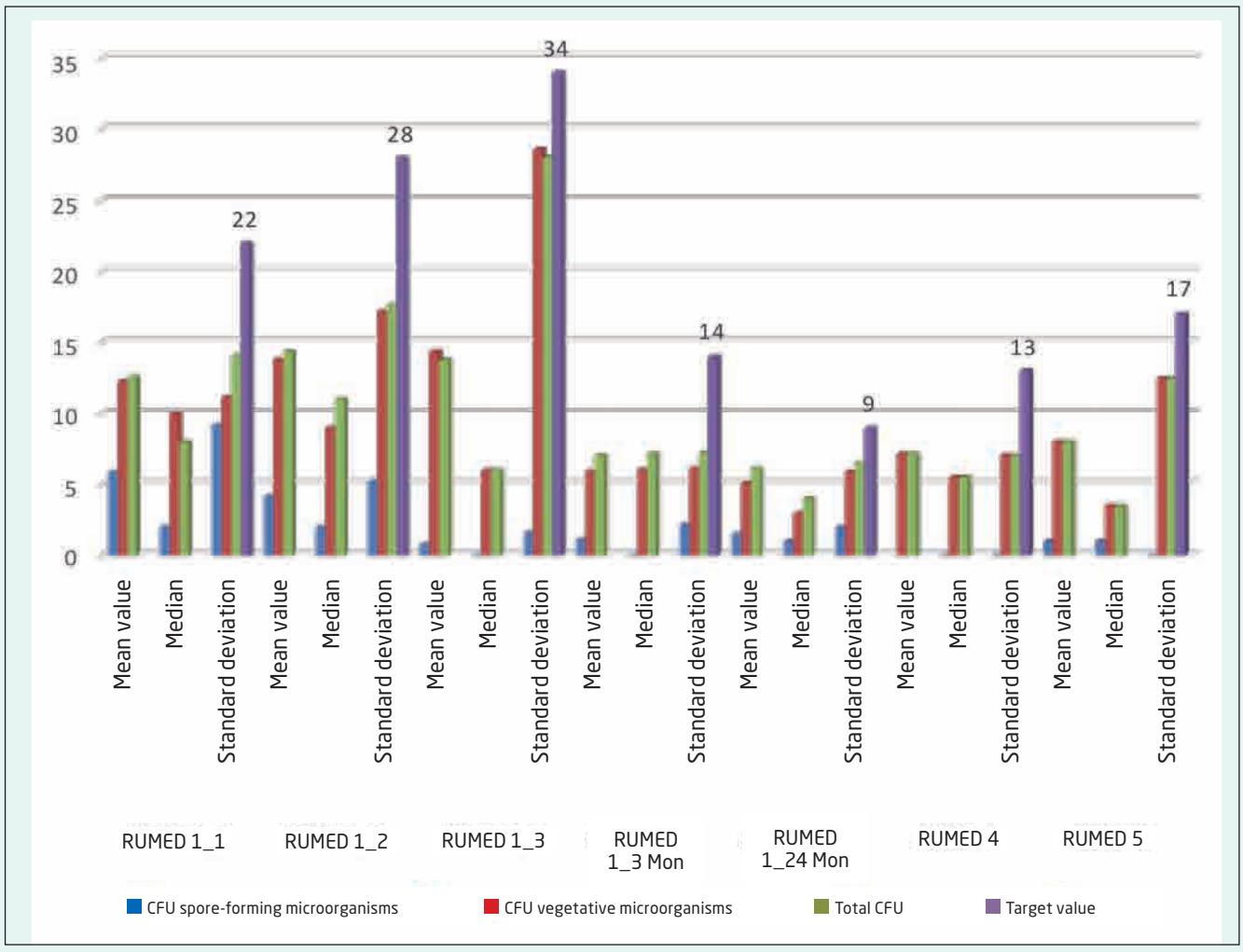

Fig. 2: Evaluation alignment for all surfaces

influenced by individual peak values. Therefore, the median was applied as an appropriate evaluation basis, as already proposed in the previous publication. This value is presented as a target value in the evaluations.

The median of the vegetative microorganisms identified on critical surfaces was between 0 and 8 and the standard deviation was between 6.11 and 16.27, giving rise to "target values" between 8 and 18. The median of the spore-forming microorganisms was between 0 and 2.5 with standard deviations between 0 and 9.6.

Concordance between the test series was very good both in terms of time (checks over two years) and for several RUMEDs, hence generalization is possible.

In the overall evaluation of all surfaces, the median of the vegetative microorganisms was between 3 and 10 with standard deviations between 5.9 and 28.57. Once again, the number of spore-forming microorganisms was low with a median between 0 and 2 and standard deviations of 0 and 9.16. Hence, the "target values" for the surfaces were between 9 and 34. This means that both the total microbial counts and the variances on the non-critical surfaces were higher. It is therefore important to evaluate these categories separately. Nonetheless, concordance between the test series is sufficient for setting the general target value proposed here.

Discussion

In the previous publication it was proposed that a RUMED-specific (in-house) target value be set by running several series of tests, which should be used as the basis for that RUMED's own quality assurance purposes. That approach is very complicated and has not prevailed in practice. We therefore evaluated these tests over time and in various RUMEDs to check the range of results obtained from surface contact plating tests carried out under real everyday conditions. In doing so, we followed up one RUMED for two years and enrolled four other RUMEDs of different sizes and supply areas. This showed that the variances are smaller than initially feared. Indeed, very good concordance was observed in particular for the critical surfaces, hence the definition of in-house threshold values can be dispensed with in favour of general ones. The highest target value in our evaluation was 18.

When all surfaces were included in evaluation, the highest target value was 34. The median target values were 17, i.e. similar to that of critical surfaces. However, the individual results were much more variable. Spore-forming microorganisms did not play any major role in any of the test series and are therefore not included in evaluation and besides, as mentioned before, there is no requirement that surface disinfection processes be endowed with sporocidal efficacy.

As in the references cited here on the formulation of threshold values for routine checks, it was revealed that at >1 CFU per cm² the probability of HAI pathogens increases, which was also confirmed for the microbial spectrum identified in our tests. That corresponds to a target value of 25 CFU/Rodac plate, which is equivalent to the requirements for a GMP class C clean room. That target value is higher than the median range obtained in our tests and was exceeded only in two cases in our tests. In *one of th*ese cases HAI pathogens like S. aureus and enterococci were also detected. Hence, this target value is well established in the literature and – as demonstrated in our tests – is realistic and suitable for everyday practice.

More stringent requirements should be applied for critical surfaces, which is why in this case the median for our tests was rounded up from 18 to 20. In this way both peak values and median can be reflected in a threshold value.

In the majority of test series, comprising non-critical surfaces, a very small number of humidophilic microorganisms belonging to the most diverse species was identified. Disinfection was generally carried out with commercially available, presaturated wipes, with contamination risks kept to a minimum when mixing disinfectant solutions and reprocessing cleaning utensils.

Moulds were also routinely identified and on surfaces were interpreted as microbes recently deposited on the surfaces. However, when identified in closed drawers or cabinets they can point to residual humidity.

Conclusion

Since the bioburden on the medical devices being reprocessed is higher in the cleaning and disinfection zone (C+D zone) than that of the surrounding environment, there is no relevant risk of the environmental bioburden negatively impacting the reprocessing process.

By contrast, environmental contamination in the packing and sterilization zones of a RUMED can impact the quality of the reprocessed medical devices. The environmental conditions under which medical device reprocessing processes are implemented must be controlled. Ways are shown how this control can be performed and the results evaluated.

The absence of pathogens is a realistic requirement even in establishments with ongoing operations. A combination of visual inspection and microbiology tests is advisable.

20 CFU/Rodac plate could be set as threshold value for critical surfaces and 25 CFU/Rodac plate (≤ 1 CFU/cm) for non-critical surfaces as well as in other areas if no measures were taken in-house to set a reference value; besides, the absence of *S. aureus* and humidophilic microorganisms and other pathogens is required.

In the event of a threshold value being exceeded, the tests must be repeated at the site yielding an unsatisfactory result as well as at four additional and similar sites.

If threshold values are continually exceeded, documented analysis of the causes must be conducted and remedial action taken.

Appendix: Recommendation for testing the environmental conditions in a RUMED

TEST LOCATION

Zones:

- Packing zone
- Sterilization zone

Surfaces:

- Critical surfaces
  - Worktops in the packing zone (packing ta-ble, heat sealer station)
  - Hand-touch surfaces/sites in both zones (e.g. mouse, touch screen, magnifying lamp, pistol handle, …)
  - Storage surfaces in both zones
- Non-critical surfaces
  - Surfaces not coming into contact with re-processed MDs (e.g. MD consignment store, MD release site, thermal protection glove, etc.)

MATERIAL + SCOPE

Test material:

- Rodac plates
  - TSA agar or TSA with neutralizer
  - 25 cm², round, rigid, with lid

Scope:

- All packing tables/heat sealer stations with at least 3 contact plate samples from:
  - Worktops and
  - Hand-touch surfaces
- At least, 5 contact plate samples from non-critical surfaces in the packing zone
- At least, 5 contact plate samples from critical + non-critical surfaces in the sterilization zone

Frequency intervals:

- Frequency intervals must be specified within the respective establishment.
- Quarterly tests are recommended; less frequent test intervals can be used if the results are normal

CONDUCT

Conduct:

- Sampling is done in workflow
- Clearly label the underside of plates with water-proof pen
  - Record date, time, room + sampling site in the accompanying document/ protocol
- With disinfected hands, remove the lid of the Rodac plate without touching the nutrient medium
- Applying gentle pressure, press the nutrient me-dium to the test surface for around 5 – 10 seconds
- Replace the lid without contaminating the nutrient medium

EVALUATION

Evaluation:

- Total CFU per Rodac plate
- Differentiation at species level, including quantitative specification per Rodac plate of Gram-negative rods, *S. aureus*, *enterococci*, *streptococci*
- Differentiation of spore-forming from vegetative microorganisms
- Differentiation of other microorganisms as needed for further evaluation (e.g. coagulase-negative *staphylococci*, *micrococci*, moulds, *Candida* spp.)

LIMIT VALUES

Limit values:

- Critical surfaces:
  - ≤ 20 CFU/Rodac plate
- Non-critical surfaces:
  - ≤ 25 CFU/Rodac plate
- The following applies for both surfaces: no evidence of
  - *S. aureus*
  - Humidophilic microorganisms
  - Pathogenic microorganisms

Limit value overshooting:

- Repeat test at unsatisfactory site
- In addition, test four similar sites
- If the threshold value is exceeded again in the repeat test, documented analysis of the causes must be conducted and remedial action taken.

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