Recommendations by the Quality Task Group (106)

No reprocessing of kidney bowls or wash bowls in bedpan washer-disinfectors

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Introduction

BEDPAN WASHER-DISINFECTORS are intended for disposal of faeces together with reprocessing of the associated containers.

The washer-disinfectors regulated by standard EN ISO 15883-3 [1] are also known colloquially as **BEDPAN WASHER-DISINFECTORS**. The terms automatic bedpan washers or faecal washers are also occasionally used. These washer-disinfectors (WDs) are primarily designed and intended for disposal of faeces together with reprocessing of the associated containers such as urine bottles, bedpans and toilet commode buckets.

However, it can be noted time and again in everyday practice that other items are also reprocessed in these washer-disinfectors. Contrary to the manual reprocessing method formerly used for wash bowls, the standard practice now in many healthcare institutions and homes for the elderly is to reprocess in such washer-disinfectors also kidney bowls, including those used for oral hygiene, as well as the wash bowls used for basic personal hygiene or partial medicinal baths.

The technical features of these washer-disinfectors are virtually unable to demonstrate the required proof of validated processes, and certainly do not assure the safety expected of modern WDs in a Reprocessing Unit for Medical Devices (RUMED). **THE A_0 VALUE REQUIRED FOR SAFE DISINFECTION** exceeds the capacity and technical facilities of the majority of the (older) washer-disinfectors currently in operation.

THE A_0 VALUE REQUIRED FOR SAFE DISINFECTION exceeds the technical facilities of the majority of the (older) bedpan washer-disinfectors.

In an age of multi-drug resistant organisms there is a particularly high risk of their transmission when disposing of faeces.

Historical background

The development of these washer machines dates back to the 1930s [2]. Connected to the cold-water pipeline (drinking water), the most they could do was to rinse off the utensils, while their main purpose was to improve the removal of faeces. Hence, manual pre-and, possibly, post-cleaning could not be avoided.

It was not until the 1960s that washer machines also facilitating chemical disinfection after cleaning were developed. These were operated by staff by activating the cleaning pushbutton but by no means was such a washer-disinfector equipped with the programme sequences as we know them today.

BEDPAN WDs WITH THERMAL DISINFECTION have been in use since the 1990s.

A further 30 years would go by before new **BEDPAN WASHER-DISINFECTORS WITH THERMAL DISINFECTION** were introduced. Their introduction was expedited by the knowledge that the majority of central dosing units for chemical disinfectants were colonized with biofilm.

Normative requirements

The bedpan washer-disinfectors regulated by ISO 15883-3, with the unwieldy title “Washer-disinfectors Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers” just about meet the minimum requirements. The term “human waste containers” is somewhat poorly defined as it also includes, in addition to urine bottles and bedpans, holders for disposable bedpans, hospital utensils, e.g. bowls, as well as similar items.

However, all these items are primarily intended for human waste. For example, among the terms mentioned in Section 3.3 are excreta and body fluids, including stools, urine, blood, pus, vomit and mucus.

THE MINIMUM A_0 VALUE for thermal disinfection in bedpan washer-disinfectors specified in the standard is not sufficient.

Section 4.5 dealing with disinfection specifies a **MINIMUM A_0 VALUE**: “Thermal disinfection must be deemed complete when all surfaces to be disinfected have been subjected to a process with an A_0 value of at least 60.”

Current situation in healthcare institutions

As reported in the Introduction above, in addition to urine bottles and bedpans, kidney bowls, wash bowls and Redon bottles (suction bottles) are also frequently reprocessed in these washer-disinfectors. Many healthcare institutions make use of these bedpan washer-disinfectors/faecal washers to reprocess kidney bowls intended for oral hygiene and wash bowls used for basic personal hygiene as well as for partial medicinal baths.

The term "faecal washer" highlights the intended purpose of these washer-disinfectors which in the standard are designated as "Washer-disinfectors employing thermal disinfection for human waste containers". For ethical reasons alone, it is not reasonable to place items intended for oral and personal hygiene in the same machine immediately used before for removal of urine or faeces from bedpans.

Moreover, the technical prerequisites are hardly ever met. Compared with a standard RUMED washer-disinfector (WD), the spray mechanics, temperature distribution in the chamber and among the materials being reprocessed are less effective. Conventional AO value tests time and again reveal weak points depending on the load and it is not uncommon to identify **VISIBLE SOILS ON THE CHAMBER WALLS, DOORS AND REPROCESSED SUPPLIES**, in particular in the case of older WDs.

VISIBLE SOILS ON THE CHAMBER WALLS, DOORS AND REPROCESSED SUPPLIES are not uncommon in older bedpan washer-disinfectors.

Throughout Germany some 1,00,000 bedpan washer-disinfectors are operated in around 20,000 healthcare establishments such as hospitals and nursing homes [3]. The largely unexplained extension of the intended use, i.e. reprocessing of urine bottles and bedpans, to now include other items of dally use must be viewed in a very critical light – **WASH BOWLS AND KIDNEY BOWLS** have no place in such washer-disinfectors! [5]

WASH BOWLS AND KIDNEY BOWLS must not be reprocessed in bedpan WDs.

The majority of bedpan washer-disinfectors in operation in Germany do not comply with the **PROVISIONS OF THE GERMAN MEDICAL DEVICES OPERATING ORDINANCE (MPBETREIBV)** [6], which stipulates the use of validated processes; the process parameters are neither recorded nor monitored Likewise, the cleaning results range from unreliable to incomplete and without manual pre- and/or post-cleaning the reprocessing outcome in bedpan washer-disinfectors is often unsatisfactory.

THE PROVISIONS OF THE GERMAN MEDICAL DEVICES OPERATING ORDINANCE (MPBETREIBV) are not fulfilled by most bedpan washer-disinfectors.

It is not uncommon to find visible residual soils in both the WD chamber and on the bedpans and bottles [5]. The addition of an appropriate chemical detergent could greatly contribute to process optimization. Since there is no automatic load detection feature, operating errors are possible if there is a choice of several reprocessing programmes.

Most bedpan washer-disinfectors are connected only to the drinking water pipeline, which may result in discolorations and residues in the chamber and on the reprocessed supplies. But faecal residues can also persist within the cleaning chamber and cause unpleasant odours and recontamination after "successful reprocessing". Apart from connections of too small dimensions to the waste water system, many bedpan washer-disinfector drains are inadequately isolated, with only an odour trap composed of a short water column separating them in the washbasin drain trap from other water supplies.

Assignment to risk categories

Depending on their use in an individual case, **URINE BOTTLES AND BEDPANS** are assigned to the "semi-critical" risk category if they come into contact with "mucous membranes or pathologically altered skin" (see KRINKO/BfArM Recommendation* [8]). Processes endowed with demonstrable bactericidal, fungicidal and virucidal efficacy must be used for final disinfection of semi-critical medical devices.

URINE BOTTLES AND BEDPANS are assigned to the "semi-critical" risk category.

For thermal processes the disinfection efficacy is determined parametrically by means of the A_0 value. Instructions to that effect are set out in the "Guideline compiled by the German Society of Hospital Hygiene (DGKH), German Society of Sterile Supply (DGSV) and Working Group Instrument Preparation (AKI) for

* KRINKO/BfArM Recommendation: Hygiene requirements for processing medical devices, jointly compiled by the Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute (KRINKO) and the Federal Institute for Drugs and Medical Devices (BfArM)

validation and routine monitoring of automated cleaning and disinfection processes for medical devices". Contrary to the A_0 value of 60 specified in the normative requirements, Information 7 of the aforementioned guideline makes in-depth reference to values of 600 and 3000; smaller values have no relevance for reprocessing.

An A_0 value of 600 is reported to constitute a minimum requirement only for devices coming into contact with undamaged skin. It somewhat corresponds to that designated as spectrum of action A in the RKI (Robert Koch Institute) list, and is used for decontamination of vegetative bacteria and fungi [9].

BEDRIDDEN PATIENTS OFTEN HAVE PATHOLOGICALLY ALTERED SKIN. In cases of doubt, a higher A_0 value shoukd be aimed for.

Bedpans and urine bottles are frequently used for several different patients. In many cases **BEDRIDDEN PATIENTS HAVE PATHOLOGICALLY ALTERED SKIN**, or even damaged open skin. The reprocessing process must effectively prevent transmission of infection with pathogens such as e.g. *Clostridium difficile*.

For conduct of risk assessment in this setting the KRINKO/BfArM Recommendation gives the following advice: "In cases of doubt, the medical device shall be assigned to the higher (more critical) risk class". That explains the rationale for a higher A_0 value of 3000, since the latter is also able to inactivate heat-resistant viruses (hepatitis B virus).

THE LOWER TEMPERATURES IN BEDPAN WASHER-DISIFECTORS require very long exposure times to achieve an A_0 value of 3000.

Unfortunately, this cannot be technically achieved in many bedpan washer-disinfectors since the thermal energy needed cannot be generated. Efforts to adjust the exposure time to compensate for that shortcoming when **USING LOWER TEMPERATURES** (≤ 65 °C) result in very long process times. To assure an A_0 value of 3000 on using an exposure temperature of 80 °C, an exposure time of 50 minutes would be needed for the disinfection cycle alone [7].

Organizational prerequisites

IF DECONTAMINATED BEDPANS AND URINE BOTTLES ARE STORED in "dirty utility rooms", recontamination of already reprocessed utensils is quite possible.

In general, washer-disinfectors are installed at decentralized locations in the healthcare institutions. In addition to reprocessing, these "dirty utility rooms" are often used to **STORE DECONTAMINATED BEDPANS AND URINE BOTTLES**. Hence, recontamination of already reprocessed utensils is quite possible, in particular, if bedpans and urine bottles are stored there on open shelves.

Semi-critical medical devices should preferably undergo automated reprocessing under the supervision of qualified personnel. In most cases the nursing staff will not have received specialist training. Induction by the WD manufacturer or by the infection control team does not suffice as proof of the expertise required by the reprocessing staff.

Recommendation

THE USE OF BEDPAN WASHER-DISINFECTORS must be restricted to human waste containers.

THE USE OF BEDPAN WASHER-DISINFECTORS must be restricted to human waste containers such as urine bottles, bedpans, toilet commode buckets, etc. Other means must be found to reprocess all other items such as wash bowls, Redon bottles, suction apparatus containers, etc. These could include, for example, reprocessing them in the RUMED [10] or opting for single-use devices.

For disinfection the KRINKO/BfArM Recommendation specifies an A_0 value of 3000. The rationale for this is explained as follows "…the measures are based on aspects aimed at continuous assurance and documentation of the standardized, reproducible and effective processes needed to meet the given specifications as well as to assure the technical and functional safety of the medical devices".

Other recommendations include:

Upgrade semi-critical to critical risk classification when reprocessing items e.g. kidney bowls/wash bowls, intended for oral/personal hygiene of mechanically ventilated, immunosuppressed intensive care patients.

Compliance with KRINKO/BfArM Recommendation, Annex 6 regarding demonstrable evidence of the expertise of personnel entrusted with manual reprocessing.

For aesthetic reasons alone, containers intended for faeces must always be reprocessed separately. The place used for disposal of excrement, the lavatory, should not be used for any other purpose. Based on the German Medical Devices Act (MPG) and MPBetreibV, extension of its use to include reprocessing of wash bowls and kidney bowls poses a hazard to patients, personnel and third parties. Mandatory reporting applies even if there is only suspicion of patient endangerment.

References: see p. 111