Dear Editor,

We read with concern a recent manuscript by Deasy et al [1] claiming "effective cleaning and decontamination" of the internal components of dental handpieces (DHPs). We feel it is important to note that the test methods and claims in the report are inconsistent with current international standards for cleaning and disinfection of reusable medical devices in washer-disinfectors[2,3,4] The aim of the manuscript was to "investigate the effectiveness of washer-disinfection at reducing microbial bioburden of internal components …of dental handpieces…". The authors state that there are no specific standards for DHPs; however DHPs, as medical devices, are given as examples of the types of devices in the washer-disinfector standard series (ISO 15883-2[3]) and specifically as powered devices. Cleaning and disinfection requirements in these standards therefore apply. For example, cleaning validation using defined test soils and disinfection efficacy requirements described in the standards[5] are applicable to these reusable medical devices.

The standards[2,3,4] specify both performance requirements and test methods for demonstrating cleaning and disinfection efficacy, but these were not used as part of the efficacy claims in this manuscript. Although the authors did use one of the test soils cited in the standard[4] (Edinburgh soil), this was diluted to 10% and is not consistent with the standards. Furthermore, the authors did not demonstrate, even with this diluted test soil, that it had sufficiently dried to create a challenge to impede removal. It is unlikely that the soil was dry within 30 mins in the lumens. It is well understood that without drying, test soil removal (including associated microorganisms) can be achieved simply by flushing the lumens with water/detergent. Dilution of the test soil would not be replicated in practice during manufacturer's type test/commissioning/periodic tests of washer-disinfectors (WDs).

The authors appear to have conflated the requirements[2,3,4] for cleaning (defined reduction of test soil analytes such as protein and total organic carbon) and thermal disinfection (verified thermometrically), with an inappropriate focus on microorganism log reduction in the washer-disinfector cycle; it is unclear why the authors used microbial inocula derived from the standards for chemical disinfectants and antiseptics to claim effective cleaning or disinfection, although such test methods may be used as the basis of chemical disinfection validation. There is no requirement to undertake specific microbiological inactivation studies for a thermal disinfection process (although required for chemical disinfection processes); the WD standards only require temperature distribution studies. We recognize that the washer-disinfector standard series have been under revision, but these essential requirements remain unchanged in the new revisions.

On some points we do agree with the authors that DHPs can be challenging to validate cleaning, disinfection and sterilization processes. For automated cleaning and disinfection, this is usually addressed by manufacturer's type testing and periodic performance qualification tests of WDs in accordance with standards[2,3,4] and national guidance. This requires co-operation between the DHP and WD manufacturers and should be reflected in the DHP instructions for use (IFU) that will give specific reprocessing instructions, compliant with ISO 17664-1[5]. The requirement for a sterile service department or dental practice to dismantle, process and reassemble a medical device, as described in the manuscript, should be strictly in line with the manufacturer's IFU; no details were provided on the DHP manufacturer's processing instructions. This may be important, considering that such devices are normally considered critical and, in addition to cleaning/disinfection are normally be

subjected to terminal sterilization. But correct investigation and validation of the cleaning process is essential to ensure adequate disinfection and/or sterilization.

We recognise the spirit of the endeavour described in the manuscript; the use of international standards should not be a barrier to innovation and development in the field of medical device decontamination, yet consensus-developed standards are considered to be best practice. The raison d'être for consensus standards is to provide a standardised state of the art benchmark for both WD manufacturers and medical device manufacturers to enable safe products. For a WD for reusable medical devices, ISO 15883-5[4] specifies maximum criteria for acceptable cleaning by way of alert levels (≥ 3 μg/cm^2) and action levels (≥ 6.4 μg/cm^2) for residual protein. The authors state a >95% reduction in protein after WD processing; it is unknown what the initial protein inoculum was, but 5% residual protein is likely to be many orders of magnitude greater than the 3 μg/cm^2 alert level, and certainly not suggesting effective cleaning. As a minimum, the methods used in assessing cleaning efficacy should be described such that correlation or conformity to the state of the art standards can be assessed. The log reductions of microorganisms tested in this study were not a surprise, given the relative sensitivity of these to heat-based processes use for disinfection and drying in WDs. But these can become easily compromised in the case of inadequate cleaning or where device damage may allow soil to build up over repeat use with the types of soils present during normal dental practice. As a further point, care should be taken in interpretation of the impact of the presence of oil-based lubrication. There may be many reasons to explain the results observed, including physical removal by flushing, but overall care should be taken to follow manufacturer's instructions for use as oil-based lubrication may not be recommended by the manufacturer.

In conclusion, we are concerned that the readership will be misled by the authors claims of effective cleaning and decontamination which are not supported by the use of consensus international standards, that this may lead to misleading claims by citing this publication, and that future workers cite this publication methodology as a pathway to claiming cleaning and decontamination efficacy of WD equipment and processes for medical device processing.

Yours sincerely,

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