A study of Dental Handpiece Manufacturers re-processing instructions using EN ISO 17664:2004

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Introduction
This study focused on handpieces supplied to general dental practitioners in the UK. Dental handpieces can be broadly sub-divided into slow speed motors, high speed turbines and surgical handpieces. Dental handpieces are complex devices presenting challenges to both cleaning and sterilization processes and require validated instructions for reprocessing. It is both helpful and informative if manufacturers provide clear and concise reprocessing instructions.

Aims

Method
The top three manufacturers of handpieces used in the UK were contacted by email to confirm their latest work instructions for care and maintenance of their dental handpieces. Information was also sourced by searching the Internet. Reprocessing instructions were compared to BS EN ISO 17664:2004.

Results
The main findings are highlighted in Table 1. Several areas were identified that were not compliant with that outlined in the standard.

Discussion
It is important that manufacturer’s instructions follow a standard and that these are presented in a meaningful way for the users to follow. Perhaps the challenge of supplying instructions that meets the requirements of several different Countries decontamination processes is too difficult for manufacturers to comply with.

Conclusion
Manufacturer’s instructions have several Gaps compared to the Standard. Closer working relations between manufacturers and Users may help improve the quality of the reprocessing instructions. Including an evidence base in the reprocessing instructions would be within the capability of the instructions of Users.

Sterilization
Vacuum autoclave, minimum 3 minutes at 134 °C. Do not exceed 137 °C.

- After manual cleaning, disinfection and lubrication you must carry out a final sterilization (wrapped) in the class 15 °C ± 5 °C sterilizer, according to EN 13060.
- Approved sterilization procedures: Follow your country-specific directives, standards and guidelines. Steam sterilization class B (pre and post vacuum) with sterilizers in accordance with EN 13060. Sterilization holding time a minimum of 3 minutes at 134 °C (273 °F).
- Required pressure 0.85 bar (12.3 psig) up to 2.16 bar (31.3 psig), or Steam sterilization class C with sterilizers in accordance with EN 13060. The sterilizer manufacturer must give its express approval for the sterilization of handpieces.

At manufacturer’s products bearing the sterilization symbol, can be sterilized in steam sterillizers (autoclaves), as per EN 13060/ISO 17665-1 and have a maximum temperature stability of up to 130 °C. The manufacturer’s coupling are not sterilizable.

- Manufacturer recommends cleaning and servicing of the handpiece as part of the reprocessing after each use, i.e., after each cleaning, disinfection, and before each sterilization.
- Remove the cutter or grinder
- Cover the medical device with the bag
- Plug the medical device to the reprocessing set and press the spray button for 2 seconds. Service the chuck for 1 second: Manufacturer recommends cleaning and servicing the chucking system once every week.
- Remove the cutter or grinder and spray into the opening of the chuck using the tip of the spray bottle (see instructions for use).
- Validated internal cleaning (RIK-compliant) with cleaning fluid containing tannic acid. Subsequent rinsing with water steam and lubrication with manufacturers guarantee safe reprocessing and value retention of medical devices.
- Attach the instruments to the service couplings.
- Close the front flap, select a fully automatic service programme and press the start button.
- Thermal disinfection: not packed in the sterilizer manufacturer medical devices sterilization symbol, can be sterilized in steam sterillizers (autoclaves), as per EN 13060/ISO 17665-1 and have a maximum temperature stability of up to 130 °C. The manufacturer’s coupling are not sterilizable. Manual Disinfection: Spray the disinfectant on a cloth, then wipe the medical device and allow the disinfectant to act according to the instructions of the disinfectant manufacturer. Follow the instructions for use of the disinfectant.

- Daily oil service: With Manufacturer Service Oil XX, follow the instructions on the oil spray can and on the packaging. Check lubrication and oil level with normal eye observation.

- Automatic lubrication using manufacturer’s oil and machine (see list below)
- Check lubrication of the chuck using the tip of the spray bottle.
- Lubricate the chuck mechanism using manufacturer’s spray plus with tip nozzle at least 2-3 times per week.
- Replace spray can
- Keep spray can in upright position
- Insert nozzle in to the rotary instrument
- Always lubricate straight handpieces with closed chuck and blanking piece inserted.
- Spray rotary instrument for 1-2 seconds holding a fully functional instrument between the head end
- Check tissue for debris and if oil is not present, repeat the cycle or use manual lubrication.
- Lubricate chuck mechanism using manufacturer’s oil with tip nozzle weekly.
- Lubricate with closed chuck and blanking piece inserted.

- Apply a small quantity of surgical grade lubricant oil to the hinges.

Cleanliness
The main findings are highlighted in Table 1. Several areas were identified that were not compliant with that outlined in the standard.

- No particular requirements. Dissassembly not required.
- Equipment: Washer/disinfector, detergent (name)
- Manual cleaning and disinfection is an appropriate brush ensuring that full depth of the feature is reached.
- Rinse and brush off under demineralized water (< 38 °C / < 100 ° F).
- Remove any liquid residues (absorbent cloth, blow dry with compressed air).

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- Remove any liquid residues (absorbent cloth, blow dry with compressed air).
- Do not place the handpiece in liquid disinfectant or in an ultrasonic bath.

- If heated: soak for disinfection. Clean with appropriate brush ensuring that full depth is reached.
- Rinse and brush off under demineralized water (< 38 °C / < 100 ° F).
- Remove any liquid residues (absorbent cloth, blow dry with compressed air).
- Do not place the handpiece in liquid disinfectant or in an ultrasonic bath.

- Manual cleaning using manufacturer’s recommended lubrication cycles, available from the manufacturer.
- Always lubricate straight handpieces with closed chuck and blanking piece inserted.
- Always complete steps 2.3.4.5 in quick succession.
- Lubricate chuck mechanism using manufacturer’s spray plus with tip nozzle at least 2-3 times per week.

- Check lubrication of the chuck using the tip of the spray bottle.
- Replace spray can

- Shake spray can
- Keep spray can in upright position
- Insert nozzle in to the rotary instrument
- Always lubricate straight handpieces with closed chuck and blanking piece inserted.
- Spray rotary instrument for 1-2 seconds holding a fully functional instrument between the head end
- Check tissue for debris and if oil is not present, repeat the cycle or use manual lubrication.
- Lubricate chuck mechanism using manufacturer’s oil with tip nozzle weekly.

- Automatic lubrication using manufacturer’s oil and machine (see list below)
- Check lubrication of the chuck using the tip of the spray bottle.
- Lubricate the chuck mechanism using manufacturer’s spray plus with tip nozzle at least 2-3 times per week.
- Lubrication and oil level with normal eye observation.

- Always lubricate straight handpieces with closed chuck and blanking piece inserted.
- Manual cleaning: with Manufacturer Service Oil XX, follow the instructions on the oil spray can and on the packaging. Check lubrication and oil level with normal eye observation.

- Automatic lubrication using manufacturer’s oil and machine (see list below)
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