FREQUENTLY ASKED QUESTIONS ABOUT HVHA STERILISATION

Q. What is High Velocity Hot Air (HVHA) technology and how does it compare to conventional dry heat sterilisation?
A. HVHA sterilisation provides uniform, high velocity hot air (190^{o} C) within the sterilisation chamber delivering rapid heat transfer for maximising microbial kill. Unlike static dry heat sterilisers which rely on gravity or low velocity fans to distribute heated air, HVHA sterilisers can process instruments in minutes (6 minutes for un-wrapped instruments; 12 minutes for pouched instruments) compared to 60-120 minutes required for static dry heat sterilisation.

Q. Are HVHA sterilisers more complicated than steam sterilisers?
A. No. HVHA sterilisers uses only rapidly moving hot dry air to sterilise instruments. As such, the only moving mechanical parts are (1) the blower (fan and motor) for moving hot dry air over a heating element, repeatedly through the sterilisation chamber and (2) the cooling fan to maintain temperature control for the printed circuit board and outer steriliser housing. There is no vacuum system, no water system or drying system as required for steam sterilisers. The HVHA unit requires little maintenance compared to the more complex steam sterilisers which require frequent maintenance and cleaning of all the mechanisms involving the management of steam, water, pressure and vacuum.

Q. How does an HVHA steriliser kill microorganisms?
A. Contrary to steam sterilisation where heat transfer is through steam contact and causes microbial death, HVHA by use of heated rapidly flowing air results in the dehydration of all forms of microorganisms, including bacterial spores. Dehydration causes the cessation of cellular metabolism as water removal from the cell increases the concentration of salts and minerals, upsetting metabolic function and resulting microbial death.

Q. Are there any other compatible technologies?
A. There are no other HVHA dry heat sterilisers that can deliver a consistent, uniform heating pattern throughout the sterilisation chamber. The Cox RapidHeat HVHA Steriliser ensures no hotspots that may melt nylon sterilisation pouches or coldspots that may influence the ability to sterilise.

Q. Has the HVHA sterilisation process received clearance as a medical device?
A. The Cox RapidHeat Steriliser was issued FDA clearances under K872643A and K881371 in 1987 and 1988, respectively allowing a 6 minute cycle for unwrapped instruments and a 12 minute cycle for wrapped (pouched) instruments at 190^{o} C. The unit has ETL, UL, CSA and Health Canada approvals and in 2017 is gaining European CE conformity through TUV Rheinland as an approved medical device. CPAC Equipment Inc., the manufacturer of the Cox RapidHeat HVHA Steriliser is an FDA QSR/ISO 13485 certified manufacturing facility.

Q. What is the effectiveness of biological kill required of and achieved with the Cox RapidHeat HVHA steriliser?
A. The COX RapidHeat HVHA steriliser has been documented via the CE and FDA 510(k) evaluation process to deliver a 12 Log kill of Bacillus atrophaeus spores at 6 minutes and 12 minutes for sterilisation cycles of un-wrapped and wrapped instruments, respectively, at 190° C.

Q. How long has the HVHA sterilisation technology been used in dental and healthcare practices?
A. The COX RapidHeat HVHA steriliser has been in successful use for over 25 years in the dental and healthcare markets.

Q. Can HVHA sterilisation be used only on metal instruments?
A. Most of today's instruments including handpieces and other instruments incorporating thermal plastic composite materials that are suitable for steam sterilisation are also suitable for the higher temperatures of the COX RapidHeat HVHA steriliser with no negative effect on the instrument lifecycle. In recent years the creation of more heat-tolerant materials (e.g., heat-resistant fluoropolymers. silicones, and polycarbonates) and their replacement of heat-intolerant materials used in medical devices has reduced significantly the number of instruments that are intolerant to HVHA sterilisation conditions.

Q. Does HVHA sterilisation contribute to instrument stress including corrosion, pitting and dulling of instruments?
A. The surgical stainless steels that are used in dental and healthcare instrumentation are also used extensively in industrial applications with operating environments in excess of 1000°C. Stainless Steel's key attribute is the ability to maintain strength and resistance to corrosion and oxidation at these elevated temperatures. Corrosion results in micro-pitting and dulling which directly impacts on the ability to properly sterilise therefore shortening the effective lifetime of an instrument. Unlike steam sterilisation where the corrodible elements of water are present, HVHA employs water and moisture-free sterilisation where no corrosion-causing elements exist.

Q. Is HVHA sterilisation compatible with dental handpieces?
A. The COX RapidHeat HVHA steriliser has been demonstrated to be compatible with dental handpieces. Non-metallic components within handpieces are constructed of high-temperature resistant materials to resist the high temperatures generated during their operation. The COX RapidHeat HVHA steriliser has a specific pre-set cycle (8 minutes) for the sterilisation of unpouched hand pieces. Pouched handpieces are sterilised on a 12 minute cycle.

Q. What are the true times required of the total HVHA treatment cycle from start to finish?
A. Unlike steam sterilisers which require pre-vacuum assist and drying cycles that add to as much as 40 additional minutes to the actual three to four-minute sterilisation cycle, the COX RapidHeat HVHA steriliser has a 12-minute cycle (for pouched instruments) plus a 2-minute warm up period which brings the sterilisation chamber back to temperature between cycles. Total time for

completing a sterilisation process from instrument loading to instrument removal is 14 to 15 minutes.

Q. Can the Cox RapidHeat HVHA steriliser replace "immediate use" sterilisation practices?
A. Since the COX RapidHeat HVHA steriliser's true CE cleared cycle is 6-12 minutes without the need for any drying, HVHA technology is an excellent choice to replace "Immediate-Use" steam sterilisation." COX RapidHeat HVHA steriliser cycles do not fall under healthcare's definition of "immediate-use" which is a standard term used for short-cutting the drying time of steam sterilisation. An "Immediate-Use" steam sterilisation cycle is used by staff when an instrument or instrument set has an emergency need to be turned around as quickly as possible. If there is improper drying, subsequent cooling will cause any moisture to condense and packaged instruments to remain wet, increasing the potential for instrument corrosion.

Q. What is the comparative cost to operate an HVHA steriliser against steam sterilisation?
A. CPAC has completed a Comparative Cost Analysis that reveals a 50% operating cost savings over a comparable steam steriliser. Exceptional savings are found in maintenance, utility, and instrument replacement costs. Operational cost can be defined by electricity costs, RO or deionised water supply costs, and equipment maintenance costs.

Q. How energy efficient is the Cox RapidHeat HVHA steriliser?
A. The New York State Pollution Prevention Institute at The Rochester Institute of Technology performed an independent third-party energy study of the COX RapidHeat HVHA steriliser, providing a comparative energy analysis with two conventional tabletop steam sterilisers. As summarized in their report, the COX RapidHeat HVHA steriliser "sterilised small batches of instruments 3x to 6x faster using 84% less energy per cycle vs. steam sterilisers."

Q. Can the cycle parameters of the Cox RapidHeat HVHA sterilisation process be monitored and recorded?
A. The COX RapidHeat HVHA steriliser monitors and records for both electronic and printed storage the critical time-temperature parameters for each sterilisation cycle via the use of a USB flash drive. The flash drive inserts in the steriliser's USB port and records cycle parameters, including start date and time, cycle phase time and temperatures (at one minute intervals), and the cycle status. The cycle status at the end of the record indicates details of the completed sterilisation cycle.