# FREQUENTLY ASKED QUESTIONS

High-Velocity Hot Air (HVHA) dry heat sterilisation represents the cornerstone of CPAC Equipment's RapidHeat™ Steriliser technology. In order to provide a clearer understanding of the operation and performance of RapidHeat sterilisers and the HVHA sterilisation technology, CPAC is providing these documented answers to frequently asked questions.

### 1. How do you define the term "High-Velocity Hot Air" (HVHA) technology that is employed in RapidHeat sterilisers and provide a comparison to the static dry heat sterilisation process.

HVHA dry heat sterilisation employs uniform, high velocity hot air (190°C) within the sterilisation chamber that allows rapid heat transfer for maximizing microbial kill. Unlike static dry heat sterilisers which rely on gravity or low velocity fans to distribute heated air, RapidHeat sterilisers employ HVHA that can sterilise instruments in minutes rather than hours required for static dry heat sterilisation. HVHA sterilisers also have validated cycles and record cycle information.

### 2. Has the HVHA sterilisation process received clearance as a medical device?

The FDA issued clearances for our RapidHeat sterilisers under K872643A and K881371 in 1987 and 1988, respectively. These units have ETL, UL, and applicable CE approvals. CPAC Equipment, Inc., the manufacturer of RapidHeat sterilisers, is an ISO 13485 certified manufacturing facility.

### 3. Is the RapidHeat Steriliser a more complicated mechanical process than a steam steriliser?

No, the RapidHeat Steriliser involves only rapidly moving hot, dry air to sterilise instruments. As such, the only moving mechanical parts of the steriliser 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 boards and outer steriliser housing. There is no vacuum system nor does the unit require water or a drying system. The steriliser is pre-set for thermocouple-controlled temperature and sterilisation cycle times. The unit requires little or no maintenance as compared to the more complicated steam steriliser technology, which requires frequent cleaning and maintenance of all the mechanisms involving the management of steam, water, pressure, and vacuum.

### 4. How does a RapidHeat Steriliser kill microorganisms?

Bacterial spore inactivation by dry heat occurs primarily from DNA damage, unlike wet heat, which kills spores by a combination of other mechanisms. Examination of the mutational events that occur after dry heat exposure has shown that spore DNA has been physically damaged by single-stranded breaks. Further examination has suggested that the process of depurination is the major mechanism by which dry heat causes damage in bacterial spores. The thermal-chemical reaction of deoxyadenosine and deoxyguanosine results in the cleavage of β-N-glycosidic bonds that release adenine or guanine leading directly to single-stranded DNA breaks. Research data suggests that

protective small, acid-soluble spore proteins are less effective at the higher dry heat temperatures, causing depurination and ultimately DNA strand cleavage which can lead to lethal mutational events and cellular death.

### 5. Are there any other compatible HVHA technologies?

There are no other HVHA dry heat sterilisers that can deliver a consistent, uniform heating pattern throughout the sterilisation chamber. Other hot air convection sterilisers don't have the ability to control chamber temperature therefore limiting the application of the steriliser to the sterilisation of only un-wrapped instruments which would also present questionable, uniform sterilisation conditions.

### 6. What is the effectiveness of biological kill (e.g., bacterial spores) required of and achieved with the RapidHeat Steriliser?

RapidHeat sterilisers have been documented via the FDA 510(k) evaluation process to deliver a 12 Log kill of Bacillus atrophaeus spores for all sterilisation cycles of un-wrapped, wrapped instruments, and handpieces. Once instruments have reached the spore kill initiation temperature, the bacterial spore kill rate is 1 Log per 32 seconds for both wrapped and unwrapped instruments. Extrapolation of that rate results in obtaining a 12 Log kill in approximately six minutes from initiation of spore kill.

### 7. How long has the HVHA sterilisation technology been used in dental and healthcare practices?

RapidHeat sterilisers have been in successful use for over 25 years in the dental and healthcare markets.

### 8. Can HVHA sterilisation be used only on metal instruments?

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 RapidHeat sterilisers 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 significantly reduced the number of instruments that are intolerant to dry heat sterilisation conditions.

### 9. Does HVHA sterilisation contribute to instrument stress including corrosion and dulling of instruments?

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 impact on the ability to properly sterilise and shortens the effective lifetime of an instrument, respectively.

HVHA operates at a fraction of the temperatures used in industrial applications. Additionally, unlike steam sterilisation where the corrodible elements of water are present, HVHA employs water-free and moisture-free sterilisation where no corrosion-causing elements exist.

### 10. Is HVHA dry heat sterilisation compatible with dental hand pieces?

RapidHeat sterilisers have 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. Handpiece organic (mineral oil based) lubricants are required to be replaced by a high-temperature synthetic (food-grade) lubricant, such as SteriLUBE. RapidHeat sterilisers have a specific pre-set cycle for the sterilisation of hand pieces.

### 11. Can instruments be pouched or wrapped for the sterilisation process to ensure their continued sterility subsequent to their removal from the HVHA steriliser?

The HVHA steriliser can process both wrapped and unwrapped instruments via pre-set sterilisation cycles. With an HVHA steriliser instruments are pouched in **non-permeable sealed nylon pouches**. Nylon is materially stronger than the semi permeable polythene autoclave pouches, improving puncture resistance from sharp instruments in sterilising and storage. Sterilisation is achieved by conduction of heat alone. The nylon pouch acts as an insulator, so the effective temperature within the pouch is 160$^{o}$C as opposed to the steriliser chamber temperature of 190$^{o}$C. Hence the cycle time for pouched instruments is 12 minutes as opposed to 6 minutes for unpouched instruments.

### 12. Is a drying cycle required of the HVHA steriliser?

No drying cycle is required of the HVHA dry steriliser since the technology relies solely on dry heat to kill microorganisms. Upon completion of the selected sterilisation cycle, the instruments are retrieved from the unit and upon cooling (approximately 5 to 7 minutes) are ready for use.

### 13. What are the times and temperatures required of the HVHA dry heat sterilisation process?

RapidHeat sterilisers operate at 190°C and have been demonstrated to achieve a Sterility Assurance Level (SAL) of 12 Logs for all sterilisation cycles. The temperature and cycle times are pre-set to assure FDA/CE compliance for time and temperature requirements based on load size, configuration, and packaging specifications. Shortest cycle time is 6 minutes for unwrapped instruments, 8 minutes for unwrapped handpieces and 12 minutes for wrapped instruments and handpieces.

### 14. What are the true times required of the total HVHA treatment cycle from start to finish?

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, RapidHeat sterilisers have pre-set sterilisation cycles of 6, 8 and 12 minutes. Door Close to Door Open times are 12, 16 and 20 minutes respectively allowing for cycle warm up and temperature stabilisation. These are true “start-to-finish” cycle times (door locked to door unlocked). No instrument drying cycle is required.

### 15. Is the throughput volume of the RapidHeat Steriliser equivalent to that of comparable tabletop steam sterilisers?

RapidHeat sterilisers have short sterilisation cycle times which allow three to four complete sterilisation cycles per hour. This results in a greater throughput of instruments on a per hour rate.

### 16. What is the comparative cost to operate the RapidHeat Steriliser?

A Comparative Cost Analysis reveals a 50% operating cost savings over a comparable steam sterilizer. Exceptional savings are found in maintenance, utility, and instrument replacement costs. Operational cost can be defined by utility costs, steriliser–required supply costs, and equipment maintenance cost.

### 17. How energy efficient is the HVHA steriliser as compared to comparable tabletop steam steriliser?

The New York State Pollution Prevention Institute at The Rochester Institute of Technology performed an independent third-party energy study of RapidHeat sterilisers, providing a comparative energy analysis with two conventional tabletop steam sterilisers. As summarized in their report, the RapidHeat Steriliser “sterilised small batches of instruments 3x to 6x faster using 84% less energy per cycle vs. steam sterilisers.”

### 18. Can the time and temperature parameters of the HVHA sterilisation process be monitored and recorded?

RapidHeat sterilisers monitor and record 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. A typical printout will display temperature readouts between 188°C and 192°C during the sterilisation cycle.

### 19. What are the utility requirements for HVHA steriliser installation?

RapidHeat sterilisers only require a standard 220-240V, 50Hz, 13-amp socket. No water, drains or other utilities are required.