HVHA - The Ultimate Advancement in Instrument Sterilization

Summary
Dry heat has long been deemed the orphan-child of thermal technologies for sterilizing medical, dental, and veterinary surgical instruments, ranking a distant second to steam (wet) heat sterilization. This has been in part due the relatively long sterilization cycles formerly required to effect microbial inactivation via the dry heat process and the potential for temperature incompatibility with an instrument or its components. While these drawbacks may have been inhibitory in the past, recent advances in dry heat sterilizer design, the introduction of thermal-resistant plastics in instrument manufacture, and recent research supporting the practicality of lower temperature cycles (≤325°F) have made high-velocity hot air (HVHA) sterilization a viable and cost-effective alternative to steam sterilization.

History
The resurgence of dry heat as a legitimate sterilization technology began in 1960 with work conducted by the National Aeronautics and Space Administration (NASA) for ensuring the sterility of lunar and planetary spacecraft. Conducted at the Army BioLabs at Fort Detrick, Maryland under the direction of Dr. Charles R. Phillips, this work led to the selection of dry heat as the only viable sterilization option for total sterilization of planetary and interplanetary spacecraft. Evaluated and found unacceptable as a means of sterilization were steam sterilization and gaseous/liquid chemical sterilants. Dry heat sterilization technology was first used on the Mars Viking I and II Landers in the mid-1970's and continues today as the primary method for sterilizing all planetary and interplanetary spacecraft.[1,2,3]

Although the use of dry heat by NASA was limited to static dry heat (non-moving air), data generated in these studies demonstrated that the rate of heated airflow over a bacterial spore populated surface significantly increased spore destruction rate. This observation was noted by Dr. Keith Cox in the mid 1980's and inspired his development of the patented COX RapidHeat™Transfer Sterilizer. Differing from the traditional dry heat sterilizer in which air remains static (air movement only by gravity convection) or in which air is minimally re-circulated by mechanical convection to enhance heat distribution, this novel approach employed directed, high velocity hot air across the surface of the instruments. The result was a marked reduction in time required for instrument sterilization from hours in a traditional static hot air sterilizer to a few minutes at 375°F in a high velocity hot air (HVHA™) sterilizer. The COX RapidHeat™ Transfer Sterilizer was granted 510(k) status from the U. S. Food and Drug Administration (FDA) in 1987 and 1988 as a Class II (Performance Standards) device. High-velocity hot air sterilization has since been recognized and validated for use in medical and dental offices, laboratories, ambulatory care clinics, and hospitals by the Centers for Disease Control and Prevention in their publications "Guidelines for Infection Control in Dental Health-Care Settings-2003" and "Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008." [4,5] High-velocity air sterilizers have been in use for over thirty years, being recognized by the American National Standards Institute and the US Food and Drug Administration.[6,7]

Instrument Thermal Compatibility

Length of cycle time and high operating temperatures associated with static dry heat sterilizers have deterred the use of advanced "dry heat" sterilization technologies as an acceptable alternative to steam sterilization for medical, dental, and veterinary instrument sterilization. The introduction of high-velocity hot air (HVHA) sterilization technology significantly reduced cycle times, but a reluctance remains to expose instruments to temperatures higher than those used in steam sterilization due to potential temperature incompatibilities. In recent years, the creation of more heat-tolerant materials (e.g., heat- resistant fluoropolymers and silicones) and the replacement of heat-intolerant materials used in medical devices has significantly reduced the number of instruments that are intolerant to the dry heat sterilization conditions. High-temperature–resistant materials (typically Torlon®, Viton™, phenolics, silicones, and polyimides) are tolerant to temperatures of more than 375°F. Their widespread use in the medical industry results in over 90% of instrument compatibility with HVHA sterilization at 375°F (See Appendix: Instrument and Material Compatibility).

Examination of the data presented in Appendix I reveals two distinct sets of chemical compatibilities: (1) Those common disposable products composed of low-temperature compatible materials of 180°F or less and (2) those re-usable products that are temperature resistant to 392°F or higher. Review of the chemical compositions found in medical, dental, and veterinary instruments and associated articles has shown few articles have thermal decomposition points at temperatures between 181°F -391°F. Those materials with low-temperature compatibility of 180°F or less are not compatible with either steam sterilization or dry heat sterilization processes. Those products with temperature resistances of 392°F and above are compatible for both steam and dry heat sterilization processes.

Handpiece high temperature compatibility has been voiced as a concern by many dental practitioners. A recent study conducted by The Dental Advisor and commissioned by CPAC Equipment, Inc. (CPAC) subjected unwrapped handpieces from four different manufacturers to 500 sterilization cycles using the RH-Pro11 HVHA system under its "handpiece" setting at 375°F.[8] At every ten cycles, the handpieces were removed, lubricated, and operated for at least 120 seconds with bur insertion before proceeding to the next ten sterilization cycles. After every 50 cycles, handpieces were operated and braked until stalling at over two minutes to simulate aggressive clinical use and to measure interim performance. Full performance testing was conducted in the initial condition, after 250 sterilization cycles and after 500 sterilization cycles. There was no detectable decrease in performance of noise generation, speed, stall torque or power output after 500 reprocessing cycles with the RH-Pro11 HVHA sterilizer for the four tested handpieces. The noise level difference before and after reprocessing was less than a decibel difference for all handpieces and considered equivalent as small ambient noise changes and differences in actual speed of operation may account for such a small difference. This study demonstrates that performance of dental handpieces is not affected by RH-Pro 375°F HVHA sterilization.

Mechanism of Dry Heat Bacterial Spore Kill

It had long been speculated that dry heat caused cellar damage through the process dehydration, which directly or indirectly affected the genetic system or metabolic systems required for reproduction. This speculation arose from research studies *circa* 1966-1972 demonstrating that within a temperature range of 90°C-135°C (194°F-275°F) a bacterial spore's resistance to dry heat diminished as relative humidity decreased.[1] Concurrently, it was noted by other investigators that high mutation rates resulted in *Bacillus* spore survivors from dry heat exposure.

In 2008 Kempf et al. (Biotechnology and Planetary Protection Group with the NASA Jet Propulsion Laboratory) further investigated the relationship between humidity and temperature in the inactivation of bacterial endospores, expanding dry heat temperature ranges. Although low humidity (25%) decreased thermal resistance at 115°C and 125°C, these results showed no detectable effect at 135°C with a potentially counterproductive effect at 150°C and above when measured against those same temperatures at ambient relative humidity (36% to 66%).[9] This study indicated that a mechanism other than dehydration accounts for bacterial endospore inactivation upon dry heat exposure and has resulted in NASA no longer requiring humidity control as a sterilization parameter.

Attention has shifted to the role of α/β-type small, acid-soluble spore proteins (SASP) and their role in protecting the spore's DNA from the damaging effects of heat, desiccation, oxidizing agents, and ultraviolet irradiation. SASPs accumulate during sporulation to levels high enough to saturate the DNA. The spore's low water content enables these proteins to bind to the spore's DNA in a non-specific manner, tightly encapsulating the DNA, thus excluding water which minimizes the formation of oxidizing radicals; alters DNA's photochemical properties, minimizes UV-generation of thymine dimers; and keeps the DNA rigid to allow for enhanced repair of double-stranded breaks.[10]

Bacterial spore inactivation by dry heat occurs primarily from DNA damage, unlike wet heat, which kills spores by a combination of other mechanisms as demonstrated by SASPs' tight binding to spore DNA, providing essentially complete DNA protection under wet heat conditions.[11] 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 hydrolytically cleavage of β-N-glycosidic bond and releases adenine or guanine which can lead directly to single-stranded DNA breaks. Data suggests that SASPs are less effective at the higher dry heat temperatures, causing depurination and ultimately DNA strand cleavage which lead to lethal mutational events.[12] These studies indicate that the damage generated by dry heat, especially at higher temperatures, causes irreversible DNA damage. This damage may be in the form of lethal mutation events or due to heat induced single-stranded DNA breaks and the formation of thymine dimers, causing the inability to faithfully transcribe or replicate spore DNA.

Mechanisms of Hot Air Conduction

There are three distinct types of dry heat sterilizers as distinguished by their degree of air convection with "convection" being defined as the transfer of heat to the bulk movement of molecules within fluids. Dry heat sterilizers utilize moving air as the fluid to transfer heat to medical instruments and are categorized as: (1) Static or passive hot air sterilizers in which air convection is generated solely by density as hot air rises and cooler air descends; (2) Mechanical low velocity forced-convection sterilizers in which heated air ismoved at less than 20 air changes per minute and which serves to minimize hot and cold areas within the chamber; and (3) High velocity hot air sterilizers in which air is moved at a high rate, such as 200 air changes per minute and in which high velocity flowing air amplifies the rate of heat conduction and improves uniformity of temperature within the sterilization chamber.

Two factors are required for temperature control of a dry heat sterilizer: (1) the ability to modulate air velocity to and through the sterilization chamber and (2) the ability to maintain a uniform and accurately controlled sterilization temperature within the sterilization chamber. Both these factors are interrelated and require integrated control for sterilization temperatures to be achieved and maintained to attain required spore inactivation thresholds in the shortest time possible. This is shown mathematically through:

(1) $Q_{Air} = \dot{m}c(\Delta T)$

Where: Q_{Air} = Heat Conduction in Joules (J) of the Air;
$\dot{m}$ = Mass Flow Rate = Volume Flow Rate of Air times the Density of Air;
c = Specific Heat in J/Kg° C of Air; and
ΔT = Difference in Temperature in ° C between heated air and instrument.

And

(2) $Q_{Instrument} = mc(\Delta T)$

Where: $Q_{Instrument}$ = Heat Conduction in Joules (J) of the Instrument;
m = Mass in Kgs;
c = Specific Heat in J/Kg° C of the Instrument; and
ΔT = Difference in Temperature in ° C between heated air and instrument.

Heated, high velocity dry air serves as a constant-temperature heat source, conducting heat directly to the instrument. For that air temperature to remain constant and to maintain maximum heat conduction efficacy, the temperature of that air must be replenished to replace the heat conducted to the instrument. A closed air handling system that rejuvenates heat-expended air by means of a blower and heating elements provides the means to control a constant and uniform infinite heat source. Equation (1) shows mathematically the heat conduction to instrument from the air, which is directly related to air velocity as defined in the Mass Flow Rate ($\dot{m}$) comprised of air density and volume flow rate. As seen in Equation (1) as the flow rate increases, an increase in heat transfer follows. Increasing airflow velocity is function of blower control which can be software driven.

As applied to medical instrument sterilization, heat conduction to the instrument is additionally governed by the instrument's mass and through the specific heat constant of its composition. Mass and specific heat remain constant through the heating process with the sole variable in Equation (2) being the temperature difference between the instrument and the air as instrument temperature increases. Combining the effects of air velocity and

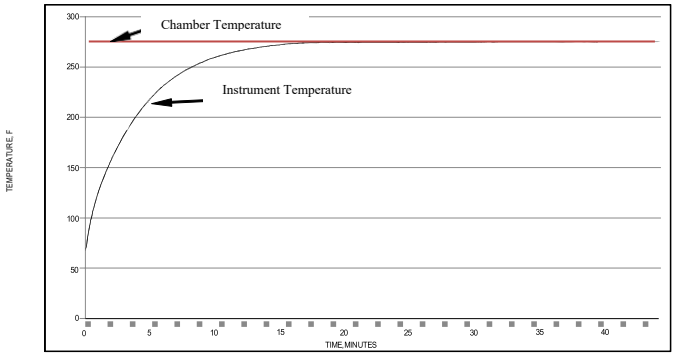
the heat applied to replenish air temperature lost to the instrument provide the means to control the rate of instrument temperature increase and maintain uniform chamber temperature through the duration of designated low-temperature cycles.

Within a dry heat sterilizer heat is transferred from the hot air to the colder instrument. Transfer of heat will continue as a difference in temperature between the air and the instrument remains. Once the two have reached the same temperature, thermal equilibrium has been established and the heat transfer stops. In a dry heat sterilizer, the temperature of the air is constantly replenished so it is the rising temperature of the instrument that will eventually bring the instrument's temperature to equilibrium with that of the designated air temperature.

The rate at which temperature changes is proportional to the rate at which heat is transferred. The temperature of an instrument changes more rapidly if heat is transferred at a high rate and less rapidly if heat is transferred at a low rate. This is shown mathematically in Equation (2) and graphically as displayed in Figure 1 below.

FIGURE 1

Dry Heat Conduction Thermal Profile Over Time



The slope of the instrument temperature is a measure of the rate of heat transfer. Over the course of time, the rate of heat transfer decreases. Initially heat is being transferred at a high rate as reflected by the steeper slopes. As time progresses the slope of the instrument temperature curve decreases. The variable that contributes to the rate of conduction is affected by the temperature difference between the cooler instrument and the hotter air. As the instrument warms, the temperature difference decreases, so the rate of temperature-increase decreases. Asthe temperature difference approaches zero, the rate of heat transfer approaches zero.

Both the temperature of applied heat and its velocity have a combined role in affecting the rate of heat transfer to an instrument. For control of dry heat sterilization at temperatures between 240°F and 375°F, integration of temperature control and air velocity is required to modulate rates of temperature rise during the instrument warm-up phase of sterilization process and for instrument temperature maintenance during the remaining time allotted to ensure the required spore inactivation threshold. For dry heat sterilization to be feasible as a sterilization process, control of the heating elements and the air blower by algorithmic software is essential for both temperature control and processing time efficacy across the range of logistically feasible temperature cycles.

Advances in HVHA Sterilization- RapidHeat Pro Series Sterilizers

To implement the requirements of maximizing sterilization efficacy of heat conduction, the COX RapidHeat™ Transfer Sterilizer was used for the conceptual base for the re-design of a HVHA sterilizer that could provide precisely controlled uniform temperature and airflow. Utilizing computer hardware and software not available during development of the COX RapidHeat™ Transfer sterilizer in the late 1980's, the RH-Pro11 sterilizer has been designed to operate at 375°F having a 7.5-fold larger instrument capacity than its COX predecessor. Total processing times to achieve a 12-Log_{10} kill at 21 minutes for wrapped instruments and 12 minutes for unwrapped instruments as defined by time of process start to time of process completion. There is no need for an instrument drying cycle in this waterless process. A comparison to equivalent steam sterilization total processing time (which includes pre-warming and acquiring designated pressure, the sterilization cycle, and the drying cycle) for wrapped instruments is shown in the Table 1below:

Table 1

Comparison of Total Pouched Instrument Processing Time Between Steam Sterilization and HVHA 375°F Sterilization Technologies

Sterilizer Type	Pre-Warm and to Pressure/Temperature	Sterilization Cycle	Drying Cycle*	Total Processing Time
Midmark M11 270°F, Pouched Instruments	17 Minutes	5 Minutes	30 Minutes	52 Minutes
RH-Pro11 375°F, Wrapped Instruments	9 Minutes	12 Minutes	0 Minutes	21 Minutes

*Default time for total drying; Cycle can be extended to 60 minutes

As seen above the RH-Pro11 can process 2.5 loads in the time it takes for one load to be processed by an equivalently sized Midmark M11 unit. Each RH-Pro11 load can process up to 3.2 kg of wrapped instruments distributed informally on four large trays. Additional RH-Pro11 pre-set processing cycles include those for unwrapped instruments, unwrapped dental handpieces, and wrapped cassettes. D-values (the time required for 90% spore kill) are calculated for unwrapped instruments, wrapped instruments, and wrapped cassettes at 27 seconds, 28 seconds, and 28 seconds, respectively (no D-value studies were performed on unwrapped handpieces due to the nature of that inactivation study). These times amount to approximately a six-minute requirement to inactivate 12 Log_{10} bacterial spores at 375°F with the additional cycle time attributed to the time required for instrument warm-up due to instrument/cassette mass or wrapped versus unwrapped configuration. Since the inauguration of the RH-Pro11, a smaller RH-Pro Series sterilizer, the RH-Pro9 is available for small applications or where space limitations exist. Both countertop-sized units operate at 120V/12 amps or 230V/6 amps with electrical being the sole utility requirement. See Figure 2 below.

Figure 2
RH-Pro11 and RH-Pro9 Sterilizers

Since the introduction of the RH-Pro Series sterilizers operating at 375°F, it was determined that the precise control of temperature and airflow within the chamber offered the ability to operate the unit at lower temperatures and thus make it competitive with those standard temperatures used in steam sterilizers, but without a moisture and pressure environment. It was known that by lowering operational temperatures would increase processing cycle length, but at what extent was undetermined. Studies were undertaken to determine if cycle lengths were logistically possible, utilizing lower temperatures to sterilize instruments or articles in a dry, non-pressurized environment.

Rationale for Expanding HVHA Sterilization to Lower Temperatures

NASA has demonstrated spacecraft components having sophisticated electronics and a myriad of chemical compositions can be successfully sterilized using dry heat technology. Although this technology originally was applied at 238°F in the 1960's and 1970's, NASA has since expanded its sterilization temperature range from 238°F to 392°F to accommodate the vast range of thermal compatibility of spacecraft components and yet minimize the time required for their sterilization when possible. However, dry heat technology has not been applied to medical instrumentation of equal sophistication, complexity, and varied chemical composition of which flexible endoscopes incorporate. With the rise in the transmission of multi-drug resistant organisms during endoscopic procedures from duodenoscopes, bronchoscopes, gastroscopes and colonoscopes (13 cases in 2014 to 1135 cases in 2021), the need for proper cleaning and assured sterilization has been recognized by ANSI/AAMI in their guidance update ANSI/AAMI:ST91: 2021 (ed. 2) "Flexible and semi-rigid endoscope processing in healthcare facilities".[13, 14] With NASA's successful use of dry heat sterilization, High-Velocity Hot Air sterilization offered by the RH-Pro Series sterilizers may provide the means to offer a thermal sterilization technology compatible with the complexity, electronics, and varied chemical composition inherent in endoscope technology. Lower dry heat sterilization temperatures may offer a solution to existing temperature incompatibilities if times required for instrument sterilization could be reduced to make these lower time-temperature parameters logistically implementable.

In applying any particular sterilization technology and its practical usefulness, several factors must be assessed: (1) any negative impact of the sterilization agent on each component within the device during the sterilization process; (2) the ability of the sterilization agent to reach all surfaces, internal and external, of the device at the level of agent required for the time required; (3) the ability to monitor the sterilization agent's effectiveness in achieving the spore inactivation threshold; (4) the ability of the process to be logistically employed within a healthcare or veterinary facility; (5) cost-effectiveness; and (6) the ability of the process to proceed in a reasonable time to achieve the required spore kill threshold. For a sterilization process to be effective and acceptable, each of these factors must be met.

The primary methodology currently used in healthcare to sterilize instruments is steam sterilization. This methodology utilizes water steam, at various pressures, to generate a standard sterilization temperature range between 250°F to 272°F, at diminishing times of exposure as the temperatures increase. Although functional for most metal devices and high temperature plastics, steam sterilization has use limitations for materials, construction, and function in the more sophisticated devices employing optics and electronic circuitry. The wet environment in the presence of pressures ranging from 15 to 30 pounds per square inch provides conditions that are incompatible with these devices. As examples, many types of endoscopes used in health screenings and surgical repair are incompatible with the steam sterilization process. This has led to the use of (1) non-thermal, chemical agent sterilization technologies or (2) techniques employing submersion in disinfecting chemical solutions as the only means to provide acceptable device processing. Those technologies using gaseous, vaporous, or liquid sterilants, are subject to additional factors that reduce the effectiveness of the chemical agent. These factors include (1) the inability of the chemical agent to contact all instrument surfaces with the required contact time and agent concentration, (2) the potential for reduced chemical agent effectiveness due to organic residues or other materials that reduce chemical agent effectiveness, and (3) the inability to monitor the effectiveness of the sterilization process to verify required microbial inactivation.

Although the use of dry heat at significantly lower temperatures would increase the time required to sterilize an instrument, these processing times are not inordinate in comparison with current chemical sterilant or high-level disinfectant technologies currently in use, when considering times necessary for treatment and the time necessary to eliminate any chemical residue from the instrument before its re-use. Depending on the highest temperature tolerated by the instrument, times required for a 12-Log bacterial spore inactivation will vary from 1 hour at 300°F, to 2 hours at 280°F, and 4.5 hours at 275°F as demonstrated within CPAC's RapidHeat™ Pro Series sterilizers adapted for lower temperature sterilization (See Table 2). These time-temperature conditions provide for the spore inactivation level required, with cycle times that are inclusive of instrument warm-up to spore inactivation temperature and the holding time required at that temperature. Since dry heat is a non-water, nonchemical technology, the instrument requires no additional time for drying or removal of chemical residue after the cycle is complete. Once cool, the instrumentis ready for immediate use.

Low-Temperature Cycle Results

Studies were conducted by CPAC to ascertain the D-values (time required for a 1 Log_{10} reduction of bacterial spores) for *Bacillus atrophaeus* spores at specific temperatures over a range of 250°F through 320°F within RH-Pro11 and RH-Pro9 HVHA sterilizers. Calculation of these D-values (e.g., time required to inactivate 90% of the spore population) provide the basis for calculating and projecting the total time necessary to sterilize an instrument at a particular temperature. It should be stated that these D-values are calculated under the conditions prescribed (see below) for sterilizing instruments in the RH-Pro11 and RH-Pro9 and should not be viewed as the true D-values for *Bacillus atrophaeus* spores as obtained under ANSI specifications. This study focused on the impact of the required time necessary to kill the 1.0 x 10^6 spores (6.0 Logs) on biological indicator strips at 250°F, 270°F, 275°F, 280°F, 300°F, 320°F, and 340°F with minimal temperature barrier interference. From the data shown in Table 2 D-values can be ascertained for each prescribed temperature.

Table 2
Low-Temperature D-Value Determination

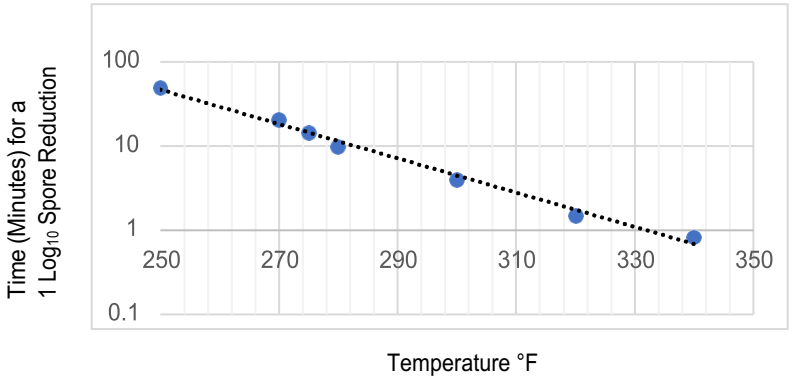
Exposure Temperature °F	Time to 6 Log_{10} Kill (Minutes)	Time to 12 Log_{10} Kill (Minutes)**	D-Value* (Minutes)
340	<5	<10	<0.83
320	10	20	1.7
300	18	36	3.0
280	60	120	10
275	86	172	14.3
270	125	250	20.8
250	300<T<325	600<T<650	50<T<54

*D-value is equal to the time it takes to inactivate 90% of the spores present or a spore reduction of 1-Log_{10}

**By extrapolation

Plotting the D-value against the temperatures at which they were measured results in a linear graph when plotted semi-logarithmically (Figure 3). This graphical representation allows a Z-value to be calculated. The Z-value is a term used in microbial thermal death time calculations. It is the number of degrees the temperature must be increased to achieve a tenfold (i.e., 1 Log_{10}) reduction in the D-value. The Z-value resulting from this graph is 50°F.

Figure 3
Z-Value Determination



A comparison can be made of D-Values obtained by NASA and CPAC over a range of temperatures between 270°F and 320°F. The NASA values presented below in Figure 4 were obtained by using the following equation generated from NASA's D-value data.[9] This equation is used by NASA and its subcontractors for sterilizing spacecraft components between 125.1°C (257°F) to 170°F (338°F):

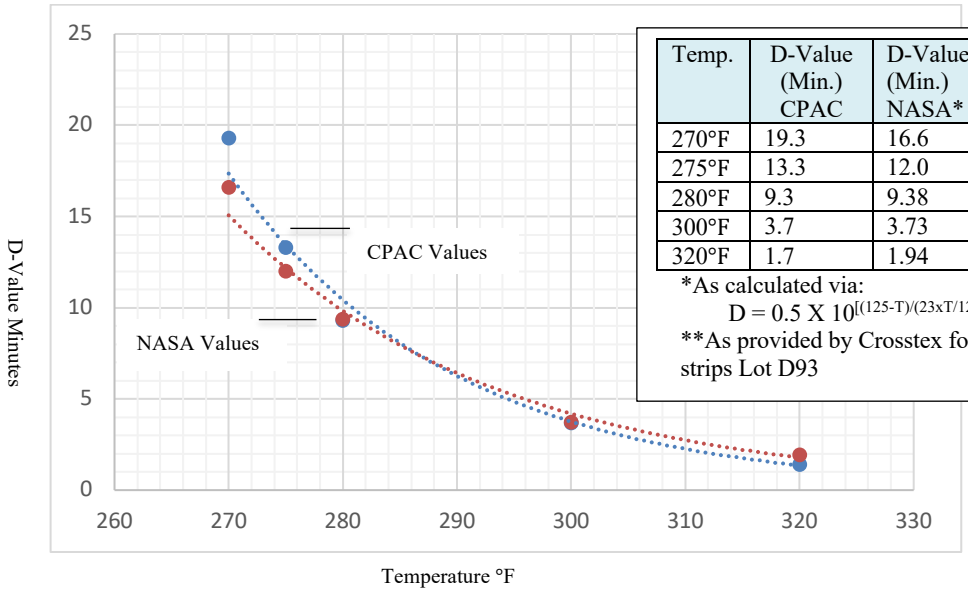
$$D = 0.5 \text{ X } 10^{[(125-T)/(23xT/125)]}$$

Where: T = temperature in °C and D-value is in hours

Plotting the CPAC and NASA derived D-Values versus temperature results in the following comparative representation seen in Figure 4:

FIGURE 4

Graphical and Tabular Comparison of NASA and CPAC Derived D-Values



Temp.	D-Value (Min.) CPAC	D-Value (Min.) NASA*	D-Value (Min.) SPS**
270°F	19.3	16.6	-
275°F	13.3	12.0	-
280°F	9.3	9.38	-
300°F	3.7	3.73	-
320°F	1.7	1.94	1.7

*As calculated via:
$D = 0.5 \text{ X } 10^{[(125-T)/(23xT/125]}$
**As provided by Crosstex for B.a. spore strips Lot D93

Using D-Value data from the spore strip inactivation analysis summarized in Table 2 provides the basis from which to determine the length of time necessary for achieving a 6-Log_{10} kill at each of the three pre-set temperatures selected for inclusion on the RH-Pro Series sterilizers. Thermocouple and biological indicators were concurrently run to monitor instrument temperature and the time required to inactivate 6 Log_{10} spores once operation temperatures (e.g., 320°F, 300°F, 280°F,) were achieved. A summary of the times required for instrument warm-up, for achieving a 6-Log_{10} kill, and achieving a 12-Log_{10} kill are provided in Table 3 and summed to provide total processing time for each cycle under prescribed loading conditions.

Table 3
RH-Pro11 D-Value and Cycle Times (in Minutes)

Temp. Setting RH-Pro11*	Warm-Up Cycle (Minutes)	D-Value (Time in Minutes	Time to 6 Log_{10} ½-Cycle**	Time to 12 Log_{10} (Full Sterilization Cycle)	Total Processing Cycle (Time Required for Warm-Up and 12-Log Kill)
320	22	1.7	10	20	42 Min.
300	22	3.0	18	36	58 Min. (1Hr.)
280	22	8.7	52	104	126 Min. (2 Hr.)

*Loading conditions defined by instrument weight and total load weight per tray for pouched instruments
**As Correlated with 6 Log Biological Spore Kill

As seen in the data obtained from these instrument studies, the D-values obtained from the instrument studies were consistent with those obtained from the D-Value data generated from spore strip exposure only (Table 2).

It is apparent that Low-Temperature instrument processing times for temperatures at least as low as 280°F (2-hour total processing time) remain competitive with those total processing times required by steam sterilization. For those sophisticated items affected by moisture andpressure at similar temperatures, HVHA may offer a significant sterilization alternative to other sterilization or high disinfection technologies.

Low-Temperature HVHA Sterilization as an Alternative to Steam Sterilization
Low-Temperature HVHA sterilization offers many advantages over steam sterilization. In addition to a water-free and pressure-free sterilization environment which reduces mechanical complexity and high maintenance costs, instruments HVHA-processed are not subjected to moisture and inherent instrument corrosion of steam sterilization. Another advantage is the low-temperature compatibility with many wraps, pouches, and other disposables used to package instruments and packs in a steam sterilization environment at temperatures ≤325°. At higher dry heat temperatures, those disposables are susceptible to adhesive failure, partial melting, and failure of material integrity. In these circumstances, other construction materials are necessitated such as nylon or polyester to avoid packaging failures. In a healthcare or veterinary environment in which both steam and HVHA sterilization may be concurrently operated, it would be best to utilize products compatible with both sterilization processes to further reduce cost of operation and minimize the potential for their misapplication. In the situations in which HVHA sterilization totally replaces steam, wrap and pouch compatibility between process ensures an easy logistical transition from steam to HVHA.

In veterinary applications this is particularly true for reusable wraps, drapes, and towels which, in most instances, are composed of a 50:50 mix of cotton and polyester. At the elevated dry heat temperatures of >340°F the cotton in this fabric tends to scorch and discolor over time, limiting their effective-use lifetime. 100% polyester construction of these reusables eliminates this problem, but would involve the replacement of the typical, less costly cotton/ polyester blend articles. It has been demonstrated in the HVHA Pro-Series sterilizers operating at 320°F - 325°F that no degradation or discoloration of these cotton/polyester blend reusables is seen during their normal lifetime. Veterinary also will use unsterilized gauze pads, preferring to sterilize them within veterinary packs containing

specific sets of wrap, drapes, towels, and instruments as defined for the surgery to be performed. Gauze pads are generally a cotton/rayon blend and are also compatible at temperatures of 320°F - 325°F.

Summary

Over the last sixty years NASA has demonstrated that hot air conduction is the most effective methodology for spacecraft component sterilization. Referred to as the "'gold standard' for microbial reduction", hot air conduction "remains the only NASA-approved method for penetrating microbial reduction for encapsulated bioburden."[3] This methodology has been advanced by CPAC providing high-velocity air movement and heating control to improve upon the heat conduction process, culminating in the development of the RapidHeat™ Pro-Series HVHA sterilizers. Comparison of NASA- and CPAC-derived D-values obtained over a range from 270°F to 320°F shows a marked similarity between D-values, a testament to the consistency and precision of the temperature control inherent in RH-Pro Series design. Having the ability to operate over a wide range of lower temperatures with the assurance of achieving and documenting required sterility levels of 6 Log_{10} to 12 Log_{10}, CPAC's high-velocity hot air (HVHA™) technology meets the sterilization requirements demanded of medical, dental, and veterinary professionals and has the potential required to sterilize sophisticated medical instrumentation such as flexible endoscopes.

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About the Author

Nelson S. Slavik, Ph.D., is senior vice president of Integrated Medical Technologies, Inc. Responsibilities include research and development of infection control, patient safety, and sterilization technologies. Academically, he holds dual graduate degrees from the University of Illinois at Urbana-Champaign, a Ph.D. in Microbiology and Master of Science in Microbiology/Biochemistry. He served on the faculty of the Department of Health and Safety Studies at the University of Illinois at Urbana-Champaign and as the Biological Safety Director for the campus for over ten years. He has authored over 80 articles on environmental and occupational safety legislation, regulations, and their application and has participated in over 100 healthcare workshops and seminars. He currently holds three patents relating to high-velocity hot air sterilization technology.

APPENDIX – INSTRUMENT AND MATERIAL COMPATIBILITY