# RapidHeat

## HIGH-VELOCITY HOT AIR STERILIZATION

## A Comparison to Steam Sterilization


CPAC
ENVIRONMENTAL SOLUTIONS

# CONTENTS



# EXECUTIVE SUMMARY

Recent advancements by CPAC Equipment, Inc. (“CPAC”) in the commercial design and engineering of tabletop versions of what the CDC describes as “forced-air” dry heat sterilization prompted CPAC and its Director of Research and Development, Dr. Nelson Slavik (author) to conduct research that would validate the effective application of “low-temperature” forced-air technology in the sterilization of medical instrumentation.

***This paper presents scientific evidence and research demonstrating that CPAC’s High-Velocity Hot Air (HVHA™) sterilization technology at 320°F is comparable to steam sterilization at 270°F in total processing times, sterilizer load capacities and instrument material compatibility.***

The ability of HVHA sterilizers to control and maintain set temperatures across a broad temperature range has led to the development of a novel approach for determining D-values under actual sterilization conditions.

During microbial spore reduction efficacy studies, a mathematical equation was derived by plotting the acquired set of D-values against their respective temperatures, enabling a D-value to be obtained for any temperature ranging from 250°F through 320°F.

Calculations can now determine the amount of spore inactivation that has occurred throughout the HVHA sterilization process. Results reveal that HVHA at 320°F achieves greater spore inactivation in lesser processing time when compared to the traditional time/temperature profiles of steam sterilization.

# INTRODUCTION

Since the dawn of medical device thermal sterilization, steam under pressure has been the primary, most universal technology to sterilize instruments. Often referred to as autoclaving, steam's principal advantage over the use of static dry heat sterilization has been a faster turnaround of instrumentation at lower temperatures. However, with recent corroborative studies of HVHA sterilization at equivalent low temperatures, the landscape of medical device sterilization is changing.

To establish a valid comparison, healthcare practitioners and infection control professionals should first dismiss negative opinions they harbor about limitations of dry heat sterilization. Most of what has previously been publicized in medical and dental trade journals or written in professional and governmental medical guidelines is outdated, with some referenced material published over 55 years ago. Incomplete and misleading information perpetuates the idea that dry heat sterilization is limited in its application and requires excessively high temperatures and long cycle lengths.

In support of dry heat as a legitimate and effective sterilization technology, an extensive study was conducted of NASA's findings in their search for the best method to decontaminate space vehicles for the planned exploration of potentially habitable planets. NASA views dry heat sterilization as "the 'gold standard' for microbial reduction and that dry heat remains the only NASA-approved method for penetrating microbial reduction of encapsulated bioburden".[1] This static dry heat process has been used as the primary option for the sterilization of planetary and interplanetary spacecraft since the Viking (I and II) Lander program in the mid-1970s, sterilizing over 61,000 spacecraft components at temperatures ranging from 233°F (111.7°C) to 293°F (145°C) depending on component thermal sensitivity to achieve 6-$Log_{10}$ bacterial spore inactivation.[2,3] Since then, NASA has expanded the sterilization temperature range upwards to 392°F (200°C) as new thermal resistant materials were created, furthering NASA's reliance on dry heat sterilization as their "Gold Standard" in achieving spacecraft sterility.

# HISTORY OF RAPIDHEAT STERILIZATION

The revolutionary breakthrough in dry heat sterilization began in the late 1980s when Dr. Keith Cox developed and patented the Cox RapidHeat™ Transfer Sterilizer which enhanced heat conduction by employing directed, high-velocity hot air across dental and medical instruments, allowing for faster sterilization times. This development marked a reduction in time required for instrument sterilization from hours in a traditional static-heat sterilizer to minutes in a RapidHeat Transfer sterilizer. The Cox RapidHeat Transfer Sterilizer was granted FDA 510(k) clearance in 1987 and 1988, operating at 375°F to achieve the required 12-$Log_{10}$ spore reduction threshold in 6 minutes and 12 minutes respectively, for unwrapped instruments and wrapped (pouched) instruments. After the patent and manufacturing rights were subsequently sold to CPAC Equipment, Inc. (CPAC) a company later acquired by IMT, there began an ambitious plan to improve the capabilities of RapidHeat, expanding its application in the fields of dentistry, animal care, patient care, life science, and materials science.

Although the introduction of the Cox RapidHeat Sterilizer offered considerably reduced cycle times, the anticipated high level of demand of the general dentistry market was tempered by the uncertainty of HVHA technology at its higher temperature to sterilize certain steam-tolerant instruments. This issue has largely been diminished in recent years as the introduction of more high heat-tolerant polymers, polyimides, silicones, phenolics, and other materials used in the manufacture of instruments has considerably narrowed the number of

instruments that HVHA's 375°F temperature cannot sterilize. However, despite HVHA's proven advantages over steam, including faster instrument turnaround, no distilled water, no instrument corrosion, less energy usage, inability to penetrate biofilm, and the absence of periodic costly maintenance, there continues to be a general apathetic view toward dry heat sterilization.

HVHA lower temperature research and development was initiated by CPAC with the objective of confirming the cost-effective and efficient sterilization process at a level that convinces HVHA skeptics to replace the expensive and cumbersome steam sterilization process. Engineering design modifications and software enhancements improved the original Cox RapidHeat Transfer technology making it functionally easier to incorporate lower sterilization temperatures and increase instrument compatibilities while maintaining sterilization cycle times that are logistically compatible with those of steam sterilization.

***This precision of temperature control coupled with high-velocity heated air amplifies the process of heat conduction throughout the instrument load, significantly decreasing the time necessary for instrument sterilization.***

These enhancements have allowed the RapidHeat sterilizers to maintain precise temperature exposure and control throughout a sterilization process in a temperature range from 250°F to 375°F. The HVHA process achieves rapid air heating while generating air temperature uniformity throughout the sterilization chamber. This process involves computer-assisted precision air heating and control at air velocities that result in 200 and 300 air exchanges per minute within the sterilization chamber. This precision of temperature control and reduced maintenance coupled with high-velocity heated air amplifies the process of heat conduction throughout the instrument load, significantly decreasing the time necessary for instrument sterilization.

The results of the studies presented in this document are in contrast to those stated by the CDC in its "Guideline for Disinfection and Sterilization in Healthcare Facilities" (2008 with a 2019 update). These guidelines state time-temperature relationships for dry heat sterilization to be 60 minutes at 340°F, 120 minutes at 320°F, and 150 minutes at 300°F based on just one cited publication, a 55-year-old 1969 reference.[4] The CDC makes only a passing comment that "forced-air" type dry heat sterilizers "permit(ting) a more rapid transfer of heat from the air to the instruments." There is no mention of cycle length reduction. There are also no referenced documents for "forced-air" dry heat sterilizers, although the Cox RapidHeat Transfer Sterilizer has had FDA clearance since 1987 and has been in continued dental medical use since that time.

The antiquated assertion of dry heat's excessively high operational temperatures and long processing times are no longer relevant in view of the technological advances incorporated into the modern HVHA sterilizers. This paper presents indisputable proof from CPAC's low-temperature HVHA studies that today's modern RapidHeat HVHA sterilizer is equal to or superior to steam sterilization in total processing times, load capacities, and instrument/packaging thermal compatibility.

# DYNAMICS OF RAPIDHEAT STERILIZER MICROBIAL INACTIVATION

Technical advances in the RH-Pro Series sterilizers have resulted in the ability to precisely control and maintain a set of temperatures ranging from a 250°F to 320°F. This significant accomplishment has made it possible to establish a mathematical gauge of the sterilization process. Better process measurement has shown that previous cycle durations were excessively long. These advancements have enabled the reduction of cycle lengths and sterilization temperatures to achieve HVHA temperatures and cycle lengths comparable with steam sterilization while maintaining similar thermal compatibilities.

The study protocols were designed to mimic real working conditions during RH-Pro Series operation, using commercially available spore strips, instrument wrap, and dental and medical instruments. Microbial spore inactivation is defined by $Log_{10}$ kill, where 1-$Log_{10}$ kill is equal to a 90% inactivation or the reduction of a microbial population to one-tenth its original number. The time necessary to achieve a 1-Log kill at any given temperature is called a D-value. It is the ability to derive accurate D-values at any temperature that allows the cumulative incremental $Log_{10}$ kill to be calculated during the full course of the HVHA sterilization process. As discussed further, the novel D-value assessment employed with RH-Pro HVHA sterilization enables:

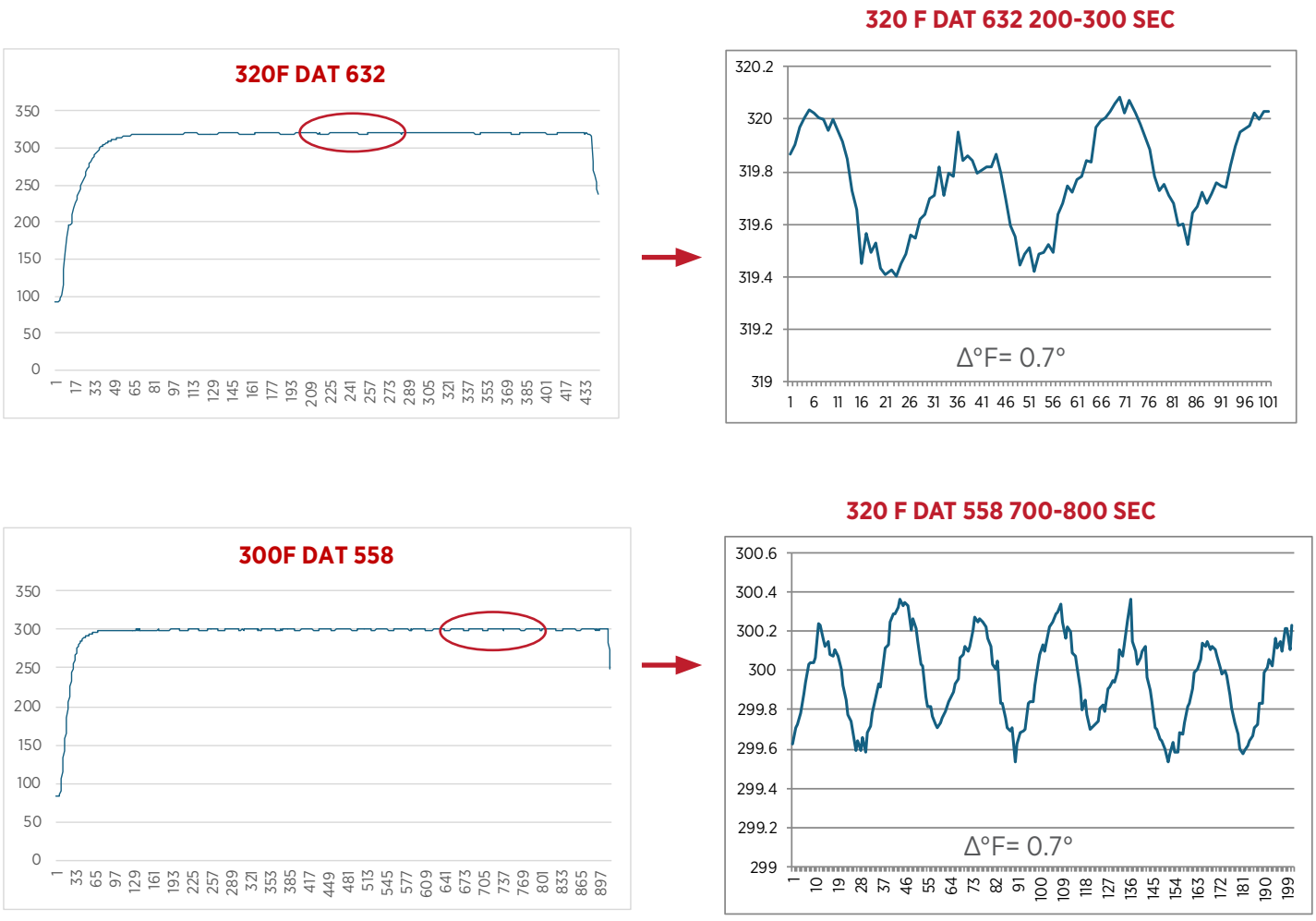
- **Calculation of D-Values with precise and consistent measurements for temperatures ranging from 250°F to 320°F.**
- **Rapid heating of the spores and their carrier to the selected temperature setting.**
- **Remarkable temperature stability of no more than +0.4°F deviation from the mean throughout each time-temperature profile (e.g., 0.3°F deviation at 250°F for 90 minutes).**
- **Correction of spore inactivation occurring during temperature ramp-up and after-cycle cooling.**
- **Data validity by obtaining linear semi-log plots when graphing D-values versus their respective temperature.**
- **Derivation of a mathematical equation from which a D-value can be obtained for any temperature ranging from 250°F through 320°F.**
- **Calculation of the incremental contribution of spore inactivation throughout the sterilization process and quantitatively document total spore inactivation efficacy for a complete cycle.**
- **Demonstration of similarity when comparing CPAC- with NASA-obtained D-values.**

D-value Calculation begins with the ability to control and maintain set temperatures during the entire course of sterilization cycles at temperature settings ranging from 250°F to 320°F. Temperature measurements were made at 320°F, 310°F, 300°F, 290°F, 280°F, 270°F, and 250°F by inserting a thermocouple sensor into the spore strip envelope directly against the spore strip. Running trials at times approximating the time required to kill all $1.9 \times 10^6$ spores (manufacturer-validated) per strip, a “bracketing” of “Growth” versus “No Growth” of each cultured strip provided the minimum amount of time required for total spore kill.

Figure I shows the time-temperature profile of two of the seven selected temperature cycles (320°F and 300°F). The left column displays the entire cycle. The circled area on each graph represents the location of the expanded graphical area shown in the column directly to the right. As seen for each temperature selected, there is a rapid rise in temperature followed by a steady, consistent maintenance of the selected temperature. The right-hand column of Figure I denotes the temperature deviation from the temperature's wave crest to trough. This temperature deviation across all seven temperatures studied ranges from 0.6°F to 0.8°F with a temperature deviation from the mean ranging from 0.3°F to 0.4°F.

## FIGURE I

### Time-Temperature Profiles of Representative D-Value Trials




Adjusting to a spore population of 1.0 x $10^6$ and accounting for spore inactivation during temperature "ramp-up" and "after-cycle" cooling (see Figure 1), adjusted D-values for each selected temperature are shown in Table I and are plotted semi-logarithmically against their respective temperature in Figure II (following page).

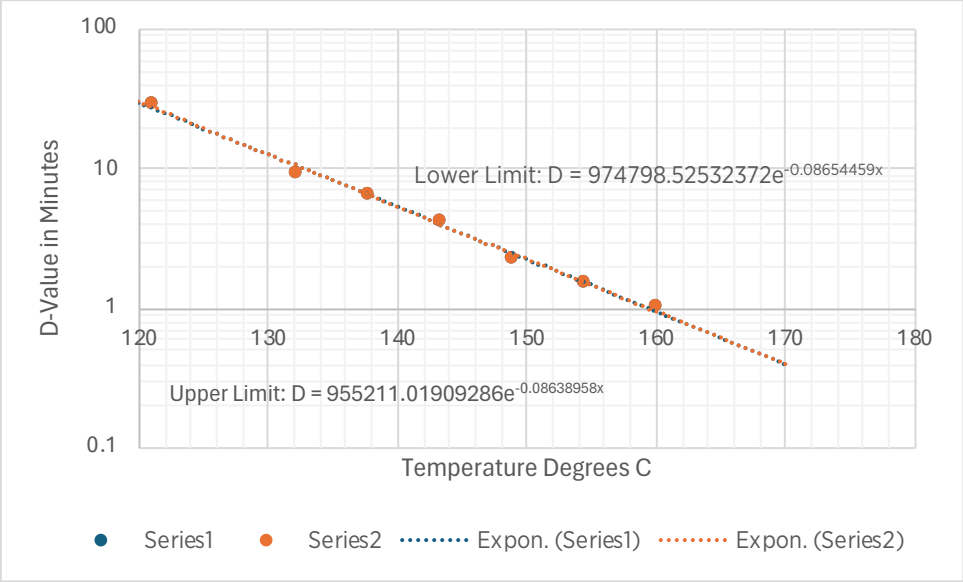
# TABLE I

## Adjusted D-Values with Both Ramp-up and After-Cycle Phase Accounting

| Trial Temp °F/°C | Average Temp °F | Upper-Limit D-Value (Mins.): Non-Adjusted/Adjusted | | Lower-Limit D-Value (Mins.): Non-Adjusted/Adjusted | |
|---|---|---|---|---|---|
| 320/160 | 319.68 | 1.20 | 1.01 | 1.11 | 1.02 |
| 310/154.4 | 310.43 | 1.70 | 1.53 | 1.61 | 1.53 |
| 300/148.9 | 299.85 | 2.50 | 2.26 | 2.41 | 2.26 |
| 290/143.3 | 290.23 | 4.50 | 4.20 | 4.41 | 4.21 |
| 280/137.8 | 279.92 | 6.90 | 6.46 | 6.81 | 6.46 |
| 270/132.2 | 270.21 | 10.00 | 9.44 | 9.01 | 9.44 |
| 250/121.1 | 250.24 | 31.00 | 29.61 | 30.01 | 29.62 |

# FIGURE II

## Adjusted CPAC Upper-Limit D-Values Versus Adjusted Lower-Limit D-Values




The D-value data obtained demonstrates remarkable linearity, as should be the case when D-values are plotted semi-logarithmically against their respective temperatures. This linearity with very little data point deviation from the generated graph provides a solid basis for using the generated equations that define each of the resulting exponential slopes (Figure II). The semi-log plots generated from the lower- and upper-limit adjusted D-values are almost identical, further substantiating the validity and accuracy of this method.

# NASA RESEARCH COMPARISON

To further the validity of CPAC's data, a comparison is made with data obtained by NASA. Although NASA's D-value data was obtained by inactivating spores by heat conduction using heated silicone oil, the data comparison demonstrated remarkable similarity.[5] In this study, NASA found that D-values generated from 135°C (275°F), 150°C (302°F), and 170°C (338°F) for both ambient and controlled humidity were statistically the same at a 95% confidence level. In plotting the ambient humidity data with ramp-up adjustment versus temperature, a semi-logarithmic graphical plot of D-values (Table II) versus temperature is shown Figure III with resulting generated exponential slope equation. A graphical comparison of the Adjusted NASA- and Adjusted CPAC-derived D-values (Table II) is also shown in Figure III. As seen, the two slopes are remarkably similar between 250°F and 340°F further validating CPAC data.

## TABLE II

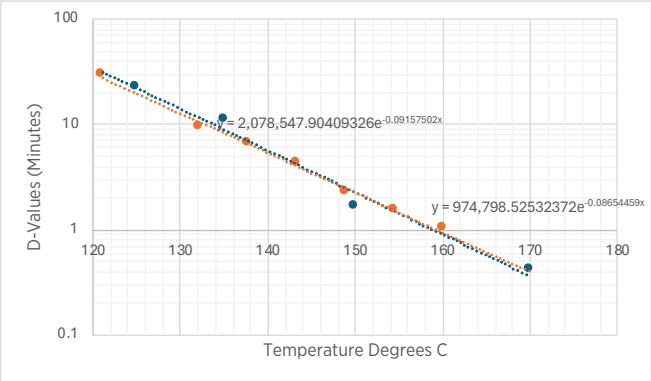
### Comparison of NASA and CPAC D-Values Adjusted

| Temperature °C/°F | CPAC D-Values Ramp-Up and After-Cycle Adjusted Upper-Limit | NASA D-Values Ramp-Up, 3-Sigma Adjusted |
|---|---|---|
| 121.1 (250) | 29.61 | |
| 125 (257) | | 21.9* |
| 132.2 (270) | 9.44 | |
| 135 (275) | | 10.8 |
| 137.8 (280) | 6.46 | |
| 143.3 (290) | 4.20 | |
| 148.9 (300) | 2.26 | |
| 150 (302) | | 1.65 |
| 154.4 (310) | 1.53 | |
| 160 (320) | 1.01 | |
| 170 (338) | | 0.41 |

*Controlled Humidity Measurement

## FIGURE III

### Comparison of NASA 3-Sigma Adjusted D-Values with CPAC Adjusted Upper-Limit D-Values




Z-values from NASA (3-Sigma and ramp-up adjusted) and CPAC (ramp-up and after-cycle adjusted) were calculated from their respective slope-derived equations (Figure III) to obtain the temperature difference spanning 10.0 $Log_{10}$. A difference in Z-value is calculated below:

Z-Value NASA 3 Sigma =133.711°C (10.000 Minutes) – 158.853°C (1.000 Minutes) = 25.14°C
Z-Value CPAC Adjusted High = 132.733°C (10.001 Minutes) – 159.331°C (1.001 Minutes) = 26.59°C
(Z-Value CPAC Adjusted High) – (Z-Value NASA 3 Sigma) = 1.45°C

The D-value and Z-value similarity between NASA and CPAC data is remarkable considering the two different approaches used to calculate D-values, leading to the credibility of the D-value data generated by CPAC across a broad range of temperatures (250°F to 340°F). It should be noted that humidity does not influence dry heat D-values from 275°F to 340°F. Calculations of these D-values provide the basis for calculating and projecting the total time necessary to sterilize an instrument at a particular temperature setting to determine if sterilization times at lower temperatures were feasible in applying the HVHA process within healthcare and veterinary care. As such, D-values obtained by CPAC's equations can be reliably used to accurately determine the amount of spore reduction occurring during instrument sterilizing cycles for the RH-Pro9 and RH-Pro11 sterilizers between 275°F - 340°F.

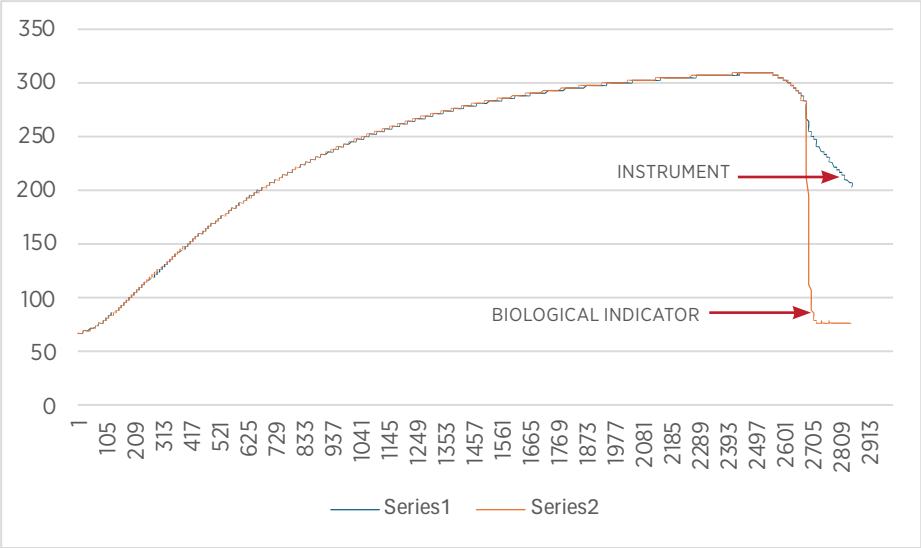
# DETERMINING STERILIZATION CYCLES FOR RAPIDHEAT STERILIZERS

The equations derived from the semi-log plots of D-values versus their respective temperatures may be used to define D-values for all temperatures within this range. This allows a quantitative measurement of $Log_{10}$ reduction for any sequential time-temperature interval during the full sterilization cycle. Summing these $Log_{10}$ reductions over the sterilization cycle can quantitatively determine the length of the sterilization cycle needed to meet the sterility and Sterility Assurance Level (SAL) requirements for instrument sterilization for varying instrument loads and types for any sterilization temperature. Coupled with the use of biological indicators to demonstrate actual half-cycle spore reduction (> 6-$Log_{10}$), the use of D-values can accurately define the additional length of the cycle necessary to achieve a total 12-$Log_{10}$ spore reduction for the SAL.

The studies undertaken involved establishing prescriptive sterilization cycles by defining challenge loads. As each of the available pre-set cycle conditions differs due to load construction, size, and mass, so must the construction of each cycle's Biological Indicator Validation Test for it to be logistically valid. Instrument surrogates were constructed that were identical to each challenge load and offered identical time-temperature profiles for both the attached biological indicators and instrument to accurately correlate spore kill that would occur on the instrument and the biological spore strip. Trials were conducted to determine the best barrier configuration for each challenge load to achieve temperature parity between the instrument and spore strip. See Figure IV.

## FIGURE IV

### Temperature Comparison Between a Large Instrument and Biological Indicator



Once achieving time-temperature parity between the biological indicator and instrument as shown above, the conditions have been established that allow for a comparable $Log_{10}$ spore measurement of the biological indicator and the instrument. The amount of $Log_{10}$ kill (spore reduction) that occurs during a half sterilization cycle can be determined by dissecting the time-temperature profile into temperature segments. By averaging the temperature within that segment applying the D-value of that averaged temperature, and dividing the length of time in minutes for that temperature segment by that segment's D-value, a $Log_{10}$ kill contribution can be calculated for that time interval. A summation of each time interval's $Log_{10}$ kill contribution results in the total $Log_{10}$ kill that has occurred during the half cycle.

In Table III $Log_{10}$ kill contributions are defined in 10-degree temperature intervals beginning at 240°F and progressing through the end of the sterilization process half-cycle. The $Log_{10}$ kill contributions for each temperature increment are additive and, upon their summation, equal to 6.90 and 6.61 Logs, respectively for the biological indicator and instrument. The "No Growth" results from culturing the biological indicator are consistent with the 6-plus $Log_{10}$ reduction shown by the $Log_{10}$ kill contributions. To determine the time necessary for achieving the necessary Sterility Assurance Level (SAL) of an additional 6 Logs, a D-value is calculated for the final temperature that was recorded from the half-cycle (i.e., a D-value of 1.66 minutes at 308°F from Table III). Multiplication of the D-value by the 6-$Log_{10}$ reduction required by the SAL equates to a 10-minute addition to the half-cycle sterilization time of 42 minutes or a total large instrument sterilization cycle time of 52 minutes under full load conditions. This process is repeated for each prescribed 320°F instrument sterilization cycle for the RH-Pro9 and RH-Pro11 sterilizers, as provided in Table IV.

## TABLE III

### Calculation of Incremental $Log_{10}$ Reduction During Large Instrument Sterilization Cycle

| Temp Range °F | Time Range (Seconds) | | Temp Avg. of Range °F | | D-Value (Minutes) of Avg. Temp | | $Log_{10}$ Kill Contribution | |
|---|---|---|---|---|---|---|---|---|
| | BL | INS | BL | INS | BL | INS | BL | INS |
| 240's | 96 | 98 | 245.1 | 245.1 | 35.31 | 35.31 | 0.05 | 0.05 |
| 250's | 111 | 114 | 255.1 | 255.1 | 22.18 | 22.18 | 0.08 | 0.09 |
| 260's | 133 | 135 | 265.2 | 265.1 | 13.87 | 13.93 | 0.16 | 0.16 |
| 270's | 164 | 169 | 275.2 | 275.2 | 8.71 | 8.71 | 0.31 | 0.32 |
| 280's | 220 | 219 | 285.3 | 285.3 | 5.45 | 5.45 | 0.67 | 0.67 |
| 290's | 320 | 324 | 295.4 | 295.4 | 3.41 | 3.41 | 1.56 | 1.58 |
| 300-end | 519 | 499 | 305.0 | 304.8 | 2.18 | 2.20 | 3.97 | 3.78 |
| Half-Cycle Processing Time = 2528 secs. = 42.08 mins. | | | | | | **TOTAL** | **6.90 NG*** | **6.61** |
| Final Temperature 308°F; D308°F=1.66 minutes • SAL Time=6 Logs @ 1.66 minutes/Log = 9.96 minutes | | | | | | | | **6.00** |
| **TOTAL $LOG_{10}$ REDUCTION** | | | | | | | | **12.61** |
| **TOTAL CYCLE TIME** | | | | | | | | **52 Min.** |

*No Growth of the biological indicator after the completion of this half-cycle (>6 $Log_{10}$ Reduction)

## TABLE IV

### Summary of Half- and Full-Cycle Times with Load Characteristics

| CYCLES: RH-Pro11 | ½-Cycle • Minutes | Full Cycle • Minutes | Maximum Weight/Tray | No. of Trays |
|---|---|---|---|---|
| Small Instruments | 38 | 47 | 800 g<br><120 g/instrument | 4 |
| Large Instruments | 42 | 52 | 800 g<br><200 g/instrument | 4 |
| Handpieces | 28 | 35 | 300 g<br>5 pouches/tray | 4 |
| Large Cassettes | 51 | 60 | 1.2 kg<br>1 cassette/tray | 4 |
| Small Cassettes | 53 | 62 | 1.4 kg<br>2 cassettes/tray | 4 |
| **CYCLES: RH-Pro9** | **½-Cycle • >6 Log** | **Full Cycle • 12 Log** | **Maximum Weight/Tray** | **No. of Trays** |
| Small Instruments | 33 | 42 | 800 g<br><120 g/instrument | 3 |
| Large Instruments | 37 | 46 | 800 g<br><200 g/instrument | 3 |
| Handpieces | 22 | 29 | 240 g<br>4 pouches/tray | 3 |
| Large Cassettes | N/A | N/A | N/A | N/A |
| Small Cassettes | 45 | 53 | 700 g<br>1 cassette/tray | 3 |

# RAPIDHEAT VERSUS STEAM STERILIZATION TIME

Total cycle processing times are compared between the Midmark M9/M11 and the RH-Pro9/Pro11 HVHA sterilizers as shown in Table V. Instruments, handpieces, synthetic lubricants, and pouches (Kraft paper/polyester cast polypropylene) demonstrate similar thermal compatibilities. Although the actual sterilization processing time for steam sterilization is much smaller than required for the HVHA sterilizers, the time required for additional steam sterilizer fill, heat-up, venting, and required drying results in their comparable total processing times since these additional required sub-cycles are not necessary for HVHA sterilizers.

## TABLE V

| Pre-Programed (Wrapped/Pouched Instruments) | Sterilization Temperature | | Hot Cycle Time: (Fill Time, Heat-up and Vent-Minutes)[2] | | Sterilization Process Time (Minutes)[3] | | Dry Time Minimum (Minutes)[4] | | Total Process Time (Minutes) | |
|---|---|---|---|---|---|---|---|---|---|---|
| | M11[1] | Pro11 | M11 | Pro11 | M11 | Pro11 | M11 | Pro11 | M11 | Pro11 |
| Small Instruments | 270°F | 320°F | 15 | 0 | 3 | 47 | 30 | 0 | 48 | 47 |
| Large Instruments | 270°F | 320°F | 17 | 0 | 5 | 52 | 30 | 0 | 52 | 52 |
| Wrapped Cassettes | 250°F | 320°F | 14 | 0 | 30 | 62 | 30 | 0 | 74 | 62 |
| Handpieces | 270°F | 320°F | 16 | 0 | 6 | 35 | 30 | 0 | 52 | 35 |
| | M9[1] | Pro9 | M9 | Pro9 | M9 | Pro9 | M9 | Pro9 | M9 | Pro9 |
| Small Instruments | 270°F | 320°F | 11 | 0 | 3 | 42 | 30 | 0 | 44 | 42 |
| Large Instruments | 270°F | 320°F | 12 | 0 | 5 | 46 | 30 | 0 | 47 | 46 |
| Wrapped Cassettes | 250°F | 320°F | 10 | 0 | 30 | 53 | 30 | 0 | 70 | 53 |
| Handpieces | 270°F | 320°F | 11 | 0 | 6 | 29 | 30 | 0 | 47 | 29 |

1) M11 and M9 data extracted from Midmark published on-line documents
2) Hot Cycle and Dry Time sequence is not applicable to RapidHeat HVHA technology
3) Sterilization Processing Time for RapidHeat HVHA technology begins at the initiation of the Processing Cycle
4) No Drying Cycle required for RapidHeat HVHA technology.

# CONCLUSION

Advances made in RapidHeat™ High-Velocity Hot Air sterilizers have resulted in highly accurate control, enabling measurement of microbial inactivation of bacterial spores exposed to constant dry heat across a wide range of temperatures. The time-temperature profile generated from each of the seven selected temperature cycles ranging from 250°F to 320°F demonstrated a temperature deviation of 0.6°F to 0.8°F crest to trough with a temperature deviation from mean ranging from 0.3°F to 0.4°F across all temperatures studied.

Precise temperature control has enabled the determination of seven D-values, which, when plotted semi-logarithmically against their respective temperature, resulted in a linear plot, validating the novel "bracketing" approach used in their determination. Comparison of the D-values observed with those D-values determined by NASA using a different approach to D-value determination revealed a remarkable similarity, having only a 1.45°C difference in Z-value which further validated CPAC's results.

These D-values were subsequently used to quantitatively determine the incremental contribution of spore reduction that occurred during 10°F temperature intervals from prescriptive instrument sterilization cycle time-temperature profiles conducted at 320°F. Utilization of incremental spore reduction values provides a quantitative measure in assessing the accurate time required for required Sterility Assurance Level spore reduction. The results of CPAC's internal studies with supportive references demonstrate that the microbial inactivation efficacy of RapidHeat HVHA sterilization at 320°F is comparable to steam sterilization in total processing times, sterilizer load capacities and instrument material compatibility.

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# ABOUT THE AUTHOR

Nelson S. Slavik, Ph.D., is senior vice president of Integrated Medical Technologies, Inc. and its wholly-owned subsidiary, CPAC Equipment, 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 a Master of Science in Microbiology/Biochemistry. He served on the Department of Health and Safety Studies faculty 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 four patents relating to high-velocity hot air sterilization technology.

# GLOSSARY:

*(Acronyms, Abbreviations, and Definitions)*

***Bacillus atrophaeus*** – A spore-forming bacterial (strain designation ATCC 9372; formerly *Bacillus subtilis* var. niger)) specified for use in determining dry heat sterilization efficacy by ANSI/AAMI in its "Dry (Heated Air) Sterilizers" ST50:2004/®2018 standards.

**D-value** – The time required to inactivate 90% of the spores (cells) present or to reduce the microbial population to one-tenth of its number or a one $Log_{10}$ reduction. The higher the temperature, the lower the D-value e.g., $D_{300°F}$ = 1.36 minutes; $D_{340°F}$ = 24.4 seconds).

**Dry Heat Sterilization** – Sterilization conditions using hot air with a relative humidity <100%.

**Static Dry Heat Sterilization** – Dry heat sterilization conditions under which air movement is only by gravity convection within the sterilization chamber.

**Forced-Air Dry Heat Sterilization** – Dry heat sterilization conditions under which air is mechanically moved within the sterilization chamber.

**Half-Cycle** – The length of a sterilization processing cycle required to inactivate 6-$Log_{10}$ of *Bacillus atrophaeus* spores or a spore reduction of 99.9999%.

**Full-Cycle** – The length of a sterilization cycle required to inactivate 6-$Log_{10}$ of *Bacillus atrophaeus* spores and an additional 6-$Log_{10}$ of *Bacillus atrophaeus* spores to meet the FDA Safety Assurance Level (SAL) requirement or a total 12-$Log_{10}$ spore reduction.

**High-Velocity Hot Air (HVHA) Dry Heat Sterilization** – A subset of forced-air dry heat sterilization under which dry hot air is moved at a high rate of speed across the sterilization chamber at an air volume exchange rate in excess of 200 times per minute.

**Humidity, Ambient or Uncontrolled** – No effort to control environmental humidity during the sterilization process. For temperatures ranging from 135.1°C (275.2°F) to 170°C (338°F), "the ambient and controlled humidity lethality rate constants are statistically the same at the 95% confidence limit." [5]

**Humidity, Controlled** – A controlled humidity defined as "an absolute humidity corresponding to relative humidity of less than 25% referenced to standard conditions of 0°C and 760 torr." [5]

**NASA** – The National Aeronautics and Space Administration. Cited references refer to NASA funded/contracted agencies and institutions.

**Sterility Assurance Level (SAL)** – The probability of a single viable microorganism occurring on a product after sterilization. A SAL of 6-$Log_{10}$ spore reduction after sterilization is equivalent to less than or equal to one chance in a million that a single microorganism is present on a sterilized item.

**Total Sterilization Process Time** – The total time required to process items from the closing of the sterilizer door and the initiation of the process to its completion and removal of the sterilized items. This time includes the acquiring of temperature and/or pressure required of the process, the holding time at temperature necessary to achieve the FDA 12-$Log_{10}$ spore reduction requirement, and the time to achieve load drying as may be necessary of the process.

**Z-value** – The number of degrees (in either Fahrenheit or Celsius) required to obtain a 1-$Log_{10}$ change in the D-value.


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