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William F. Gale
Hyacinth S. Gale
Air Transportation Center of Excellence for
Airliner Cabin Environment Research
Auburn University, AL 36849

Jean Watson
Office of Aerospace Medicine
Federal Aviation Administration
Washington, DC 20591

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Final Report

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ABBREVIATIONS

As used in this report, the following abbreviations/acronyms have the meanings indicated:

Abbreviation	Meaning
APU	Auxiliary power unit
BIs	Biological indicators
ECBC	Edgewood Chemical Biological Center
ECS	Environmental control system
FAA	Federal Aviation Administration
OSHA	Occupational Safety and Health Administration
PCA	Preconditioned air
PEL	Permissible exposure level
RH	Relative humidity
TWA	Time weighted average
VHP	Vaporized hydrogen peroxide

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Field Evaluation of Whole Airliner Decontamination Technologies for Narrow-Body Aircraft

INTRODUCTION

A field evaluation of a thermal decontamination system, used both as a stand-alone technology and as a means of delivering vaporized hydrogen peroxide (VHP[1]) in a narrow-body aircraft, will be discussed in this report. This report is written in the context of a decontamination technology down-select exercise (Gale et al., 2006) and work conducted on the efficacy of thermal decontamination (Rudnick and Spengler, 2006). AeroClave[2] LLC's thermal decontamination system and STERIS Corporation's VHP ranked highest during the previously referenced decontamination technology down-select exercise. It must be stressed that the stand-alone thermal decontamination system is not intended to extend beyond the elimination of viruses.

[1] VHP is a trademark of STERIS Corporation, Mentor, OH.

[2] AeroClave LLC is based in Orlando, FL.

Preliminary laboratory work on efficacy (Rudnick and Spengler, 2006) has suggested that thermal decontamination at 60º C or above and at a relative humidity (RH) of >35% is capable of producing a significant rate of viral deactivation > 2.2 log h^{-1} at least in the case of vaccinia[3]. The extent to which the thermal decontamination system was capable of controlling temperature and humidity was unclear. In the case of VHP, ample efficacy data existed, but prior attempts to apply VHP to aircraft, as in the case of the C–141 demonstration (Raine, 2005), were not compatible with airline operations, in that bulk vaporizers were required to be mounted within the cabin. The field evaluation described in this report represents an attempt to address these two considerations.

[3] Work is underway to extend the thermal decontamination efficacy studies to seasonal influenza.

In the field evaluation, performed using AeroClave LLC's DC–9, it was found that the stand-alone thermal decontamination system exhibited reasonable temperature and relative humidity control capabilities. Indeed, the thermal decontamination system reproduced the environmental conditions identified in an earlier efficacy study (Rudnick and Spengler, 2006) as being necessary, to be efficacious as an antiviral process. Addition of a humidifier, not included in the original design of the thermal decontamination system, was found to be necessary. The addition of the humidifier did not seem to present issues for implementation of the thermal decontamination process.

In the demonstration, a capability for decontaminating the cargo area, without modification to the aircraft was not demonstrated. No attempt was made to demonstrate the use of VHP behind panels, given the known inability of VHP to penetrate into largely, but not entirely occluded spaces.

METHOD

Objectives

Stand-Alone Thermal Decontamination System

The aim was to demonstrate the ability of the system to heat the entire cabin to a temperature of 60º C under conditions of controlled relative humidity (RH) without significantly over-shooting this temperature at any location, hold the entire cabin isothermal at 60º C for an arbitrary time without significant temperature fluctuations, and to cool back to room temperature rapidly but in a controlled fashion.

VHP Add-In

In this instance, the goal was to demonstrate the feasibility of using the stand-alone thermal decontamination system as a means of delivering VHP in an efficient fashion, without requiring bulky vaporizers or other heavy equipment within the cabin, and that the system is capable of delivering controlled quantities of VHP, such that sporicidal conditions can be achieved throughout the cabin.

Methodology

The thermal decontamination system, as a stand-alone technology, was deployed in its standard configuration. Details of this may be found in the outcomes of the decontamination technology down-select (Gale et al., 2006). In summary, the thermal decontamination system is designed to deliver heated or cooled air under feed-back control from a self contained unit housed on a semi-trailer. The unit was connected to the cabin via flexible air delivery and return hoses. Custom door plugs connected to the inlet and outlet hoses were employed. In this configuration, the air inlets were at the emergency exit doors above the wing and the air outlets at the front and rear cabin doors. Air was also blown into the preconditioned air (PCA) inlet with the intent of decontaminating the ductwork.

It is important to note that the DC–9 aircraft, which was used in the evaluation, had been stripped of both its engines and auxiliary power unit (APU); without these it was not possible to operate the aircraft's environmental control system (ECS). Without the aircraft's own fans operating, there are likely to be some parts of the ECS for which efficient air access cannot be achieved. This was not addressed in the present study. Furthermore, for the evaluation described in this document, an effort was not made to decontaminate the cargo bay.[4]

[4] Thermal decontamination of the cargo area has been demonstrated, but this required removal of a panel from one of the ECS ducts to enable significant airflow from the cabin to the cargo area. The focus of the present evaluation is decontamination of aircraft as-is, without structural modifications, and hence the decision was made to return the ECS duct to its original condition and exclude the cargo area from the present evaluation.

The thermal decontamination system in its original configuration did not include a humidification capability. Hence, on heating, the relative humidity in the cabin dropped quickly. Based on the results of an earlier study (Rudnick and Spengler, 2006), which indicated a need to

maintain a RH of >35% at 60º C, the equipment manufacturer opted to add a steam-based humidification system, which was employed during the evaluation described in this report.

In the case of the VHP add-in, a detailed description of the setup employed may be found elsewhere (Thomas, 2006), and hence only the key points are discussed here. VHP was injected into the air delivery system from an external bank of four vaporizers, located in a trailer adjacent to the thermal decontamination system. However, there is no obvious technical barrier to embedding the vaporizers into the thermal decontamination trailer in the future.

It is important to note that the intended function of the thermal decontamination system changes depending on which mode this is employed in.

In the stand-alone configuration, the thermal decontamination system is intended to deliver hot air of controlled humidity to achieve viral decontamination and then cool the aircraft back to a desired temperature and relative humidity so that people may re-enter the cabin. The thermal decontamination system may also have other applications, such as non-chemical disinsection, as was discussed in the technology evaluation (Gale et al., 2006).

The thermal decontamination system, when used in conjunction with the VHP add-in, produces environmental preconditioning, prior to the injection of VHP. This involves reducing the RH to below 40%, ideally 30% or lower, delivery of VHP to the cabin, and aeration to extract VHP from the cabin.

Protocols

Stand-Alone Thermal Decontamination System

The cabin of the DC–9 was instrumented with 2 relative humidity sensors (one in the front and one at the rear of the cabin) and 36 thermocouples (including the baggage hold), and data were logged continuously.

In addition to data collected on a series of cycle development runs, prior to a formal on site evaluation, follow up data were collected from three runs after the evaluation. For the formal on site evaluation, one run was conducted with observers from the Federal Aviation Administration (FAA) and the Edgewood Chemical Biological Center (ECBC). In the post evaluation runs, a target cabin surface temperature of 60º C was maintained at all locations for at least two hours; temperature at the air inlet was not permitted to exceed 65º C; RH at temperature was maintained at 50% while no effort was made to control conditions in the cargo area. One run meeting the latter conditions was completed during the formal evaluation.

VHP Add-In

The cabin was instrumented with the same instrumentation as for the stand-alone thermal decontamination system. Six hydrogen peroxide vapor sensors for the working concentration of the VHP were included. Due to existing wiring, these sensors were placed in the same locations as in initial work on the DC–9 aircraft.

Twenty-eight Apex 6 log *G. stearothermophilus* biological indicators (BIs) were placed throughout the cabin for the formal evaluation; 20 were placed in the same locations as for the initial exploratory runs, and the remaining 8 were located by mutual agreement on site, and included partially occluded locations, to the extent that this was reasonably practicable, within the confines of the demonstration and bearing in mind that the DC–9 does not have a functional ECS.

Peripheral sensors were placed around the aircraft, including near the outlet used to flush the VHP, to demonstrate compliance with OSHA PEL and other relevant exposure limits. Handheld sensor(s) with manual data recording were used in lieu of suitably calibrated automated sensors that were not available on-site.

Multiple runs were performed, including one formal evaluation run with personnel from the FAA and ECBC observing. Runs were performed under the following conditions. The VHP concentration was maintained at 150 ppm or higher at all locations sampled for at least two hours and was not allowed to exceed 500 ppm at any location to minimize the risk of condensation. VHP concentrations were monitored on entering the cabin after each run using suitable hand held instrumentation. This did not exceed the 1 ppm PEL for those runs in which aeration was allowed to run to completion.

In view of time constraints, the run during the ECBC (Rastogi, 2006) and FAA visit was terminated at 2 – 5 ppm, while ensuring that the duration of exposure for personnel harvesting the BIs was carefully monitored so that no individual exceeded the OSHA 1 ppm TWA PEL. In the case of the proving runs, the monitoring described above was repeated the morning after the run to detect any VHP out gassing from porous media within the cabin. Additional aeration was employed as was found necessary, and the measurements repeated.

RESULTS

Stand-Alone Thermal Decontamination System

During the early stages of the work (and especially before the decision had been made not to attempt to control the cargo bay temperature as described in the methodology), some issues were encountered with cabin surface temperature exceeding 70º C in the immediate vicinity of the air inlet (Figure 1). In contrast, once the decision was made to not control the cargo bay temperature, it proved possible to achieve a fairly stable cabin surface temperature in excess of 60º C at all locations, with the surface temperature adjacent to the air inlet remaining significantly below 70º C (Figure 2).

It should be noted that an effort was made to sample the temperature at locations throughout the cabin, encompassing surfaces comprised of a wide range of materials and thermal masses. All temperatures specified are surface temperatures, not air temperatures. Some run-to-run scatter was apparent for runs conducted with identical control parameters. However, the extent of run-

to-run scatter does not appear to be a major problem. Some oscillations were observed in the thermal data. However, these seem quite well controlled in the later runs and hence are not expected to cause major concern. The results are described in further detail in another report (Gale, 2007). Indeed, it may simply be the case that the thermal decontamination unit's heating system is oversized for the volume of the DC-9, causing the unit to "hunt," and that this would function better with a larger aircraft.

The addition of a humidifier enabled an RH of around 50% to be maintained, which is important as an elevated RH is needed to achieve antiviral efficacy (Rudnick and Spengler, 2006).

VHP Add-In

The combined system appeared to be capable of controlling the VHP concentration, based on the output from 6 hydrogen peroxide sensors (Thomas, 2006). It was possible to maintain a cabin hydrogen peroxide concentration of around 125 – 200 ppm, which should be more than

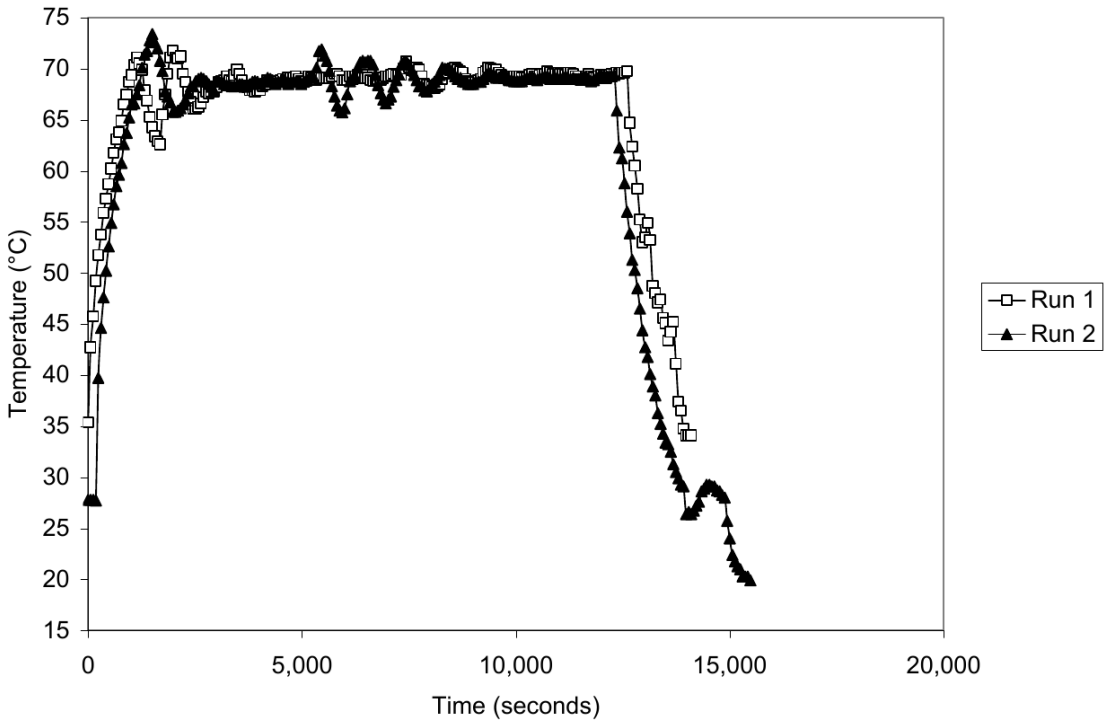


Figure 1. Profile near supply (with control of cargo bay)

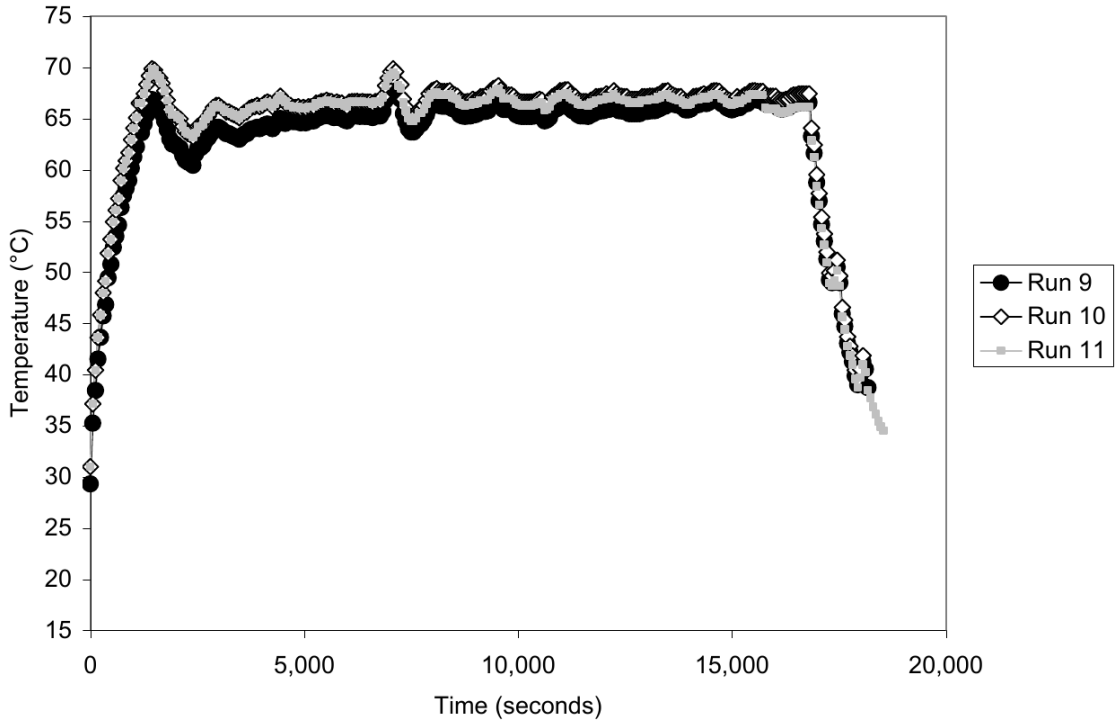


Figure 2. Profile near supply row (without control of cargo bay)

sufficient to produce a sporicidal action (concentrations above ~ 80 ppm are usually considered sporicidal). The hydrogen peroxide concentration measured adjacent to the inlet did not exceed 225 ppm, and hence there does not appear to be a risk of macroscopic condensation of the peroxide (and localized condensation would require pockets of high humidity).

Twenty-eight 6 log *G. stearothermophilus* biological indicators (BIs) were placed throughout the cabin, and all of these were deactivated, except in the case of runs for which there were known control issues. At both the 48-hour interim evaluation and 7-day final evaluation, all exposed biological indicators were negative for growth, and all positive controls showed normal growth (Thomas, 2007).

DISCUSSION

Stand-Alone Thermal Decontamination System

Some issues were not addressed, or at least not fully addressed during the evaluation. The assumption was made that the maximum temperature at which thermal decontamination could be safely performed was 60º C. However, this 60º C value has not been enshrined in any formal document, and hence materials compatibility issues remain to be resolved. As has already been noted, it was not possible to decontaminate the cargo bay without removing panels from the aircraft's ECS. This may be less of an issue with modern aircraft and, in the worst case, should be relatively easy to address by adding a separate feedback controlled decontamination loop to

the thermal decontamination system. Similarly, full decontamination of the ECS would require the ability to operate the ECS fans. A good means has not been found for evaluating the efficacy of the thermal decontamination system in-situ. Hence, it has been necessary to assume that the efficacy observed in the laboratory would also be achieved in the field, given the similarity in temperature and relative humidity. This is probably a reasonable assumption, as such differences in environmental conditions as exist between the laboratory studies and the field (e.g., the laboratory studies used still air, and the field system employs flowing air) are likely to be of secondary importance to temperature and relative humidity. Of greater importance is the issue that the laboratory studies used exclusively hard surfaces, and a good means has not been found for assaying viral viability on porous media such as seat fabrics.

VHP Add-In

No effort was made to locate BIs behind cabin panels, since VHP is known to have only a limited ability to penetrate spaces with poor airflow or adjacent surfaces that are in direct contact with each other[5]. Of course, if there is insufficient airflow to blow biological agents into such spaces and between adjacent surfaces, this would not be an issue. There are however, two reasons to remain concerned. First, air flow patterns with the ECS on will be different from those during the tests for which it was not possible to run the ECS, as noted previously. Second, weaponized spores use a carrier that is designed to maximize dispersal. If the ECS were on during the contamination of an aircraft, this could lead to areas of significant contamination that would only be accessible to VHP vapor if the ECS were operating during the decontamination process. A demonstration of this type was not possible on the DC-9 aircraft used in the present study because it lacked a functional ECS.

[5] STERIS Corporation has indicated to the authors of this report that STERIS makes no label claims for Vaprox® sterilant, STERIS's brand of 35% liquid hydrogen peroxide, having efficacy for the decontamination of (partially) occluded locations when used with a STERIS VHP generator as part of a VHP delivery system. Hence, the present author notes that a different approach may be preferred for such regions of the cabin. This could be performed either before or after decontamination of the main cabin with VHP.

VHP is known to be absorbed by porous media. It was not possible to measure VHP concentrations below 1 ppm, and hence the extent to which there may be slight re-emission of VHP is uncertain at this time. The OSHA-permissible limit for personal exposure is 1 ppm (8-hour TWA). This level is easily measurable, allowing an accurate determination of whether a uniform space or the atmosphere immediately adjacent to an object is at or above the permissible limit. Note that the effects of absorbed VHP on properties such as flammability are in the process of being assessed in laboratory studies of materials compatibility.

Standard spore-based BIs are metal-backed, and decontamination efficacy might differ on porous media. In subsequent studies, it may be possible to develop BIs that use a somewhat porous backing.

VHP was vented to the environment. This does not seem to be as much of a concern as would be the case with most decontamination chemistries, as VHP breaks down readily to water and

oxygen. Nonetheless, the use of a fully closed-loop system (as is employed in laboratory scale systems) might be desirable, from the standpoint of industry acceptability, if the test bed were to be converted into a production system. This does not appear to be difficult to achieve in the future, when the VHP unit would presumably be integrated with the thermal decontamination system at the time of design, rather than a post-production add-on, as was the case for this demonstration.

CONCLUSIONS

As a result of the field evaluation of the stand-alone thermal decontamination system and the VHP add-in, the following conclusions have been drawn:

The thermal decontamination system appears to be capable of reproducing in the field the environmental conditions (temperature and RH) that were found in an earlier study to be efficacious as an antiviral process (Rudnick and Spengler, 2006).

The thermal decontamination system was also found to provide an effective means of achieving environmental preconditioning for the subsequent use of VHP along with aeration after the VHP cycle, hence eliminating the need for bulky equipment within the cabin. In addition, the thermal decontamination system, in tandem with a suitable vaporizer array, was capable of delivering VHP to all non-occluded regions of the cabin.

The thermal decontamination plus VHP add-in combination was found to be sporicidal at numerous locations within the cabin. All exposed BIs were negative for growth, and all positive controls showed normal growth.

A number of issues remain to be resolved. Principal among these issues is the lack of clear manufacturer guidance on the maximum acceptable temperature for thermal decontamination. Second, implementation of a capability for decontamination of the cargo area without changes to the aircraft, and finally, the inability of VHP to penetrate into largely, but not entirely occluded spaces, should be addressed.

Overall, the field evaluation of both the stand-alone thermal decontamination system and the VHP add-in can be described as successful, both in terms of the ability to perform the evaluation under controlled conditions and the outcomes of the evaluation.

As the next logical step, a follow-up study on a wide-body aircraft (Boeing 747) has just been completed and will be documented later.

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ERRATA

The corrections and notes below were made when this report was prepared for republication through the National Transportation Library. Minor typographical, spelling, and punctuation errors were also corrected and are not listed individually.

Corrections Made in This Edition

1. Introduction: “technology-down selection exercise” and “technology-down select exercise” corrected to “technology down-select exercise,” matching the Method section.
2. Protocols, VHP Add-In: “instrumented with the following same instrumentation as for” corrected to “instrumented with the same instrumentation as for.”
3. Citations: “Rudnick et al., 2006” corrected to “Rudnick and Spengler, 2006” (the reference has two authors).
4. Species name: “G. Stearothermophilus” corrected to “*G. stearothermophilus*.”
5. Results: missing parenthesis restored in “(Figure 1).”

Discrepancies Noted but Not Changed

6. Footnote 5 refers to “the present author,” although the report has three authors. Retained as originally published.
7. The text cites “Thomas, 2007”; the reference list gives “Thomas, J.A. (2006 and 2007). Private Communication.” Retained as originally published.