

White Paper: Synopsis of Johnson & Johnson’s ‘Evaluation of the ClorDiSys FLASHBOX-mini as an efficient decontamination tool’

The Sterility Assurance Department at Johnson and Johnson performed testing in 2018 to determine the Flashbox-mini’s ability to disinfect commonly used small devices within aseptically controlled areas. The Flashbox-mini is a small ultraviolet light disinfection chamber that produces an efficient UV-C output of 500 $\mu\text{W}/\text{cm}^2$ to get a calculated 99% reduction of MRSA in 10 seconds and *Clostridium difficile* spores in 2 minutes. The aim of this study was to evaluate the Flashbox-mini as an alternative to liquid sanitizing agents and manual wiping of small tools and supplies. The following will re-state the highlights of the study with the entire write-up also attached, so the information can be seen in its original, un-edited context.

Summary

Robust cleaning is a challenge for small devices and tools found in an aseptic area. A high-level disinfection that can be achieved quickly, without damaging the object, and is independent of operator technique would be a better solution than manually spraying liquid sanitizers. Ultraviolet light has been used for disinfection since the 19th century, but several factors have historically limited the technology from being widely used. New designs in both bulbs and ballasts that prevent critical degradation of intensity as the bulbs age have helped alleviate the concerns. This study was designed to evaluate the Flashbox-mini as a tool to perform rapid decontamination of small devices. The environmental microorganisms selected, *Bacillus licheniformis*, *Staphylococcus epidermidis*, and *E. Coli*, were exposed to ultraviolet light within the small chamber for varying times, 0 exposure (control), 30 second exposure, 60 second exposure and a 5-minute exposure. The challenge times were chosen as an easily achievable time to include as part of gowning routine. The Flashbox-mini was able to achieve a high level of disinfection on the selected tools after a 5-minute exposure time with no negative effects.

Please read the original paper for more details.

Evaluation of the ClorDiSys FLASHBOX-mini as an efficient decontamination tool

This study was designed to evaluate the FLASHBOX-mini as a tool to perform rapid decontamination of small devices required for use within aseptically controlled areas. UV radiation has been used for decontamination since the 19th century, but several factors including safety concerns, reliability of UV bulbs and ineffectiveness due to shadowing have limited the technology from being widely used. (1) Efficient communication revolutionized by cell phones is finding its place in aseptically controlled areas. Robust cleaning is a challenge for small devices and tools that may be required for use in an aseptic area. (3) Frequently liquid sanitizing agents are applied to small devices along with wiping. This application of liquid sanitization has drawbacks; potential for insufficient exposure to the sanitizing agent (poor wiping or complex surface features that limit wetting, contact time may not be achieved, surface tension and the micro structure of the item can prevent wetting and proper disinfection. (4) Superior disinfection is achieved through gassing or radiation exposure which is active at molecular sizes and lower. A better solution would achieve a high level of disinfection quickly, does not damage the object, has some level of penetration into the micro structure of the device and is independent of operator technique.

A study was conducted using the ClorDiSys FLASHBOX-mini to evaluate the system's ability to disinfect some small commonly used items. The Flashbox-mini contains 1 shelf to support the item(s) being disinfected. It simply plugs into any wall outlet. The disinfection chamber produces an efficient UV-C output of 500 $\mu\text{W}/\text{cm}^2$ to get a calculated 99% reduction of MRSA in 10 seconds and *Clostridium difficile* spores in 2 minutes. (2) The unit has two control dials one to select the light configuration; top or bottom or both (recommended). A bottom dial selects the exposure time. One, five, ten and fifteen-minute marks are indicated on the dial. The door is interlocked to prevent unintentional UV exposure. Through the window an operator can visually confirm the lights are on and working and the window blocks UV light so there is no danger to an operator. The study was conducted using a spiking and recovery technique.

Environmental microorganisms selected as challenge organisms were *Bacillus licheniformis*, *Staphylococcus epidermidis* and *E. Coli*. These organisms were inoculated on the surface of the items and allowed to dry. Replicate inoculations were performed in triplicate. The items were targeted with a 100 cfu inoculation. Actual counts of the inoculated surface were as follows; *B. licheniformis* 50 cfu, *S. epidermidis* 150 cfu, *E. coli* 85 cfu. Controls of unexposed items were compared to the Flashbox exposed items. Exposure times were varied, 0 exposure (control) 30 second exposure, 60 second exposure and a 5-minute exposure. A calibrated timer was used to measure exposure times. The challenge times were chosen as an easily achievable time to include as part of gowning routine that would not be burdensome to a gowning session. The items challenged in the FLASHBOX-mini were a cell phone, and a pen.

Recovery of the spiking was performed using contact plating of the inoculated surfaces. Recoveries are recorded below in Figures 1-2.

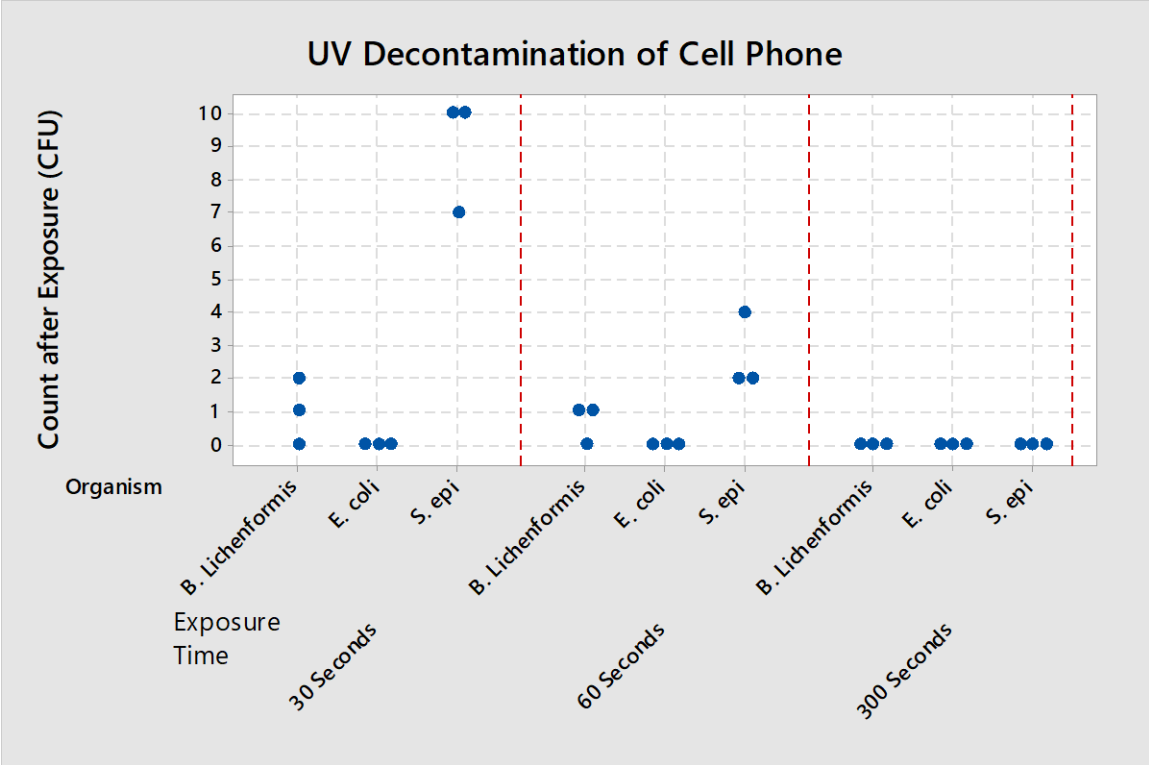


Figure 1

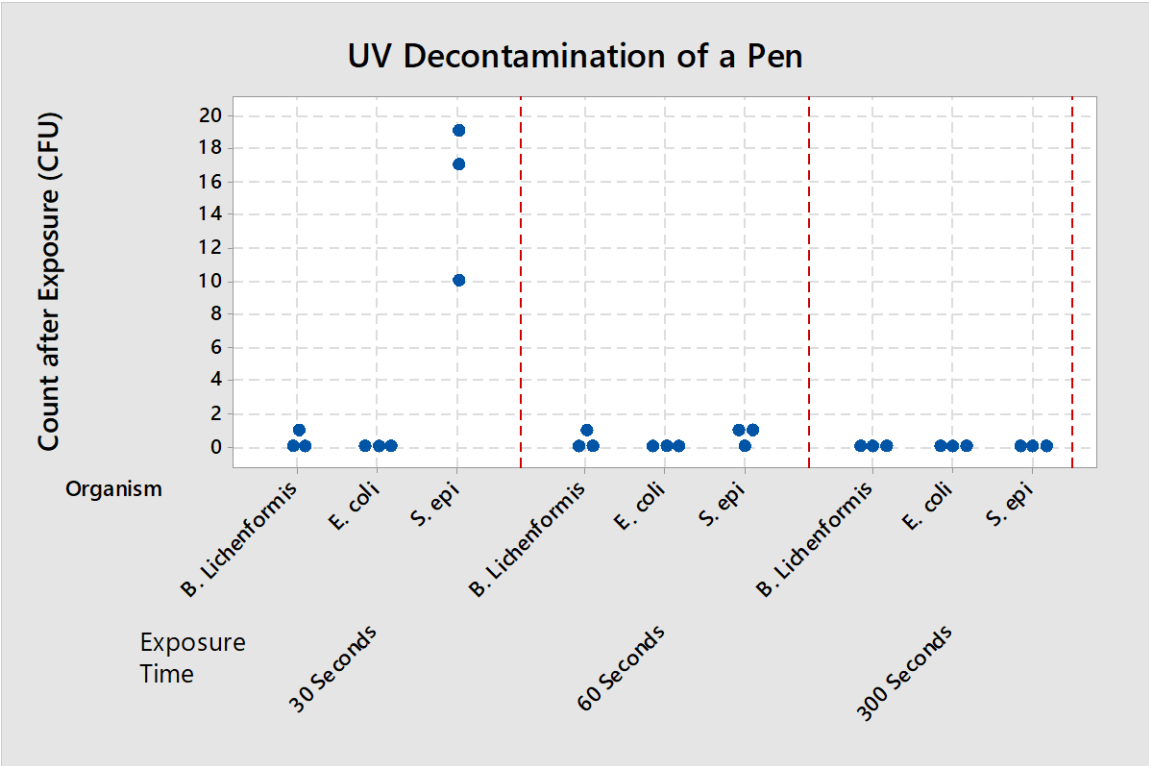


Figure 2

Review

This aim of this study was to evaluate the ClorDiSys FLASHBOX-mini as a convenient tool to replace manual wiping of small tools that are frequently required to be utilized in an aseptic area. The FLASHBOX-mini has a selectable dial to set the time. This dial can be used to approximate the time only and is not capable to be calibrated which is why a separate timer was used to measure exposure time for this study. The unit was able to achieve a high level of decontamination on the selected tools after a 5-minute exposure time. No growth for any of the spiked organisms was recovered. A five-minute time is easily accommodated as part of routine gowning activities and the use of a simple device like the FLASHBOX-mini may speed entry into an aseptic area by replacing manual wiping with the UV light exposure.

References

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