

Independent Disinfectant Compatibility Report

I.V. House FaceShield with ID Band

I.V. House, Inc. was established in 1991 and has been dedicated to improving patient safety and increasing nurse efficiency. During the COVID-19 global pandemic health care providers expressed a need for reusable medical-grade personal protective equipment (PPE). I.V. House is honored to be able to provide this protection to health care providers.

The I.V. House FaceShield with ID Band is made in the USA with high-quality materials and includes a write-on strip to allow the wearer to add a name, title, or other information. The US Food and Drug Administration recommends that manufacturers validate disinfection processes and instructions. During the research and development phase for this PPE, I.V. House partnered with Community Health Associates, LLC. for their expertise in clinical product development for an evaluation of the wearability and reusability of the device.

The following pages include the objectives of the trial, results, implications and recommendations for use, and disinfectant compatibility.

If you have any questions or would like to order a sample, please contact us at IVinfo@ivhouse.com.



Objectives of the Experiment:

The purpose of this experiment is twofold:

1. To determine how many cycles of disinfection with an EPA-registered product (3 brand name disinfectant formulations in 4 delivery systems) can the proposed face shield withstand without degradation
2. To determine how many uses, at various time intervals, the face shield can be worn comfortably without degradation of the device which may result in unsafe exposure to potential pathogens

This experiment was commissioned at the request of the client and performed according to good laboratory practices. Medical device compatibility can be impacted by the type of disinfectant formulation (active and inert chemical ingredients), the type of surfaces being disinfected and their construction, how the device is being used and how long it is being used, the frequency that the device will be disinfected, and device design characteristics such as grooves, plastics, etc.

Given the increasingly importance of the availability of reusable Personal Protective Equipment as a result of the ongoing COVID-19 pandemic, face shields are playing an increased role in protecting not only healthcare workers, but also members of the commercial and community sectors.

Materials and Methods:

This experiment was commissioned at the request of the client to determine simulated use of the proposed face shield prototype. The prototypes were provided by the face shield manufacturer, I.V. House. The US Food and Drug Administration (FDA) recommends that manufacturers validate disinfection processes and instructions. The US Environmental Protection Agency (EPA) regulates all disinfectant products in the US. For purposes of this experience, four EPA-registered, hospital-grade disinfectants were utilized in accordance with the manufacturer's instructions for use regarding application and overall contact time. All requirements for the use of Personal Protective Equipment found on the product's EPA Master Label were closely adhered to during the simulated use test. Four key properties were observed during this experiment to determine the rate of potential degradation. These observed properties included:

- Device Fatigue
- Discoloration
- Corrosion
- Residue and/or Fogging

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Results:

Interpretation Key:

NO SIGNIFICANT DAMAGE-USER CAN UTILIZE PRODUCT SAFELY

BEGINNING SIGNS OF DEGRADATION-USER RECOMMENDED TO DISCARD DEVICE

SIGNIFICANT DAMAGE-DEVICE SHOULD BE DISCARDED

Cycles of Simulated Use (In Individual Uses)	Super Sani-Cloth RTU Wipe	Clorox Healthcare Bleach RTU Wipe	Clorox Healthcare Hydrogen Peroxide RTU Wipe	Clorox Healthcare Hydrogen Peroxide RTU Spray
1	NO SIGNIFICANT DAMAGE-USER CAN UTILIZE PRODUCT SAFELY			
5	NO SIGNIFICANT DAMAGE-USER CAN UTILIZE PRODUCT SAFELY			
10	NO SIGNIFICANT DAMAGE-USER CAN UTILIZE PRODUCT SAFELY			
15	NO SIGNIFICANT DAMAGE-USER CAN UTILIZE PRODUCT SAFELY			
20	NO SIGNIFICANT DAMAGE-USER CAN UTILIZE PRODUCT SAFELY			
25	NO SIGNIFICANT DAMAGE-USER CAN UTILIZE PRODUCT SAFELY			
30	NO SIGNIFICANT DAMAGE-USER CAN UTILIZE PRODUCT SAFELY	RECOMMENDED	NO SIGNIFICANT DAMAGE-USER CAN UTILIZE PRODUCT SAFELY	NO SIGNIFICANT DAMAGE-USER CAN UTILIZE PRODUCT SAFELY
35	NO SIGNIFICANT DAMAGE-USER CAN UTILIZE PRODUCT SAFELY	BEGINNING SIGNS OF DEGRADATION-USER RECOMMENDED TO DISCARD DEVICE	NO SIGNIFICANT DAMAGE-USER CAN UTILIZE PRODUCT SAFELY	NO SIGNIFICANT DAMAGE-USER CAN UTILIZE PRODUCT SAFELY
40	NO SIGNIFICANT DAMAGE-USER CAN UTILIZE PRODUCT SAFELY	BEGINNING SIGNS OF DEGRADATION-USER RECOMMENDED TO DISCARD DEVICE	NO SIGNIFICANT DAMAGE-USER CAN UTILIZE PRODUCT SAFELY	NO SIGNIFICANT DAMAGE-USER CAN UTILIZE PRODUCT SAFELY
45	NO SIGNIFICANT DAMAGE-USER CAN UTILIZE PRODUCT SAFELY	BEGINNING SIGNS OF DEGRADATION-USER RECOMMENDED TO DISCARD DEVICE	NO SIGNIFICANT DAMAGE-USER CAN UTILIZE PRODUCT SAFELY	NO SIGNIFICANT DAMAGE-USER CAN UTILIZE PRODUCT SAFELY
50	RECOMMENDED	BEGINNING SIGNS OF DEGRADATION-USER RECOMMENDED TO DISCARD DEVICE	RECOMMENDED	RECOMMENDED
55	NO SIGNIFICANT DAMAGE-USER CAN UTILIZE PRODUCT SAFELY	SIGNIFICANT DAMAGE-DEVICE SHOULD BE DISCARDED	BEGINNING SIGNS OF DEGRADATION-USER RECOMMENDED TO DISCARD DEVICE	BEGINNING SIGNS OF DEGRADATION-USER RECOMMENDED TO DISCARD DEVICE
60	BEGINNING SIGNS OF DEGRADATION-USER RECOMMENDED TO DISCARD DEVICE	SIGNIFICANT DAMAGE-DEVICE SHOULD BE DISCARDED	SIGNIFICANT DAMAGE-DEVICE SHOULD BE DISCARDED	SIGNIFICANT DAMAGE-DEVICE SHOULD BE DISCARDED
65	SIGNIFICANT DAMAGE-DEVICE SHOULD BE DISCARDED			
70	SIGNIFICANT DAMAGE-DEVICE SHOULD BE DISCARDED			

Based on the findings, the non-bleach products afford the face shield an extended repeated use shelf life of approximately fifty (50) uses under ideal circumstances. For the bleach-based products, the repeated use shelf life is approximately thirty (30) uses.



Implications and Recommendations:

Given the differences in environmental and user conditions by healthcare professionals, it would be recommended to take a conservative approach to repeated use of the devices and also provide the users with specific details about how to best reprocess and store the devices. These additional recommended instructions include:

- Do not store the device rolled up, but rather in its original shape and form to prevent damage.
- If fogging occurs, wipe the face shield off with a mild cloth with water to remove any disinfectant residue from the device.
- When using a disinfectant product, allow the product to air dry in accordance with the manufacturer's instructions for use. If residue remains, the user should wipe the face shield off with a wet paper towel to remove any disinfectant residue.

Conservatively, the recommended repeated uses of the face shield can be broken down into two categories:

1. Scenario #1: If the healthcare customer is using Clorox Healthcare Bleach wipes or another similar bleach solution, the recommended repeated uses is no greater than thirty (30) uses.
2. Scenario #2: if the healthcare customer is using either the PDI Super Sani-Cloth wipe, Clorox Healthcare Hydrogen Peroxide wipe, or Clorox Hydrogen Peroxide spray, then the recommended repeated uses is no greater than fifty (50) uses.

Disclaimer: *This simulated use test was conducting in a controlled environment that could most appropriate simulate clinical use. Environmental and user factors may differ by user location and personal use. This report makes grants no liability for specific user situations or use practices, but rather provides an estimate of estimated usage in ideal environments.*

END OF REPORT



Community Health Associates Company Background

Community Health Associates, LLC was formed in 2006 to serve the continuing education needs of the healthcare community. Our organizational capabilities include:

- Live and Recorded Webinars
- Podcasts
- Live Presentations for Sales/Marketing Meetings
- Key Opinion Leader Meetings
- Medical Writing
- National and Corporate Accounts Support
- Continuing Education Workshops, Webinars, and Articles
- Sales and Marketing Clinical Training
- Case Studies and White Papers
- Clinical Product Development
- Speaking Engagements (Domestic and International)
- Medical Affairs Consulting
- Customer Consultation

Community Health Associates, LLC and its associated Key Opinion Leaders have extensive expertise in the following key clinical areas:

Infection Prevention and Control, Dental Infection Prevention and Control, Public Health, Infectious Diseases, Epidemiology, Patient Safety, Vascular Access, Infectious Diseases, Long Term Care Nursing, Professional Board of Directors Development, Strategic Planning, Medical Publications, Regulations and Infection Control, Clinical Research, Emergency Medicine and Critical Care Medicine, Sterilization and Disinfection, Hand Hygiene, Skin Antisepsis, Medical Science Liaison, Clinical Affairs, Medical Affairs, Clinical Regulatory Affairs, Medical Device Hygiene, Certification, Board Certification, Food Safety and Outbreaks.

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