Log Reduction & UV Deceptive Advertising

ALTAPURE

Sellers of both UV-C and PX-UV (pulsed UV) light room treatment products are **falsely claiming** that their products can disinfect, sterilize, or decontaminate, hospital facilities. The peered reviewed evidence clearly shows that they **cannot**. This abuse has been validated by *new* independent peer-reviewed research data reported in well known research journals, showing that UV-C and PX-UV systems do **not** meet the minimum Federal standards for Disinfection, Hospital disinfection, and Sterilization. The performance requirement for Decontamination is also **not** met.

1. INTRODUCTION: UV Light & Why The Terms "Disinfection", "Sterilization" and "Decontamination" Are Important:

In order to claim ***Disinfection*** a cleaning process, whether chemical or ultraviolet, must attain at least a **6 Log reduction** of specific organisms, in a certain amount of time. ***Sterilization*** means a kill of at least **6+ Log** organisms, while leaving no growth or viable survivors.

The following are different United States Government performance standards that must be met in order to claim disinfection or sterilization (in 10 minutes or less, except for sterilants) :

a) General Disinfection = **6 Log** reduction of "Staphylococcus aureus" **AND** "Salmonella enterica"
b) Hospital Disinfection = **6 Log** reduction of "Staphylococcus aureus" **AND** "Pseudomonas aeruginosa"
c) Disinfectant with Fungicidal claims = **6 Log** reduction of "Trichophyton mentagrophytes"
d) Sterilant with C-Diff. Spore Claims = **6 Log** reduction of "Clostridium difficile (C. difficile) spores"

None of the the UV-C and PX-UV light room treatment systems meet these definitions !

The Merriam Webster dictionary defines the term ***decontaminate*** as "to rid of contamination; to remove dirty or dangerous substances". UV-C and PX-UV light devices for room disinfection do **NOT** rid or remove dangerous pathogens, and while they may reduce some, they do **NOT** remove or eliminate them. The UV-C and PX-UV light room treatment industry misuses this term and has clearly taken advantage of the fact it is an unregulated industry.

The term ***Disinfection*** and ***Decontamination***, have been specifically defined by the EPA. These definitions have specific mathematical and scientific meaning, that have direct health and safety implications. UV-C and PX-UV light room treatment industry has abused both the statutory and accepted scientific definitions, by unreasonably puffing the capabilities of ultraviolet radiation.

2. WHAT LOG REDUCTION MEANS:

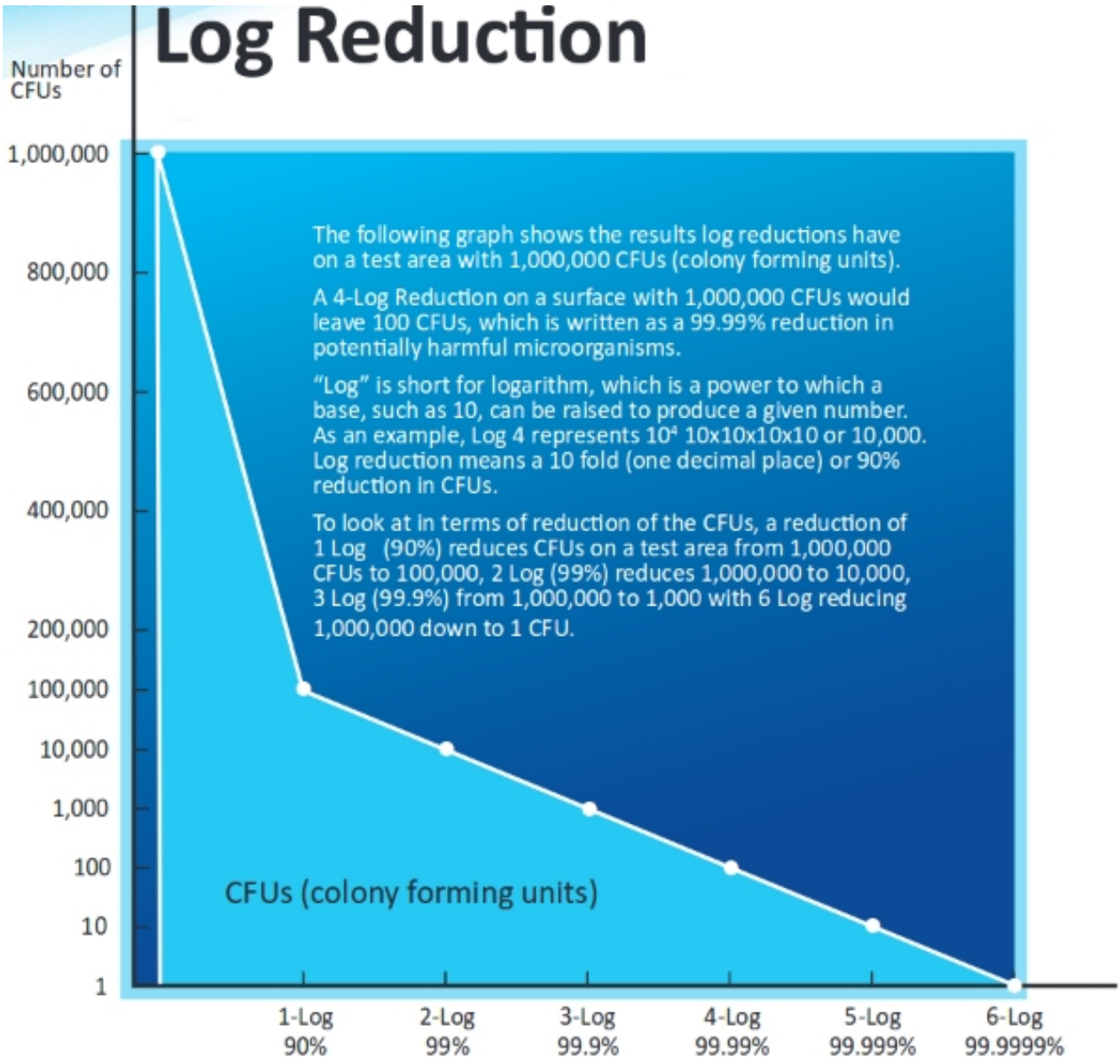
It is important to understand what *Log Reduction* is and why it is important to the process of *surface disinfection*, *surface sterilization*, and *surface decontamination*. Scientists, engineers, and other professionals who are responsible, or even legally responsible, for preventing illness and contamination, are concerned with *Log Reduction* or elimination of pathogenic bio-burden.

The term **Log** is short for logarithm, a mathematical term for a power to which a number can be raised. For example, using 10 as the given number, a **Log 2** increase can be shown as 10^2 or 10 x 10 = 100.

Alternatively, a **Log Reduction** is taking the power in the opposite direction. For example, a *Log Reduction* of **1.0 Log** is equivalent to a 10 fold reduction or, stated another way, moving down one decimal place, or a 90% reduction.

Product efficacy testing is done by counting the number of "colony forming units" (CFU) of the given pathogen / bacteria at the start of the treatment, and then performing a count again after the required treatment time. The result of the difference between the start and end numbers is then expressed as a *Log Reduction*.

For example, if the number of bacteria or bacterial colony forming units (CFU) in the beginning was one million or 1,000,000 (or 10^6), and the end result after the treatment was 1,000 (or 10^3) survivors, that would be a **3.0** Log Reduction (Log 3 reduction) or a reduction of 99.9%.



As a rule of thumb, for every additional *Log Reduction* number, you add the number 9 to the percentage reduction, so a *Log Reduction* of **3.0 Log** is a 99.9% reduction compared with a *Log Reduction* of **6.0 Log** which is equivalent to a 99.9999% reduction.

Below is an example of *Log Reduction* values using a starting point of one (1) million bacteria or 1,000,000 CFU's on a surface (ie: under bed rails in a hospital), as outlined below:

Log Reduction	Number of cfu's	Percent Reduction
0 log (Log 0)	1,000,000	0%
1 log (Log 1)	100,000	90%
2 log (Log 2)	10,000	99%
3 log (Log 3)	1,000	99.9%
4 log (Log 4)	100	99.99%
5 log (Log 5)	10	99.999%
6 log (Log 6)	1	99.9999%

3. WHY UNDERSTANDING LOG REDUCTION IS IMPORTANT:

Hospital surfaces can be contaminated with pathogenic organisms (bio-burden), and only achieving a *Log Reduction* below **6.0 Log** means dangerous viruses, bacteria, fungus, and Clostridium difficile (C-diff) spores, can or will be left behind to proliferate and repopulate surfaces within the treated area. The literature has shown that bio-burden can be spread around to contaminate patients and/or grow new bacterial and fungal colonies on new surfaces. (**1**)

The number of bacterial survivors is very important because they can quickly increase their populations exponentially / logarithmically. For example, Staphylococcus aureus or (S. aureus) (under ideal conditions) doubles in 24-30 minutes (Generation Time, G), this means 1,000 or 10^3 or *Log 3*, bacterial survivors would increase to 2,000 after 30 minutes, after 60 minutes they would increase to 4,000, and after two hours to 16,000 and then increase to over one million or 1,024,000 after 5 hours or more, if the growing environment is optimal.

a) Log Reduction Examples for Clostridium difficile (C-diff) spores:

In one example, a UV-C product, in this case sold under the name **Tru-D**, was shown by Dr. Donskey and Cadnum (2016), to achieve a low *Log Reduction* of only about **3.3 Log** at four (4) feet from the light source **after 40 minutes** on an inoculated surface, for exposed surfaces presented in a manner that was favorable (ie: facing light source and 4 ft or less away). (**2**)

When calculating Log Reduction of **3.3 Log**, if the surface is contaminated with 1,000,000 bacteria, that means there will be more than 100 **C. difficile** survivors remaining that can populate surfaces and infect people. **This is NOT disinfection, decontamination, or sterilization**!

Worse, a UV-C light product was shown by Dr. J. Boyce, MD (2016), to achieve a *Log Reduction* range of (**2.0 - 4.0**) for **C. difficile**, after a manufacturer recommend **fifteen (15) minute treatment**, on an inoculated surface at a zero (0) degree angle to the light, and only four (4) feet from the light source. (**3**)

When calculating *Log Reduction* of Log **2.0** to **4.0 Log**, if the surface is contaminated with 1,000,000 bacteria, that means there will be between about 100 to 10,000 **C. difficile** survivors remaining. **This is NOT disinfection, decontamination, or sterilization**!

In another example, a PX-UV product (pulsed UV), sold under the name **Xenex**, was shown by Dr. Donskey and Nerandzic (2015), to achieve a very low *Log Reduction* range of about (**0.5 - 0.8**) for **C. difficile** at four (4) feet from the light source **after 10 minutes** on an inoculated surface if exposed surfaces are presented in a manner that is favorable (ie: facing light source and 4 ft or less away). (**7**)

When calculating *Log Reduction* of about **0.5 Log** to **0.8 Log**, if the surface is contaminated with 1,000,000 bacteria, that means there will be at least 100,000 **C. difficile** survivors remaining that can populate surfaces and infect people. **This is NOT disinfection, decontamination, or sterilization**!

b) Log Reduction Examples for MRSA (*Staphylococcus aureus*):

In another example, a UV-C product (**Tru-D**) was shown by Dr. J. Donskey and Cadnum (2016) to only achieve a maximum *Log Reduction* of about **5.2 Log** for the **vegetative bacteria** (non-spore) **MRSA (***Staphylococcus aureus***)** at four (4) feet from the light source after **forty (40) minutes** on an inoculated surface *at its very best* if the exposed surfaces are presented in a manner that is favorable (ie: facing light source and 4 ft or less away). (**2**) **This is NOT disinfection, decontamination, or sterilization!**

The same UV-C product (**Tru-D**) was also shown by Dr. J. Donskey MD and Cadnum (2016) to only achieve a *Log Reduction* of about **3.2 Log** for **MRSA (***Staphylococcus aureus***)** at a zero (0) degree horizontal orientation, at four (4) feet from the UV light source, and a *Log Reduction* of about **4.6 Log** for **MRSA (***Staphylococcus aureus***)** at a ninety (90) degree vertical orientation, at four (4) feet from the light source. Both exposures were for **ten (10) minutes**. (**2**) **Again, this is NOT disinfection, decontamination, or sterilization!**

In another example, a PX-UV product (pulsed UV), sold by **Xenex**, was shown by Dr. Donskey MD and Nerandzic (2015), to achieve a *Log Reduction* of about **2.0 Log** for **MRSA (***Staphylococcus aureus***)** at four (4) feet from the light source **after 10 minutes** on an inoculated surface if exposed surfaces are presented in a manner that is favorable (ie: facing light source and 4 ft or less away). However, a lower *Log Reduction* of only **1.5 Log** was achieved **after 10 minutes** on an inoculated surface that was shaded from the light, and only four (4) feet from the light source. (**7**) **This is NOT disinfection, decontamination, or sterilization**!

For sake of calculating *Log Reduction*, if the surface is contaminated with 1,000,000 **MRSA** bacteria, that means there will be less than 10 **MRSA** survivors for a *Log Reduction* of about **5.2 Log**, less than 1,000 **MRSA** survivors for a *Log Reduction* of about **3.2 Log,** less than 100 **MRSA** survivors for a *Log Reduction* of about **4.6 Log**, about 10,000 **MRSA** survivors for a *Log Reduction* of **2.0 Log**, and greater than 10,000 **MRSA** survivors for a *Log Reduction* of about **1.5 Log**.

This performance does **NOT** meet the definition of disinfection, hospital disinfection, or sterilization, as outlined by the United Stated EPA, as shown below. Instead, there will still be surviving bacteria left to grow and replenish their populations and infect people.

4. IMPLICATIONS

The data shown above is very significant because the United States government demands that any hospital cleaning process that claims **Hospital Disinfection**, must show at least a **6.0 Log** reduction for **both** Staphylococcus aureus **AND** Pseudomonas aeruginosa, **within ten (10) minutes or less**.

In addition, any cleaning process that claims **General Disinfection** must show at least a **6.0 Log** reduction for **both** Staphylococcus aureus **AND** Salmonella enterica, **within ten (10) minutes or less**. Neither of these standards have been shown to be met by the UV-C and PX-UV (pulsed UV) light room treatment products in independent third party testing that was peer reviewed and published in leading scientific journals.

Further, the United States government requires that any hospital cleaning process that claims **efficacy against C. difficile Spores**, must achieve **NO GROWTH**, which means NO SURVIVORS that can multiply and create new bacterial colonies. No independent third party data that has been peered reviewed supports the UV-C or PX-UV industry's claims against C. difficile.

Questions: Why are UV-C and PX-UV (pulsed UV) light room treatment products allowed to claim Disinfection and Hospital Disinfection even though they **cannot meet** the **6.0 Log Reduction** requirements mandated by the EPA? Also, why are UV-C and PX-UV light room treatment products allowed to claim efficacy for C. difficile spores, while functioning outside of US Federal standards by leaving viable spores? All other disinfectant and sterilant products on the market have to meet and abide by the strict government guidelines shown below.

Alternatively, Altapure's process uses an EPA approved *Cold Sterilant*, and when used in accordance with the manufacturer's directions, will consistently achieve much greater then a **6.0 Log Reduction.** This process results in a Total Kill and No Growth result for: viruses, bacteria, and C. difficile (C-diff), on all treated surfaces.

5. UNITED STATES GOVT. DEFINITIONS REGARDING DISINFECTION & STERILANTS

a) U.S. Regulatory Definition for "General Disinfection / Broad Spectrum Efficacy"

Reference: OCSPP 810.2200 (3)

DEFINITION: General or broad spectrum efficacy products - When a disinfectant is represented in labeling as having efficacy against both Gram-negative and Gram-positive bacteria, the product is considered a "*general or broad spectrum*" disinfectant.

According to the United States Environmental Protection Agency (EPA), *Disinfection* is defined as set forth in EPA Product Performance Test Guidelines, OCSPP 810.2200.

The test microorganisms are:

1) Effective against **both** Gram-negative **and** Gram-positive bacteria.
2) Staphylococcus aureus (S. aureus)(ATCC 6538) for effectiveness against Gram-positive bacteria.
3) Salmonella enterica (ATCC 10708) (S. enterica) for effectiveness against Gram-negative bacteria.

The test criteria states:

"Evaluation of confirmatory general or broad spectrum disinfectant success. *The product should kill all the test microorganisms on all carriers in ≤ten minutes*. In addition, per the 2009 AOAC revisions for the Use-Dilution Method, the mean log density for S. aureus is to be at least 6.0 (corresponding to a geometric mean density of 1.0 x 10^6); *a mean log density <6.0 invalidates the test. For the Hard Surface Carrier Test, the dried carrier counts should be 0.5 –2.0 x 10^6 for Salmonella enterica and 1 – 5 x 10^6 for Staphylococcus aureus*." (emphasis added) (**4**)

*** Summary:** To meet the definition of "General Disinfection" a ***6 log kill*** has to be obtained for both S. aureus and S. enterica in less than 10 minutes.

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b) US Legal Definition for "Hospital Disinfection"

Reference: OCSPP 810.2200 (5) & (6)

The EPA has a specific category established for the hospital and healthcare markets. For these markets, the following efficacy is required to meet the definition of disinfection as set forth in EPA Product Performance Test Guidelines, OCSPP 810.2200.

The test microorganisms are:

1) Effective against **both** Gram-negative **and** Gram-positive bacteria.
2) Staphylococcus aureus (S. aureus)(ATCC 6538) for effectiveness against Gram-positive bacteria.
3) Pseudomonas aeruginosa (P. aeruginosa)(ATCC 15442) for effectiveness against Gram-negative bacteria.

The test criteria states:

"Evaluation of confirmatory hospital or healthcare disinfectant success. *The product should kill all the test microorganisms on all carriers in ≤ten minutes. In addition, per the 2009 AOAC revisions for the* Use-Dilution Method, the mean log density for S. aureus and P. aeruginosa is to be at least 6.0 (corresponding to a geometric mean density of 1.0 x 10^6); a mean log density <6.0 invalidates the test. For the Hard Surface Carrier Test, the dried carrier counts should be 1 –5 x 10^6 for both Staphylococcus aureus and Pseudomonas aeruginosa." (emphasis added) (**4**)

*** Summary:** To meet the definition of "Hospital Disinfection" a ***6 log kill*** has to be obtained for both S. aureus and P. aeruginosa in less than 10 minutes.

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c) US Legal Definition for "Disinfectants With Fungicidal Claims"

Reference: OCSPP 810.2200 (9)(e)

The test microorganism is:

1) Trichophyton mentagrophytes (T.mentagrophytes)(ATCC 9533)

Two samples representing two different batches of the product should be evaluated for efficacy against Trichophyton mentagrophytes (T. mentagrophytes)(ATCC 9533). The inoculum employed should provide a concentration of ≥*5 x 10^6* conidia/mL.

Evaluation of fungicidal success. For the AOAC International Fungicidal Activity of Disinfectants test, all fungal spores at 10 and 15 minutes should be killed to support a 10 minute exposure time. For the AOAC International Use-Dilution Methods, ***all*** *fungal spores on all 10 carriers should be killed in ≤ten minutes*. (emphasis added) (**4**)

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d) US Legal Definition for "Sterilant w/ Clostridium difficile Claims"

Reference: OCSPPP 810.2100 (d)(2) and (g)

General Liquid Sterilants Claims - Mandated Log Reductions:

5-6 Log reduction minimum for BOTH Bacillus subtilis (B. subtilis) spores and Clostridium sporogenes (C. sporogenes) spores, AND must reach at least **6 Log** reduction minimum for Clostridium difficile (C. difficile) spores, to be classed as liquid Sterilant w/ Clostridium difficile (C. difficile) Claims. Kill everything, **no growth**, on ALL slides in less than XX minutes (time not specified).

The test microorganisms are:

1) Effective against: (B. subtilis) **and** (C. sporogenes) **and** (C. difficile)
2) Clostridium difficile (C. difficile) (ATCC 700792), (ATCC 43598) or (ATCC 43599)
3) Bacillus subtilis (B. subtilis) (ATCC 19659)
4) Clostridium sporogenes (C. sporogenes) (ATCC 3584)

Evaluation of sterilant success. *The inoculum employed should provide a count of 1 x 10^5 – 1 x 10^6 spores per carrier*. The product should kill the test spores on all 120 carriers without any failures (e.g., growth of test organism after carrier treatment constitutes failure). (**5**)

6. REFERENCES

1) Sreelatha Koganti, MD, and Curtis Donskey, MD - "Evalution of Hospital Floors as a Potential Source of Pathogen Dissemination Using a Nonpathogenic Virus as a Surrogate Marker", Infection Control & Hospital Epidemiology, November 2016, Vol. 37, No. 11.

2) Jennifer L. Cadnum, BS, and Curtis Donskey, MD - "Effect of Variation in Test methods on Performance of Ultraviolet-C Radiation Room Decontamination", Infection Control & Hospital Epidemiology, November 2016.

3) John M Boyce, MD - "Impact of Room Location on UV-C Irradiance and UV-C Dosage and Antimicrobial Effect Delivered by a Mobile UV-C Light Device", Infection Control & Hospital Epidemiology, June 2016, Vol. 37, No. 6.

4) https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0150-0021

5) https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0150-0020

6) Log Reduction graphic courtesy of: http://www.bestsanitizers.com

7) Nerandzic, and Curtis Donskey, MD – "Evaluation of a Pulsed Xenon Ultraviolet Disinfection System for Reduction of Healthcare-Associated Pathogens in Hospital Rooms", Infection Control & Hospital Epidemiology, February 2015, Vol. 36, No. 2.

