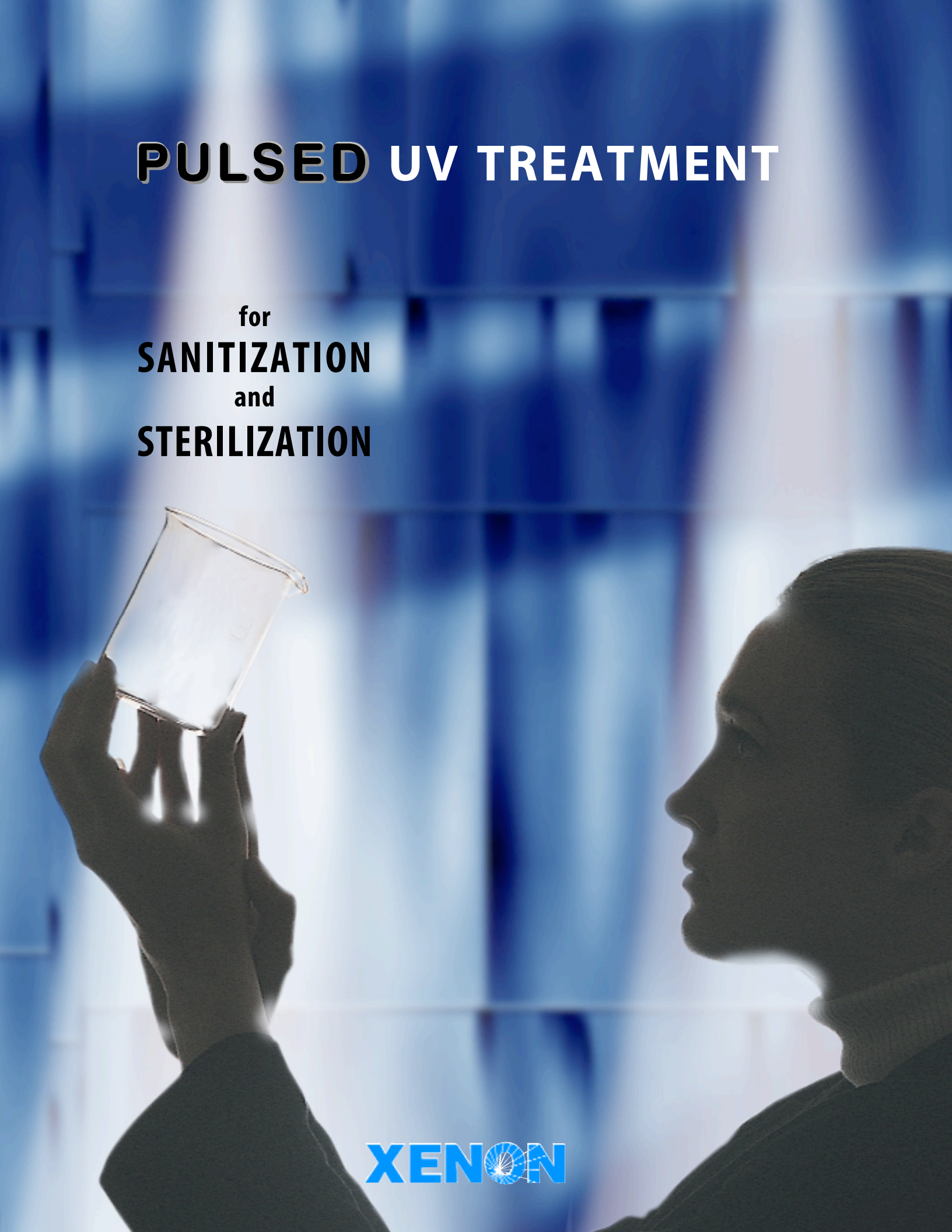
PULSED UV TREATMENT

for
SANITIZATION
and
STERILIZATION



XENON

"Xenon's pulsed UV is an advanced sterilization agent which can displace continuous wave UV mercury vapor arc lamps in all applications and is effective for many applications that currently use or are not compatible with gamma radiation, heat, or chemical sterilants." *Louis R. Panico, CEO, Xenon Corp*

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PHOTOCHEMICAL STERILIZATION

Chemical bond dissociation induced by light occurs when a photon's wavelength-dependent quantum energy is equal to or greater than the energy of the molecular bond upon which it is incident. Photochemical damage to a life-critical biological structure can be induced by irradiation with photons having energy levels corresponding to the bond energies of biomolecular chemical bonds. Upon UV photon absorption, excited states and reactive species are created which react to form biologically non-functional reaction products.

The history of photochemical microbial inactivation dates back to the discovery in 1877 by Downes and Blount (1) that ultraviolet light can damage microorganisms. In 1928 F.L. Gates (2) made the formal discovery that specific monochromatic wavelengths of UV light are bactericidal. The physical mechanism connecting specific wavelengths of light with specific molecular bonds was finally revealed by quantum mechanics, developed by Planck, Einstein, Bohr, Sommerfeld, de Broglie, Heisenberg, Dirac, Pauling and others during the first half of the 20th century. Biochemical research since then has shown that the most effective wavelengths, 250 nm to 280 nm, coincide with the peak absorption spectra of nucleic acids (3). On the basis of this correlation, and the observation that the majority of damage to inactivated microbes is found in their genetic material, the primary mechanism in UV induced microbial inactivation is now known with certainty to be biomolecular damage to DNA and RNA nucleic acids.

Photochemical sterilization of microorganisms is achieved by high flux UV irradiation in the germicidal wavelength range from 200 nm to 320 nm. Absorbed UV photon energy dissociates C, N, O, and H covalent bonds resulting in irreversible molecular damage to nucleic acids and cell death. Xenon Corporation's *SteriPulse-XL*™ photochemical sterilization systems generate the most effective form of germicidal UV light known - high flux broad spectrum pulsed xenon arc radiation - and achieve high assurance USP sterility levels for all known microorganisms.

UV radiation damage to DNA includes formation of cyclobutane pyrimidine dimers (CPDs) and pyrimidine-pyrimidone 6-4 photoproducts (6-4 PP's) (4, 5, 6, 7), as shown in Fig. 1-1. CPDs are formed by covalent bonding between two same strand adjacent pyrimidines. UV irradiation usually generates thymine dimers in the greatest quantity, cytosine dimers in low quantity, and mixed dimers at an intermediate level (8). In UV irradiated RNA viruses, the nucleotide uracil forms pyrimidine photoproducts. At irradiation flux magnitude and total dose high enough to irreversibly inactivate nucleic acid repair mechanisms, nucleic acid damages result in irreversible mutations, impairment of replication and gene transcription, and eventual death of the organism.

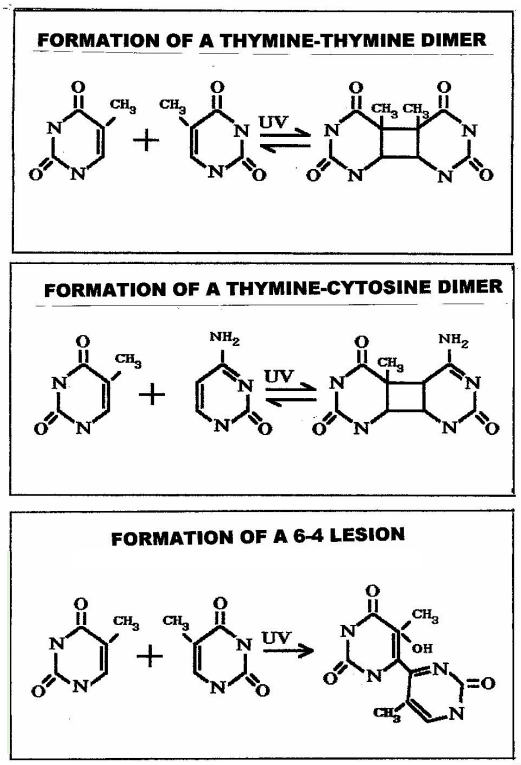

Figure 1-1 Formation of Dimers and 6-4 Lesions

Conventional low pressure monochromatic and medium pressure polychromatic mercury vapor arc UV lamps are inherently low radiance sources and cannot practically deliver radiant flux magnitudes required for irreversible inactivation of nucleic acid repair mechanisms. Pulsed xenon arc sources are inherently high radiance, high power devices which easily and practically yield high over-kill radiant flux magnitudes sufficient to cause irreversible inactivation of all nucleic acid repair mechanisms and consequent lethal nucleic acid injury.

The inherent advantages of high peak pulsed UV, when compared to mercury vapor arc exposure, have established pulsed UV technology as the UV source of choice for high sterility sterilization systems. Xenon Corporation, the acknowledged leader in pulsed UV technology, is the supplier of choice for high sterility pulsed UV photochemical sterilization systems.

For a more complete discussion on the photochemistry of UV induced damage to nucleic acids, and on repair mechanisms, the reader is referred to the excellent treatment by Blatchley and Peel (9).

Sterilization results on *Bacillus subtilis,* shown inFigure 1-2, demonstrate the remarkable rapidity and effectiveness with which high flux pulsed UV light eradicates microorganisms. Only three 360 microsecond pulses at 1.2 joules/cm^2-sec yield a greater than log 6 kill.

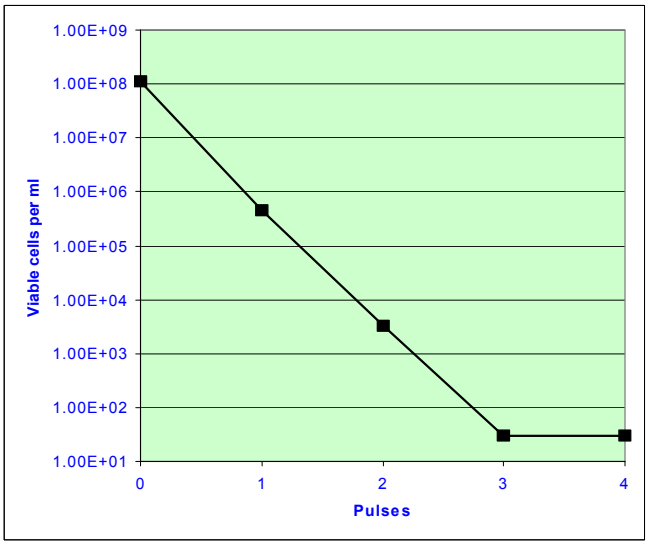

Figure 1-2 Example of the lethality of Pulsed UV exposure on Bacillus subtilis. Determined experimentally by Abraham L. Sonenshein, PhD, Tufts University School of Medicine and Xenon Corporation

High peak power pulsed UV creates excited states and reactive species in very large concentrations. One joule contains on the order of 10^{18} UV photons. Delivered at high power in microseconds, these photons produce far more biological damage than they would if delivered by a mercury vapor source at low power over longer time. For equal total energy absorbed, bactericidal damage is inversely related to duration of energy – a work-time relation which is consistent with the finite characteristic energy dissipation rates typical of molecular structures in general and nucleic acids and their repair mechanisms in particular, and which underscores the virtue of high peak power pulse UV energy.

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APPLICATIONS OF PULSED UV LIGHT

History

The first reported discovery that specific monochromatic wavelengths of UV light are bactericidal was made as early as 1928 (3). Since then UV lamps have been continuously developed and commercialized for a variety of sanitization and sterilization applications. The most common commercial sources of monochromatic UV light are continuous wave low and medium pressure mercury vapor arc lamps. Low pressure lamps are electrically efficient UV sources, but they are inherently low power devices (10's of watts) suitable for a very limited range of disinfection uses, are not capable of complete microbial sterilization, do not inactivate cellular repair processes, and are difficult to control in inline processes due to high output variability. Medium pressure lamps are more powerful (100's of watts), produce a wider UV spectrum, and generate sterilization levels of UV irradiance. They are constrained to an extremely limited application range, however, due to their very high operating temperatures (400°C – 1000°C), non-uniform output behavior, low electrical efficiency, and high cost (4). Finally, the extreme toxicity of mercury vapor poses a serious safety threat.

Mercury vapor arc lamp systems have undergone many engineering refinements and the technology has reached the limits of its device-physics defined performance envelope. In order to meet the growing needs in science, engineering, and industry for a better UV light source, Xenon Corporation has developed and refined to maturity a new UV light source technology – the Pulsed Xenon Arc Lamp. Superseding mercury vapor technology and its attendant limitations, Xenon Corporation's pulsed xenon light source technology produces high peak power pulsed UV light, at irradiance magnitudes and dose flux rates that induce complete microbial sterilization and eliminate post-exposure repair mechanisms (5) – at ordinary operating temperatures, and with the controlled quantitative repeatability necessary for high sterility assurance level inline implementation. By utilizing controlled high irradiance UV light, delivered in short, microsecond wide pulses, at total doses on the order of 1.27 joules/cm^2, Xenon Corporation's *SteriPulse-XL* systems can provide equivalent or better sterility assurance levels than conventional sterilization technologies, such as moist heat, dry heat, chemical sterilants, and gamma radiation. This performance is delivered without unwanted thermal, chemical, or ionizing radiation induced collateral damage to pharmaceutical packaging, proteins, enzymes, and antigens, and is accomplished with relatively safe, economical, and reliable equipment. Pulsed UV was approved by the FDA in 1999 for the treatment of food.

Applications Overview

All microorganisms, with the exception of Mad Cow Disease, contain DNA. Therefore, a technology that destroys DNA will provide an effective means of sanitization, decontamination and sterilization. Because high peak power pulsed UV light kills DNA and inactivates *all* types of microorganisms, including fungal yeasts and molds, bacteria, rickettsiae, mycoplasma, and viruses, it is classified as a sterilization agent. It can be used in all applications that currently utilize continuous wave UV mercury vapor arc lamps. Examples are in research (R&D) studies, surface treatment, liquids and air decontamination.

a - Research Applications

Pulsed UV is an ideal research tool for the study of the destruction of microorganisms. Xenon's SteriPulse-XL systems are being used in research labs around the world including United States, Canada, Spain, China and the Food Institute of Technology in Taiwan. Much of the investigative research is done in conjunction with the needs of industry.

b - Surface Applications

Pulsed UV light can be used for sanitization,

decontamination and sterilization of smooth, dry surfaces such as aluminum, paper, glass, medical devices and packaging materials with implementation in clean room pass-through tunnels, and above mail conveyor belts. Additionally, pulsed UV light can be used for decontamination of rough surfaces found on food and other surfaces such as laboratory benches and inside safety hoods.

c. Liquid Applications

Pulsed UV light can be used for sanitization, decontamination, and sterilization of UV transmissive liquids, such as water, process chemicals, clear liquid pharmaceutical products, buffers, and dilute protein solutions for virus inactivation procedures.

d. Air Applications

By mounting pulsed UV lamps on walls and/or ceilings, inside heating, ventilation, and air conditioning ducts, pulsed UV light can be used for decontamination of publicly shared atmospheres in hospitals, large group living quarters, office buildings, hotels, microbiology laboratories, as well as inside contained spaces such as a sterile glove, clothing, instrument cabinets and drawers.

Material Compatibility Studies

Chemical and structural stability of items after exposure to pulsed UV light, for example pharmaceutical packaging materials, and implantable medical devices, can be determined with an investigational protocol similar to ones used for conventional sterilants such as ethylene oxide, moist or dry heat, and gamma radiation. As already emphasized, the SteriPulse-XL RS-3000C employs a bench-top sterilization chamber, making it an ideal engineering development tool for determination and validation of all critical inline process operating parameters, including material compatibility, required radiant flux dose levels, optimal throughput rate, product stability, target medium effects, and sterility assurance level. Irradiation effects on materials under study are determined by controlled variation of system operating parameters. First order critical parameters that determine irradiated material stability are energy per pulse, pulse width, pulse interval, pulse quantity, spectral distribution of pulse radiant flux, and total energy deposited in the sample. All of these variables can be quantitatively controlled, monitored, measured, and recorded, with the SteriPulse-XL RS-3000C benchtop system.

The importance of quantitative control over all critical parameters is best understood by example. Certain classes of polymers used for medical devices are damaged if exposed to 4 joules/cm² total dose delivered in 4 pulses at 1 joule/cm² per pulse, but are not damaged if exposed to 4 joules/cm² total dose delivered in 8 pulses at 0.5 joules/cm² per pulse. This energy versus time sensitivity is typical of many packaging materials which develop black spots at high energy per pulse but not at low energy per pulse.

Effective sterilization of the contents inside a container depends on transmission of short wavelength UV photons through the container walls. A good candidate for container testing is selected by choosing material with known UV transmission characteristics. Published examples of UV transmissive materials include low density polyethylene, high density polyethylene, and polyamides (nylon). In general, caution should be observed. Transparency in the visible provides no knowledge of UV transmissivity. Glass containers, for example, have excellent visible band transmissivity, but are essentially UV opaque. Quartz, on the other hand, is transmissive in both the visible and UV. Furthermore, since the mechanism of pulsed xenon UV microbial sterilization is irreversible due to photo-biochemical damage to genetic material induced by high energy UV-B and UV-C exposure in the 240 nm – 280 nm wavelength range, determination of spectral transmissivity in this range is correspondingly essential.

Microbiology Studies

A significant number of publications and presentations at scientific meetings have publicized and documented the ability of pulsed UV light

to destroy microorganisms of all origins and phenotypes (1, 2 and 6). There is currently no evidence of a resistant organism. Universal lethality is accomplished by irreversible damage to nucleic acids. Some evidence has been published to support the hypothesis that a highly localized heating mechanism might cause cell death (7). It has been shown that sample temperature does increase measurably after exposure to sterilization levels of pulsed xenon broad spectrum UV light. Since proteins retain function after exposure to pulsed UV at doses that completely inactivate nucleic acids (8), it is unlikely that cell death is caused by a thermal mechanism. Given that proteins are sensitive to heat, it is reasonable that heat might play a role in cell death at dosages higher than those required for microbial sterilization.

Research Studies

The SteriPulse-XL system affords researchers a convenient and unique tool to assist in the study of the destruction of DNA using high energy pulsed UV light. Pulsed ultraviolet light is a proven technology to sanitize surfaces and under certain circumstances achieves 10^6 sterility assurance levels. The high intensity pulses allow efficient transmission of the UV light through not only cell walls and membranes, but also bacillus spore coats causing irreversible damage to the nucleic acids present in the cellular material. In recent years, numerous laboratories have reported inactivation of all classes of bacteria, fungi, protozoa and virus particles. Higher efficiencies of inactivation are observed with respect to exposure time due to the peak intensity of pulsed UV delivered in microseconds as compared to conventional UV light that requires significantly longer exposure times to deliver an equivalent amount of energy. Pulsed UV is an excellent replacement of conventional mercury UV lamps for decontamination of food, water, and related packaging. Pulsed UV is an excellent technology to reduce the probability of the spread of microorganisms including virus particles by surface contact. It is used in worldwide research facilities, including the following:

- AINIA Centro Tecnologico, Laboratorio de Bioensayos, Valencia, Spain
- Alabama A&M
- American Red Cross Holland Laboratories
- College of Food Science – Fujian Agriculture and Forestry University, China
- Cornell University
- Florida Dept of Citrus
- Fort Valley State University
- Georgia State University
- Institute of Food Technology – Taiwan
- McGill University
- Nissan Pharmaceuticals
- Pennsylvania State University
- Rutgers University
- University of Massachusetts
- U.S. Department of Agriculture

Model viruses that have been tested with Pulsed UV:

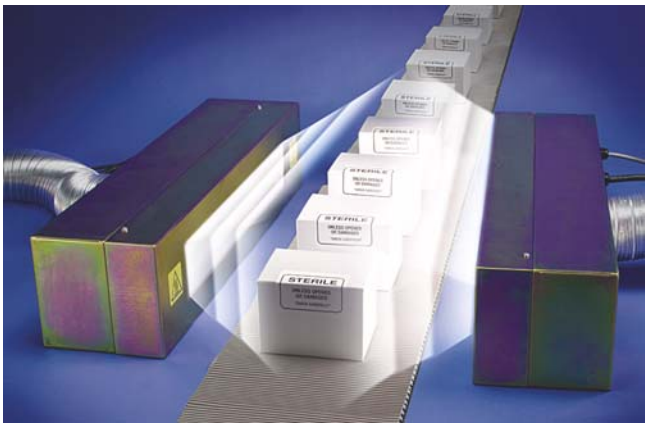
- SV40
- Canine Parvovirus
- Porcine Parvovirus
- Simian Rotavirus (SA11)
- Bacteriophage PRD-1
- Poliovirus Type I
- Reovirus
- Bacteriophage MS-2
- Encephalomyocarditis Virus (EMC)
- Hepatitis A Virus
- Human Immunodeficiency Virus (BVDC)
- Sindbus Virus
- Vaccinia Virus
- Vesicular Stomatitis Virus

Experimental Results Using the SteriPulse-XL System on *Bacillus subtilis* Spores

The high peak power pulsed UV light generated by Xenon Corporation's SteriPulse-XL model RS-3000C system has been experimentally proven to inactivate microorganisms, including bacterial endospores, which are known to be extremely resistant to radiation and other physical and chemical agents. In one exemplary study, Dr. Abraham Sonenshein at Tufts University demonstrated the system's effectiveness by irradiating *Bacillus subtilis* spores with pulsed

UV light generated by the SteriPulse-XL system. Dr. Sonenshein's report, presented in detail in Chapter 3, demonstrates that the number of surviving spores decreased in each sample after irradiation. The sample with population of 10^7 spores per ml decreased below the detection limit after three pulses. Similar results were obtained on the sample with 10^8 spores per ml. As expected on the basis of geometrical shadowing at very high concentration, the sample containing 10^9 spores per ml was not completely inactivated. In this regard it should be noted that validation studies for the medical device and pharmaceutical industries use concentrations of 10^7 or less per ml.

Bacillus spores are used to validate medical devices and pharmaceutical products as surrogates because these spores are more resistant than all other types of microorganisms. Successful inactivation of *Bacillus subtilis* spores proves the SteriPulse-XL system to be an effective sterilization technology.



Shown above and to the left are examples of Pulsed UV lamps applied to sanitize the outside of packages containing sterile contents as well as containers prior to filling with sterile material. These non-contact systems prevent the introduction of microorganisms to sterile areas, such as clean rooms, and eliminate the need for chemical vapors.

Sanitizing Surfaces

Pharmaceutical and medical device companies are increasingly manufacturing their products in clean rooms equipped with two types of enhanced clean room devices. One device is the simple hood or flow cabinet, the second is a fully enclosed clean work environment known as the isolator or barrier isolator. The common feature of clean room devices is the increased separation of the manufacturing activity from the human clean room technician. A key function of clean room devices is to control microbial contamination near and within the manufacturing area. This is accomplished by air flow through HEPA filters and the construction of walls or barriers. The ultimate success of the clean room device depends upon the ability to transport materials into and out of the clean work environment without the introduction of microbial contamination. Xenon Pulsed UV Light Systems are designed to work in these clean room devices and control microbial contamination.

Completely enclosed barrier isolator manufacturers have designed transfer ports to move material into the isolator while controlling the introduction of microbial contamination. The transfer ports are designed differently than conventional transfer hatches or airlocks. The transfer ports are equipped with a method to steril-

ize the surface of materials entering the isolator and to allow a rapid transfer of materials. Systems equipped with slow acting vapor phase hydrogen peroxide or conventional UV light are being displaced with the more rapid decontamination agent, pulsed UV light, that is capable of sterilizing the surface of materials in seconds without significantly increasing the temperature in the chamber. Pulsed UV light systems also sterilize the empty transfer port after each use. No vapor or gaseous decontamination chemical is used or introduced into the clean room.

Completely enclosed barrier isolators and open isolators (hoods) must be decontaminated before and after each use as a clean work environment. Common methods employed by industry include vapor phase hydrogen peroxide, ozone based procedures, liquids such as peracetic acid or hydrogen peroxide. These systems normally achieve a 3-6 log kill to meet most application regulatory requirements. Each method requires the surface to be cleaned prior to applying the decontamination chemical. Pulsed UV light is an acceptable alternative that can be applied in seconds without labor and does not involve the introduction of a gaseous chemical or create a toxic waste. Pulsed UV light applications are fully automated and designed as an integral component of the system, eliminating the potential introduction of human-borne microbial contamination.

As clean room technology advances to automation and further isolation of the work environment, equipment and system design will consider the application of pulsed UV light as a safe and effective method to sanitize surfaces in less than a second without the use of gaseous or liquid toxic chemicals, without causing a significant increase in surface temperature, and without generating waste products.

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USE OF PULSED UV TREATMENT TO KILL BACILLUS SPORES

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Rationale

Bacterial endospores, of the type by *Bacillus* and *Clostridium* species, are known to be highly resistant to various forms of radiation and other physical and chemical agents. High-intensity ultraviolet light, however, was suspected to overcome such resistance and to kill spores efficiently. To test this hypothesis, I irradiated samples of *Bacillus subtilis* spores (in collaboration with Roger Williams, Xenon Corporation) and measured the loss of viability as a function of UV dose and position with respect to the axis of the lamp.

Protocol

Four 2-L flasks, each containing 500 ml of DS medium (a nutrient broth-based growth and sporulation medium for *Bacillus subtilis*), were inoculated with *B. subtilis* strain SMY (a standard wild-type strain) and incubated with vigorous shaking for 36 hrs at 37°C. Spore formulation was verified microscopically. Spores were harvested by centrifugation and washed twice with sterile, deionized water. The stock of spores was stored in water at 4°C.

The spore stock was diluted in sterile, deionized water to give concentrations of approximately 1 x 10^9, 1 x 10^8 or 1 x 10^7 spores per ml. Fifty microliter samples of each dilution were placed at three different locations with respect to the UV source (see below) and irradiated with one-to-four pulses of light. The samples were recovered, diluted as necessary with sterile water, and spread on agar plates containing a nutrient medium that supports growth of *B. subtilis.* After overnight incubation at 30°C, the colonies that arose were enumerated. Based on the number of colonies obtained at a given dilution of the irradiated spores, the surviving titer of each sample was calculated.

The UV source was a SteriPulse-XL, model RS-3000C provided by Xenon Corporation and operated by Roger Williams (Applications Engineer/Lamp Engineer; Xenon Corporation). The samples were placed as follows:

Position 1 – on the lamp axis and at the midpoint of the lamp;
Position 2 – 1 cm above the lamp axis and on the midpoint of the lamp;
Position 3 – 1 cm above the lamp axis and 6.803 (172 mm) to the right of the midpoint of the lamp.

Results

As shown in the accompanying table and figures, killing of spores was observed for all dilutions of the spore preparation at all positions with respect to the axis and midpoint of the lamp. Killing was most effective, however, when the sample was on the lamp axis and at the midpoint of the lamp. The rate of killing was similar for all dilutions at a given position, although the most concentrated suspension may be killed slightly less effectively. If borne out by further experiments, such a result might imply that spores shield each other when they are above a certain concentration.

Microscopic analysis after irradiation (Sample A, 4 pulses) revealed that most of the spores had disintegrated.

Conclusions

1) The SteriPulse-XL RS-3000C system is an effective device for reducing the viability of *B. subtilis* spores in suspension. Killing is rapid (1 second or less) and reduces viability by a significant factor. Starting with spore suspensions at 1 x 10^8 (Sample B) or 1 x 10^7 spores (Sample C) per ml, it was possible to completely eliminate viability with three pulses of UV light.

2) The most concentrated sample (A)

was reduced in viability by 100,000-fold with three pulses, but a fourth pulse gave no further killing. The basis for the lack of additional killing is unknown and may warrant further experimentation.

3) Killing at position 1 was much faster than at positions 2 or 3. Thus, the most effective sanitization occurs on the lamp axis. The exact relationship between killing and the midpoint of the lamp remains to be determined. Since there was only a small difference between the results obtained at positions 2 and 3, it is likely that irradiation is equally effective across nearly the entire width of the lamp.

4) Since other species of *Bacillus* and *Clostridium* are thought to have similar responses to UV light, it is reasonable to assume that the methods described here would give similar results with spores, including *Bacillus anthracis*.

Viable Cells per ml						
Sample	Position	0 Pulse	1 Pulse	2 Pulses	3 Pulses	4 Pulses
A	1	1.4×10^9	4.4×10^7	8.8×10^5	8.9×10^3	6.7×10^3
A	2	1.4×10^9	2.0×10^8	9.0×10^7	$>6.0 \times 10^6$	5.6×10^6
A	3	1.4×10^9	6.0×10^8	1.7×10^8	$>1.5 \times 10^7$	$>9.0 \times 10^6$
B	1	1.1×10^8	4.5×10^5	3.3×10^3	<30	<30
B	2	1.1×10^8	1.0×10^7	1.0×10^6	4.0×10^5	1.9×10^4
B	3	1.1×10^8	3.6×10^7	2.0×10^6	1.9×10^6	4.4×10^5
C	1	1.3×10^7	1.2×10^5	$<3.0 \times 10^3$	<30	<30
C	2	1.3×10^7	9.8×10^5	1.9×10^5	1.5×10^4	1.2×10^4
C	3	1.3×10^7	1.5×10^6	3.8×10^5	1.5×10^5	6.4×10^4

Table 3-1 Viable counts of spores before and after irradiation

Log Data Charts Showing Lethality of Pulsed UV exposure on *Bacillus subtilis*

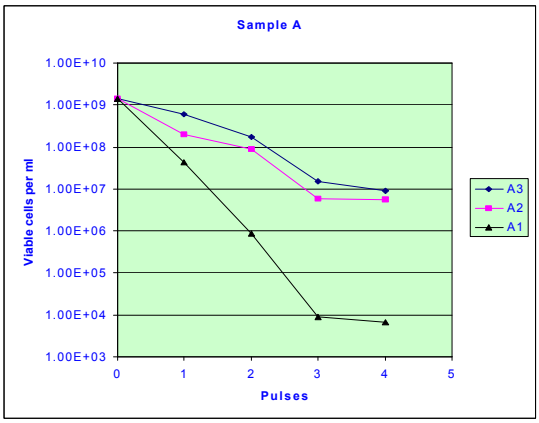


Figure 3-1 Sample A at positions 1, 2, and 3

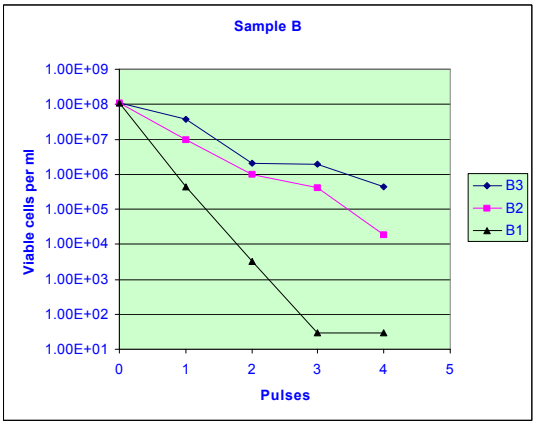


Figure 3-2 Sample B at positions 1, 2, and 3

Log Data Charts Showing Lethality of Pulsed UV exposure on *Bacillus subtilis* (Continued)

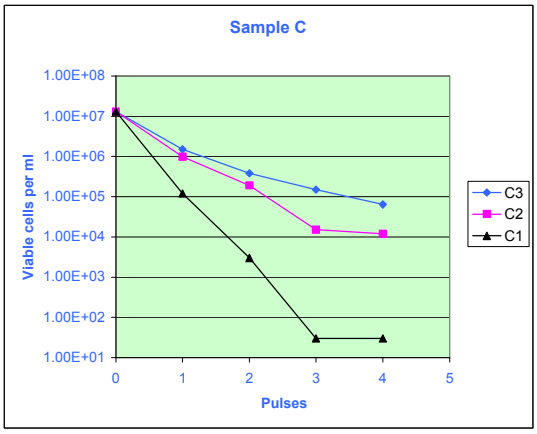


Figure 3-3 Sample C at positions 1, 2, and 3

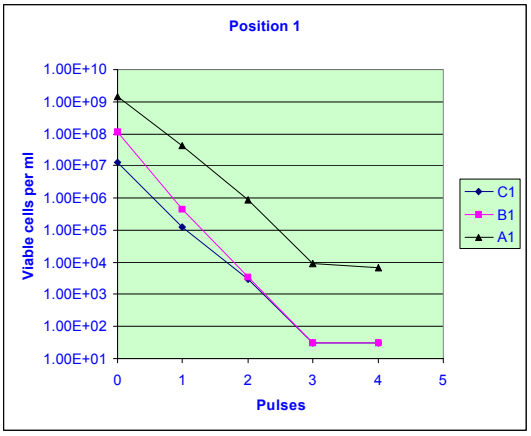


Figure 3-4 Samples A, B, and C at position 1

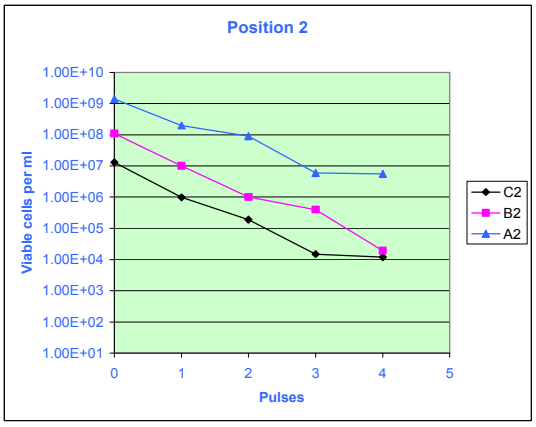


Figure 3-5 Samples A, B, and C at position 2

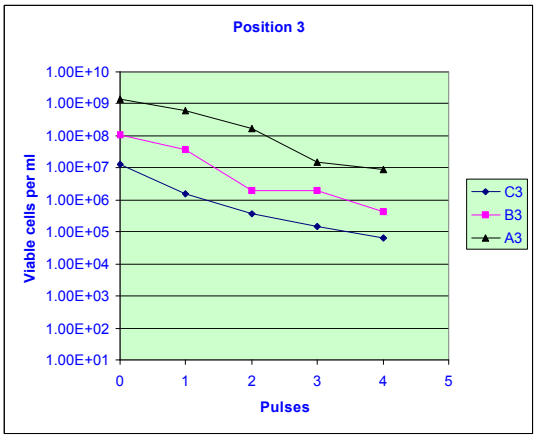


Figure 3-6 Samples A, B, and C at position 3

Report completed November 21, 2001

PULSED UV TECHNOLOGY

Pulsed vs Continuous UV Light

There are several sources of plasma-created UV, the most common being the electric arc, the mercury lamp, and the most efficient of all, the pulsed xenon lamp. The arc discharge is difficult to use in practical applications, thus leaving two means to provide UV light. Delivery of UV light from a mercury lamp is continuous due to the required lamp warm up time. However, the xenon lamp requires only microseconds to turn on/off, and is thus operated in a pulsed mode.

If we review how energy is delivered by these two different means, continuous versus pulsed, we quickly understand significant differences. Consider how the sun delivers energy versus a lightning bolt. The sun can shine on a tree for a year with no apparent damage. A lightening bolt, with a fraction of the energy the sun delivers in 12 months, will have a uniquely different effect on the tree. Similarly, pulsed UV will impact DNA in a more severe way than will continuous UV.

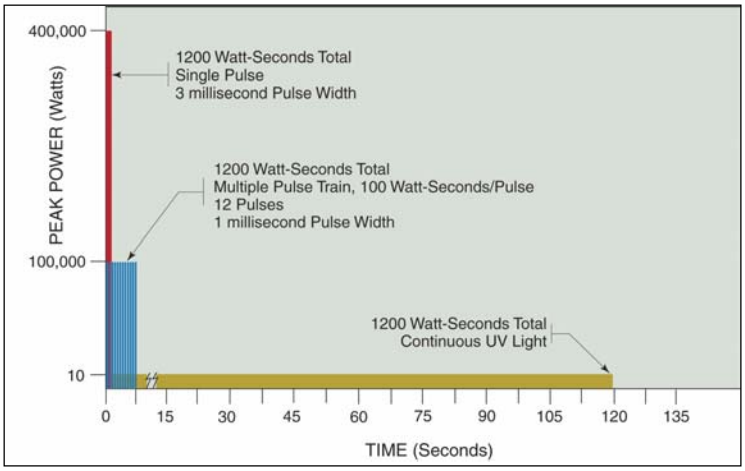


Figure 4-1 Comparison of pulsed vs. continuous UV light (pulsed light illustrated in single pulse and burst modes)

Pulsed UV Light Properties

The intrinsic difference between pulsed UV light and continuous UV light is illustrated in Figure 4-1 in terms of peak energy delivered over time. The low intensity horizontal line represents the continuous mercury UV light and the vertical lines represent pulsed UV light. The peak intensity of pulsed UV can be as high as 100,000 times the intensity of the sun on the surface of the earth. Pulsed UV light can be delivered as a single pulse or a train of controlled pulses.

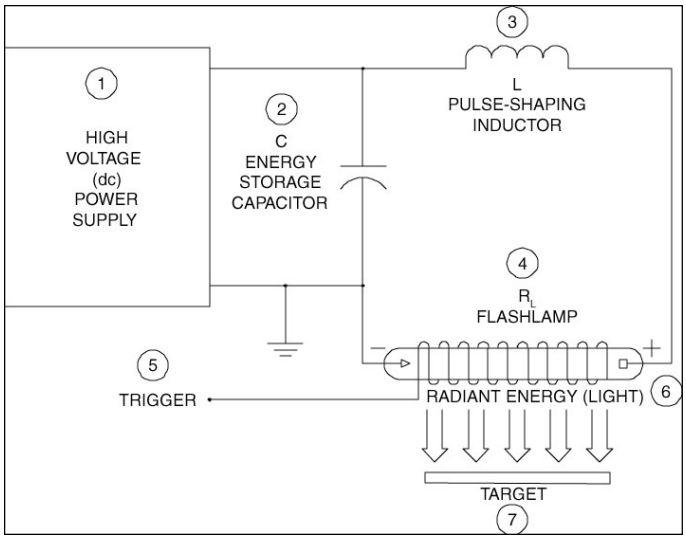


Figure 4-2 Functional diagram of a high-intensity pulsed UV light system.

Pulsed UV System

Figure 4-2 illustrates the functional elements of a high energy, pulsed UV light system. The high voltage power supply ① provides electrical power to the storage capacitor ②. The storage capacitor stores electrical energy for the flashlamp ④. The pulse-forming network ③ determines the pulse shape and spectrum characteristics. A trigger signal ⑤ initiates discharging electrical energy through the flashlamp. This

energy ionizes the xenon gas in the flashlamp. The flashlamp converts electrical energy to pulsed radiant energy ⑥, transmitting pulsed UV light to the target ⑦.

Advantages of Pulsed UV Light

Pulsed UV light is particularly useful in applications where continuous mercury UV is unable to meet the requirements for complete DNA destruction, process speed, penetration, low product temperature, personnel safety and process flexibility. Pulsed UV light offers faster processing, little or no product temperature buildup, process flexibility, freedom from toxic lamp materials, penetration of plastic packages, and ease of meeting special lamp configuration requirements. Pulsed UV light is the technology of choice for sanitization and sterilization applications when total DNA destruction, low heat, and penetration are required.

The most important reasons for considering pulsed UV light systems for sanitization are:

- Total DNA destruction
- Safety
- In-line production
- Temperature integrity
- Process effectiveness
- Process speed
- Process flexibility
- Free of toxic substances
- Worker-friendly (safe and easy to use)
- Minimum space requirements

These features originate from the following attributes of pulsed UV light technology:

- Very high peak power
- Controlled, narrow pulses
- Instant on/off (no warm-up required)
- Low inherent heat
- No Mercury
- Special lamp configurations

Penetration

With its high peak power, the UV light from a pulsed UV lamp penetrates packaging material and totally destroys the DNA. In comparison, a continuous mercury UV lamp delivers much of its energy in the form of heat and cannot, except under carefully controlled laboratory conditions, totally destroy the DNA. Consider two ways of expending the equivalent of 100 joules of energy: one can either power a 10 watt continuous lamp for 10 seconds or power a 1,000,000 watt pulsed lamp for 100 microseconds. This is analogous to penetrating a block of wood with a nail: one could press a nail into the wood with a finger for 10 seconds without effect, or exert the same amount of energy and drive the nail instantaneously into the wood with a single strike of the hammer. Pulsed UV, like the hammer, delivers light at high peak power for deep penetration, resulting in DNA destruction.

Penetration and process effectiveness also depends on another pulsed UV characteristic: pulse width. Baxter Corporation tests with pulsed UV light for sterilizing blood bags concluded a 100 microsecond pulse duration was more effective for penetration when compared to pulse durations in the range of 500 to 1,000 microseconds.

Temperature

Lower temperatures achieved with pulsed UV light can help improve the integrity of the product being treated. Five key reasons why pulsed UV light minimizes temperature buildup are outlined below:

- The short-duration UV pulses reduce the time for heat buildup
- The presence of a cooling period between the UV pulses
- Pulsed UV lamps do not operate at the extreme high temperatures required to vaporize mercury in lamps used in continuous UV systems
- The high peak pulse power and low duty cycle reduces average power delivered
- Pulsed UV lamps are turned completely off/on in microseconds, reducing the thermal component completely during non-treatment times

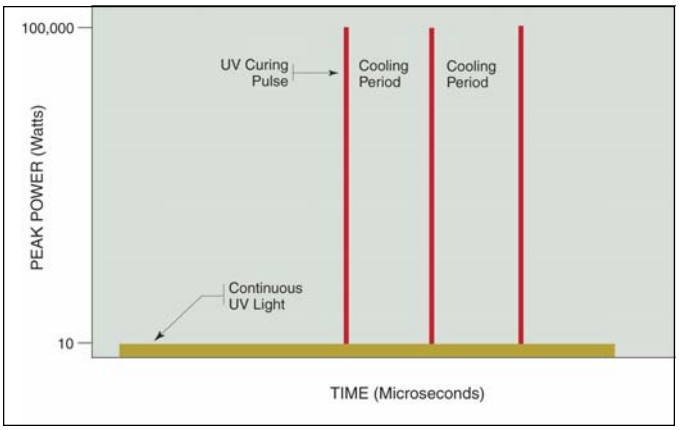


Figure 4-3 Instead of continuously warming the substrate, as does continuous UV light, pulsed UV light provides cooling periods between pulses

Instant ON/OFF Control

The instant on/off capability of a pulsed UV light system is particularly effective, for example, in high-speed insulin production lines where the capsule travels rapidly through the various process stages. Only the tip of the capsule can be exposed to the UV light, not the insulin in the main part of the capsule. By turning the UV light off instantly as the center of the capsule moves past the lamp, insulin exposure to UV light is prevented.

In order for a mercury UV lamp to work, the mercury must be first heated to a high operating temperature to vaporize the mercury. Because of this long warm-up period, the mercury UV lamp cannot be turned on/off rapidly in a continuous, high speed, production line application. As a result, the mercury UV lamp is left on at all times. This is a particular disadvantage with start/stop/start manufacturing applications, requiring mechanical shielding during the non-exposure phase of the process. This shielding presents safety and process issues. The diagram in Figure 4-3 illustrates the instant on/off capability of pulsed UV light technology. Typical turn-on times are in the range of 1 to 5 microseconds, representing virtually zero warm-up time.

The world's first fully automated medical device production line is shown in Figure 4-4. Medical device guide wires are coated and then treated with pulsed UV. This is a start/stop/start process requiring critical temperature control of the guide wires. Low product temperatures are successfully achieved by insuring the UV light is off during the stop part of the process. This manufacturing process demonstrates how pulsed UV's instant on/off capability matches demanding medical device requirements.

Figure 4-4 A pulsed UV system for curing lubricious coatings on medical guide wires is integrated into an automated production environment. (Photo courtesy Guidant Corporation)

Lamp Spectrum

Electromagnetic radiation is the theory of propagation of all energy, extending from the extremes of sound to gamma rays, and includes radio waves, microwaves, infrared, visible light, x-rays and ultraviolet light. Ultraviolet light occupies the region of the spectrum between visible light and x-rays.

Whatever the application, the need for increased UV energy is increasing, and the demand for more efficient UV generators increases with new applications. For pulsed UV, about 45% to 50% of the input electrical energy is converted to optical energy, with an efficiency in the range of about 150 to 280 lumens/watt when operated under optimum conditions.

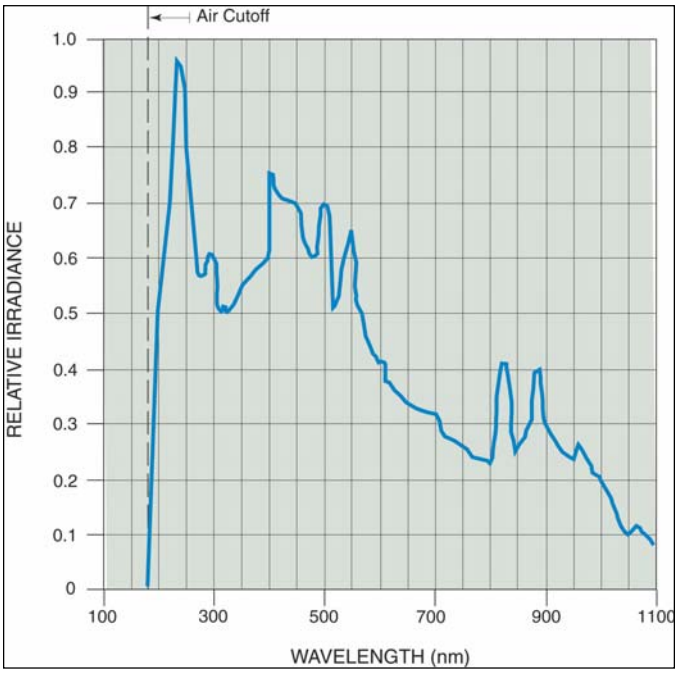


Figure 4-5 Pulsed UV light is rich in the 200 to 300 nanometer region

A primary characteristic of a pulsed UV lamp is its capability of generating wideband radiation with unequalled high efficiency … especially in the ultraviolet spectral region from 180 nm (air-cutoff) to 400 nm. A typical spectral profile of pulsed UV lamps is shown in Figure 4-5.

Flexibility

There are three other characteristics that demonstrate the applicability of pulsed UV technology for sanitization and sterilization applications : (1) the ability to provide specialized lamp shapes matching the requirements for different optical targets; (2) the ability to operate without the constraints of a lamp housing; (3) the ability to set the pulse repetition rate and lamp spectrum. Examples of customized pulsed UV lamps, each matching a specific application, are shown in Figure 4-6 on the next page.

Figure 4-6 Pulsed UV lamps can be custom manufactured to meet virtually any design requirement for the purpose of focusing high energy pulsed UV light onto a specific target or optical footprint.

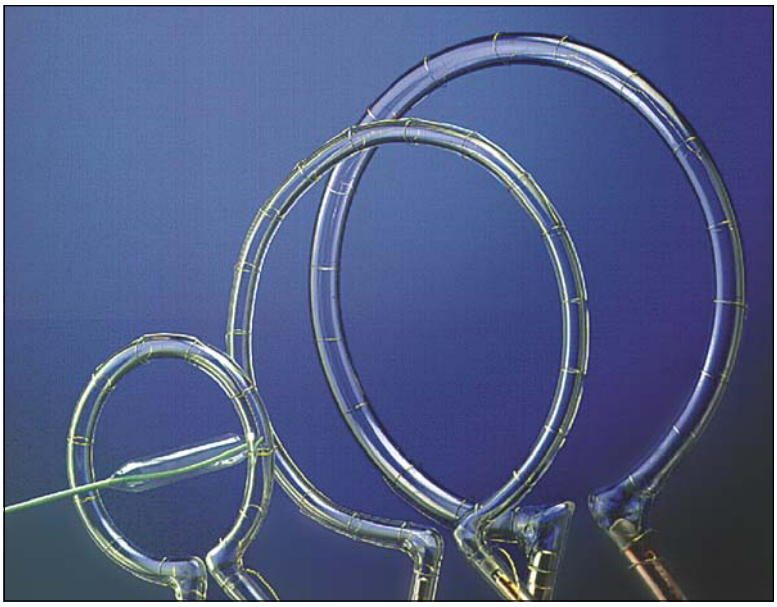


Figure 4-7 Lamps for pulsed UV light systems can be configured for specific applications. This circular lamp provides 360° illumination for curing balloon catheters.

The circular lamps, shown in Fig. 4-7 below, are widely used in medical device manufacturing, where 360° irradiation uniformity is critical. Guidant Corporation, a major medical device manufacturer, uses a pulsed light helix to process coatings on medical device guide wires. Continuous mercury UV lamps that use light guides to surround a circular product deliver bright spots to those points adjacent to the light guides, producing inferior uniformity.

Safety

Pulsed UV lamps are safer than mercury UV lamps for several reasons. Pulsed UV lamps do not contain toxic chemicals, do not contain gas at high atmospheric pressure and do not have to stay on during start/stop/start processes. The mercury contained in most standard continuous UV lamps represents a hazard for personnel in the event of damage to the lamp envelope.

STERIPULSE-XL PRODUCTS

Achieving an Efficient System Design

Studies in medical and industrial sterilization range from 180 to 300 nm, and the quest for increased energy is almost always in demand. For proficiently designed pulsed UV lamps, about 45% to 50% of the input electrical energy is converted to optical energy when operated at optimum conditions.

Collection and redirection of the UV energy is another critical design element and becomes even more important for system effectiveness when designing a sterilization system. Reflective (or refractive) optics can easily make the difference between success and failure for an application. Improper or inefficient optical design will require increased and unnecessary source energy, with the consequences of increased size, dissipated heat, and cost of the power supply and controlling electronics.

In summary, system optimization, maximum efficiency, and minimum operating and maintenance cost require that attention be paid to:

- Matching the pulsed UV spectral output to the sterilization objectives
- Optimizing the operating parameters of the pulsed UV lamp, power supply, and pulse control electronics
- Maximizing the collection and redirection of UV with well designed optics
- Measurement of UV dose

Xenon Corporation's SteriPulse-XL systems generate pulsed UV light at irradiance amplitudes up to 100,000 times earth surface sunlight levels. The high energy short wavelength UV-B and UV-C components that are removed from sunlight by atmospheric absorption are present in pulsed UV light. These high energy short wavelength components generated by SteriPulse-XL systems achieve high assurance sterilization by selective biomolecular destruction of the genetic material of microorganisms. The universal lethality of high intensity UV light for all microorganisms is well established. Similarly widely known is Xenon Corporation's acknowledged leadership in the design and manufacture of high power pulsed UV lamps and systems.

SteriPulse-XL Systems

Turnkey SteriPulse-XL systems are available in several application-specific configurations, ready for use in a variety of settings ranging from research and clinical laboratories to commercial process in-line rapid sterilization and disinfection facilities. The SteriPulse-XL models RS-3000B and RS-3000M are systems configured for in-line commercial processes such as foodstuff decontamination, medical device and pharmaceutical packaging, sterilization, inactivated vaccine manufacture, building air supply disinfection, and decontamination of high purity water systems. The SteriPulse-XL RS-3000C, which employs a benchtop sterilization chamber, can be used for R&D as well as an engineering development tool for determination and validation of critical in-line process operating parameters, including required radiant flux dose levels, optimal throughput rate, product stability, target medium effects, material compatibility, and measuring the sterility assurance level.

The considerable design and configuration flexibility inherent in Xenon's pulsed UV technology permits straightforward development of custom systems tailored for specialized use. The engineering advantages of pulsed UV technology include universal lethality, short-pulse rapidity of treatment and consequent high system throughput, irradiative consistency, controllability, rugged reliability of pulsed UV light sources, and modest power requirements due to high efficiency electrical-to-optical energy conversion. These advantages eminently qualify Xenon's advanced SteriPulse-XL technology for implementation as rapidly deployable field mobile systems, suitable for use in civil public health and military bio-terror national defense applications.

Features of SteriPulse-XL Systems

- R&D Sterilization Chamber - Model RS-3000C
- High Speed In-line surface processing - Models RS-3000B and RS-3000M
- Low Heat with short UV pulses
- Total DNA destruction in seconds
- Instant ON/OFF control
- Toxic materials, such as mercury or microwaves are not involved
- Programmable Logic Control (PLC) - Model RS-3000M

Research System

Model RS-3000C is a complete benchtop sterilization system with controller and separate sterilization chamber containing a 16" lamp housing and clear fused quartz (CFQ) lamp. The controller provides power to the lamp housing as well as complete operator control of the sterilization process. Safety interlocks are provided to protect the user from exposure from the pulsed UV lamp when the chamber door is open.

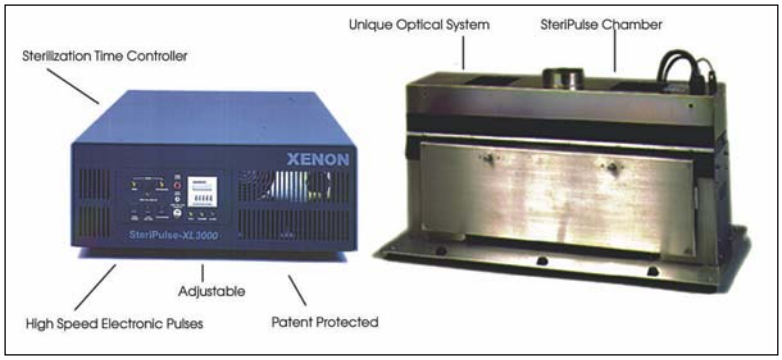


Figure 5-1 Model RS-3000C System Controller and Sterilization Chamber

The RS-3000C Sterilization Chamber, with removable lamp housing, is detached from the controller. Ozone is evacuated to ensure EPA ozone level compliance in the workplace. Forced air evacuation is in the range of 1-4 volumes per minute to ensure no heat buildup within the chamber during sterilization. The chamber does not evacuate air borne pathogens nor introduce air borne pathogens into the chamber while the system is in the ON cycle. Microbe filters, ozone resistant, are used at both the inlet and outlets of the ventilation path to ensure containment of air borne pathogens. The chamber has an interlocking door for lockout during the sterilization ON cycle. The door interlock switch is connected with the safety interlock switches in the controller. The chamber and insert are made of stainless steel construction for ease of sterilization and disinfection. This construction also insures the chamber is able to withstand UV light and heat conditions, experienced under normal operating conditions.

RS-3000C System Configurations

Model	Description
RS-3000C-3	SteriPulse-XL Chamber System with LiteMark-XL Light Monitor
RS-3000C-4	SteriPulse-XL Chamber System with LiteMark-XL Light Monitor and Blower Kit

In-Line Surface Treatment Systems

Model RS-3000B is a basic sterilization system offering a controller and a stand-alone 16" lamp housing with pulsed UV lamp. The LiteMark-XL light monitor is provided mounted on the lamp housing. The small bore lamp and elliptical reflector provide high peak UV energy for deep penetration and DNA destruction at high speed, as well as maximum energy for dose-dependent sterilization. The controller provides all power to the lamp housing as well as complete operator control of the sterilization process using front-panel controls.

Figure 5-2 Model RS-3000B System Controller, 16" Linear Lamp Housing and LiteMark-XL

RS-3000B System Configurations

Model	Description
RS-3000B-1	SteriPulse-XL Basic System
RS-3000B-2	SteriPulse-XL Basic System with Blower Kit
RS-3000B-3	SteriPulse-XL Basic System with LiteMark-XL Light Monitor
RS-3000B-4	SteriPulse-XL Basic System with LiteMark-XL and Blower Kit

Model RS-3000M is a modular system designed for ease of integration into large scale sterilization systems. The RS-3000M includes a controller, high voltage power supply module, and a standalone 16" lamp housing with pulsed UV lamp. The LiteMark-XL light monitor is mounted on the lamp housing. RS-3000M systems can be configured with multiple lamp housings to effectively increase the linear radiation length. System control is via a remote PLC. The ability to implement remote programmable logic control (PLC) for timed sterilization (stop and sterilize), permits ease of integrating RS-3000M systems into small and large scale manufacturing systems.

Figure 5-3 RS-3000M System with power supply, controller, lamp housing and LiteMark-XL

RS-3000M System Configurations

Model	Description
RS-3000M-1	SteriPulse-XL Modular System
RS-3000M-2	SteriPulse-XL Modular System with Blower Kit
RS-3000M-3	SteriPulse-XL Modular System with LiteMark-XL Light Monitor
RS-3000M-4	SteriPulse-XL Modular System with LiteMark-XL and Blower Kit

LiteMark-XL™ Light Monitor System

A useful accessory item that can be supplied with the SteriPulse-XL systems is the LiteMark-XL Light Monitor. The LiteMark-XL is a photo-electric detector module which is factory supplied and mounted on a lamp housing or sterilization chamber to enable the operator to monitor, on a real-time basis, the performance of a pulsed UV system during its operating life. Such a capability allows the lamp to be changed before the output falls below a predetermined safe minimum. The LiteMark-XL senses the light intensity from each pulse which is scattered sideways in the lamp housing window, relating it to the side-scattered intensity produced by the same lamp when new. The side-scattered intensity produced by a new lamp is designated as the "100% level", and the intensity at any later time is compared to that 100% level to produce a percentage value slowly declining from 100% as the lamp continues in use, indicative of the status of the lamp at any given time. A correlation chart is used in conjunction with the LiteMark-XL data to obtain the reduced exposure percentage.

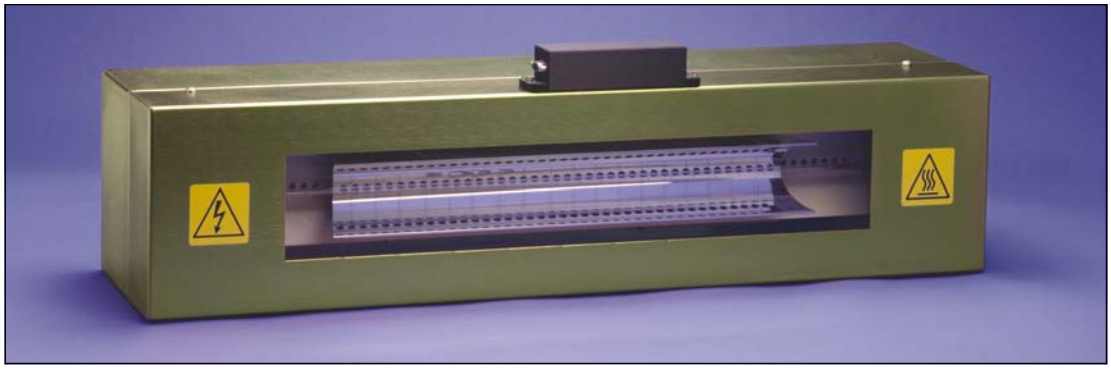


Figure 5-5 LiteMark-XL Mounted on 16" Lamp Housing

Data Logger Systems

The Data Logger is a computerized data collection and analysis system which captures, records, processes, stores and prints radiant energy information from any Xenon Corporation lamp housing or sterilization chamber fitted with a LiteMark-XL Light Monitoring System. The incorporation of the Data Logger System into the LiteMark-XL Light Monitoring System enables the process to be carried on continuously without the need for operator calculations. The data logger interfaces to a personal computer through an analog-to-digital converter (ADC) which is built into the output connector of the data logger cable, plugging directly into the computer printer port. The system operator can observe the flashlamp intensity display on his computer monitor as either tabulated data or as a graph. Additionally the operator can input the data into an Excel™-style spreadsheet for further processing off-line.

Data Logger System Configurations

Model	Part Number	Used with SteriPulse-XL System
LM-1411	400-0005	RS-3000B-3, -4 and RS-3000M-3, -4
LM-1611	400-0005	RS-3000C-3, -4

STERIPULSE-XL SPECIFICATIONS

System Components

Controller	Sterilization lamp power and front panel operator controls
Lamp Housing[1]	Lamp Housing with 16" Linear UV lamp
Sterilization Chamber	Lamp Housing mounted on top; access door on front
LiteMark-XL	Lamp intensity monitor; mounted on Lamp Housing
Blower Kit[2]	Provides filtered air to the Lamp Housing to cool lamp
Interconnecting Cables	10-ft Lamp Control cable attached to Lamp Housing
	10-ft High Voltage cable attached to Lamp Housing

Controller - Supplied with Models RS-3000B and RS-3000C

Front Panel Controls	
Timer Power	ON/OFF
High Voltage	ON/OFF
Continuous mode	ON/OFF
Pulse Mode Select	Timed or Continuous
Programmable Timer	1 to 999 seconds in 1 sec intervals
Timed Start	Pushbutton
Output	
Pulse Width	360 µs
Pulse Rate[3]	3 pulses/sec
Electrical Energy	505 joules/pulse; 1,516 joules/sec
Mains Line Voltage	200-240 Vrms (±10%), (50/60 Hz), single phase
Line Current	20 ampere @ 50 Hz, 18 ampere @ 60 Hz, maximum
Mains Line Power	2500 W, maximum
Mains Power Cord	8-ft (2.4 meters)
Warm-up time	1 minute
Outline Dimensions	8.0" x 18.5"x 27.0" (203 x 470 x 686 mm) (H x W x D)
Weight	90 pounds (40.8 kg)

Lamp Housing

Pulsed UV lamp	16-inch linear clear fused quartz; non-toxic; mercury free
Radiant Energy	1.27 joules/cm^2 @ 0.76" (19.3 mm) from window face
Flashlamp Footprint	16" x 1" (406.4 x 25.4 mm)
Reflector Type	Ellipsoid
Mounting Position	May be mounted in any position; cooling must be provided
Air Cooling	Minimum 300 cfm of filtered air at 2.0" water gauge (free flow)
Outline Dimensions	7.5" x 30.0" x 7.0" (190.5 x 762 x 178.8 mm) (H x W x D)
Weight	36 pounds (16.35 kg)

Sterilization Chamber - Supplied with Model RS-3000C

Access Door	Hinged; 18" x 6" (457.2 x 152.4 mm)
Material	Metal grade stainless steel with clear passivate overcoat
Disinfecting Methods	Note 4
Door Interlock	High Voltage disabled at controller when chamber door open
Chamber interlock cable	2-ft (0.6 meters)
Mains Power Cord	7-ft (2.1 meters)
Outline Dimensions	11.61" x 30.5" x 16.0" (294.9 x 774.7 x 406.4 mm) (H x W x D)
Voltage (includes internal fan)	200-240 Vrms (±10%), (50/60 Hz), single phase, 3 amperes
Weight	57 pounds (25.9 kg)

System Environmental

Temperature, ambient	
Rated Performance	0 to +40°C (+32 to +104° F)
Storage	-40 to +85°C
Relative Humidity	10 to 80% @ +40°C noncondensing

Notes

1. Supplied as a stand alone unit (models RS-3000B/M) or mounted on Sterilization Chamber (model RS-3000C)
2. Blower kit includes blower, blower filter, metallic ducting, duct clamps and mains power cord
3. Pulse rate is factory set and cannot be changed by user
4. The sterilization chamber and tray can withstand sterilizing or disinfecting methods such as autoclaving (276°F steam at 30 psi for 30 minutes), glutaraldehyde (Cydex) and/or 7% chlorine bleach disinfectant wash

Specifications subject to change without notification.

XENON CORPORATION PROFILE

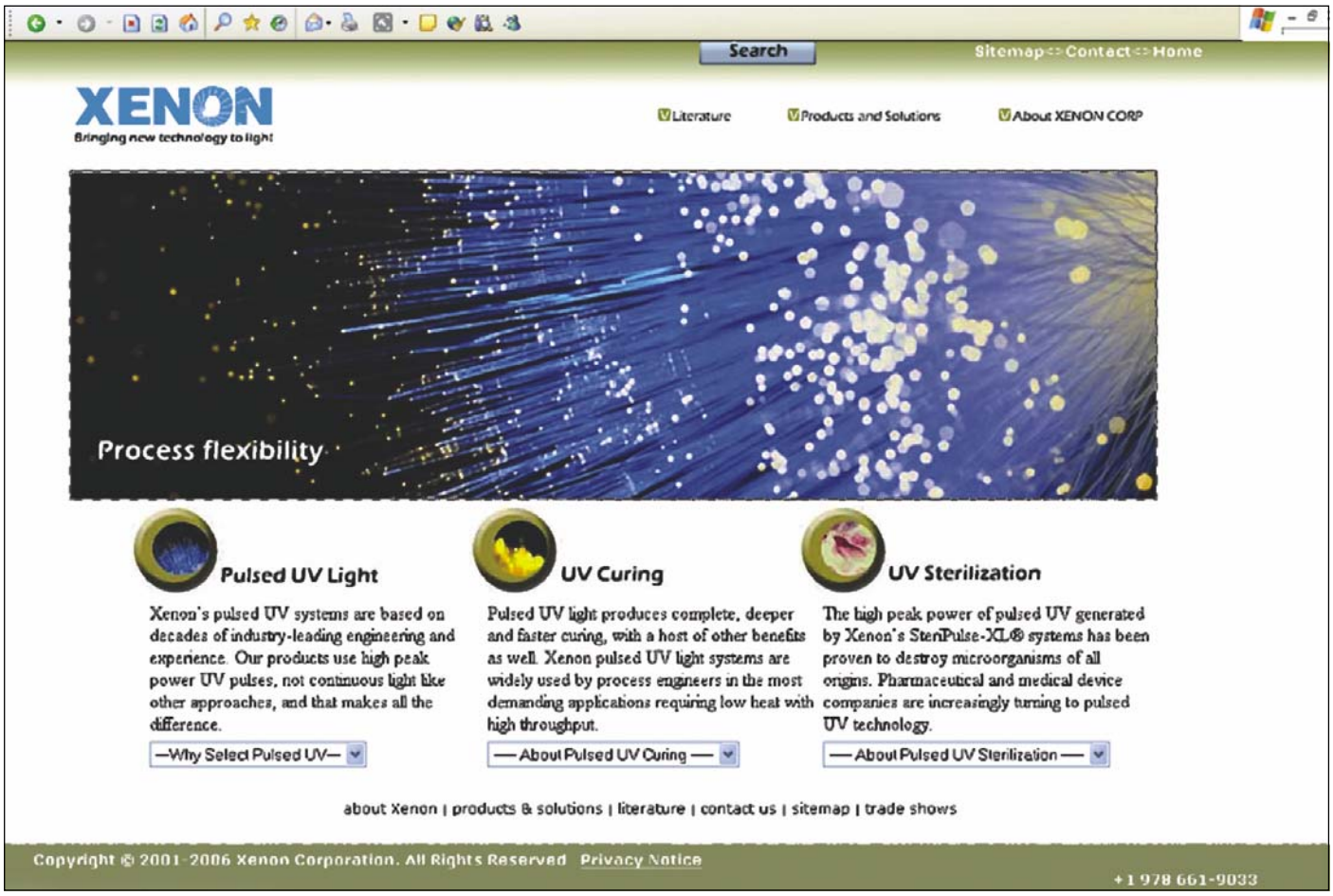
Xenon Corporation was founded in 1964 to develop and manufacture high performance flashlamps for pumping high energy pulsed laser systems. Since that first product introduction in 1964, scarcely a year has passed that Xenon Corporation has not announced another break-through in light technology: The first commercially available flash photolysis system for fast reaction photochemical and photobiological analysis … the first high voltage hold-off fast-extinguishing flashtube … the world's first dye laser pump lamps … low temperature, pulsed UV curing processes … benchtop and in-line sterilization systems … the list of Xenon Corporation-developed products grows each year.

Xenon Corporation is an innovative company. Innovation is defined as a solution that helps make our customers' applications successful. Illustrating innovation at Xenon Corporation is its list of US patents and roster of new products. Xenon Corporation will continue to build upon its traditions of innovation to continue its leadership in the field of pulsed UV light.

Xenon Corporation has a deserved reputation for creativity. The company works with customers to develop solutions to new applications. Xenon Corporation engineers have solved low temperature curing problems for manufacturers of semiconductors, digital video discs, medical devices, automotive and electronic products.

Dedication to the safety of the workplace and the quest for a superior sanitization and sterilization technology led Xenon Corporation into the development of Pulsed UV Light SteriPulse-XL systems. Today, when one thinks of pulsed light, Xenon Corporation is the first in the mind of the customer.

Xenon Corporation enjoys a reputation for superior customer service and sophisticated products that are robust and reliable. Our customers worldwide count on our products for long life, greater reliability and less down time. At Xenon Corporation, quality in design and manufacturing is always what we offer our customers. The light sources, components and systems are produced precisely to specification and are fully tested before being shipped. Rapid and effective customer support is always available. Xenon Corporation is prepared to work on the more difficult applications and provide customers with unique solutions matching their specific requirements.



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