

Feel the pulse

Figure 2: SteriBeam desktop intense pulsed UV system for 360° illumination of samples



Figure 1: The Flash Lamp Pulsed UV Module

The unique sterilisation properties of intense pulsed ultraviolet (PUV) have been recognised during the past 15-20 years through several interesting r&d developments. The particular properties of PUV are summarised in some ground-breaking papers written by this author^{1-3, 5} and by others, most notably Louis Panico⁴, which are referenced at the end of this article. As stated in these articles, sterilisation systems using intense pulsed UV light feature the following advantages:

Sterilisation is achieved in a fraction of a second;

A few or, in some cases, just one pulse can achieve up to a 6 log reduction for most micro-organisms;

By using the UVB part of spectra, sterilisation action can penetrate most clear packages (not possible with standard 254nm mercury-based lamps);

The systems offer a high UV output and the full UV spectrum;

An adjustment of flash lamp spectra enables the major output to fit into a specific UV band (UVC: 200-280nm, UVB: 280-315nm, or UVA: 315-400nm). They also offer a low infrared or heat part of lamp spectra (> 700nm); The lamps can be turned on or off in an instant;

They are environmentally benign (contain no mercury);

They offer deep UV penetration in purification and surface treatment processes.

A few years ago the US Food & Drug Administration (FDA) acknowledged these advantages by approving PUV light for the sterilisation of packaging and food, and without stipulating any requirement for labelling the sterilised products. This is the great benefit for future users of PUV systems and contrasts with gamma or e-beam sterilisation systems, where users have to label products accordingly.

These benefits also mean there is a solid potential for the use of PUV systems in cleanrooms in the pharmaceutical industry. So far the pharmaceutical manufacturer's main means of sterilisation has been through radiation sources (gamma and e-beams) or hazardous substances, such as peroxide, ozone, ethylene oxide, with or without autoclaves, or steam.

At present just a handful of companies are engaged in the production of PUV systems, mostly in the form of PUV modules, which are then sold to full-scale equipment manufacturers who build them into production lines. The reason for this is the current absence of a clear-cut market for such systems, the lack of an established track record of their use and, as yet, low demand for large-scale PUV systems for sterilisation.

The current demand is for small units for varying tasks in niche markets.

To combat this situation, SteriBeam has positioned itself as a designer and

Pulsed UV sterilisation is a relatively new technology in the world of aseptic processing but interest is growing as new systems are tailored to specific applications. Dr Alex Wekhof, of SteriBeam Systems in Germany, outlines some of their applications and benefits

manufacturer of full turnkey sterilisation equipment to perform specific tasks in the pharmaceutical market, particularly in the cleanroom segment, where aseptic requirements are important. An example of a SteriBeam system is shown in figure 1. Such systems can be used to perform up to a 6 log sterilisation of all micro-organisms in following applications:

Sterilising surfaces of syringe tubes in class C rooms before their automatic transfer to aseptic class A rooms;

Sterilising surfaces of various vials before or after filling;

Sterilising the content of vials and eye drops bottles, before being shipped to the end-user;

Sterilising surfaces in cleanrooms without creating associated problems with chemicals, handling, dust etc;

Sterilising air (in combination with pre-filters);

Sterilising medical devices, packaging materials or textile items being moved through to cleanrooms by means of pass-through conveyor tunnels;

Sterilising of packaged food to prolong its shelf life by 15-40%.

The Flash Lamp Pulsed UV Module, shown in figure 1 has an active lamp length of 40cm and a reflector width of 12cm. The system is capable of delivering up to 200 mJ/cm² per pulse in UVC+UVB, at the repetition rate of one to a few pulses/sec.

Such a module can be mounted in pass-

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through conveyor tunnels leading from a class C cleanroom to a class A cleanroom, or in air ducts of ventilation systems, or on walls to disinfect the air. The visible light from the lamp can be absorbed by a filter, letting only UV light pass through.

Such a module can be connected to a power-control unit by a cable of up to 3m in length. It can also be mounted over a conveyor carrying food items to reduce the bacterial count in order to increase the shelf-life of various foodstuffs.

Tests with SteriBeam desktop systems were successfully performed in some European food centres and showed positive results for fish, some meat products, some fruits and vegetables and some baked products. PUV systems can also be used to sterilise packages, medical devices and instruments^{2,5}.

Steribeam also offers a 6 log sterilisation PUV tunnel (see figure 2) that has a 360° capability to illuminate all open sides of a product. It also has the ability to pass through UV-transparent packaging, such as polypropylene (PP) bags containing saline.

Such a system is designed to serve as a pass-through tunnel to an aseptic class A cleanroom. It complies fully with GMP (aseptic room) specs by having a full HVAC (filtered and temperature-controlled) ventilation system, maintaining the air pressure at a slight increase in each of the three sequential processing sections which are separated by alternating doors.

These include: the product sorting and entrance section, the product handling and PUV sterilising section, and the exit section where the sterilised product is released into the aseptic class A room. The system is fully robotic and comes complete with controls and recording systems, including a video-camera and a thin film transistor (TFT) display to monitor product passage through the system.

Another such tunnel has been developed for sterilising vials (normal glass, UV glass and various plastic materials, transparent to UV light: LDPP, Nylon, Teflon, PE, etc), with

volumes from as low as 20ml to 100ml, and productivity rates up to 3,600 vials/hr.

The full processing costs for sterilisation of products with PUV ranges from 0.02 per tub to 0.0001 per vial. This cost includes depreciation, maintenance and energy costs.

Intense PUV systems can also be a very efficient way of supplying sterile air to cleanrooms. Respective PUV modules can be mounted easily in existing heating, ventilation and air conditioning ducts for decontamination of air in hospitals or on the walls or ceiling in microbiology laboratories or in any other cleanroom facilities.

References:

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3. Wekhof A., Trompeter I.-J., Franken O., "Pulsed UV-Disintegration, a New Sterilization Mechanism for Broad Packaging and Medical - Hospital Applications", *Proc. First Intl. Congress UV Technol.*, Washington, DC, 14-16 June, 2001, International Ultraviolet Association, P.O. Box 1110, Ayr, ON, Canada N0B 1E0.
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Medical cables can handle repeated sterilisation

Tyco Electronics has recently introduced autoclaveable cable assemblies fabricated from Sterilene-enhanced silicone for surgical video and power tools. This latest innovation in material technology eliminates the surface tackiness of silicone and appeals to end-users in hospitals and clinics, by providing a cleaner look and smoother feel.

The Precision Interconnect cable assemblies with Sterilene-enhanced silicone cable jackets maintain their smooth feel, flexibility and strength after repeated autoclave sterilisation. Even after being subjected to 1000 autoclave cycles, 500 Sterrad (100) cycles and 1000 Steris (System 1) cycles, the biocompatible cables show no measurable degradation in jacket lubricity or electrical and mechanical properties.

The new cable jackets slip comfortably over gloved hands, scrubs and surgical drape. This extra degree of cable



manoeuvrability makes it easier to manipulate hand-held surgical devices that are linked by cables to controllers or power sources.

The Sterilene-enhanced silicone is available on Precision Interconnect pre-engineered Basis cable assemblies as well as on custom cable assemblies.

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New sterile wiper line for cleanrooms

Kimberly-Clark Professional has introduced a complete line of dry, pre-saturated and sterile wipers for all cleanroom environments.

The new Kimtech Pure CL3 product line now includes both dry and sterile wipers that can be used for the most critical surface wiping tasks in ISO Class 3 or higher cleanroom environments.

The dry wipers are 100% continuous filament double-knit polyester and, in independent testing, achieved more than 25% better surface wipe drying than a leading competitive brand. They absorb liquids on contact while still delivering the low particle and extractable levels expected from polyester wipers.

Both solvent- and abrasion-resistant, the dry wipers have four laser-sealed edges to minimise particle generation, are cleanroom laundered in water filtered to 0.2µm to minimise the potential for ion contamination, and are double-bagged to maintain cleanliness.

They are also compliant with AAMI Guidelines, gamma irradiated to a 10⁻⁶ Sterility Assurance Level.

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