Validation of a UV torch

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Introduction

The Klercide UV Validation Torch is a unique innovation in cleanroom technology - making the invisible visible. The ability to highlight overlooked areas enables organisations to solve problems before they become costly. The torch is used for process improvements, for example to highlight changes that need to be made to transfer disinfection procedures, and can be a valuable technician training aid for demonstrating correct surface and disinfection techniques and their effectiveness. Ideally, the process of detection can be carried out over the whole cleaning and disinfection process in order to identify high risk areas as well as to confirm the removal of contamination. Additionally it can be used to ensure that hard to reach areas are actually cleaned and it is a crucial aid when clearing up after a spill, allowing the operator to confirm that all contamination has been removed.

There are already a number of ways of ensuring that a cleanroom is clean and that standard operating procedures are effective. These include visual inspection, particulate and microbiological monitoring and residue measurement. The Klercide UV Validation Torch offers the opportunity to move beyond these methods with a highly sensitive instant visual result. This technical report summarises the validation performed on the torch to explore its effectiveness.

Background

UV light is emitted from the torch and excites the electrons in the atoms or molecules of the particles in question. The atoms or molecules can only temporarily harness the energy from the torch (absorption) and they quickly release this additional energy as light (emission). It is the released light energy from the atoms or molecules of the particles that makes the particles visible to the naked eye when previously they could not be seen therefore "Making the Invisible Visible". Figure 1 shows the absorption and emission process in action.

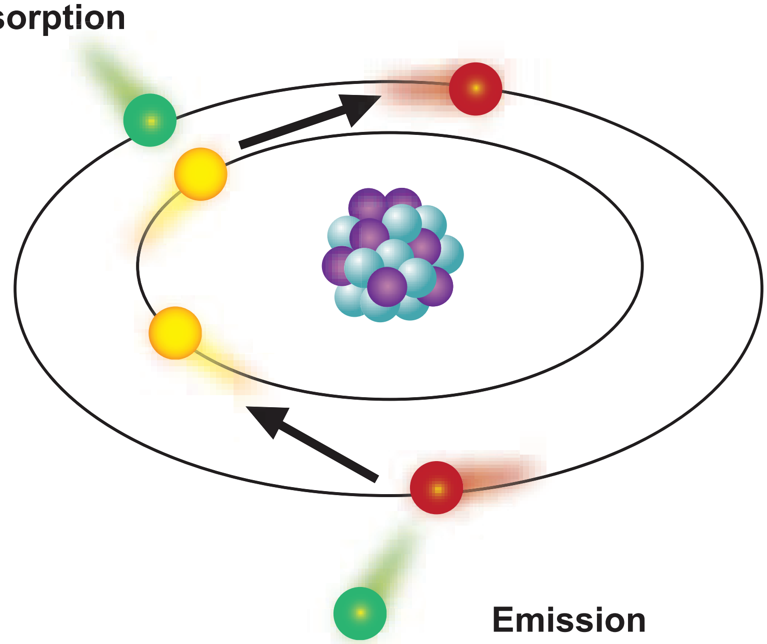


Figure 1: The absorption and emission processes

Protocol

The torch was tested for the effect of the following parameters on the visible detection of particles in order to verify the robustness of the detection process.

- Particle size
- Background lighting level
- Backgroundsurface material
- Distance from UV source
- Fluorescence of different materials

In addition tests were carried out with trained operators to verify the effectiveness of their procedures and with operators undergoing training to verify the effectiveness of the training.

Particle size

Latex particles of varying sizes (as used for validation of particle counters) were diluted in water and applied to a surface to determine of the limit of detection.

Background lighting level

Tests were carried out at various background lighting levels to determine at what background lighting level the particles ceased to be visually discernable and at what level optimum detection of surface contamination could be achieved.

Background surface material

A number of different background surfaces were used to determine if their light absorption or contrast properties had an effect on the visibility of the emitted light.

Distance from UV source

Tests were carried out with the UV source (torch) at varying distances from the surface to determine at which point the source became too weak to detect particles.

Fluorescence of different materials

It is hypothesised that, due to the way the torch works, the fluorescence of a particle will be dependent on the density and homogeneity of the material.

Test method

Materials

Latex particles (0.7µm / 3.0µm / 30 µm / 50 µm)
Water (filtered)
Conical flask (glass) 100ml particle free

Microscope slide (glass)
Ependorf pipette
Drying oven
Stainless steel plate 10 x 10 cm
Plexiglass plate 10 x 10 cm
Makrolon (polycarbonate) 10 x 10 cm
Pharma Terrazzo 10 x 10 cm
Hypalon (glove material) 10 10 x 10 cm
RODAC plate ($25cm^2$)
LUX2 – measuring instrument
Neon tube (adjustable)
IPA wipes
Torch mounting plate
Meter rule
Various materials as shown in Table 2
Klercide UV Validation Torch

Particle size

Individual suspensions were made in the 100ml conical flask at a concentration of 0.25g of each size of particle in 3.75ml of water. The suspensions were applied to the microscope slide and fixed with a secondary slide on top of this. The slides were dried in a drying oven for 1 hour at 45°C. On completion of the drying process the slides were examined with the aid of the torch for visual detection of the particles and the results recorded.

Background lighting level

The LUX detector was set up underneath the adjustable neon light tube to measure the amount of background light. The Stainless steel plate was marked by contact from a TSA RODAC plate. The lighting level was increased gradually from 0 LUX (the lowest lighting level). The steel plate was examined for residues detectable with the UV torch at the various LUX levels and the results recorded.

The surface used for this experiment with and without the use of the Klercide UV Validation Torch can be seen in Figure 2. The results are recorded in Table 1.

Background surface material

A range of commonly encountered cleanroom surface materials were prepared by removing any particles with a high grade pre-impregnated IPA wipe. A 50µm particle suspension was dispensed on to these surfaces in a unidirectional airflow bench. The samples were dried for 1 hour at 40°C in the drying oven. The surfaces were then examined with the UV torch. The results are shown in Table 2.

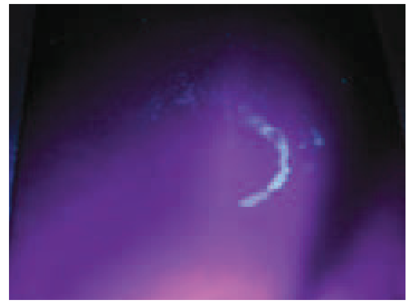


Figure 2: Background surface used for testing the effect of background lighting level, left: without the use of the torch and right: with the use of the torch

Figure 3: Test set up for measuring the effectiveness of the UV torch at varying distances from the surface

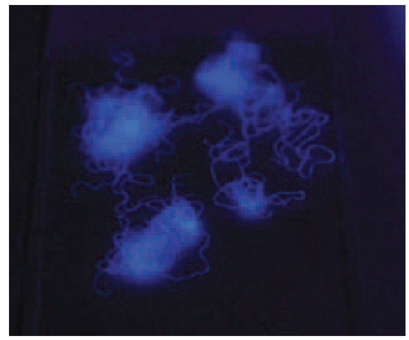


Figure 4: An example of a material detected by the UV torch.

Figure 5: 'Dummy' RABS

Distance from UV source

A stainless steel surface was cleaned with a high grade pre-impregnated IPA wipe as per the process above. The surface was then 'contaminated' with a small amount of the 50µm particle suspension. The UV torch was then set at varying distances from the plate and the plate examined for the visibility of the contamination. The equipment used for this experiment can be seen in Figure 3. The results are shown in Table 3

Fluorescence of different materials

Small samples of different materials were fixed between two microscope slides. Each sample was examined with the UV torch and the results recorded. The results for different materials are shown in Table 4.

Training

Two groups of 10 trained cleaning operatives and 10 untrained operatives were assigned the task of cleaning a 'dummy' RABS (restricted access barrier system) as shown in Figure 5 with pre-impregnated IPA wipes. The RABS was marked with 12 areas of contamination which were detectable with the UV torch. Each operative in turn cleaned the RABS. Following each cleaning, the RABS was examined for confirmation of the effectiveness of the cleaning. The results are shown in Table 5. The untrained operatives were then trained and repeated the exercise. The results are shown in Table 6.

Results

Visibly detectable particle size

The 50 µm particles were clearly visible on the slide and can be said to be the lower limit of detection.

Table 1 – Optimal background light

LUX	Visible
50	Yes
100	Yes
150	Yes
200	Yes
250	Yes
500	Yes
1000	Yes
1500	With difficulty
2000	With difficulty
2100	No
2500	No

Table 2 – Different material background surfaces

Material	Visible
Stainless steel plate	Yes
Plexiglass plate	Yes
Makrolon (polycarbonate)	Yes
Pharma Terrazzo	Yes
Hypalon (glove material)	Yes

Table 3 – Distance from source

Distance (cm)	Visible
10	Yes(very good)
20	Yes (good)
30	Yes (good)
50	Yes (moderate)
100	No

Table 4 – Fluorescence of different materials

Material	Visible
Rubber bungs	NO
White plastic packaging	YES
Transparent plastic sheet (PVC)	NO
Cardboard	YES
Syringe packaging pouch (plastic and paper)	NO
Filter gasket	NO
Elastic band from face mask	NO
Standard facemask (clean room standard)	YES
Sterile clothing (single use)	YES
The zip from sterile clothing	YES
Multi-Use sterile garments (sown)	YES
Sterile mop cap	YES
Clean room goggles (plastic)	NO
Clean room grade socks	YES
Sterile clean room wipes	YES
Sterile clean room paper	YES
Filter material	YES
PTFE Sealing ring	NO
Autoclave band	YES
Single use sterile head cover	YES
Single use pipette tip (plastic)	YES

Table 5: Cleaning effectiveness of trained and untrained operatives

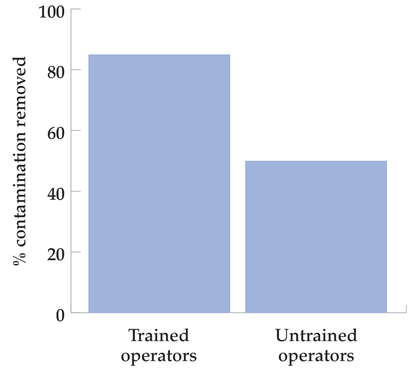
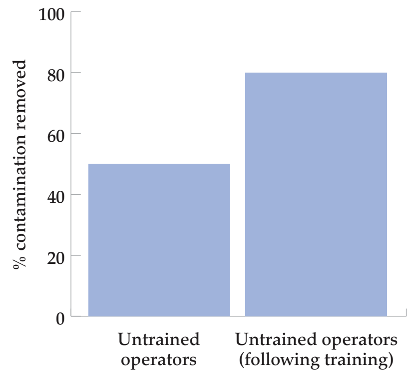


Table 6: Cleaning effectiveness of untrained operatives before and after training



Conclusions

The Klercide UV Validation Torch is a unique innovation that allows users to observe surface contamination that they might otherwise miss, with the opportunity to make instant process corrections.

The results show that, under normal operating conditions, the torch will highlight contamination by a variety of particles on all surfaces.

In addition to showing the parameters within which the torch will operate effectively, the tests also highlight the significant importance that the torch can play in operator training and confirmation of training effectiveness.

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