# The performance of Ultravision in reducing aerosolization of viral-sized particles during laparoscopic surgery.

## Executive Summary

Viruses have been reported in aerosolized surgical smoke in the literature. Previously reported applications of electrostatic precipitation have reported the successful collection of viruses and virus-sized particles. In a bench setting, Ultravision, which uses electrostatic precipitation as its mode of action, has been shown to effectively eliminate the aerosolized particle mass present in surgical smoke in an enclosed atmosphere by 99.9% and particle number by 99.7%, including sub-viral particle sizes.

## Background

On March 19th 2020 the Society of American Gastrointestinal and Endoscopic Surgeons ("SAGES") published recommendations regarding the surgical response to the Covid-19 crisis[1]. With regard to the management of surgical plume ("smoke") that is created by energy-based instruments, the following guidance was provided:

*"For procedures deemed urgent and necessary, it is strongly recommended that consideration be given to the possibility of viral contamination during laparoscopy. Such risk should be individually weighted against the benefit of laparoscopy for a patient's health and recovery. While it is unknown whether coronavirus shares these properties, it has been established that other viruses can be released during laparoscopy with carbon dioxide. Erring on the side of safety would warrant treating the coronavirus as exhibiting a similar property. For laparoscopic procedures, use of devices to filter released* $CO_2$ *for aerosolized particles should be strongly considered."*

As a result of this recommendation, employees of the Company have been contacted by healthcare providers asking for guidance and clarification on the performance of Ultravision relative to this recommendation.

## Purpose of this document

The purpose of this document is to provide a summary of the relevant data held on file by Alesi, such that consistent information can be provided to relevant healthcare professionals.

## Recap – why was Ultravision developed?

Ultravision was developed to address three issues that are commonly experienced during laparoscopic surgery:

1. **Inefficiency, caused by the build-up of surgical smoke within the pneumoperitoneum** leading to obscuration of the visual field and associated issues such as soiling of the camera lens.
2. **The release of surgical smoke into the operating room ("venting")**. This is required in order to improve the quality of the visual field such that the procedure can be carried out safely. The long-term exposure to surgical smoke is considered a health and safety issue for OR personnel.

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[1] https://www.sages.org/recommendations-surgical-response-covid-19/

3. **The amount of cold, dry carbon dioxide that the patient is exposed to during the procedure.** Although inert, excessive $CO_2$ exposure has negative implications for the patient and AORN guidelines are that that volume and pressure of $CO_2$ that a patient is exposed to should be minimized[2]. Continued replenishment of $CO_2$ as a result of venting leads to excessive patient $CO_2$ exposure.

Ultravision's mode of action – "*electrostatic precipitation*" – is unique in that the smoke that is created during surgery is eliminated from the operative field by rapidly suppressing its aerosolization. This contrasts with the four other means of addressing this problem. All of these involve removal of smoke-containing $CO_2$ from the abdomen and dilution of the remaining $CO_2$ with fresh $CO_2$. The four options are:

1. "**Venting**" the aerosolized smoke into the operating room;
2. Using a "**passive filter**" which attaches to one of the surgical access ports;
3. Using an "**active smoke evacuator"** which extracts and filters aerosolized smoke using a vacuum-based evacuation; and
4. Using an "**advanced insufflator**", which combines the functionality of an insufflator (the device used to introduce the $CO_2$) with the ability to extract and filter aerosolized smoke during the procedure.

Filter-based products typically contain Ultra Low Particulate Air (ULPA) filters. Although there are several, country-specific means of determining performance the technique used in the harmonized standard ISO 29463[3] for the determination of the overall efficiency of a ULPA filter employs particle counting at the most penetrating particle size (MPPS), which, for micro-glass filter mediums, is usually in the range of 0.12µm to 0.25µm. These test conditions are larger than many viruses (see below).

## Ultravision – mode of action

Electrostatic precipitation is a highly characterized process that has been extensively used in industrial applications in order to remove fine particulate matter from an atmosphere. The physics and performance in removing such fine particulates are well understood and widely published in the literature[4]. In summary, it involves the creation of gas ions in an atmosphere to temporarily impart an electrical charge on particulate matter. As a result of this transient charge, the matter moves through an electrical field such that it is deposited on a collector surface. As the particles land, the charge is released and flows back to the power supply.

In this surgical application, the Ultravision generator creates the power that is responsible for creating the gas ions. This power, which is extremely low, is delivered to the patient's abdomen using an electrode, the "Ionwand" (**Figure 1**). The Ionwand is inserted into the patient's abdomen prior to use of an energy-based instrument. The electric field is established by the use of a standard patient return electrode, which is connected to the Ultravision generator and that may be shared with an electrosurgical unit (**Figure 2**).

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[2] 2017 AORN Guidelines for; "Use of $CO_2$ at a Glance."

[3] ISO 29463-2:2011(en). High-efficiency filters and filter media for removing particles in air — Part 2: Aerosol production, measuring equipment and particle-counting statistics

[4] https://www3.epa.gov/ttncatc1/cica/files/cs6ch3.pdf

**Figure 1: Ultravision generator and single-use electrode**

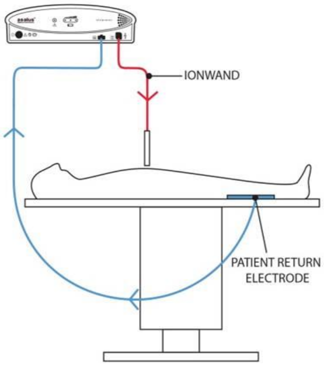

**Figure 2: Setup of Ultravision**

When the electrosurgery instrument creates smoke, the gas ions which are created by the Ionwand migrate towards patient tissue collide with, and attach to, the particulate matter such that it is **rapidly precipitated within the patient's abdomen**. Of particular relevance is that such precipitation does not require any exchange of $CO_2$, thereby (1) eliminating the need to vent the particulate matter into the operating room; and (2) minimizing the amount of cold, dry $CO_2$ that the patient is exposed to.

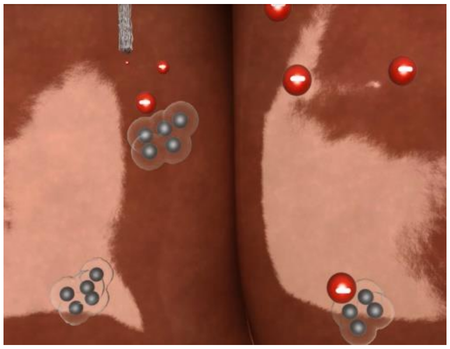

**Figure 3: Ions precipitating particulate matter**

Applications using electrostatic precipitation to precipitate viruses and/or virus-sized particles have previously been reported for air sampling[5] and sampling and detection of airborne influenza virus for a point-of-care application[6]. One study has reported the efficient capture of T3 and MS2 bacteriophages (viruses with diameters of 45 and 25nm, respectively, that attack bacteria) using electrostatic precipitation and its concomitant deactivation as a result of this mode of action[7].

## Surgical smoke: viruses

The composition of surgical smoke has been highly characterized and is widely reported in the literature[8]. Particulate size is determined by the type of energy used. Electrosurgery using radiofrequency ("RF") devices generates particulates with the smallest mean aerodynamic size, 70nm[9,10]; laser tissue ablation

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[5] Development of a new portable air sampler based on electrostatic precipitation. Roux JM et al., Environ Sci Pollut Res Int. 2016 May;23(9):8175-83

[6] Sampling and detection of airborne influenza virus towards point-of-care applications. Ladhani L et al., PLoS One. 2017 Mar 28;12(3)

[7] Airborne Virus Capture and Inactivation by an Electrostatic Particle Collector, Kettleson EM et al., Environ. Sci. Technol. 2009, 43, 5940–5946

[8] Surgical plume and its implications: A review of the risk and barriers to a safe work place. Tan E and Russell K. ACORN: the journal of perioperative nursing in Australia, 30(4), 33-39.

[9] Aerosols created by some surgical tools: particle size distribution and qualitative haemoglobin content. Heinsohn P et al., App Occup Environ Hyg 1991; 6: 773-776

[10] Exposure to blood-containing aerosols in the operating room: a preliminary study. Heinsohn P, Jewett DL. Am Ind Hyg Assoc J 1993; 54: 446-453.

creates particulates with a mean size of 310nm[11]; ultrasonic devices generate the largest particulates, with a mean size 350nm-6.50um[12,13]. There have been reports of HPV, HIV and Hep B viruses present in surgical plume[14,15]. This is consistent with the fact that viruses measure between 20-260nm in diameter**[16]**, all within the range of particulates reported to be in surgical smoke. SARS-CoV-2 ("Covid 19") belongs to the betaCoVs category. It has round or elliptic and often pleomorphic form, and a diameter of approximately 60–140nm[17] (0.06-0.14um).

| Virus | Diameter |
|---|---|
| **Parvovirus** | 20nm |
| **Hepatitis A** | 30nm |
| **Hepatitis B** | 42nm |
| **Hepatitis C** | 50nm |
| **Dengue virus** | 50nm |
| **Papillomavirus** | 60nm |
| **Rotavirus** | 80nm |
| **Adenovirus** | 90nm |
| **Influenza virus** | 100nm |
| **SARS** | 120nm |
| **HIV-1** | 120nm |
| **Measles** | 150nm |
| **Herpes virus** | 200nm |
| **Variola virus** | 360nm |

**Table 1 – diameters of common viruses**

## Ultravision – review of relevant data

Alesi has quantified the performance of Ultravision in eliminating aerosols created using electrosurgical instruments as part of its regulatory filing requirements in the USA, Europe and Japan. This work was carried out independently at a laboratory in Cardiff University (U.K.) and performance assessed relative to "nothing" (i.e. allowing the particulate matter to sediment naturally using gravity) or a smoke evacuator (RapidVac, Medtronic).

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[11] Smoke from laser surgery: is there a health hazard? Nezhat C et al., Lasers Surg med 1987; 7: 376-382

[12] Aerosol exposure from an ultrasonically activated (harmonic) scalpel. Ott De, Moss E, Martinez K. J Am Assoc Gyn Laparoscopists 1998; 5: 29-32

[13] Surgical smoke – a review of the literature. Is this just a lot of hot air? Barrett WL, Garber SM. Surg Endosc 2003; 17: 979-987

[14] Awareness of surgical smoke hazards and enhancement of surgical smoke prevention among the gynecologists. Liu Y et al., Journal of Cancer 2019; 10(12): 2788-2799.

[15] Detecting hepatitis B virus in surgical smoke emitted during laparoscopic surgery. Kwak HD et al., Occup Environ Med. 2016 Dec;73(12):857-863. doi: 10.1136/oemed2016-103724. Epub 2016 Aug 2.

[16] https://viralzone.expasy.org/5216

[17] Features, Evaluation and Treatment Coronavirus (COVID-19). Cascella M et al.,. https://www.ncbi.nlm.nih.gov/books/NBK554776/

**Figure 5** shows the performance of Ultravision when switched on and left on for 10 minutes (600 seconds) either before or after the creation of surgical smoke using a monopolar instrument in an enclosed atmosphere. The particle mass produced by 30 seconds of total cutting in a sealed 6l chamber, spread over a two-minute period was the same in all four test conditions.

In the control condition, particle mass decreased by 62% over 600 seconds in the experimental chamber as a result of the combination of particle sedimentation and the small leakages that are unavoidable using laparoscopic access ports.

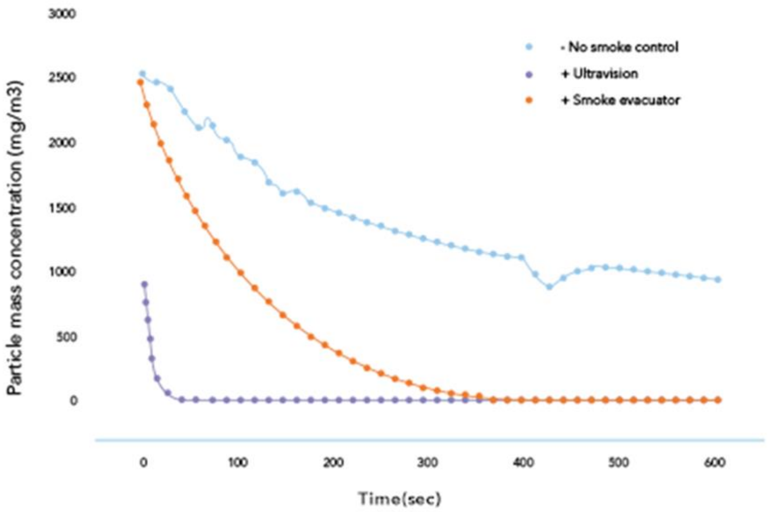

**Figure 5: Ultravision performance in vitro**

The comparator device accelerated the rate at which the particle number decreased over this time period because it removed the $CO_2$ in the test box at a rate of approximately 2l/minute (to simulate needing to reduce the loss of pneumoperitoneum in a real-world setting) and replaces it with fresh $CO_2$ from the insufflator. Ninety-eight percentage of the particle mass was removed by the smoke evacuator over 600 seconds.

Compared to the vacuum-based device, when switched on ***after*** cutting Ultravision reduced 99.9% of the produced particle mass within 200 seconds. The effect was more dramatic when Ultravision was switched on ***before*** cutting commenced, taking 65 seconds when compared to 'without' the Ultravision ($p<0.05$). The maximum detectable particulate mass was much lower than in the other test conditions, as a result of the Ultravision device continually reducing aerosolization as particles were produced during the cutting period.

**These finding demonstrate that:**

1) **The remaining aerosolized particles are rapidly eliminated from the atmosphere; and**
2) **When switched on prior to using an energy-based instrument, performance is enhanced because Ultravision is capable of reducing the amount of aerosolized particles as they are created.**

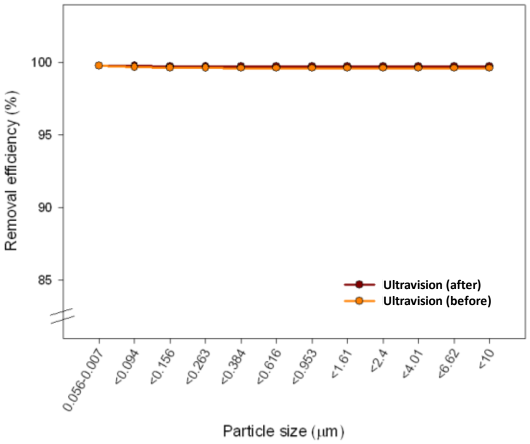

**Figure 6: Ultravision performance across particle sizes**

The ability to eliminate particles of different sizes, across the relevant size range of 10um to 7nm (i.e. 0.01um to 0.007um) was also assessed (**Figure 6**). This size range includes all known viruses.

Ultravision precipitated 99.7% of particle number, when switched on either before or after smoke creation. This was independent of particle size from 7nm to 10µm.

These findings demonstrate that Ultravision is effective at eliminating particles from the atmosphere across the size range of 7nm-10um, with >99% efficiency.

## Conclusions

1) Viruses are between 20-260nm in diameter and have been reported in aerosolized surgical smoke in the literature.
2) Previously reported applications of electrostatic precipitation have reported the successful collection of viruses and virus-sized particles.
3) In a bench setting, Ultravision has been shown to effectively eliminate the aerosolized particle mass in an enclosed atmosphere by 99.9% and particle number by 99.7% across the particle size range of 7nm to 10um.

***DISCLAIMER – all data specific to Ultravision contained within this document relate to particles of a specific size present in surgical smoke and NOT to viral particles. Whilst Alesi Surgical considers that Ultravision can play a role in hospitals' risk management strategies, as with other manufacturers of smoke management products it makes no representation or warranty on the ability of Ultravision to reduce the risk of dissemination of active viruses that may be present in surgical smoke.***