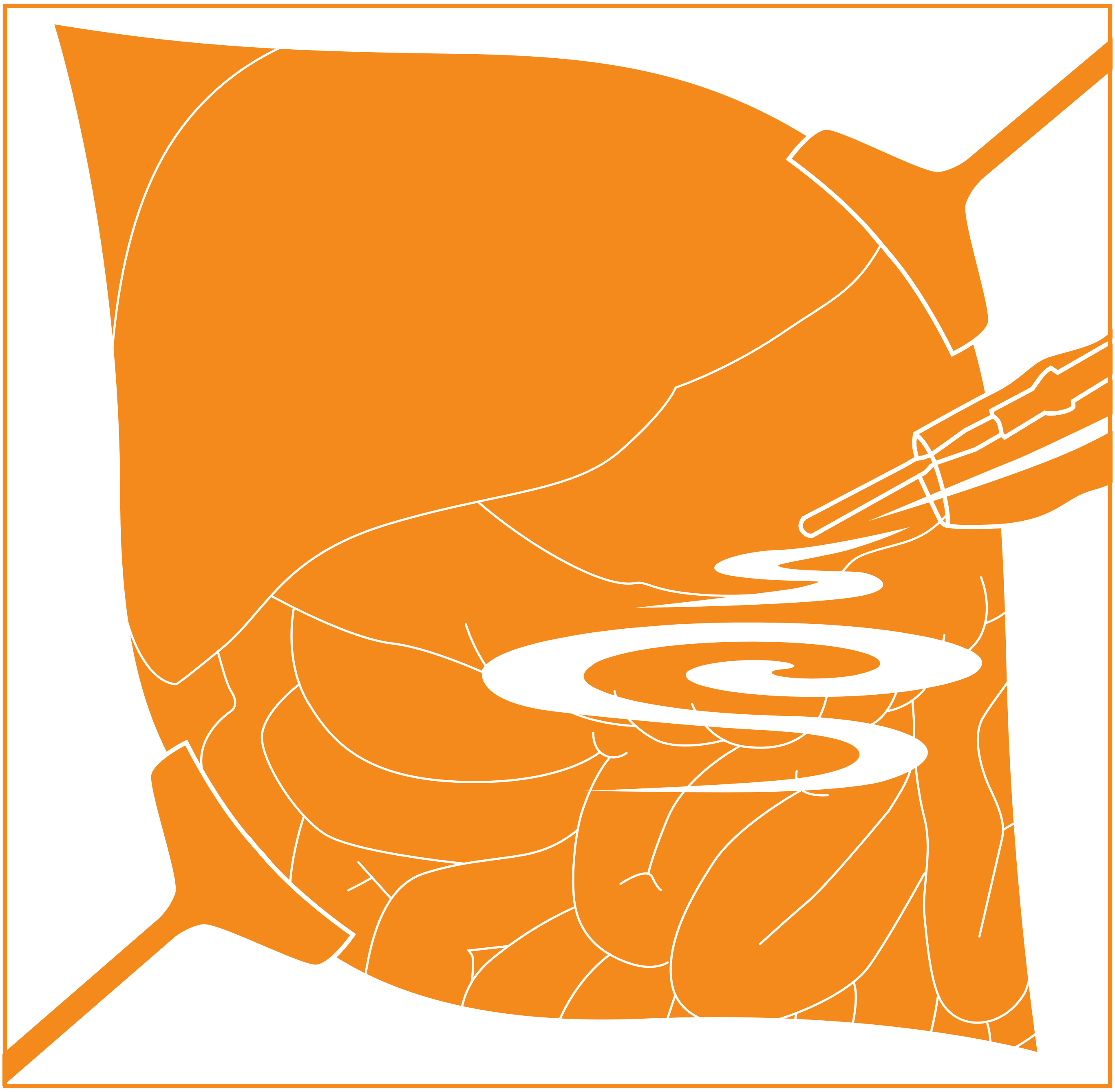
BOWA
ACADEMY

SMOKE-FREE OPERATING THEATRES



THE EFFECTS OF SURGICAL SMOKE | LEGAL BACKGROUND | SOLUTION FROM BOWA | FAQ | REFERENCES

IMPORTANT INFORMATION

While BOWA electronic GmbH has taken the greatest possible care in drafting this brochure, mistakes may nonetheless occur.

BOWA is not liable for any damages arising from the recommendations for settings or other information contained herein. Any legal liability is limited to wilful intent and gross negligence.

All information on recommended settings, points of application, duration of application and instrument use is based on clinical experience. Some centres and physicians may prefer settings other than those recommended here.

The settings indicated herein are for guidance only. The user is responsible for checking their viability.

Depending on individual circumstances, it may be necessary to deviate from the settings indicated in this brochure.

Medical technology is advancing continuously through ongoing research and clinical experience. For this reason, too, it may be expedient to deviate from the settings indicated in this brochure.

Although our published material may specify a particular gender for the sake of readability, any statements naturally apply equally to both genders.

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1 | THE EFFECTS OF SURGICAL SMOKE[1]

The smoke produced by high frequency electrosurgery or laser interventions and incisions exposes operating theatre staff to unpleasant odours. However, few people stop to think of the possible health risks of these gas-, vapour- and solid particle-emitting procedures[2]. Surgical team members are in fact exposed to a complex mixture of biological, cellular, particulate and gaseous substances. The exposure involved may be significant. In the course of some surgical procedures – tumour reduction, for example – the excision of tumour tissue, the parietal peritoneum, various internal organs and electrocoagulation of tumour nodules on the surface of the visceral peritoneum may last anything from 2 to 12 hours, which may involve prolonged exposure to surgical smoke[3].

Before exploring the potential hazards of these procedures, it is important to analyse the components of surgical plume in qualitative and – insofar as possible – quantitative terms.

1.1 | QUALITATIVE AND PARTICULATE COMPOSITION

Depending on the procedures employed and tissues treated, the quantitative composition of surgical smoke may fluctuate greatly[4]. However, it is possible to get an idea of the qualitative composition. This is shown in the following. For physiological reasons, water vapour is the main constituent of the smoke and aerosols. It is estimated to account for as much as 95 %. The exact level is probably related to the type of tissue involved. This water vapour acts as a vehicle for the other components [4].

The size of the particles produced ranges from more than 200 micrometres to less than 10 nanometres. The mean particle diameter depends on factors including the intensity of the energy acting on the tissue. The following particle sizes have been reported[5]:

- **Electrocautery:** mean particle diameter (d): 0.1 μm
- **Laser (tissue removal):** mean particle diameter (d): approx. 0.3 μm
- **Ultrasound scalpel:** mean particle diameter (d): approx. 0.35–6.5 μm

This means that a very large fraction of these smoke particles is inhaled and can deposit in the alveoli of the lungs. Measurements during peritoneal carcinomatosis procedures and other gastro-intestinal tract interventions ranged from 1 to 10 μm for “conventional” particles and from 0.02 to 1 μm for “nanometric” particles (note: a nanoparticle is defined in the literature as a particle with a diameter of 0.1 μm or less). Samples are taken at the level of the airways. The results indicate a higher level of exposure for high-power, i. e. high-voltage cautery of peritoneal carcinomatosis than for conventional methods (e. g., colon cancer resection). The cumulative values are 9.3 x 10^6 particles / (ml h) versus 4.8 x 10^5 particles / (ml h) for personal samplings and 2.6 x 10^6 particles / (ml h) versus 3.9 x 10^4 for stationary samples taken from ambient air[6].

The results are confirmed by other measurements evaluating exposure to ultrafine particles (0.01 to 1 μm) during a variety of surgical interventions[7]. The procedures associated with the highest exposure include electrocautery and argon laser tissue coagulation. The authors ascertained average concentrations of 1 930 particles / cm^3 peaking at 183 000 for electrocautery of adhesions. The highest concentrations were measured during surgery for hemangioma of the liver, with average levels of

12 200 and peak levels of 490 000 particles/cm^3. Unlike gallbladder removal, tumour ablation in the posterior abdomen and inguinal hernia surgery is associated with a high level of exposure to hazardous substances.

1.1.2 | ORGANIC TOXINS

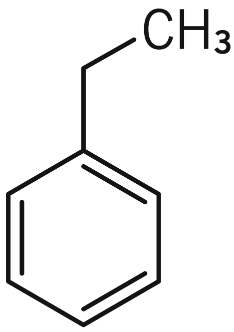
Numerous organic pyrolysis products have been found in surgical smoke, including – but not limited to – the following: aromatic hydrocarbons (benzene, toluene, ethylbenzene and xylenes), hydrogen cyanide (HCN), formaldehyde and, of course, polycyclic aromatic hydrocarbons[8]. Various authors[4, 8, 9] have attempted a more precise breakdown of the chemical constituents of surgical smoke. They conclude among other things that the composition of the smoke varies greatly and depends on the type of intervention and instruments employed.

1.1.3 | INORGANIC TOXINS

As with any process of combustion, electrosurgery procedures produce carbon oxides (CO and CO_2), sulphur and nitrogen oxides and ammonia. These agents may cause respiratory tract irritation and tissue hypoxia.

1.1.4 | BIOLOGICAL TOXINS

Tissue vaporisation releases smoke and aerosols that may contain large quantities of particles. These may be intact cells,



Ethylbenzene

cell fragments, blood cells and viral DNA fragments.

Viable bacteria have been cultured from laser smoke, with organisms including Bacillus subtilis and Staphylococcus aureus as well as mycobacteria such as Mycobacterium tuberculosis[10].

One study of the distribution and viability of bacteria after CO_2 laser treatment goes back to 1987[11]. The authors coated tubes with a nutrient broth inoculated with Escherichia coli and Staphylococcus aureus. The tube interiors were then lasered and the smoke thus produced was collected. The plume contained viable pathogens, notably staphylococci.

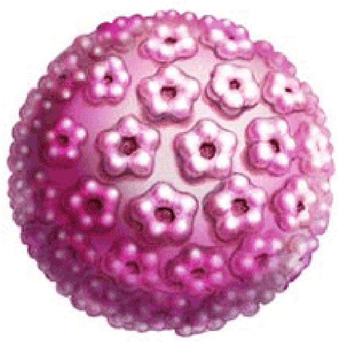
Biohazard warning sign

Infectious viruses including HIV (human immunodeficiency virus), HBV (hepatitis B virus), BPV (bovine papillomavirus) and HPV (human papillomavirus)[9] were also detected in the smoke. The nature of the microorganic contamination also depends largely on the type of procedures performed. Most papers focused on the human papillomavirus, and HPV DNA was repeatedly detected in samples of smoke produced during laser coagulation of warts[9, 12–15]. Laryngeal papillomatosis diagnosed in one nurse was officially recognized as an occupational disease. She had assisted during papillomatosis treatment procedures[16].

It is difficult to determine the viability of DNA detected in smoke. No specific test for the purpose exists. Garden[12] (1988)

QUALITATIVE LIST OF THE MAIN CHEMICAL – PRIMARILY ORGANIC – CONSTITUENTS IN LASER SURGERY SMOKE [16]

Acetonitrile	Formaldehyde	Butadiene	Propene
Acetylene	Carbon Monoxide	Butane	Pyridine
Acrolein	Cresol	Butylene	Pyrrole
Acrylonitrile	Methane	Hydrogen Cyanide	Styrene
Alkylbenzenes	Phenol	Ethane	Toluene
Benzene	Polycyclic Aromatic Hydrocarbons	Ethylene	Xylene



Human Papillomavirus

Human immunodeficiency virus

screened CO_2 laser smoke for bovine papillomavirus (BPV) and human papillomavirus (HPV) DNA without being able to demonstrate that this DNA was still infectious. In support of this research work, three sheep were inoculated with smoke captured during removal of bovine warts by CO_2 laser treatment. Two of the three animals developed a characteristic tumour at the transmission site[12, 17].

Cell cultures were inoculated with HIV viruses in an in-vitro experiment[18]. These cultures were exposed to the effects of various medical devices that generate aerosols during normal use. Only devices that generate so-called "cold" aerosols were able to transmit viable viruses. In contrast, plume smoke from electrocoagulation or cutting tools contained no viable viruses.

Fletcher et al.[19] detected viable melanoma cells in the plume smoke from electrocautery of a melanoma lesion. The number of viable cells was larger in association with intervention at a high power setting (30 W) than at 10 W.

1.2 | EFFECTS OF THE COMPONENTS

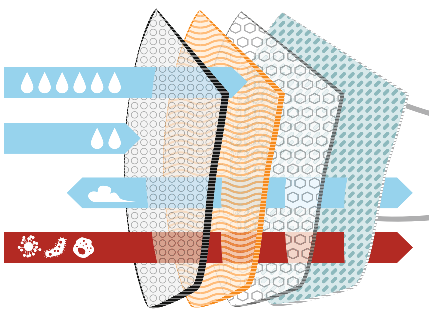
Surgical smoke dose-dependently causes symptoms of acute toxicity in the form of headaches, feeling weak, nausea, muscle weakness, and irritation of the eyes and respiratory tract.

People with asthma are more vulnerable to the effects of inhaled particles.

The smoke may also generate unpleasant odours which operating theatre personnel frequently find troublesome, and may obstruct the surgeon's view of the surgical site.

1.2.1 | PARTICLES

The effects of particles on the organism depend on their size and chemical composition. Particles smaller than 3 μm are termed "alveolar fraction" in Germany and those smaller than 10 μm are called "thoracic fraction." Particles of this size may penetrate into the bronchial tree, deposit on bronchial structures and cause cellular damage. The effects vary, ranging from contamination of the airways with inert particles (e. g., titanium dioxide) to local irritation (rhinitis, bronchitis), to malignant tumours (sinuses, bronchi). Some particles may enter the bloodstream and cause systemic toxicity (metals).



Mask layers let pathogens and particles through

Ultrafine airborne dirt particles emitted in industrial and diesel engine gases have been shown to have toxic effects that are hazardous to human health (respiratory allergies, rhinitis, bronchitis, cardiovascular problems, especially in susceptible individuals). Certain components found in laser fumes are also detected in polluted air.

It has also been conclusively demonstrated that nanometric particles differ in their toxicity from micro- or macroscopic particles with the same substance composition (e. g., nanometric titanium dioxide).

1.2.2 | CHEMICAL TOXINS

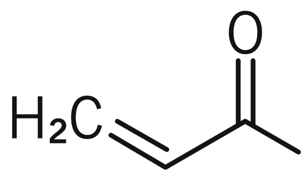
For detailed information on the toxicology of the substances discussed below, please consult the "Fiches toxicologiques" of the INRS or the DGUV's "GESTIS" substance database (www.inrs.fr or www.gestis.de). The described effects are of a general nature and as a rule bear no direct relation to the concentrations associated with electrosurgical procedures.

AROMATIC HYDROCARBONS

The aromatic hydrocarbon family is essentially composed of three chemical compounds. Benzene, classified by the IARC as being carcinogenic to humans, can cause bone marrow aplasia and leukaemia. Acute exposure manifests as central nervous system depression. Symptoms such as feeling weak, feeling intoxicated, nausea, dizziness, headache and narcosis all occur at concentrations above those found in surgical smoke.

TOLUENE AND XYLENE

Toluene and xylene have the same central depressant properties. They are also skin, eye and respiratory tract irritants.



Acrolein

ALDEHYDES

Formaldehyde, acetaldehyde and acrolein are respiratory tract irritants. These effects are manifest even at low concentrations and may cause major damage to the bronchial lining. Formaldehyde also causes skin and respiratory organ allergies and has been linked to cancer of the sinuses.

POLYCYCLIC AROMATIC HYDROCARBONS

Health problems linked to polycyclic aromatic hydrocarbons (PAHs) include irritation of the eyes, nose, throat, skin and airways, fatigue, headache, nausea and difficulty sleeping. Some reports mention non-malignant lung diseases such as bronchitis, emphysema and asthma.

A number of polycyclic aromatic hydrocarbons (including benzo[a]pyrene and dibenzo[a,h]anthracene) have proven carcinogenic activity and are classified by the European Union as category 2 carcinogenics: some have a category 1B classification. Other aromatic compounds, including certain heterocyclic compounds (benzonaphthothiophene, for example) or substituted PAHs may have genotoxic activity.

CRESOLS

The three cresol isomers may cause nervous system impairment, gastrointestinal disorders and skin conditions. Damage to the liver, kidneys and lungs of varying severities has also been observed. Cresols enter the body through the mouth, skin or respiratory system. Individuals exposed to heavy contamination soon develop irritation of the eyes with conjunctivitis, headache, a sensation of intoxication, impaired vision and hearing, tachycardia and dyspnoea.

Repeated exposure causes vomiting, loss of appetite, neurological problems, headache, intoxication and skin conditions.

Health hazard pictogram

PHENOL

Phenol irritates the eyes and respiratory tract lining. Chronic exposure causes difficulty swallowing, vomiting, diarrhoea, haematuria, loss of appetite, headache, confusion, behavioural disorders, dark urine and temporary redness.

HYDROGEN CYANIDE

The amounts of hydrogen cyanide (HCN) in laser plume are not enough to cause acute symptoms; however, chronic toxicity is possible in individuals with frequent exposure. The usual manifestations of chronic toxicity are headache, feeling weak, dizziness, tremors, nausea, vomiting, stomach pain, weight loss and conjunctivitis. Thyroid problems may also occur.

CARBON MONOXIDE

The symptoms of incipient poisoning tend to be unspecific: headache, dizziness, feeling weak and gastrointestinal problems. Carbon monoxide poisoning in its

CHEMICAL COMPOUNDS IN SURGICAL SMOKE AND THEIR HEALTH EFFECTS[27]

Acetonitrile[1]	Creosote[3]	2-Methylfurane
Acetylene	1-Decene	6-Methylphenol
Hydrogen cyanide[1]	2,3 Dihydro-Indene[1]	2-Methylpropanol
Palmitic acid	Ethane	PAH[3]
Acrolein[1]	Ethylene	Phenol[1,9]
Acrylonitrile[1,2,5]	Ethylbenzene	Polypropylene[1,8]
Alkylbenzene sulfonate	Formaldehyde[1,2,4,8]	Pyridine[1,11]
Benzaldehyde[1]	Furfural[1,2,9]	Pyrrole
Benzene[1,3,4,9,11]	Indole[1]	Styrene[1]
Nitrile benzene	Isobutane	Toluene[9,11]
Butadiene[1,2,4,9]	Methane	Xylene[11]
Carbon disulphide[1,6,7]	3-Methylbutane	m-Cresol[1,11]
Carbon monoxide[7]		

1. Irritates the eyes and airways
2. Suspected human carcinogen
3. Confirmed human carcinogen
4. Suspected human mutagen
5. Suspected animal mutagen
6. Affects semen quality
7. Asphyxiant, embryotoxic and fetotoxic
8. May cause respiratory sensitization
9. Suspected animal teratogen
10. Suspected human teratogen
11. Central nervous system depression

The unlabelled substances have either not been sufficiently characterized in toxicology studies or only have asphytic activity at high concentrations.

POSSIBLE HEALTH RISKS FROM SURGICAL SMOKE PLUMES[12]

Irritation of the eyes	Hypoxia, dizziness
Lachrymation	Colic
Sneezing	Cardiovascular problems
Nasopharyngeal irritation	Hepatitis
Acute or chronic respiratory tract inflammation (bronchitis, asthma, emphysema)	HIV infection
Headache	Dermatitis
Feeling weak	Anaemia
Nausea, vomiting	Leukaemia
Anxiety / agitation	Carcinoma

most serious form may cause coma and death. Serious neurological sequelae are possible. The problem of chronic toxicity has attracted much attention. It is believed to be a starting point for vascular damage and an associated increased risk of myocardial infarction as well as constituting a risk factor for certain neurological disorders, possibly including (for example) Parkinson's. The table below summarizes the main toxicities of various hazardous substances in laser plume[20].

VOLATILE ORGANIC COMPOUNDS

Some organic toxins belong to the heterogeneous group of volatile organic compounds (VOCs), representatives of a number of different chemical families. VOCs are detected in indoor air in varying concentrations.

1.2.3 | BIOLOGICAL TOXINS

Very few studies are available on the risks associated with the biological effects of inhaling laser and high-frequency electrosurgical smoke in the operating theatre. Alongside general effects, mutagenicity and carcinogenicity have been the main focus of attention[21].

1.3 | EFFECTS ON HEALTH

1.3.1 | GENERAL EFFECTS

The general effects / symptoms have been documented in a registry on the basis of the usual (known) constituents of laser smoke[5]. This registry is not based on epidemiological research, but rather is a list of theoretical risks of these constituents. It includes the possible acute (irritation) and chronic (cancers) effects of the individual ingredients.

Two experimental studies by Baggish and coworkers[22, 23] demonstrated the possibility of respiratory tract irritation. In one of these rat studies, intraalveolar instillation of particles from CO_2 laser tissue vaporisation caused interstitial congestive pneumonia, bronchiolitis and emphysema. Lung irritation was observed in rats exposed to CO_2 laser smoke in the other study.

This effect was less marked when the smoke had first been filtered through a conventional commercially available evacuation system. No effect (neither clinical nor histological) was observed when the rats had been exposed to smoke that had been filtered through an ultralow penetration air filter equipped to trap particles as small as 0.1 micrometres.

Freitag et al.[24] likewise demonstrated the irritant activity of laser smoke on the respiratory system. Sheep were exposed to a concentration of 0.92 mg particles / l with a mean particle diameter of 0.54 micrometres. In this case, the irritant effect was rated by analysing cells obtained by bronchoalveolar lavage.

1.3.2 | SPECIFIC EFFECTS

The only specific effects of surgical plume investigated to date are genotoxicity and cytotoxicity, but the few studies performed are insufficient to provide conclusive evidence.

GENOTOXICITY

The only effect studied in experimental conditions is mutagenicity using the Ames test (with or without activators). Tomita et al.[25] evaluated the mutagenicity of CO_2 laser smoke applied to canine tongue tissue. The condensates were produced by evacuation of smoke through filter paper followed by dilution with DMSO (dimethyl sulfoxide). The mixture thus generated was tested using the salmonella strains TA 98 and TA 100 employed in the Ames test. The result was positive for TA 98 (with and without metabolic activation) and TA 100 (with metabolic activation S9 mix from polychlorinated biphenyl-induced rat livers).

In a similar study[26], a sample of air was obtained during mastectomy by electrocautery. The condensate thus produced was also tested using the salmonella strains TA 98 and TA 100. In the presence of a metabolic activator (S9 mix from Aroclor 1254-induced rat livers) mutagenic activity was demonstrated for TA 98.

Although these results are positive, they are few in number. These outcomes are not necessarily representative for every plume. The smoke produced differs depending on laser performance, the tissue treated and the environment.

CYTOTOXICITY

The smoke generated in experimental conditions by repeatedly cutting pig liver with a high-frequency electrosurgical hook knife was exposed to a culture of breast cancer cells (MCF-7). The viability of this cell culture then declined by at least 30%, indicating that the smoke is cytotoxic. However, this study conducted in special experimental conditions (helium atmosphere) is not necessarily representative of the plume produced in operating theatres[27].

With the kind permission of the International Social Security Association, Section on Prevention of Occupational Risks in Health Services, taken from: Eickmann U, Falcy M, Fokuhl I, Rüegger M, Bloch M, Merz B. Surgical Smoke: Risks and Preventive Measures. Ed: International Section of the ISSA on Prevention of Occupational Risk in Health Services. 2011.

The source also contains reports of human experience and a summary assessment.

2 LEGAL BACKGROUND

Occupational health and safety legislation is in force in many westernized countries around the world. In the USA, Canada and Denmark, smoke evacuation is compulsory. TRGS 525[28], a set of regulations requiring the use of smoke evacuation in hospitals, has been applied in Germany since September 2014. Relevant national regulations are summarized in the following.

2.1 | GERMANY

TRGS 525, 8.1 SURGICAL PLUME (EXCERPT)

TRGS 525, 8.1.2 Protective measures

The amount of smoke generated depends on many factors that can be influenced by instrument technology and the user. As with exposure to tobacco smoke or other products of pyrolysis, the hazards featured in item 8.1.1 require compliance with the general principle of minimizing exposure and the application of suitable safety measures:

1. The equipment used should be state of the art. If the release of surgical smoke cannot adequately be prevented, attempts should be made to capture it at the source, for example through the use of handpieces with integrated evacuators or a standalone local evacuation system.

2. Equipment likely to generate surgical smoke should only be used in procedure rooms (e. g., operating theatres) with modern ventilation and air conditioning systems, for example in accordance with DIN (German Industrial Standard) 1946 Part 4. These precautions can prevent relevant persistent pollution of the entire operating theatre with surgical smoke during electrosurgical and laser procedures to avoid exposure of the remaining surgical team. However, depending on the intensity of smoke-generating procedures, it may be necessary to use local evacuation systems to further reduce local smoke pollution in the immediate surgical area, for reasons including the potential risk of infection. Likewise, other factors may necessitate the use of local evacuation systems, e. g. in veterinary medicine. The recirculation of evacuated air in working premises without air conditioning is allowed only if, in addition to a HEPA filter for retention of particulate matter in smoke, an activated carbon filter is used to capture gaseous and vaporous components.

3. Employees must be briefed in line with § 2 MPBetreibV (Medical Devices Operator Ordinance) and § 14 GefStoffV (Hazardous Substances Ordinance) on the mechanisms underlying smoke production and how to minimize it through appropriate equipment use.

4. If the above technical and organizational measures are insufficient to eliminate the hazards caused by surgical smoke, risk assessment is required to determine the need for additional safety measures, which may include improved ventilation or half face particulate masks (FFP2) in accordance with DIN EN 149. Ordinary surgical masks provide inadequate protection against surgical smoke.

2.2 | AUSTRALIA

AUSTRALIAN COLLEGE OF OPERATING ROOM NURSES (ACORN)[29]

ACORN is a professional organisation that develops standards and recommendations to promote excellence in perioperative care. The following is ACORN's standard:

Standard S20

- Personnel shall utilize appropriate equipment and procedures to prevent exposure to surgical plume. Exposure to surgical plume shall be minimized during the surgical procedure.
- Surgical smoke capture devices shall be available for use during procedures in which surgical smoke is generated (ACORN 2006).

2.3 | DENMARK

DANISH WORKING ENVIRONMENT AUTHORITY[30]

Danish Working Environment Authority is an agency under the auspices of the Ministry of Employment. The Danish Working Environment Authority is the authority which contributes to the creation of safe and sound working conditions at Danish workplaces. The agency is responsible for administering the Working Environment Act in Denmark, and guides companies on health and safety rules at the workplace.

AT-Instructions 4/2007 and 11/2008

- It is mandatory to implement a measurable setup for local evacuation of harmful substances, such as surgical smoke.
- Such a setup must be equipped with a monitoring feature to indicate if the evacuation system's suction is inadequate.
- Surgical smoke should be removed with local evacuation and as close to the source as possible.
- The filtered air must lead out into the open (read: outside the OR).

2.4 | CANADA

CANADIAN STANDARDS ASSOCIATION (CSA)[31]

The CSA developed and released one of the furthest reaching standards relating to the management of surgical plume.

CSA Z301-13 Plume scavenging in surgical, diagnostic, therapeutic, and aesthetic settings

This standard details a comprehensive approach to managing plume and extends its mandates to all surgical settings based on risk assessment. General requirements include:

- Facility policies and procedures shall be written in accordance with this standard.
- Plume shall be evacuated in accordance with this standard.
- If a facility employs techniques that create plume, they shall have policies that address the potential hazards.

2.5 | UNITED STATES OF AMERICA

OCCUPATIONAL SAFETY & HEALTH ADMINISTRATION (OSHA)[32]

OSHA is the only U.S. regulatory body to date that has legal authority in the United States granted by Congress. They estimate that 500,000 healthcare workers are exposed to surgical smoke and bio-aerosols each year. On a number of occasions OSHA has reiterated that the management of surgical plume is a healthcare worker safety issue. They have also indicated that plume hazards fall under the scope of the following:

General duty clause

"Each employer shall furnish to each of his (sic) employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees."

Personal Protective Equipment (PPE)

Controlling a hazard at its source is the best way to protect employees.

2.6 | UNITED KINGDOM

MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY (MHRA)[33]

Medicines and Healthcare Products Regulatory Agency (MHRA) is responsible for regulating all medicines and medical devices in the UK by ensuring they work and are acceptably safe. The following is MHRA's recommended practice:

MHRA DB2008(03) April 2008

Recommends that smoke evacuation systems are to be used during laser surgery. In addition, it is specified that masks and operating room laminar flow systems are not suitable for protection from surgical smoke.

ASSOCIATION FOR PERIOPERATIVE PRACTICE (AFPP)[34]

Association for Perioperative Practice (AfPP) works to encourage the exchange of professional information between members and co-operation with other professional bodies. They are not a regulatory agency but a recommending agency. The following is AfPP's standard:

Standard 2.6 Lasers-standards and recommendations for safe perioperative practice

The standard states that 'Dedicated smoke evacuation machines must be used to remove the smoke' (AfPP 2007).

3 SOLUTION FROM BOWA

SHE SHA – BOWA's surgical smoke evacuation system – is designed to evacuate and filter the surgical smoke and aerosols generated during the use of surgical equipment for tissue dissection, for example during the use of lasers, electrosurgical systems and ultrasonic devices.

SHE SHA surgical smoke evacuation comes with a powerful vacuum suction motor that is extremely low-noise in operation and enables a range of flow rates. Surgical smoke is pumped through the vacuum tube into the filter of the SHE SHA surgical smoke evacuator where it is processed through a series of filter layers. SHE SHA uses a single disposable filter, which makes removal and installation easier when changing filters. The filter is fully contained to protect staff from any contamination during filter changes.

A filter such as used in SHE SHA surgical smoke evacuation filters smoke in 4 stages using a different filter layer in each case.

In the first filtration stage, a primary filter traps coarse particles and fluids and removes them.

In the second filtration stage, a ULPA (ultra low penetration air) filter traps particles and microorganisms. Its leading edge patented design (U.S. Patent #5874052) enables the filtration of particles as small as 0.1 to 0.2 microns with 99.999 % efficiency.

In the third filtration stage, a high quality activated carbon filter adsorbs and removes odours and toxic gases generated when biological tissues are heated to high temperatures. These harmful gases may constitute a health risk for operating theatre staff exposed to them for long periods. The activated carbon used in SHE SHA smoke evacuation removes toxic organic gases primarily and water vapour secondarily and provides optimum odour elimination.

In the fourth filtration stage, an expanded foam prevents fine particles of activated carbon from leaving the filter.

The electronic operating elements on the front panel of the SHE SHA smoke evacuator are user-friendly for easy start-up and operation.

TECHNICAL DATA

Acoustic emission	Max. 55 dBA
Size (H x L x W)	6 inch x 11 inch x 15.5 inch (15 cm x 28 cm x 39.5 cm)
Flow rate	Max 708 litres per minute (with a 22-mm tube)
Weight	4,4 kg (5,5 kg incl. Filter)
Filter type	4 layer filter (prefilter, ULPA, activated carbon, postfilter)
Particle size	0,1–0,2 µm at 99,999 % efficiency

SHE SHA SET

	SHE SHA Smoke evacuation system incl. remote sensor and pneumatic foot switch (REF 950-001)

ACCESSORIES

 SHE SHA filter for 35 hours (2 pcs.) (REF 951-001)	 SHE SHA handle, adjustable length, 2 buttons, knife electrode, 3 m, single-use, sterile (10 pcs.) incl. holster (REF 802-033)	 SHE SHA handle, 2 buttons, knife electrode, 3 m, single-use, sterile (10 pcs.) incl. holster (REF 802-032)
 SHE SHA hose for laparoscopy, 3 m, single-use, sterile (12 pcs.) (REF 952-200)	 SHE SHA hose for handle, 3 m, single-use, sterile (10 pcs.) (REF 952-001)	

4 FAQ – BOWA FOR SURGICAL SMOKE EVACUATION

Is ordinary operating theatre ventilation sufficient to provide protection against surgical smoke?

No. Room ventilation is not sufficient to remove aerosols and gases at the source.

Is an ordinary surgical fluid aspirator sufficient to remove surgical smoke?

No. Surgical fluid evacuation systems are designed to evacuate fluids. This type of evacuation can contaminate the vacuum system. In any case, surgical evacuation systems are not sufficiently powered, with a performance rate of approximately 40 l/min. Effective smoke evacuation requires an evacuation rate of at least 600 l/min.

Do masks provide protection against surgical smoke?

No. Ordinary masks do not provide protection against surgical smoke. Their only purpose is to protect patients from infection from organisms exhaled by the surgical team.

What is the use of a surgical smoke evacuation system?

Surgical smoke evacuation effectively removes and filters surgical smoke directly at the source. This significantly reduces health risks for users and surgical staff.

Evacuation during procedures also prevents any obstruction of surgical field visibility from surgical smoke.

Does smoke evacuation add to the noise level in the operating theatre?

No. Modern surgical smoke evacuation systems have a volume of less than 60 dB(A), which approximates the noise level of normal conversation.

Does the surgical smoke evacuator need to be switched on during surgery as needed?

No. The smoke evacuation system switches on automatically when HF devices are activated. In the absence of HF, the evacuator can be activated using a foot switch.

Is the BOWA smoke evacuation system suitable for use with a variety of device types?

Yes. The smoke evacuator is universally compatible. An active HF lead is attached to the activation sensor for use with HF devices.

What is the purpose of the shut-off delay feature in a smoke evacuation system?

The individually adjustable shut-off delay allows residual plume to be evacuated after HF devices have been switched off.

How do I know that the filter needs changing?

There is an indicator on the evacuator display showing the condition of the filter. The filter is also recognized automatically and the filter condition is memorized.

What happens when the filter is used up?

When a filter is flagged as used up, there is still time to complete the current procedure. The filter should be replaced before starting the next surgical procedure.

Does the smoke evacuator stop when HF activation ends?

Yes. If the activation sensor is in use, evacuation is synchronized with HF activation. An individually adjustable shut-off delay option is also available.

5 REFERENCES

1. Eickmann U, Falcy M, Fokuhl I, Rüegger M, Bloch M, Merz B. Chirurgische Rauchgase: Gefährdungen und Schutzmaßnahmen: Internationale Sektion der IVSS für die Verhütung von Arbeitsunfällen und Berufskrankheiten im Gesundheitswesen; 2011.

2. Lewin JM, Brauer JA, Ostad A. Surgical smoke and the dermatologist. Journal of the American Academy of Dermatology. 2011 Sep;65(3):636-41. PubMed PMID: 21550691.

3. Sugarbaker PH. Peritonectomy procedures. Surgical oncology clinics of North America. 2003 Jul;12(3):703-27, xiii. PubMed PMID: 14567026.

4. Al Sahaf OS, Vega-Carrascal I, Cunningham FO, McGrath JP, Bloomfield FJ. Chemical composition of smoke produced by high-frequency electrosurgery. Irish journal of medical science. 2007 Sep;176(3):229-32. PubMed PMID: 17653513.

5. Alp E, Bijl D, Bleichrodt RP, Hansson B, Voss A. Surgical smoke and infection control. The Journal of hospital infection. 2006 Jan;62(1):1-5. PubMed PMID: 16002179.

6. Andreasson SN, Anundi H, Sahlberg B, Ericsson OG, Walinder R, Enlund G, et al. Peritonectomy with high voltage electrocautery generates higher levels of ultrafine smoke particles. European journal of surgical oncology : the journal of the European Society of Surgical Oncology and the British Association of Surgical Oncology. 2009 Jul;35(7):780-4. PubMed PMID: 18922668.

7. Bruske-Hohlfeld I, Preissler G, Jauch KW, Pitz M, Nowak D, Peters A, et al. Surgical smoke and ultrafine particles. Journal of occupational medicine and toxicology. 2008;3:31. PubMed PMID: 19055750. Pubmed Central PMCID: 2621226.

8. Dobrogowski M, Wesolowski W, Kucharska M, Sapota A, Pomorski LS. Chemical composition of surgical smoke formed in the abdominal cavity during laparoscopic cholecystectomy--assessment of the risk to the patient. International journal of occupational medicine and environmental health. 2014 Apr;27(2):314-25. PubMed PMID: 24715421.

9. Barrett WL, Garber SM. Surgical smoke: a review of the literature. Is this just a lot of hot air? Surgical endoscopy. 2003 Jun;17(6):979-87. PubMed PMID: 12640543.

10. Walker B. High efficiency filtration removes hazards from laser surgery. NATNews. 1990 Jun;27(6):10-2. PubMed PMID: 2395451.

11. Byrne PO, Sisson PR, Oliver PD, Ingham HR. Carbon dioxide laser irradiation of bacterial targets in vitro. The Journal of hospital infection. 1987 May;9(3):265-73. PubMed PMID: 2886531.

12. Garden JM, O'Banion MK, Shelnitz LS, Pinski KS, Bakus AD, Reichmann ME, et al. Papillomavirus in the vapor of carbon dioxide laser-treated verrucae. Jama. 1988 Feb 26;259(8):1199-202. PubMed PMID: 2828703.

13. Gloster HM, Jr., Roenigk RK. Risk of acquiring human papillomavirus from the plume produced by the carbon dioxide laser in the treatment of warts. Journal of the American Academy of Dermatology. 1995 Mar;32(3):436-41. PubMed PMID: 7868712.

14. Kashima HK, Kessis T, Mounts P, Shah K. Polymerase chain reaction identification of human papillomavirus DNA in CO_2 laser plume from recurrent respiratory papillomatosis. Otolaryngology--head and neck surgery : official journal of American Academy of Otolaryngology-Head and Neck Surgery. 1991 Feb;104(2):191-5. PubMed PMID: 1848926.

15. Sawchuk WS, Weber PJ, Lowy DR, Dzubow LM. Infectious papillomavirus in the vapor of warts treated with carbon dioxide laser or electrocoagulation: detection and protection. Journal of the American Academy of Dermatology. 1989 Jul;21(1):41-9. PubMed PMID: 2545749.

16. Calero L, Brusis T. [Laryngeal papillomatosis – first recognition in Germany as an occupational disease in an operating room nurse]. Laryngo- rhino- otologie. 2003 Nov;82(11):790-3. PubMed PMID: 14634897. Larynxpapillomatose – erstmalige Anerkennung als Berufskrankheit bei einer OP-Schwester.

17. Garden JM, O'Banion MK, Bakus AD, Olson C. Viral disease transmitted by laser-generated plume (aerosol). Archives of dermatology. 2002 Oct;138(10):1303-7. PubMed PMID: 12374535.

18. Johnson GK, Robinson WS. Human immunodeficiency virus-1 (HIV1) in the vapors of surgical power instruments. Journal of medical virology. 1991 Jan;33(1):47-50. PubMed PMID: 1901908.

19. Fletcher JN, Mew D, DesCoteaux JG. Dissemination of melanoma cells within electrocautery plume. American journal of surgery. 1999 Jul;178(1):57-9. PubMed PMID: 10456705.

20. Frenette Y. Les fumées chirurgicales. Connaissez vous les risques? Travail et Santé. 2003;19(4):34-6.

21. Hill DS, O'Neill JK, Powell RJ, Oliver DW. Surgical smoke – a health hazard in the operating theatre: a study to quantify exposure and a survey of the use of smoke extractor systems in UK plastic surgery units. Journal of plastic, reconstructive & aesthetic surgery : JPRAS. 2012 Jul;65(7):911-6. PubMed PMID: 22445358.

22. Baggish MS, Baltoyannis P, Sze E. Protection of the rat lung from the harmful effects of laser smoke. Lasers in surgery and medicine. 1988;8(3):248-53. PubMed PMID: 3393053.

23. Baggish MS, Elbakry M. The effects of laser smoke on the lungs of rats. American journal of obstetrics and gynecology. 1987 May;156(5):1260-5. PubMed PMID: 3107392.

24. Freitag L, Chapman GA, Sielczak M, Ahmed A, Russin D. Laser smoke effect on the bronchial system. Lasers in surgery and medicine. 1987;7(3):283-8. PubMed PMID: 3626753.

25. Tomita Y, Mihashi S, Nagata K, Ueda S, Fujiki M, Hirano M, et al. Mutagenicity of smoke condensates induced by CO_2-laser irradiation and electrocauterization. Mutation research. 1981 Jun;89(2):145-9. PubMed PMID:7027028.

26. Gatti JE, Bryant CJ, Noone RB, Murphy JB. The mutagenicity of electrocautery smoke. Plastic and reconstructive surgery. 1992 May;89(5):781-4; discussion 5-6. PubMed PMID: 1561248.

27. Hensman C, Newman EL, Shimi SM, Cuschieri A. Cytotoxicity of electro-surgical smoke produced in an anoxic environment. American journal of surgery. 1998 Mar;175(3):240-1. PubMed PMID: 9560129.

28. Technische Regel für Gefahrstoffe 525, TRGS 525 (2014).

29. Nurses ACoOR. Surgical Plume. Australian College of Operating Room Nurses 2006.

30. Arbejdstilsynet. At-intern instruks IN-17-3. Flere arbejdsmiljøemner: Arbejdstilsynet; 2007.

31. Association CS. Plume scavenging in surgical, diagnostic, therapeutic, and aesthetic settings. Canadian Standards Association; 2013.

32. Administration OSH. OSH Act of 1970. Occupational Safety & Health Administration; 2004.

33. Agency MaHPR. Device Bulletin. Guidance on the safe use of lasers, intense light source systems and LEDs in medical, surgical, dental and aesthetic practices 2008.

34. Surgical Smoke: What we know, Association for Perioperative Practice (2009)

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BOWA-APG-MN031-644-SMOKE-EN-20200415 Printed in Germany We reserve the right to make technical and structural amendments