LOW-TEMPERATURE STEAM AND FORMALDEHYDE AS A METHOD FOR STERILIZATION

Recent years have shown a significant increase in the use of heat-sensitive medical devices, and this development will most likely continue (for example with endoscopic surgery techniques like NOTES). Therefore, the need for reliable and efficient low-temperature sterilization processes increases rapidly, and it is important to be able to make an informed decision on the choice of technology. This overview focuses on one of the accepted and approved technologies – the combination of low-temperature steam and formaldehyde – and evaluates it from an efficacy, compatibility, safety and economical point of view.

The low-temperature steam and formaldehyde sterilization process (often shortened to LTSF) is one of the main technologies for low-temperature sterilization. Other technologies include ethylene oxide gas (EOG or ETO) and hydrogen peroxide gas plasma (PLASMA).

One very important area of use for low-temperature sterilization is the processing of flexible endoscopes. While the use of flexible endoscopes increases, the risk of hospital-acquired infections related to endoscopes must be minimized. This represents a challenge since flexible endoscopes may be damaged in temperatures above 55°, and their complex construction with long, narrow lumens puts extra high demands on reliable efficacy of the methods used.

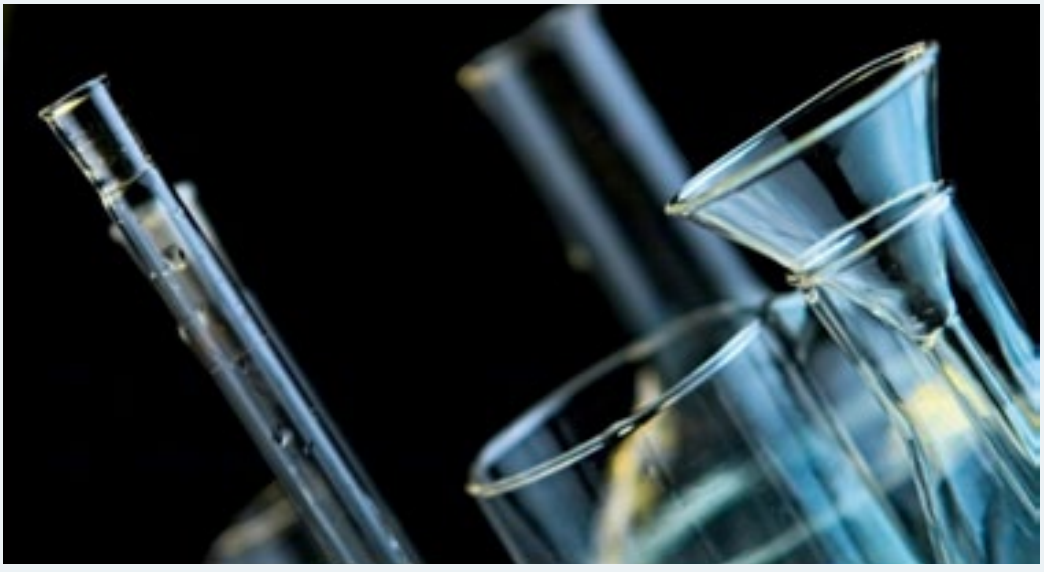
In addition to various GI endoscopes and endoscopes for surgical procedures, low-temperature sterilization is needed for heat-sensitive eye-surgery instruments, plastic materials like syringes, coils tubing, diathermic cables and much more.

THE STERILIZING AGENT IN THE LTSF PROCESS

Formaldehyde has been used in the LTSF process since the late 60s. The process works at sub- atmospheric pressure and uses a mixture of formaldehyde and low-temperature saturated steam to create a sterilant.

Formaldehyde is a naturally occurring substance in the environment made of carbon, hydrogen and oxygen. As the simplest aldehyde, it is a well-known and important precursor to many other chemical compounds, and also widely used as a disinfectant thanks to its germicidal effect.

Formaldehyde is also a key building block in the chemical industry, where millions of tons are used each year in the production of other chemicals, various plastics, disinfectants and adhesives for making particleboard, plywood etc. for the furniture and construction industries. In hospitals, formaldehyde solutions are widely used in autopsy, surgical and pathology departments and also, to a lesser extent, in dermatology and surgical clinics, X-ray departments and other health-care units. The principal use in hospitals is for fixation of tissues.



Formaldehyde is a widely used chemical compound. In addition to its use as a disinfectant and biocide, it is used in many industrial applications.

Sterilization of flexible endoscopes requires highly efficient processes with documented efficacy for sterilization of long, narrow lumens – while also offering 100% material compatibility.

MICROBIOLOGICAL EFFICACY

A sterilization process must result in an approved sterile product, free from hazardous levels of residuals. In Europe, the standard EN 14180 is used for steam/formaldehyde sterilization, just as EN 285 is used for steam sterilization. Both biological and physical testing is used for validation of LTSF process efficiency. The biological indicators most resistant to chemical inactivation with formaldehyde, and which consequently pose the greatest challenge to LTSF sterilization, are spores from Bacillus Stearothermophilus. Additionally, spores from Bacillus Subtilis, which are difficult to inactivate when there is insufficient moisture, may be used for supplementary testing. Recommendation for indicator systems and their use at validation are given in the World Standard EN ISO 11138-5.

In a comparative study performed in Japan 2005[1], the efficacies of the LTSF, EOG and PLASMA methods were compared. Some commonly used medical tools were contaminated with Bacillus Stearothermophilus spores. In addition, biological indicators were placed in both a Helix PCD (Process Challenge Device) and a modified, longer and more narrow device. As seen in the diagrams, both LTSF and EOG completely eradicated the spores, while the PLASMA method was unsuccessful in all of the trials.

The report concludes that "LTSF sterilization demonstrates excellent efficacy" and that "LTSF could potentially act as a substitute if EOG becomes unavailable due to environmental concerns"[1,2].

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Sterilizers for medical purposes - Low temperature steam and formaldehyde sterilizers - Requirements and testing

Stérilisateurs à usage médical - Stérilisateurs à la vapeur et au formaldéhyde à basse température - Exigences et essais

Sterilisatoren für medizinische Zwecke - Niedertemperatur-Dampf-Formaldehyd-Sterilisatoren - Anforderungen und Prüfung

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Growth from biological indicators after sterilization of PCD

		Sterilization System								
		EOG			PLASMA			LTSF		
Process Challenge Device	**Positive Control**	**1**	**2**	**3**	**1**	**2**	**3**	**1**	**2**	**3**
Helix PCD* (ID, 2 mm; hose, 1.5 m)	+	-	-	-	+	-	+	-	-	-
Modified process challenge device (ID, 0.96 mm; hose, 1.5 m)	+	-	-	-	+	+	+	-	-	-
Modified process challenge device (ID, 0.96 mm; hose, 3.0 m)	+	-	-	-	+	+	+	-	-	-

ID = internal diameter; EOG = ethylene oxide gas; PLASMA = hydrogen peroxide gas plasma; LTSF = low-temperature steam formaldehyde.
*Getinge AB, Getinge, Sweden.

Efficacies of low-temperature methods to sterilize medical instruments contaminated with *B. stearothermophilus* spore

	Sterilization System								
	EOG			PLASMA			LTSF		
Instrument	**1**	**2**	**3**	**1**	**2**	**3**	**1**	**2**	**3**
Forceps	-	-	-	-	+	-	-	-	-
Dissector	-	-	-	-	+	-	-	-	-
Airway tube	-	-	-	-	-	-	-	-	-

EOG = ethylene oxide gas; PLASMA = hydrogen peroxide gas plasma; LTSF = low-temperature steam formaldehyde.

MATERIAL COMPABILITY

Flexible endoscopes are both sensitive and expensive. It is vital that the complex functions and material properties are not jeopardized. Therefore, documented material compatibility is one of the most important factors when evaluating technologies for low-temperature sterilization.

The LTSF process as carried out in the equipment manufactured by Getinge Infection Control has been thoroughly tested with the leading brands of endoscopes. For example, it is approved and recommended by Olympus for sterilization of Olympus surgical endoscopes.


OLYMPUS

HAZARD POTENTIAL

A process for low-temperature sterilization must be safe for both the operator and the patient. It should also have the lowest possible environmental impact.

Since the point of chemical sterilants is their biocidal efficiency, it is natural to expect that they are also harmful to human health in cases of uncontrolled or excessive exposure. Ethylene oxide (ETO) is a known human carcinogen[3], hydrogen peroxide (PLASMA) is irritant and hazardous with the target organs being the eyes and respiratory system[4]; and formaldehyde can be toxic, allergenic and carcinogenic[5].

Naturally the use of formaldehyde in sterilization processes is heavily regulated in order to eliminate any potential health risks. Scientific studies have established 0,0168 g as a 24-hour intravenous exposure limit for a human 70 kg adult. The limit value in the standard EN 14180 was set at 0,0002g. This is approximately 80 times lower than the above-mentioned limit of 0,0168 g.

The OSHA regulations stipulate a maximum of 2 ppm exposure during a period of 15 minutes for the operator, or 0.75 ppm continuously over a 8-hour work period. The EN 14180 regulations define values of 1 ppm/15 minutes and 0,5 ppm/workday.

This can be compared with the average value of 0,1 ppm inside the chamber of a Getinge LTSF sterilizer. The maximum occurrence inside the chamber is 0.5 ppm.

It can also be compared to the exposure caused by drinking two cups of coffee, which equals 24 hours of inhalation of air containing 1 ppm of formaldehyde.

When it comes to the environment, formaldehyde is naturally and quickly biodegradable, and is thus not in any way environmentally hazardous at the discharge levels related to sterilizers.

N.B.: Misinformation that formaldehyde should have been banned from the EU under the REACH legislation has recently been spread. This is a misconception probably related to the Biocidal Products Directive, which bans formaldehyde from use in certain applications (preservatives for liquid-cooling and processing systems, slimicides, metalworking-fluid preservatives, and anti-fouling products)[5].

ECONOMICAL FEASABILITY

A low-temperature sterilization process must also be inexpensive and its running costs should be as low as possible.

In addition to the very low cost level of formaldehyde as a sterilizing agent, LTSF sterilizers can offer low total costs by combining low- and high-temperature sterilization in the same machine. For example, Getinge's combination sterilizer can process loads of up to 15 endoscopes, or up to 8 STU of ordinary, not heat-sensitive goods.

In addition, the same standard wrappings used in normal steam sterilization, e.g. as described in the European standard EN 868-5, can also be used in LTSF processing. This means no additional wrapping costs.

PROS AND CONS OF MAIN LOW-TEMPERATURE STERILIZATION TECHNOLOGIES

LTSF

+ High efficacy, cost-efficient
+ Combination sterilizers

– Longer cycle times than PLASMA
– Toxic, carcinogen

EOG

+ High efficacy

– Long cycle times
– Toxic, carcinogen
– Additional investment cost for ventilation and reinforced walls

PLASMA

+ Very short cycle times

– No combination sterilizer
– Low capacity
– High cost for machine and consumables
– No standard for plasma

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GETINGE GROUP

Getinge Infection Control · SE-31044 Getinge, Sweden · Phone +46 10 335 00 00
E-mail: info@getinge.com · Internet: www.getinge.com