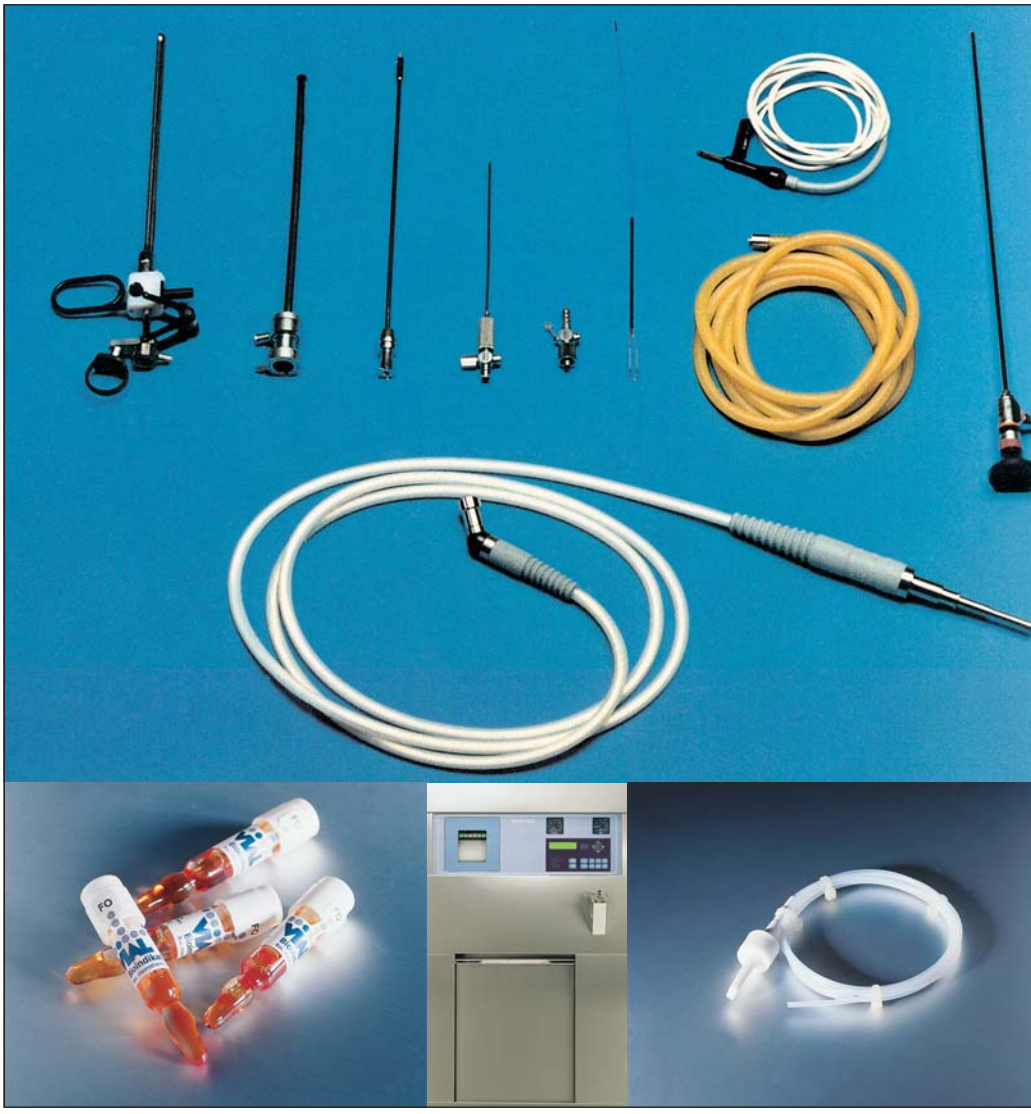
LTSF

# Low-temperature sterilization using low-temperature steam and formaldehyde



**Getinge's LTSF sterilizer units provide reliable sterilization of heat-sensitive goods.**

GETINGE

## Inside this issue:



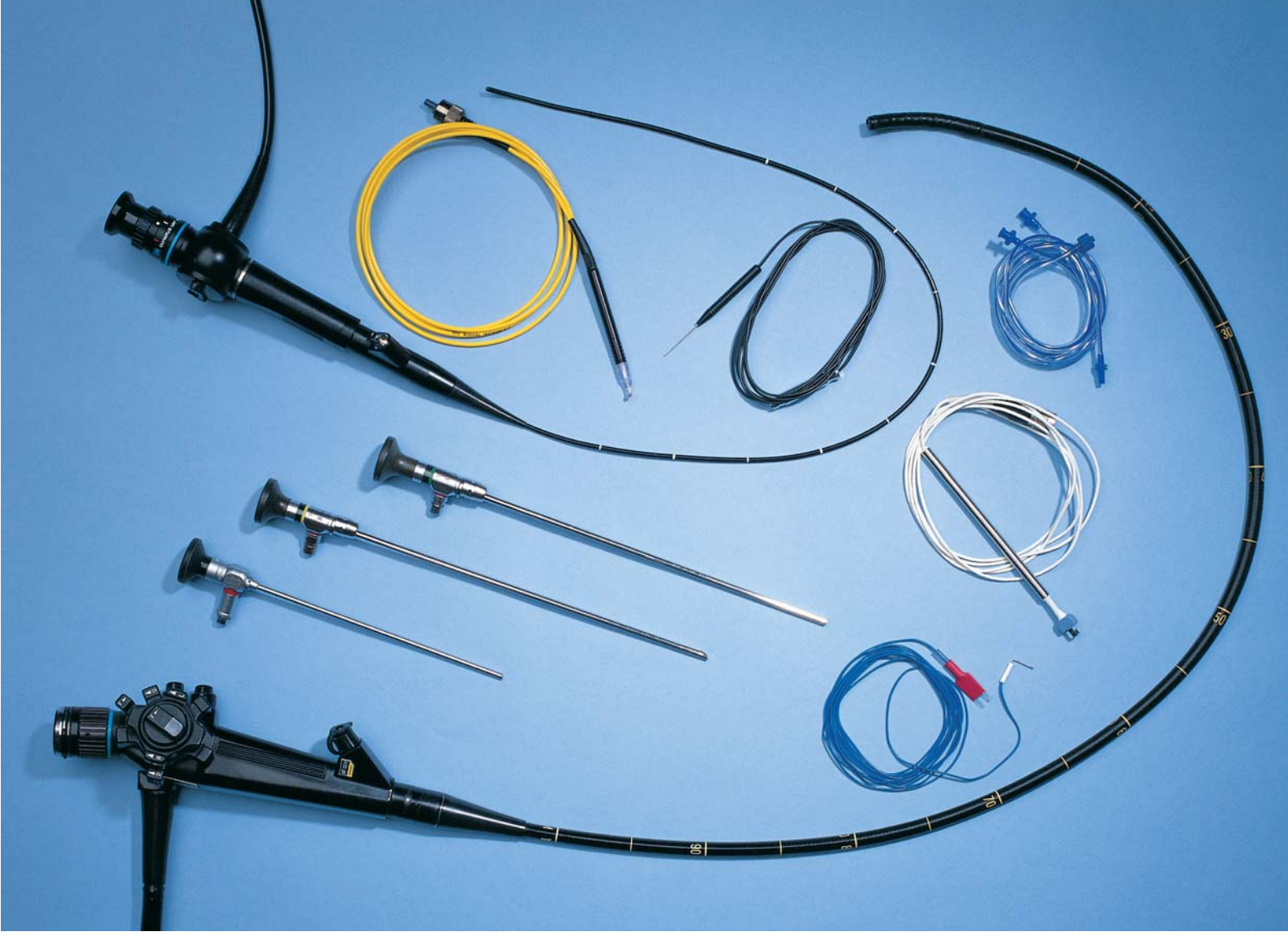
### IMPORTANT DEFINITIONS

Pathogenic infectious matter consists of various types of microorganisms such as bacteria, microscopic fungi and viruses.
Disinfection and sterilization are the processes required for infection control.

**Disinfection**, according to the internationally accepted definition, is the killing of non-sporiferous and vegetative microorganisms.

Steam and hot water are the most common and efficient agents used in the health care environment. A cleaning and disinfection unit, where cleaning is performed by flushing with cold and warm water, followed by heat disinfection at a minimum temperature of +80° C (176° F) for ten minutes or at +90° C (194° F) for one minute ( Ao = 600 ), is a good solution.

**Sterilization**, on the other hand, kills all viable microorganisms, including the spores.
The safest and most economical method is heat treatment, i.e. steam under pressure in a sterilizer, achieving sterilization within a minimum of 15 minutes at +121° C (250° F) or 3 minutes at +134° C (273° F).



# The need for low-temperature sterilization

**The most widely recognized and well-established method of sterilization is using high-pressure steam.**

**Why? Because it is the most effective method of killing microorganisms and because most products can withstand it.**

**There are, however, some products made of or including parts with materials that cannot stand the heat of such processes, normally +121° C or 134° C.**

**Typical equipment suitable for processing with Getinge Low-Temperature Steam Formaldehyde sterilizers:**

- **Most types of endoscopes – both rigid (straight) and flexible: arthroscopes, cystoscopes, laparoscopes, bronchoscopes, coloscopes, gastroscopes, duodenoscopes, choledochoscopes, laryngoscopes, nephroscopes etc.**
- **All heat-sensitive instruments for advanced eye surgery, e.g. cryo-instruments.**
- **Most plastic materials: syringes, coils, tubing, diathermic cables etc.**

# Requirements for using the Low-Temperature Steam & Formaldehyde sterilization process

Whatever the process, it must result in an approved sterile product, free from hazardous levels of residuals.
It must be reasonably easy to use and capable of physical monitoring, have a short process time, be possible for the normal packaging staff to operate and control – and be inexpensive.
Moreover, the process should allow the product to be packaged in normal wrapping material so as not to create additional costs.
It must result in a product available for immediate use.
It must be safe to use with standard pre-processing and have good safety margins.
Low-temperature steam formaldehyde sterilization fulfils all these requirements.

# Formaldehyde sterilization

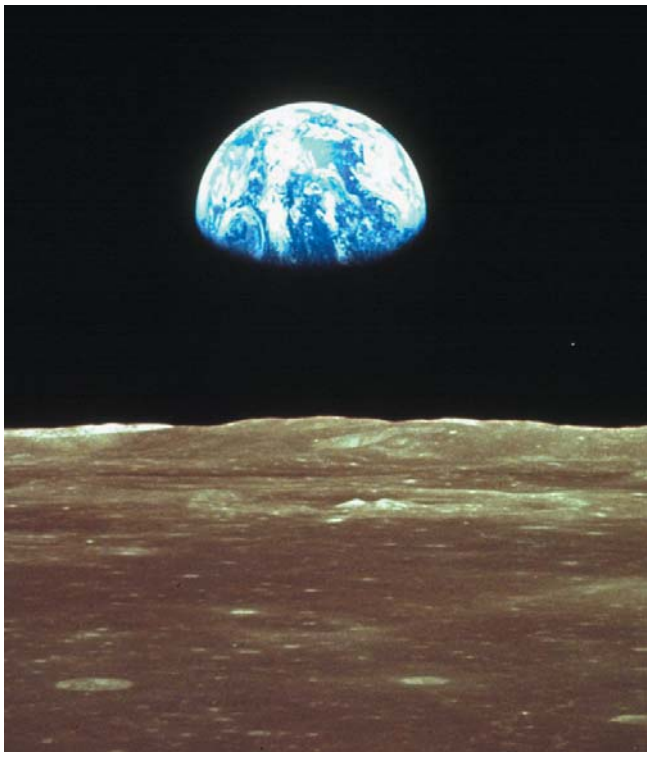

## WHAT IS FORMALDEHYDE?

Formaldehyde comes from the Latin formica, ant (ants produce formic acid as a natural defence).
It is a colourless gas, but is normally distributed as a solution (generally referred to as formalin), and is known to most people within hospitals as an important disinfectant, which has, been in use since the late 1800s.
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.

## USES WITHIN THE HOSPITAL

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.

# Health & environmental facts



## TOXIC GAS

Formaldehyde is a colourless, toxic gas, highly soluble in water and commercially available as a 35% solution called formalin. This solution is a clear, colourless liquid, with a highly irritating smell and ”burning” taste that affects mucous membranes.

| | | | |
|---|---|---|---|
| $CH_3OH$ ⟶ | $HCHO$ ⟶ | $HCOOH$ ⟶ | $CO_2 + H_2O$ |
| Methanol | Formaldehyde | Formic acid | Carbon dioxide + Water |

## HEALTH IMPACT

Formaldehyde occurs naturally in most living things and is a vital part of our ecology.
Formaldehyde is an important intermediate biochemical of the cellular metabolism and acts as basic element to found bodily substances. (2)
Formaldehyde is naturally decomposed by the human body and is not accumulated.

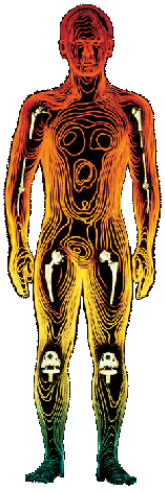
*An Embryo.*

## IS FORMALDEHYDE ALLERGENIC?

Formaldehyde solutions are known to be toxic, irritating and allergenic.
The solution is irritating to the skin and can cause allergy on long or frequent contact exposure.
However, even exposure to low, harmless doses causes irritation in the eyes, nose and throat.
This irritation compels the person exposed to avoid further contact; i.e. formaldehyde has a built-in warning signal.
Consequently, allergic reactions due to presence of formaldehyde in the air are unusual.

## IS FORMALDEHYDE CARCINOGENIC?

Research on possible carcinogenic effects, based on animal studies conducted by IARC in the USA, showed little to indicate such effects of formaldehyde (1).
The tests were conducted by exposing mice and rats to extremely high concentrations of formaldehyde for two years.
In mice, no changes were found even from exposure to a concentration level of 2 ppm (the level of painful nasal irritation in humans starts at 0.01 ppm!).
When subjecting mice to extremely high concentrations (5.6-14.3 ppm), it was possible to induce chronic changes in nasal tissues.
This included two cases of nasal cancer.
Since the same incidence of nasal cancer is found in unexposed mice, it was concluded that the study gave no clear evidence of any carcinogenic effects of formaldehyde.
In the tests with rats, severe chronic changes in nasal tissues occurred at levels of 5.6 ppm and the incidence of cancer at the highest exposure level was higher than for mice.
Extensive epidemiological studies on industrial workers, pathologists and embalmers – who are regularly exposed to concentrations higher than 10 ppm – have shown no long-term adverse effects (2).



## CONCLUSION

Long-term exposure to high concentrations of formaldehyde is thought to have carcinogenic effects on animals. Formaldehyde is therefore classified as a suspected carcinogen in humans. (8) (9)
However, since the extremely irritating smell of formaldehyde at very low levels tends to prevent exposure to higher concentrations, long-term exposure to carcinogenic levels is extremely rare.

## ALL AROUND US

Here are some examples of the occurrence of formaldehyde in nature and elsewhere in our daily lives:

| | | | |
|---|---|---|---|
| Apples | 20 | mg/kg | (2) |
| Coffee | 50 | mg/l | (2) |
| Pathologist's laboratory | 10 | mg/m$^3$ | (2) |
| Exhaust fumes (car) | 150 | mg/m$^3$ | (2) |

- Smoking 20 cigarettes exposes you to 1 mg. (3)
- Adult exposure through food is an average of 1.5-14 mg/day (mostly in a bound, non-active form). (4)
- Gas stove without forced ventilation: 275 ppm. (5)
- "Digesting" 2 cups of coffee is the equivalent of 24 hours of inhalation of air containing 1 ppm of formaldehyde (2 times the maximum recommended level)! (2)

1 ppm = 1.25 mg/m$^3$

## AIRBORNE FORMALDEHYDE LEVELS (PPM)

| | | |
|---|---|---|
| 0.05 ppm | You can smell this level! | (6) |
| 0.01-1.2 ppm | May irritate your eyes. | (6) |
| 0.5 ppm | Full-day working limit. | (7) |
| 0.05-1.2 ppm | May irritate your nose. | (6) |
| 1.0 ppm | Max. level for 15 minutes. | (7) |
| 4.0 ppm | Brings tears to your eyes. | (2) |

## FORMALDEHYDE SUMMARY

- Natural product
- Biodegradable
- Non-toxic end-product
- Produced by oxidation of methanol
- Produced in the body, e.g. when "digesting" coffee and some medicines
- "Digested" in the body by enzymes
- Decomposed in air
- Highly soluble in water
- Human smell threshold significantly lower than acceptable maximum concentration

# Steam & formaldehyde as sterilizing agents

## STERILIZATION BY STEAM

When destroying contaminating microorganisms with heat, the relationship between temperature and time depends on whether wet or dry heat is used.
If a steam sterilizer is used at a processing temperature of 121° C, the objects are considered sterile after a minimum of 15 minutes exposure time. If the temperature is 134° C, sterilization takes place in as little as 3 minutes (8).
In practice, the exposure time is somewhat longer than the minimum requirements.
Moist heat is more effective than dry heat, which requires 2 hours' holding time at 160° C (320° F).
Heat kills microorganisms by promoting chemical reactions that denature proteins in the cell.
Heat transfer is slower at dry conditions and since spores contain less water than vegetative cells, they are more difficult to destroy.

It is important for the steam to be in contact with the organism to be destroyed.
The first stage in most steam sterilization processes is air removal, where chamber air is replaced by steam, often using a pulsating pre-vacuum system. (Any air remaining in the load might prevent direct steam contact, thereby jeopardizing sterilization.)
Air removal thus assures effective penetration of steam and provides moist sterilizing conditions throughout the load.

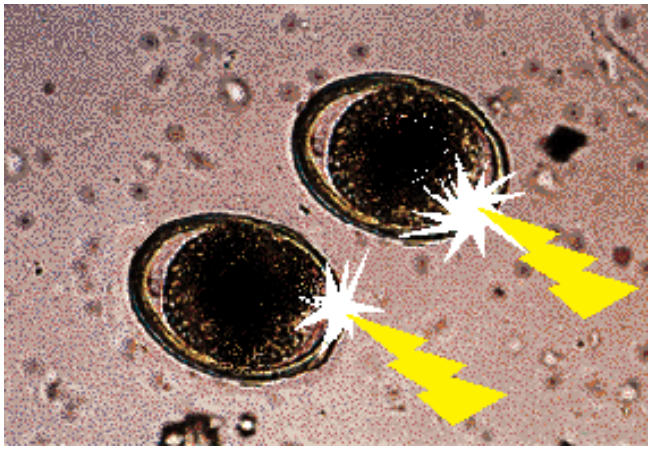


*Illustration: Moisture in the form of low-temperature steam, together with formaldehyde gas, destroys any microorganisms.*

## STERILIZATION BY LTSF
## – Low-Temperature Steam and Formaldehyde

In the LTSF process, the pure heat energy of steam sterilization is replaced by a mixture of steam and formaldehyde gas at temperatures of either 80, 65, 60, 55 or 50° C (176, 149, 140, 131 or 122° F).
The presence of steam allows the formaldehyde to penetrate and kill any microorganisms.

# The Getinge LTSF process

## FOR HEAT-SENSITIVE GOODS

This sterilization process is intended for heat-sensitive goods, especially plastic and hollow instruments (e.g. rigid and flexible endoscopes etc), which may be damaged by the high temperature of a conventional steam sterilizer.

## THE PROCESS CONSISTS OF FOUR STAGES:

*Pre-treat-ment* *Form-aldehyd admission* *Sterilization* *Post-treatment*

**Pre-treatment**

Before the formaldehyde is admitted, the goods are subjected to pre-treatment consisting of repeated evacuations and steam flushes.

This very important procedure aims at removing air from the goods and the chamber, while simultaneously humidifying the microorganisms to make them susceptible to formaldehyde.

The effectiveness of the humidifying part of the pre-treatment is essential for the rest of the process.

**Formaldehyde admission**

A formalin solution is injected from a sealed bottle.

The formalin is then evaporated and enters the chamber as a gas. A vacuum in the chamber assists the admission of the gas. Steam is then added to keep the temperature at the pre-determined level.

The admission is repeated several times to enhance the penetration into long, narrow lumens and cavities.

**Sterilization**

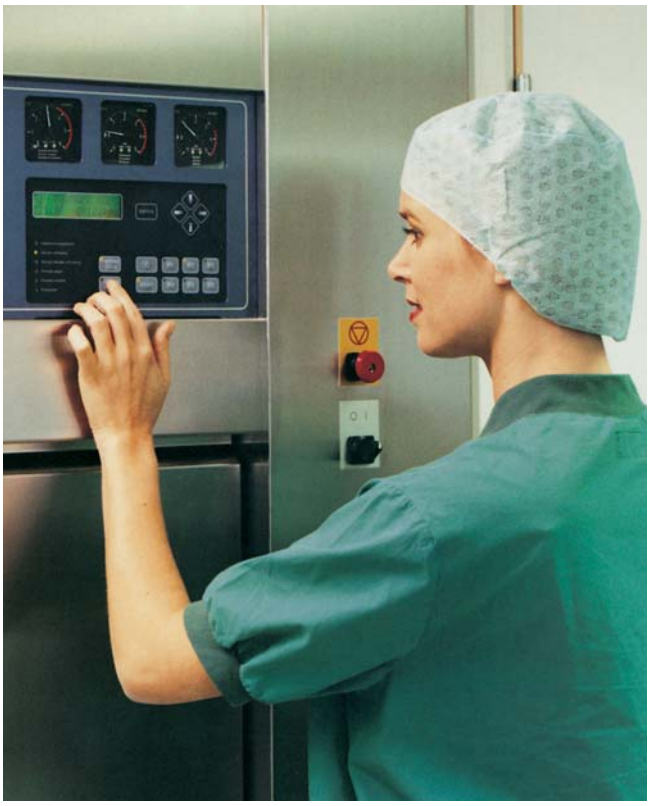
During the exposure time, the chamber is maintained at the specified temperature, sterilant concentration, pressure and humidity.

**Post-treatment**

After the predetermined sterilizing exposure time, the formaldehyde is effectively removed from the goods by repeated vacuum and intermediate steam flushes.

The post-treatment process ends with a deep vacuum, followed by a huge number of pulsating air flushes via the air admission filter.

This part of the process removes residual formaldehyde in the goods and the chamber.



*Getinge sterilizers use a 35 % formalin solution, which is evaporated before entering the chamber. Formalin is inexpensive to produce and is generally available at your local pharmacy.*

## LTSF – SAFE TO USE

The formaldehyde concentration in the air by the sterilizer door is generally a maximum of 0.5 ppm, and drops to zero ppm within a few minutes!

Formaldehyde in the sterilizer drain is diluted to 0.01 % and is then decomposed quickly by microorganisms in the sewage.

When using the Getinge range of LTSF sterilizers the operator will not come in contact with formalin, as this is only handled in closed bottles or piping systems.

## RECOGNIZED STERILIZATION METHOD

- For sterilization temperatures of 50*, 55, 60, 65 or 80° C.
- Especially suitable for hollow instruments, e.g. rigid and flexible endoscopes.
- Approved in accordance with DIN 58 948 (parts 13 and 14) requirements.
- EN standard under preparation.
- Used worldwide.

* – As option on model Gef 449 perFORMer Cool

# Checking the process

## DAILY TESTS

Medical authorities worldwide have recognised that it is not enough to check the sterilization process by physical means (charts and gauges). Additional controls – primarily chemical and biological – are also required.
Various biological and chemical control methods, with varying degrees of accuracy and reliability, are available today.
Getinge is constantly evaluating, developing and validating various brands to make the use of such products easy and reliable for the responsible staff.

## CHEMICAL INDICATORS

This control method gives clear, instant pass-or-fail indication by a change of colour.
Indicators are available as spots or strips.
Spots are normally used as indicators on the outside of a pack, while the strip indicator should be placed inside the pack or inside a challenge device to show, via colour change, that formaldehyde gas has penetrated and been present in sufficient quantity and for a sufficient period of time, to achieve sterilization.

*Chemical Indicators.*

## BIOLOGICAL INDICATORS

As mentioned above, vital factors for good sterilization results are the removal of air and the access of humidity and sterilizing agent. This can be difficult to achieve if a sterilizer with a poorly designed vacuum system is used.
Biological indicators, prepared from Bacillus Stearothermophilus and resistance-tested against formaldehyde, are placed inside a pack and provide reliable controls.


*Challenge device.*


*Self-contained indicators.*

## TWO TYPES ARE AVAILABLE:

**Challenge devices**
For laboratory cultivation. Since the low-temperature steam formaldehyde sterilization process is mainly used for narrow and optical instruments, a special challenge test method has been developed to simulate a complex instrument.
The challenge test unit consists of a narrow (2 mm inside diameter), one-way lumen, 1.5 m long, with an indicator at the closed end of the tube.

**Self-contained biological indicators**
For local testing. Include both the test organism and the cultivation broth.

## RESIDUAL TESTS

This challenge method of testing for formaldehyde residuals is based on filter paper. Evaluation is performed in a chemical laboratory, according to standard practice (10).
In this test, residuals represent a worst case (absorbing materials) and are not representative of residuals on non-absorbing instruments.

## GETINGE FORMALDEHYDE COMPLIANCE

As shown on the previous pages, independent tests confirm that the Getinge's formaldehyde sterilizers comply well with the specified bacteriological regulations. Moreover, residuals from Getinge sterilizers are far below regulated values.

# Approved sterilization process

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15.04.97

**Report on Getinge AB Formaldehyde Sterilizers GE 449/2 and GE 666/2.**

**1. Introduction**

At the Getinge factory, sterilizers GE 449/2 and GE 666/2 have been testet for efficacy according to DIN 58948 part 13-14. The scope of the test corresponds to a type approval test, where apart from the evaluation of three different types of bio-indicators, also temperature and pressure curves were measured by means of PT 100 (RTD) sensors, thermocouples and high-precicion pressure transducers.

**2. DESCRIPTION OF PRODUCT**

Both models work as follows:

*Prevacuum*

*Flushing 1 (Conditioning):*
four fractional flushes with saturated steam

*Sterilizing agent addition:*
ten injections of formaldehyde gas followed by saturated steam

*Sterilization:*

| Sterilizer model/type | Temperature | Time |
|---|---|---|
| 449/2 | 50 - 60 °C | 60 - 30 min |
| 666/2 | 55 - 65 °C | 45 - 30 min |

## 6. EVALUATION:

As shown by the evaluated pressure- and temperature records, the sterilizer model 449 provides excellent physical values in the entire temperature range studied, i.e. from 50°C to 60°C. During the sterilization process the deviation from the set values was 0.04 % higher for pressure and 1% higher for temperature. The sterilizer model 666 showed pressure deviations of 1.5 % and a temperature error of 0.9 % with a tendency to higher values.

The microbiological investigations with various bio-indicators as well as various test specimens were irreproachable.

In conclusion both sterilizers provide very reliable results. The sterilizer model 449 also ensures an exceptionally stable process in the lower temperature range of 50 °C.

Streifeneder Clemens
Hygieneingenieur

Dr.Dr. Anton Hartinger
Chefarzt

Enclosure: test survey, test arrangement, test results, ev

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DK 615.478.73 : 614.484 : 547.281.1 : 620.1 Januar 1987

Sterilisation
**Gas-Sterilisatoren**
Prüfung auf Wirksamkeit von Formaldehyd-Gas-Sterilisatoren

DIN 58 948 Teil 13

Sterilization; gas sterilizers; efficiency testing of low temperature steam and formaldehyde gas sterilizers

Maße in mm

**1 Anwendungsbereich**

Diese Norm gilt für die mikrobiologische Prüfung von Formaldehyd-Gas-Sterilisatoren, in denen Sterilisiergut von Krankenanstalten, ärztlichen Praxen oder ähnlichen Einrichtungen sterilisiert wird.

**2 Zweck**

Durch diese Festlegungen soll der Nachweis erbracht werden, daß die zur Behandlung im Formaldehyd-Gas-Sterilisator vorgesehenen Materialien sterilisiert werden.

**3 Prüfungsarten**

**3.1 Typprüfung**

Die Typprüfung dient der Ermittlung der Betriebsdaten eines Formaldehyd-Gas-Sterilisator-Typs.

Anmerkung: Die Typprüfung wird im Regelfall beim Hersteller durchgeführt.

**3.2 Prüfung nach Aufstellung**

Die Prüfung nach Aufstellung des Formaldehyd-Gas-Sterilisators am Aufstellungsort soll nachweisen, daß der Formaldehyd-Gas-Sterilisator den Anforderungen über Formaldehyd-Groß-Sterilisatoren (siehe DIN 58 948 Teil 12 (z. Z. Entwurf)) und Formaldehyd-Klein-Sterilisatoren (Norm in Vorbereitung) entspricht.

**3.3 Periodische Prüfung**

Die periodische Prüfung wird am Aufstellungsort in bestimmten Zeitabständen (Norm in Vorbereitung) durchgeführt. Sie soll nachweisen, daß der Formaldehyd-Gas-Sterilisator bei Einhaltung der Bedienungsanweisung sterilisiert.

**3.4 Außerordentliche Prüfung**

Die außerordentliche Prüfung ist eine Prüfung, die durchgeführt wird, wenn Zweifel an der Wirksamkeit des Formaldehyd-Gas-Sterilisators bestehen.

**4 Behandlungskontrolle**

Die Behandlungskontrolle dient zur Vermeidung von Verwechslungen zwischen behandeltem und unbehandeltem Sterilisiergut. Sie wird mittels Behandlungsindikatoren [1]) durchgeführt. Eignung und zweckmäßige Handhabung vorausgesetzt, weisen diese nur nach, daß das Sterilisiergut der Einwirkung des Sterilisiergases ausgesetzt wurde. Ein Umschlag des Behandlungsindikators berechtigt nicht zu der Aussage, daß das behandelte Gut steril ist.

[1]) Begriff siehe DIN 58 900 Teil 1

**5 Beladung**

Der Formaldehyd-Gas-Sterilisator wird mit Sterilisiergut nach den Angaben der Bedienungsanweisung beladen.

Enthält diese keine entsprechenden Angaben, wird die Beladung in zweckmäßiger Weise vorgenommen, wobei dem Verwendungszweck des Formaldehyd-Gas-Sterilisators Rechnung getragen werden muß (siehe Erläuterungen).

**6 Prüfkörper**

Der Prüfkörper muß in seinen Abmessungen (Länge, Breite, lichte Weite) dem am schwersten zu sterilisierenden Sterilisiergut entsprechen.

**6.1** Der Standard-Prüfkörper für den Bereich der Medizin und Pharmazie besteht aus einem Polytetrafluorethylen(PTFE)-Schlauch mit einem Innendurchmesser (2 ± 0,3) mm und einer Länge von (1,5 ± 0,01) m, der an einer Seite durch eine Vorrichtung verschlossen wird, die einen Bio-Indikator nach DIN 58 948 Teil 14 enthält.

Anmerkung: Es sind auch andere Bio-Indikatoren mit Keimträgern aus Filtrierpapier oder Leinenzwirn (z. B. Leinenzwirn*), naturfarben, Länge 1 cm) zulässig, wenn sie als Testkeime Sporen von Bacillus stearothermophilus enthalten, mit einer Suspension aus 1 Teil defibriniertem Schafblut und 9 Teilen physiologischer Kochsalzlösung getränkt und getrocknet werden oder eine dieser Suspension mindestens entsprechende Eiweißbelastung aufweisen und dann der Resistenz nach DIN 58 948 Teil 14 mit gleicher oder längerer Haltbarkeit entsprechen.

**6.2** In dem Teil des Prüfkörpers, der den Bio-Indikator enthält, darf nach Einlegen des Bio-Indikators das freibleibende Volumen nicht größer sein als das Volumen eines entsprechend gleich langen angeschlossenen Schlauchstückes.

**6.3** Der Prüfkörper muß so beschaffen sein, daß der Bio-Indikator nach der Sterilisation ohne Rekontamination auf überlebende Keime untersucht werden kann.

**6.4** Der Prüfkörper nach Abschnitt 6.1 ist in eine Klarsichtsterilisierverpackung einzusiegeln bzw. in betriebsüblicher Art zu verpacken (siehe Erläuterungen).

Anmerkung: Ausführungsbeispiele eines Prüfkörpers werden im Anhang B gegeben.

*) Auskunft über Bezugsquellen gibt der Normenausschuß Medizin, Burggrafenstraße 6, 1000 Berlin 30.

Fortsetzung Seite 2 bis 8

Normenausschuß Medizin (NAMed) im DIN Deutsches Institut für Normung e.V.



Tests made in accordance with DIN 58 948, parts 13 and 14, showed approved, reliable results.

# The Getinge LTSF Sterilizer Range

The Getinge LTSF sterilizer range comprises several models, including single- or double-door designs.
There are two basic models with the chamber opening: 445 x 445 mm or 672 x 672 mm.

| Getinge LTSF sterilizer model range | | | | | |
|---|---|---|---|---|---|
| Dim. | Units | GEf 449 | GE 2606 | GE 2609 | GE 2612 |
| *Chamber volume* | *L/cu.ft* | 185/6.5 | 298/10.5 | 415/14.5 | 564/20 |
| *Chamber width* | *mm/in.* | 445/17.5 | 672/26 | 672/26 | 672/26 |
| *Chamber height* | *mm/in.* | 445/17.5 | 672/26 | 672/26 | 672/26 |
| *Chamber depth* | *mm/in.* | 940/37 | 660/26 | 920/36 | 1250/49 |

## FLEXIBLE DESIGN

The range includes models, which are either steam-heated from a central steam supply or have a built-in electrical steam generator.
Sterilizers can also be installed as recessed units or designed as freestanding cabinets.

*The Getinge 2066-series LTSF sterilizer, with chamber opening 672 x 672 mm.*

## COMBINED INSTALLATION

All Getinge LTSF sterilizers can be installed in the same front as your steam sterilizers, i.e. no dedicated room is required.

## EXCELLENT CHAMBER UTILIZATION

The sterilizer chambers are adapted to standardised goods carriers for optimal utilisation.
The smaller sterilizer provides extra utilisation when used in combination with special optional wire baskets.

## COMBINED STERILIZERS

The range includes models with the unique combination of low-temperature steam and formaldehyde (LTSF) and steam sterilization at 121–134° C.

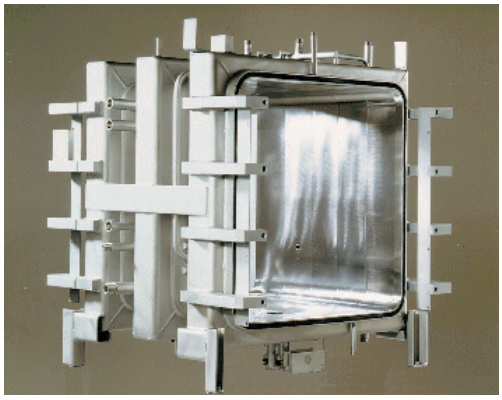
*Below: The LTSF sterilizers can be installed in the same front as steam sterilizers, saving space and management.*

## THE GETINGE GEF 449 ”perFORMer” LTSF STERILIZERS

This is the model used mainly where a dedicated LTSF sterilizer is required and the demands for high capacity, together with a minimum of floor space requirements, is essential.
This sterilizer is however as well installed, side-by-side, with steam sterilizers.

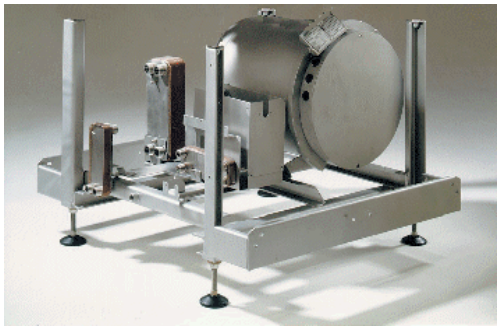
## SOLID STAINLESS CHAMBER

The sterilizer chamber, made of solid, acid-proof stainless steel, is easy to clean using standard detergents and has a superior lifetime. The chamber features temperature-controlled heating of the chamber walls.



## MEETS ALL STANDARDS

All pressure vessels from Getinge are manufactured in accordance with the specifications of the authorities in your country, and meet the world´s toughest standards of quality and safety, including ASME, TÜV, BS, MOL, DRIR, ISPESL, AFS etc.



*Robust, stainless steel framework.*

## SLIDING DOORS

All models have vertical sliding doors for safe and easy operation, thereby minimizing space requirements around the installation.
Getinge´s doors include all interlocking safety devices prescribed by the world´s safety standards, and since the surface temperature of the door never exceeds 45° C (113° F), the risk of burn injuries is eliminated.

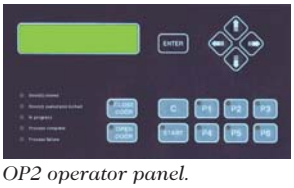
## RELIABLE VACUUM PUMPS

The liquid-ring vacuum pump is mounted on anti-vibration dampers. The entire vacuum system is designed to achieve the highest possible capacity utilisation, complete reliability of sterilization results, longer lifetime and lower noise levels.

*The Getinge Gef 449 ”perFORMer” LTSF sterilizer, with chamber opening 445 x 445 mm.*

## MICROCOMPUTER CONTROLLED

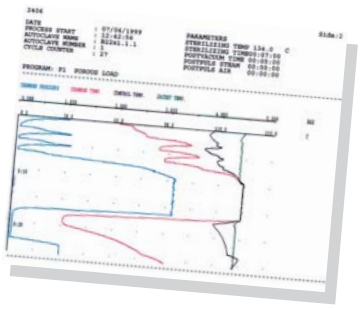
Getinge LTSF sterilizers are all designed with the same advanced microcomputer control system – PACS 2000 – as all other Getinge sterilizers.
This unit is specially developed for Getinge sterilizers and is designed to handle the sterilization process with consistently superior results. The automatic diagnosis of faults means faster service and lower costs.
The PACS 2000 microprocessor is an extremely user-friendly control unit, where each step in the cycle is clearly shown on the front panel, along with the current time and temperature.



*OP2 operator panel.*

## DOCUMENTATION

As standard, all sterilizers have an integrated line recorder, fully independent from the control system, for continuous registration of temperature and pressure inside the sterilizer chamber throughout the process.



*Process information can also be printed on a standard A4-printer, as option.*

## A SELECTION OF CONVENIENT OPTIONS

**PACS SUPERVISOR**

A completely independent monitoring and recording unit that's receives signals simultaneously from the control system and from its own temperature and pressure sensors located on the sterilizer.
The SUPERVISOR gives all process data on one printout, thereby eliminating the need for a separate recorder.

**Label printer**

A label printer is connected to the PACS 2000 control system for printouts (after completion of cycle) of process information on labels for attaching to each package. For more advanced use, see the Getinge T-DOC-system.

## INJECTION – SAFE TO USER

The sterilizing agent is stored in liquid state in a single-dose bottle.
A needle, in the holder punctures the sealed bottle, and the formalin is evaporated before it enters the chamber.
If the formalin is not fully used, the bottle is completely and safely emptied at the end of the process, ready for recycling.

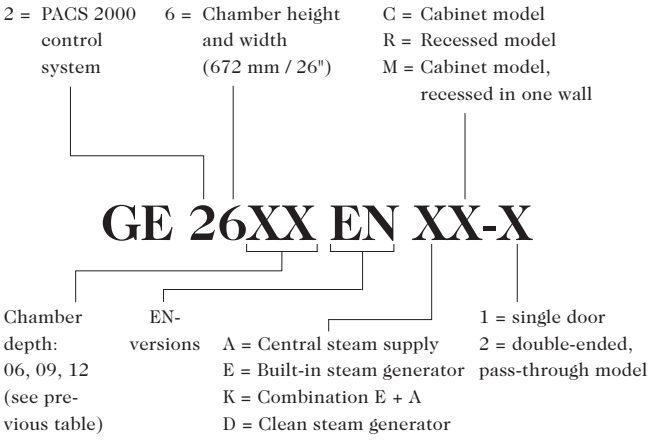
## AUTOMATIC CLEANING PROGRAM

In order to avoid accumulation of residuals on chamber walls and in piping after long-term use, the sterilizer is provided with an automatic cleaning program, which is normally run once a week.

## MODEL CODES

**The 2066-series LTSF range**

Thanks to an ingenious modular construction, Getinge´s 2066-series LTSF sterilizers offers great flexibility.
In fact, you can practically have your sterilizer tailored to your specifications, as illustrated below by the model code descriptions:




All these sterilizers are designed as a combined LTSF and steam sterilizer, equipped with the sterilization program type 2511, including 5 preset steam cycles (acc. to EN 285) and 2 LTSF cycles at 80 or 65° C.

**The GEf449 perFORMer range**

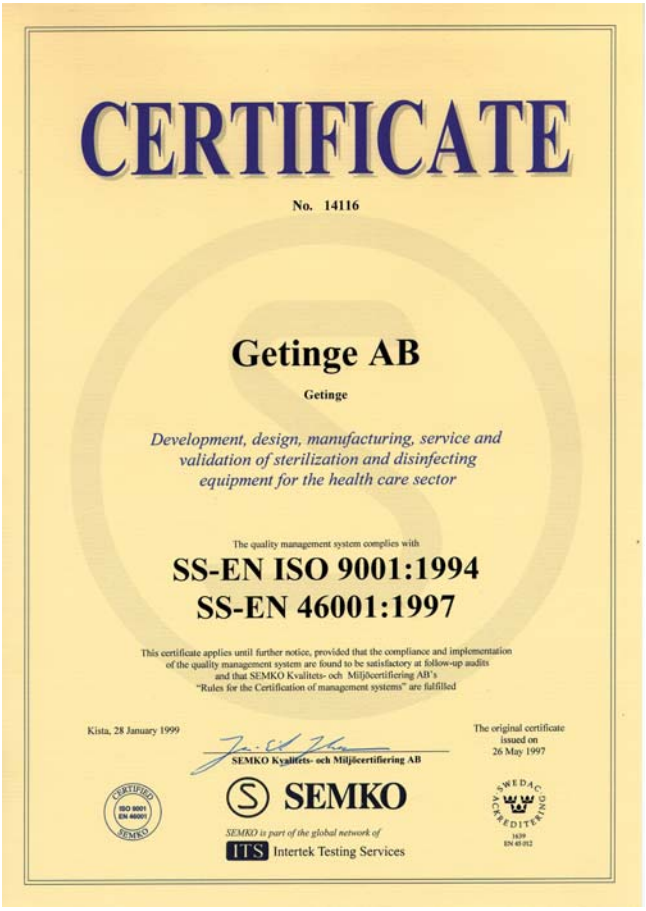
The smaller sterilizer, Gef 449 "perFORMer", can as well be specified by use of the last 3 signs above.
These models are available in 3 different designs:

GEf449 perFORMer – the standard dedicated LTSF sterilizer including preset sterilizing processes at 80 and 65° C.

GEf449 perFORMer Cool – as the standard model, further extended with a preset 55° C LTSF process.

GEf449 perFORMer Combi – designed with the unique combination LTSF and steam sterilization, including 5 preset steam processes (acc. to EN 285) and 3 LTSF processes at 80 and 65 or 60° C.

# Getinge´s manufacturing facilities meet quality standards as ISO 9001 and EN 46001



CERTIFICATE

No. 14116

Getinge AB

Getinge

*Development, design, manufacturing, service and validation of sterilization and disinfecting equipment for the health care sector*

The quality management system complies with

**SS-EN ISO 9001:1994**
**SS-EN 46001:1997**

This certificate applies until further notice, provided that the compliance and implementation of the quality management system are found to be satisfactory at follow-up audits and that SEMKO Kvalitets- och Miljöcertifiering AB's "Rules for the Certification of management systems" are fulfilled

Kista, 28 January 1999

SEMKO Kvalitets- och Miljöcertifiering AB

The original certificate issued on 26 May 1997

SEMKO

*SEMKO is part of the global network of*

ITS Intertek Testing Services

*EN 46001 – Manufacturing quality system for medical equipment.*

SIS SAQ

Certificate

This is to certify that the Quality System of

Getinge AB

in the field of

development, design, production and service of sterilization equipment for the health care sector, the pharmaceutical industry and laboratries

has been found to conform to

SS-EN ISO 9001

Certificate No 701

21/12/1998

Replaces Certificate No 001 issued by SAQ Kontroll AB 02/06/1994

SIS SAQ Certifiering AB

Harald Rach
Managing Director

Bengt Fransson
Manager Certification

1241
EN 45 012

SIS SAQ Certifiering AB is a member of IQNet, the International Certification Network

*The scope and conditions of the certification are specified in the certification decision*

*ISO 9001 – Manufacturing quality system approval.*

CE 0413

*Getinge LTSF sterilizers are all marked according to MDD.*

## REFERENCES


*1) CIIT (Chemical Industry Institute of Toxicology).*
*Final report on a chronic inhalation toxicology study in rats and mice exposed to formaldehyde.*
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*3) Weber - Tschopp A, Fischer T. and Grandjean E.*
*Reizwirkungen des Formaldehyds (HCHO) auf den Menchen.*
*Int. Arch. Occup. Health 39, 1977, 207 -18*

*4) WHO, Indoor Air Quality: Radon and Formaldehyde.*
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*Committee on Toxicology, National Academy of Sciences, Washington, D.C. 1980*

*6) Gamble J., Effects of formaldehyde on the respiratory system.*
*In: Formaldehyde toxicity.*
*Ed. Gibson JE. Hemisphere Publishing Corporation, Washington, 1983, 175 - 97.*

*7) German MAK - und BAT - Werte - Liste*

*8) Minimum, according to EN-standards*

*9) A C G I H (American Conference of Governmental Industrial Hygienists)*

*10) V. Handlos, Determination of formaldehyde residuals, in autoclave sterilized materials.*
*Arch. Pharm. Chemi, Sci. Ed., 5 , 163, 1977*

## KEY FEATURES

- RECOGNIZED STERILIZATION METHOD
- SUITABLE FOR HOLLOW INSTRUMENTS
- HIGH CAPACITY
- EASY AND SAFE TO USER
- STANDARD WRAPPING MATERIAL USED
- LOW RESIDUALS
- COMBINED STEAM/LOW-TEMPERATURE STEAM AND FORMALDEHYDE STERILIZER AS OPTION

GETINGE – THE NAME YOU CAN COUNT ON

Getinge´s remarkable record of success for nearly a century is attributable to our range of top-quality, high technology products, together with our ability to offer complete working systems. No wonder Getinge is today the world leader, with sterilizers in more than 2500 hospitals in 100 countries!

Getinge also leads the world in the design, development and manufacture of sterilization equipment for the pharmaceutical industry and laboratory markets.

GETINGE

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