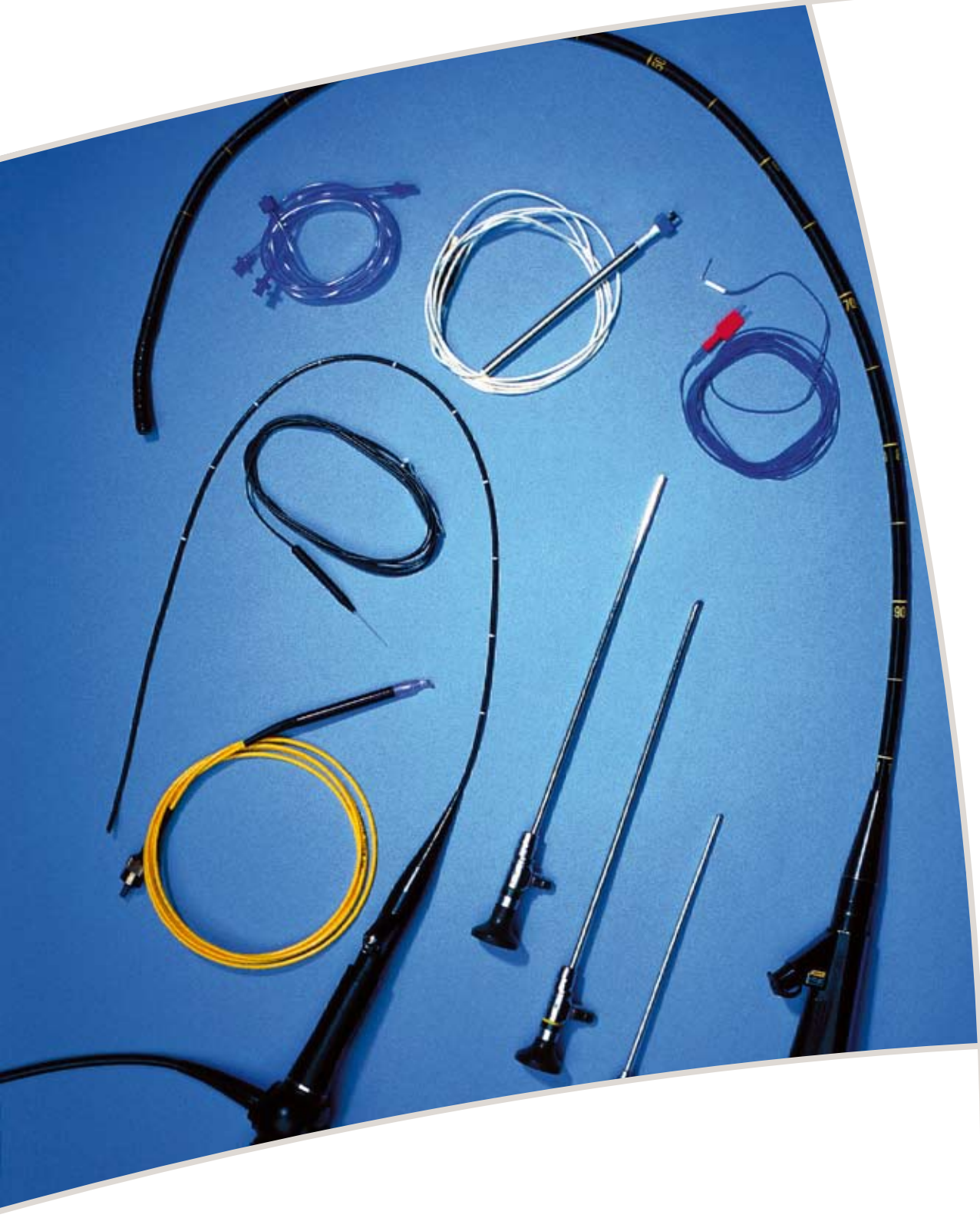
GETINGE

GETINGE HS66 LTSF STERILIZER SERIES

LOW-TEMPERATURE STERILIZATION USING LOW-TEMPERATURE STEAM AND FORMALDEHYDE



FORMALDEHYDE AS A STERILIZING AGENT

Every sterilization process must result in an approved sterile product, free from hazardous levels of residuals. The process 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 -- not least important -- be inexpensive. Moreover, the process should allow the product to be packaged in normal wrapping material and not require special wrapping that would mean additional high costs. Low-temperature steam-formaldehyde sterilization fulfils all these requirements.

The word ”formaldehyde” comes from the Latin formica, ”ant”. Formaldehyde (molecular formula HCHO) was discovered in 1859 and is a natural, organic compound belonging to the aldehyde group. The simplest of the aldehydes, it is well known and widely used as a disinfectant thanks to its germicidal effect.

Since formaldehyde has a broad spectrum of action on microorganisms, it has been used in the Getinge LTSF sterilization process for more than 30 years. This 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 temperatures (normally 121 or 134°C) of conventional steam sterilizers. Typical equipment suitable for processing with Getinge LTSF sterilizers includes:

- Most types of endoscopes (both rigid 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, diathermy cables etc).

The LTSF Process - an easy-to-use, reliable and controllable sterilizing process

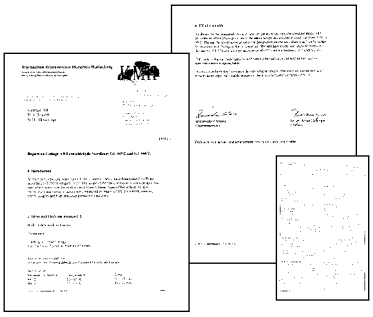
The Getinge Low-Temperature Steam-Formaldehyde process is a synergetic sterilization process working at sub-atmospheric pressure, using a mixture of low-temperature saturated steam and formaldehyde to create a sterilant. Steam at approx 100% relative humidity acts together with reactive formaldehyde without the presence of air. The laws of physics assure distribution of the sterilant in both its gaseous and liquid forms.

The Getinge LTSF sterilization process ensures that all surfaces of all items come in contact with formaldehyde, even in the cavities, and are thus subjected to highly favorable biocidal and sporicidal conditions.

The LTSF process also secures the reproducibility of the process conditions involved in microbial inactivation. Finally, it assures that formaldehyde residues and emissions will be far below hazardous limits.

Instant use

A general advantage of using formaldehyde as a sterilant, e.g. compared to ethylene oxide, is that any absorbed residues in the sterilized items quickly dissipate. Consequently, items that have been subjected to modern LTSF sterilization may be used directly without being stored and aerated.



EN 14180 low-temperature sterilization formaldehyde standard, together with the EN 15424 validation standard.

Validated and approved sterilization process

In Europe, biological testing and to some extent physical testing are currently 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 Stearo-thermophilus. Additionally, spores from Bacillus Subtilis, which are difficult to inactivate when there is insufficient moisture, may be used for supplementary testing. Recommendations for indicator systems and their use at validation are given in the World Standard EN ISO 11138-5.

The GETINGE LTSF process has been developed and tested in accordance with EN 14180 and the successful result is documented as a part of the technical file qualifying the product and process.

Standard packaging material = inexpensive processing

Medical devices subjected to LTSF sterilization should preferably be wrapped in pouches of paper or plastic/paper composite. 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 LTFS processing. This means no additional wrapping costs.

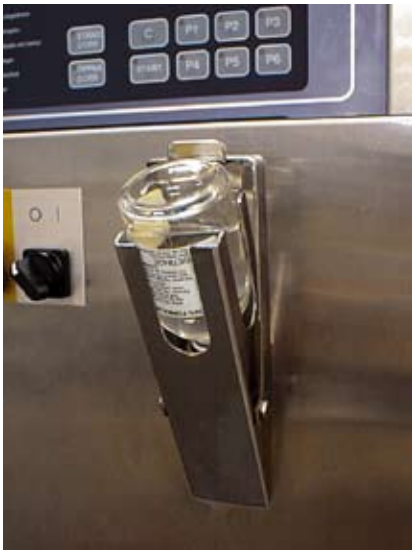
THE GETINGE HS66 LTSF STERILIZER

The Getinge HS66 LTSF range (models 6610 and 6613) includes the unique processing combination of low-temperature steam and formaldehyde (LTSF), plus steam sterilization at 121-134°C, giving flexibility, reduced installation space and improved control.

Modern Getinge LTSF process technology enables the creation of the precise chemical and physical conditions required for microbicidal efficacy. Physical or chemical conditions such as temperature, pressure, sterilant concentration, humidity and absence of air, all of major importance for the microbicidal effect, are precisely defined and controlled.

The capacity of formaldehyde to destroy microbe structures is strengthened by the presence of saturated steam at pre-set pressure and moisture levels.

The thermodynamics of steam ensure both the correct temperature and massive sterilant penetration, even at spots that are difficult to reach. The unique, safe, Getinge Pacs control system secures the required process reproducibility and reliability. For more information about the Getinge HS66 sterilizer, please ask for the Getinge HS66 sterilizer leaflet.



The Getinge HS66 LTSF sterilizer has an injection bottle holder for the formalin on front. The content inside the bottle can be easily observed before use. Alarm is activated when an empty bottle is used.

NATURALLY BIODEGRADABLE

Formaldehyde in its pure form is a gas that is easily soluble in water. The solution is called formalin. Formaldehyde is a powerful sterilant that must be diluted in process water before disposal.

Most of the process water used comes from the cooling water that has been used for the vacuum pump or for steam condensation. In Getinge sterilizers, the dilution ratio of formaldehyde is normally 1:300,000 (~0.003%) at disposal.

Formaldehyde occurs naturally in most living things and is a vital part of our ecology. In humans, the body's own production of formaldehyde is essential for metabolism. Industrially, formaldehyde is produced by reacting methanol, air and water over a catalyst. As formaldehyde is a fundamental chemical building block, it has a tremendous number of commercial applications. Global production currently amounts to more than 35 million tons.

In high concentrations, formaldehyde is toxic -- hence its powerful microbicidal effect -- but its piercing odor provides a built-in warning signal at concentrations below harmful levels.

Formaldehyde is naturally and quickly biodegradable, and is thus not in any way environmentally hazardous at the discharge levels related to sterilizers. In the atmosphere, formaldehyde is degraded by photochemical reactions and its half-life is a couple of hours. In this respect it differs from many other chemicals, as no enrichment in nature takes place.

Getinge provides complete solutions for effective and efficient cleaning, disinfection and sterilization in the healthcare and life science sectors. Our know-how comprises everything from architectural planning, production and handling equipment, to systems for full traceability of sterile goods. Our commitment covers expert advice, training and long-term technical support.

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