

HILOTHERM devices

Hygiene Guideline for Cooling Circuits

1. Subject

HILOTHERM information letter on the topic "Hygiene Guideline for Cooling Circuits"

2. Description

This **S**ervice **I**nformation **L**etter (SIL) is the guideline on how to create and maintain a hygienically risk-free cooling circuit in HILOTHERM devices.

The recommended cooling medium is demineralized water. Demineralized water is the optimal medium to promote the lifetime of the device. Distilled water can also be used, however this contains higher content of minerals which leads to an earlier calcification. Since the devices are neither built nor operated in a sterile environment, it is normal that in the cooling medium, *if no germ-killing agent are supplied to it*, can form microorganisms after a certain time. HILOTHERM's recommendation is to change the water at least every 6 month. These microorganisms are usually bacterial strains and are not critical for people with intact immune systems.

However, if the Hilotherm devices are used on immune-compromised people or in rooms/buildings where immunosuppressed people are present, e.g. in hospitals, then care must be taken to ensure that the cooling circuit is hygienically safe. This requirement also applies if there is a possibility that water from the cooling circuit could enter open wounds or body openings

3. Disinfectant

The disinfectant approved by HILOTHERM is **Sanosil S003**.

Sanosil disinfectants are so-called multi-component disinfectants. Hydrogen peroxide is used as an oxidizing agent, which is bound with colloiddally dissolved silver to form a complex solution.

Sanosil S003 is a DGHM/VAH certificated, very flexibly applicable universal disinfectant with long-lasting depot effect.

S003 is suitable for:

- Water disinfection
- Surface disinfection
- Wipe disinfection
- Spray disinfection

Product Type

- Ready to use

Effectiveness:

- Bacteria, viruses (Influenza), yeasts and fungi

Contact time:

- 1 – 30 min.* (DGHM 15 min with high organic load)
* depending to germ type, temperature, organic load and surface

Shelf life:

- 2 years

Active ingredients:

- 1,5% Hydrogen peroxide, 0,0015% silver

Safety Precautions:

- None

Sanosil is also effective against Biofilm deposits.

4. Cleaning and disinfection process

For clean new devices, the standard addition of Sanosil according to the prescribed concentration may be sufficient.

For older devices or devices with uncertain hygienic condition in the tank, the following process steps must be carried out:

- Opening the device tank and manual cleaning
- Shock disinfection of the tank and the piping system
- Continuous disinfection and monitoring of concentration with Sanosil

4.1 Opening the device tank and manual cleaning

Apart from bio-deposits, inorganic deposits such as lime (if no demineralized water is used) may have settled in the water cycle. These inorganic deposits should be removed before disinfecting.

In many cases – if household cleaning products are not successful - only disassembling and manual cleaning is effective to remove these kinds of deposits.

HILO THERM or authorized dealers can do this service.

Note: For HTP1 Pro devices a disassembly of the tank is not possible. However the other process steps are identical.

4.2. Shock disinfection of the tank and the piping system

Fill the device tank up to 2mm above the filler neck with 50% water and 50% Sanosil. Then close any cuff over the 2m long extension hose and let the device run for 4 hours with the pump switched on. This will safely disinfect the cooling circuit and the pipe system. The device can then be emptied.

4.3. Continuous disinfection and monitoring of Sanosil concentration

| Part to be disinfected | Method | Concentration: S003 / Water | Duration | Verification/ Validation * | Note |
|------------------------|---------------------------------|--|---|---|---|
| Cooling water | S003 put into the cooling water | New device: 100ml / 2,5 l (full tank) Dirty device (with Biofilm): 150ml/ 2,5 l (full tank) | Cooling medium is used until the concentration of Sanosil is < 20 mg/l ** | Colour identification of Sanosil Test Strips 100. Test cycle: every month *** | Change the cooling medium if the concentration is < 20 ppm ** |

* Verification/Validation must be made by a local resident hygienic manager who knows the local environmental conditions

** The active components of the disinfectant are used up after a while. So the concentration is an indicator for disinfection of the water. If concentration is > 20ppm the water is not infected.

*** Depending on the environmental conditions of the devices, the active components of the disinfectant break down at different rates. The concentration must be checked after first device installation on a monthly basis. Depending on the results, this test interval can be extended or may even have to be reduced.



5. Alternative disinfectants

Alternative disinfectants for the water circulation can be used. The prerequisite for this is that the intended disinfectant is listed in the national disinfectant list. The facility that uses this agent is responsible for verifying and validating alternative disinfectants..

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