



Hygiene Guideline

Following HILOTHERM Hygiene regulations in the latest issues are applicable:

- > QM-SIL-20181019_0x disinfection of devices and cuffs
- > QM-SIL-20241022_0x hygiene guidelines for cooling circuits
- > QM-SIL-20241105_0x Manual-S003



valid from: 06.11.2024

Christian Stegmann









HILOTHERM devices

Hygiene Guideline for devices and cuffs

1. Subject

HILOTHERM information letter on the topic "Hygiene Guideline for cleaning and disinfection of devices and cuffs"

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.

This information letter describes the procedure for cleaning and disinfecting devices and cuffs. Sections 4 ff and section 9.7 in the latest version of the instructions for use are explained.

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 devices, accessories and the cuffs are hygienically safe.

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 colloidally 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 (no follow-up treatment required)
- Wipe disinfection (no follow-up treatment required)
- Spray disinfection (no follow-up treatment required)

Product Type

Ready to use

Effectiveness:

Ref:Prod - SIL - JJJJMMDD



> Bacteria, viruses (Influenca), 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.

For the various disinfection tasks (surface disinfection, wipe disinfection, spray disinfection) the disinfectants approved in hospitals and care facilities can be used, provided that they have been approved and validated in accordance with the rules applicable in the facilities.

In this case, a consultation with HILOTHERM is recommended even as the HILOTHERM products can withstand most disinfectants.



Further Informations to SANOSIL S0003 (Safety data sheet SDS and brochure) are on the webpage <u>www.Sanosil.com</u>



4. Cleaning and disinfection process

The disinfection cycle for i. and iii. must be determined by the hospital/facility itself, because that cycle depends on the general hospital/facility guidelines.

The method of application of the disinfectant and the exposure time are specified by the application specification of the disinfectant

i. Device disinfection

i. Surface

The device surface is disinfected by wiping and in inaccessible areas by spray disinfection.

ii. Device interior

The interior of the device can be disinfected in a cold spray disinfection chamber.

iii. Water circulation

QM-SIL-20241022_xx hygiene guidelines for cooling circuits is applicable.

ii. Cuff disinfection

There are single-patient-use cuffs and multiple use cuffs. Single-patient-use cuffs are usually disposed of after use or remain in the hands of that one patient for repeated use.

Multiple-use cuffs are used on several patients; *appropriate disinfection must be carried out when moving from one patient to another*

i. Cuffs inside

The inside of the cuffs either lies directly on the skin or via an intermediate layer on the body surface. The inside of the cuff is always smooth and is disinfected by wiping disinfection.

ii. Outside of the cuff

The outside-facing side of the cuffs can either be made of insulating fabric material or can be smooth. In case of a smooth surface, wipe disinfection should be used. For fabric-like surfaces, spray disinfection is used.

iii. Accessories disinfection

The outside-facing side of the cuffs can either be made of insulating fabric material or can be smooth. In case of a smooth surface, wipe disinfection should be used. For fabric-like surfaces, spray disinfection is used.

Ref:Prod - SIL - JJJJMMDD



valid from 05.11.2024

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QMB / Technical Direktor





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 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 Hillotherm 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 colloidally 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 (Influenca), 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.

HILOTHERM 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 I (full tank) Dirty device (with Biofilm): 150ml/ 2,5 I (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 concentartion 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 of 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..

valid from: 05.11.2024

Christian Stegmann n N



Dr. rer. nat. Trudi Schaper

Medical Advisor







10kg

Sanosil S003

Ready-to-use surface disinfectant

www.**sanosil**.com

Sanosil S003

Disinfectant for surface disinfection

Reliable and versatile disinfectant for surfaces and equipment

S Highly effective against bacteria, viruses (enveloped), yeasts and fungi, VAH listed.

Sanosil S003

10kg

- Seasy and safe application (ready to use)
- \bigcirc Does not leave any adhesive residues on the surface
- Solution Does not cause unpleasant odours
- Solution No alcohol, chlorine/chlorine compounds or QAC
- ♂ No dyes or fragrances
- S With catalytically enhanced hydrogen peroxide
- S The hydrogen peroxide completely (100%) decomposes into water and oxygen
- Shelf life of over 2 years
- S High-quality product made in Switzerland





PRODUCT DESCRIPTION

Sanosil S003 is a surface disinfectant with medical DGHM/VAH certification and long-lasting depot effect. It is based on the proven Sanosil hydrogen peroxide/silver formulation and does not release any flammable or foul-smelling vapours.

Hydrogen peroxide is used as the active ingredient. It is also stabilised and its disinfecting effect is catalytically enhanced several times over by adding a minimal amount of silver ions.

This process can increase the disinfection effect by up to 800%. After application, hydrogen peroxide also completely decomposes into water and oxygen.

The small amounts of silver remaining on the surface after the peroxide has broken down inhibit germ multiplication for up to 72 hours.



DISINFECTION: BACKGROUND KNOWLEDGE

Note 1: The cleaner a surface is cleaned first, the better the disinfection results! Visible dirt can severely impair the disinfection performance.

Note 2: Spray-wipe disinfection or application with a moistened wipe is clearly superior to spraying alone. Spraying alone (especially with a hand sprayer) can leave gaps in effectiveness and should be avoided.



SHORT INFO

PRODUCT TYPE Ready-to-use

SUITABLE FOR Wipe disinfection, targeted spraying with a device

EFFECT AGAINST Bacteria, yeasts, viruses (Influenza A, Corona), fungi

SHELF LIFE 2.5 years

CONTENTS 1.5g/100g hydrogen peroxide, 0.003g/100g silver



HOW IT WORKS

The oxygen $({}^{1}O_{2}/{}^{-}O_{2})$ split off by the hydrogen peroxide attacks the cell walls of the microorganisms.

Oxidation (cold combustion) denatures and destroys them.

The effect is supported by silver ions, which catalytically strengthen the effect of the peroxide.

In addition, they block the metabolism (where present) and the ability of the germs to multiply.





SURFACE DISINFECTION

Spray - Wipe Method

Note: When decanting S003 into spray bottles or similar, it is mandatory to attach a label with information about the contents to the outside of the corresponding container.



STEP 1

Clean the surface to be treated thoroughly with a cloth and suitable cleaning agent.

STEP 2

Put on gloves. Moisten a wipe with undiluted Sanosil S003. Dosage on smooth surfaces: 30-50 ml /m²





STEP 3

Wet the surface to be disinfected with the cloth so that an even, gapless, moist film remains. Avoid the formation of puddles. **If drops or puddles remain on smooth surfaces, spread them with the wipe.**



EFFECTIVENESS

TEST STANDARDS & EXPOSURE TIMES

BACTERIA

Bactericidal: EN1276: low organic load: 5 min EN1276: organic load: 15 min EN13697: organic load: 30 min EN16615: organic load: 15 min

YEAST

Levurocidal: EN1650: organic load: 30 min EN13697: organic load: 5 min EN16615: organic load: 5 min

FUNGI

Fungicidal: EN1650: low organic load: 30 min

VIRUS

Virucidal: EN14476: low organic load (Influenza A *) : 30 sec

* also applies to coronaviruses according to the Swiss health authority*

STEP 4

Allow the agent to dry in. This normaly happens within **15 min.**

Note: When spraying directly with a device, aerosol formation should be avoided as much as possible. For applications larger than normal household areas / for more than 30 min per day, appropriate respiratory protection should be worn to avoid irritation of the respiratory tract.



SANO DISINFECTANTS FOR LIFE WWW

SURFACE DISINFECTION

(with SanoWipes)

Sano Wipes are dry wipes in a practical dispenser bucket with a resealable lid. They are soaked with disinfectant before use and are then ready for use for several weeks. Soaked SanoWipes are ideal for quick intermediate disinfection of smaller surfaces.



STEP 1

Put on gloves. (Basic safety recommendation when handling disinfectants).

STEP 2

Remove the protective foil from the wipes roll and place it in the bucket.





STEP 3

Soak the roll with undiluted Sanosil S003. Dosage 1 - 1.2 | per roll

STEP 4

Pull the first wipe through the dispenser opening and close the transparent lid tightly. (Note: due to the influence of light, the wipes may discolor slightly over time, but this does not represent a loss of quality.







STEP 5

Remove a soaked SanoWipe and thoroughly wipe the surface to be disinfected several times. Wear gloves to avoid prolonged skin contact.



SINFECTANTS FOR LIFE



SANOSIL AG • CH-8634 Hombrechtikon • Switzerland E-mail: service@sanosil.com www.sanosil.com





MATERIAL PET- optimized for the application of liquids

WIPES PER ROLL 90 pcs

DIMENSIONS OF WIPES 36 x 20 cm

SURFACE DISINFECTION

(with sprayer - for professional users)

Caution: When using professional spraying equipment, a certain amount of aerosols is always produced, which could affect health. Therefore, always wear a P3 full face respirator during extended spraying work to prevent irritation of the respiratory tract and eyes. (Respirator with gas filter (against hydrogen peroxide) Filter type: ABEK-P3

STEP 1

Clean the surfaces to be treated thoroughly with a suitable cleaning agent. The better the cleaning, the more effective the disinfection.

Fill the required amount of Sanosil S003 into the storage tank of a sprayer (e.g. Sanosil Stream / Stream Compact, pressurised storage sprayer with compressed air connection, airless sprayer, etc.).



STEP 2

Choose the finest possible atomisation method and spray the surfaces to be disinfected in such a way that a slightly moist surface is created throughout. (Cf. fogged-up bathroom mirror when showering).

Guide dosage: 30 - 50ml / m²

Avoid drips/puddles and runs. Prevent aerosols from entering parts of the room with unprotected persons.



STEP 3

Allow the product to take effect. For safety reasons, no one should enter the room without protective equipment for up to 2h after spray disinfection.

(Limit level hydrogen peroxide in the air: 1ppm)

If the level is too high, extend the waiting time or thoroughly ventilate. There must not be a disinfectant smell or irritation of the respiratory tract/eyes.



Note: The finer the droplets, the better the wetting. Avoid drips/ puddles and runs due to excessive material application. If this happens anyway - wipe with a wipe cloth before it dries. Otherwise, there is a risk of discolouration.





FLOOR DISINFECTION

(with spray mop)

Note: As an alternative to a spray mop system, pre-wetted exchangeable mop covers are also suitable. For larger surfaces (e.g. sports mats), the parallel use of a powerful hand sprayer for spraying and a mop for wiping is also a good idea.

STEP 1

Clean the surface to be treated thoroughly with a mop and a suitable cleaning agent.

STEP 2

Fill Sanosil S003 into the reservoir of a suitable mop applicator.

STEP 3

Wet the surface with the applicator, leaving an evenly damp film that dries in a few minutes. Allow the product to act / dry.

DISINFECTION OF SMALL PARTS

(Seals, O-rings, etc.)



STEP 1

If possible, clean the parts to be treated in the dishwasher or by hand.

STEP 2

Fill Sanosil S003 into a container and place the parts in it. After a few minutes, remove and allow to dry. Provided the disinfectant does not become contaminated, the solution can be used several times.

Use biocides safely. Always read the label and product information before use. Our technical application advice, both written and verbal, is based on extensive testing. We give advice to the best of our current knowledge, but without any liability, as application and storage are beyond our direct control. Product descriptions or information about the properties of the preparations do not contain any statements about liability for any damage.







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