



## Evaluation of Antigermix® S1

The National Center for Infection Control has been asked to make an evaluation of Antigermix® S1. This is an UVC-based disinfection device which is used for disinfection of certain ultrasound probes. The product cannot be used for disinfection of ultrasound probes with canals or other medical equipment.

The product is produced and marketed by the French company Germitec. Besides relevant scientific literature on UVC disinfection, this evaluation is based on

- a leaflet in English
- further information provided by the company
- microbiological test reports in English and French performed by the independent French laboratory Biotech-Germande.

The National Center for Infection Control has not tested the product.

### Leaflet and information provided by the company

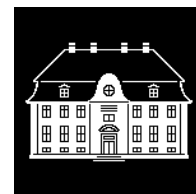
According to the leaflet, Antigermix® S1 is a product based on UVC technology which can perform high-level disinfection of external, endovaginal and endorectal ultrasound probes. This disinfection system cannot be used for ultrasound probes with canals or any other medical equipment. The device uses germicidal UVC radiation (wavelength: 200-280 nm) and is a cylindrical box consisting of 6 UVC tubes – 4 tubes surrounding the probe and 2 beneath the probe. There are two optical sensors automatically controlling the disinfection process during each cycle by measuring the dose received by the ultrasound probe and comparing it with the required dose for each cycle. After each cycle an automated verification of the disinfection status is done (the display shows okay / not okay) and a cycle report (printed or electronic version) is made.

The disinfection device is equipped with traceability software (Germitrac®) which stores all kind of information concerning disinfection cycles, and other important information such as hospital/clinic/department, patient ID, probe ID, device ID, indications of date and time. All this information can be printed on a ticket and placed in the medical record.

The probe can be easily disinfected between two consecutive patients without disconnecting it from the ultrasound device.

The method is fast with two options – cycle I with a mean disinfection time of 90 seconds (high-level disinfection including sporicidal efficacy) and cycle II with a mean disinfection time of 200 seconds (high-level disinfection including sporicidal and *Aspergillus niger* efficacy).

The UVC lamps have a life cycle of 7000 hours but they should be changed for every 3000 hours. Control of the device is performed every second year or after 4000 disinfection cycles and the device is guaranteed for one year.



The disinfection process causes no harm to the material and sensors in the ultrasound probes except for a slight change of colour of the plastic material. According to the leaflet and the company, the use of this device does not have any toxic risks for the healthcare professional or the patient and it is environmentally-friendly too.

Antigermix® S1 has received the CE mark from the French certification organization LNE/G-MED and has been positively evaluated by the French Health Products Safety Agency (Agence Française de Sécurité Sanitaire et des Produits de Santé (AFSSAPS)).

### Microbiological test results

The following microbiological tests have been performed by Biotech-Germande (European reference laboratory): ASTM E 1053-97, EN 14347, EN 14561, EN 14562, EN 14563, EN 14476.

Basic virucidal effect was shown by the ASTM E 1053-97 test, and basic sporicidal effect by EN 14347.

A quantitative carrier test for bactericidal effect of the device against the following four bacteria was performed (EN 14561): *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *E. coli*, and *Enterococcus hirae*. The device showed a 5 log<sub>10</sub> reduction for all four bacteria in ≤ 60 seconds.

A quantitative carrier test for virucidal effect of the device against the following three viruses was performed (EN 14476): orthopoxvirus, enterovirus, and adenovirus type 5. There was a 4 log<sub>10</sub> reduction in ≤ 60 seconds for all three viruses.

A quantitative carrier test for fungicidal effect of the device against the following three fungi was performed (EN 14562): *Candida albicans*, *Aspergillus fumigatus*, and *Aspergillus niger*. There was a 4 log<sub>10</sub> reduction in ≤ 60 seconds for *Candida albicans* and *Aspergillus fumigatus* and the same reduction of *Aspergillus niger* in 180 seconds.

The same EN 14562 test as mentioned above was performed for sporicidal effect against the following three sporogenous bacteria: *Bacillus subtilis*, *Bacillus cereus*, and *Clostridium sporogenes*. In spore preparations of these three bacteria there was a 4 log<sub>10</sub> reduction in ≤ 60 seconds.

Finally a quantitative carrier test for mycobactericidal effect of the device against the following two mycobacteria was performed: *Mycobacterium terrae* and *Mycobacterium avium*. There was a 4 log<sub>10</sub> reduction for both these bacteria in 60 seconds.

In conclusion: all relevant EN-tests for microbiological effect have been performed and all the examined microorganisms passed the tests.

### Conclusions

Antigermix® S1 can be recommended for disinfection of designated ultrasound probes, for the following reasons:



- a broad spectrum microbiological effect against a relevant test panel of bacteria, viruses, fungi, and mycobacteria.
- furthermore, the product is sporicidal against *Clostridium sporogenes* and fungicidal against *Aspergillus niger*.
- the product has a high safety profile causing no toxic side effects to human beings or to the environment.
- causes no effects on the sensor and other materials of the ultrasound probe.
- represents a good alternative to other disinfection methods used for disinfection of ultrasound probes.