Germitec

ANTIGERMIX (UV HLD)

FREQUENTLY ASKED QUESTIONS

THE ULTIMATE SOLUTION

Ultrasound scans are now becoming the cornerstone in the diagnosis and treatment of patients in all fields of medicine. To meet the fast workflow demands of medical teams, healthcare departments today are looking for a solution that can rapidly disinfect ultrasound probes between patients, safely and effectively. This is why Germitec® has developed UV based High-Level Disinfection (HLD) products such as Antigermix® AS1 and Hypernova Chronos providing a chemical free cycle in 90 seconds, thus maintaining a safe and efficient workflow while improving compliance to HLD requirements.

Germitec strived to differentiate its products offering with much safer environmental outcomes, delivering quicker workflow times and traceability.

For further information contact **Medisound** - E: info@medisound.com.au | P: 1300 21 4449
www.medisound.com.au | www.germitec.com

FREQUENTLY ASKED QUESTIONS

What TGA Microbicidal effectiveness has been proven for the Antigermix AS1 & Hypernova Chronos 90 seconds cycle? 3

How is UV HLD efficacy positioned compared to other classical HLD products? 4

Is the Antigermix TGA compliant? 5

Has UV HLD been proven to work on Reusable Medical Devices (RMDs) in a clinical setting? 5

What are the Occupational Health and Safety benefits of using UV HLD ? 6

How does the UV HLD mitigate environmental impact? 7

What UVC dose is needed in order to adequately High Level Disinfect? 7

How is the UVC dose measured? 7

What quality Monitor is in place for the Optical Diodes? 8

How often is calibration of the photodiodes recommended? 8

What training and accreditation is offered for the Antigermix? 8

How does the Antigermix compare to other methods of HLD? 8

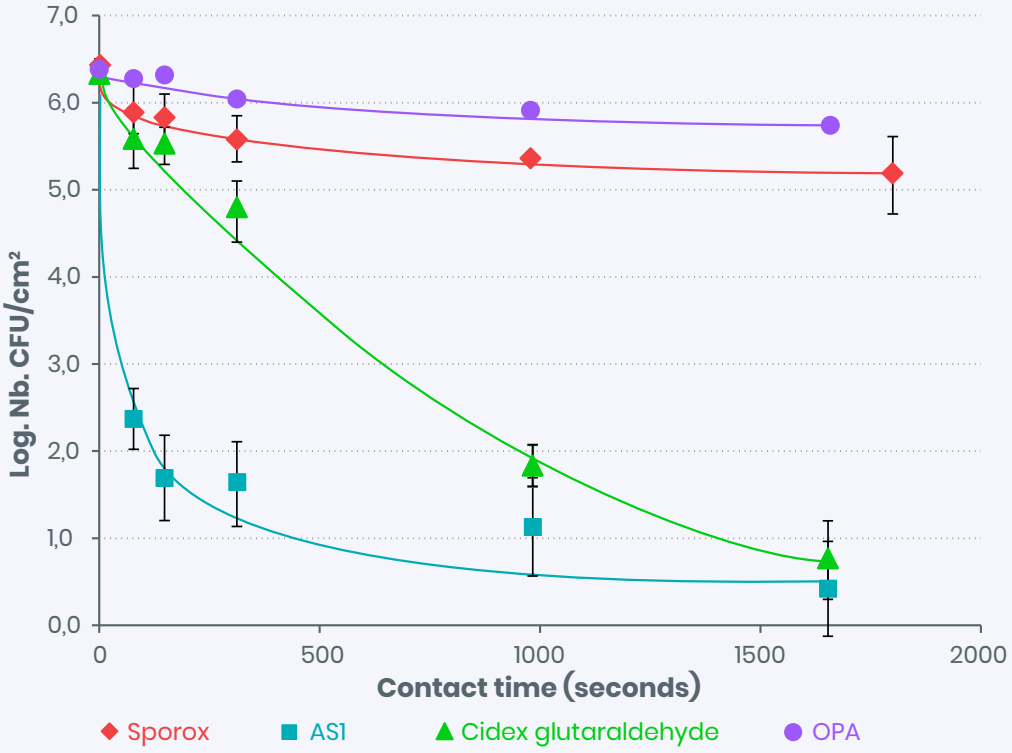
Probe compatibility compliance Program 10

What TGA Microbicidal effectiveness has been proven for the Antigermix AS1 & Hypernova Chronos 90 seconds cycle?

Organisms	Reference Standards	Tested strains	Result (UV HLD 90s cycle)
Bacteria	AOAC 955.14, 955.15, 964.02	*Salmonella enterica*	✔
		Staphylococcus aureus	✔
		Pseudomonas aeruginosa	✔
Viruses	ASTM E1053-11	*Orthopoxvirus*	✔
		Enterovirus polio 1	✔
		Adenovirus type 5	✔
		Human Papilloma Virus	✔
		Herpes Simplex Virus 2	✔
		Minute Virus Murine (MVM "Parvovirus »)	✔
		Polyomarivus	✔
Fungi	AOAC 955.17 EN 14562	*Trichtophyton mentagrophytes*	✔
		Aspergillus brasiliensis	✔
Mycrobacteria	AOAC 965.12	*Mycobacterium terrae*	✔
Spores	AOAC 966.04 TGA Guidelines for the evaluation of sterilants and disinfectants (1998)	*Bacillus subtilis*	✔
		Clostridium sporogenes	✔

How is UV HLD efficacy positioned compared to other classical HLD products?

Independent tests have been carried out to compare Antigermix to other classical HLD chemical soaking products intended for ultrasound probes, and show that UV HLD is much more efficient than most of them (study 2345.GER.14):



Evolution of the number of viable Bacillus subtilis ATCC 19659 spores on the carrier tests according to contact time with UVC in the ANTIGERMIX S1 (GERMITEC) unit or with high level disinfectants (Sporox, Cidex glutaraldehyde, Cidex OPA)

Result of comparative sporicidal testing (Bacillus subtilis ATCC 19659) of AS1 and candidate predicate HLD products.

HLD Product Name	Germicidal Technology	HLD Exposure Time	Inoculation (Log_{10} spores ± SD)	Microbial Count Post HLD (Log_{10} spores ± SD)	Log_{10} Reduction at Labeled Contact Time
Antigermix S1	UVC	78 sec	6.4 ± 0.1	2.3 ± 0.3	4.1
Cidex OPA	Liquid – OPA	12 min (at 20°C)	6.4 ± 0.0	5.9[2]	0.5[2]
SPOROX II	Liquid – hydrogen peroxide	30 min (at 20°C)	6.4 ± 0.1	5.2 ± 0.4	1.2
Cidex Activated glutaraldehyde solution	Liquid – Glutaraldehyde	20 min (at 25°C)	6.4 ± 0.1	1.5[2]	4.9[2]

Is the Antigermix TGA compliant?

To obtain TGA approval all evidence must be submitted and assessed by TGAs Biologics team. The CE mark documents are not perceived as proof of effectiveness for a HLD device. The Antigermix ARTG is Class IIb (ARTG certificate is attached as Appendix 3). The TGA states:

"Sponsors who wish to import these disinfectants and sterilants for use on medical devices need to ensure that the Australian regulatory requirements for Class IIb medical devices have been met by the manufacturer. Assessments performed for Europe for the purposes of affixing the CE Mark may not be sufficient for inclusion in the ARTG as a Class IIb medical device".

To comply with the TGA requirements manufacturers are required to submit microbiological efficacy testing on mandatory micro-organisms. Germitec testing is conducted through external testing facilities to remove any bias. This is the gold standard in supplying HLD disinfection products Class IIb to the Australian healthcare market with microbiological efficacy testing documents supplied by independent testing facilities.

Has UV HLD been proven to work on Reusable Medical Devices (RMDs) in a clinical setting?

UV HLD has well documented evidence of efficacy for Ultrasound Transducers both in Simulated Use Tests and in clinical settings (In Use Tests).

In the research and development stages of photonics UV-C based HLD technology (UV HLD) Germitec products have become more efficient and effective in cycle times while ensuring required microbiological efficacy is achieved. Here are described few In Use Tests:

1. Evaluation of a new disinfection procedure for ultrasound probes using ultraviolet light. G. Kac and al. Journal of Hospital Infection (2007), Vol. 65, Issue 2, p163 – 168

This study uses a 10 minute cycle with Germitec first version of Antigermix (much less powerful), and compares UV disinfection against antiseptic wiping and dry wiping the ultrasound probe surface. The median microbial reduction was 100% for UVC, 98.4% for antiseptic wiping and 87.5% for dry wiping. The percentage of negative specimens was 88% for UVC, 16% for antiseptic wiping and 4% for dry wiping. After reprocessing, the only pathogen isolated was one isolate of K. pneumoniae after antiseptic wiping.

2. Evaluation of Ultraviolet C for Disinfection of Endocavitary Ultrasound Transducers Persistently Contaminated despite Probe Covers. G. Kac and al. Infect Control Hosp Epidemiol 2010; 31:165-170

This study mentioning 5 minute cycle was made on vaginal and rectal ultrasound probes, with a UV HLD chamber similar to the current Antigermix AS1

& Hypernova Chronos chamber but running on a time based cycle, which is harder to control and having reached systematic HLD in a short time. Germitec systems later moved to a dose controlled cycle and substantial additional scientific work has been performed.

After removal of probe covers, contamination by pathogenic bacteria was found for 15 (3.4%) of 440 probes, and viral genome (including HPV) was detected on 5 (1.5%) of 336 probes. After cleaning with a towel impregnated with a disinfectant spray and disinfecting with UVC light, neither bacterial pathogenic flora nor viral genome was recovered from the probe.

3. Bloc S. and al., Evaluation of a new disinfection method for ultrasound probes used for regional anesthesia: ultraviolet C light. J Ultrasound Med. 2011 Jun;30(6):785-8.

This study was performed with current version of Antigermix AS1 with a 90 seconds cycle. 15 ultrasound probes used in anesthesia for block placement were exposed to a large inoculum of 3 bacteria : Staphylococcus aureus, Escherichia coli, and Enterococcus faecalis. All probes were infected after inoculation (>150 colony-forming units) but were considered sterile (<10 colony-forming units) after disinfection. Moreover, for the authors, this method could obviate the use of sterile probe covers, which can improve echogenicity.

4. Pending publication (report available upon request), the Hospices Civils de Lyon (2nd largest public group of hospitals in France) have performed an in-use study on vaginal probes (AS1, 90 seconds cycle) showing:
   – 100 probes after UV HLD are not contaminated by HPV DNA nor Human DNA
   – On 47 probes, after cleaning with the wipe and before UV HLD, 7 were Human DNA positive and 1 was positive with HPV-51 (High Risk HPV), these 8 probes were negative after UV HLD.

To Germitec knowledge, with this report, UV HLD 90 seconds cycle is the only disinfection for ultrasound probes that has been proven efficient against HPV both in laboratory and in real usage conditions.

What are the Occupational Health and Safety benefits of using UV HLD ?

UV HLD uses no chemicals therefore there is no need to manage staff exposure and risks associated with processing chemicals is eliminated. There are no risks associated with high temperatures, and chemical burns on users face or hands. Since UV-C light has now chemical residue or toxins from vaporised microorganisms there is no need for rinsing or wipe the probe after the disinfection cycle. This also reduces the risk of cross contamination and the need for special ventilation requirements such as fume cabinets and air quality monitoring to remove chemical fumes or remove airborne toxins produced from chemical deactivated microorganisms,

The Antigermix and Hypernova ranges of products are a safe solution for both staff and patients.

How does the UV HLD mitigate environmental impact?

The UV HLD is the safest environmental choice of HLD available for the following reasons:

- No consumables, no waste products.
- No chemical waste or residuals,
- No water waste in washing excess chemical residuals left on equipment.
- No refrigeration needed for storage and transport as no chemicals are required.

This no waste and no chemical approach is central to Germitec's ecological and environmental protection philosophy. The system itself is also fully recyclable and Medisound and Germitec provide a guarantee to take back the system at the end of its useful life for recycling.

What UVC dose is needed in order to adequately High Level Disinfect?

The disinfection is achieved when the probe has received a sufficient germicidal UV-C dose. The dose required was determined by:

- Results from microbiological tests (see reference sheet).
- Accuracy of the effective dose measuring sensors.

Shading factor related to the presence of the probe in the Antigermix enclosure. Using a dose threshold guarantees that an adequate disinfection level has been achieved.

	Effective dose (GU*)	Average cycle time
Antigermix AE1	≥4040	180 seconds
Antigermix AS1 or Hypernova Chronos	≥2394	90 seconds

*Germitec Unit (GU) is a ratio of energy/surface.

How is the UVC dose measured?

Germitec UV HLD systems have an inbuilt quality assurance check to reliably measure the UV-C dose, and detect any potential error.

The dose measurement is conducted through two independent optical sensors (photodiodes) with a spectral sensitivity focused on 254 nm (germicidal wavelength).

The system declares the disinfection "COMPLETE" only when the photodiodes have measured the target UV-C dose. Each diode reads the dose independently. If there is too much variance between the two measures from each of the diodes or if the target dose is not reached before the time limit, the disinfection cycle is stopped with an alarm message.

What quality Monitor is in place for the Optical Diodes?

The 2 optical diodes are each calibrated using a medical calibration device. (See calibration of Photodiodes paper for detailed information)

The Maximum deviation from the medical calibration device and the photodiode is a stringent Coefficient standard deviation.

How often is calibration of the photodiodes recommended?

The medical calibration device is performed when the system has one of the following

- Annual calibration check
- Preventative Maintenance
- Any change of parts

What training and accreditation is offered for the Antigermix?

Applications training for staff on the use of the Antigermix products or Hypernova Chronos is conducted during the installation. A comprehensive e-training presentation will also be available as well as a Competency Assessment checklist.

How does the Antigermix compare to other methods of HLD?

HLD Selection Criteria	Antigermix/ Chronos	Soaking System	Wipe System	H2O2 System
Proven to Kill HPV both in vitro and in clinical use	YES	NO	NO	NO
Probe compatibility compliance program	YES	YES	YES	YES
Use Chemicals	NO	YES	YES	YES
Internal dosage validation system	YES	NO	NO	NO
Time period to HLD	90secs	12mins	30secs to 4 mins	7 min
Level of Innovation according to NHS England Rapid Review Panel*	R2 (in 2015)	x	x	R5 (in 2012)

* "R5: Evidence presented does not demonstrate that the product is more efficient or efficacious at improving infection prevention and control interventions to reduce healthcare associated infections than other available products currently in use"

"R2: Basic research and development has been completed and the product may have potential value; the RRP recommends in use evaluations and trials to demonstrate improved efficiency or efficacy in improving infection prevention and control to reduce healthcare associated infections are considered within an active NHS clinical setting"

Further information https://www.gov.uk/government/publications/rapid-review-panel-recommendation-listing

A comprehensive literature review of all published journal articles on the available methods of High Level Disinfection was conducted by the NHS Scotland and Health Protection Scotland. This paper compared available evidence for the use of ultraviolet light systems, hydrogen peroxide devices and manual wipes for the decontamination of Semi-Critical probes. This covered specifically; semi-invasive probes (SIUPs) and non-invasive ultrasound probes in semi-critical procedures.

Guideline Reference: NHSScotland Guidance for Decontamination of Semi-Critical Ultrasound Probes; Semi-invasive and Non-invasive Ultrasound Probes March 2016 (PDF, 1489KB)

The evidence from the literature review shows:

- There is high level (1+ and level 2) published evidence to support the use of Ultra Violet light systems for decontamination of SIUPs
- There is low level published evidence (level 3) to support the use of automated chemical systems (hydrogen peroxide) for decontamination of SIUPs
- There is low level published evidence (level 3) to support the use of a manual detergent/disinfection/rinse (multi-wipe) system for decontamination of SIUPs
- There is no published scientific evidence available to review to support the use of an EWD for decontamination of TOE Probes
- Non-invasive ultrasound probes were not included within the remit of the literature review. However, the Spaulding classification system (referenced within the literature review) describes any device which comes into contact with broken skin as semi-critical.1 This is the same for semi-invasive probes and the rationale for inclusion within the guidance document.

Reference: 1. Rutala WA, Weber DJ, Centers for Disease Control. Guideline for disinfection and sterilization in healthcare facilities, 2008. 2008. Centers for Disease Control (US).

Levels of evidence

The following grades were given to the available evidence within the literature review using SIGN methodology.

1+ Well conducted meta analyses, systematic reviews of RCTs, or RCTs with a low risk of bias

2 Well conducted case control or cohort studies with a low risk of confounding, bias, or chance and a moderate probability that the relationship is causal

3 Non-analytic studies, e.g. case reports, case series

Probe compatibility compliance Program

Germitec product Antigermix AS1 complies to the National Safety and Quality Health Service Standard and the European Directive 93/42/CEE. These regulations in-forces, the Germitec Company lists the Medical Devices (External, TV et TR probes) which are compatible or non-compatible with its products (Antigermix AS1). The concept of compatibility between Medical Devices needs to be stated and that a proof of compatibility between two Medical Devices has to be realised.

It points out that several approaches do exist to determine this compatibility:

- Medical Device manufacturers claim together compatibility in their respective IFU.
- One manufacturer can claim on its own compatibility with other manufacturers Medical devices. It must then demonstrate the compatibility with the Medical device with whom it is associated

In order to do so, the Company Germitec performs:

- Tests in laboratories on the probes themselves or on materials given by the manufacturer
- Tests in laboratories on material representing the one used on the probes
- Fields observations of probes in real use
- Documentary studies

This list evolves and is updated regularly following tests performed by Probes Manufacturers and/or Germitec.

In achieving Full transparency with its customer base, the Company Germitec has published a list of compatible probes in 3 different categories:

- **Category 1:** Probes which have been jointly approved by the probe manufacturer and Germitec. In the enclosed list, they are identified with a Blue square.
- **Category 2:** Probes which have been approved by the Company Germitec and are waiting for Probe manufacturer tests. In the enclosed list, they are identified with a Green square.
- **Category 3:** Probes which are not considered as compatibles by the Germitec Company (This category does include also probes which are not meant compatible by the probe manufacturer). In the enclosed list, they are identified with an Orange square.

If the probe you are looking for is not in the list, it doesn't mean it is not compatible, it can be under testing.

Company	Category 1	Category 2	Category 3
Germitec Approval	Yes	Yes	No
Probe Manufacturer Approval	Yes	N/A	-
Colour Code	●	●	●

For example – **Alpinion:** ● **L3-12** ● **L3-12T** ● **L3-8** ● **L3-8i**