Germitec

ANTIGERMIX

User's Notice AS1

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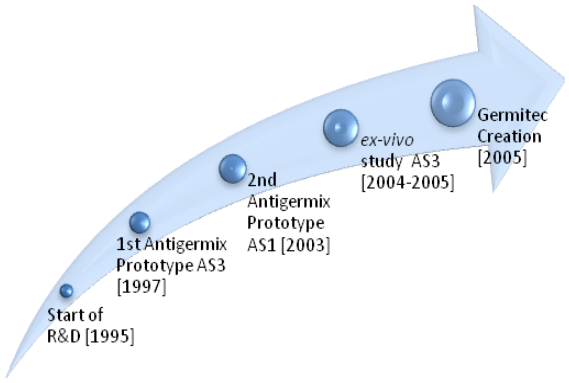
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1 INTRODUCTION

1.1 Germitec

In 1995, the Company GRED, after many solicitations from its clients (radiologists, cardiologists, nurses, etc.) worked with an engineering team to create a non-chemical solution for the disinfection of ultrasound probes.



Genesis of Germitec

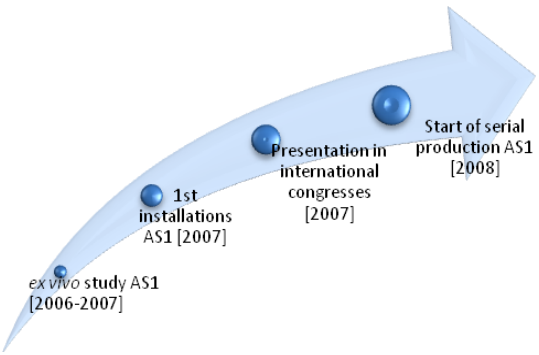
Following a period of fundamental research from 1995 to 2004 Germitec was created in 2005. Germitec is certified to ISO 9001 & ISO 13485 and collaborates with numerous advanced technology consultants.

NF EN ISO 13485
ISO 9001

Antigermix S1 birth

Product development and product engineering were completed between 2004 and 2008 under the GRED-GERMITEC patronage in collaboration with a number of advanced French technology companies and laboratories: AVSIS, ALTEN, PR[I]ME (ALTRAN), BIOTECH-GERMANDE laboratory, GREMI (CNRS) laboratory, HEGP laboratory, EXSTO, ELLIPSE, BAULE SYSTEME laboratory, SAGEIS, etc. as well as close to fifteen international scientific and technical consultants.

This work that was performed with GRED-GERMITEC lead to the invention in 2008 of an innovative system to easily disinfect ultrasound transducers: Antigermix S1.



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Claimed use of ANTIGERMIX S1

HIGH LEVEL DISINFECTION OF EXTERNAL OR ENDOCAVITARY ULTRASOUND TRANSDUCERS BY UV-C AS ALTERNATIVE TO CHEMISTRY

1.2 Antigermix S1

The Antigermix S1 (AS1) is a liquid free process for high-level disinfection of ultrasound transducers using UV-C.

The ergonomic characteristics of the AS1 allows it to fit smoothly into the user workflow, and facilitate high level disinfection without disconnecting the ultrasound probe. This disinfection process is safe and does not require a highly skilled operator.

AS1 includes a complete and automated control and tracking system which provides a traceable, easy to use system for healthcare workers and their patients in validating every disinfection cycle. The tracking system links the probe ID to the cycle data and measured parameters (temperature, UV-C dose, etc.). The AS1 is therefore able to validate the disinfection cycle by comparing the data with internal standards. This data is available for archiving and retrieval for proof of proper HLD practice.



Disinfection Process: UV-C Radiation

The AS1 assures transducer disinfection by UV-C radiation exposure.

Radiation wavelengths ranging from 200 to 280 nm possess a strong germicidal effect with a particular efficiency around 254 nm.

The absorption of UV-C photons by the micro-organisms creates a RNA and DNA molecular dissociation.

2 STATUTORY INFORMATION, SAFETY RULES, WARNINGS, AND LABELING

2.1 Certification

The system is labelled: CE 0459 and cULus XXXX
Date of affixing the first CE mark: May 18, 2007

The AS1 complies with the following standards:

Standards	Application
EN 61326	Electromagnetic compatibility
IEC 61010-1 IEC 61010-2-40 CAN/CSA-22 NO.61010-2-040 UL 61010-1	Electrical safety
ISO 14971 : 2012	Risk management

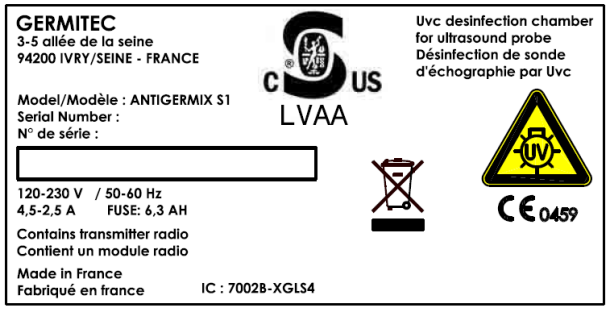
2.2 Safety Rules

- If the AS1 is subject to a mechanical shock, falls over, or is damaged, contact your authorized Service representative.
- If damage to the AS1 is suspected, do not use the AS1.
- Do not force the door or back panels during the operation cycle.
- Do not try to open or repair the AS1. The AS1 should only be repaired by your authorized Service representative.
- Do not bypass the safety devices and interlocks.
- Do not open the back panels. (See section 8 and 9)
- Warning: avoid exposure to UV-C radiation. Exposure to UV-C radiation can cause severe burns or eye injuries.
- Only the OZONE FREE UV-C lamp provided by Germitec can be used with the AS1.
- When changing lamps, wait 5 minutes to allow lamps to cool down and avoid burns.
- During technical interventions, the technician must wear appropriate eye protection.
- Even when the device has been switched off, voltage levels are still present inside. Unplug the AS1 before any further technical intervention.

2.3 Usage warnings

- The AS1 is a disinfection system which is part of the general probe cleaning protocol.
- The AS1 is for medical use only. The AS1 can only be used with external or endocavitary ultrasound transducers.
- Remove all gel marks or soiling on the probe before placing it in the AS1.
- Before placing the probe into the AS1, see the operating procedure in section 5.
- Do not pour liquid in or on the AS1. See section 9 'Cleaning' for the appropriate cleaning protocol.
- Data must be saved daily. Germitec or its authorized representatives are not responsible for the loss of data on the hard disk. It is recommended to back up the data on an external support media (such as a USB key, flash card, external hard disk, or similar device).

2.4 Labeling

	**Identification label**: Manufacturer's name and address, model, serial number, class and electrical specifications, country of manufacture.
	**Risk of Electrical shock**
	**High-temperature**
	**Risk of UV-C Radiation exposure:** This system is designed so that users are protected from UV-C radiation; however, extended direct exposure to UV-C radiation must be avoided.
	**Do not dispose with domestic waste** This symbol indicates that waste from this electrical device must not be disposed of with domestic waste. It must be disposed of separately. Please contact the authorized representative or a Company specialized in waste treatment for disposing of your device.

3 ANTIGERMIX S1 DESCRIPTION

3.1 Intended Use

The AS1 is a High Level Disinfection system indicated for the disinfection of external or endocavitary ultrasound transducers. The process is based on UV-C radiation as an alternative to a chemical process.

3.2 Disinfection Performance, in vitro tests

The AS1 was successfully tested against the same in vitro tests as for chemical disinfection.

Activity	Standard	Tested strains
Simulated use test	EN 14563 / EN 12353	*Mycobacterium terrae*
Bactericidal	AOAC use-dilution methods 955.14, 955.15, 964.02 EN 14561	*Staphylococcus aureus*
		Pseudomonas aeruginosa
		Escherichia coli
		Enterococcus hirae
Virucidal	ASTM E 1053-97 NF EN 14476	*Orthopoxvirus*
		Enterovirus polio 1
		Adenovirus type 5
Fungicidal	AOAC 955.17 EN 14562	*Candida albicans*
		Trichtophyton mentagrophytes
		Aspergillus fumigatus
Mycobactericidal	EN 14563 EN 12353	*Mycobacterium terrae*
		Mycobacterium avium
Sporicidal	EN 14562	*Bacillus subtilis*
		Bacillus cereus
		Clostridium sporogenes

3.2.1 Disinfection Efficiency by Dose Measurement

GERMITEC's expertise on UV-C makes efficiency control by dose measurement (mJ/cm²) a perfectly reliable method. The dose measurement is performed through two optical sensors (photodiodes) with a spectral sensitivity focused on 254 nm (germicidal wavelength). The required dose is determined by:

- ⇨ Results from microbiological tests (see section 3.2)
- ⇨ Accuracy of the effective dose measuring sensors.
- ⇨ Shading factor related to the presence of the probe in the AS1 enclosure.

Using a dose threshold guarantees that an adequate disinfection level has been achieved.

The two optical sensors in the AS1 measure the energy received by all surfaces of the probe. Therefore, the AS1 can reliably control the dose actually received by the probe and detect a potential error.

Warning

On the digital panel interface, the dose is expressed in GERMITEC UNIT (GU). 1 mJ/cm² = 10 GU

3.2.2 Duration of Disinfection Cycle

The control of disinfection efficiency can lead to variations in cycle time. When the required dose is reached, the cycle is automatically stopped.

	UV-C dose to insure efficient High Level Disinfection	Displayed on digital Panel	Average time
HLD CYCLE I	**239,4 mJ/cm²**	**239**	**90s**

3.2.3 Disinfection Performance

The AS1 was tested under unfavorable conditions as well as probe maximum distance from the lamp:

- ⇨ Results under standardized dirty conditions demonstrated the AS1 delivered an effective disinfection even under unfavorable conditions.
- ⇨ Results showed that the AS1 delivered an effective disinfection even when the probe was at maximal distance from the UV-C lamp.

3.2.4 Disinfection Homogeneity

The disinfection homogeneity has been analyzed through the following studies:

- ⇨ An optic ray simulation, based on Z-Max model, demonstrated the AS1 disinfection homogeneity on all probe surfaces, even if the probe profiles are unfavorably designed.
- ⇨ A microbiological study, compliant with the standard 'characterization of a sterilization process ISO14937', and performed on abdominal probes (unfavorable case for homogeneity), showed that the AS1 disinfection is homogeneous on all probe surfaces.

In conclusion, the specific design of the AS1 allows probes homogeneous disinfection.

3.3 Validation of UV-C Efficiency in a Clinical Setting

UV-C efficacy in disinfecting ultrasound probes has also been demonstrated through two clinical studies using AS1 prototypes:

- ⇨ In 2005 on 183 patients by HEGP (Hôpital Européen Georges Pompidou) [1]
- ⇨ In 2007 on 440 patients by HEGP, Necker hospital and IRP (Institut de Radiologie de Paris) [2]

These studies demonstrated the UV-C efficacy in disinfecting ultrasound probes.

3.4 Tracking Software: Germitrac®

The Germitrac software facilitates the consultation and visualization of tracking data related to disinfection cycles. Tracking data is stored in the AS1 system and can be accessed from specifically authorized computers. The Germitrac software offers different tools to manage the data (filters, printing, etc). Data displayed by Germitrac:

- **"Probe"**: Identification of the probe (model, serial number and customer identification number)
- **"Day Nb"**: Daily cycle number

[1] **Evaluation of a new disinfection procedure for ultrasound probes using ultraviolet light.** G. Kac, M. Gueneret, A. Rodi, E. Abergel, C. Grataloup, N. Denarié, S. Peyrard, G. Chatellier, J. Emmerich, G. Meyer. Journal of Hospital Infection (2007), Vol. 65, Issue 2, p163 – 168

[2] **Ineffectiveness of Probe Covers in Preventing Contamination of Endocavitary Ultrasound Transducers under Routine Conditions and Evaluation of a New Disinfection procedure using UV light.** G. Kac, A. Rodi, C. Grataloup, I. Podglajen. Presented in 2008 at the Society for Healthcare Epidemiology of America (SHEA), under publication, http://www.shea-online.org/Assets/files/08a_Disinfection_and_Sterilization.pdf

- **"Date":** Cycle date
- **"Hour"**: Cycle time (hh:mm:ss)
- **"Cycle type"**: CYCLE I HLD
- **"Patient name"**: Patient name (to be optionally filled manually)
- **"Disinfection status"**: A successful disinfection is symbolized by, a failed one by.

3.5 Parameters Monitored by the Antigermix S1

AS1 includes an electronic system to assist the user which automatically manages the different parameters listed in this section. These parameters are communicated to the user via the user interface 4.2 and pertaining information in section 5.5.

3.5.1 Remaining Time on Cycle

The effective cycle time is determined by the AS1. The digital display on the front panel informs the user of the remaining cycle time.

3.5.2 UV-C Lamp Status

Each UV-C lamp is managed separately. The digital display on the front panel shows the UV-C lamp position in the enclosure and their operating status.

3.5.3 UV-C Lamp Usage

The AS1 records the number of cycles the UV-C lamps have gone through. The digital display on the front panel shows the number of hours in operation.

3.5.4 UV-C Dose Received by the Probe

The dose measured by the sensors is recorded.

3.5.5 Temperature

The AS1 includes an internal sensor which monitors the temperature.



3.6 Label Printer

The AS1 printer prints the disinfection label after each cycle.

The label displays the cycle information, the probe ID and the disinfection status.

System identification

Name of Establishment
Free Field (see 3.7)
Serial Number of the system

Date and Time of Disinfection
Probe Identification
Cycle type
Disinfection Status (Success/Failed)
Dose Delivered (GU)
Number of cycles per Day - per Year

User Signature (Manual Input)

AS1
Hopital Pasteur Service Echographie 14S1P1B00100
Date - Hour : 11/04/2014 - 17:25:25 Probe ID : intracavity 001 Cycle type : Cycle 1 Disinfection : Success Dose : 7 553 GU Counters Daily - An : 2 - 31
User

AS1
Hospital Pasteur Echographie Department 14S1P1B00100
Date - Hour : 11/04/2014 - 17:27:20 Probe ID : intracavity 001 Cycle type : Cycle 1 Disinfection : Failed Dose : 1 553 GU Counters Daily - An : 3 - 31
User

ERROR

3.7 Personalization

The following information can be personalized on the label:

- Name of Establishment
- Free field (Department, Responsible Person…)

Additionally, the number of labels printed at the end of each cycle can be set.

These are configured by the technician during the installation of the AS1.

4 INSTALLATION

4.1 Contents of Package

The package contains the following elements:

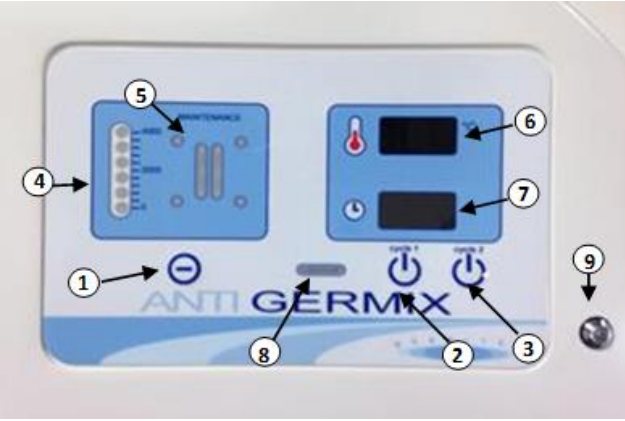
- 1 x Antigermix S1
- 1 x Quartz Plate
- 1 x Printer
- 1 x Label Roll
- 3 x Probe Hanger RFID Rings
- 1 x Kit of Silicone Washers
- 1 x RJ45 Network Cable
- 1 x Power Supply Cable
- 1 x User's Manual

4.2 Digital Display and Connectors

The digital display is located on the front panel. The network connectors are located at the top of the back panel. The power supply is located at the bottom of the back panel.

User interface

Details and functions are in section 5.5 'Use'.

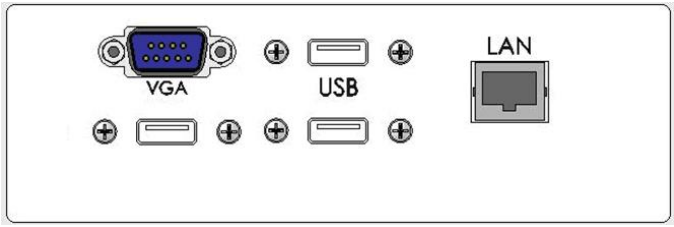


Legend

1: Stop button
2: CYCLE I button of cycle
3: NA
4: UV-C lamp operating status
5: Faulty UV-C lamp location
6: Temperature display or remaining dose display
7: Counter of Cycle
8: Ultrasound probe detection indicator
9: Activity light indicator

Peripherals interface

The back panel enables the connection to the Ethernet network and the label printer.



Power supply

The connection is done with the standard IEC cable supplied with the AS1.



4.3 Installation Process

4.3.1 Antigermix S1 Positioning

To facilitate use of the AS1 and benefit fully from its ergonomics, it should be placed near the ultrasound unit. If it is to be used with several ultrasound units, place it in the most convenient location.

4.3.2 Antigermix S1 Connections

Warning

Keep the power supply cord accessible at all times as it is used as power cut device (if necessary).

Connect to an electrical installation conforming to electrical code.

Connect to a 120VAC sector on a 2 pins and ground receptacle to avoid electrical shocks.

Use only the cable provided with the AS1.

Do not connect peripherals on VGA or USB connectors.

- ⇨ Plug the power cable to the IEC connector at the back of the AS1.
- ⇨ Connect the RJ45 cable from the LAN plug at the back of the AS1 to the Ethernet network.
- ⇨ Connect the PRINTER plug on the back of the AS1 to the printer.

4.3.3 Installation of Hanger and Tracking RFID Rings

The hanger and tracking RFID rings must be installed and configured by your authorized Service representative.

If a ring is missing, contact your authorized Service representative.



4.3.4 Operation of the Antigermix S1

To power the AS1 on and off, see section 5.1.

4.3.5 Issues during Installation or Operation

In case of issues during the installation or operation, see section 8 'Maintenance'.

5 USE OF ANTIGERMIX S1

5.1 User profil

All persons having read and understood the User's Notice, who use diagnostic Ultrasound probes and/or having the need to disinfect them before 2 patients. As examples, health profesionnal as physicians, radiologist, nurses, clinic technical staff,…

5.2 Switch On

Before switching the AS1 on, check the following:

1. Check that no probe is in the AS1. If a probe is present, remove the probe.
2. Close the door.
3. Switch the AS1 on (switch is on the lower back panel).
4. The AS1 beeps and the activity light flashes.
5. Wait during the initialization of the AS1 (about 45 seconds).
6. After initialization, the display panel switches on and the AS1 beeps.
7. The AS1 is ready.

In case of error during start-up, see section 8. 'Maintenance'

5.3 Switch Off

Warning

Do not switch off with the switch at the back of the device, this could damage the AS1 and tracking data may be lost.

1. Press the stop button on the front panel during 3 seconds.
2. The system beeps and the display panel switches off.
3. Wait at least 45 seconds after the last flash of light activity before switching off with the switch on the back panel.
4. The AS1 is now powered off.

5.4 Operating Procedure

Warning

Only probes with a hanger RFID ring can be disinfected in the AS1.

Never put more than one probe per cycle.

Before placing the ultrasound probe in the AS1, check that it has been properly cleaned, including that there is no gel left on the probe.

Do NOT disinfect transesophageal endoscopes, fibrescopes, ENT endoscopes.

1. Open the door of the AS1.
2. Slide the trapdoor open and hang the probe with the RFID color label facing towards the rear of the AS1.
3. Check that the AS1 detects the probe by verifying the probe detection light (item #8 in section 4.2 figure)
4. Slide the trapdoor close and place the cable of the probe in the reception channel.

5. Gently close the door until the door lock 'clicks'.
6. Verify that the cable is not pinched.
7. Start the cycle by pressing the CYCLE I button. The remaining time is visible on the front panel.
8. Wait for the beep at the end of the cycle. The software processes the tracking data.
9. Label will print.
10. The message  indicates than the disinfection is a success. If the message  is displayed, the disinfection failed, see section 8. 'Maintenance'.
11. Open the door and the trapdoor and recover the probe.

5.5 User Interface

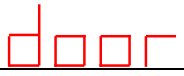
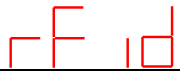
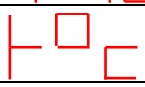
The display panel provides information about the AS1 operations.

There is no need to control these indicators during the cycle.

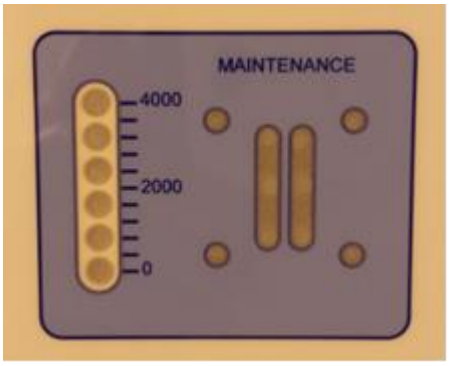
Temperature display (item #6 in section 4.2 figure)

Display	Context	Meaning
	/	Temperature in Celsius. Display accuracy: 1/10th of °C
	During cycle	Remaining dose in Germitec unit (GU)
	/	Error See error codes in 8.2.

Cycle time display (item #7 in section 4.2 figure)

Display	Context	Meaning
	Counter of cycle	Decreasing the number of cycles
	End of cycle	Disinfection is a success
	Startup	Trapdoor is opened
	Startup	Door is opened
	Startup	No probe in the AS1
	During cycle	Warning: Temperature is too hot. The cycle is automatically stopped.
	"Err" instead of temperature display	Error code See section 8.2
	Probe status	Recognized probe in the database
	Probe status	Probe not recognized in the database

UV-C lamps useful life (item #4 in section 4.2 figure)



This warning light indicates the total lifetime of the UV-C lamps.

Localization of UV-C lamps, in case of error (item #5 in section 4.2 figure)

A warning light indicates which UV-C lamp is faulty.

Contact your authorized Service representative.

5.6 Adding cycles

To add the cycles contained on the GERMICARD that you have purchased, approach the card of the RFID reader. A long beep (2 seconds) signals charging.
Cycles are added to the dashboard display





ALARM
Below 200 cycles the dashboard display flashes
Between 199 and 150 cycles: every 10 cycles, the AS1 emits 2 beeps of 1 second at the start of the cycle
Between 149 and 50 cycles: every 5 cycles, the AS1 emits 2 beeps of 1 second at the start of the cycle
Between 49 and 1 cycle: every cycle, the AS1 emits 5 beeps of 1 second at the start of the cycle.

5.7 Printer

> Warning
> *Use only the printers supplied with the AS1.*
> *Use of another printer may result in unproper output and will void the warranty of the system.*

Printer operation

The printer is automatically piloted by the AS1. Before starting a cycle, check that:

- There are labels in the printer.
- The printer is switched on (green light is lit).

Change of the label roll

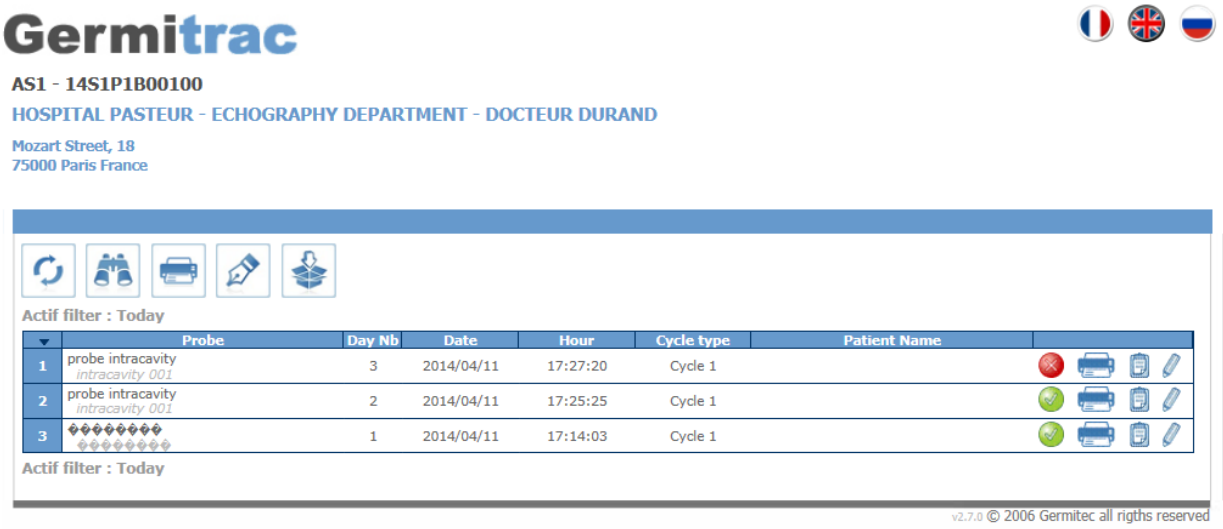
See section 9.3 'Maintenance'.

5.8 Germitrac® Tracking Software

The Germitrac software allows the user to consult and visualize tracking data for the probes disinfected with the AS1.

> ***Warning***
> *AS1 is not to be used as an archiving device or media.*
> *Save data every day on appropriate external storage media.*

The Germitrac software is used with a WEB browser.



Compatible browsers: Internet Explorer; Google Chrome; Opera; Mozilla Firefox; Safari

6 DISINFECTION WITH THE ANTIGERMIX S1

6.1 Purpose

Antigermix is an innovative technique of disinfection which is intended to be adapted to the local cleaning practice. No additional activities with relation to cleaning are expected. Please use the usual detergents adapted to the medical device cleaning. Germitec preconizes the devices are cleaned according to their manufacturers' specifications.
For an example cleaning & disinfection protocol, please refer to Appendix A of this User's Notice.

6.2 Good Practices Reminder: Distinguish Cleaning and Disinfection

Respect the hygiene principle: *disinfect only what is clean*.

> The efficiency of disinfection, including chemical soaking, requires the device to be clean: "Cleaning must always precede high-level disinfection and sterilization. (…) Use of liquid chemical sterilants is a reliable method of sterilization only if cleaning precedes treatment, which eliminates organic and inorganic material"[3].

Thus, even if the Antigermix efficiency has been validated in sub-optimal conditions, the AS1 is not an exception: cleaning must be performed before disinfection.

> Accordingly, the role of disposable protection is to make cleaning easier. Although the use of protection does not decrease the disinfection level needed, it allows replacing the soaking required before disinfection by a simple cleaning (ex: detergent wipes). Disposable protection as part of a cleaning process is confirmed by several renowned societies such as the American Institute of Ultrasound in Medicine: "one should therefore perform high-level disinfection of the probe between each use and use a disposable protection as an aid to keeping the probe clean"[4].

6.3 General Rules to Include in a Disinfection Protocol

The AS1 is a High Level Disinfection system indicated for the disinfection of external or endocavitary ultrasound transducers. It must be used in line with a global ultrasound transducers hygiene protocol. Thus, whichever the protocol:

- ⇨ Follow hand hygiene protocols (gloves, hydroalcoholic solution, etc)
- ⇨ Follow precautions and cleaning instructions provided by the probe manufacturers.
- ⇨ Respect sterility requirements and normative category for the gloves, gel and disposable protections. These should be in compliance with local regulatory requirements.

[3] **Disinfection and Sterilization in Health Care Facilities: What Clinicians Need to Know** ; Pr. W. Rutala, Hospital Epidemiology, University of North Carolina Health Care System, and Division of Infectious Diseases, University of North Carolina School of Medicine, Chapel Hill ; September 2004.
[4] **Guidelines for Cleaning and Preparing Endocavitary Ultrasound Transducers between Patients**, American Institute of Ultrasound in Medicine. Approved June 4, 2003

7 TECHNICAL SPECIFICATION OF ANTIGERMIX S1

7.1 Characteristics

Diameter:	55cm
Height:	106cm
Weight	43kg
Alimentation	120-240 VAC
Power	510 Watt
Intensity	4,5 – 2,5 A
Frequency	50-60 Hz
Disinfection Time	CYCLE I : [90s]
Functioning temperature	[+ 15°C ; + 45°C]
Maximum of functioning humidity	90%
Maximum of functioning altitude	2000m

7.2 Transportation and Storage

Transportation must be done in packaging adapted for the AS1 such as the packaging provided at first delivery.

Storage temperature: +5 to +50°C.

8 MAINTENANCE

8.1 Error Management

The AS1 is equipped with sensors to ensure correct operation.

If the AS1 detects an error, even temporarily, the cycle is stopped and the AS1 displays an error code. This function ensures a disinfection cycle is valid.

The AS1 displays the corresponding error code on the front panel. See below for more information.

In case of error, note the error code and apply the reactivation procedure below.

AS1 reactivation



Warning

Don't manipulate the AS1 during initialization.

Don't switch off the AS1 during initialization.

This action can take several minutes.

- ⇨ To reactivate the AS1, press the stop button on the front panel.
- ⇨ The AS1 beeps and the front panel shuts down.
- ⇨ The AS1 reinitializes. This action can take several minutes.
- ⇨ After initialization, there are three possible cases:

After initialization	Action
The AS1 restarts normally. No error occurs.	Notify the authorized Service representative and provide details.
The AS1 starts but detects an error.	Identify the error code in the list. Contact your authorized Service representative to schedule an inspection.
The AS1 does not start.	Contact your authorized Service representative to schedule an inspection.

8.2 Error Codes

These are the error codes which can be displayed by the AS1:

Nb	Error
00	No error
03	RFID is disconnected
04	UV-C lamp 1 error
05	UV-C lamp 2 error
06	UV-C lamp 3 error
07	UV-C lamp 4 error
08	UV-C lamp 5 error
09	UV-C lamp 6 error
10	Dose error
11	Temperature
12	Incorrect probe
13	Probe lost
14	Trapdoor closed
18	Ini file corrupted
19	Door sensor error
20	Forcing door
21	Life time overrunning
22	Internal error
23	Dose threshold
24	Lifetime threshold
25	Cycle interruption
26	Service end
30	Low temperature
31	No calibration done
32	Locking mechanism opened during cycle
33	Threshold limit dose
34	Calibration error
35	Not Used
36	Error button

9 CLEANING

9.1 External Cleaning

Warning

Do not spread liquid in and on the AS1.

To clean the outside of the device, use a paper or cloth chiffon soaked with water or disinfectant.

9.2 Internal Cleaning

Warning

Do not spread liquid in and on the AS1.

Cleaning of internal surface must be performed by your authorized Service representative.

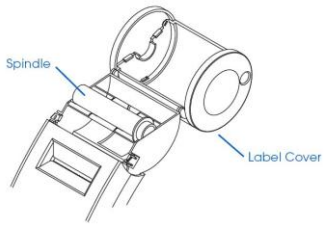
During these maintenance operations, it's recommended to use ultra-smooth chiffon (optical quality) soaked with hydroalcoholic solution.

9.3 Printer Paper Change

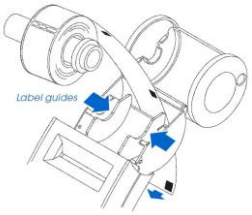
Warning

Only the label format sold by Germitec is compatible with the printer.

1. Stop the printer and open the top cover.



2. Place the cylindrical support in the label roller as indicated below.



3. Insert the extremity of the strip at the back of the printer.
4. Close the cover and press the 'on' button.

10 WARRANTY

The Antigermix S1 comes with a one year warranty for manufacturing defects. Refer to your Contract Agreement for more details about the warranty.

The Antigermix S1 must be repaired solely by your authorized Service representative.

11 CONTACT

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APPENDIX A EXAMPLE OF COMPLETE USAGE PROTOCOL

Material:

- *a flat surface next to Antigermix (ex. mobile tray)*
- *sterile papers*
- *disposable gloves*
- *a single-use protection*
- *a disposable dry wipe*
- *a wipe soaked in a detergent solution*



Make sure that all waste is treated with respect of internal procedures for infection risk material treatment.

Disinfected probes must be stored and transported in appropriate conditions.

***Pre-requisite**: put a single-use protection for endocavitary probes before the examination.*

Probe cleaning

1. For endocavitary probes, remove the single-use protection and discard it.
2. Wipe the gel and other soil with a dry wipe and discard it.
3. Place the probe on a clean paper on the flat surface.
4. Dispose of the gloves and put a new pair of gloves.
5. Clean the probe starting from the cable below RFID tag (do NOT touch the RFID tag) to the end of the probe with a cleaning wipe soaked in a detergent solution.
6. Make sure the cable and probe are visibly clean (if not repeat the process with a new cleaning wipe from the spot that is not visibly clean).
7. Discard the cleaning wipe and gloves.
8. Place the probe on one of the clean papers on the flat surface.
9. Perform hand hygiene and put a new pair of gloves.

Disinfection with Antigermix

10. Open the door and the sliding shield of the AS1.
11. Hold the probe by the RFID Tag (it is the first time that the RFID tag is touched) and hang it in the AS1.
12. Using the gloved hand that was NOT in contact with the RFID tag, close the trap door at the RFID Tag level and the door. Press the button to launch a disinfection cycle.
13. Discard all the remaining materials (paper & gloves).
14. At the end of the HLD cycle, please check Antigermix for errors. Make sure the HLD proof is printed or check for the cycle completeness in Germitrac.

Post-disinfection

15. Before touching the disinfected probe, put on new gloves.
16. Open the AS1 door and security shutter.
17. Take out the probe.