GERMITEC®

ANTIGERMIX®

USER MANUAL

MAN-AE1-EN v11 - *February 2024*

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CE 0459

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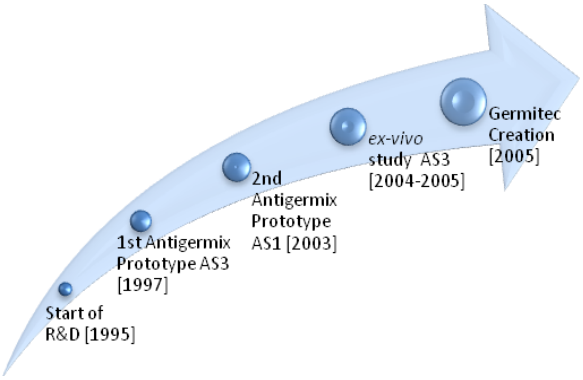
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1 INTRODUCTION

1.1 Presentation of Germitec

From 1995, the Company GRED, after many solicitations of its clients (radiologists, cardiologists, nurses, etc…) worked with an engineer team to create a non-chemical solution to probes disinfection.

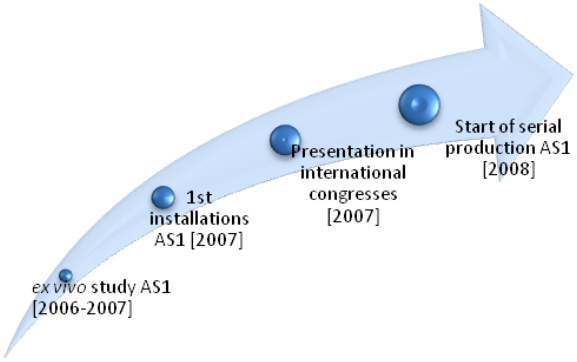


Genesis of Germitec

The R&D fundamental phase (1995-2004) bears the Germitec Company in 2005. Germitec, certified ISO 13485, counts 40 persons at full time and collaborates with advanced technology consultants.

Antigermix E1 birth

The qualification and industrialization phase (2004-2008) under the GRED-GERMITEC patronage enabled to collaborate with French advanced 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 almost fifteen famous international scientific and technical consultants.



The GRED-GERMITEC involvement has conveyed, in 2011, to the advent of an innovating system to easily disinfect transducers: Antigermix E1.

Claimed use of ANTIGERMIX E1

High Level Disinfection including sporicidal action of:
transoesophageal & endocavitary ultrasound transducers
and ENT scopes without operator channel
by UV-C as alternative to chemistry

1.2 Presentation of Antigermix E1

The Antigermix E1 (AE1) is a dry disinfection process for ultrasound transducers and ENT scopes without operator channels. It performs a High Level Disinfection including sporicidal action.

AE1 ergonomy enables an economic disinfection between each patient (consumable is avoided). Moreover, the disinfection process is safe and do not require specific operator since less than 1 minute manipulation is needed.

AE1 includes a complete automated system of control and tracking which provides serenity to healthcare workers and patients in validating each & every disinfections. The tracking system links the probe ID to the cycle data and parameters measured (temperature, UVC dose, etc.). The system is therefore able to validate or unvalidate the disinfection by comparing these data with internal standards. All the data and validations are archived and available for consultation. Therefore, if needed, helthcare workers can provide proofs of good practice.





Disinfection Process: UV-C Radiation

The Antigermix assures the transducer disinfection by UV-C radiation exposure.
Radiation wavelengths, ranging from 200 to 280 nm, strong germicidal effect. A germicidal effectiveness peak near 254 nm is worth noting.
UV light at these germicidal wavelengths causes adjacent thymine molecules on DNA to dimerize, if enough of these defects accumulate on a microorganism's DNA its replication is inhibited

2 STATUTORY INFORMATION, SAFETY RULES AND USAGE WARNING

2.1 Certification

The system is designed according to the 93/42/CEE directive for medical devices. According to this directive, Antigermix E1 belongs to class IIb.

The system is labelled CE 0459 and Curtis Strauss PXAA

According to the 93/42/CEE directive, the Antigermix E1 complies with the following norms:

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

2.2 Safety rules

- Do not shock the enclosure. If it falls down or it is damaged, return it to the manufacturer for repairing.
- In doubt of damage, do not use the device.
- Do not force the enclosure's door or back panels during the cycle operation.
- Do not try to open or repair the enclosure. The Antigermix E1 can only be repaired by the manufacturer.
- Return the device to the manufacturer for any repairing. Open back panels, cancels the guarantee. (See section 11)
- Do not expose the enclosure or accessories to temperature below 5°C or above 45°C, or humidity above 75%.
- Never be exposed to UVC radiation. An overexposure to UVC radiation can cause sunburn.
- Only OZONE FREE UVC lamp provided by Germitec can be used in the Antigermix E1.
- For each lamp replacement, we have to wait 5 minutes for cooling down, to avoid hands from burning.
- For all technical intervention, technician must wear glasses.
- When the device is stopped by the switch on front panel, cabling is always switched on. Unplug the Antigermix E1 before any intervention.
- The device should be disposed of or recycled in accordance with the applicable laws

2.3 Usage warning

- The AE1 is a disinfection automaton which can be inserted into a general treatment protocol to handle the probe preparation and disinfection. See Section 7 'Disinfection protocol'
- The Antigermix AE1 is only reserved to medical usage. Only transoesophageal, Endocavitary ultrasound transducers and ENT scopes without operator channel can be placed in the enclosure.
- Remove all gel marks or soiling on the probe before placing it in the AE1.
- Before placing the probe into the AE1, see the operating procedure in section 5 'Use'
- The Antigermix E1 is not a storage rack. Do not leave a probe in the enclosure after a cycle.
- Do not pour liquid in and on the Antigermix E1. See section 10 'Cleaning' for the appropriate cleaning protocol.
- The data must be daily saved. The Company Germitec cannot be responsible for the loss of data on the hard disk. It is recommended to realize an archive on external support (like USB key, Flash card, external hard disk, …)

Warning to users in Canada :

The device complies with Industry Canada Licence-exempt RSS Standard(s). Operation is subject to the following two conditions:

(1) This device may not cause interference, and

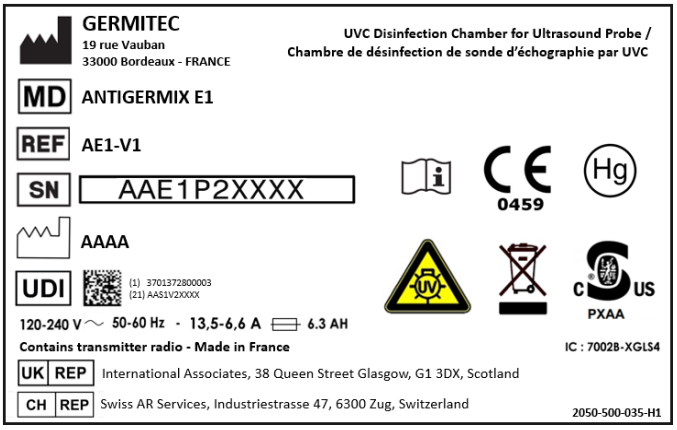
(2) This device may accept any interference, including interference that may cause undesired operation of the device.

Under Industry Canada Regulations, this radio transmitter may only operate using an antenna of a type and maximum (or lesser) gain approved for the transmitter by Industry Canada.

To reduce potential radio interference to other users, the antenna type and its gain should be so chosen that the equivalent is isotropically radiated power (e.i.r.p.) is not more than that necessary for successful communication.

The device complies with Industry Canada RF radiation exposure limits set forth for the general population (uncontrolled exposure). This device must be installed to provide a separation distance of at least 20cm from all persons and must be not be collocated or operating in conjunction with any other antenna or transmitter.

2.4 Labeling

<table>
<tr>
<td>
</td>
<td>Rating plate:
Manufacturer's identification
Description of the equipment
Model
Serial number
Electrical characteristics
Country of manufacture
Manufacturing date
Markings
UDI-DI number with associated QR code
UK Rep contact
CH Rep contact</td>
</tr>
<tr>
<td></td>
<td>Risk of Electrical shock:
Only authorized person can open access trapdoor to the maintenance area.</td>
</tr>
</table>

	**High-temperature** : Do not touch lamp during 5 minutes after the cycle.
	**Risk of UVC Radiation exposure:** This system is designed to prevent user from being exposed to UVC radiation, however: Never stay exposed to UVC radiation.
	**Do not dispose with domestic waste** This symbol indicates than waste from electrical device must not be dispose with domestic waste. Its must be disposed separately. Please contact the manufacturer or other Company specialized in waste treatment for disusing your device.
	**Manufacturer** This symbol adjacent to Germitec indicates that Germitec is the manufacturer of this equipment.
	**Information in the manual** This symbol indicates that the user must read the manual before using the device.
	**Manufacturing date** This symbol indicates the manufacturing date (in year) of the device.
	UVC lamp containing mercury

3 ANTIGERMIX E1 DESCRIPTION

3.1 Usage

Antigermix E1 is an automaton performing a High Level Disinfection including sporicidal action on Transoesophageal and Endocavitary ultrasound transducers and ENT scopes without operator channel. The process is based on UVC radiation. It is an alternative to chemical process.

3.2 Description of disinfection cycle

3.2.1 Definition of disinfection cycle

Antigermix E1 is able to execute a disinfection cycle, of which characteristics are described hereunder. A cycle is named CYCLE I.

3.2.2 Disinfection performance, in vitro tests

The protocol of system evaluation has been made from in vitro tests used to validate chemical disinfection.

Activity	Norm	Tested strains	Performance obtained by AE1 CYCLE I (HLD)
Bactéricidie	AOAC use-dilution methods 955.14, 955.15, 964.02 EN 14561	*Staphylococcus aureus*	✓
		Pseudomonas aeruginosa	✓
		Escherichia coli	✓
		Enterococcus hirae	✓
Virucidie	ASTM E 1053-97 NF EN 14476	*Orthopoxvirus*	✓
		Enterovirus polio 1	✓
		Adenovirus type 5	✓
Fongicidie	AOAC 955.17 EN 14562	*Candida albicans*	✓
		Trichtophyton mentagrophytes	✓
		Aspergillus fumigatus	✓
Mycobactéricidie	EN 14563 EN 12353	*Mycobacterium terrae*	✓
		Mycobacterium avium	✓
Sporicidie	NF EN 14562	*Bacillus subtilis*	✓
		Bacillus cereus	✓
		Clostridium sporogenes	✓
Simulated use tests AOAC	EN 14563 EN 12353	*Mycobacterium terrae*	✓

3.2.3 Control of disinfection efficiency by dose measure

GERMITEC's expertise on UVC makes efficiency control by dose measurement (mJ/cm²) a perfectly reliable methode.
The dose measurement is done through two optical sensors (photodiode) with a spectral sensitivity focused on 254 nm (germicidal wavelength).

The dose required is determined by:

- Conclusion of microbiological tests (See array in section 3.2.2)
- Accuracy of the sensors used to measure effective dose.
- Shading factor due to the presence of the probe in the AE1 enclosure.

The dose threshold enables to insure the disinfection level corresponding.

The two optical sensors are placed in the enclosure to measure redundantly the energy received by all the surface of the probe. Therefore, AE1 can control with sturdiness the dose actually received by the probe and can detect a potential dysfunction.

3.2.4 Time of disinfection cycle

The control of disinfection efficiency leads to create variation in cycle time. When the required dose is reached, the cycle is automatically stopped.

	Effective Dose	Average cycle time
CYCLE I (HLD)	**4040 GU**	**[180s]**

3.2.5 Disinfection homogeneity

The homogeneity of this disinfection has been analysed by the following studies:

- An optic ray simulation, based on Z-Max model, demonstrated AE1 good disinfection homogeneity on all probe surfaces, even if the probe profiles are unfavourably designed.

As a result, AE1 specific design enables a homogeneous disinfection of the probe.

3.3 Validation of UVC efficiency in real conditions

- the effectiveness of UVC disinfection TOE probes has been demonstrated through a clinical trial using prototypes Antigermix:
  The study was performed in 2011 on 150 patients by (HEGP) Hôpital Européen Georges Pompidou in Paris and Hospital Henri Mondor in Créteil, France.
- the effectiveness of UVC disinfection ultrasound ENT scopes has been demonstrated in a study conducted at QUEEN ELISABETH HOSPITAL (Birmingham, England)

3.4 Description of tracking software: Germitrac® (optional)

Germitrac® is software which enables to consult and visualize all tracking data related to disinfections performed with Antigermix E1.

All tracking data are stored in Antigermix E1 system. Usefull data record can be accessed from all specifically authorized computers. Germitrac® software offers to the user different tools for managing data (filters, printing …).

Main data for each cycle are the following:

- **"Probe"**: identification of the probe by the model and the identification number
- **"Day Nb"**: Daily cycle number
- **"Date":** Cycle date
- **"Hour"**: Cycle hour
- **"Cycle type"**: CYCLE I
- **"Patient name"**: Patient name (to fill manually)
- **"Disinfection status"**: A successful disinfection is symbolised by , a failed one by .

3.5 Description of parameters supervised by the Antigermix E1

Antigermix E1 is composed of an electronic system assisting the user. This system supervises automatically different parameters listed in this section.
The communication of these parameters to the user is done by the user's interface described in the section 4.2.

3.5.1 UVC dose remaining

The effective dose is supervised by the AE1. A digital display, on the front panel, informs the user of the remaining dose.

3.5.2 Tubes working

Each tube is supervised separately. A visualisation synoptic, on the front panel, indicates the tubes positions in the enclosure.

3.5.3 Using time of the tubes

The AE1 supervises the using time of the tubes. The visualisation of the using time is possible in the front panel (the time is expressed in hour).

3.5.4 UVC dose received by the probe

The dose measured by the sensors is saved and is included in tracking data.

3.5.5 Temperature

The AE1 has a security system which supervises the temperature.

3.6 Label Printer

The system is supplied with a printer. This printer enables to print the disinfection report after each cycle.



Label tracking data

We can find on the label all tracking information which enables to identify the cycle, the disinfected probe and to confirm the proper disinfection.

System identification

Establishment name
Responsible name
Serial Number of device

Date and Hour of disinfection

Probe identification

Type of the realized cycle
Success of the disinfection
Delivered dose (GU)
Annual counter / annual limit
Daily cycle number

AE1	
	Hospital Pasteur Cardiology 0720E0004
Date - Hour : 25/02/2016 - 10:25:15 Patient : Durand Probe ID : Z6Ms: 51510524 Cycle type : Cycle 1 Disinfection : Success Dose : 4 042 GU Counters Daily - An : 2 - 1487	
User	

AE1	
	Hospital Pasteur Cardiology 0720E0004
Date - Hour : 25/02/2016 - 10:29:14 Patient : Durand Probe ID : Z6Ms: 51510524 Cycle type : Cycle 1 Disinfection : Failed Dose : 328 GU Counters Daily - An : 3 - 1487	
User	

ERROR

Cycle error

3.7 Personalisation of information

The user can configure information in the ticket:

- Establishment name
- Responsible healthcare worker name
- Number of printed label at the end of the cycle

These data are configured by the technician during the installation of the device.

4 INSTALLATION, SETTINGS AND COMMISSIONING

4.1 Package

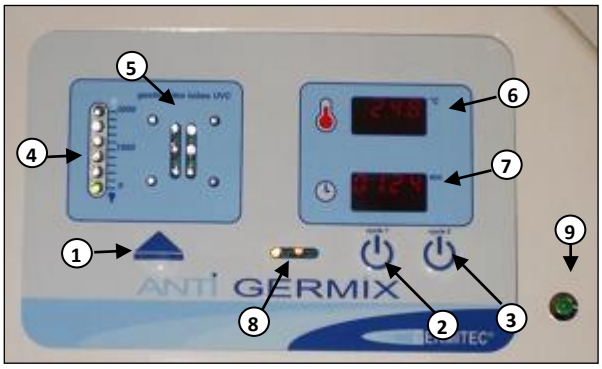
The package contains following elements:

- 1 x Antigermix E1
- 1 x quartz plate
- 1 x Printer
- 1 x label roller
- 3 x Hanger ring for probe
- 1 x Kit of silicone washers
- 1 x RJ45 network cable
- 1 x power supply cable
- 1 x user's instructions

4.2 Interfaces presentation

The system has a user interface on the front face. The connectors for the connection of peripherals and Ethernet network are placed at the top back of the device.
The power supply system is placed at the bottom back of the device.

User interface

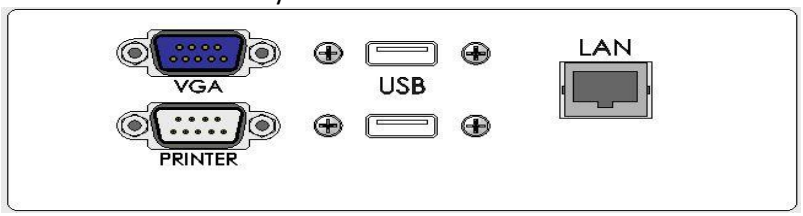


Legend
1: Stop button
2: CYCLE I button
3: CYCLE II button validate to calibration
4: Tubes lifetime
5: Location of faulty tube
6: Temperature display
7: Hour or cycle time display
8: Probe presence light
9: Activity light (inactive)

Concerning the signification of the information display by user interface, see the section 5. 'Use'.

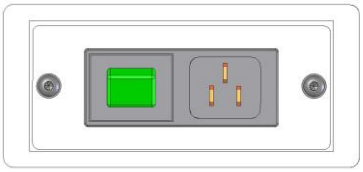
Peripherals interface

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



Power supply

The connection is done with the standard IEC cable supplied with the device.
The switch is lighted when the system is switched on.



4.3 Installation process

4.3.1 Device positioning

To facilitate device using and totally use its ergonomics, it must be placed near the ultrasounds. If you use it with several ultrasounds or ENT scopes units, it can be placed in the most adapted place.

4.3.2 Device connections

Warning

The power supply is used as power cut device (if it is necessary), it must be easily accessible.

The Antigermix E1 must be connected to an electrical installation conforms to the regulation. This connection must be made by a qualified person.

The Antigermix connection is done on 120V to 240V AC sector. Check the electrical network is conformed to the label. This product is electrically class 1; it must be plugged to the ground. Without this, the danger of electric shock is possible.

Only the cable delivered with the device can be used.

Never connect peripherals on VGA or USB connectors.

- Plug the power supply to the IEC connector at the back of the enclosure.
- Plug the other extremity on a 120 to 240VAC receptacle (2P + G) 16 amp. This plug must be protected by a 13 amp circuit breaker.
- Connect the Antigermix E1 on the Ethernet network by using RJ45 cable from the LAN plug at the back of the device to your Ethernet network.
- Connect the printer to the PRINTER plus at the back of the device.
- Make ensure that the connected cables are of the RJ45 type.

4.3.3 Installation of hanger and tracking rings

The quartz support and hanger tracking rings must be installed and configured by a technician authorized by Germitec.

In case of ring lack on the probe cable, contact a technician authorized by Germitec.



4.3.4 Switch on

To switch on the device, see the section 5.2 explaining the AE1 use.

4.3.5 Switch off

To switch off the device, see the section 5.3 explaining the AE1 use.

4.3.6 Dysfunction case during installation

In case of dysfunction seen during the installation, report to the chapter ‘Maintenance’.

5 USE

5.1 User profile

All persons having read and understood the Instructions for Use, who use diagnostic Ultrasound probes or ENT scopes without operator channel and/or need to disinfect them between 2 patients. For example, health professionals such as physicians, radiologists, nurses, clinics technical staff,…

5.2 Switch on

Before switching on, check that the preliminary tasks of installation have been correctly done.

1. Check than no probe is in the enclosure. If it is not the case, remove the probe.
2. Close the device door.
3. Switch on the device with the switch (placed at the bottom back of the device). The switch lights up.
4. The device emits a beep.
5. Wait the starting up and initialisation of the system (the starting time is nearly 30 seconds).
6. After initialisation, the display panel switches on and the system emits a beep.
7. The system is ready.

In case of dysfunction during switching on, report to the chapter 9. ‘Maintenance’

5.3 Switch off

Warning

The system must never be directly switched off with the switch at the back of the device, not to damage and loss tracking data saved in the device.

1. Press the stop button on the front panel during 3 seconds.
2. The system emits a beep and the display panel switches off.
3. Wait nearly 20 seconds after the last flash of activity light before switching off the device with the switch placed on the back of the enclosure.
4. The Antigermix E1 is now powered off. The power cut can be done by unplug the power supply.

5.4 Using mode of the Antigermix E1

Warning

Only probe with ring or quartz support hanged can be disinfected in the Antigermix.

Never put more than one probe per cycle.

The system can be used only with Ultrasound probes and ENT scopes without operator channel.

Before placement of the probe in the enclosure, check than no gel trace is present on the probe

Before proceeding to the setting up of the probe in the Antigermix E1, check that all recommendation described in the section 7 ‘Disinfection protocol’ are correctly followed.

1. Open the door of the Antigermix E1
2. Hang up the probe in the enclosure with the hanged ring.
3. Check the detection of the probe with the probe detection light (number 8 in the figure of the section 4.2)

4. Put the sensor cable on the shelf at the top.
5. Close quietly the door until hearing the locking 'click'.
6. Start the cycle by pressing CYCLE I button. The time count is starting and can be visualized on the front panel.
7. At the end of the cycle, a beep is emitted. The software processes the tracking data.
8. Label Printing.
9. The message End indicates than the disinfection is a success. If the message Err is displaying, the disinfection is a failure, see the section 9. 'Maintenance' in this case.
10. Open the door. Before proceeding to the probe recovering, check that the recommendation of the section 7. 'Disinfection protocol' is correctly followed.

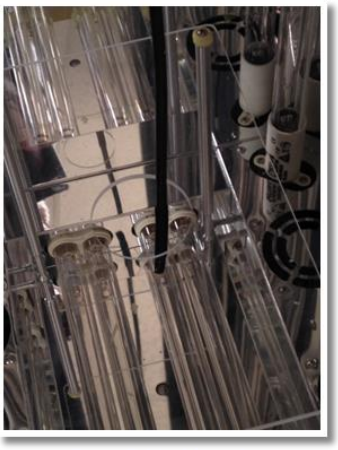
5.5 Inserting the probe into the disinfection chamber

5.5.1 TEE Probe

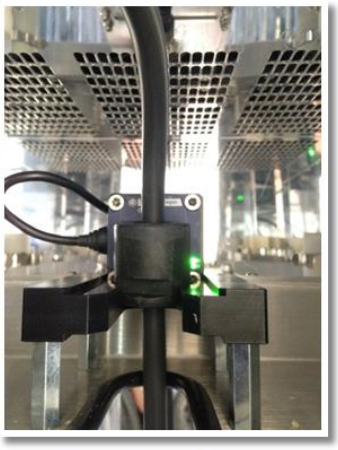
1: Probe cleaning as per standard protocol by Hospital Infection Control Authorities.



2: Take the probe by the TAG and the head



3: Place the Head of the probe through the quartz plate



4: Put the TAG on the RFID reader



5: Put the cable and the connector on the shelf

5.5.2 Nasofibroscope

1: Probe cleaning as per standard protocol by Hospital Infection Control Authorities.

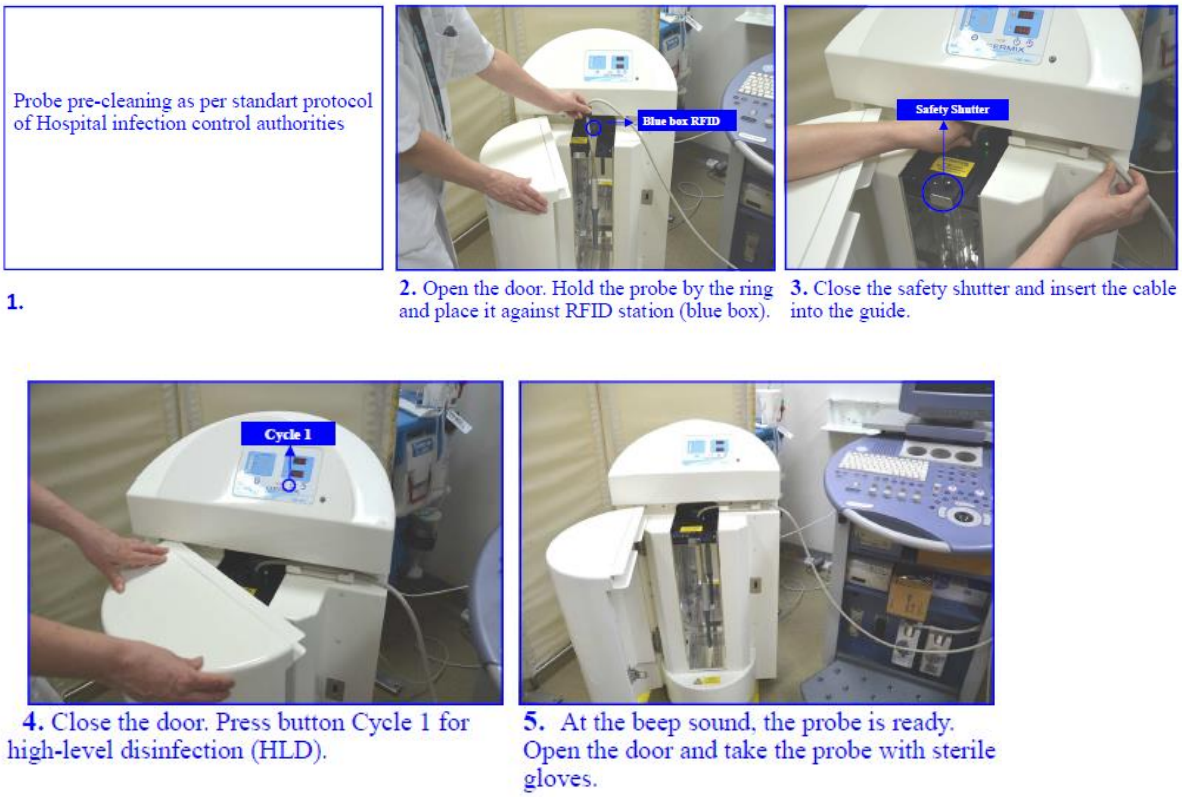


2: Put the Quatz Hanger with TAG on the RFID reader



3: Put ENT Scope on the Quartz Hanger

5.5.3 Endocavitary & external Probe



1.

2. Open the door. Hold the probe by the ring and place it against RFID station (blue box).

3. Close the safety shutter and insert the cable into the guide.

4. Close the door. Press button Cycle 1 for high-level disinfection (HLD).

5. At the beep sound, the probe is ready. Open the door and take the probe with sterile gloves.

5.6 Signification of information displayed on the user interface

The front panel gives information about system functioning.
The control of these indicators is not necessary during the cycle.

Temperature display (referenced 6 in the figure of the section 4.2)

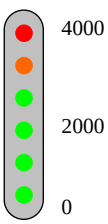
Display	Context	Meaning
23.6	/	Temperature in degree Celsius. Display accuracy: 1/10ème of °C
Err	/	Dysfunction of the system The error is identified by a number.

Cycle time display (referenced 7 in the figure of the section 4.2)

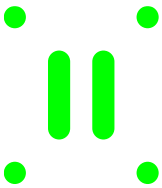
Display	Context	Signification
10:28	Out of cycle	Hour in the format: "hour: minute"
0120	During cycle	Remaining dose in germitec unit (GU)
End	End of the cycle	Disinfection is a success
SECU	Inactive	Inactive
door	Cycle beginning	The door is opened
rFid	Cycle beginning	No probe in the enclosure
HOt	During cycle	Warning: The temperature is too hot. The cycle is automatically stopped.
28	Displaying of the message "Err" on temperature display	Identification number of the error

Tubes lifetime (referenced 4 in the figure of the section 4.2)

This warning light indicates the total cycles of the tubes.



Localisation of tubes in case of dysfunction (referenced 5 in the figure of section 4.2)



In case of tube dysfunction, a warning light indicates the faulty tube and its position in the system.

5.7 Printer

> Warning
> *Only printers supplied by Germitec are compatible with the Antigermix system.*
> *Using another printer does not guarantee the good working of the system.*

Printer use

The printer is automatically piloted by the Antigermix.
Before starting a cycle, you have to check:

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

Change of the label roller

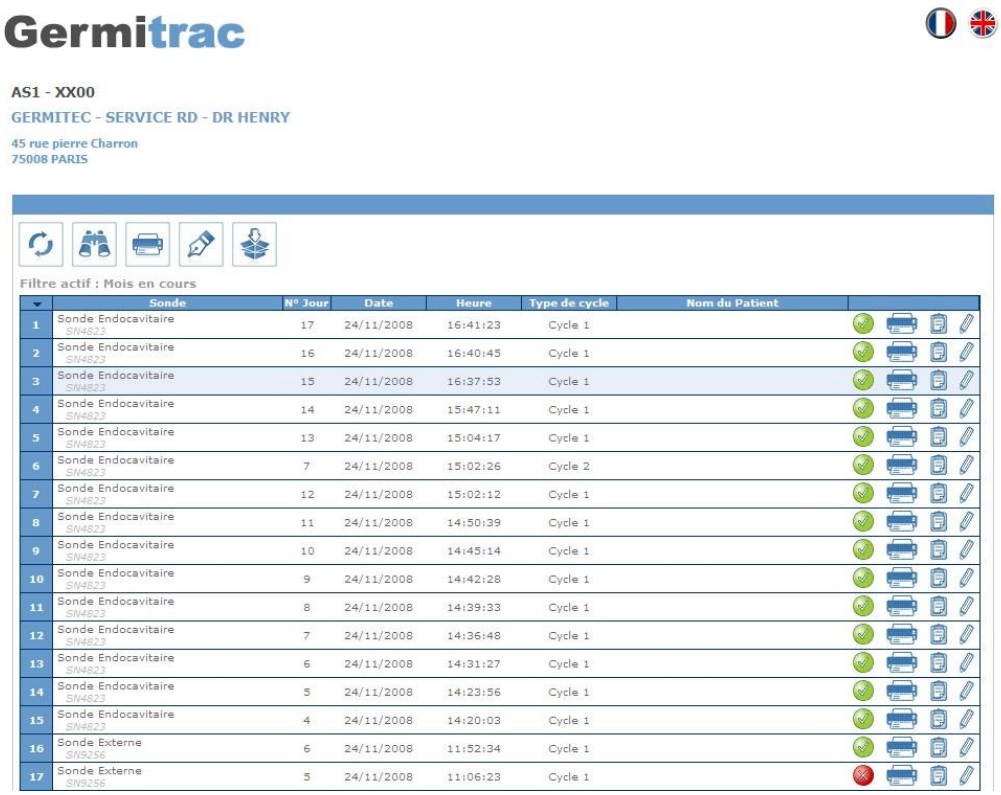
See the section 10.3 ‘Maintenance’.

5.8 Tracking software Germitrac® (Optional)

Germitrac® is the software which enables to consult and visualize all tracking data in relation with the probe disinfection operates on the Antigermix.

> ***Warning***
>
> *Antigermix does not archive automatically data.*
>
> *It is imperative to save data every day on the hard disk of your computer.*
>
> *It is recommended to make a copy on an external storage support.*

The software Germitrac® is used with a WEB browser.



	Sonde	N° Jour	Date	Heure	Type de cycle	Nom du Patient
1	Sonde Endocavitaire SN4823	17	24/11/2008	16:41:23	Cycle 1	
2	Sonde Endocavitaire SN4823	16	24/11/2008	16:40:45	Cycle 1	
3	Sonde Endocavitaire SN4823	15	24/11/2008	16:37:53	Cycle 1	
4	Sonde Endocavitaire SN4823	14	24/11/2008	15:47:11	Cycle 1	
5	Sonde Endocavitaire SN4823	13	24/11/2008	15:04:17	Cycle 1	
6	Sonde Endocavitaire SN4823	7	24/11/2008	15:02:26	Cycle 2	
7	Sonde Endocavitaire SN4823	12	24/11/2008	15:02:12	Cycle 1	
8	Sonde Endocavitaire SN4823	11	24/11/2008	14:50:39	Cycle 1	
9	Sonde Endocavitaire SN4823	10	24/11/2008	14:45:14	Cycle 1	
10	Sonde Endocavitaire SN4823	9	24/11/2008	14:42:28	Cycle 1	
11	Sonde Endocavitaire SN4823	8	24/11/2008	14:39:33	Cycle 1	
12	Sonde Endocavitaire SN4823	7	24/11/2008	14:36:48	Cycle 1	
13	Sonde Endocavitaire SN4823	6	24/11/2008	14:31:27	Cycle 1	
14	Sonde Endocavitaire SN4823	5	24/11/2008	14:23:56	Cycle 1	
15	Sonde Endocavitaire SN4823	4	24/11/2008	14:20:03	Cycle 1	
16	Sonde Externe SN9256	6	24/11/2008	11:52:34	Cycle 1	
17	Sonde Externe SN9256	5	24/11/2008	11:06:23	Cycle 1	

The compatible browsers are: Chrome ; Internet Explorer ; Mozilla Firefox ; Opera ; Safari

6 INTRODUCTION OF THE DISINFECTION BY ANTIGERMIX E1

6.1 Antigermix E1 function

The Antigermix E1 is a disinfection automaton of which use is in line with a global protocol concerning ultrasound probes and ENT scopes hygiene at care establishment initiative. It enables to perform a High Level Disinfection including sporicidal action. (HLD on the active part of the TEE and ENT probes)

6.2 Good practises reminder: distinguish Cleaning and disinfection

According to the hygiene principle: ”We disinfect well only what is clean”.

The efficiency of a mode of disinfection, comprising chemical soaking, needs the tool to be cleaned: « 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 »[1].

Thus, even if the Antigermix efficiency has been validated in dirty conditions, AE1 is not an exception: a cleaning is needed before the disinfection.

In this sense, it is necessary to remember than the role of disposable protections (probe cover) is to make cleaning easier. If the use of protection does not decrease the disinfection level needed, it enables to replace the detergent soaking demanded before all disinfection by a simple cleaning (ex: detergent wipes). The aim of disposable protections as cleaning process is confirmed by several reknown societies as the American Insitute of Ultrasound in Medicine: « one should therefore perform high-level disinfection of the probe between each use and use a probe cover or condom as an aid to keeping the probe clean »[2].

6.3 General rules to include in disinfection protocol

The Antigermix E1 enables the disinfection of ultrasound probes and ENT scopes without operator channel, needing HLD incl. sporicidal action. Its use has to be included in a global approach of ultrasound transducer hygiene. Thus, for each protocol, it is necessary to:

- ⇨ Respect the process of hand hygiene during all the protocol (gloves, hydroalcoholic solution …)
- ⇨ Respect using precaution and cleaning of the probe manufacturer.
- ⇨ Respect the sterile character and normative category of gloves, gel and disposable protections (Sheath). These elements must be conformed to the legislation in effect.

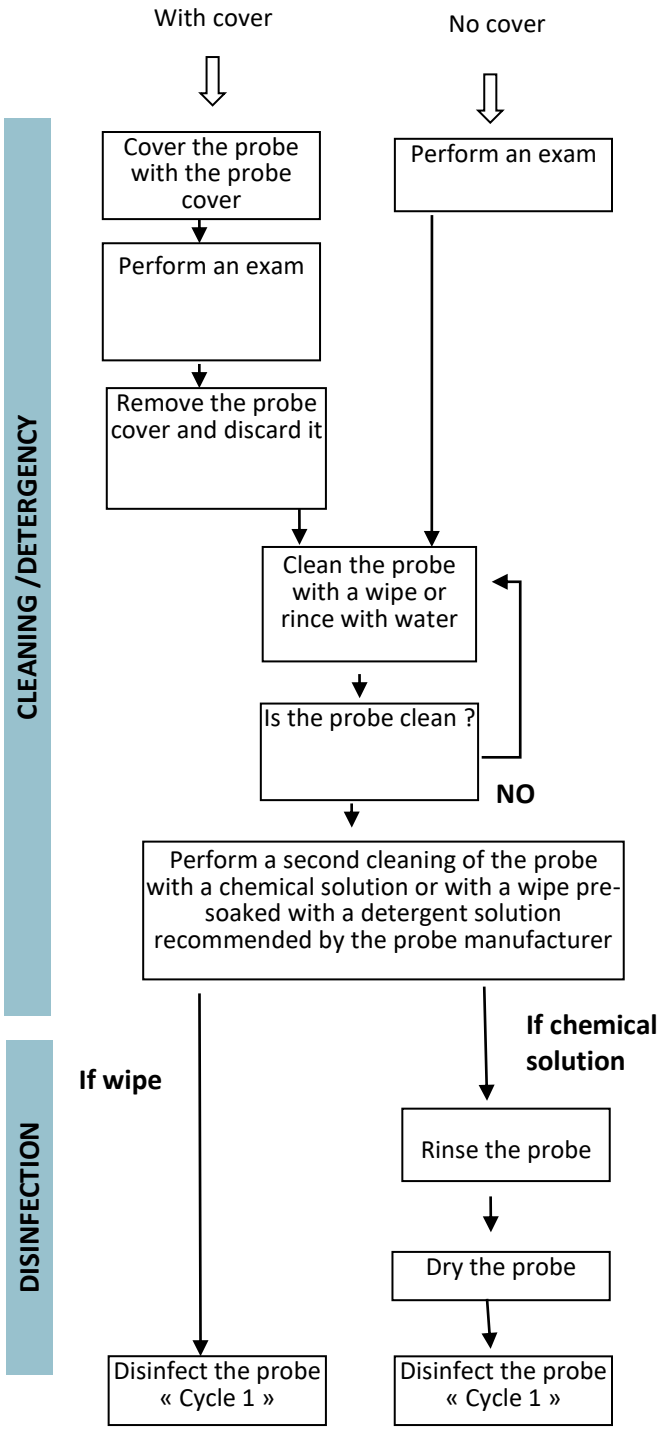
[1] **Disinfection and Sterilization in Health Care Facilities: What Clinicians Need to Know** ; Pr. W. Rutala, Hospital Epidemiology, University of North Carolina Health Care System, and Division of Infectious Diseases, University of North Carolina School of Medicine, Chapel Hill ; September 2004.

[2] **Guidelines for Cleaning and Preparing Endocavitary Ultrasound Transducers between Patients**, American Institute of Ultrasound in Medicine. Approved June 4, 2003

7 DISINFECTION PROTOCOL BY ANTIGERMIX E1 (EXAMPLE)

7.1 Cleaning step

According to the good practices, to qualify the success of a cleaning, the criterion is the visual cleanness of the ultrasound probes and ENT scopes.



7.2 Desinfection step

To achieve a high level disinfection (HLD) of the probe, I start the cycle according to the operating procedure described in 5.4

8 TECHNICAL SPECIFICATION OF ANTIGERMIX E1

8.1 Characteristics

Size	Cylindrical enclosure: - diameter: 55cm - height: 210cm
Weight	110kg
Alimentation	120 – 240 volts VAC
Power	1430 Watt
Intensity	13,5 – 6,6 A
Frequency	50/60 Hz
Disinfection Time	**CYCLE I** : [180s] **CYCLE II** : inactive
Functioning temperature	[+ 15°C ; + 45°C]
Accoustic pressure	67 dB
Maximum of functioning humidity	75%
Maximum of functioning altitude	2000m
Environment	Lamps contain Mercury

8.2 Transport and storage

The transport must be done in packaging adapted for the enclosure like the packaging provided at the first delivery. Once unpacked, the Antigermix E1 must be moved horizontally, door to the top.

Respect storage and transport condition of the device:
Storage temperature: +5 à +50°C.

9 MAINTENANCE

9.1 Dysfunction management

The Antigermix is equipped with many sensors to insure the well functioning.

If the Antigermix E1 detects a dysfunction, even temporarily, the cycle is stopped and the system is set to an error mode. This function insures the validity of a disinfection cycle.

The system displays the corresponding code of the error on the front panel. See the below array for more information about codes list.

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

Your after-sales representative should be notified of each error requiring a system reactivation.

In case of impossibility to use the device, alternative high-level disinfection methods such as chemical soaking should be used.

System reactivation



Warning

Do not manipulate the system during initialisation. Do not switch off the device during initialisation. This action can take several minutes.

- ⇨ To reactivate the system, press the stop button on the front panel.
- ⇨ The system emits a beep and the front panel shut down.
- ⇨ The system is reinitialised. This action can take several minutes.
- ⇨ After initialisation, three cases are possible:

After initialisation	Action to do
The system starts normally. No error occurs.	Notify the technical department about this error.
The system starts but detects an error.	See the list of error code to have precision about the error. Alert technical department to plan an intervention.
The system does not start.	Alert technical department to plan an intervention.

9.2 Error codes

There are 32 error codes which can be display by the Antigermix E1:

Nb	Error
00	No error
01	No paper in printer
02	Printer disconnection
03	RFID disconnection
04	Tube 1 dysfunction
05	Tube 2 dysfunction
06	Tube 3 dysfunction
07	Tube 4 dysfunction
08	Tube 5 dysfunction
09	Tube 6 dysfunction
10	Dose error
11	Temperature
12	Incorrect probe
13	Probe lost
14	Trapdoor closed (inactive)
15	Trapdoor wedged open
16	Hard disk access
17	Door open during starting
18	Ini file
19	Door sensor incoherence
20	Forcing door
21	Lifetime overrunning
22	Internal error
23	Dose threshold
24	Lifetime threshold
25	Cycle interruption
26	Service end
30	Low temperature
31	No calibration done
32	Bolt open during cycle

9.3 Wear part replacement

Only qualified personnel are authorized to do maintenance operation on the Antigermix E1.

Tubes replacement

> ***Warning***
>
> *Don't' touch tube during 5 minutes after the last cycle to avoid burning.*
>
> *Tubes must be manipulated with gloves to avoid staining tubes.*
>
> *Used tubes must be recycled or take back by Germitec.*

In case of dysfunction of a tube, it must be changed like this:

1. Stop the system using the procedure of the section 5.3.
2. Unplug the power supply.
3. Open the door and remove the used tube one after one, this action must be done with adapted gloves.
4. Take new tubes and insert the tubes one after one, take car to push it until the end stop.
5. Reconnect and switch on the system.
6. Initialize the parameters in relation with the tubes management.
7. Realize calibration procedure.

The tubes replacement is done every 4000 cycles. Sensor calibration is needed after each tube replacement.

Calibration of dose measure sensors

> ***Warning***
>
> *Only technician certified by Germitec are authorized to realize the calibration of UVC measure sensors.*
>
> *Not respect the calibration period of the sensors can lead to a dysfunction of the Antigermix E1. Germitec cannot be responsible for this.*

The Antigermix E1 is equipped with precision sensor which measure UVC radiations to control the delivered dose. To insure the performance, these sensors must be checked and calibrated by a technician certified by Germitec. The measuring device is a Solo® monitor, branded Gentec®, associated with a photodiode PH100, the accuracy is 5%.

The calibration proceeding is the following:

1. Plug the measure device on USB port.
2. Put the photodiode in the Antigermix E1, press it against the security plate.
3. Switch on measure device.
4. Check that the printer is connected to power supply and to USB.
5. Launch calibration using the service Antigermix and wait during measure process.
6. At the end of the calibration, one ticket per measure cycle is printed with the calibration result.
7. Keep the tickets as proof of wall calibration.
8. Press button CYCLE I, then CYCLE II to validate calibration cycle.

The calibration proceedings are done at each maintenance visit and at each tubes replacement.

Air filter replacement

The proceeding to follow is:

1. After having done the switch off proceeding (section 5.3), unplug the power supply.
2. Lay down the enclosure (door to the up)
3. Remove covering grill.
4. Change filters (3) and replace the covering grill.
5. Replace the enclosure on its wheels (vertically) and start the system.

10 CLEANING

10.1 External cleaning

Warning

Do not spread liquid in and on the Antigermix E1.

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

10.2 Internal cleaning

Warning

Do not spread liquid in and on the Antigermix E1.

Cleaning of internal surface must be realised by a technician agreed by Germitec.

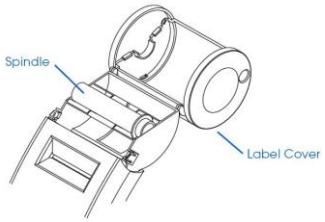
Cleaning internal surface must be realised by personal agreed by Germitec. During these maintenance operations, it is recommended to use ultra-smooth chiffon (optical quality) soaked with hydroalcoholic solution.

10.3 Printer paper change

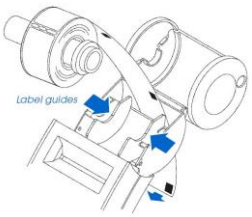
Warning

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

1. Stop printer and open superior 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 switch on button.

11 GUARANTEE

The Antigermix E1 is guaranteed for 18 months. This guarantee includes pieces default and workforce during I year, starting at the delivery date.
The Antigermix must exclusively be repaired by the manufacturer or by a repair center agreed by the manufacturer.
In case of reparation during the guarantee period, join the bill with the Antigermix E1.

12 CONTACT

For any information, contact the customer service department: support@germitec.com

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Notes