GERMITEC®

# Chronos®

# USER MANUAL

**MAN-N001-US Rev2 - November 2024**



**This manual must be read**
**before using the Chronos® disinfecting system.**

This ensures that it is used under the safest and most efficient conditions.



For any questions regarding the equipment, its maintenance, breakdowns, or end-of-life disposal, please contact your Germitec Authorized Service Representative.

The description of the disinfection system is accurate on the date of printing of this manual.

Chronos® is a medical device from the Hypernova™ product family. The Chronos® disinfecting system is identified as Chronos® within this document. The model of the device is AS1-V2.

The technology within the Chronos® disinfecting system is protected by several Germitec patents.

The Chronos® has the following Curtis Straus marking:

C US
NCCA

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# 1 INTRODUCTION

## 1.1 Chronos® device description

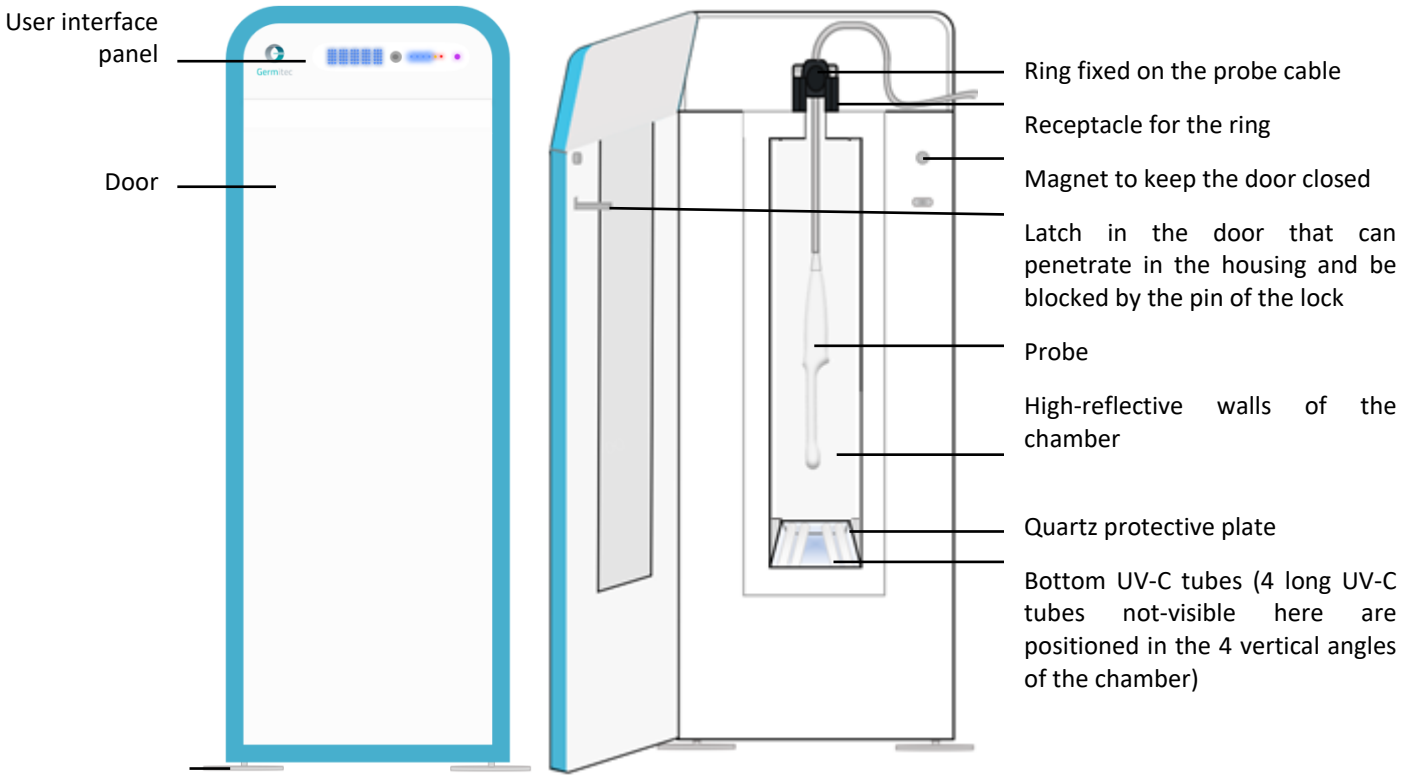
The Chronos® is designed to provide fast, High-Level Disinfection (HLD) for reusable ultrasound probes using intense Ultraviolet C-band (UV-C) radiation. The High-Level Disinfection process is free of any liquids, chemicals, fumes, reagents, or consumables/indicators.

The Chronos® incorporates 6 UV-C tubes (lamps) positioned within the disinfection chamber. Two optical sensors (UV-C sensitive photodiodes) measure the UV-C dose until a preset UV-C exposure is reached. This sensor feedback provides assurance that all surfaces of the ultrasound probe receive a sufficient germicidal UV-C dose during each HLD cycle. An independent, third photodiode performs a second, confirmatory, feedback-controlled monitoring that a sufficient dose of UV-C was delivered to the HLD chamber, and only then approves the disinfection cycle.

Each disinfection treatment cycle can incorporate one probe. The ID of each probe is identified by reading the barcode on a ring pre-installed on the probe cable. The barcode is used to associate the particular characteristics of each ultrasound probe with an appropriate HLD cycle dose delivered by the Chronos®.

The Chronos® contains completely automated controls and a traceability system. The traceability data are stored and retrievable. Healthcare professionals can, thus, control and provide proof of each disinfection procedure for each ultrasound probe.

The Chronos® can achieve cost-effective disinfection without the need to disconnect the probe from the ultrasound equipment. The disinfection step is safe and easy to perform, ensuring an efficient workflow that allows each probe to be completely disinfected between patients.

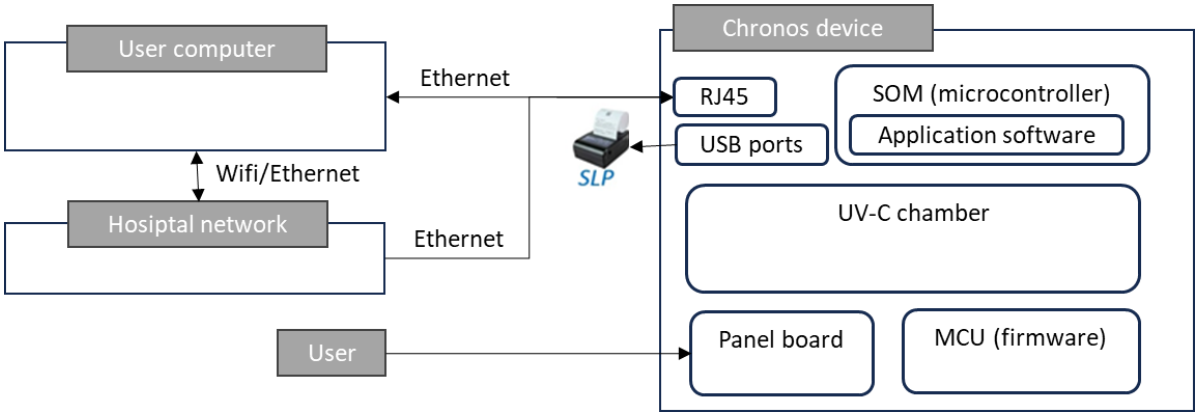


## 1.2 Users and environment

The Chronos® is intended for use in hospitals, especially exam rooms and Point-of-Care settings, radiology suites, or sonography practices, and in primary-care or specialist physician practices.

It is designed to be used under the supervision of healthcare professionals such as sonographers, radiologists, gynecologists, obstetricians, cardiologists, urologists, primary-care physicians, nurses, and healthcare assistants.

The Chronos® has the possibility to be interfaced with the hospital network and user computer to access traceability functions. The different interfaces are described in the below figure:




## 1.3 List of compatible probes

Contact your Germitec authorized representative to obtain a complete list of compatible probes.

The only probes that are compatible (probes) with the Chronos® device are those with a barcode ring mounted by a Germitec authorized representative during installation. These probes are compatible with the Chronos® device and recognized in the Chronos® device and thus can be used automatically in the Chronos® device.

The UST-5712 is non-compatible with the Chronos® device.

## 1.4 Accessories

The Chronos® may be used with an optional label printer provided by Germitec. The printer is supplied with a power cable and USB connection to plug it to the Chronos® device. If the user wishes to keep a written record or log of each HLD cycle, a customizable number of labels is printed with the details, at the end of each cycle.

The Chronos® also comes with its designated power cable, a set of rings that are used to identify those ultrasound probes that fall within the list of ultrasound probes that can be disinfected by the Chronos®. Each identifying ring must be installed on the ultrasound probe by a Germitec Authorized Service Representative. A quartz plate is also supplied with the Chronos® and should be placed inside the disinfection chamber by a Germitec Authorized Service Representative at the time of Chronos® installation. An Ethernet cable is supplied as well to provide access to an interface that is used to trace Chronos®'s use and performance.

## 1.5 Technical characteristics

| | |
|---|---|
| Cycle time | Dependent on the target dose of UV-C that is specific to the ultrasound probe model.<br>A typical cycle time is 90 seconds and never more than 5 minutes. |
| External dimensions | 40.1” height x 14.9” width x 16.9” depth<br>(H102 x W38 x D43 cm) |
| Weight | 79 pounds (36 kg) |
| Disinfection chamber dimensions (internal) | 22.1” height x 11.1” width x 11.1” depth<br>(H56 x W28 x D28 cm) |
| Power supply | 120-240 V / 50-60 Hz |
| Power consumption | 495 W |
| Disinfection efficacy | High-Level Disinfection |
| External operating temperature | Between 50 °F and 104 °F (+10°C to +40°C) |
| Maximum relative humidity | 90% without condensation |
| Maximum operating altitude | 6500 ft (2000 m) |

# 2 INTENDED USE AND INDICATIONS

## 2.1 Intended use

The Chronos® is indicated for use in a healthcare environment to achieve High-Level Disinfection (HLD) of the surfaces of external, transvaginal and transrectal ultrasound probes that do not contain lumens and that do not contain indentations or channels that are deeper than their widths.

## 2.2 Indications for use

The Chronos® is indicated for use in a healthcare environment to achieve a High-Level Disinfection of the surfaces of external, transvaginal and transrectal ultrasound probes that do not contain lumens and that do not contain indentations or channels that are deeper than their widths.

## 2.3 General information on selection and use of germicides for medical device reprocessing

The US FDA classifies sterilant and high-level disinfectants according to an adapted Spaulding classification scheme. Under this scheme:

- Critical devices are introduced directly into the bloodstream or contact a normally sterile tissue or body space during use. Critical reusable devices must be sterilized between uses. A sterilant destroys all viable forms of microbial life, when used according to its labelling.
- Semi-critical devices contact intact mucous membranes and do not penetrate the blood barrier or otherwise enter normally sterile areas of the body but may contact broken skin (such as use of external ultrasound probes on broken skin). Semi-critical reusable devices should also be sterilized between uses whenever feasible, but at a minimum, high level disinfection is acceptable. A high-level disinfectant inactivates all microbial pathogens, except large numbers of bacterial endospores, when used according to its labeling.

Therefore, users should choose a germicidal method that is appropriate for the reusable medical device and the level of antimicrobial activity suitable for the intended use of the reusable device. The Chronos® provides a High-Level Disinfection for ultrasound probes used for external (transcutaneous) or intracavitary examinations. Each ultrasound probe should be cleaned after each use in a patient according to the ultrasound probe manufacturer's instructions before being placed in the Chronos®, where a HLD can be achieved according to the instructions provided below.

# 3 CONTRAINDICATIONS

The Chronos® is not intended to be used as a sterilizer for ultrasound probes. Probes that require complete sterilization for safe re-use should be sterilized in accordance with the manufacturer's instructions for any ultrasound probe that requires sterilization.

Only ultrasound probes that Germitec lists as suitable for HLD in the Chronos® may be disinfected in the device. Any probe not included in the list of probes certified for HLD by Germitec may not be properly disinfected if placed in the Chronos® device. Any probes deemed not suitable for HLD should be disinfected according to the manufacturer's instructions using the alternate method(s) identified by the probe manufacturer.

# 4 PRECAUTIONS

## 4.1 Training

The device's owner is responsible for:

- All users are trained according to the instructions and warnings contained in this manual.
- All users are aware of the risks and the preventive measures described in this manual.

## 4.2 Precautions for use

- Installation of the Chronos® should be performed by a Germitec Authorized Service Representative and maintenance should be performed in accordance with the indications set out in Section 0 "Scheduled maintenance".
- The Chronos® is an automated, High-Level Disinfection system that must be part of a general probe-handling protocol that includes initial cleaning according to the ultrasound manufacturer's instructions prior to HLD in the Chronos®.

- The Chronos® must be used in compliance with the operating procedure described in Section 7 "Use".
- The Chronos® should be used in a clean and dust-free environment.
- The Chronos® is only approved for medical uses to achieve HLD of ultrasound probes. Only surface (e.g., abdominal) or endocavitary ultrasound probes should be placed in the disinfection chamber.
- The Chronos® is intended to be used exclusively in healthcare facilities by trained health professionals in accordance with this user manual.
- Disinfect only one probe at a time.
- The Chronos® is not indicated for device sterilization.
- Do NOT use the Chronos® for reprocessing single-use devices.
- Do NOT use the Chronos® if the surface of the ultrasound probe is broken or defective.
- Do NOT use the Chronos® to pre-clean ultrasound probes. Probes must be pre-cleaned BEFORE each ultrasound probe is disinfected in the device. See Section 7.3 for pre-cleaning instructions. Ensure that all traces of ultrasound gel and debris are removed from the probe before placing it in the HLD chamber of the Chronos®.
- If each ultrasound probe is not first cleaned according to the manufacturer's instructions, there is a risk that the disinfection cycle may be unable to provide High-Level Disinfection.
- The Chronos® is not a storage cabinet. Do NOT leave probes inside the chamber after disinfection. Any probes left in the chamber for more than 60 minutes must be disinfected again.
- The product has a safety interlock to prevent the chamber door from being opened during a disinfection cycle. The safety interlock also prevents the disinfection cycle from starting if the door is open. In case of inadvertent opening of the door, the circuit will shut off automatically to stop UV-C lamp from operating. Do NOT force open or damage the chamber door safety interlock.
- Only probes fitted with a ring and barcode can be disinfected with Chronos®.
- Do NOT modify the device or attempt to circumvent the device's sensors and safety features, or serious permanent injury could result.
- Do NOT attempt to remove or reposition the ring or affix a ring to a new or different probe.
- Do NOT immerse the ring in any liquid.
- Do NOT spread liquid inside and over the Chronos®.
- During the disinfection cycle, maintain a distance from the Chronos® of at least 12 inches (30 cm).

## 4.3 Use of accessories

- The Chronos® must only be used with ultrasound probes that have a ring and optically scannable barcode mounted on the ultrasound probe cable. The installation of the ring must be performed by a Germitec Authorized Service Representative.
- The use of accessories, transducers, and cables other than those specified or provided by the equipment manufacturer may increase electromagnetic

emissions or reduce the equipment's immunity to interference from other devices, potentially leading to inappropriate operation.
- To allow the Chronos® to communicate with the Germitrac communication interface, the Chronos® must be used with the Ethernet cable provided.

## 4.4 Handling precautions

- The Chronos® weighs approximately 79 pounds (36 kg). Use safe handling techniques, in accordance with the health and safety rules at your place of work.
- Do NOT subject the Chronos® to any impacts. If it falls or is damaged, return it to the manufacturer for evaluation and repair or contact a Germitec Authorized Service Representative.
- Do NOT use the Chronos® if there is any evidence of damage. Instead contact a Germitec Authorized Service Representative.
- Do NOT force open the door, especially not during an operating cycle.
- Do NOT attempt to disassemble or repair the device. The Chronos® must be repaired exclusively by the manufacturer or contact a Germitec Authorized Service Representative. Opening the equipment's rear panels by anyone other than a Germitec Authorized Representative will void the warranty.
- Do NOT bypass the equipment's safety systems and interlock.
- Incorrect loading of the probe in the disinfection chamber may damage the probe. The probe must NOT touch the walls of the disinfection chamber. To find out more about the proper positioning of the probe, consult Section 6.3 "Installation", if more information is needed, contact a Germitec Authorized Service Representative.

## 4.5 Environmental precautions

- Use the Chronos® and its accessories at temperatures between 50°F and 104°F/10 and 40°C, and at a relative humidity of less than 90%.
- The Chronos® and its accessories may be stored at temperatures between -14°F and 122°F/-10°C and 50°C.
- Avoid using the Chronos® device adjacent to other equipment (2 to 3 inches, 5 to 7 cm) or stacked on top of other equipment as this may result in incorrect operation. If this type of use is necessary, the operation of this equipment and any other equipment must be observed to verify normal operation.
- Portable RF communication devices should not be used (including peripherals such as antenna cables and external antennas) at less than 12 inches (30 cm) from any part of the Chronos®, including the cables specified by the manufacturer. If not, the performance of such equipment may be adversely affected.

## 4.6 Electricity

- The Chronos® must be connected to a grounded power outlet. Ensure that the power cable used is the one provided with the equipment. This product is categorized as Class 1 electrical equipment, and therefore, designed to be connected to a protective ground. Failure to use a properly grounded connection may expose users to the risk of an electric shock.
- The Chronos® must be connected to an AC power supply that has a voltage between 120 and 240 VAC / 50-60 Hz. Check that the power source is in accordance with is indicated on the label. Connect the equipment only to a

power supply having the appropriate voltage and frequency. The use of an incorrect voltage or AC frequency may damage the equipment.

- Only power cables provided with the Chronos® may be used to plug it in.
- The power cable is used as a circuit-breaker (cut-off) for electrical power if necessary) and must therefore be accessible.
- The user must take precautions to prevent the ingress of liquids into the equipment (other than liquids intended for maintenance; see Section 9 “Maintenance”). Please do not use unauthorized liquids within the Chronos®. If unauthorized liquids are accidentally introduced, it may create an electrical hazard, please contact a Germitec Authorized Service Representative if unauthorized liquids enter the Chronos®.

## 4.7 UV-C lamp and radiation precautions

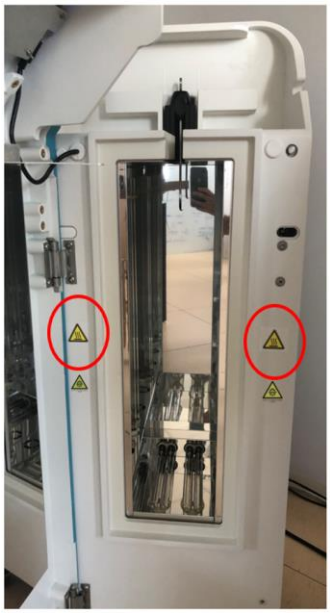
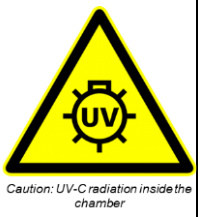
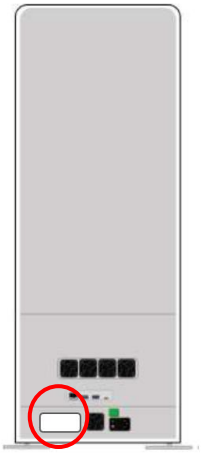
- Do NOT attempt to disassemble the Chronos®, as unauthorized or improper disassembly may create a UV-C leak risk.
- Do not use Chronos® if any UV-C lamps are broken or missing.
- UV-C lamps can only be replaced, cleaned, and maintained by Germitec Authorized Service Representatives.
- Only UV-C lamps supplied by Germitec may be placed in the Chronos®.
- Do NOT clean the UV-C lamps.
- Do NOT clean behind and in immediate proximity to the UV-C lamps.

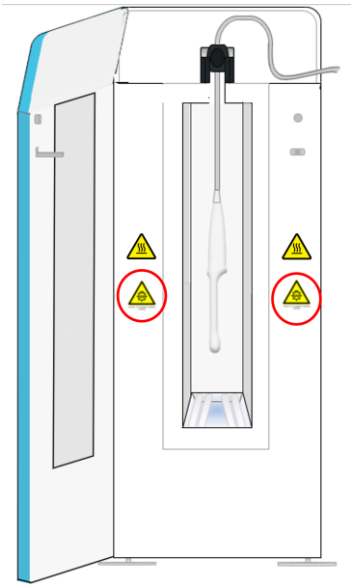
## 4.8 Cybersecurity

- Do NOT write down your Germitrac interface password
- Users should connect to the RJ45 interface of Chronos® with a computer respect your Health Deliver Organization’s network security protocol, and have anti-virus/anti-malware installed.
    - The computer must have a recent web browser application installed (e.g. Chrome, Firefox, Edge, Opera 2018 version or later).

# 5 LABEL, SYMBOLS AND WARNINGS

## 5.1 Label and symbols

| Symbol | Symbol meaning | Positioning |
|---|---|---|
|  | **Hot surface**<br>Do NOT touch the tubes within 2 minutes after the end of a cycle. | On each side of the entrance of the disinfection chamber<br> |
| <br>*Caution: UV-C radiation inside the chamber* | **Risk of exposure to UV-C radiation**<br>This symbol acts as a reminder that UV-C radiation is emitted inside the equipment. The system is designed to prevent the exposure of users to UV-C radiation. Never expose yourself to UV-C radiation. | On the label<br><br>at the back |

| | | |
|---|---|---|
| | | <br>at the front<br> |
|  | **Do not dispose of the specified material with municipal waste**<br><br>This symbol indicates that waste originating from electrical and electronic equipment (WEEE) must be handled with care and must not be disposed of with unsorted municipal waste. WEEE can pollute the environment and must be handled in a waste stream that is appropriate for WEEE. Contact the manufacturer or a company specialized in waste disposal to handle the disposal of this equipment. | On the label |
|  | **Manufacturer**<br><br>This symbol adjacent to Germitec indicates that Germitec is the manufacturer of this equipment. | On the label |

| | | |
|---|---|---|
|  | **Information in the manual**<br>This symbol indicates that the user must read the manual before using the device. | On the label |
|  | **Manufacturing date**<br>This symbol indicates the manufacturing date (YYYY-MM-DD) of the device. | On the label |

## 5.2 Warnings

- The equipment must be used in accordance with the instructions given in this manual, in particular:
  - by the users and in the environment described in Section 1.2,
  - for the claimed use and intended use described in Sections 2.
- Using the equipment in any other way is prohibited and contraindicated by the manufacturer as, if not used according to the manufacturer's instructions:
  - The user and third parties may be seriously injured.
  - The equipment's interlock could be undermined.
  - The equipment may be damaged.
  - The probes may be degraded.
  - The adjacent equipment and environment may be at risk and may be harmed.
- Do NOT touch the tubes within 2 minutes after the end of a cycle to avoid burns.
- All processes associated with commissioning an ultrasound probe for High-Level Disinfection with the Chronos®, including fixing a ring on a probe cable, must be performed by a Germitec Authorized Service Representative. Improper installation by the user may result in a risk of probe incompatibility, inadequate disinfection, or damage to the ultrasound probe.
- Obey all instructions for proper operation and installation of the Chronos® device. If the procedures, as described in these instructions, are not performed, the equipment's interlock could be weakened, the equipment may be damaged, the user and third parties may be seriously injured, the probes may be degraded, and adjacent equipment and the environment may be at risk.
- Do NOT attempt to disassemble the equipment, as this may result in electrocution.
- Darkly pigmented fungi spores (e.g., Aspergillus brasiliensis) may form and thus the Chronos® device may not achieve a HLD when exposed to UV-C light within the design specifications of the Chronos®.

- Do NOT perform cleaning inside the disinfection chamber within the first 2 minutes following a disinfection cycle. The tubes are still hot and present a burn hazard.

- In case of UV-C lamp breakage:
    - **Evacuate the room then air out for 5-10 minutes to outdoor environment and shut off central forced air conditioning.**
    - Do not vacuum the breakage as a means of removing debris from the lamp.
    - Collect broken glass with gloves and visible powder with stiff paper or cardboard and pick up remaining small fragments by using sticky tape.
    - Place cleanup materials in a sealable and hazardous waste container and check with your local government about disposal requirements in your area or contact Germitec Authorized Service Representative for support.
- Do not remove the broken ends of the lamp from their receptacles in the chamber. Contact a Germitec Authorized Service Representative to perform the UV-C lamp replacement.
- For the broken pieces, follow the EPA guide: “Cleaning Up a Broken CFL” (https://www.epa.gov/cfl/cleaning-broken-cfl).
- The user should never allow himself or herself to be exposed to UV-C radiation from the Chronos® device. Acute overexposure may result in:
    - incapacitation due to eye discomfort
    - skin lesions resulting in erythema, redness of the skin similar to sunburn, but without tanning. If exposure occurs, please contact your physician, or go to the nearest healthcare facility.

# 6 INSTALLATION, ADJUSTMENTS, AND COMMISSIONING

## 6.1 Packaging contents

The packaging contains the following components:

- 1 x Chronos
- 1 x Quartz plate
- 1 x AC power cable
- 3 x Kits of rings for probes
- 1 x Ethernet network cable (RJ45)
- 1 x User manual
- 1 x Label printer (option)
- 1 x Label roll (option)

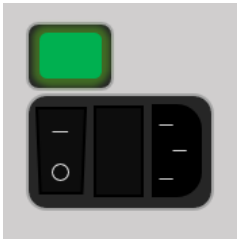
## 6.2 Presentation of the interfaces

### Connection to the AC power

The AC power connector is positioned at the lower rear part of the equipment.

Connection to AC power is made with the IEC-standard cable (AC power cable) provided with the equipment. Plug it into a power socket.

To turn the system on, put the switch in position (-), and the indicator lamp should turn green.

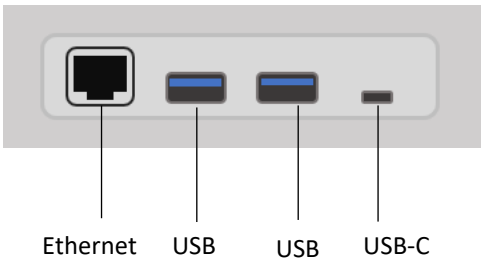


To turn the system off, please see section 7.2 Switching off the Chronos®.

### Peripheral connection interface

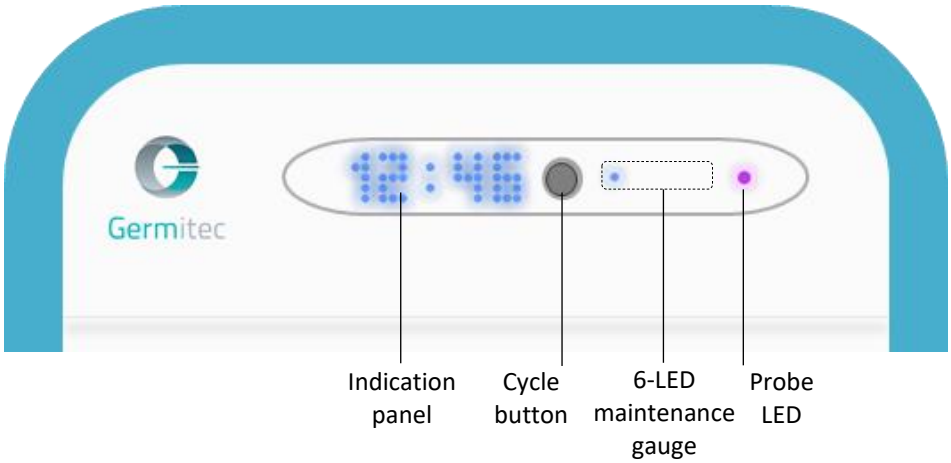
The other connectors (1 Ethernet and 2 USB) are located just above the equipment's rear panel. The connector's green LED lights up when the Ethernet connection is set.

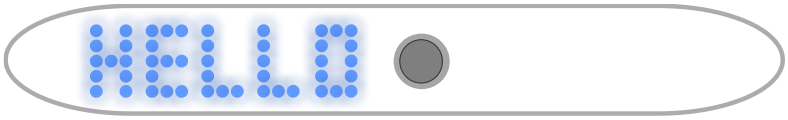
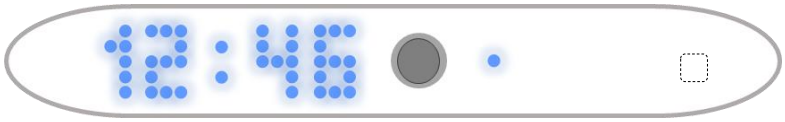
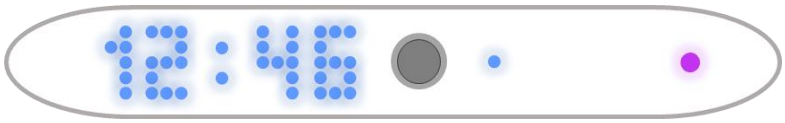
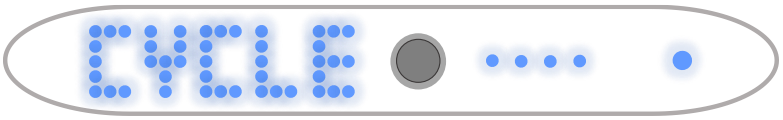
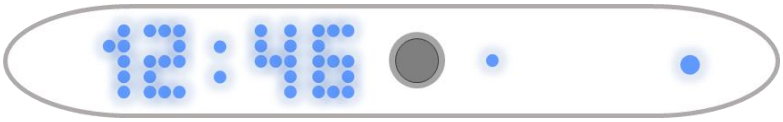
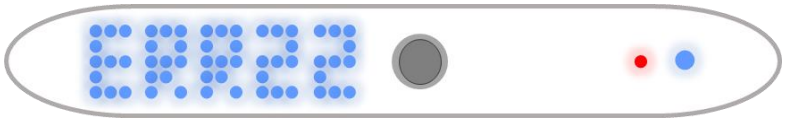
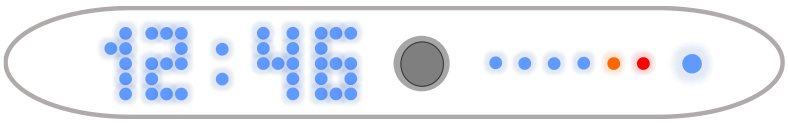
The USB-C port on the lower right is the port for software installation; this port is deactivated during standard use, and consequently not available to the user for connection.




### User interface

The user interface is at the top of the door.



| Display | Meaning |
|---|---|
|  | Startup in progress |
|  | - Time display (in blue LEDs)<br>- Probe LED not lit =<br>no probe identified inside |
|  | Probe LED purple = the probe is identified and considered NOT DISINFECTED |
|  | - “Cycle” display: Disinfection cycle on-going<br>Probe LED flashes in blue |
|  | Probe LED blue = the probe is DISINFECTED |
|  | - A red LED = An error code<br>Check in Section 0<br>the recommended actions associated to the displayed error, here ERR22. |
|  | Maintenance gauge:<br>- The number of blue lights increases when maintenance approaches. |

| | |
|---|---|
| | - Fifth LED orange = Maintenance should be programmed<br>- Sixth LED red =<br>Maintenance out of date<br>See Section 0. |

## 6.3 Installation

### 6.3.1 Placement

The equipment must be installed on a hard and flat floor.

A gap of at least 7.9” (20 cm) must be left at the rear between the equipment and the closest wall.

Once the equipment has been positioned, the quartz protective plate can be installed. Please note that the quartz protective plate is installed by Germitec Authorized Service Representative (cf. Technician manual)

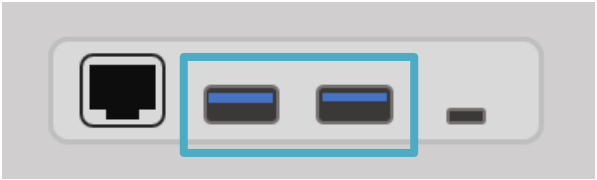
### 6.3.2 Connection to electrical power

- Connect the power cable to the IEC connector at the rear of the Chronos®.
- At the other end, plug it to a 16-Amp power outlet (2P+G).
  This outlet must be protected by a 3 A circuit-breaker on 240 VAC or a 6 A circuit-breaker on 120 VAC.

### 6.3.3 Connection of accessories

*Never connect peripheral devices (printers, memory devices, etc.) other than those indicated below.*

- To connect the equipment to a computer or a local Ethernet network, insert one side the Ethernet cable to the Ethernet connector at the equipment’s rear panel and the other side to a network outlet.
- To connect the equipment to a label printer, plug the printer's cable to one of the two USB connectors located in the equipment’s rear panel.



- Plug the printer to a power outlet using the cable provided.



*Only printers provided by Germitec are compatible with the Chronos®.*

*The use of any other printer does not guarantee the proper operation of the system.*

### 6.3.4 Installation of rings on probes

To be disinfected with the Chronos®, each probe must first be fitted with a ring incorporating a barcode to identify it.

These rings must be installed exclusively by a Germitec Authorized Service Representative.

Contact your Germitec Authorized Service Representative if there is no ring on the probe cable.



*Only probes fitted with a ring and barcode may be disinfected using the Chronos®.*

*The user should not attempt to remove or reposition the ring or affix a ring to a new or different probe. All processes associated with commissioning an ultrasound probe for High-Level Disinfection with the Chronos®, including configuring a ring on a probe cable, must be performed by a Germitec Authorized Service Representative. Improper installation by the user may result in a risk of probe incompatibility, inadequate High-Level Disinfection, or damage to the ultrasound probe.*

# 7 USE

## 7.1 Switching on

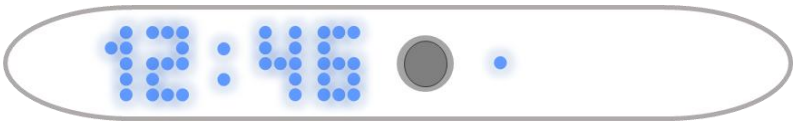
*As for any electrical equipment, malfunctions may arise over the lifetime of the product. Therefore, before switching on, ensure that the installation steps described above have been properly completed and ensure that maintenance has been performed in accordance with the indications set out in Section 9 "Scheduled maintenance". In the event that these operations are not performed, the equipment's interlock could be undermined; the equipment may be damaged; the user and third parties may be seriously injured; the probes may be degraded; and adjacent equipment and the environment may be at risk.*

- To turn the system on, put the switch in the on position (-) (located at the bottom rear of the device).

The green indicator lamp lights. 'HELLO' is displayed on the panel during the startup sequence (about 30 seconds). A melody indicates the end of the startup, and the system is now ready for use.

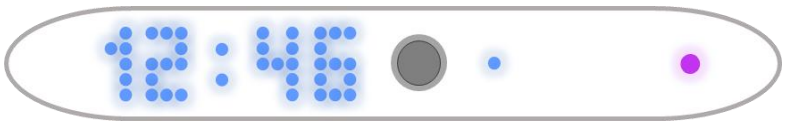
In the event of any malfunctions being observed when switching the device on, refer to Section 0 "Troubleshooting".

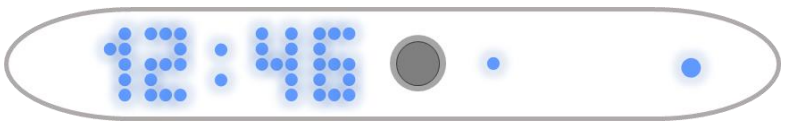
Once the equipment is switched on, and as long as a cycle has not been initiated, the interface displays the time and the maintenance indicator LED:



The powered Probe LED on the far right indicates proper recognition of a probe:

- the purple color corresponds to a probe that is NOT DISINFECTED (top picture below),
- the blue color indicates that the probe has been DISINFECTED (bottom picture below).





To switch on the printer, press the ON button ( ⏻ circled in blue in below picture).




## 7.2 Switching off the Chronos®

- To switch off the device, press the button on the user interface located at the top of the door, and hold for at least 3 seconds.

A melody sounds, the interface displays ‘BYE’, then switches off.

- Press the illuminated AC power switch at the rear of the device to position (O).

The green indicator lamp switches off. The Chronos® is now powered off.

Any residual of AC power can be completely removed by disconnecting the AC power cable from the device.

## 7.3 Pre-cleaning of ultrasound probes

### 7.3.1 Good practices reminder: distinguish cleaning from disinfection

The Chronos® is a medical device for High-Level Disinfection of ultrasound probes that must be used in conjunction with the manufacturer’s specific cleaning instructions of the ultrasound probes.

Ensure that the following is performed prior to using the Chronos® device:

- Follow hand hygiene protocols (including use of gloves, hand sanitizer, etc.).
- Follow all precautions and cleaning instructions provided by the ultrasound probe manufacturers.
- Follow your healthcare facility protocols related to the use of gloves, ultrasound gel, and disposable protection (probe sheath or condom). These should be in compliance with local regulatory requirements.
- Be mindful of possible latex allergies in some patients. In such cases, alternative material (e.g., polyurethane, nitrile, etc.) must be used.

**Hygiene best practice: disinfect only what is already clean.**

Prior to placing the ultrasound probe in the Chronos® device for HLD, please make certain the ultrasound probe has been cleaned according to manufacturer instructions.

Please note, cleaning of the ultrasound probe is a mandatory requirement for HLD efficacy, as presented in the statement below:

*Cleaning must always precede High-Level Disinfection and sterilization.*[1]

*Accordingly, the role of disposable protection (probe cover or condom) 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 probe cover or condom as an aid to keeping the probe clean.*[2]

### 7.3.2 Sample Cleaning Protocol

As per best practices, cleaning is:

*the removal of visible soil (e.g., organic and inorganic material) from objects and surfaces*.[3]

An example of cleaning protocol is provided hereafter.

In all cases, the user should adhere to any specific cleaning requirements and instructions provided by the probe manufacturer and should follow any hospital or clinic standard operating procedures to clean ultrasound probes.

- Once the ultrasound exam has been completed, remove any disposable protection from the ultrasound probe (if used) and dispose of the disposable protection according to local requirements.
- Carefully wipe the probe with a clean, dry towel to remove ultrasound gel and any other soiling.
- Carefully wipe the probe with a moist, cleaning wipe as recommended by the probe manufacturer.
- Inspect the probe to ensure that all visible traces (of gel, of soiling, etc.) have been removed.

The probe is now ready for High-Level Disinfection.



*If the probe is not first cleaned, there is a risk that the disinfection cycle may not be able to provide High-Level Disinfection .*

### 7.3.3 Cleaning agent

Consult the instructions of use for each probe to select suitable cleaning agents accordingly.

---

[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, Sep. 2004

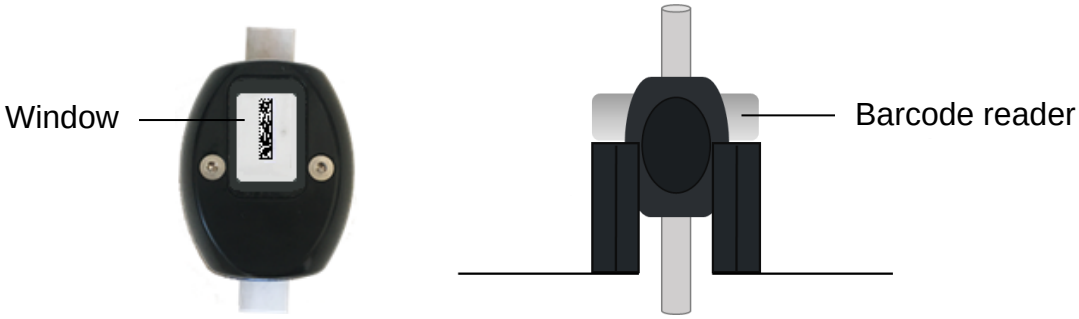
[2] **Guidelines for Cleaning and Preparing Endocavitary Ultrasound Transducers between Patients**, American Institute of Ultrasound in Medicine, Jun. 2003

[3] **Guideline for Disinfection and Sterilization in Healthcare Facilities**, Pr. W. Rutala, D. J. Weber, and the Healthcare Infection Control Practices Advisory Committee (HICPAC), update May 2019

## 7.4 Disinfecting a probe

*Only probes with Germitec's pre-installed rings can be disinfected in the Chronos® chamber. The ring must NOT be moved or removed by the user.*

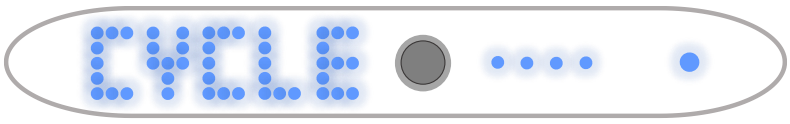
- Open the door of the Chronos®.
- Hang the probe in the chamber by installing its ring in its receptacle. The window must be turned towards the device barcode reader opening.




The Probe LED, on the fac right of the user interface panel turns purple - indicating that an authorized probe is detected inside the Chronos® device but NOT DISINFECTED yet. The Chronos® device beeps simultaneously to the LED switching on.

- Bring the cable out via the side opening.
- Gently close the door.
- Visually check that the cable has not been pinched during closure.
- Initiate the disinfection cycle by pressing the button on the user interface panel.

A beep confirms the cycle initiation. The user interface panel displays “Cycle”:




The LEDs in the gauge LED bar scroll, from left to right, during the cycle.

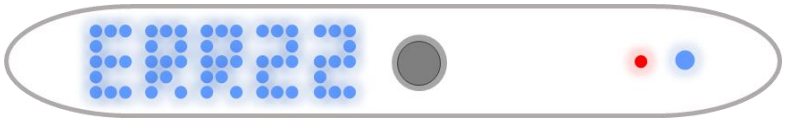
A melody indicates the end of the cycle. The user interface panel displays “CYCLE OK”. The Probe LED on the far right turns blue.

The optional printer, if turned on, prints the defined number of labels.

- Open the door.
- Remove the probe.

If a probe is inside the disinfection chamber and must be removed urgently, press on the button on the user interface pane until “STOP” is displayed on the panel. The cycle is stopped, a sound indicates when the door may be opened, and the Probe LED remains purple meaning that the probe is not considered as DISINFECTED.

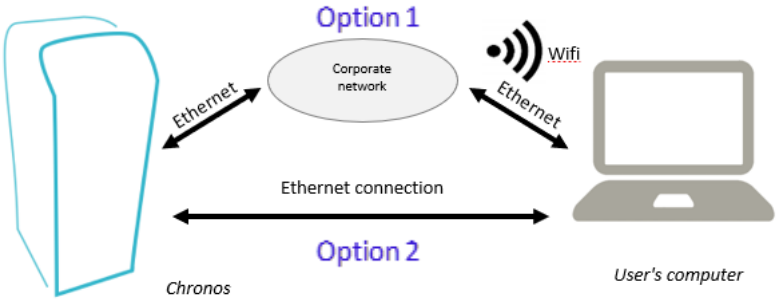
In the event of an error, the cycle is stopped automatically, and the user interface panel displays an error which alternates with a short error name. In this case, refer to Section 0 “Troubleshooting”.



## 7.5 Use of the Germitrac communication interface

Germitrac is the communication interface that allows access to all traceability data relating to the probes disinfected by the Chronos®.

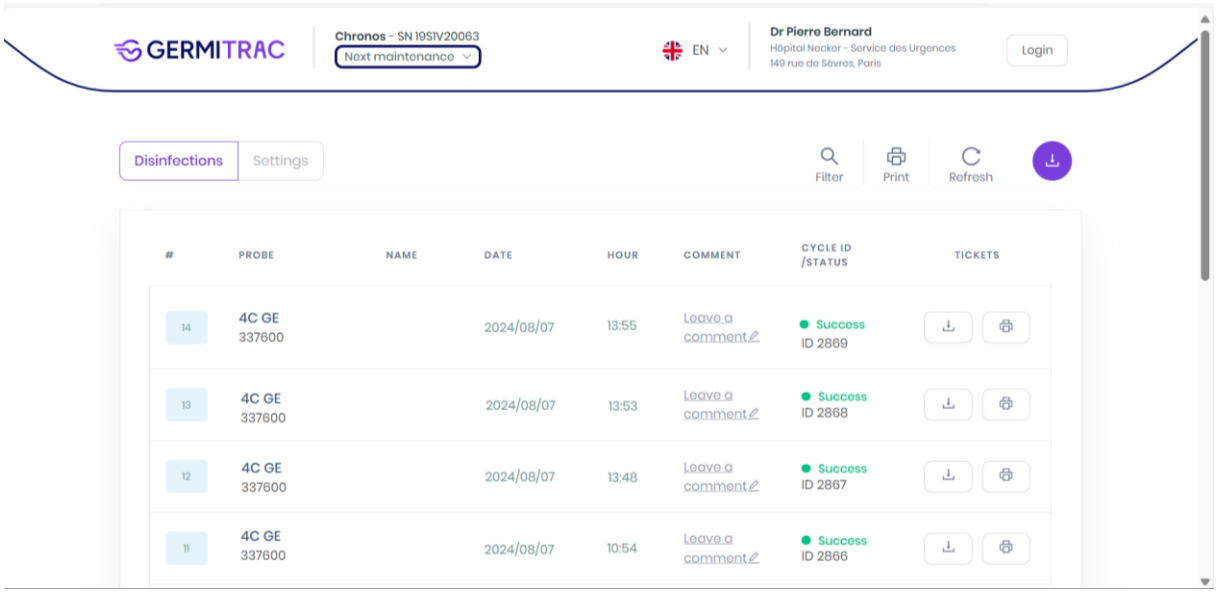
Germitrac is a Webpage hosted on a browser and accessible thanks to a computer connected to Chronos®, via the Ethernet cable (RJ45).




To connect to Germitrac®:

1. Open a web browser application.
2. Type the device’s IP address into the address bar and press enter
    - If you are connected through the hospital network (option 1 figure above), the IP address is given at the end of installation by your Germitec Authorized Service Representative.
    - If you connect directly your laptop to the device (option 2 figure above), you can also use the following address:
        - https://169.254.XX.XX a fix IP address, where XX.XX are the 4 last digits of the serial number of the CHRONOS® (local Ethernet), e.g. https://169.254.03.19 for the CHRONOS® SN 20S1V20319
        - https://CHRONOSXXXX.local with the name of the device, where XX.XX are the 4 last digits of the serial number of the CHRONOS® (local Ethernet), e.g. https://CHRONOS®®0319.local for the CHRONOS® SN 20S1V20319.

3. The Germitrac main page is displayed.




The compatible browsers are indicated below:

| Browser | Minimum version |
|---|---|
| Chrome | 8.0 |
| Internet Explorer | 7.0 |
| Mozilla Firefox | 2.0 |
| Opera | 9 |

### 7.5.1 Germitrac® Main Interface

The main interface is accessible by all users, without any need for login information or password. The page gathers general information on the device and the disinfection cycles.

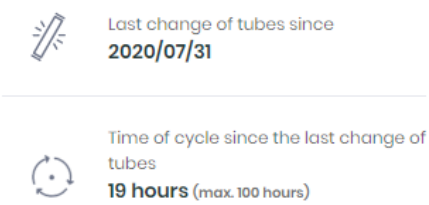
General information is displayed at the top of every page:

- CHRONOS® serial number
- Information about the next maintenance (when to change the tubes)
- Site
  - Main user
  - Site name
  - Address



Information about tube changeover ("Next maintenance") contains two criteria:

- Date of the last change
- Hours of use

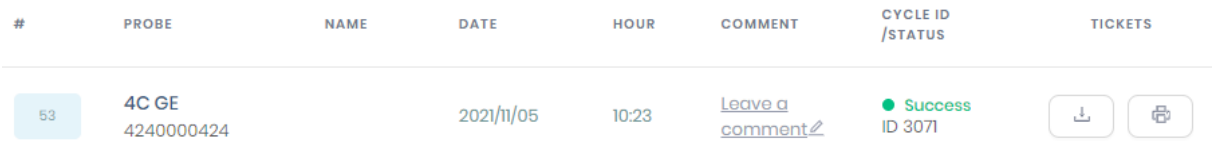



Tubes need to be changed after 2 years of operation or 100 hours of use, **whichever comes first.**

### 7.5.2 Disinfection data

Data from each disinfection cycle is displayed:

- Disinfection number (which is incremented by 1 with each new disinfection)
- Probe model and serial number
- A name for the individual probe which can be set by the end-user (optional)
- Date and time of disinfection
- A comment which can be added by the end-user (optional)
- Disinfection result: Success or Failure, with any appropriate notifications about what disrupted the cycle
- The unique cycle ID
- Ticket




### 7.5.3 Filters

The data on the main page can be filtered on:

- Probe model
- Probe serial number
- Probe username
- Date range
- Comment
- Disinfection status

Several filters can be applied simultaneously.

### 7.5.4 Downloading data

The download button  allows the end-user to download data in the form of a .csv file which can be opened with software like Excel, to safeguard their records.

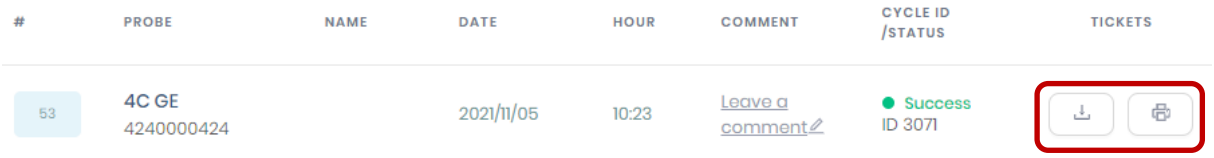
This file contains all disinfection cycle data **returned by the selected filters**.

The printing button at the top of the page allows the user to print the disinfection table for the page displayed with the web browser used.



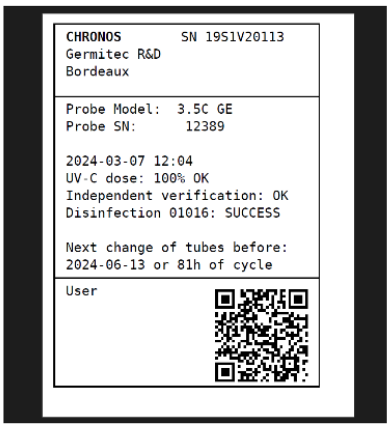

*It is recommended that data be backed up daily. It is also recommended that a security backup be performed to transfer data to another drive. Germitec may not, under any circumstances, be held responsible for the loss of data stored in the equipment.*

### 7.5.5 Managing tickets




The  button allows the user to download the ticket of a cycle as a .pdf file.

The  button enables the ticket to be printed on the printer connected to the CHRONOS®.



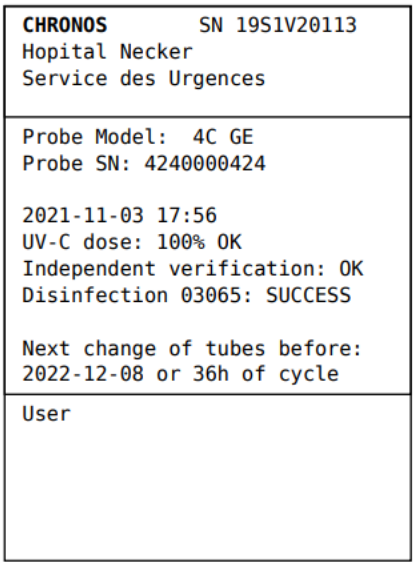

## 7.6 Label printing

To print one or more labels, ensure that there are blank labels in the printer.

> *Only printers provided by Germitec are compatible with the Chronos®.*
>
> *The use of any other printer does not guarantee the proper operation of the system.*

### 7.6.1 Label traceability data

The labels display all traceability data associated with a disinfection cycle.




*Device identification (name, serial number)*

*Name of the healthcare center*

*Probe identification (model, serial number)*

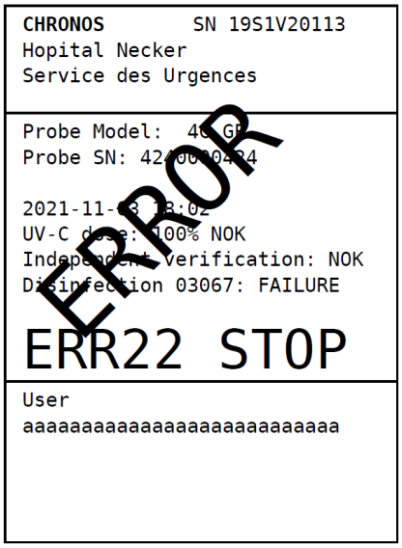
*Disinfection cycle data*
*(date and time, percent of targeted UV dose – OK or NOK, result of the verification by the internal independent monitoring system – OK or NOK, disinfection unique ID, final disinfection status: SUCCESS or FAILURE)*

*Information regarding the next change of UV-C tubes*

*User field (free use or comments completed in Germitrac)*
*QR code*

### 7.6.2 Label in the event of a disinfection failure

In the event of any disinfection failure, regardless of the origin, the failed status of the disinfection is clearly indicated on the label.




*Device identification (name, serial number)*

*Name of the healthcare center*

*Probe identification (model, serial number)*

*Disinfection cycle data*
*(date and time, percent of targeted UV dose – OK or NOK, result of the verification by the internal independent monitoring system – OK or NOK, disinfection unique ID, final disinfection status: SUCCESS or FAILURE)*

*Error identification (code, short name)*

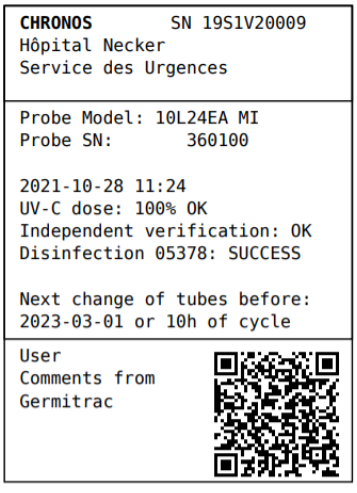
*User field (free use or comments completed in Germitrac)*
*QR code*

In this case, consult the error messages in Section 0 to determine the origin of the failure and take the steps necessary to resolve the problem and proceed with another disinfection cycle for the probe.

### 7.6.3 QR code on the ticket

The option “QR code on the ticket in Germitrac” can be activated by a Germitec Authorized Service Representative.

The QR code appears in the bottom part of the ticket.
It is readable with a QR code reader.




Information is included as a serialized string text with a field separator as ‘|’:

SN of the Chronos: Text, 10 chars | Probe Model: Text, up to 10 chars | Probe SN: Text, up to 10 chars | Cycle ID: Number, up to 5 digits | Date: Number, 8 digits, format: YYYY-MM-DD | Time (in local hour): Number, 4 digits: HH:MM | Result: Text, 1 char, S for « Success » or F for « Failure » | Comment: Text, up to 32 chars

Example:

‘19S1V20009|10L24EA MI|360100|5378|2021-10-129|11:14|S|Comments from Germitrac’

# 8 ROUTINE CARE

## 8.1 External cleaning

For cleaning the outside of the Chronos® device and the ring, use a cloth or paper cloth, dampened with water or standard hospital disinfectant.

> *Do NOT spread liquid within or on the Chronos®.*
>
> *Do NOT immerse the ring in any liquid.*

## 8.2 Cleaning internal walls

The internal surfaces of the Chronos® disinfection chamber should be cleaned only by a Germitec Authorized Service Representative during annual maintenance operations.

> *Cleaning of internal surfaces must be performed by a Germitec Authorized Service Representative.*
>
> *Do not spread liquid inside the chamber.*
>
> *In case of visible dirt inside the chamber, please contact your Germitec Authorized Service representative.*

## 8.3 Replacing printer paper

> *Use only the label format provided by Germitec with the printer.*
>
> *Use only the printer provided by Germitec*

- Switch off and unplug the printer and open the top cover.
- Place the cylindrical holder into the label roll.
- Insert the end of the roll in the slot as shown in the figure:




- Close the cover.
- Plug and switch on the printer and press the power button.

# 9 SCHEDULED MAINTENANCE

Scheduled maintenance must be performed every year (12 months).

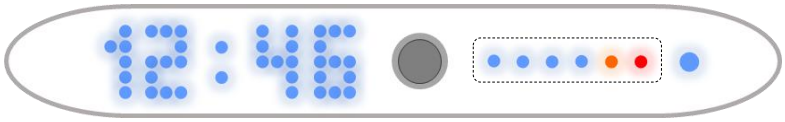
> *Non-compliance with this period and the recommended operations may result in dangerous situations as the equipment's interlock could be undermined; the equipment may be damaged; the user and third parties may be seriously injured; the probes may be degraded; and adjacent equipment and the environment may be at risk.*

Only Germitec Authorized Service Representatives are authorized to perform maintenance operations on the Chronos®.

Please contact your Germitec Authorized Service Representatives for the scheduled maintenance.

The UV-C tubes must be replaced every 2 years or every 100 hours of cumulative cycle time (whichever comes first). The duration of use of the UV-C tubes is indicated by LED indicators, as follows:

From left to right, the 6-LEDs indicate the extent of equipment use before the next tube change and signal when UV-C tubes need to be changed. When the sequence of LEDs ends with the orange LED (5th LED), it is recommended that a maintenance intervention be scheduled with a Germitec authorized representative. When the red LED in the sequence of LEDs is switched on red (6th LED), it is recommended to perform a maintenance intervention as soon as possible.



Scheduled maintenance includes:

- A general system check
- A cleaning of external and internal parts
- The replacement of worn parts, the UV-C tubes, if necessary
- The calibration of the photodiodes
- The replacement of the ventilation filter, if necessary
- Update of the firmware/software, if necessary
- Verification of the event log files to detect any cybersecurity event. In case of cybersecurity events, users will be informed, and necessary precautions will be taken.

The Germitec Authorized Service Representative disposes of the used UV-C tubes in accordance with local regulatory requirements.

Operations of firmware/software update will include any update necessary to maintain security of the Chronos® device. A security software update will include any patches needed to address new vulnerabilities, as well as any security updates related to off-the-shelf software components. Updates must only be performed by Germitec Authorized Service Representatives. If the update is minor, it will be performed during the scheduled maintenance, if the update is major and linked to a critical vulnerability, the user will be notified, and a corrective maintenance will be planned in a timely manner.

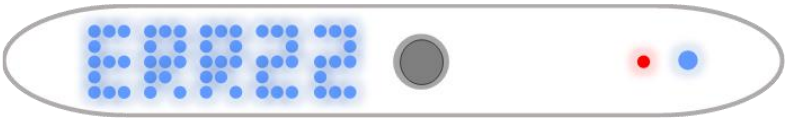
# 10 TROUBLESHOOTING

## 10.1 System errors

The Chronos® is equipped with numerous sensors (temperature, optical, etc.) which monitor the device to ensure proper operation.

If the Chronos® detects a malfunction during the cycle, even if only temporary, UV-C emission is stopped and the system enters into error mode.

The system displays, on the user interface panel, the code corresponding to the error.



Below is a list of Error codes and possible debugging actions. If the error persists after several attempts to debug the device, contact your Germitec Authorized Service Representatives.

| *Error code* | *Error meaning* | *Possible debug action* |
|---|---|---|
| **ERR01 START** | Failure of initialization | Acknowledge the error by pressing the button on the user interface panel.<br>If the error occurs again, switch off the device, check if the power cable is well plugged in, and restart the device. |
| **ERR02 DETEC** | Barcode not valid | Check that the ring is correctly placed in the receptacle. Visually check that the barcode is legible by the barcode reader in the ring's window. |
| **ERR03 START** | Failure of the barcode reader initialization | Acknowledge the error by pressing the button on the user interface panel.<br>If the error occurs again, switch off the device, check if the power cable is well plugged in, and restart the device. |
| **ERR04 DOOR** | Door not closed properly | Make sure the door is properly closed.<br>Acknowledge the error by pressing the button on the user interface panel, open and close the door, and restart the cycle. |
| **ERR05 LOCK** | Door lock not properly engaged | Acknowledge the error by pressing the button on the user interface panel, open and close the door, and restart the cycle. |

| *Error code* | *Error meaning* | *Possible debug action* |
|---|---|---|
| **ERR06 PROBE** | Loss of probe detection during the cycle (for example, ring moved up by pulling the cable) | Acknowledge the error by pressing the button on the user interface panel, verify the ring position and restart the cycle. |
| **ERR07 HOT** | Detection of too high temperature in the chamber | Check if the ventilation is activated.<br>Check that there is a free space of at least 7.9 inch (20 cm) behind the device.<br>Check that the external temperature is below 104 F (40°C).<br>When all the above conditions have been checked, wait 5 minutes for the system to cool, preferably by leaving the door open, then acknowledge the error by pressing the button on the user interface panel. |
| **ERR08 TUBE** | UV-C tube or its power supply is not operating properly | Acknowledge the error by pressing the button on the user interface panel, open the door, check visually that nothing seems abnormal on the tubes, check that the LED bar has not reached the red level (it would mean that the maintenance due date is passed), and restart the cycle. |
| **ERR09 CUVE** | Detection of unusual light distribution | Acknowledge the error by pressing the button on the user interface panel, open the door, check that no object has been forgotten in the chamber and that visually everything is clean, then restart the cycle.<br>Pay attention to not move the device during a cycle. |
| **ERR10 EVO1** | Detection of unusual light distribution | Acknowledge the error by pressing the button on the user interface panel, open the door, check that no object has been forgotten in the chamber and that visually everything is clean, then restart the cycle.<br>Pay attention to not move the device during a cycle. |
| **ERR11 EVO2** | Detection of unusual light distribution | Acknowledge the error by pressing the button on the user interface panel, open the door, check that no object has been forgotten in the chamber and that visually everything is clean, then restart the cycle.<br>Pay attention to not move the device during a cycle. |

| *Error code* | *Error meaning* | *Possible debug action* |
|---|---|---|
| **ERR12 PREV1** | Detection of unusual light distribution | Acknowledge the error by pressing the button on the user interface panel, open the door, check that no object has been forgotten in the chamber and that visually everything is clean, then restart the cycle.<br>Pay attention to not move the device during a cycle. |
| **ERR13 PREV2** | Detection of unusual light distribution | Acknowledge the error by pressing the button on the user interface panel, open the door, check visually that no object has been forgotten in the chamber and that everything is clean, then restart the cycle.<br>Take care to not move the device during a cycle. |
| **ERR14 DELAY** | Maximum cycle time exceeded | Acknowledge the error by pressing the button on the user interface panel, open the door, check visually that no object has been forgotten in the chamber and that everything is clean, then restart the cycle. |
| **ERR15 DELAY** | Reserved for service representative use only. | Error code not possible to occur with the user. |
| **ERR16 UV3** | Invalidation of the cycle by the independent monitoring system | Acknowledge the error by pressing the button on the user interface panel, open the door, check that no object has been forgotten in the chamber and that everything is clean, then restart the cycle.<br>Take care not to move the device during a cycle. |
| **ERR17 SOLO** | Reserved for service representative use only. | Error code not possible to occur with the user. |
| **ERR18 SOLO** | Reserved for service representative use only. | Error code not possible to occur with the user. |
| **ERR19 DEVIA** | Reserved for service representative use only. | Error code not possible to occur with the user. |

| *Error code* | *Error meaning* | *Possible debug action* |
|---|---|---|
| **ERR20 CREDT** | Reserved for service representative use only. | Error code not possible to occur with the user. |
| **ERR21 CALIB** | Reserved for service representative use only. | Error code not possible to occur with the user. |
| **ERR22 STOP** | Cycle manually stopped by a long press on the button | Acknowledge the error by pressing the button on the user interface panel.<br>Restart the cycle. |
| **ERR23 UVOFF** | Incorrect signal from a UV sensor | Acknowledge the error by pressing the button on the user interface panel, open and close the door, and restart the cycle. |
| **ERR24 SIGN** | Incorrect signal from a UV sensor | Acknowledge the error by pressing the button on the user interface panel, open and close the door, and restart the cycle. |

Other situations that are not associated with an error code are listed in the table below along with suggested actions to trouble shoot each situation described.

| *Symptom* | *Checks to be performed / explanations* |
|---|---|
| Nothing is displayed.<br>No sound emitted by the equipment. | Check that the AC cable is well inserted into AC power connector, in the lower rear part of the equipment.<br>Check that the equipment is well connected to the AC supply.<br>Check that the power button is in position 1.<br>Check that the green indicator lamp next to the power connector is illuminated.<br>If no indicators are illuminated, disconnect and replace fuses positioned in the lower rear part of the equipment. |

| | |
|---|---|
| | The fuses must be replaced in accordance with the characteristics indicated on the rating plate (6.3Ah). |
| Impossible to open the disinfection chamber door. | Check that a cycle is not in progress. |
| Impossible to install the probe properly in the disinfection chamber (the Probe LED at the far right of the indication panel does not light) | Check that the ring has been installed on the probe.<br>Check that the barcode is visible through the ring's window.<br>Check that the ring's window is turned towards the barcode reader. |
| The Probe LED at the far right of the indication panel is purple. | This is normal if the probe has not been properly disinfected. The purple Probe LED indicates the presence of a probe that hasn't been DISINFECTED yet. |
| The maintenance gauge on the user interface panel has reached the orange and/or red LED (5 and 6th). | The orange LED indicates that a maintenance intervention should be scheduled soon (about 2 months or 400 cycles remain when this indicator lights for the first time).<br>The red LED indicates that a maintenance intervention must be performed immediately. |
| Impossible to start the cycle when pressing the button. | Check that a probe with a ring has been inserted into the device. |

Your Germitec Authorized Service Representative should be notified of each error requiring an acknowledgement.

In case the Chronos® device is out of service, please refer to your healthcare facility protocols for an alternative method for High-Level Disinfection of the medical devices that would normally be High-Level Disinfected in the Chronos® device.

## 10.2 Cybersecure event monitoring and troubleshooting

All the actions and commands on the different interface, such as USB and Ethernet connection are logged in the Chronos device software system.

All the actions on through the web interface and direct ethernet connection are logged, such as authentication, and different command requests.

During scheduled maintenance, Germitec Authorized Service Representative will analyze the event log data to monitor security compromises and act accordingly if one identified.

If the user/Healthcare Organization detects a cyberattack, the user can urgently request the verification of event logs by a Germitec Authorized Service Representative through corrective maintenance.

In case of a cyberattack and before Germitec Authorized Service Representative intervention, unplug Chronos® device from the network. If there is a risk of impact to the Chronos® device integrity, switch off the device and please refer to the healthcare facility protocols for an alternative method to perform High Level Disinfection.

# 11 TRANSPORTATION OF THE CHRONOS® DEVICE

The Chronos® must be transported in the packaging designed for it, such as the original packaging in which it was shipped.

Once unpacked, the Chronos® can be moved carried by two people. Each person carrying the equipment should grip it with one hand under the device as close as possible to the door and the other hand at the top rear of the device.

Before moving the equipment, ensure it is disconnected from the power supply, remove the quartz protective plate, and close the door.

Comply with the equipment's storage and transport requirements:

- Storage temperature:  between 14 and 122°F /-10 and 50°C
- Relative humidity: less than 90 % non-condensing

# 12 DISPOSAL

The Germitec Authorized Service Representative will dispose of the used UV-C tubes in accordance with local regulatory requirements.

Please note that UV-C tubes must be replaced solely by a Germitec Authorized Service Representative. UV-C tubes replacement performed by an independent 3rd party may result in damage to your device.

# 13 WARRANTY

The Chronos® device is under warranty from the date of delivery, according to Warranty Agreement signed with the Health Facility. This warranty covers defective parts and repair labor. See servicing manual.

The Chronos® device must be repaired exclusively by the manufacturer of the Chronos® device or a repair center authorized by Germitec or Germitec Authorized Service Representative. Contact your Germitec Authorized Service Representative to organize this repair before returning the equipment.

# 14 CONTACT

| MANUFACTURER | LOCAL ENTITY | US AGENT |
|---|---|---|
| GERMITEC<br>19 rue Vauban, 33000<br>Bordeaux, France<br><br>+33 (0)1 49 87 18 00<br>contact@germitec.com | Germitec North America Inc.<br>888 Prospect ST STE 200<br>La Jolla, CA 92037, USA<br><br>customer service:<br>customerservice@germitec.com<br>Support service<br>service@germitec.com | Keith Koby<br>409 El Dorado Pkwy<br>W, Cape Coral,<br>Florida, 33914 |

In case of reportable event, please contact **vigilance@germitec.com**

# APPENDIX – MICROBIOLOGICAL EFFICACY TESTS

A demonstration of effectiveness of the Chronos® device achieving High-Level Disinfection of ultrasound probes was conducted using stringent and rigorous test methods against the following microorganisms.

Microbicidal activity: the following table indicates the spectrum of activity as demonstrated by testing of Chronos® device at minimum effective UV-C dose.

| Microbicidal activity | Organisms |
|---|---|
| **Sporicidal** | *B. subtilis* |
| | *B.pumilus* |
| | *C .sporogenes* |
| **Fungicidal** | *C.aurius* |
| | *C.albicans* |
| | *Trichophyton mentagrophytes* |
| **Mycobactericidal** | *M. terrae* |
| | *M. avium* |
| | *M. bovis* |
| **Bactericidal** | *S. aureus* |
| | *P. aeruginosa* |
| | *S. enterica* |
| | *D. radiodurans* |
| | *P. fungorum* |
| **Virucidal** | *Poliovirus Type 1* |
| | *Adenovirus Type 5* |
| | *Murine Norovirus* |
| | *Vaginal Herpes* |
| | *Polyomavirus* |
| | *HPV16 / HPV18* |

Sporicidal Activity Testing: the following table indicates the sporicidal activity as demonstrated by testing of the Chronos® device following a prolonged contact time (greater than 24h) against most UV-C resistant microorganisms:

| Sporicidal activity | Organisms |
|---|---|
| **Trichomaceae family (spore forming molds)** | *Aspergillus brasiliensis* |
| | *Aspergillus fumigatus* |