GERMITEC®

Your Partner in Preventing Infection.

Chronos® Max



User Manual

MAN-N002-INT Rev 4 / February 2026

Chronos® Max

User Manual

EN

MAN-N002-EN

This manual must be read before using the Chronos® Max device.
This will ensure its use under the safest and most efficient conditions.

For any questions concerning the equipment, its maintenance, breakdowns, or end-of-life, please contact your Germitec Authorized Service Representative.
The accuracy of the High-Level Disinfection device description is based on the version and date of the manual.

The UV-C High-Level Disinfection device is called Chronos® Max (AE1V2) in this document.
The Chronos® Max device is a unit from the Germitec product family.

The equipment's technology is protected by several Germitec patents.



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1 INTRODUCTION

1.1 The Chronos® Max device description

The Chronos® Max device (AE1V2) is designed to provide rapid, High-Level Disinfection (HLD) of the following Medical Devices: transesophageal (TEE/TOE), long endocavitary ultrasound probes and ENT endoscopes without operating channel, 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® Max device 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 Medical Device (MD) 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.

Only one Medical Device at a time can be placed into Chronos® Max. Thanks to the RFID reader (13.553 to 13.567 MHz and -54.0 dBm max) placed inside the chamber, each Medical Device is identified by reading the RFID chip on a Chronos® Max strap pre-installed on the MD's. The RFID strap is used to recognise only compatible models.

The Chronos® Max device is equipped with an automated control and traceability system that enables healthcare professionals to check the status of disinfection cycles (success or failure) between each patient. Traceability data associate each Medical Device with the cycle performed and can be consulted, archived, and downloaded via an intuitive user interface: Germitrac.

Germitrac can be used with a computer's web browser. It is also possible to automatically print a traceability label for each cycle, to validate or invalidate the success of the HLD cycle. With Chronos® Max, healthcare professionals can provide proof of their disinfection practices, with the aim of ensuring patient safety. The disinfection step is safe and easy to perform and optimizes workflow and maximizes the number of patients seen, while guaranteeing quality of care.

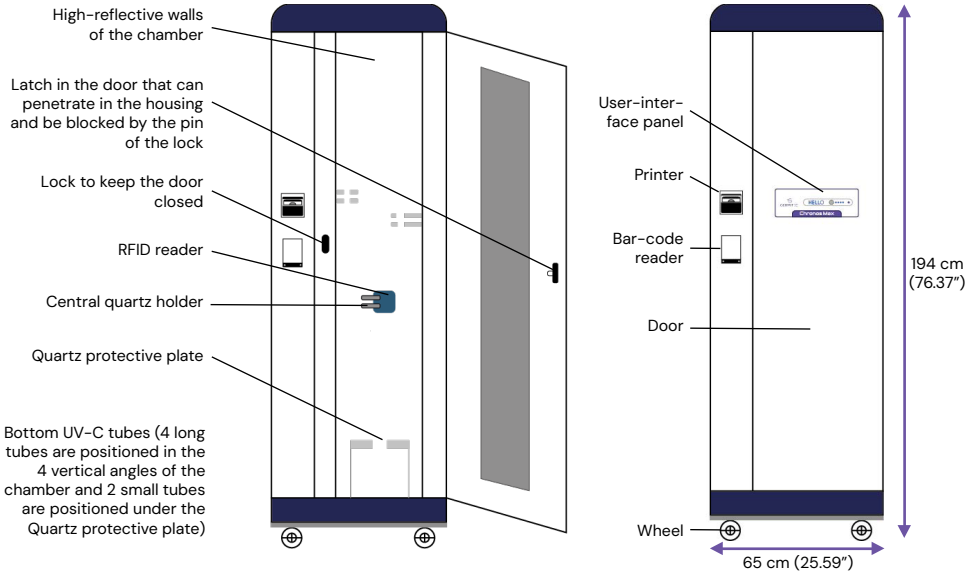


Figure 1: Chronos® Max (AE1V2) with labeled components

1.2 Users and environment

The Chronos® Max device is intended mainly for use in hospitals, radiology or sonography practices, and primary-care or specialist physician practices.

It is designed to be used by healthcare professionals such as sonographer technicians, sterilization technicians, decontamination technicians, medical physicians, radiologists, cardiologists, ENT physicians and healthcare assistants. It must be used in a dedicated utility room or central decontamination room for reprocessing Medical Devices.

The Chronos® Max device has the possibility to be interfaced with the hospital network and user computer to access traceability functions. The figure below describes the various possible interfaces:

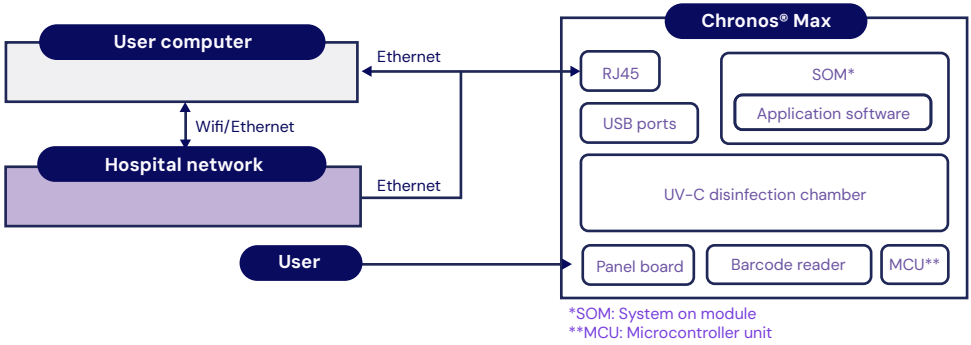


Figure 2: The Description of the various possible interfaces

1.3 List of compatible Medical Devices

Contact your Germitec Authorized Service Representative to obtain our compatibility catalogue.

1.4 Associated components

The Chronos® Max device comes with a pack of RFID straps used to identify compatible Medical Devices which can be disinfected by the Chronos® Max device. Each RFID strap must be installed on the MD by a Germitec-approved technician (see Technical Manual MAN-N002-T-EN) or a trained Advanced user (see Advanced User Manual MAN-N002-A-EN).

The Chronos® Max device comes with its designated power cable and an Ethernet cable (RJ45) to connect a computer to the Germitrac interface.

It provides intuitive access to all traceability data related to Medical Devices disinfected by the Chronos® Max device.

1.5 Technical characteristics

Cycle time	In the range of 240 ± 30 seconds
External Dimensions (H x W x D)	194 cm x 65 cm x 55 cm (76.4" x 25.5" x 21.6")
Weight	82 kg (180.7 lbs)
Disinfection chamber dimensions (internal - H x W x D)	164 cm x 28 cm x 38 cm (64.6" x 11.0" x 14.9")
Power supply	120-240 VAC 50-60 Hz
Power consumption	1650 W
Disinfection efficacy	High-Level Disinfection
External operating temperature	10°C to 40°C (50°F to 104°F)
Relative humidity	Less than 90% without condensation
Maximum operating altitude	2000 m
Current rating	13,5 – 6,6A
Overvoltage category	II
Sound volume (when ventilators are activated)	46 dB

2 INTENDED USE AND INDICATIONS

2.1 Intended use

High-Level Disinfection including sporicidal action of transesophageal & endo-cavity ultrasound probes and ENT scopes without operator channel by UV-C as alternative to chemistry.

Note: according to Spaulding classification, the Chronos® Max device is intended to disinfect semi-critical transducers (in contact with non-intact skin, mucous membranes, blood contact).

3 CONTRAINDICATIONS

The Chronos® Max device is not intended to sterilize (ultrasound) Medical Devices. MDs that require complete sterilization for safe re-use should be sterilized in accordance with the manufacturer's instructions.

Only transesophageal & endo-cavity ultrasound probes and ENT scopes compatible with the Chronos® Max device can be disinfected in the disinfection chamber. Medical Devices not mentioned in the compatibility catalogue must not be placed in the Chronos® Max device as disinfection cannot be guaranteed. Medical Devices deemed unsuitable for HLD should be disinfected according to the manufacturer's instructions.

4 PRECAUTIONS

4.1 Training

It is the responsibility of the owner of the device to ensure that:

- All users are trained regarding 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

- The Chronos® Max device installation should be performed by a Germitec Authorized Service Representative and maintenance should be performed in accordance with the indications set out in Section 9 "SCHEDULED MAINTENANCE".
- The Chronos® Max device is an automated High-Level Disinfection system part of a general Medical Device-handling protocol that includes, prior to the Chronos® Max device HLD initial cleaning according to the ultrasound manufacturer's instructions.
- This device must be used in compliance with the operating procedure described in Section 7 "USE".
- The Chronos® Max device is only approved for medical uses to achieve HLD on specific applications. Only transesophageal & endo-cavity ultrasound probes, ENT scopes without operator channel must be placed in the disinfection chamber.
- The Chronos® Max device is intended to be used exclusively in healthcare facilities by trained healthcare professionals in accordance with this user manual.
- Do NOT use the Chronos® Max device for single-use devices reprocessing.
- Do NOT use the Chronos® Max device for ultrasound Medical Devices pre-cleaning. Medical Devices must be pre-cleaned BEFORE being placed into the Chronos® Max device. See Section 7.3. "Prerequisites to Medical Device disinfection" for pre-cleaning instructions. Ensure that all traces of ultrasound gel and body fluids are removed from the Medical Device before HLD cycle in the Chronos® Max device.

- The Chronos® Max device is not a storage cabinet.
- In case the Chronos® Max device is out of function, alternative methods of High-Level Disinfection such as chemical soaking should be used to disinfect the Medical Devices.

4.3 Use of power supply cable



Any damage during transport or storage may be a source of danger.
Therefore, the user must check the integrity of the device before installation.



The Chronos® Max device must be connected to an electrical installation compliant with current regulations and connection must be performed by a qualified person.
The Chronos® Max device is connected to an AC power supply (voltage between 120 and 240 VAC). Power source must fit with what is indicated on the label. This product is considered as Electrical Class 1 and is therefore designed to be connected to a protective ground. If this is not the case, this may expose users to the risk of electric shock.
Only power cable provided with the equipment must be used. This cable is used as a circuit-breaking system (cut-off of electrical power if necessary) and must therefore be accessible.
The system should never be switched off using AC power switch at the risk of irremediably damaging the machine and losing the saved traceability data.

- Warning: The use of accessories, transducers, and cables other than those specified or provided by the equipment manufacturer may result in an increase in electromagnetic emissions or a reduction of the equipment's immunity and cause inappropriate operation.

4.4 Handling precautions

- The Chronos® Max device weighs 82kg (180,7 lbs). Use safe handling techniques, in accordance with health and safety rules at your place of work.
- Do NOT subject the Chronos® Max device to any impact. If it falls or is damaged, contact a Germitec Authorized Service Representative and return it to the manufacturer for repair.
- Do NOT use the Chronos® Max device if there is any suspicion of damage.
- Do NOT force open the door, especially not during an operating cycle.
- Do NOT attempt to disassemble or repair the device. The Chronos® Max device must exclusively be repaired by a Germitec Authorized Representative. Opening the equipment's rear panels by anyone other than a Germitec Authorized Representative will avoid the warranty.
- Do NOT bypass the equipment's safety systems and interlocks.
- Incorrect loading of the Medical Device in the disinfection chamber may damage the Medical Device. It must NOT touch the walls of the disinfection chamber. To find out more about the proper positioning of the Medical Device, consult Section 6.3 "Installation" or contact a Germitec Authorized Service Representative.

4.5 Environmental precautions

- Use the Chronos® Max device and its accessories between 10°C and 40°C (50°F and 104°F), and a relative humidity below 90% without condensation.
- The Chronos® Max device and its accessories may be stored at temperatures between -10°C and 50°C (50°F and 122°F).
- Use the Chronos® Max device in a degree 2 pollution environment.

4.6 Electricity

- The Chronos® Max device must be connected to a grounded power outlet. Make sure that the used power cable is the one supplied with the equipment. The Chronos® Max device must be connected to an AC power supply (voltage between 120 and 240 VAC / 50-60 Hz). Power source must fit with what is indicated on the label. Only connect the equipment to a power supply having the appropriate voltage and frequency. Incorrect voltage or AC frequency may damage the equipment.
- User must take precautions to prevent the ingress of liquids into the equipment (other than liquids intended for maintenance; see Section 9 "SCHEDULED MAINTENANCE"). Please do NOT use unauthorized liquids within the Chronos® Max device. If unauthorized liquids are accidentally introduced, it may create an electrical hazard. If so, please contact a Germitec Authorized Service Representative.
- Do NOT connect the Chronos® Max device to power strips. Connect it only to mains power supplies.
- Supply network voltage fluctuation must be lower than ± 10%.

4.7 Electromagnetism

- Avoid using the Chronos® Max device adjacent to other equipment (within 5 to 10 cm - 1,97" to 3.93") or stacking it on top of other equipment as this may result in incorrect operation. If this use is necessary due to equipment configuration, operation of all devices must be observed to verify normal running.
- Portable Radio Frequency (RF) communication devices should not be used (including peripherals such as antenna cables and external antennas) less than 30 cm (11.81") from any part of the Chronos® Max device including cables supplied by the manufacturer. If not, performance of portable RF equipment may be adversely affected.
- The use of accessories, transducers, and cables other than those specified or provided by the equipment manufacturer may result in an increase in electromagnetic emissions or a reduction of the equipment's immunity and cause inappropriate operation.

4.8 UV-C lamp and radiation precautions

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

4.9 Cybersecurity

- Do NOT write down your Germitrac interface password.
    - To access Germitrac Chronos® Max's interface, users should connect, thanks to the Ethernet cable (RJ45), a computer that respects Health Deliver Organization's network security protocol and has an updated anti-virus/anti-malware. The computer must have a recent web browser application installed (e.g. Chrome, Firefox, Edge, Opera 2018 version or later).

4.10 Recommended use

- Disinfection data are saved in Germitrac, the Chronos® Max's embedded software. These data may be downloaded thanks to a computer connected to the Chronos® Max device.

4.11 Certification

The Chronos® Max device is compliant with Medical Devices Regulation (MDR) 2017/745. According to this regulation, it is a class IIb device.

This model carries the CE marking and has also the BV NRTL marking 

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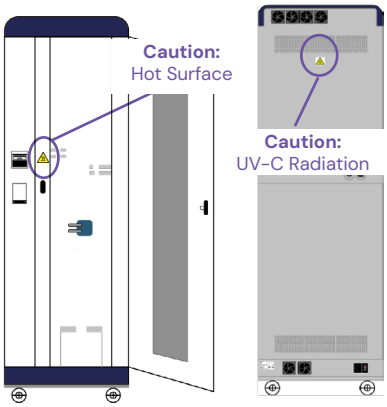
In accordance with the requirements of the Medical Devices Regulation (MDR) 2017/745, the Chronos® Max device is compliant with the following standards:

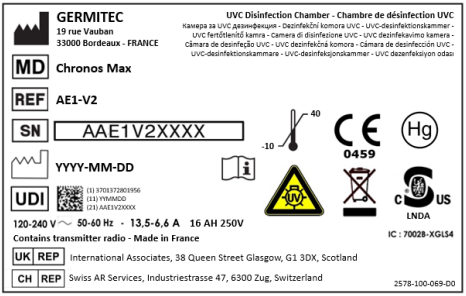
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EN 61326-1	Electromagnetic compatibility
IEC 61010-1 IEC 61010-2-40	Electrical safety - specific requirements for sterilizers and disinfecting washers
EN ISO 14971	Risk management
EN 62366-1	Application of usability engineering
IEC 62304	Medical-device software

5 LABEL, SYMBOLS AND WARNINGS

5.1 Label and symbols

<table>
<tr><th>Symbol</th><th>Symbol meaning</th><th>Positioning</th></tr>
<tr><td>
Caution:
Hot surface</td><td>Risks of burns
Do not touch the tubes within 2 minutes after the end of a cycle.</td><td rowspan="2">On the front

On the back
</td></tr>
<tr><td>
Caution:
UV-C Radiation
(inside the chamber)</td><td>Risk of exposure to UV-C radiation
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.</td></tr>
<tr><td></td><td>Do not dispose of the specified material with municipal waste
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.</td><td>On the label</td></tr>
<tr><td></td><td>Manufacturer
This symbol adjacent to Germitec indicates that Germitec is the manufacturer of this equipment.</td><td>On the label</td></tr>
<tr><td></td><td>Information in the manual
This symbol indicates that the user must read the manual before using the device.</td><td>On the label</td></tr>
</table>

	Manufacturing date This symbol indicates the manufacturing date (YYYY-MM-DD) of the device.	On the label
Hg	**Mercury** This symbol indicates the presence of mercury inside UVC tubes.	On the label
	**Rating plate:** Manufacturer's identification Description of the equipment in all European required languages Model Serial number Electrical characteristics Country of manufacture Markings UDI-DI number with associated QR code UK REP Contact CH REP Contact

EN

5.2 Warnings

- The equipment must be used in accordance with the instructions provided in this manual, particularly:
  - by the users and in the environment described in Section 1.2 "Users and environment".
  - for the claimed use and intended use described in Sections 2 "INTENDED USE AND INDICATIONS".
- 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 MDs may be degraded.
  - Adjacent equipment and environment may be at risk and harmed.
- Do NOT touch the UV-C tubes within 2 minutes of the end of a cycle to avoid burns to the hand.
- For proper operation and installation of the Chronos® Max device, follow all instructions. If procedures, as described in these instructions, are not performed, the equipment's interlocks could be undermined, the equipment may be damaged, the user and third parties may be seriously injured, the MDs may be degraded, and adjacent equipment and the environment may be at risk.
- Do NOT attempt to disassemble any component of the equipment, as this may cause electrocution.
- 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 and shut off central forced air conditioning.**
  - Do NOT vacuum lamp debris. Collect broken glass and visible powder with stiff paper or cardboard and pick up remaining small fragments with 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 Representatives 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).

- User should NEVER expose himself to UV-C radiation from the Chronos® Max 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 Chronos® Max (AE1V2)



1 pack including:

- 3 RFID straps for Medical Devices
  + 3 positioning labels



- 1 AC power cable



- 25 Barcode label for operator identification



- 2 Barcode label for standard operator



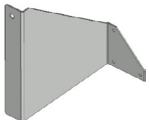
- 1 Ethernet network cable (RJ45)



- 1 Specific label roll for printer



- 2 Mounting brackets



- 1 User manual



6.2 Presentation of the interfaces

Connection to the AC power supply

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

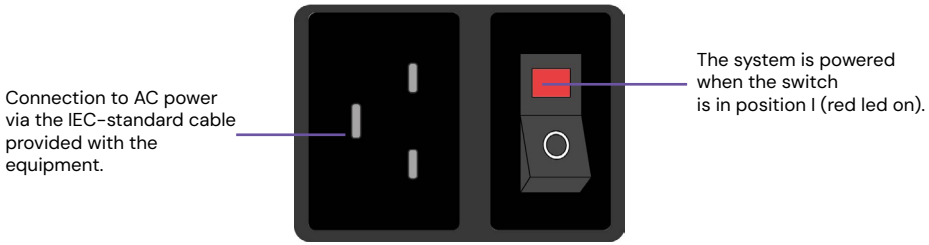


Figure 3: AC power connector

To turn the system off, please see Section 7.2 “Switching off“.

Peripheral connection interface

The other connectors are located just above the equipment’s rear panel.

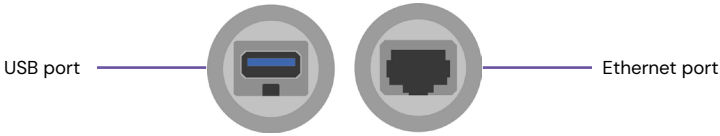


Figure 4: Other connectors

User interface

The user interface is in the middle of the door.

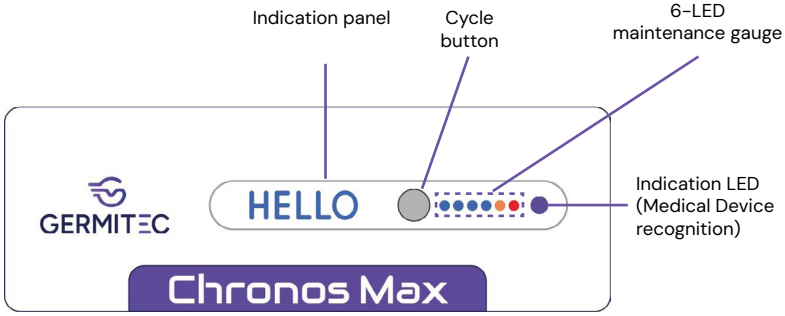
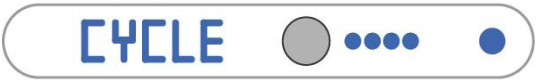
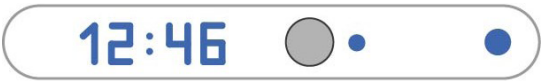
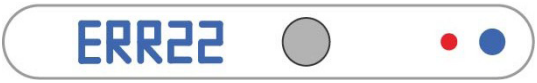


Figure 5: The user interface

Display	Meaning
	- **Startup in progress**
	- **Time display** - **Right LED not lit** = No Medical Device inside the disinfection chamber.
	- **Far right LED purple** = Medical Device identified and NOT disinfected.
	- **Far right LED flashes in blue** = On-going disinfection cycle.
	- **Far right LED blue** = The Medical Device is now disinfected.
	- **Red LED** = Error Check in Section 10 “ERRORS“ the recommended actions associated to the displayed error, here ERR22.
	**Maintenance gauge:** - The LED number and colors increase when maintenance approaches. - **Fifth LED orange** = Maintenance should be programmed - **Sixth LED red** = Maintenance out of date See Section 9 “SCHEDULED MAINTENANCE“

6.3 Installation

6.3.1 Placement

In the context of shared use, the Chronos® Max device may be centralized in an appropriate reprocessing area/ room.

- The equipment must be installed on a flat floor.
- A gap of at least 20 cm (7.87“) must be left at the rear between the equipment and a wall. In normal use, it is recommended to fix the device to the wall using the mounting brackets. Once the machine is in position, lock the brakes on all 4 wheels, then follow the fixing procedure in appendices. Please note that if the device is not fixed to the wall, it may tip over if force is applied to one of its sides.

6.3.2 Connection to electrical power

- Connect the power cable to the IEC connector at the rear of the chamber.
- Connect the plug at the other end of the cable to a 16-Amp power outlet (2P+G). This outlet must be protected by a 8 A circuit-breaker on 240 VAC or a 16 A circuit-breaker on 120 VAC.

6.3.3 Connection of periphery

Never connect peripheral devices (memory devices, etc.) to the connectors other than those indicated below.

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To connect the equipment to a computer or a local Ethernet network, connect the Ethernet cable RJ45 to the Ethernet connector at the rear and to a network connector. Ensure that the connected cables are of the RJ45 type.

6.3.4 Installation of RFID label on Medical Devices

Only Medical Device fitted with a Chronos® Max RFID (radio frequency identification) strap can be disinfected by the Chronos® Max device. Frequency band of the RFID reader is 13.553 to 13.567 MHz.

These RFID straps must be installed exclusively by Germitec Authorized Service Representative or a trained Advanced user (see Technical Manual MAN-N002-T-EN).

- If a Medical Device IS NOT equipped with an RFID strap, contact your Germitec Authorized Service Representative.

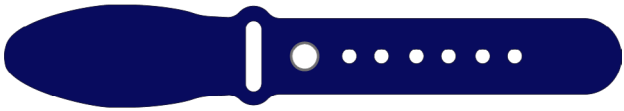


Figure 6: RFID strap

Only MDs fitted with their RFID strap can be disinfected using the Chronos® Max device.
Do NOT slide the strap on the cable, do NOT tear the strap, do NOT fold the strap.

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 that the maintenance has been performed in accordance with the indications set out in Section 6 "Scheduled maintenance".
If these operations are not performed, the equipment's interlocks could be undermined, the equipment may be damaged, the user and third parties may be seriously injured, the MDs may be degraded, and adjacent equipment and the environment may be at risk.

- Apply power to the equipment by pressing the power switch (located at the bottom rear of the unit).
- The green indicator lamp lights. The equipment displays HELLO during its startup sequence (about 30 seconds). A melody indicates the end of the startup, and the system is ready for use.

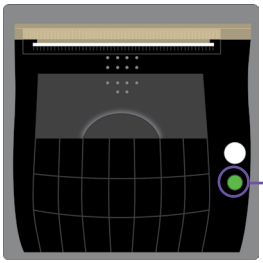
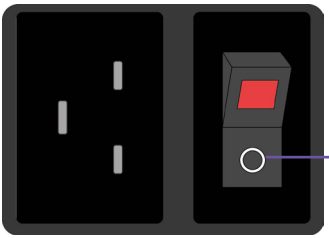


Figure 7: The printer

In the event of any malfunctions call your Germitec Authorized Service Representative.

7.2 Switching off

- To switch off the unit, press the button on the panel, and hold on for at least 3 seconds. A melody sounds, the interface displays BYE, then switched off.
- Press the illuminated AC power switch at the rear of the device



The red indicator lamp is switched off. The Chronos® Max device is now powered off.

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

7.3 Prerequisites to Medical Device disinfection

"Only clean items can be properly disinfected."

The Medical Device must be cleaned and dried before being placed in the Chronos® Max device for any High-Level Disinfection process.
For additional information on suitable cleaning procedures, consult Medical Device instructions.

> *The Medical Device must be cleaned before being placed into the Chronos® Max device. In particular, ensure that all traces of gel or body fluids are removed as, if not, High-Level Disinfection can't be guaranteed.*

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7.4 Disinfecting Medical Device

7.4.1 MD with cable

> *Only one Medical Device at a time can be placed into the Chronos® Max device. Ensure that, while placing the Medical Device into the chamber, it doesn't touch any walls.*

1. Open the hands-free door of the Chronos® Max device with your foot. Make sure there is no torsion no entanglement of the cable, and follow the following steps for MD installation:
2.
   a. Put the handle (1) in its holder,
   b. Put the connector (2) in its holder,
   c. Then place the cable and the RFID strap in the central quartz holder, the RFID strap must be in front of the RFID reader.

Note: For TEE/TOE probes, make sure that the active part, while inserted into the quartz protection plate hole, does NOT touch the UV-C tubes at the bottom of the chamber.

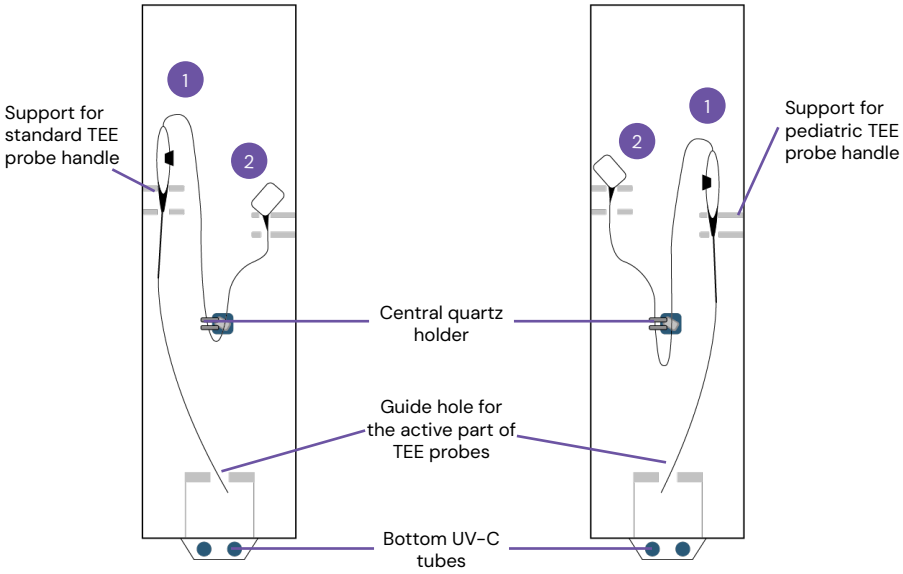


Figure 8: How to install a Medical Device with cable inside the disinfection chamber

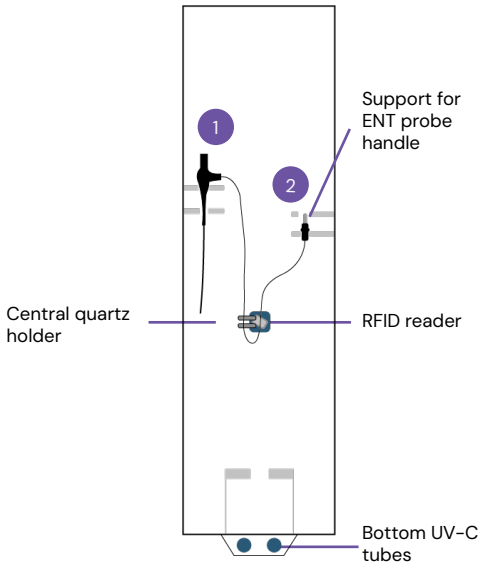


Figure 9: How to install a Medical Device without cable inside the disinfection chamber

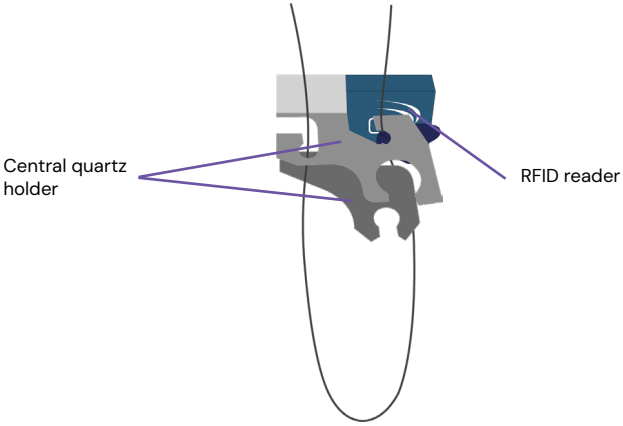


Figure 10: Focus on the central quartz holder and RFID reader inside the disinfection chamber

On the panel, the LED on the far right turns purple indicating the MD is identified but NOT disinfected.
Before closing the hands-free door verify that:

- The RFID strap is still in front of the RFID reader,
- The MD cable is NOT touching chamber's walls.

3. Gently close the door.
4. Initiate the disinfection cycle by pressing the button on the panel.

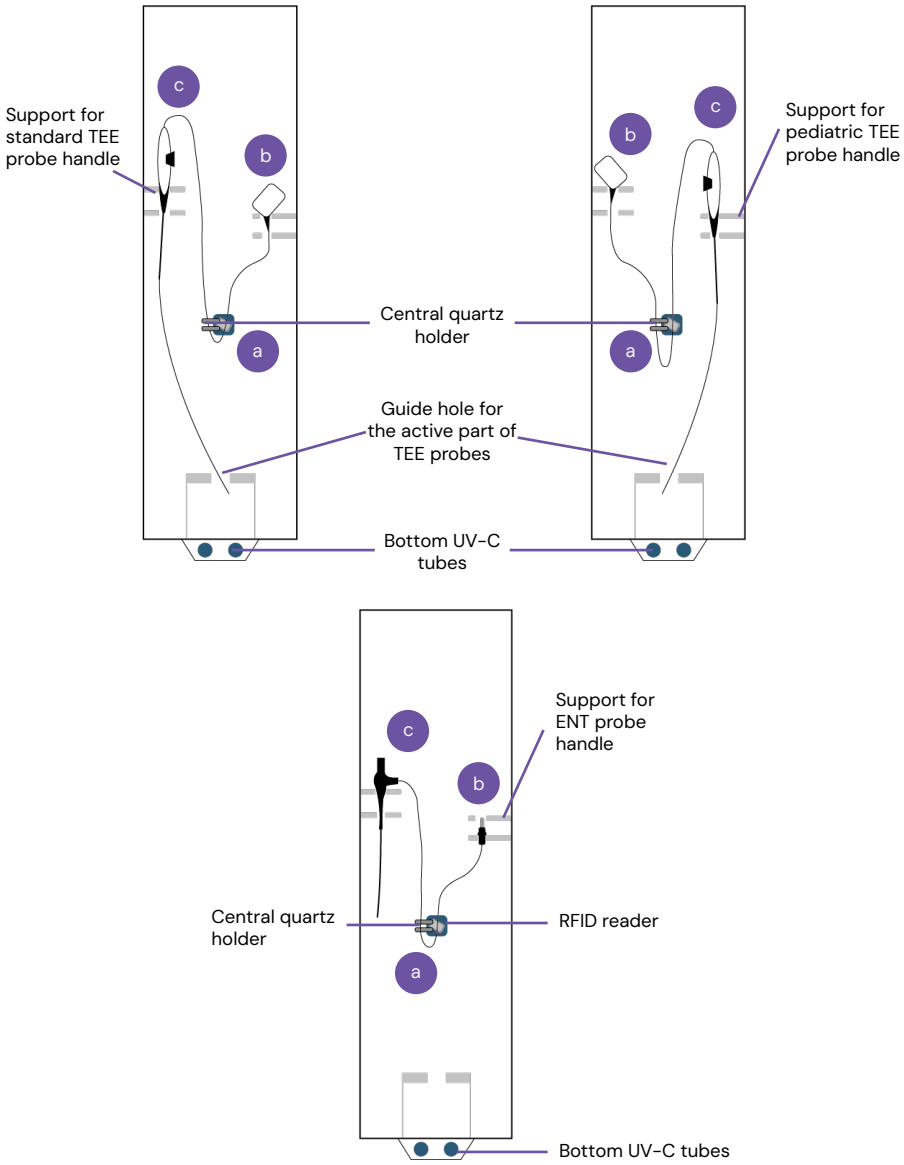
A beep confirms cycle initiation. The panel displays "CYCLE":



The LEDs in the gauge LED bar scroll during the cycle.
The end of the cycle is indicated thanks to a melody and the panel displays “CYCLE OK”.
The LED on the far right becomes blue, meaning that the MD IS NOW disinfected.

The printer prints the defined number of labels.

5. Open the hands-free door.
6. Remove the MD:
    a. First, grab the two parts of the cable in the double hook,
    b. then grab the connector,
    c. finally grab the handle.



7.4.2 MD without cable

Only one Medical Device at a time can be placed into the Chronos® Max device. Ensure that, while placing the Medical Device into the chamber, it doesn't touch any walls.

1. Open the hands-free door of the Chronos® Max device with your foot and follow the following steps for MD installation:
2.
   a. Put the DM (1) in its holder,
   b. Put the RFID strap on top of the RFID reader (2).

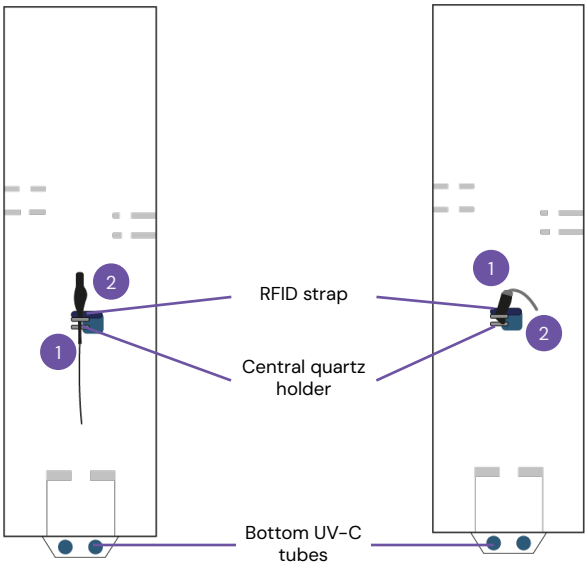


Figure 11: How to install a Medical Device without cable inside the disinfection chamber

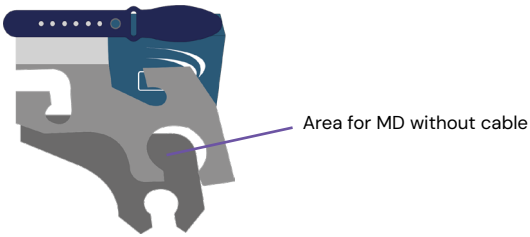


Figure 12: Focus on the central quartz holder and RFID reader inside the disinfection chamber

On the panel, the LED on the far right turns purple indicating the MD is identified but NOT disinfected. Before closing the hands-free door verify that the RFID strap is still on top of the RFID reader.

3. Gently close the door.
4. Initiate the disinfection cycle by pressing the button on the panel.

A beep confirms cycle initiation. The panel displays "CYCLE":



The LEDs in the gauge LED bar scroll during the cycle.
The end of the cycle is indicated thanks to a melody and the panel displays “CYCLE OK”.
The LED on the far right becomes blue, meaning that the MD IS NOW disinfected.

The printer prints the defined number of labels.

5. Open the hands-free door.
6. Remove the MD:
    a. Retrieve the RFID strap,
    b. retrieve the DM.

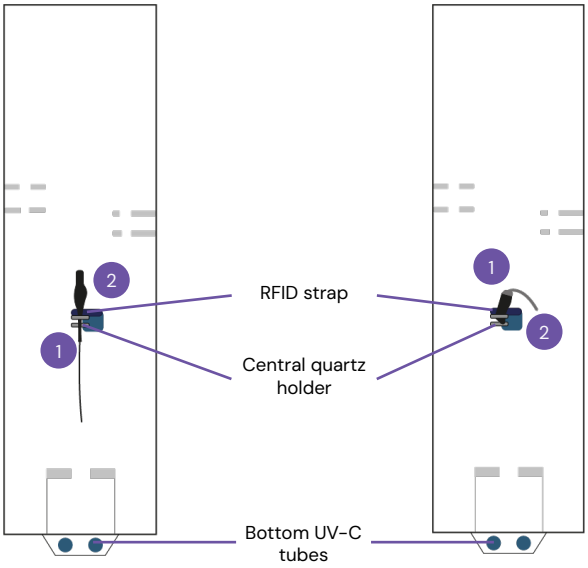


Figure 13: How to retrieve a Medical Device without cable from the disinfection chamber

If an MD is inside the disinfection chamber and must be removed urgently, press long on the button. The cycle is stopped, a sound signal indicates when the door may be opened and a failed HLD ticket is printed.

In the event of an error, the cycle is automatically stopped. In this case, refer to Section 10 “ERRORS”.

7.5 Operator identification

The medical device allows operators to be identified using the barcode reader in front of the device.

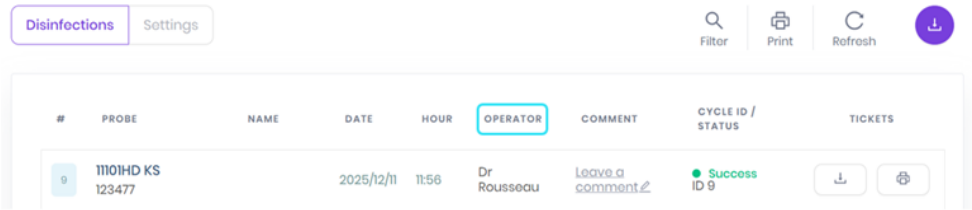


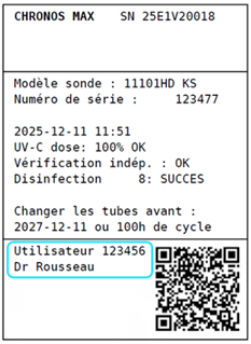
Barcode label format

The identification step must be carried out after placing the probe in the device and closing the door, just before starting the disinfection cycle.

The requirement to scan a badge before each cycle is left to the discretion of the hospital; this option can be changed in Germitrac by an advanced user or technician.
If the option is selected, it is not possible to start a cycle without being identified.

After a cycle is done with an operator identified, the operator will be traced in the disinfection page and also on the ticket of traceability.





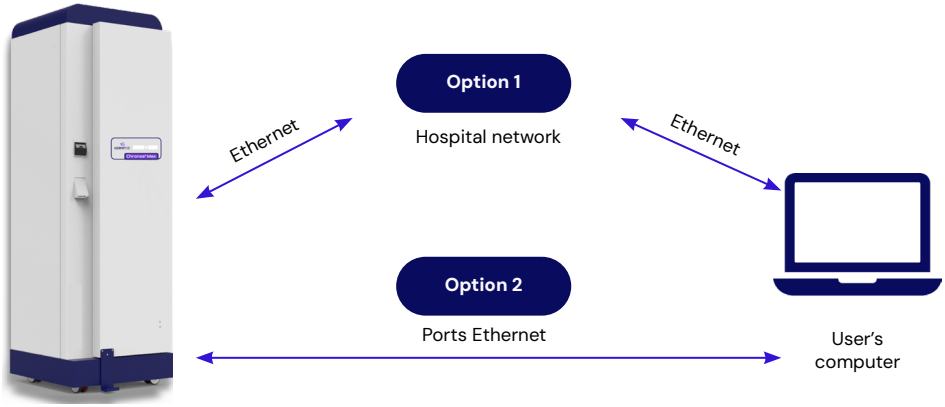
A standard barcode label '000000' will be provide to all center facility in case operator lose their barcode, the operator will then be identified as "standard".



7.6 User of the Germitrac communication interface

Germitrac, intuitive user interface and Chronos® Max's embedded software provides intuitive access to all traceability data related to Medical Devices disinfected by the Chronos® Max device.

Germitrac can be used with a computer's web browser thanks to an Ethernet cable (RJ45) connected to both the Chronos® Max device and a computer.



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.1.XX a fix IP address, where XX.1.XX are the 4 last digits of the serial number of the Chronos® Max (local Ethernet), e.g. https://169.254.03.1.19 for the Chronos® Max SN 23E1V20319
   - https://ChronosmaxXXXX.local with the name of the device, where XXXX are the 4 last digits of the serial number of the Chronos® Max (local Ethernet), e.g. https://Chronosmax0319.local for the Chronos® Max SN 23E1V20319

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

The HTML pages can be opened with at least Firefox, Chrome, Edge and Safari in their first 2018 version.

7.6.1 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.

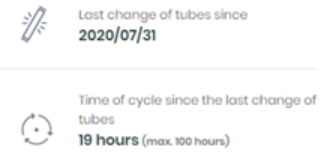
General information is displayed at the top of every page:
- Chronos® Max serial number
- Information about the next maintenance (when to change the tubes)
- Site:
    - Main user
    - Site name
    - Address



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

- Date of the last change
- Hours of use

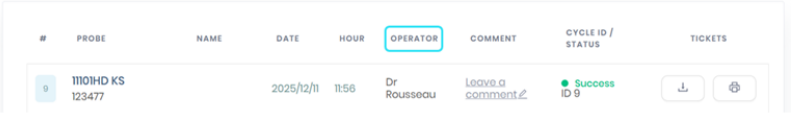
Tubes need to be changed after 2 years of operation or 100 hours of use, whichever comes first.



7.6.2 Disinfection data

Data from each disinfection cycle is displayed:
- Disinfection number (which is incremented by 1 with each new disinfection)
- Probe/Medical Device model and serial number
- A name for the individual probe/Medical Device 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

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7.6.3 Filters

The data on the main page can be filtered on:
- Probe/Medical Device model
- Probe/Medical Device serial number
- Probe/Medical Device username
- Date range
- Comment
- Disinfection status

Several filters can be applied simultaneously.

7.6.4 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.

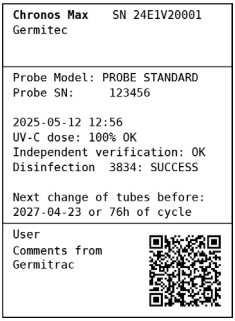
Print The printing button at the top of the page allows the user to print the disinfection table for the page displayed with the web browser used.

It is recommended to backup data daily. It is also recommended to then perform a security backup on another drive. Germitec may not under any circumstances be held responsible for the loss of data stored in the equipment.

7.6.5 Managing tickets

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

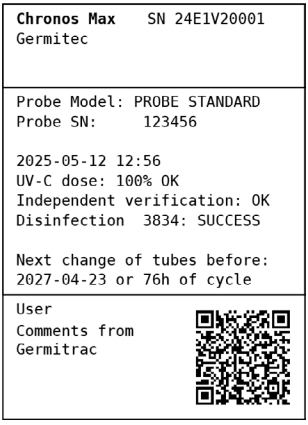
The  button enables the ticket to be printed on the printer connected to the Chronos® Max.



7.7 Label printing

7.7.1 Example of a traceability label - Successful HLD cycle

Traceability labels contain information validating or invalidating the HLD 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 made 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 identification (if applicable)

User field (free use or comments completed in Germitrac)

QR code

7.7.2 Example of a traceability label - Failed HLD cycle

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 made by the internal independent monitoring system – OK or NOK, disinfection unique ID, final disinfection status: SUCCESS or FAILURE)
Error identification (code, short name)

User identification (if applicable) User field (free use or comments completed in Germitrac)

QR code

In this case, consult the error messages in Section 10 "ERRORS" to determine the origin of the failure, follow the steps to resolve the problem and proceed with another disinfection cycle for the Medical Device, as it IS NOT disinfected YET.

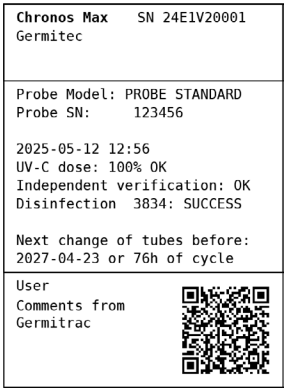
7.7.3 Example of a QR code on the traceability label

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 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® Max device: Text, 10 chars | Probe/Medical Device Model: Text, up to 10 chars | Probe/Medical Device 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 » | ID user: Text, up to 10 chars | Comment: Text, up to 32 chars



Example:
'23E1V20011|10L24EA MI|360100|5378|2021-10-129|11:14|S|0123456789|Comments from Germitrac'

8 ROUTINE CARE

8.1 External cleaning

To clean the external part of the Chronos® Max device and the strap, use a cloth or paper cloth, dampened with water or a surface cleaner/disinfectant.

⚠	*Do NOT immerse the strap in any liquid.*

⚠	*Do NOT immerse the strap in any liquid.*

8.2 Internal cleaning

A super-soft cloth (optical quality) soaked in a water-alcohol solution may be used to clean the lateral MDs supports, the bottom quartz plate and the white side surface.

⚠	*Do NOT perform cleaning in the 2 minutes following a disinfection cycle. The tubes are still hot and present a burn hazard.* *Do NOT clean the tubes.* *Do NOT clean behind and in immediate proximity to the tubes.*

The rest of the internal walls must be cleaned by a Germitec Authorized Service Representative during maintenance operations.

8.3 Replacing label rolls

⚠	*Only label rolls sold by Germitec are compatible with the embedded printer.*

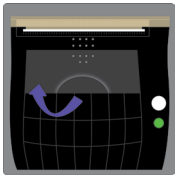
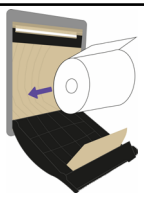
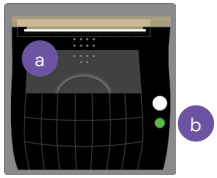
1) Open the printer hatch	2) Remove the empty paper roll and place the cylindrical holder into the new label roll
	
3) Insert a new paper roll with the end of the roll exiting the printer	4) Close the printer hatch (a). Light should be green (b)
	

Figure 14: Replacing the paper roll

9 SCHEDULED MAINTENANCE

Scheduled maintenance must be performed every year.

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

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Only a technician approved by Germitec is authorized to perform maintenance operations on the Chronos® Max device.

The UV-C tubes must be changed every 2 years or every 100 hours of cumulative cycle time (whichever comes first).

Scheduled maintenance includes:
- A general system check
- An internal and external cleaning if necessary
- Replacement of wear parts and/or the UV tubes, if necessary
- Photodiodes' calibration
- Ventilation filter replacement if necessary

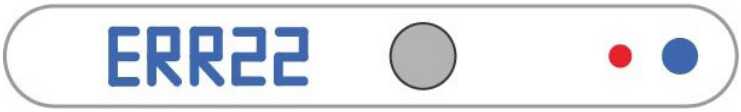
Only Philips UV-C tubes supplied by Germitec must be used with the Chronos® Max device.
The worn are collected by the Germitec-approved technician and will be disposed in accordance with local regulatory requirements.

10 ERRORS

The Chronos® Max device is equipped with numerous sensors (temperature, optical, etc.) which monitor High-Level Disinfection cycles to ensure proper operation.

If the Chronos® Max's embedded software detects a malfunction during the cycle, even if only temporary, UV-C emission is stopped and the system goes into error mode.

The system displays the code corresponding to the error on the panel.



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

Error code	Error meaning	Possible debug action
ERR01 START	Failure of initialization (including RFID reader)	Acknowledge the error by pressing the button. If the error occurs again, switch off the device, check if the power cable is well plugged, and restart.
ERR02 DETEC	RFID not valid	Check that the RFID strap is well installed in the double hook. Visually check that the RFID strap is facing the RFID reader.
ERR03 START	Failure of the barcode reader initialization	Acknowledge the error by pressing the button. If the error occurs again, switch off the device, check if the power cable is well plugged, and restart.
ERR04 DOOR	Door not closed properly	Make sure the door is closed properly. Acknowledge the error by pressing the button, open and close the door, and restart the cycle.
ERR05 LOCK	Door lock not properly engaged	Acknowledge the error by pressing the button, open and close the door, and restart the cycle.
ERR06 PROBE/ MEDICAL DEVICE	Loss of Medical Device detection during the cycle (for example, strap moved up by pulling the cable)	Acknowledge the error by pressing the button, verify that the RFID strap position is still in front of the RFID reader and restart the cycle.
ERR07 HOT	Detection of too high temperature in the chamber	Check if the ventilation is activated. Check that there is a free space of at least 20 cm (7.87") behind the device. Check that the external temperature is below 40°C (104°F). When all the above conditions have been checked, wait 5 minutes for the system to cool off preferably leaving the door open, then acknowledge the error by pressing the button.
ERR08 TUBE	UV-C tube or its power supply is not operating properly	Acknowledge the error by pressing the button, open the door, check 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, open the door, check that no object has been forgotten in the chamber and that everything is clean, then restart the cycle. Ensure to not move the Medical Device during an HLD cycle.
ERR10 EVO1	Detection of unusual light distribution	Acknowledge the error by pressing the button, open the door, check that no object has been forgotten in the chamber and that everything is clean, then restart the cycle. Ensure to not move the Medical Device during an HLD cycle.
ERR11 EVO2	Detection of unusual light distribution	Acknowledge the error by pressing the button, open the door, check that no object has been forgotten in the chamber and that everything is clean, then restart the cycle. Ensure to not move the Medical Device during an HLD cycle.

ERR12 PREV1	Detection of unusual light distribution	Acknowledge the error by pressing the button, open the door, check that no object has been forgotten in the chamber and that everything is clean, then restart the cycle. Ensure to not move the Medical Device during an HLD cycle.
ERR13 PREV2	Detection of unusual light distribution	Acknowledge the error by pressing the button, open the door, check that no object has been forgotten in the chamber and that everything is clean, then restart the cycle. Ensure to not move the Medical Device during an HLD cycle.
ERR14 DELAY	Maximum cycle time exceeded	Acknowledge the error by pressing the button, open the door, check 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 only seen by Germitec Authorized Service Representative.
ERR16 UV3	Invalidation of the cycle by the independent monitoring system	Acknowledge the error by pressing the button, open the door, check that no object has been forgotten in the chamber and that everything is clean, then restart the cycle. Ensure to not move the Medical Device during an HLD cycle.
ERR17 SOLO	Reserved for service representative use only	Error code only seen by Germitec Authorized Service Representative.
ERR18 SOLO	Reserved for service representative use only	Error code only seen by Germitec Authorized Service Representative.
ERR19 DEVIA	Reserved for service representative use only	Error code only seen by Germitec Authorized Service Representative.
ERR21 CALIB	Reserved for service representative use only	Error code only seen by Germitec Authorized Service Representative.
ERR22 STOP	Cycle manually stopped by a long press on the button	Acknowledge the error by pressing the button. Restart the cycle.
ERR23 UVOFF	Incorrect signal from a UV sensor	Acknowledge the error by pressing the button, open and close the door, and restart the cycle.
ERR24 SIGN	Incorrect signal from a UV sensor	Acknowledge the error by pressing the button, open and close the door, and restart the cycle.
ERR25 BASE	Reserved for service representative use only.	Error code only seen by Germitec Authorized Service Representative.
ERR26 SHUT	Device switched off during a cycle	Acknowledge the error by pressing the button. Restart the cycle.
ERR30 OP	Operator not recognized (if the option has been selected).	After placing the probe inside the device and closed the door, present a configured barcode in front of the barcode reader before launching the cycle.

Other situations might happen without any error code and are listed in the table below with according debug actions.

Symptom	Checks to be performed / explanations
Nothing is displayed. The Chronos® Max device does NOT emit any sound.	Check that the Chronos® Max device is well connected to an electrical socket via the AC cable. Check that the AC button is switched on (position I) and that the green indicator lamp is illuminated. If nothing lights up, contact your Germitec Authorized Representative to potentially replace fuses. The fuses must be replaced in accordance with the characteristics indicated on the rating plate (16 Ah).
Impossible to open the disinfection chamber door.	Check that a cycle is not in progress.
Impossible to install the MD properly in the disinfection chamber (the LED at the far right of the panel does NOT light when placing a Medical Device in the Chronos® Max device)	Check that an RFID strap has been installed on the Medical Device cable Check that the RFID strap is not damaged. Check that the RFID strap is in the front of the RFID reader.
The LED at the far right of the indication panel lights purple.	The purple LED indicates the detection of a Medical Device that HAS NOT been disinfected YET.
The maintenance gauge on the panel has reached the orange and/or red LED (5 and 6th).	The orange level indicates that a maintenance intervention should be scheduled soon (about 2 months or 400 cycles remain when this indicator lights for the first time). The red level indicates that a maintenance intervention must be performed immediately.
Impossible to start the cycle when pressing the button.	Check that a Medical Device has been placed into the Chronos® Max device as the machine cannot start an HLD cycle without any Medical Device in.

Your Germitec Authorized Service Representative should be notified of each error requiring an acknowledgement.
In case of impossibility of using the Chronos® Max device, Germitec recommends the use of alternative High-Level Disinfection methods such as chemical soaking.

11 TRANSPORT AND STORAGE

For transport, the Chronos® Max device must be appropriately packed with the case provided on initial delivery. Before moving the Chronos® Max device, ensure it is disconnected, close the door, and unlock the 4 braking wheels. Once unpacked, the Chronos® Max device can be moved by 1 person. Follow the procedure indicated in the appendices to fix the device to the wall.

Following with the equipment's storage and transport requirements:
- Storage temperature: -10°C to +50°C (14°F to 122°F).
- Relative humidity: less than 90% without condensation

12 DISPOSAL

When the Chronos® Max device reaches the end of its life, the owner must dispose of the equipment in accordance with the current applicable regulations (DEE 2012/19/UE 4 July 2012).

13 WARRANTY

The duration of the Chronos® Max device warranty is in the sales agreement. This warranty covers defective parts and repair labor.

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

14 APPENDICES

14.1 Wall mounting procedure

14.1.1 Material

This procedure details step-by-step how to properly fix the Chronos® Max device to a wall using mounting brackets.

- 2 mounting brackets, provided
- 1 Torx T-20 bit/key, not provided
- 6 Torx M4x12 screws, provided
- 6 M4 serrated washers, provided

14.1.2 Preparation

Roll the device to its final location. The device fits under all standard doors up to 1.95m high.

For non-standard door between 1.85m and 1.94m high, you can still remove the fairing to be able to pass under the door. See figures below.

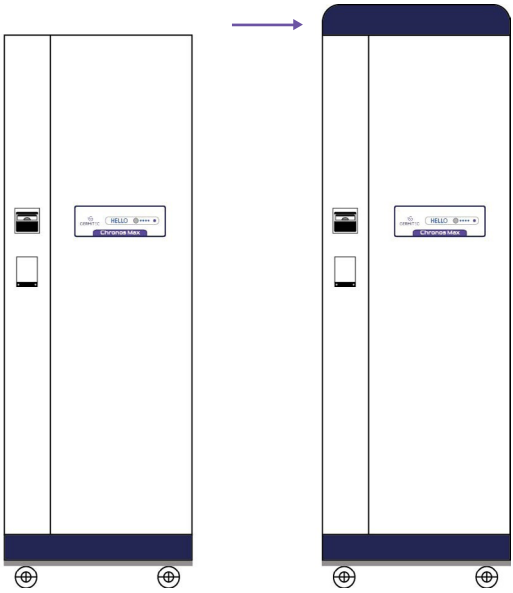


Figure 15: Device without fairing

Figure 16: Device with fairing

14.1.3 Material

1. Unpack the mounting brackets and the 6 Torx M4x12 screws / M4 lock washers needed to screw the b rackets to the Chronos® Max device

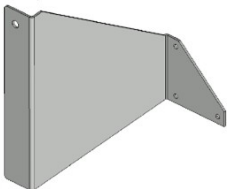


Figure 17: Mounting bracket

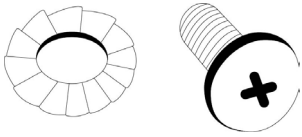
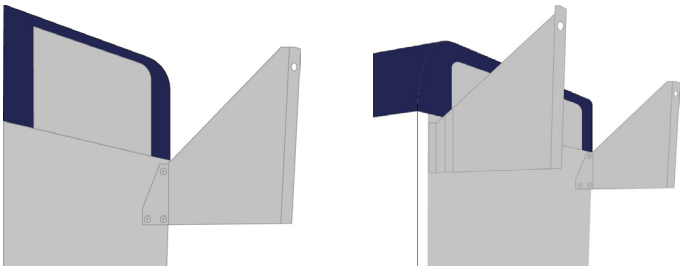


Figure 18: Notched washers M4 / Torx screws M4x12

14.1.4 Preparation

2. Unpack the mounting brackets and the 6 Torx M4x12 screws / M4 lock washers needed to screw the brackets to the Chronos® Max device

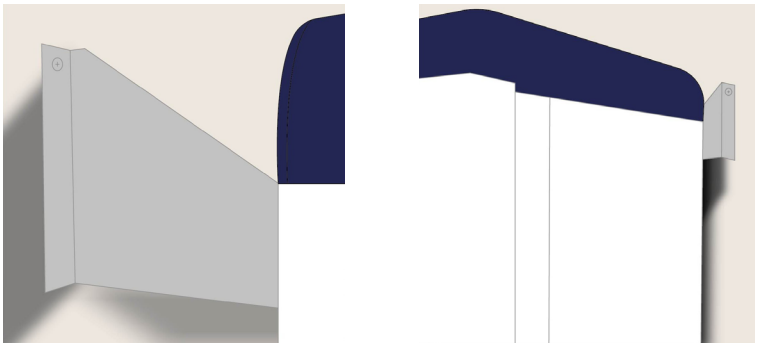


Figures 19 & 20: Brackets fixed to the device

14.1.5 Fitting to the wall

These steps should be carried out by hospital staff:

1. Place the device facing the wall and identify the location of the holes.
2. Drill and fit the two wall plugs.
3. Place the device in front of the wall plugs and screw it to the wall



Figures 21 & 22: Device fixed to the wall

CONTACT

The user and/or patient that any serious incident that has occurred in relation to the device should be reported to the manufacturer at prrc@germitec.com and the Competent Authority of the Member State in which the user and/or patient is established.

For any further information, contact your after-sales representative or the Germitec customer service:

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Notes

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