GERMITEC®

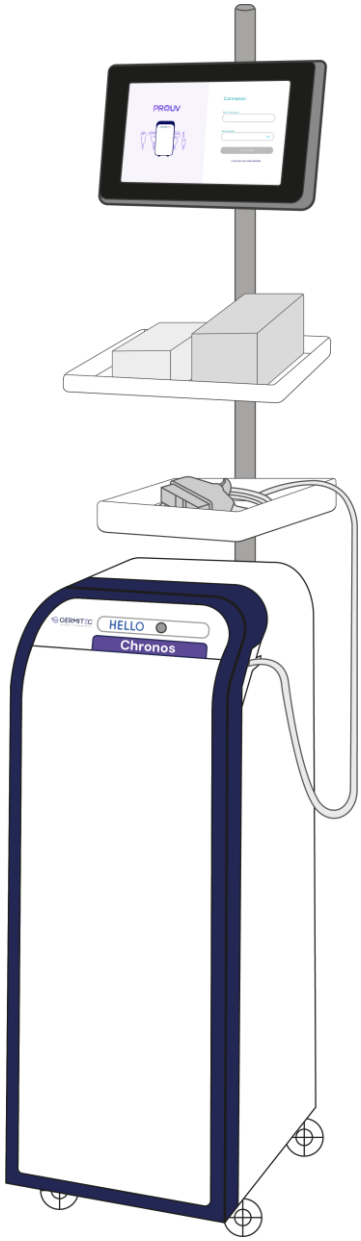
Your Partner in Preventing Infection.

PROUV

User manual

MAN-N005-EN Version 3 – June 2026

This manual must be read
before using the PROUV® interoperability system.
This ensures that it is used under the safest and most efficient conditions.



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For any questions regarding the equipment, its maintenance, a breakdown or once it has reached the end of its service life, contact the service representative.
The description of the disinfection system is accurate on the date this manual is printed.

PROUV® is a registered trademark of Germitec.

PROUV® is protected by a patent held by Germitec.

This manual is the property of:

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1 INTRODUCTION

1.1 Introducing PROUV®

1.1.1 Intended use

PROUV® is a traceability and interoperability system used in addition to Germitec's disinfection devices.

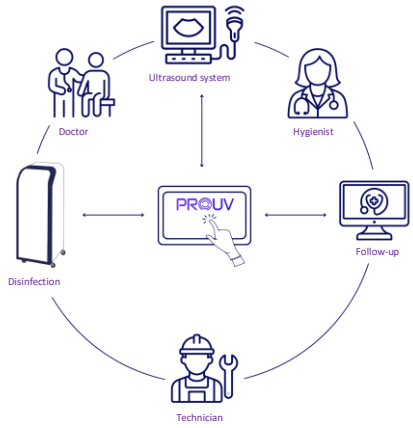
This traceability system is not a medical device within the meaning of Regulation (EU) 2017/745. It constitutes computer equipment intended to be used in combination with the Chronos® medical device.
It therefore does not bear the CE marking under the Medical Devices Regulation.

1.1.2 Description and environment

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

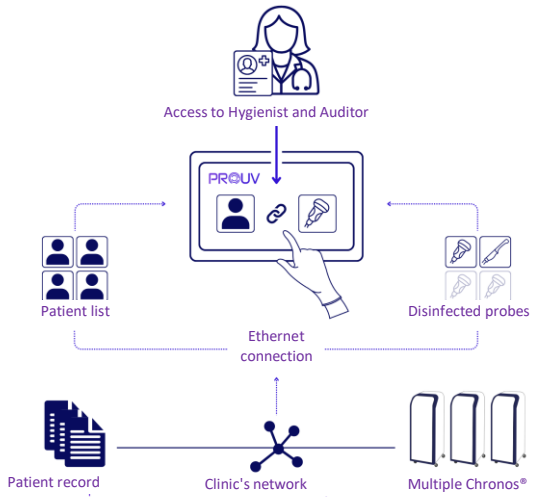
It is designed for use under the supervision of healthcare professionals such as medical radiology technologists, radiologists, gynecologists, obstetricians, cardiologists, urologists, general practitioners, nurses, nursing assistants, medical hygienists, and biomedical engineers.

It is the responsibility of the owner of the device to ensure that:
- All users are trained with regard to the instructions and warnings contained in this manual.
- All users are aware of the risks and the preventive measures described in this manual.



PROUV® is an interoperability system that makes it possible to associate disinfection operations with the actors involved during a medical examination requiring the use of one or more ultrasound probes. It is in the form of an intuitive touchscreen interface placed and connected to the site network in order to associate all the data.

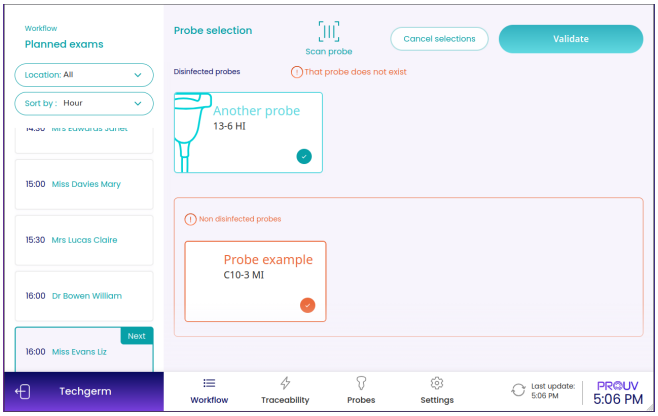
1.1.3 Simplified workflow



The PROUV® system gathers all the information on a single screen: patient and probe disinfection status, guiding the practitioner through the reprocessing process and ensuring digital traceability.

1.1.4 Disinfection status becomes visible

The PROUV® system's user interface provides a snapshot of the probes' disinfection status by presenting them under two distinct categories:



"Disinfected probes" (blue) or "Non-disinfected probes" (orange).

By default, only probes in the blue category "Disinfected probes" can be selected to be associated with an examination. A setting is available to select and associate a non-disinfected probe according to the customer's need.

The probes are considered "Non-disinfected" if the last disinfection was more than one hour ago (default setting) or if they were used on a patient. A setting is available to change the validity period of the disinfection according to the customer's requirements.

1.1.5 Sharing of disinfection and examination data

The traceability history provided by the PROUV® system can be exported in different ways, depending on its connection mode:

- from a computer through the local network,
- from a USB stick connected to the PROUV® system,

In addition, an automatic export can be sent to the patient file.

1.2 Recommended use

- PROUV® is an interoperability system to be integrated into a disinfection procedure.
- The PROUV ® system is a strictly reserved as a support for medical uses.
- The PROUV® system must be connected to a list of patients from the healthcare facility.

- Only disinfection devices can be connected to it.
- This device must be used in compliance with the operating procedure described in the section "Use".
- The disinfection and association data are saved in the system. This data can be downloaded from a computer or USB stick connected to the device. Germitec recommends backing them up at least once a week.

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 1.1.2,*
- *in accordance with the intended use and the recommended use respectively described in sections 1.1.1 and 1.2.*

Any other use of the device is prohibited and contraindicated by the manufacturer, as it could damage the device, seriously injure the user and third parties, damage nearby equipment as well as the surrounding environment.

1.3 Accessories

- The PROUV® system must be operated using the provided power and Ethernet cord.
- The PROUV® system can be used with a barcode reader supplied by Germitec.
- The PROUV® system can be used with other accessories supplied by Germitec, such as the mounting kit to install it on a mast above a Chronos®

1.4 Certification

The PROUV® system is CE marked, FCC Class A, LVD and RCM certified.
The PROUV® system is not considered a medical device in the European Union, the United Kingdom, Canada, Australia, New Zealand and the United States.

1.5 Management of personal data

In Standalone mode, the PROUV® system can store personal and patient data. The PROUV® system adheres to *privacy principles by design and by default*. The management of personal data is the responsibility of the site that uses PROUV® and must comply with local regulations.
In Connected mode, PROUV® does not store personal or patient data.

1.6 Technical characteristics

Touchscreen	10.1” totally flat
Dimensions	L 257.2 x D 45.95 x W 70 mm (10.1 x 1.8 x 6.7 in)
Weight	1.2 kg (2.6 lbs)
Power supply	120-240 VAC 50-60 Hz (with supplied adapter)

Compatibility with disinfection systems	Chronos®
Memory	Sufficient for more than 100,000 disinfections and patient associations
Import / export protocol	Import: DICOM Export: DICOM / HL7 version 2
Ready to connect to	Hospital Manager (Softway Medical) and any other system capable of integrating an HL7 message
Protection	IP65
Operating external temperature	-20°C to +60°C (410°F to 392°F)
Storage temperature	-30°C to +70°C (410°F to 392°F)
Relative humidity	95% non-condensing
Cooling solution	Passive - Fanless

2 SAFETY RULES AND OPERATING PRECAUTIONS

2.1 Safety rules

The following rules must be distributed by the equipment owner to all potential users of the PROUV® system. Failure to follow these instructions may result in damage to the device, serious injury to the user or others, or damage to nearby equipment and the surrounding environment.

2.1.1 Handling

- The equipment weighs approximately 1.2 kg.
- Do not bump the PROUV® system. If it falls or is damaged, contact Germitec.
- Do not use the PROUV® system when damage is suspected.
- Do not attempt to disassemble or repair the device.

2.1.2 Environmental conditions

- Use the PROUV® system and its accessories at temperatures of between -20 and 60°C, and at a relative humidity below 95% without condensation.
- Do not store the PROUV® system or its accessories at temperatures below -30°C or above 70°C.
- PROUV® can be used in an environment with a level-2 pollution level.

2.1.3 Use

- The PROUV® system is intended to be used exclusively for the use described previously, in the environment described previously, and by the personnel described previously. Any other use is prohibited.

- The PROUV® system is not a computer on which it is possible to install software or navigate outside the pages presented in this manual.
  In the event of failure of the PROUV® system, it is possible to use alternative methods of traceability of disinfections such as Germitrac®, the Chronos® embedded software.

2.1.4 Power supply

- The equipment must be connected to a grounded power outlet. Ensure that the power cord provided with the equipment is used.
- Connect the equipment only to a power supply having the appropriate voltage and frequency, as specified in the next section “Installation”. The use of an incorrect voltage may damage the equipment.
- Any attempt to disassemble one of the components of the equipment may cause electrocution.
- The user must take all necessary measures to prevent the entry of liquid into the device, as this could create an electrical hazard.
- The fluctuation of the supply voltage must be less than ± 10%.

2.2 Markings

RoHS	This symbol indicates that the manufacturer is ROHS COMPLIANT. This Directive lays down rules on the restriction of the use of hazardous substances in electrical and electronic equipment (EEE) with a view to contributing to the protection of human health and the environment.
	**Do not dispose of 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.
	**RCM – Regulatory Compliance Mark** The RCM is a symbol that represents compliance with two independent schemes: EESS (Electrical Equipment Safety System) and ACMA’s (Australian Communications Media Authority) labelling requirements. This symbol certifies that the product complies with Australian and New-Zealand mandatory requirements according to AS/NZS 4417. The RCM is a trademark owned by the electrical regulator (Regulatory Authorities (RAs)) and ACMA.

3 INSTALLATION, SETTINGS, AND START-UP

3.1 Packaging contents

The packaging contains the following components:

- 1 touchscreen
- 1 power cable
- 1 Ethernet cable

Optional components may also be present:

- 1 optional barcode reader with its USB cable

- 1 optional mounting bracket.

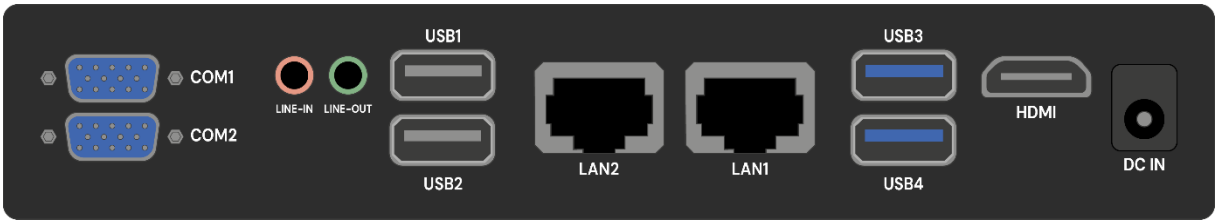
3.2 Presentation of the interfaces

Connecting to the mains supply

The connection to the mains is made using the mains adapter supplied with the device.
The system is powered on by pressing the power button once.
The power button is located on the top side of the device, in the upper left corner.

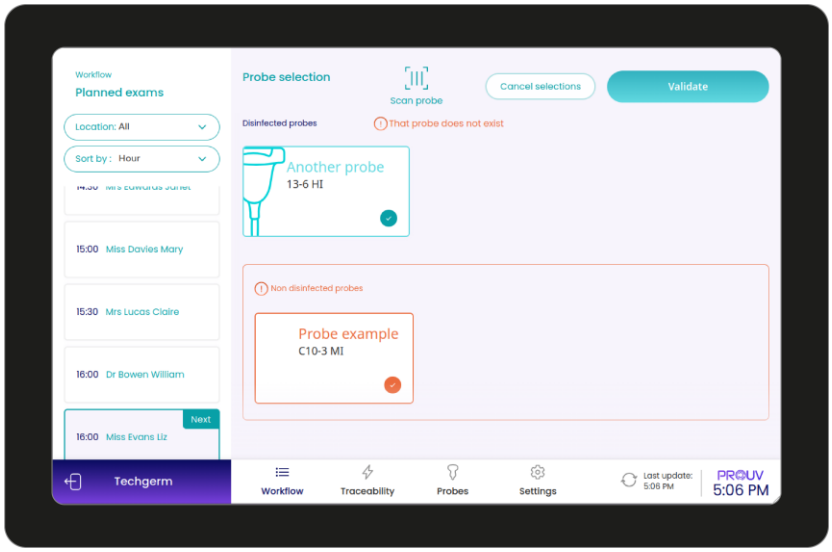
Peripheral connection interface

The other connectors (Ethernet) are located on the outside of the touch screen:



User interface

The user interface is a 10.1-inch touchscreen.



3.3 Installation

Users are not allowed to install the PROUV® system, only a qualified technician can do so.
The main steps of the installation are presented in the following sections.

3.3.1 Verification

Any damage during transport or storage may be a source of danger.

Furthermore, the user must verify the integrity of the equipment before its installation.

3.3.2 Placement

The PROUV® system is designed to be placed in each examination room near the ultrasound equipment, even if Chronos® is shared between several rooms. PROUV® will access its data from the exam room via a network connection.

The PROUV® system must be placed in a fixed position, at an adjustable height of 1.2 meters. The height can be adjusted depending on the environment and the size of the operator using the device.

3.3.3 Connection to electrical power

Warning

The PROUV® system must be connected to an electrical installation that is compliant with the current regulations. This connection must be performed by a qualified technician.

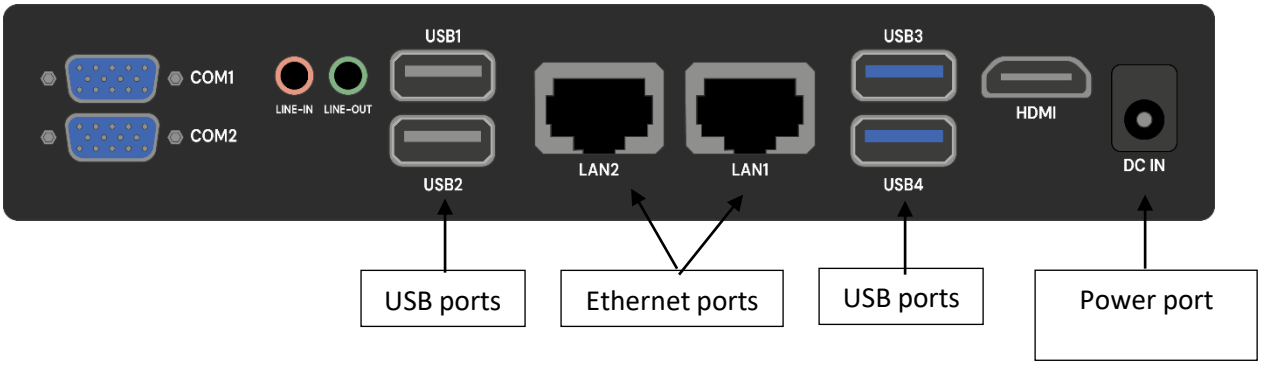
The PROUV® system is connected to an AC adapter that must receive a voltage between 120 and 240 VAC. Check that the power source is compliant.

Only power cords provided with the equipment may be used to connect it.

- Connect the adapter power cable to the touchscreen.
- Connect the plug at the other end of the adapter to a 16 amp outlet (2P+T). This outlet must be protected by a 3 A circuit-breaker on 240 VAC or a 6 A circuit-breaker on 120 VAC.

3.3.4 Connection of accessories

Never connect other peripherals to the connectors than those indicated below.



- To connect the PROUV® system to the client network, connect the Ethernet cable to the Ethernet port behind the touchscreen and to a network connector in the room.

- If the disinfection device is not on the client network, connect it to the PROUV® system with an Ethernet cable via the Ethernet port located behind the touchscreen and to the Ethernet socket of the disinfection device.

- If the client setup requires the optional barcode reader, to connect a barcode reader to the PROUV® system, connect the reader to one of the USB ports located behind the touchscreen.

Only manufacturer-supplied barcode scanners are compatible with the PROUV® system. The proper functioning of the system is not guaranteed with another reader.

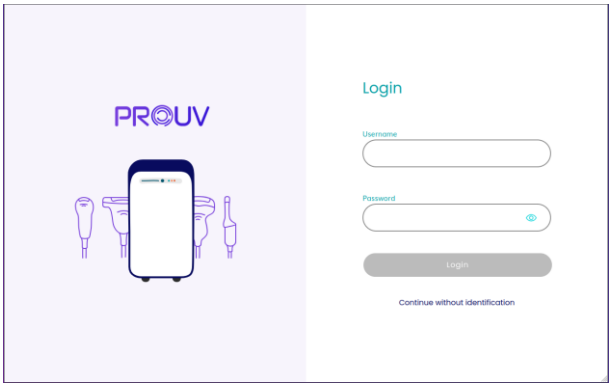
4 USE

4.1 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 carried out, the device may be damaged, the user and third parties may be seriously injured, nearby equipment and the environment may be damaged.

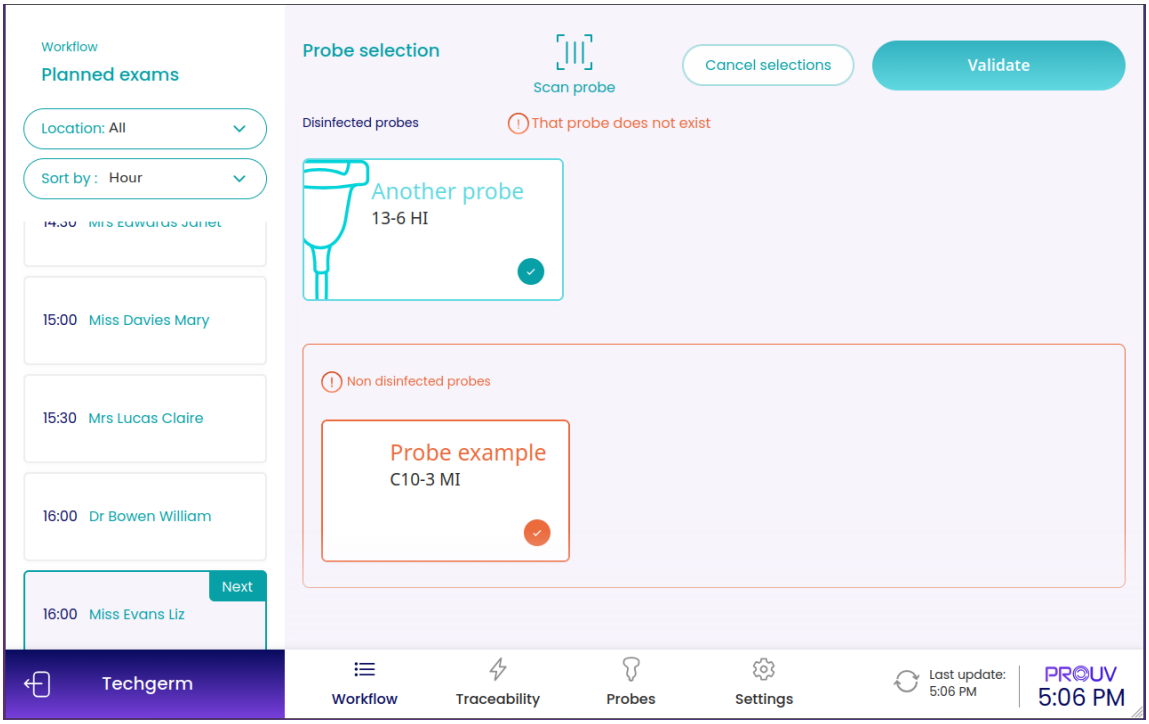
- Press the small button on the back of the touchscreen.

4.1.1 Homepage



4.1.2 Workflow

- Once logged in, the workflow page appears.



Before the examination, **check the patient's name**. A patient name is automatically selected based on the current time, it can be changed by selecting the name of another patient.

By default, patients from all examination locations are displayed. Depending on the setup settings, to view appointments scheduled for a specific location only (e.g. exam room A), select the location by tapping the “**Location**” drop-down menu at the top of the exam list.

Next, select all ultrasound probes you intend to use during the exam by simply tapping the probes in the list of disinfected probes.

If necessary, you can add additional ultrasound probes during the exam.

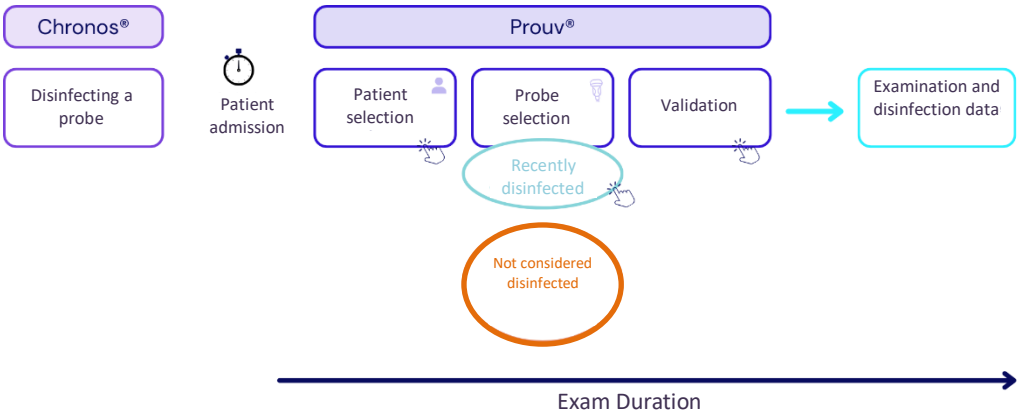
Depending on preference, manual confirmation may be required to "validate" your selection and create a unique traceability record. Or this validation can be done automatically after a predefined time (5 minutes or 10 minutes).

To manually start the validation process, press the “Validation” button in the upper right corner of the PROUV® screen. A progress bar will indicate the end of the validation process.

If you wish to cancel your selection before validation, deselect the targeted probe directly or press "Cancel" next to the "Validation" button.

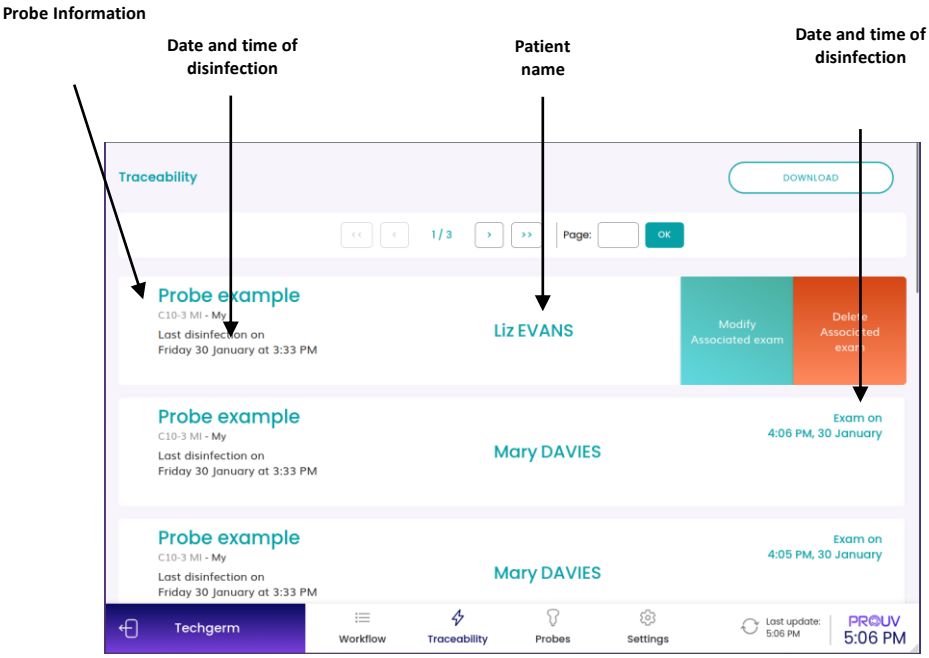
A list of non-disinfected ultrasound probes can also be displayed, but by default they cannot be selected. To access one of these probes, it will first be necessary to disinfect it using Chronos®. The disinfected probes will then appear on the screen as "Disinfected", with the probes disinfected last appearing first.

The main workflow is described below:



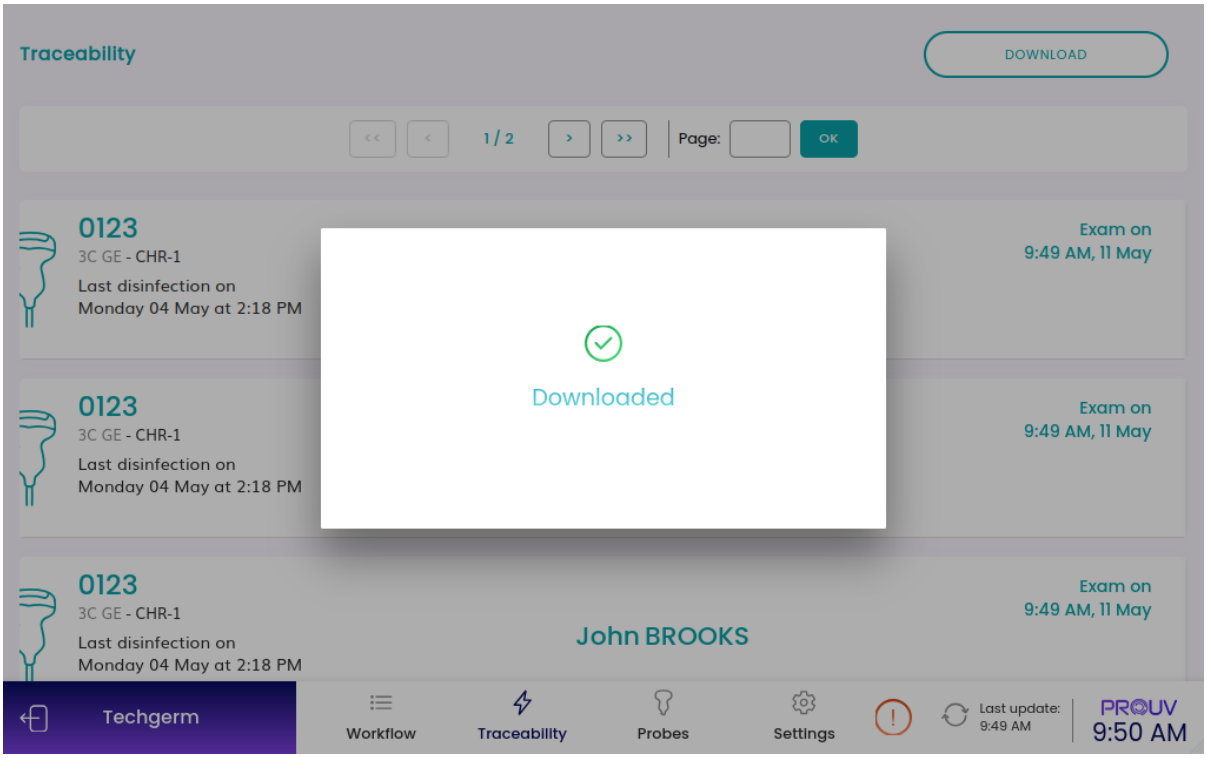
4.2 Verification of association and disinfection

- ➢ At the bottom of the screen, tap the “Traceability” symbol.
- ➢ A list of disinfections and the respective associations under examination is displayed.

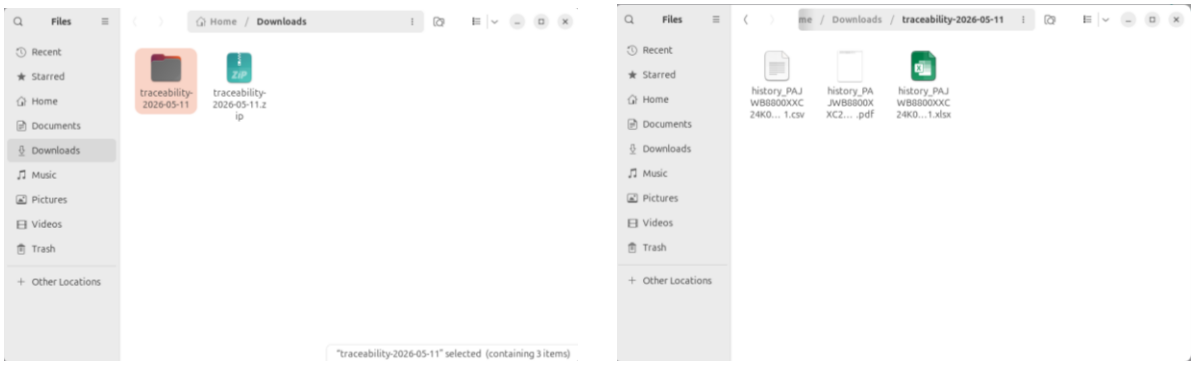


4.2.1 Downloading traceability history

The traceability data can be downloaded and exported by clicking on the "download" button. A window appears to confirm the correct download of the data.



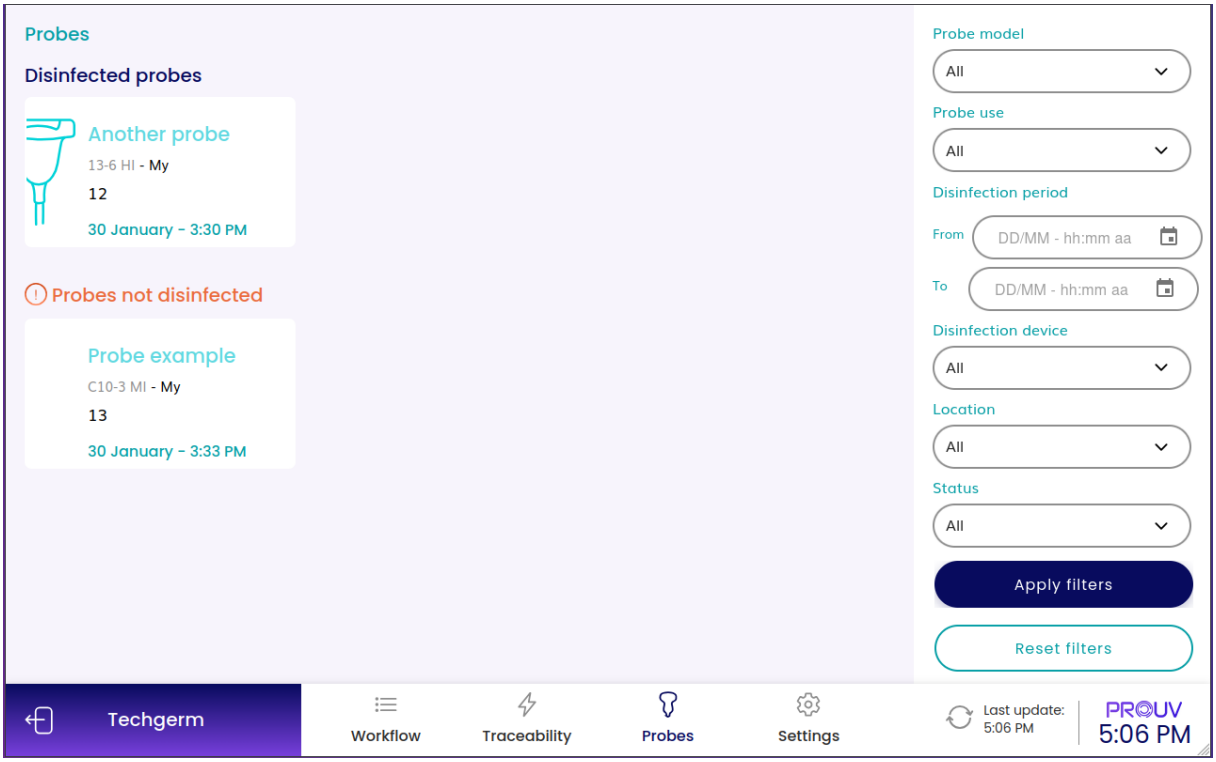
The generated files can be saved locally on the tablet, or on a USB stick if previously connected to one of the USB ports.



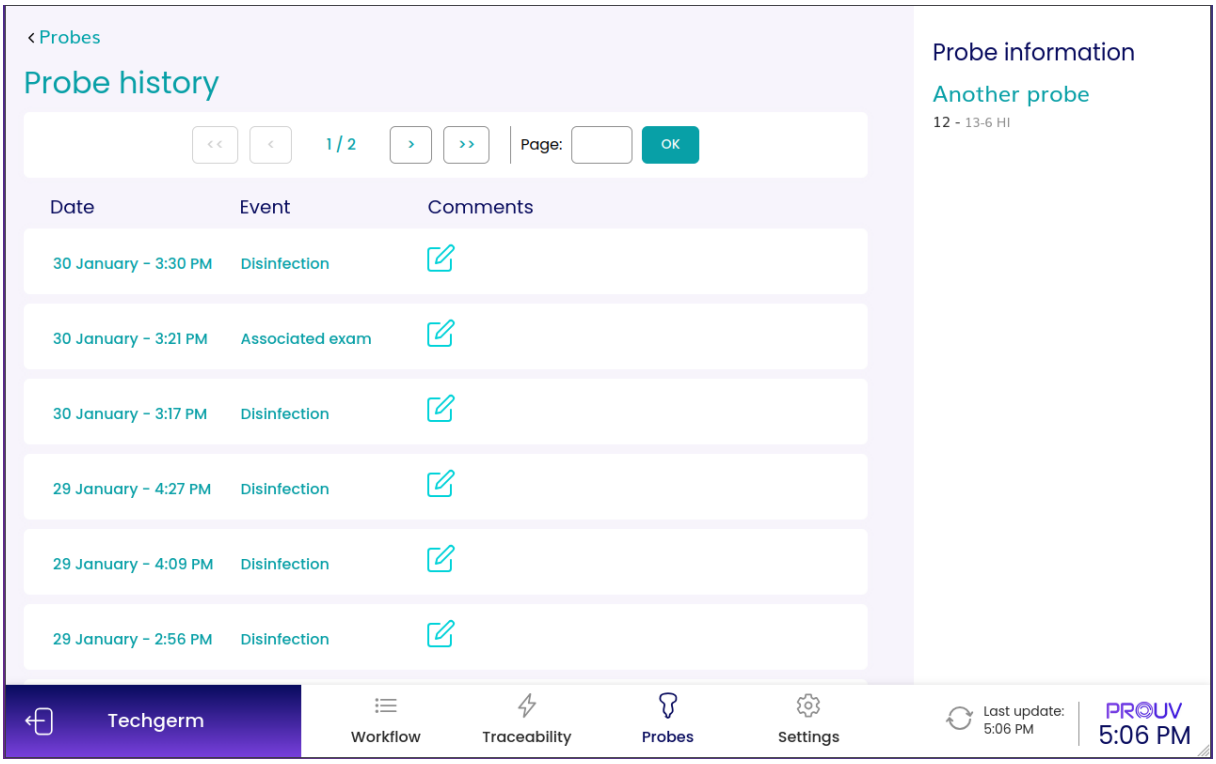
4.2.2 Probe management

The "Probes" section of the bottom menu displays all the probes available in the system, grouped under the categories "Disinfected" and "Non-disinfected".

The list of probes can be filtered by modifying various criteria, such as the serial number of the Chronos® used for disinfection, the username, the disinfection period, the disinfection location, the examination location and the condition of the probe (for example, disinfected or non-disinfected) or to find a specific probe or group of probes.
To return to the full list of probes, tap “Reset Filters” under the “View” button.



To access history or add a comment to a probe-related event, simply tap the probe in the list. On a probe's history page (see image below), it is possible to comment on any operation.



4.3 Settings

4.3.1 Access management

From the login interface, a "guest" access is possible to access the contents of the PROUV® system.

It is also possible to create as many "operator" accesses as desired via the settings – request the creation and management of profiles from your administrator.

4.4 Switching off

The system should never be switched off by directly unplugging the device at the risk of irremediably damaging it and losing the saved traceability data.

➢ Press the small button on the back of the touchscreen.

➢ Select shutdown on the touchscreen.
➢ The PROUV® system is now switched off.
➢ Disconnect the mains power cable to cut off all mains power.

5 ROUTINE MAINTENANCE

5.1 Exterior cleaning

- Before cleaning the touchscreen, turn it off and unplug it.
- Wear disposable gloves.
- Spray disinfectant on a microfiber cloth. If you don't have a microfiber cloth, use 100% cotton fabric or another soft material.
- Wipe the entire surface of the touchscreen, paying particular attention to the gaps around the screen.

Do not spill liquid inside and on the touchscreen and do not spray the touchscreen directly.

Do not mix cleaning chemicals or use non-recommended products, especially ammonia-based products and those with an alcohol concentration greater than 70%.

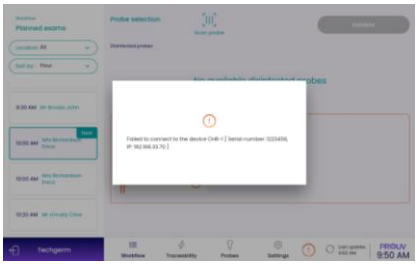
6 PREVENTATIVE MAINTENANCE

Preventive maintenance of PROUV® must be carried out simultaneously with Chronos® one and must be performed exclusively by a Germitec-approved service agent. It includes cleaning and checking network connections.

If software updates are available, they can be installed by an authorized Germitec service agent during preventive maintenance of disinfection devices, or during specific maintenance.

7 TROUBLESHOOTING

The PROUV® system is designed to detect and react to different scenarios.

Error designation	Advanced diagnostics
Black screen	The screen may be in standby mode, double tap the screen to re-activate the display. If there is no reaction, check that the power cable is properly connected. If yes, try restarting the tablet using the lower switch.
Screen frozen	Try restarting the tablet using the switch. If the error persists, contact a technician or your local representative.
Network connection failed 	The software cannot connect to the worklist server. Check that the Ethernet cable is properly connected at both ends.
Failed to connect to disinfection devices 	The software cannot connect to the defined Chronos®. Check that the Ethernet cable is properly connected at both ends.
	License is not usable or has expired. Contact a technician or your local representative.

License expiration	
Internal error	Contact a technician or your local representative.
[Pop up] **Failed to send message**	Failed to export HL7 message to patient folder. Check the Ethernet cable connection, HL7 configuration and network settings of the tablet.
Close the PROUV app 	Drag two fingers up and down, click in the upper left corner to collapse the window, hold the finger for 2 seconds on the window and click on the cross in the upper right corner once it appears.
Relaunch the PROUV application in the event of an unexpected closure 	Click on the blank page and double click on the Germitec icon.

8 TRANSPORT AND STORAGE

The device must be transported in suitable packaging as provided upon initial delivery. At the place of installation, it can be moved with both hands. Before moving the device, make sure it is unplugged.

Comply with the device's storage and transport requirements:

- Storage temperature: -30 to +70°C
- Relative humidity: less than 95 % without condensation

9 DISPOSAL

See section 2.2 on Markings.

10 WARRANTY

The PROUV® system 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 PROUV® system must be repaired exclusively by the manufacturer or a repair center authorized by the manufacturer. Opening the device voids the warranty. Contact your after-sales representative to organize this repair before returning the equipment.

11 CONTACT

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

Germitec Customer Service
19 rue Vauban - 33000 Bordeaux
Tel: +33 (0)1 49 87 18 00 – support@germitec.com

Notes