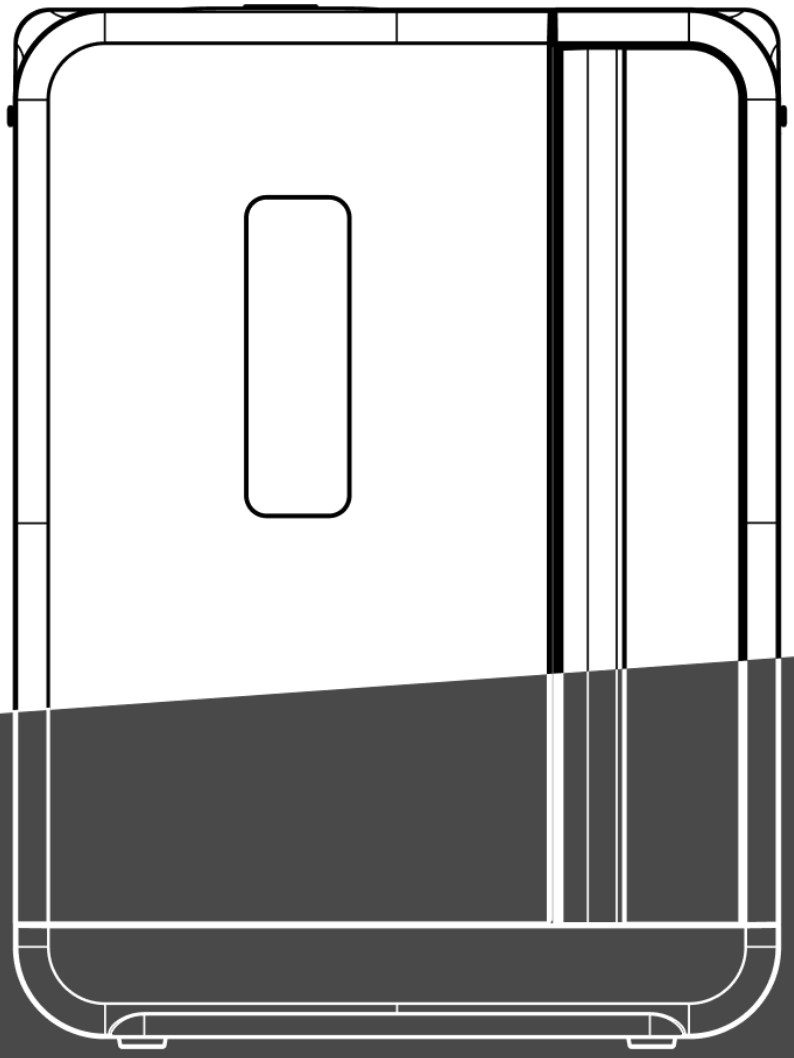
UVsmart

UV Smart D45



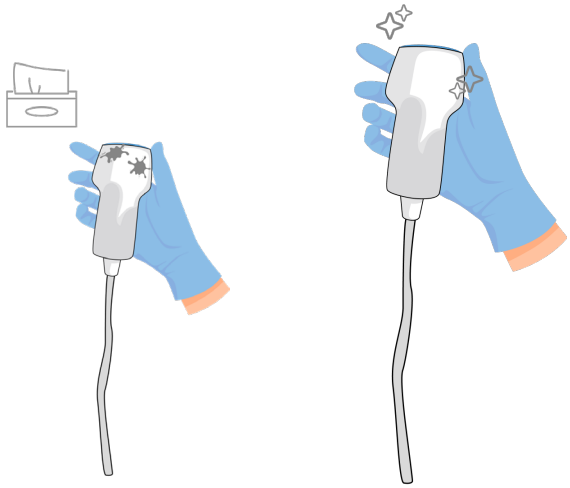
Instructions for Use

To avoid the risk of accidents or damage to the D45, it is essential to read these instructions before it is installed and used.

US **United States of America**

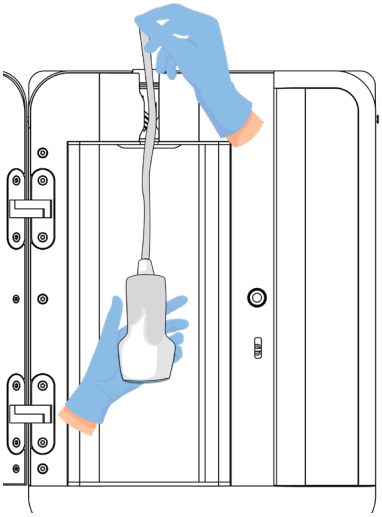
Use of the D45: Quickstart Guide

1 *Before using the device, make sure to clean your ultrasonic transducers following the instructions provided by the manufacturer.*

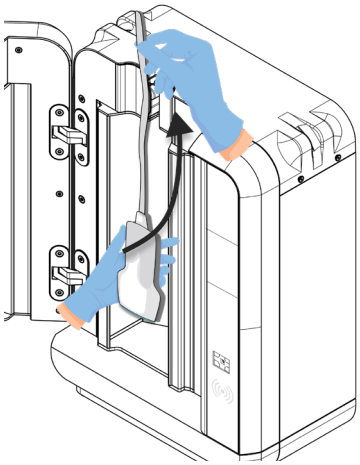


2 *Follow the instructions displayed on the D45 screen and press the green button to start the disinfection process.*

3 *First, position the cable of the transducer parallel to the cable holder.*

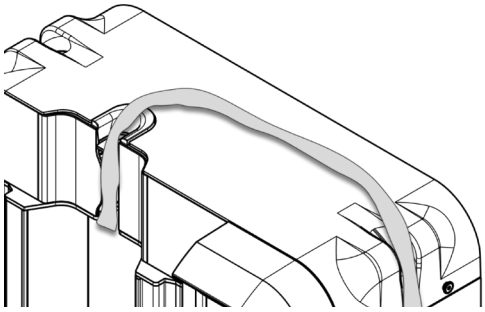


4 *With care, pull the cable in an upwards motion into the cable holder to secure it in place. Let the transducer hang freely***

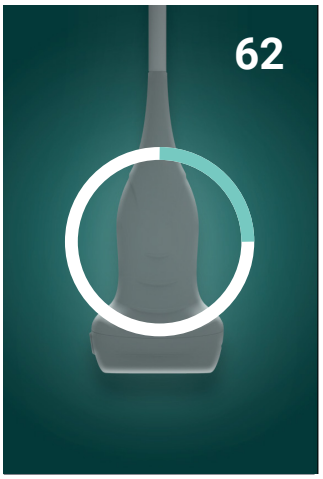


***Hang freely here implies: not touching the sides, nor the bottom or top of the disinfection chamber.*

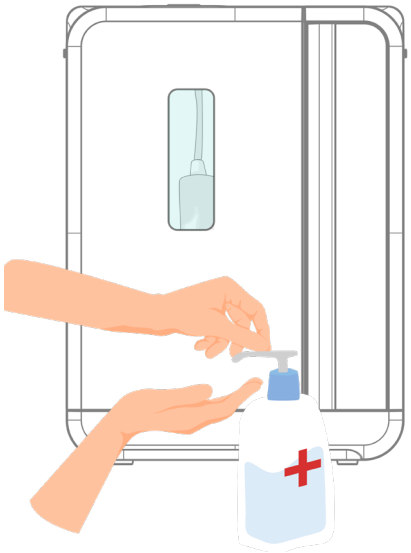
5 *Guide the remaining cable into the cable guides located on top of the device. Make sure the cable is away from the door while closing the door.*



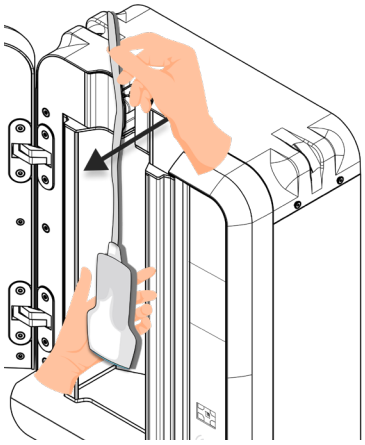
6 *The cycle will start automatically when the door is closed.*



7 *Wait for the cycle to finish. In the meantime disinfect your hands according to protocol.*



8 *When the cycle is completed carefully take out the disinfected transducer from the D45. The transducer is now safe to use.*



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1. Introduction

The UV Smart D45 is a Class IIa medical device (MDR (EU) 2017/745). The UV Smart D45 is intended to High-Level Disinfect ultrasonic transducers (also referred to as ultrasound transducer or probe) by using UV light.

The D45 consists of a high reflective disinfection chamber for UV light. Inside, two lamps are positioned on each side of the chamber to ensure complete irradiation of the transducer placed inside. The transducer is suspended in the disinfection chamber by its cable. Once inserted, the clamping mechanism will detect a transducer present, and the D45 will initiate a disinfection cycle upon closure of the door.

The emitted light used is UV-C, ranging from 100-280nm (peak at 253.7nm). The lamps each have an intensity of 60W. The light is diffusely distributed throughout the whole disinfection chamber.

When in use, the UV light that is used for disinfection cannot escape the disinfection chamber. The glass in the door filters out all harmful properties of the light. In case the door is opened during a disinfection cycle, the lamps will be shut off by both the software – registering opening using a sensor – and an interlock switch which operates independently from the software, and provides a hard circuit-break.

The germicidal effect of UV light will not penetrate dirt, debris and grime. To allow the D45 to perform optimally it is required that all transducers are pre-cleaned before use, according to the corresponding instructions for use provided by the transducer manufacturer.

The UV Smart D45 is suitable for use by any instructed medical professional or laymen working under the supervision of an instructed medical professional. The Instructions for Use should therefore be read prior to operation.

In case they might occur, serious incidents should be reported to UV Smart or your local reseller and competent authority of the member state.

The UV Smart D45 is a Risk Group 2 device. This device complies with part 15 of the FCC Rules. Operation is subject to the condition that this device does not cause harmful interference.

FCC Regulatory Notices:
This device complies with Part 15 of FCC Rules, Operation is Subject to following two conditions:
(1) This device may not cause harmful interference, and
(2) This device must accept any interference received including interference that cause undesired operation.

Caution: Any changes or modifications to the equipment not expressly approved by the party responsible for compliance could void user's authority to operate the equipment. This equipment has been tested and found to comply within the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation.

This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

• Re-orient or relocate the receiving antenna
• Increase the separation between the equipment and receiver
• Connect the equipment into an outlet on a different circuit from that to which the receiver is connected
• Consult the dealer or an experienced radio/TV technician for help.

ISED Canada Regulatory Notices:

This device is compliant with ISED Canada license-exempt RSS standards. Operation is authorised under the following two conditions:

1 - the device may not cause harmful interference;

2 - the device must accept any interference received, even if it compromises operation.

RF Exposure information

FCC:

This device complies with FCC RF radiation exposure limits set forth for an uncontrolled environment. This device complies with the safety requirements for RF exposure for mobile (>20cm) use conditions in accordance with FCC rule part 2.1091.

ISED Canada:

This equipment complies with ISED Canada RSS-102 radiation exposure limits set forth for the general population. This equipment complies with the safety requirements for RF exposure in accordance with RSS-102 Issue 5 section 2.5.2 for mobile (>20cm) use conditions. The minimum compliance distance is 20cm.

2. Intended Use

2.1. Intended Use

The UV Smart D45 is intended to High-Level Disinfect ultrasonic transducers by using UV light. This is achieved after the transducer is pre-cleaned and checked according to the manufacturer's protocol.

The medical devices that can be disinfected with the D45:

• Non-invasive transducers;

• Invasive transducers

The device does not support or sustain life. Moreover, the D45 has no patient interaction. It is used on transducers which come in contact with the patient. No substances/tissues (derived) of human and/or animal origin are present in the D45. After a disinfection cycle the D45 can be reused directly after performing the steps indicated in chapter 10.3.

2.2. Intended Medical Indication

The UV Smart D45 is intended for High-Level disinfection of ultrasonic transducers physically able to fit inside the disinfection chamber's designated volume.

2.3. Indication(s) for Use

The UV Smart D45 can be used in case of the following needs:

- High-Level disinfection;
- Automated disinfection;
- Consistent disinfection;
- Disinfection on location.

Previously administered or manual disinfection methods can be applied in case of device failure.

2.4. Contra-Indications for Use

The UV Smart D45 cannot be used in case:

- The Indications for Use are not met;
- The D45 is damaged;
- The user comes in direct contact with UV light, produced by the device;
- The transducer has visible debris on it;
- There is any doubt about how to use the D45.

2.5. Intended Users

The UV Smart D45 is suitable for use by any instructed medical professional or laymen working under the supervision of an instructed medical professional. A medical professional is an individual qualified by education, training, licensure or facility privileging who performs a professional service within his/her scope of practice. Medical professionals include doctors, nurses, hospice workers,(emergency) medical technicians and other trained caregivers.

2.6. Intended Use Environment

The intended use environment of the UV Smart D45 is medical related meaning; hospitals, medical clinics, nursing home, doctor's office, reprocessing facilities, etc

The UV Smart D45 shall be used in the following environmental conditions:

Temperature:	5°C – +40°C
Relative Humidity:	20% – 85% (without condensation)
Atmospheric pressure:	800hPa - 1060hPa

2.7. Claimed Performance

The required reduction of micro-organisms is based on the EN-14885:2022 to compare it to the state of the art of disinfection methods. The following reductions are determined and claimed:

Claim	Micro-organism	Strain	Log reduction
Bactericidal	Staphylococcus aureus	ATCC 6538	≥ 5,0
	Pseudomonas aeruginosa	ATCC 15442	≥ 5,0
	Enterococcus hirae	ATCC 10541	≥ 5,0
	Escherichia coli	ATCC 10536	≥ 5,0
Fungicidal	Candida albicans	ATCC 10231	≥ 4,0
	Aspergillus brasiliensis	ATCC 16404	≥ 4,0
Yeasticidal	Candida albicans	ATCC 10231	≥ 4,0
	Candida auris	DSM 21092	≥ 4,0
Sporicidal	Bacillus subtilis	ATCC 6633	≥ 4,0
	Bacillus cereus	CIP 105151	≥ 4,0
	Clostridium difficile	NCTC 13366	≥ 4,0
Mycobactericidal	Mycobacterium avium	ATCC 15769	≥ 4,0
	Mycobacterium terrae	ATCC 15755	≥ 4,0
Tuberculocidal	Mycobacterium terrae	ATCC 15755	≥ 4,0
Viricidal	Poliovirus type 1, LSc-2ab (Picornavirus)	LSc-2ab	≥ 4,0
	Adenovirus type 5, strain Adenoid 75	strain Adenoid 75, ATCC VR-5	≥ 4,0
	Murine Norovirus, strain S99 Berlin	Strain S99 Berlin	≥ 4,0
	Vacciniavirus	Strain Ankara (MVA), ATCC VR-1508 or strain Elstree, ATCC VR-1549	≥ 4,0
	Polyomavirus SV40, strain 777	Incertae sedis	≥ 4,0

Table 1: Specific micro-organism reduction by the UV Smart D45

3. Clinical Benefits

The reproducible use process of the D45 results in a consistent disinfection efficacy. This means the D45 reduces risk of transducers related cross infection within a facility. Moreover, reprocessing personnel are less burdened because of the simple and quick use of the D45.

4. Residual Risks

Any residual risks related to the use of the D45 are mentioned in the Warnings and precautions chapter. When the D45 is used according to its Intended Use and this Instructions for Use those risks mentioned and any undesirable side-effects are reduced as far as possible.

5. Material Compatibility Statement UV Smart

UV Smart issues and regularly updates a statement addressing specific brands/types of transducers. The purpose of this statement is to alleviate any concerns related to the disinfection of transducers using the UV Smart D45 disinfection device with Impelux™ technology (hereinafter referred to as D45).

In this statement UV Smart guarantees any damage on transducers which would have as exclusive origin, determined by an independent laboratory, disinfection with the D45. This excludes discoloration of materials. UV Smart is properly insured, should any damage occur. In other words, UV Smart will pay for any damage caused by the D45 on listed devices (excluding discoloration).

For the complete statement and the list of covered models/brands please refer to

- http://www.uv-smart.com/compatibility (USA).

6. Warnings and Precautions

6.1. Warnings

⚠ Upon delivery, check that all items are present, without visible debris and undamaged. Do not use a damaged D45. If you think the D45 is damaged, dirty or items are missing, please contact your local distributor.

⚠ Do not use the D45 in an oxygen enriched environment or in the vicinity of combustible gases (e.g. anesthetics).

⚠ Do not use the device outside the prescribed conditions as stated in the Intended Use Environment paragraph (2.6).

⚠ The D45 must only be connected to a mains power supply with protective earth, to avoid the risk of electric shock.

⚠ When connecting the D45 to a mains power supply (wall socket), make sure the power supply is reachable to users so the D45 can be shut off in case of emergency. Shutting off can be done by unplugging the power cable from the wall socket.

⚠ Visible debris should be removed from the transducer surface according to the corresponding instructions for use provided by the equipment manufacturer before placing it inside the D45 for disinfection.

⚠ Protect the D45 and the power supply against liquids and moisture.

⚠ Follow the instructions in the instructions for use.

⚠ Do not insert transducers made of organic materials.

⚠ Only insert transducers consisting of hard, non-porous outer surfaces.

⚠ Do not insert sharp objects.

⚠ Do not insert humans or animals.

⚠ Do not insert flammable substances in the D45 to prevent damage and risk of fire/explosion.

⚠ Do not insert a transducer larger than the dimensions as defined in the Product overview chapter (7). This could damage the medical equipment/D45 and/or jeopardize the disinfection performance.

⚠ Inserted transducer should not touch the side walls nor the bottom or ceiling of the disinfection chamber.

⚠ Do not close the D45 door with excessive force.

⚠ Do not open the D45 door during a disinfection cycle, unless it is instructed by the display or when strictly necessary because of external factors.

⚠ Do not take out transducer before the disinfection cycle has finished, unless it is instructed by the display or when strictly necessary because of external factors.

⚠ Do not shut off the D45 during a disinfection cycle.

⚠ Do not attempt to repair without proper training the device during its intended lifetime. Refer to the Warranty chapter (16).

⚠ Do not open the D45 service area. Only qualified personnel is classified to open the D45's housing.

⚠ Do not connect any accessories to the D45 that are not mentioned in this Instructions for Use.

⚠ The D45 should not be used for in vivo use.

⚠ To be disinfected surfaces should not be shadowed or covered during the disinfection process.
Use of the D45 could influence the color of the outer surface of the disinfected equipment.

⚠ Do not stick anything to the inside or outside of the D45.

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Do not remove the USB flash drive during the data importing and exporting processes.

Do not place any transducer on the D45 disinfection chamber floor.

The UV-C lamps in the D45 disinfection chamber contain mercury. Handle the D45 with care to prevent any damage. In case of damage, refer to chapter 13.

Do not modify the D45 without authorization of the manufacturer.

With initial placement of the D45, it is recommended to mount the D45 to the Trolley or Wall Mount. Be aware that the device may tip over when a force is applied to the sides of the D45.

Do not use power cord with inadequate rating.

Do not use the D45 other than as prescribed as this might affect your safety.

Do not use the device with broken door window(s) and/or lamp glass covers.

Do not transport the device on the trolley unless it is properly positioned and securely fixed.

Installation of the Wall Mount is at the customer's own risk.

The UV Smart D45 is a Risk Group 2 device. Caution: Possibly hazardous optical radiation emitted from this product. Do not stare directly at operating lamp. May be harmful to the eye.

Caution. UV ray exposure.

Caution hot surface.

6.2. Precautions

⚠ With initial use, the user is required to read the Instructions for Use.

⚠ According to the D45 Intended Use, the user is required to be informed.

⚠ Do not transport (carry) the D45 when its door is open.

⚠ Do not transport (carry) the D45 when a transducer is present in the disinfection chamber.

⚠ Make sure the D45 is properly positioned on a level and steady surface or on the Trolley or Wall Mount.

⚠ Avoid applying external force in the ‘opening’ direction of the D45 door when the door is fully opened.

⚠ Gently place/remove transducer in/from the disinfection chamber of the D45 to prevent damage to the D45 and transducer.

⚠ Always visually verify if the UV-C lamps switch on when a disinfection cycle is ongoing.

⚠ Only clean the D45 following the cleaning instructions in the Maintenance chapter (12).

⚠ After a disinfection cycle a smell can be identified: this is caused by the germicidal effect of the UV light on micro-organisms. The smell is not harmful.

⚠ The D45 connection with a client’s intranet is realized through an ethernet cable. Therefore, the client is responsible for any intranet security protocols that apply.

⚠ Do not touch the UV-C lamps.

⚠ To prevent the risk of electric shock and/or jeopardizing the disinfection performance of the device, do not modify the D45 in any way if you are not authorized.

⚠ During cleaning make sure to use gloves.

⚠ When closing the door, keep your hands free from the door opening.

⚠ Avoid applying external force on the door window(s) and on the lamp glass covers.

7. Product Overview

7.1. Packaging Content

Items

- D45 medical device
- D45 Instructions for Use
- Power cable

7.2. Features and Dimensions

Features

1. D45 unit
2. Disinfection chamber
3. Cable holder roller
4. Cable guide
5. Cable holder fixed roll
6. Rubber sealing cable guide
7. Door housing
8. Door handle
9. Door window (external)
10. Display housing
11. LCD touch screen
12. Barcode scanner
13. RFID reader
14. Door magnet (lock)
15. Bumper feet (4x)
16. USB port
17. Ethernet port
18. Circuit breaker (opening)
19. Main power supply inlet
20. On/off-switch
21. Service lid*
22. Back panel*
23. Back panel plint*
24. Transmissive glass
26. Circuit breaker pin
27. Cable guide

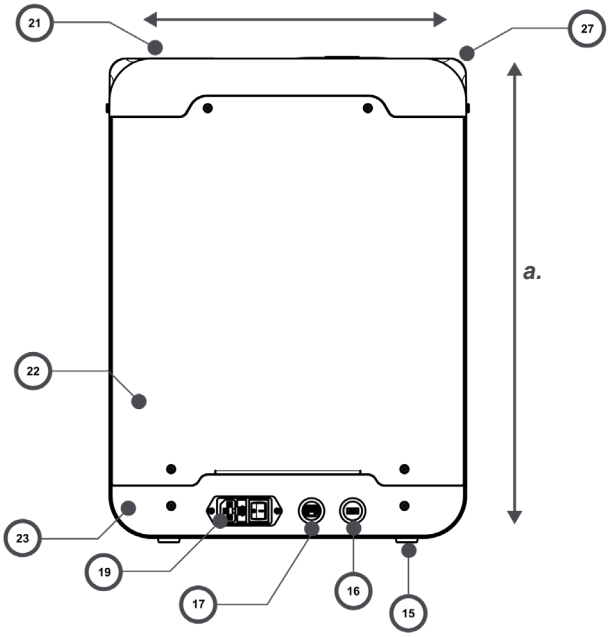


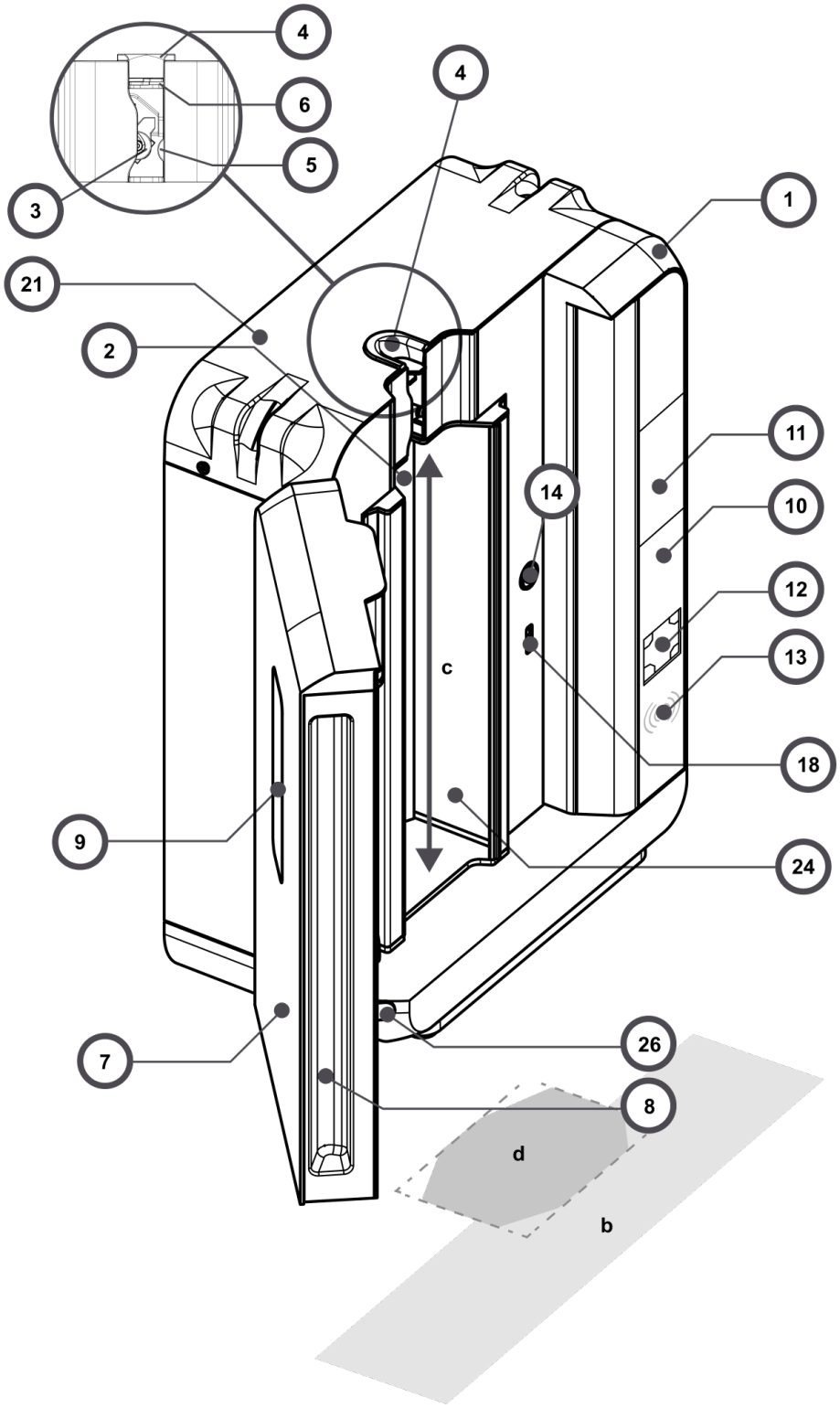
Fig 1.1 D45 product overview

Dimensions

a. Device height	525mm
b. Device area (WxD)	390mm x 202mm
c. Disinfection chamber height	400mm
d. Disinfection chamber area (WxD)	140mm x 118.7mm
e. Maximum ultrasonic transducer length**	380mm
f. Minimum transducer cable diameter**	6mm
g. Maximum ultrasonic transducer cable diameter**	14mm

* The D45 Service lid (21), Back panel (22) and Back panel plint (23) are parts that shall only be removed by UV Smart qualified servicing personnel, to access maintenance/ service parts of the device.

**Consult UV Smart or your local reseller in case of any questions.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8. Interface

The D45 interface consists of a touch screen, RFID reader, barcode scanner, speaker and (color) LEDs.

Touch Screen

The touch screen is located on the front of the D45. With touch input the user can navigate through the interface of the screen and control the D45. Throughout the D45 use, the D45 displays a variety of screens. Specific screens are explained throughout the Instructions for Use.

Barcode Scanner

The barcode scanner is located below the touch screen on the front of the D45 display housing. During a disinfection process, the barcode scanner facilitates traceability of equipment and ID cards equipped with barcodes.

RFID Reader

The RFID reader is located below the barcode scanner in the D45 display housing. During a disinfection process, the RFID reader facilitates traceability of transducer and ID cards equipped with MIFARE Classic.

Speaker

The speaker is located behind the display housing and gives feedback about the D45 use status. The meaning behind the sounds is explained in chapter 9.

LEDs

The LEDs are integrated into the disinfection chamber and give feedback about the D45 use status. The meaning behind the LEDs is explained in chapter 9.

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9. Sounds and Lights

Use the following table to identify the meaning behind the D45 sounds and lights.

	Sound/light	Possible meanings	Action options
/	**Negative / (Blinking) red**	The transducer has not been successfully disinfected	▪ Check display for instructions ▪ Close the door manually ▪ Contact your local reseller
		The lamps are not functioning properly	▪ Check display for instructions ▪ Contact your local reseller
		The door has been opened too soon	▪ Check display for instructions ▪ Close the door manually
/	**Positive / green**	The transducer has been successfully disinfected	▪ Check display for instructions ▪ Take out equipment
		Setup is successful	▪ Check display for instructions
/	**Attention / Blinking white**	The transducer has not been taken out of the disinfection chamber	▪ Check display for instructions ▪ Take out equipment ▪ Close the door
		The door is not (properly) closed	▪ Check display for instructions ▪ Close the door ▪ Contact your local reseller
		The D45 needs cleaning	▪ Clean the D45 manually ▪ Check display for instructions
/	**No Sound / White**	D45 is ready to be used	▪ Initiate a disinfection cycle
		D45 is in setup mode	▪ Check display for instructions
		D45 is in menu mode	▪ Navigate through the menu
		D45 is in the middle of a process	▪ Check display for instructions

10. Use

10.1. Standalone and Connected D45

Two configurations of the D45 are available: A connected D45 and a standalone D45. During the first time use (setup), the configuration selection is made by the user, depending on the user's needs. The difference between the configurations is described below:

Connected D45

A connected D45 is connected to the client's intranet, via ethernet cable. This D45 works together with UV Soft, UV Smart's data logging software. The software is installed on a client's PC, connected to the same intranet. Within UV Soft, users and equipment for disinfection can be added and edited and use data can be viewed and exported.

Standalone D45

A standalone D45 is not connected to any network. Users and equipment for disinfection are imported into the D45 via USB flash drive. Disinfection data can be viewed and exported from the D45 interface.

10.2. First Time Use (Set-up)

The initial setup is performed by the user. The user will connect the D45 power cable to the mains power supply (wall socket) and make sure the wall socket where the D45 power cable is plugged into is always in reach of users in case of emergency. In case of emergency, users can unplug the power cable from the wall socket to shut off the D45. After connecting the D45 to the mains power supply, the personnel will then switch on the D45 and start disinfection cycle when the device is ready.
After connecting the D45 to the main power supply, the qualified individual will then switch on the D45 and perform the first time setup.

During setup the following settings are configured:
- Language
- Time zone
- Time and date
- Network settings
- ID necessity: Does the client want to make use of user identification?
- Equipment ID necessity: Does the client want to make use of equipment identification?
- Printer necessity: Does the facility want to use a printer?

These settings can be adjusted at any moment by a master user in the D45 menu.

10.3. Before Every D45 Use

Perform the following steps before every D45 use.

1. Make sure the D45 shows no signs of damage or material degradation.
2. In case the display indicates an error or maintenance state, contact your local reseller.
3. Make sure no transducer from the previous disinfection cycle is present in the disinfection chamber.
4. Make sure all visible debris is removed from the disinfection chamber.
5. Make sure the door is closed.
6. Make sure the D45 setup has been performed.

When all steps have been performed and the D45 display allows starting the disinfection process, the D45 is suitable for use.

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10.4. After Every D45 use

Perform the following steps after every D45 use.

1. Remove the transducer from the disinfection chamber.
2. Make sure all visible debris is removed from the disinfection chamber.
3. In case you use the D45 for only one disinfection cycle, close the door. In case of running multiple disinfection cycles, repeat the process starting at the Before every D45 use-paragraph (10.3).

10.5. Placement of Transducer Guide

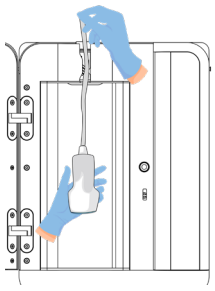
Transducers with the following dimensions are suitable to be placed inside the D45 disinfection chamber:

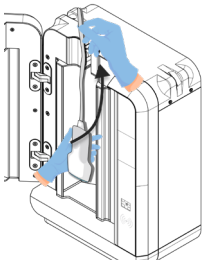
Maximum transducer length	380mm*
Minimum transducer cable diameter	6mm*
Maximum transducer cable diameter	14mm*

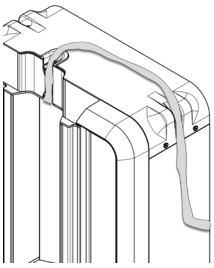
When placing the transducer inside the D45 disinfection chamber, be aware of the following:

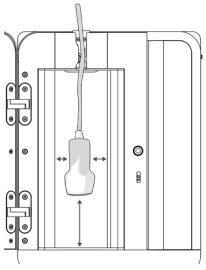
1. First, position the cable of the transducer parallel to the cable holder.
2. With care, pull the cable in an upwards motion into the cable holder to secure it in place. Let the transducer hang freely.
3. Guide the remaining cable onto the cable guides located on top of the device. Make sure the cable is away from the door while closing the door.
*4. The transducer should hang freely; meaning not touching the sides, nor the bottom or top of the disinfection chamber. The transducer should be hanging at least **2cm** above the disinfection chamber bottom plate.*

These steps can be remembered by mnemonic **PECO**:
Position, **E**quipment, **C**able, **O**pen and free

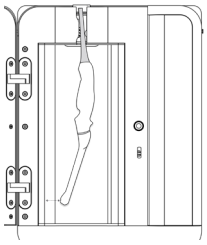

Position


Equipment


Cable


Open and free

*In case you are not sure if your transducer fits, ask your local distributor or UV Smart.
**In case of an angular transducer, make sure to position it towards the UV-C lamp.
***Do not let the tip of the transducer touch the glass, walls or the bottom of the chamber.



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10.6. D45 Daily Use

Follow the steps below to correctly use the D45 for disinfection of transducers. Make sure to read the before every D45 use-paragraph (10.3) first.

1. *Pre-clean your transducer according to the instructions for use provided by the manufacturer of the transducer. (Make sure the transducer is dry after pre-cleaning)*

Follow the instructions on the D45 display (for reference in chapter 10.6.1: D45 use flow):

2. *On the D45 display, touch the green button to start the D45 disinfection process.*
3. *Scan your ID using the D45 scanner or RFID reader. Use the keyboard in the corner to enter your user pin code if scanning is not possible. This step is not prompted if ID scanning is not applicable according to how the D45 is setup.*
4. *Scan the transducer using the D45 scanner or RFID reader. Use the keyboard in the corner to enter the equipment number if scanning is not possible. This step is not prompted if transducer scanning is not applicable according to how the D45 is set up.*
5. *Confirm pre-cleaning according to protocol.*
6. *Confirm the preparation summary.*
7. *Carefully insert the transducer into the D45 disinfection chamber according to* **PECO** *(10.5).*
8. *Close the door. The D45 disinfection cycle will start automatically. Wait for the disinfection cycle to finish.*
9. *In the meantime, disinfect your hands according to protocol.*
10. *After the disinfection cycle has finished, scan your ID using the D45 scanner or RFID reader. Use the keyboard in the corner to enter your user pin code in case scanning is not possible. This step is not prompted if ID scanning is not applicable according to how the D45 is set-up.*
(For a successful cycle, after the scan is complete, the printer generates a ticket of the disinfection log. This step does not occur if printer is not enabled)
11. *Carefully take-out the disinfected transducer from the D45.*

12. *In case you use the D45 for only one disinfection cycle, close the door. In case of running multiple disinfection cycles, repeat the process starting at the Before every D45 use-paragraph (10.3).*

*Geometry varies per transducer. Consult UV Smart or your local reseller in case of any questions.

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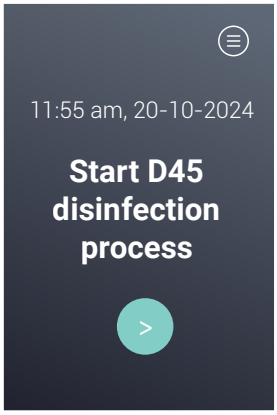
10.6.1. D45 Use Flow



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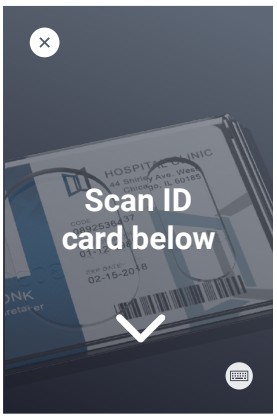

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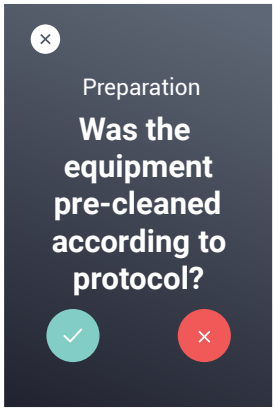
4



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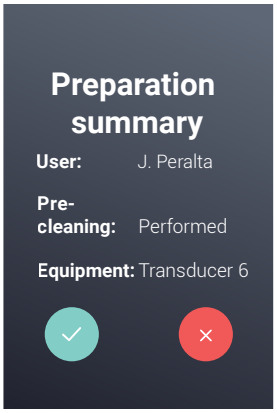

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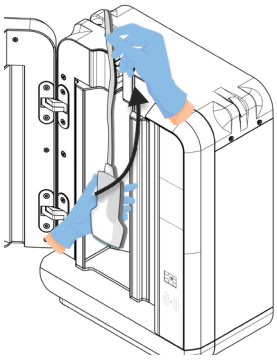

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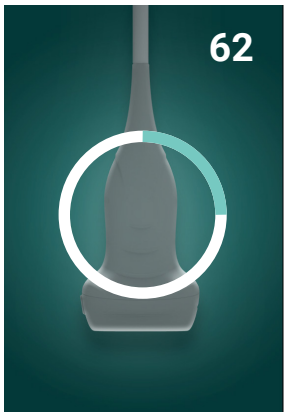

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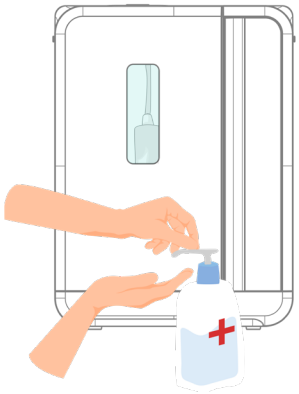

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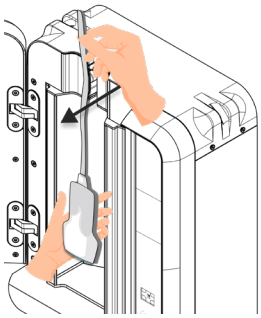

11

10.7. Navigating the D45 Menu

The D45 menu is accessed by pressing the three-striped icon in the top-right of the home screen. The D45 menu has a structure as displayed below. The next pages describe the path to each end point in more detail.

- **Menu**
  - **Disinfection log**
    - Disinfection log
  - **System**
    - Settings
      - Language
        - Select language
      - Daylight saving time
        - DST settings
      - Time & date
        - Set time and date
      - Printer
      - Printer settings
      - User ID scan necessary
      - Equipment ID necessary
    - User database
      - User database
    - Equipment database
      - Equipment database
    - Network
      - Setup network
    - USB import/export
      - Insert USB flash drive
        - USB flash drive detected
          - Import data
            - Confirm/decline
              - Data imported
          - Export data
            - Confirm/decline
              - Data exported
    - Interface
      - Interface
    - Factory reset
      - Reset confirmation
        - Reset successful
    - Maintenance
      - Only accessible to qualified personnel
    - System Log
      - System Log
  - **Info**

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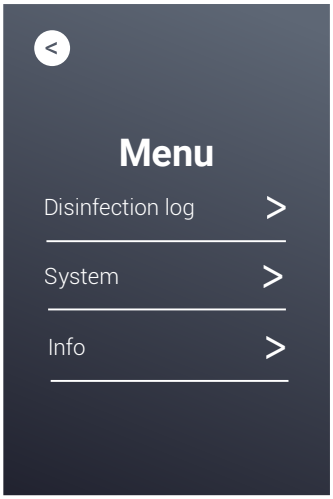
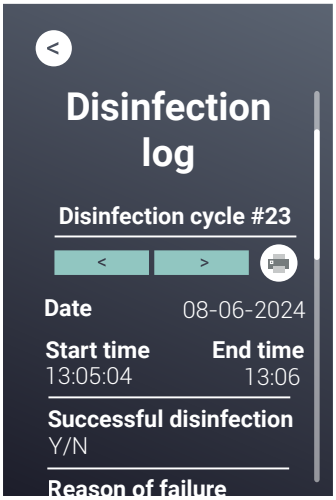
10.7.1. Disinfection Log

Navigate to the disinfection log by pressing Disinfection log. The disinfection log also provides the option to reprint the most recent ticket if needed (and if enabled).
The Disinfection log displays the following information:

Disinfection start	Time stamp, date	**Pre-clean performed**	Yes
Disinfection finish	Time stamp, date	**UV-C dose**	Measured UV-C dose
Disinfection result	Successful/Reason of failure	**Amperage**	Amperage
User IN	User inserting equipment		
User OUT	User taking out equipment		
Equipment	Equipment inserted		





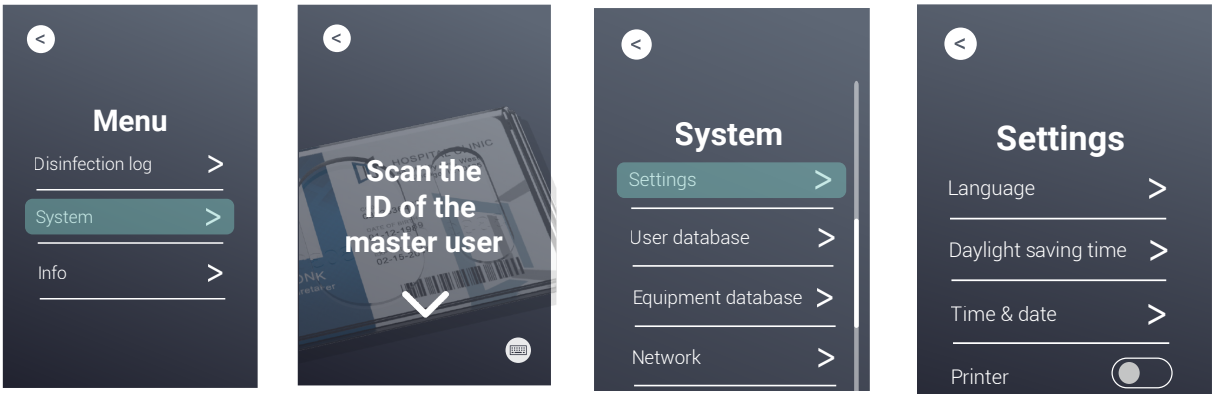
10.7.2. Info

Navigate to the info panel by pressing Info. The info panel displays the following information:

Legal manufacturer	Legal manufacturer
Software version	Software version
Database version	Database version
Upcoming maintenance	Date
Description	Description of the D45
Cycle information	Total cycles, cycles since last maintenance
MAC Adress	MAC Adress

10.7.3. Set Language, Time Zone, Time & Date, User ID Scan & Equipment ID Scan Necessity.

Navigate to the settings by pressing System > Scan master user ID > Settings. From here, choose the applicable sub menu.

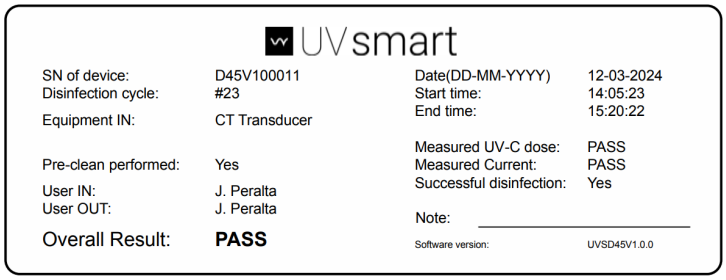


10.7.4. Printer

Navigate to the settings by pressing System > Scan master user ID > Settings. Here the user has the ability to enable the printer function with the D45.

The main function of the printer is to (re)print tickets with the disinfection result of a disinfection cycle in the D45. The tickets have an adhesive layer which can be attached to disinfected transducers for traceability.

Note: The printer used with the D45 is the Zebra ZD421t (Health Care) thermal transfer only (also provided by UV Smart or your local reseller).
The printer is an optional accessory that can be connected to the USB port of the D45.



UVsmart

SN of device:	D45V100011	Date(DD-MM-YYYY)	12-03-2024
Disinfection cycle:	#23	Start time:	14:05:23
Equipment IN:	CT Transducer	End time:	15:20:22
Pre-clean performed:	Yes	Measured UV-C dose:	PASS
User IN:	J. Peralta	Measured Current:	PASS
User OUT:	J. Peralta	Successful disinfection:	Yes
Overall Result:	**PASS**	Note:	
		Software version:	UVSD45V1.0.0

Enabling the Printer via the D45 Display

1. Navigate to the menu.

2. Select System.

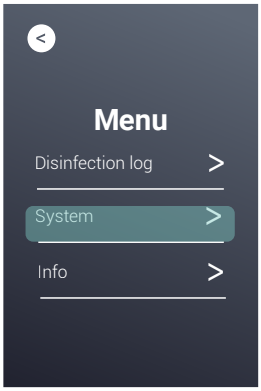
3. Scan the master user ID.

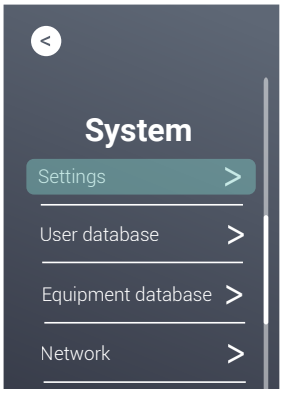
4. Enable the Printer toggle.

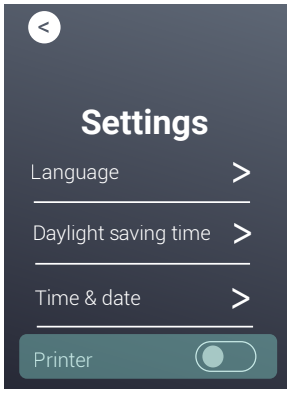
5. Wait for 10 seconds for the printer to be recognized by the D45.

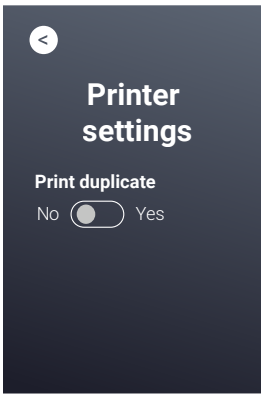
6. Once enabled, the user is automatically redirected to Printer settings.

7. In Printer settings, the printer is set to no duplication of ticket by default. The user has the option to enable printing of duplicate tickets. This setting can be accessed by the user anytime after the printer is connected.



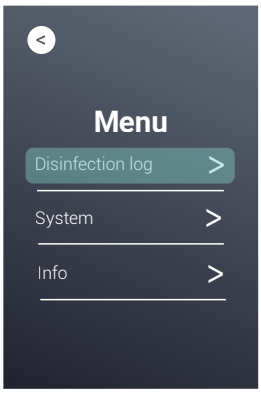


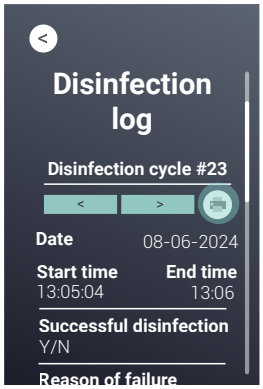




8. In case another ticket is required, the user can reprint the same ticket from the disinfection log: navigate to Menu > Disinfection Log.

Note: Only successful logs can be reprinted after the cycle is over.

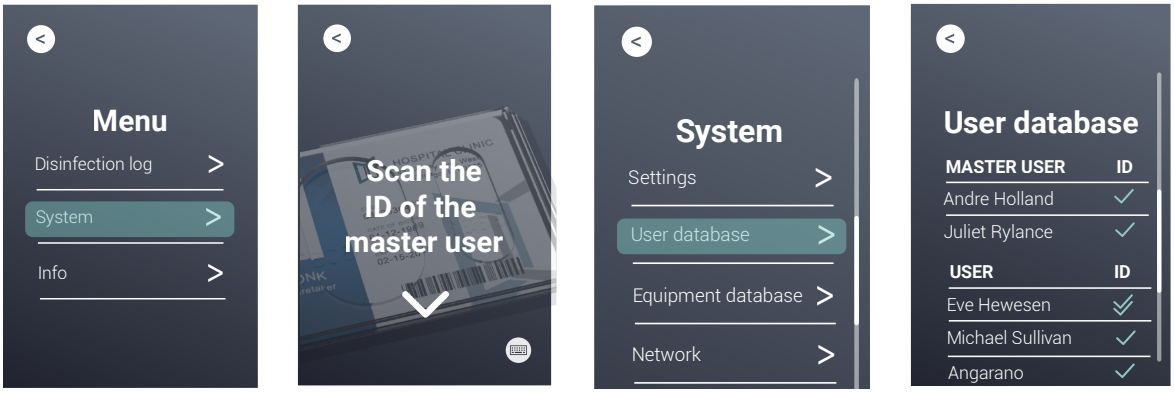




10.7.5. User Database

To navigate to the user database, select System > Scan master user ID > User database. Here, you'll see an overview of all registered users. The user database displays checkmarks indicating if an ID and/or PIN is set for each user:
1 white checkmark: User is in the database, but no ID or PIN is set.
1 green checkmark: Either an ID or PIN is set.
Double green checkmarks: Both an ID and PIN are set.

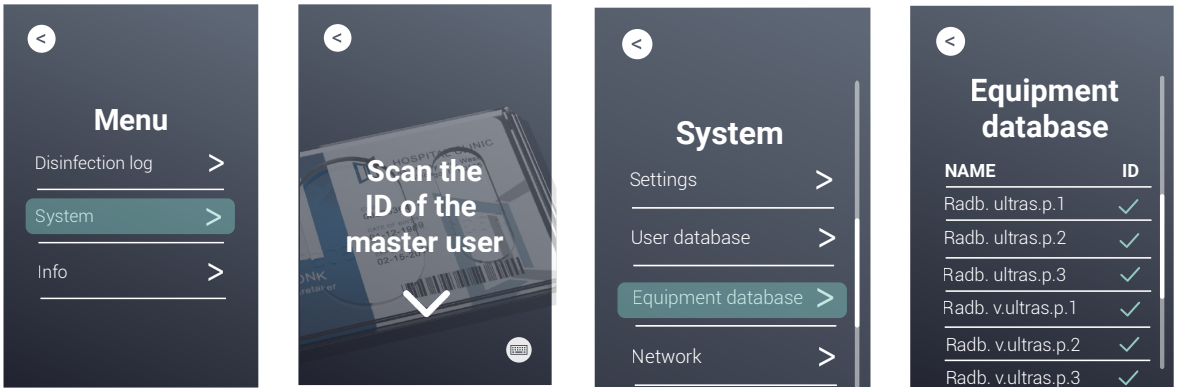
Depending on the D45 configuration, the ID and/or PIN can be added differently. This is explained in more detail in the Adding/Editing users-chapter (10.9). After the D45 setup the device comes with 4 users pre-installed (1 master user and 3 normal users). The standard pincode for the master user is '2289'. To prevent unauthorized users from changing settings it is recommend to change this pin in the User database to your personal preference and remember this or write it down.



10.7.6. Equipment Database

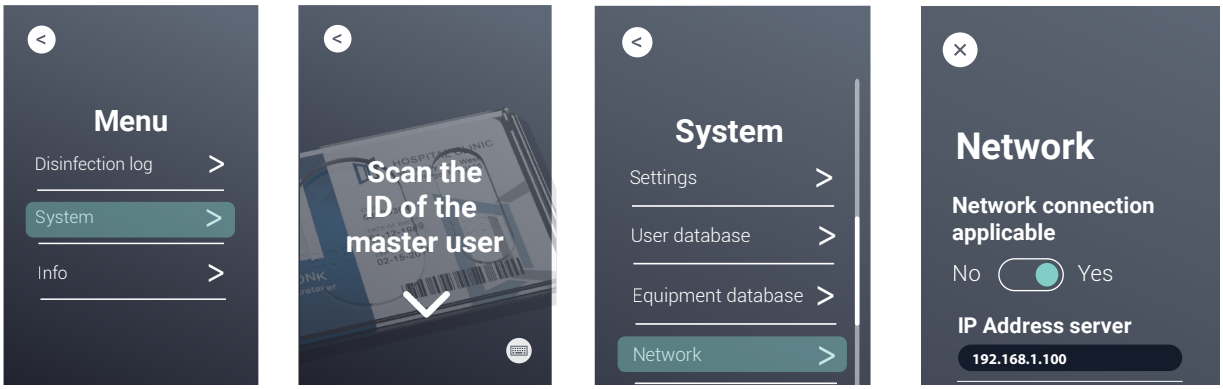
To navigate to the equipment database, select System > Scan master user ID > Equipment database. Here, you will see an overview of all registered equipment, with checkmarks indicating the ID status:
1 white checkmark: Equipment is in the database, but no ID is set.
1 green checkmark: Either an ID or another identifier is set for the equipment.
Double green checkmarks: Both an ID and an additional identifier are set for the equipment.

Depending on the D45 configuration, the ID can be added differently.
This is explained in the Adding/Editing equipment-chapter (10.8).



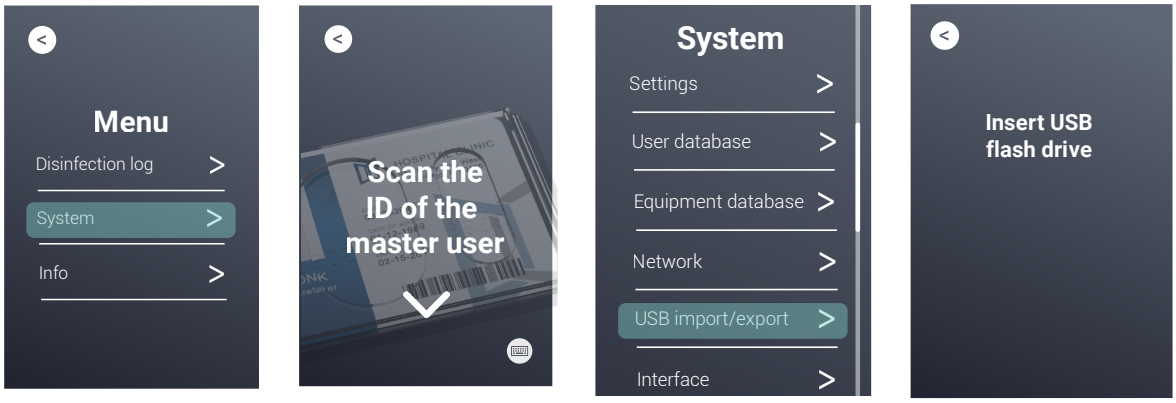
10.7.7. Network

Navigate to the Network settings by pressing System > Scan master user ID > Network. Press continue to save the network settings. *Note: make sure the network settings correspond with the network settings of UV Soft.*



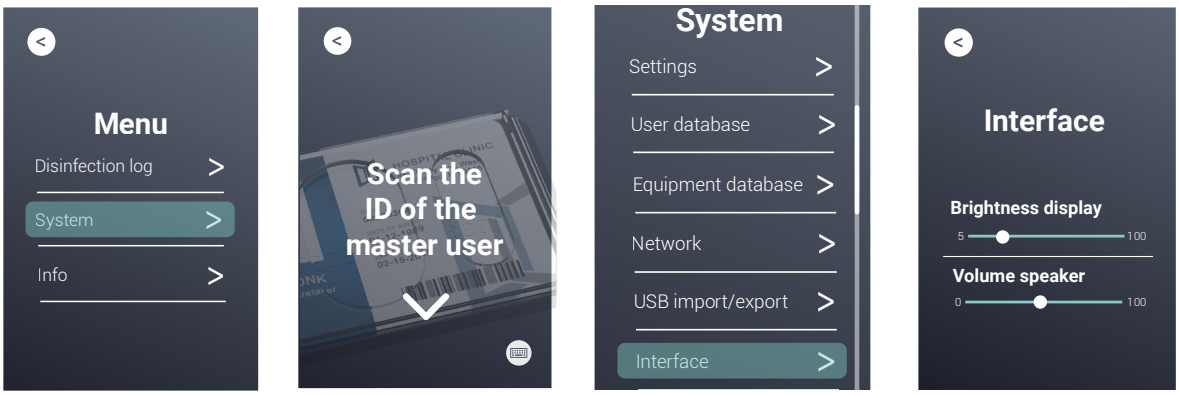
10.7.8. USB Import/Export of Data

Navigate to USB import/export by pressing System > Scan master user ID > USB import/export. Chapters 10.8, 10.9 and 10.10 explain importing and exporting in more detail.



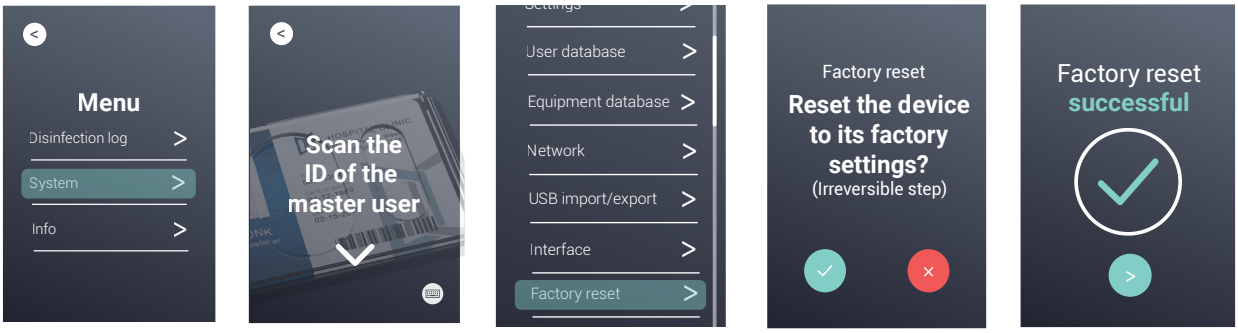
10.7.9. Adjusting Brightness and Volume

Navigate to the interface settings by pressing System > Scan master user ID > Interface. Use the sliders to adjust to the desired brightness and/or volume. Press continue to save to the settings. Note that, even when the volume has been set to 0, warning sounds will still be audible.



10.7.10. Factory Reset

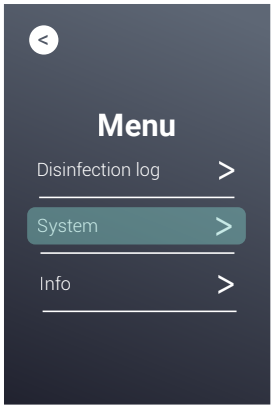
Navigate to Factory reset by pressing System > Scan master user ID > Factory reset. Press continue to set the D45 back to its factory settings (this step is irreversible) or press cancel to go back.

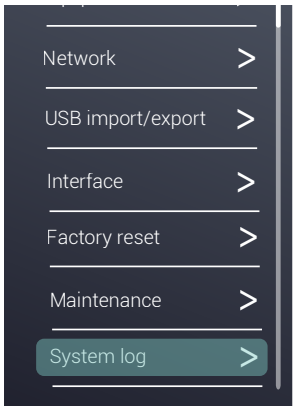


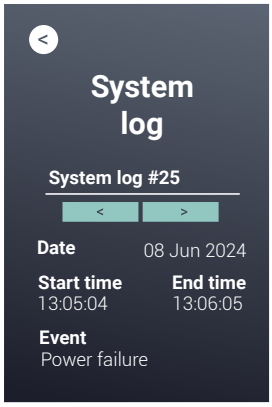
10.7.11. System Log

Navigate to the system log by pressing System > Scan master user ID > System log. The system log displays the following information:

D45 cleaning	**Power failure**	**Maintenance performed**
Person responsible	Time stamp	Person responsible
Time stamp	Date	Time stamp
Date		Date







10.8. Adding/Editing Equipment

Adding or editing equipment to the D45 is different for a network-connected and standalone D45. Follow the instructions to add or edit equipment in line with your type of D45.

10.8.1 Connected D45

Adding and/or editing equipment data via UV Soft

1. Open UV Soft on your computer.

2. Navigate to the Equipment tab.

3. Login with master user credentials.

4. Change existing equipment or add new equipment. Click save.

5. Return to the D45 Menu

6. Navigate to the menu.

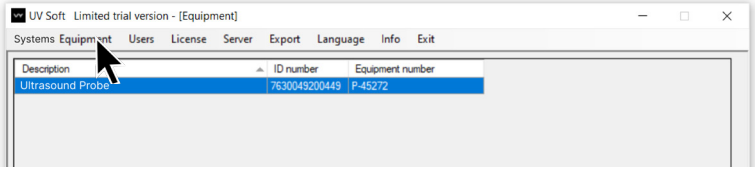
7. Press System.

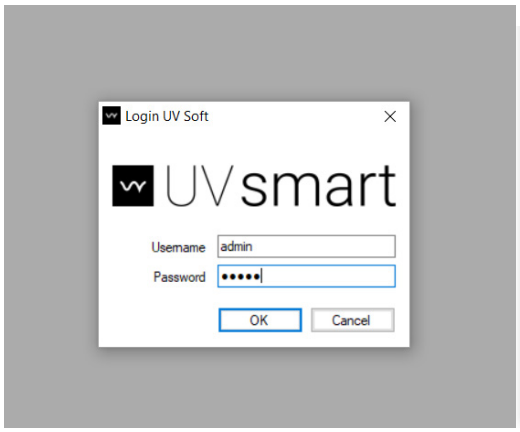
8. Identify yourself as a master user.

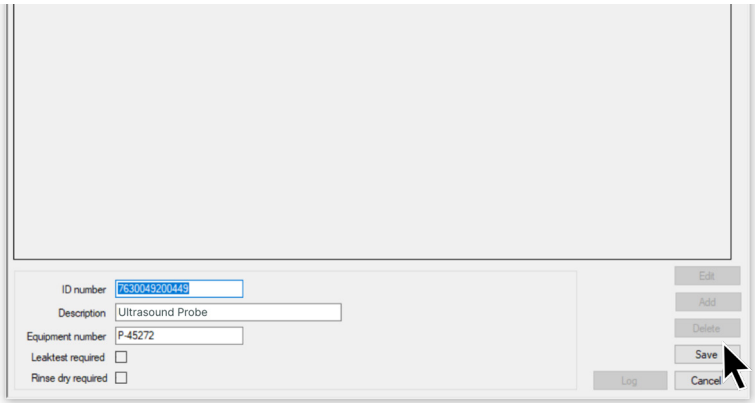
9. Press Equipment database

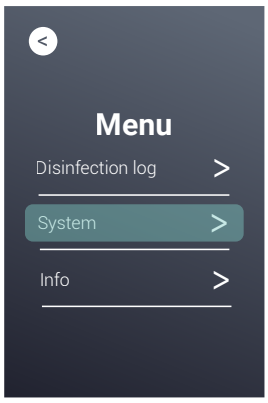
10. Syncing takes place

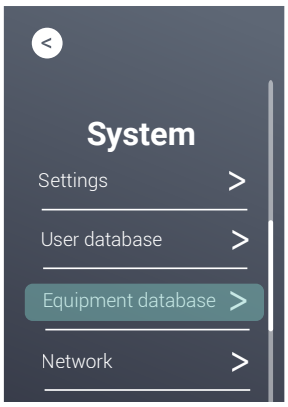
Equipment database is now updated

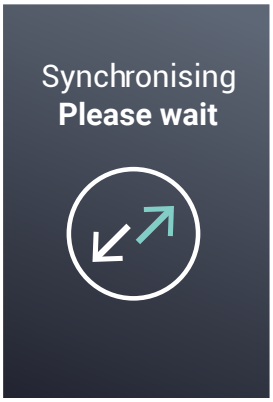


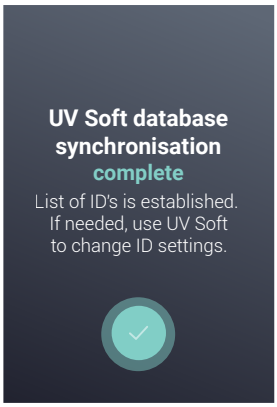












10.8.2 Standalone D45

Adding and/or editing RFID tag / Barcode data via the D45 display

1. Navigate to the menu.

2. Press System.

3. Scan master user ID.

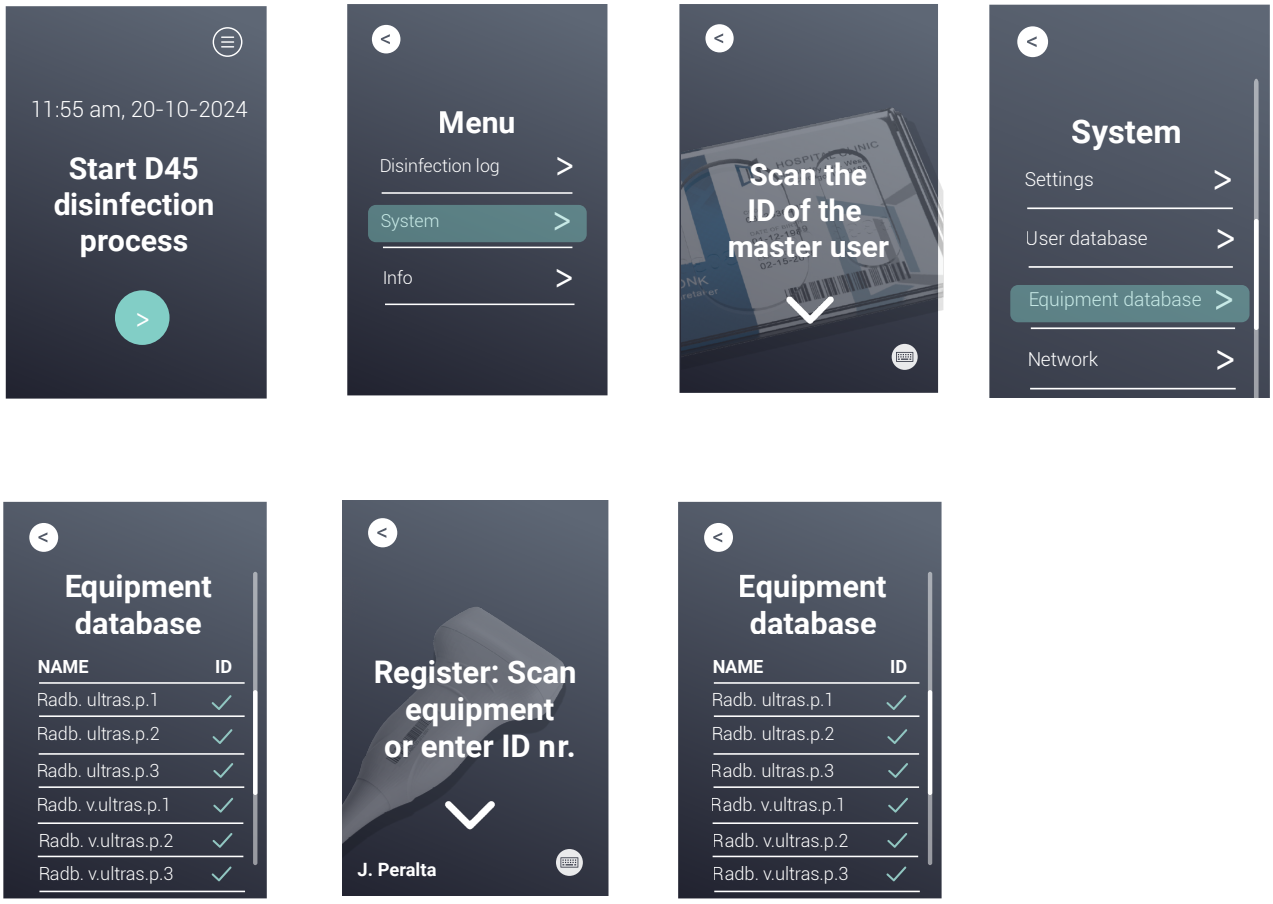
4. Press Equipment database.

5. To edit an RFID tag / Barcode connected with a piece of equipment, press the checkmark of the applicable equipment.

6. Scan the new RFID tag / Barcode that is related to that piece of equipment.

7. The equipment has been updated.

Note: The user database can be edited via the D45 display in the same way.



Adding equipment via USB flash drive

1. Open the Equipment database csv file in Microsoft Excel (to obtain this file, please refer to paragraph 10.10).

2. Add new equipment and/or add/edit equipment ID(s) exactly according to the format given in the Excel table.

3. Save the excel-file (as .csv) to a flash drive and return to the D45.

4. Navigate to the menu.

5. Press System.

6. Identify yourself as a master user.

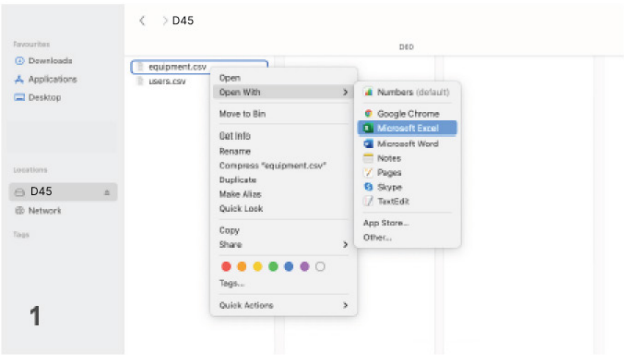
7. Select USB import/export.

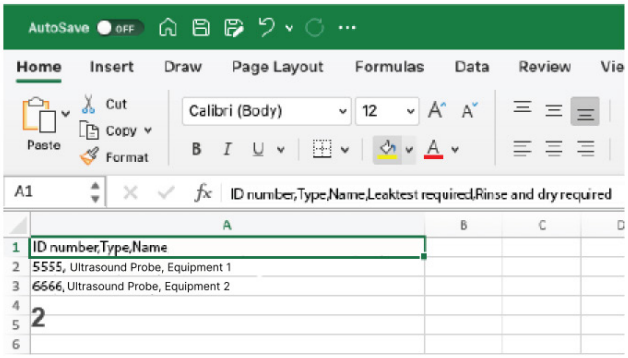
8. Insert the flash drive into the D45.

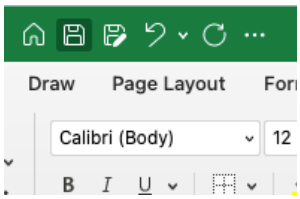
9. Press import.

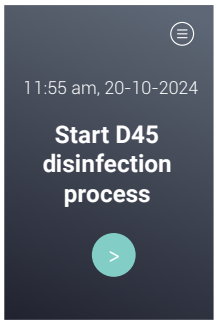
10. Accept.

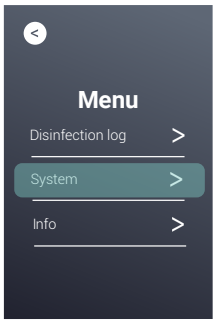
11. The Equipment database is now updated. Remove the USB flash drive.

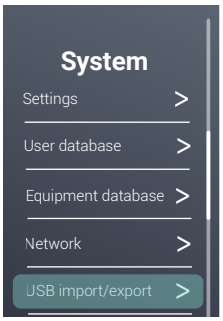


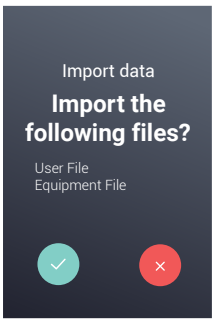


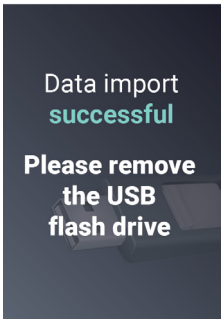












10.9. Adding/Editing Users

Adding or editing users is different for a network-connected and stand-alone D45. Follow the instructions to add or edit users to/in the D45.

10.9.1. Connected D45

Open UV Soft on your computer.

2. Navigate to the user database.

3. Login with master user credentials.

4. Add new user(s) and/or add/edit user ID(s) and/or user PIN(s). Click save.

5. Return to the D45,

6. Navigate to the menu.

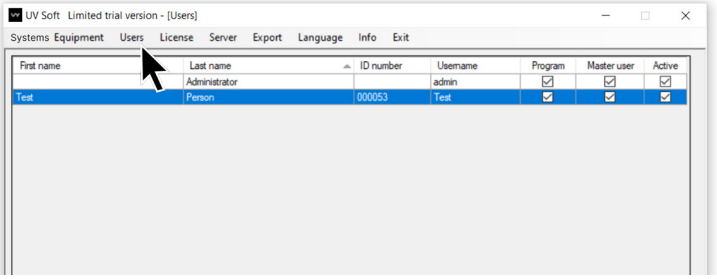
7. Press System.

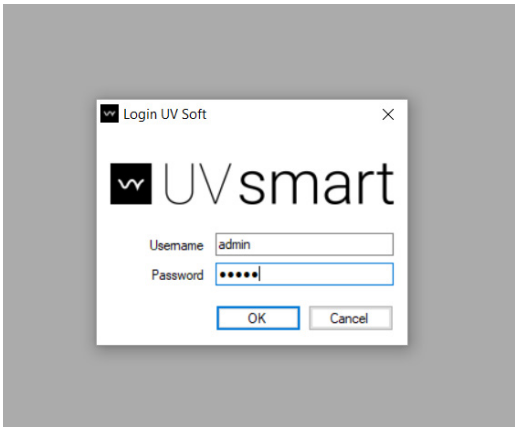
8. Identify yourself as a master user.

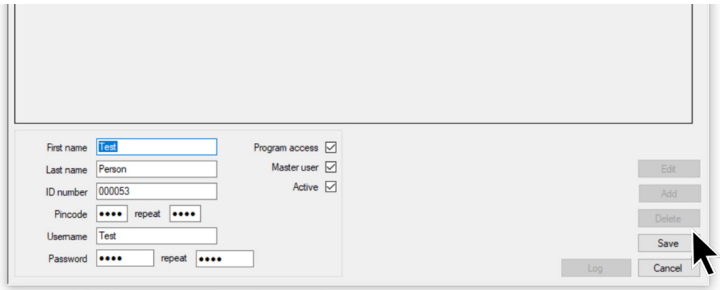
9. Press Equipment database

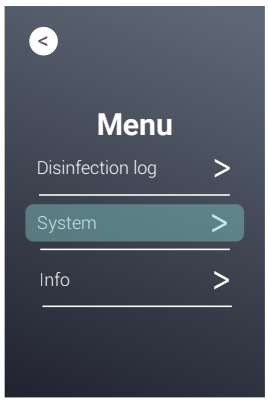
10. Syncing takes place

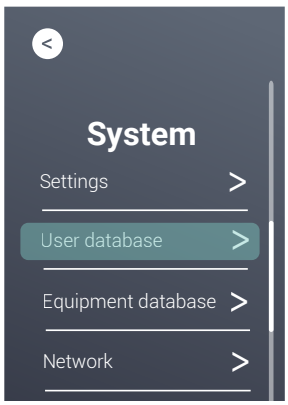
Equipment database is now updated

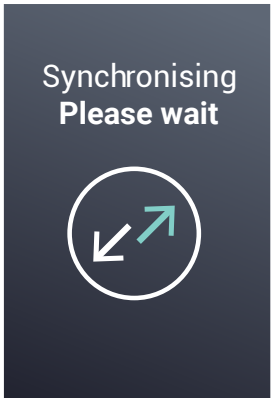


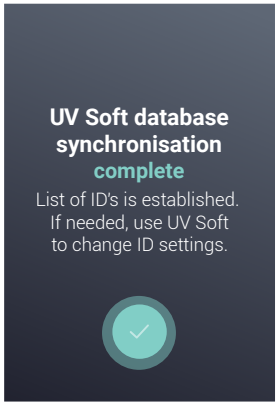












10.9.2. Standalone D45

Adding users via USB flash drive

1. Open the User database csv file in Microsoft Excel (to obtain this file, please refer to paragraph 10.8).

2. Add new user(s) and/or add/edit user ID(s) and/or user PIN(s) exactly according to the format given in the Excel table.

Note: assigning '1' to the 'Master user'-position in the excel table makes a user a master user. A '0' makes a user a normal user. In the example below, Eve is a master user, Andre is a normal user.

3. Save the excel-file (as .csv) to a flash drive and return to the D45.

4. Navigate to the menu.

5. Press System.

6. Scan master user ID.

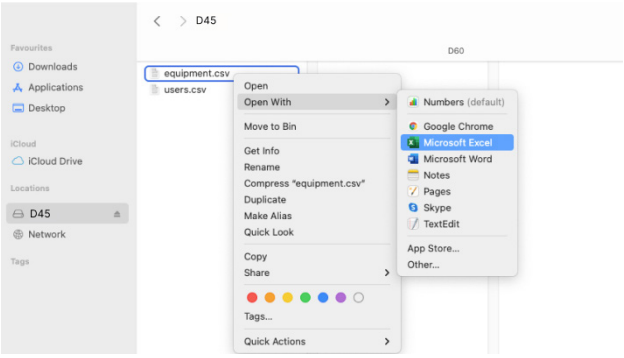
7. Select USB import/export.

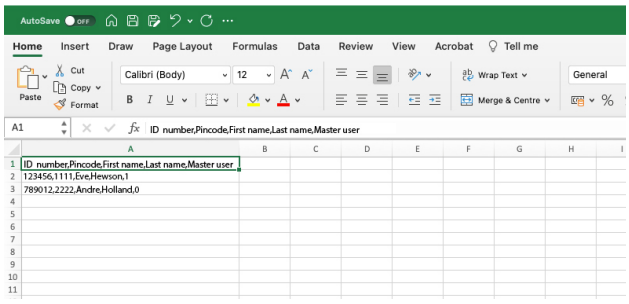
8. Insert the USB flash drive.

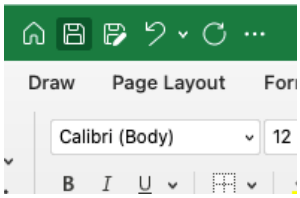
9. Press import.

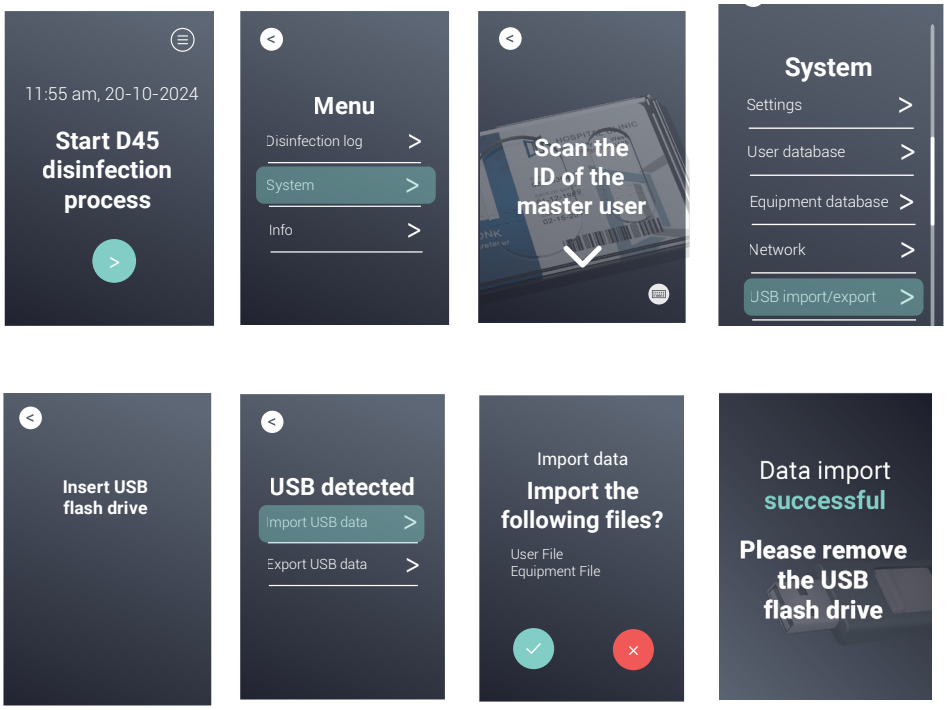
10. Accept.

11. The User database is now updated. Remove the USB flash drive.







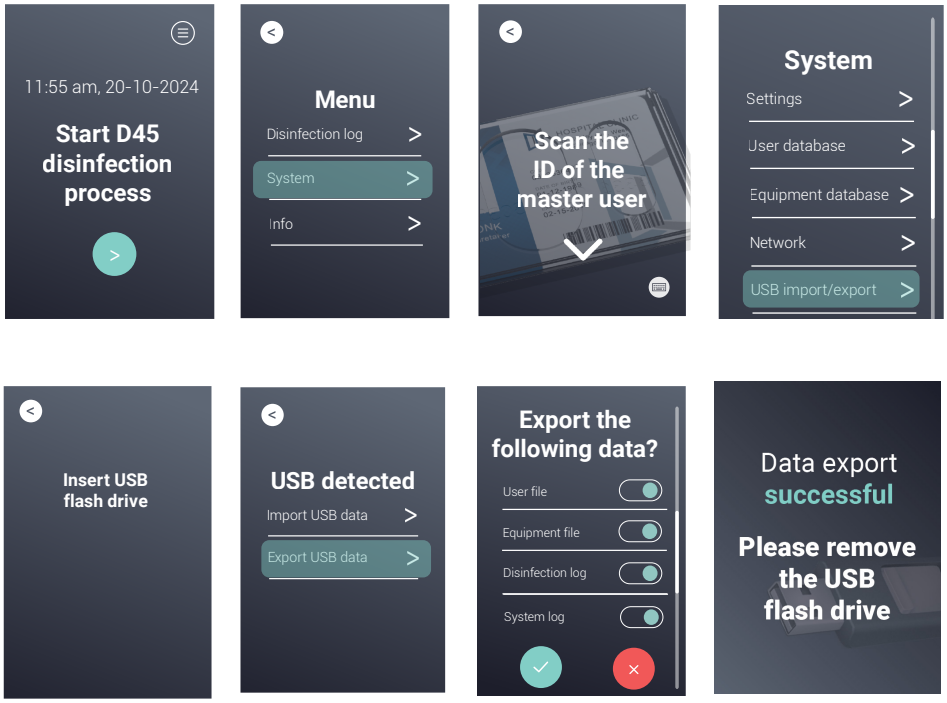


10.10. Exporting Data via USB

During its lifetime the D45 collects data about its use. The following data can be exported from the D45 via the D45 display, using a USB flash drive. Make sure to yearly backup an export of the D45 data.

Export
User data
Equipment data
Access and use log
Maintenance report
System log

Follow the instructions below to export data from the D45:
1. Navigate to the menu.
2. Press System.
3. Scan a master user ID.
4. Press USB import/export.
5. Open the D45 control panel with the corresponding key. Insert a USB flash drive.
6. Click export data.
7. Confirm by clicking the green button. To return, click the red button or the arrow in the top left. Note that exporting data might take a few minutes. Please wait until the export has finished.
8. When the screen indicates that data has been exported successfully it is safe to remove the USB flash drive.



11. UV Soft

Two configurations of the D45 are available: A connected D45 and a standalone D45. During the first time use (setup), the configuration selection is made by the user, depending on the user's needs. A connected D45 is connected to the client's intranet, via ethernet cable. A connected D45 works together with UV Soft, UV Smart's data logging software. This chapter explains the use of UV Soft.

11.1. First Time Use

Use the following steps when UV Soft is used for the very first time.

1. Installation, licensing and network connection

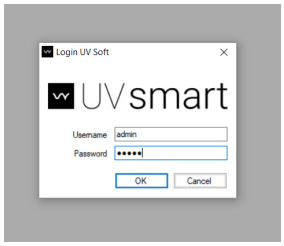
Upon D45 implementation at the client, UV Smart qualified personnel shall install the UV Soft software on the client's computer. This includes the licensing of the software according to your agreement. Additionally, a UV Soft and D45 connection to the client's network shall be established.

2. Login

Open UV Soft. Click on one of the following tabs in the menu bar: 'D45s', 'Equipment', 'Users' or 'Export'. You will be prompted to login. Enter the following credentials and press OK.

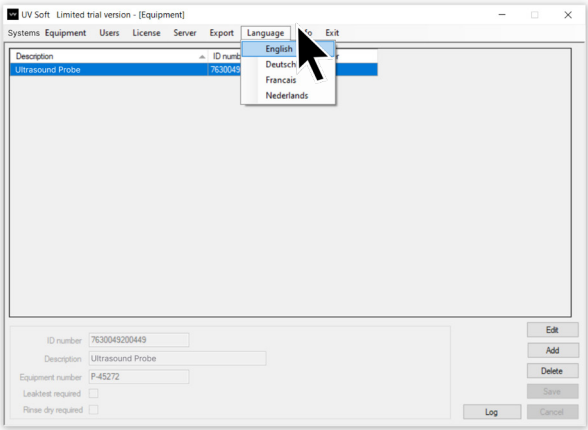
Username admin

Password admin



3. Language

Navigate to the Languages-tab. Select your preferred language



4. Setting up the Master User

The master user has the most accessibility in UV Soft and the D45. The default master user is set to ‘Administrator'. For security reasons is it important to change the admin details to the details of the person responsible appointed by the client where the D45 is placed. Enter the following credentials:

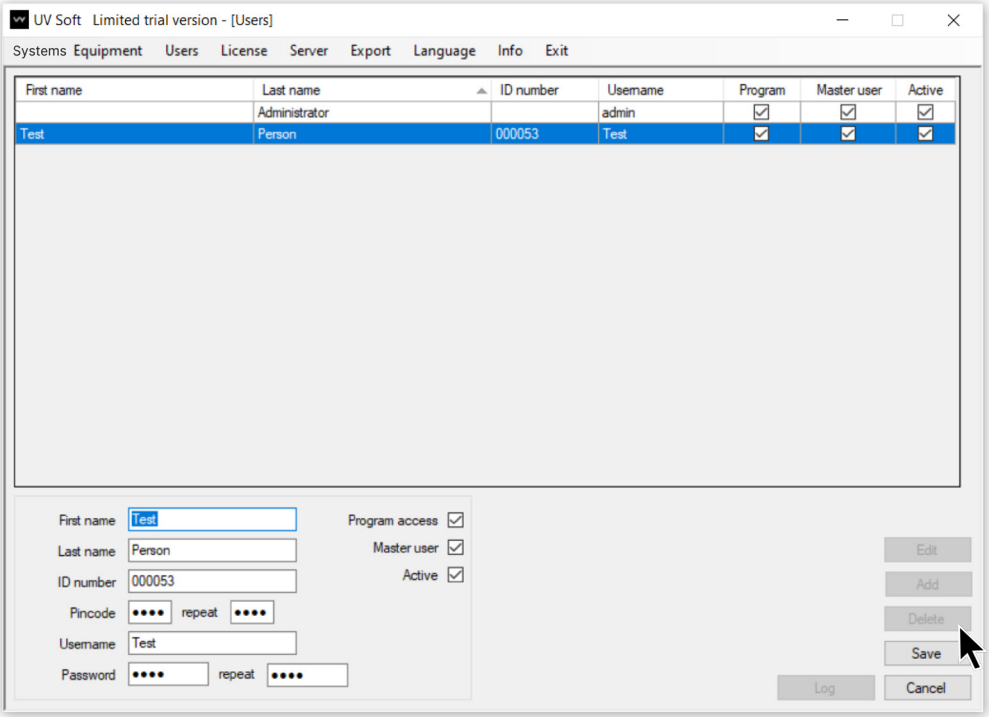
First name	First name user
Last name	Last name user
ID number	User hospital ID number/Badge number
Pincode	4 digit code for D45 use
Username	User (nick)name for UV Soft use (make sure to remember this name well)
Password	6 character code for UV Soft use (make sure to remember this code well)

Next to the credentials three checkboxes are listed, indicating a user’s authority.

Program access	Indicating whether a user can make changes within UV Soft.
Master user	This user can use UV Soft, the D45 and access all menus in the D45 (except for the Maintenance menu). When this checkbox is not checked, a user is automatically a normal user. A normal user can use the D45 and only access the Disinfection log and Info menu in the D45.
Active	Indicates if a user is still making use of the D45/UV Soft. When this checkbox is not checked for a particular user, the user will be inactive but is still present in the logged data. When a user is deleted, his/her logged data will be deleted as well.

For a master user, check the ‘Program access’, ‘Master user’ and ‘Active’ checkboxes.

Press ‘Add’ to add the master user.



5. Connect to the server

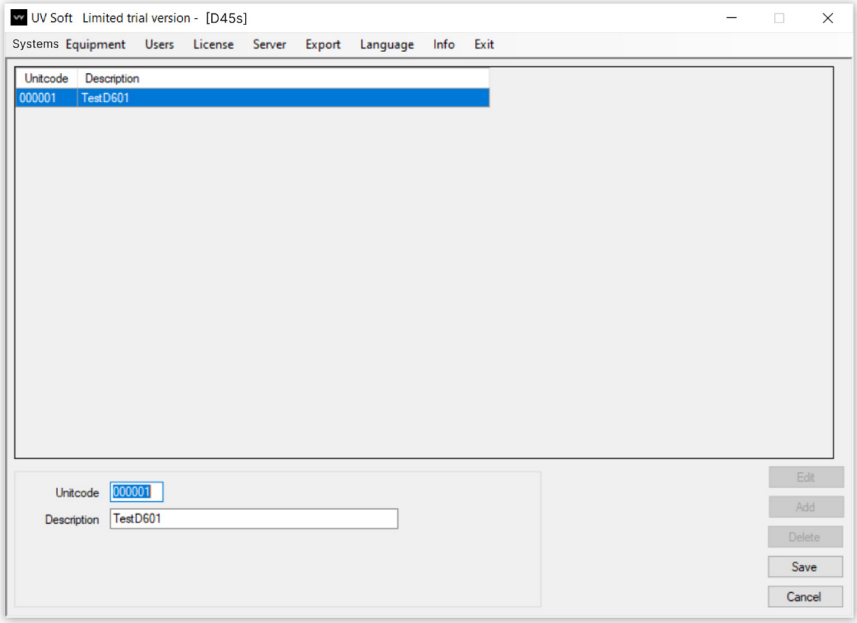
Upon D45 implementation at the client, UV Smart qualified personnel shall connect UV Soft to the client's network.

6. Add a D45

Navigate to the D45-tab. Click "Add" and enter the following credentials:

Unit code	A 6-digit code identical to a D45. This code is used to establish the connection between UV Soft and the D45. A user can pick a unit code according to their own preference
Description	The description briefly describes the D45. For example: "D45 - Amsterdam Hospital - Wing X'

Click "Save".



7. Connect with a D45

A connection between UV Soft and a D45 can take place when the following steps have been performed:

- UV Soft and the D45 are connected to the same network
- The D45 has been added within UV Soft with the same Unit code that has been entered into the D45 network settings
- Firewall does not block the communication port

11.2. D45 Settings

Within UV Soft, one or more D45s can be added, edited and its use log can be viewed.

Add a D45

Navigate to the D45-tab. Click “Add” and enter the following credentials:

Unit code	A 6-digit code identical to a D45. This code is used to establish the connection between UV Soft and the D45. A user can pick a unit code according to their own preference
Description	The brief description of the D45. For example: “D45 - Amsterdam Hospital - Wing X’

Click “Save”.

Edit a D45

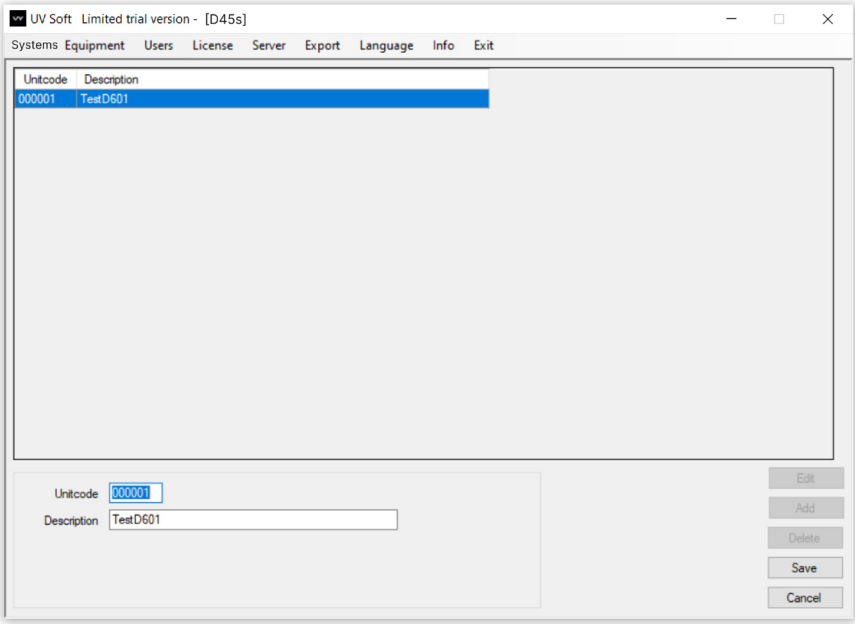
Navigate to the D45-tab. Select the applicable D45 in the list and click “Edit”. Click “Cancel” to abort the editing process. Edit the credentials as desired and click “Save” to save the newly edited credentials.

Delete a D45

Beware: this step is irreversible. Navigate to the D45-tab. Select the D45 in the list you wish to delete and click “Delete”. Note: This is only possible with a D45 that does not contain logs.

D45 Log

Navigate to the D45-tab. Click “D45 Log”. All D45-related data is visible.



11.3. Equipment Settings

Within UV Soft, one or more D45s can be added, edited and its use log can be viewed.

Add a D45

Navigate to the D45-tab. Click “Add” and enter the following credentials:

ID number	The barcode/RFID number of the piece of equipment
Equipment name	The RFID ID of the piece of equipment
Equipment description	The name of the piece of equipment. For example: “Ultrasound Probe”
	The description of the piece of equipment. For example: Black Brand X Ultrasound Probe, short insertion tube

Note: In the UV Soft interface for the use of D45, please keep 'Leaktest required' and 'Rinse/dry required' unchecked.

Edit equipment

Navigate to the Equipment-tab. and click “Edit”. Click “Cancel” to abort the editing process. Edit the credentials as desired and click “Save” to save the newly edited credentials.

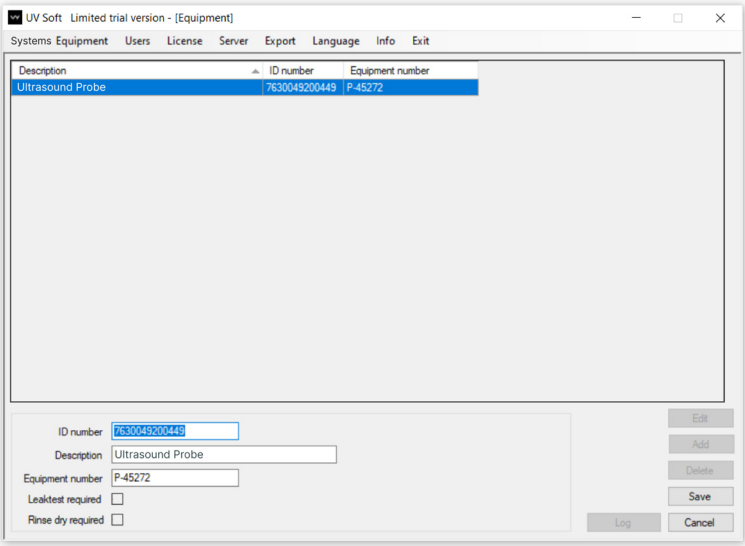
Delete a piece of equipment

Beware: this step is irreversible. Navigate to the Equipment-tab. Select the equipment in the list you wish to delete and click “Delete”.

Note: This is only possible with equipment that does not contain logs.

Equipment Log

Navigate to the Equipment-tab. Click “Equipment log” to see the equipment log.



11.4. User Settings

Within UV Soft, different users can be added, edited and its use log can be viewed.

Add a user

Navigate to the User-tab. Click “Add” and enter the following and click “Save” to save the newly edited credentials.

First name	First name user
Last name	Last name user
ID number	User hospital ID number/Badge number
Pincode	4 digit code for D45 use
Username	User (nick)name for UV Soft use (make sure to remember this name well)
Password	6 character code for UV Soft use (make sure to remember this code well)

Next to the credentials three checkboxes are listed, indicating a user’s authority.

Program access	Indicating whether a user can make changes within UV Soft.
Master user	This user can use UV Soft, the D45 and access all menus in the D45 (except for the Maintenance menu). When this checkbox is not checked, a user is automatically a normal user. A normal user can use the D45 and only access the Disinfection log and Info menu in the D45.
Active	Indicates if a user is still making use of the D45/UV Soft. When this checkbox is not checked for a particular user, the user will be inactive but is still present in the logged data. When a user is deleted, his/her logged data will be deleted as well.

For a normal user, uncheck the ‘Program access’ and ‘Master user’ checkboxes and check the ‘Active’ checkbox. Press ‘Add’ to add the normal user.

Edit a user

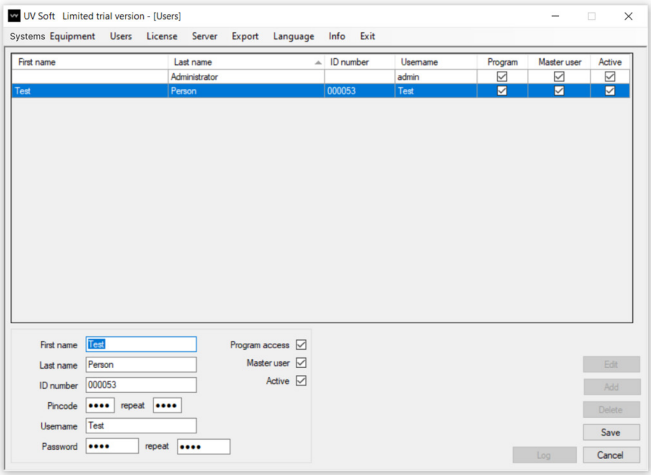
Navigate to the User-tab. and click “Edit”. Click “Cancel” to abort the editing process. Edit the credentials as desired and click “Save” to save the newly edited credentials.

Delete a user

Beware: this step is irreversible. Navigate to the User-tab. Select the user in the list you wish to delete and click “Delete”. Note: This is only possible with a D45 that does not contain logs.

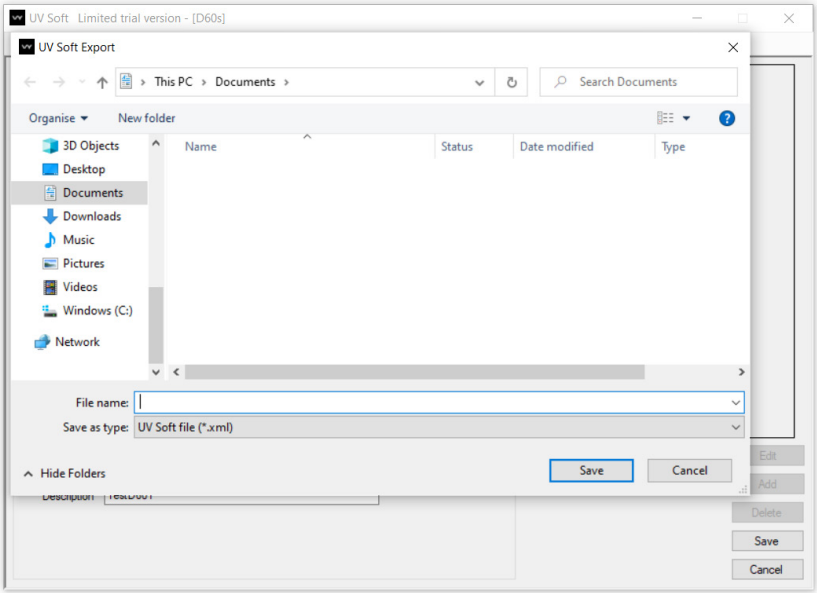
User Log

Navigate to the User-tab. Click “User log”.
All user-related data is visible.



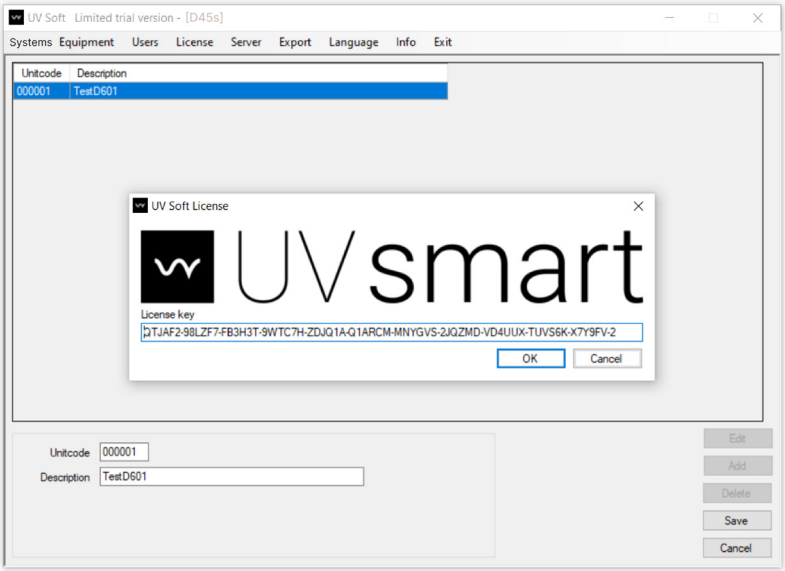
11.5. Export

Logged data can be exported. Navigate to the Export-tab and click “Export”. A new window pops up. Select the desired export directory and click “Save”. Open the exported file to see the logged data.



11.6. License

Navigate to the Licensing-tab to see the current license key. When applicable, a new key can be entered here.

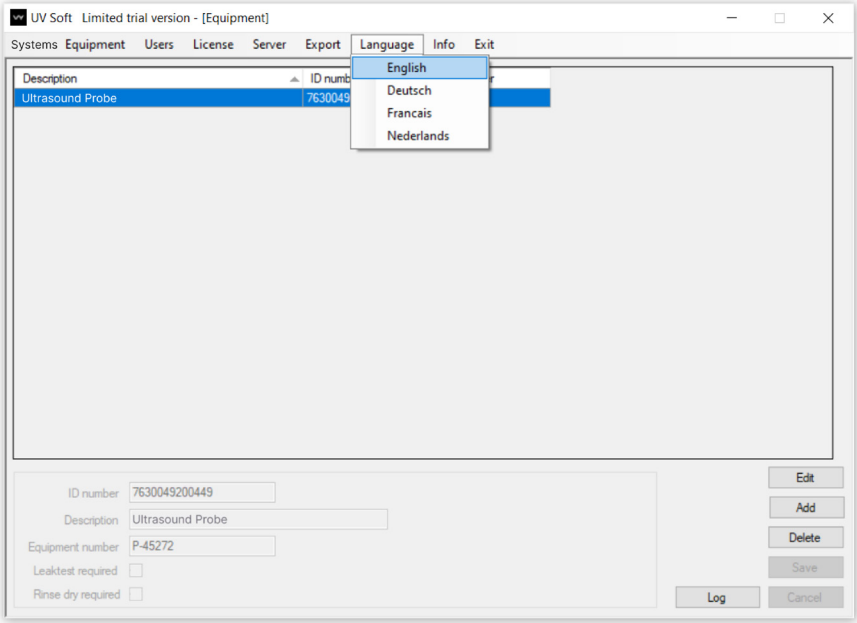


11.7. Server

Upon D45 implementation at the client, UV Smart qualified personnel shall connect UV Soft with the client’s network.

11.8. Language

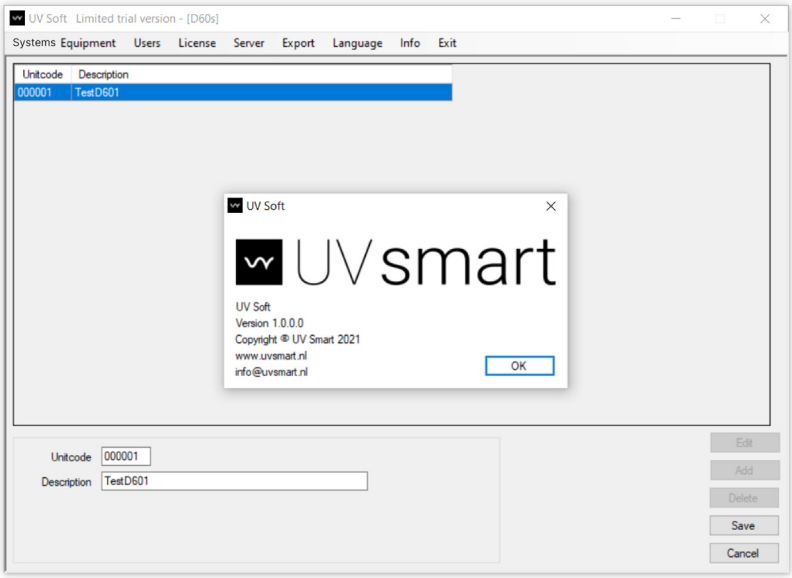
Navigate to the Languages-tab. Select your preferred language.



11.9. Info

Navigate to the Info-tab, click “Info”. The following data is displayed. Press OK to exit.

UV Soft
Version
Copyright
www.uvsmart.nl
Info@uvsmart.nl



11.10. Exit

Navigate to the Exit-tab. Click “Exit”.

12. Maintenance

12.1. Maintenance

Maintenance on the D45 shall be periodically performed (every 12 months) based on the service agreement and should be documented. Maintenance should exclusively be performed by qualified personnel. Do not attempt to open the D45 and/or perform maintenance on the D45 yourself.

If maintenance has not been performed for an extensive amount of time the D45 will go out-of-use. The D45 can only be used again after maintenance has been performed. Contact your local reseller for further information.

12.2. Cleaning/Reprocessing

The UV Smart D45 is a multiple use device. Clean the internal and external surfaces with a soft cloth and non-aggressive cleaning agents only (preferably UV Smart device cleaner). Every 48 hours or 50 cycles the D45 reminds the user to clean the device.

The following surfaces should be cleaned:

- Handle
- Door
- Display
- Cable clamp
- Reflective side of the door
- Inside of the disinfection chamber

Thoroughly dry the surfaces and check for visible debris after cleaning. Do not spray disinfectants into the openings and the disinfection chamber of the D45 or at the mains power connection. Do not use aggressive cleaning agents like bleach, paint thinner, acetone or acids; **this will damage the D45 and might cause the invalidity of its warranty.**

12.3. Transport

During transportation of the D45, ensure that the device is switched off, and disconnect the power cable from the grounded mains power source. If the D45 is not being transported on the D45 Trolley, it is mandatory to have at least two people lift the device to the desired location. Additionally, make sure to close the D45 door before initiating transport.

12.4. Technical Inspection (Service/Maintenance)

Periodic maintenance should be performed on the D45 based on the service agreement. The technical safety check is obligatory to be carried out every year and should be documented. This check should be carried out exclusively by qualified personnel. Contact UV Smart or your local reseller for further information.

12.5 Disposal

Dispose the D45 at your local community waste collection/ recycling center for electrical and electronic appliances. UV-C lamps in the D45 contain mercury, manage in accordance with disposal laws, see: www.lamprecycle.org. Please contact your local reseller for further information.

13. Problem Solving

13.1. Problem Solving

In case of an occurring problem/error, please refer to the Sounds and Lights chapter (9) to identify the meaning behind interface feedback and take corresponding action. When the problem/error is still present, rebooting the D45 may resolve the problem. To reboot the D45, unplug the power cable from the wall socket, wait for 10 seconds and plug the cable back into the wall socket. Contact your local reseller in case you were not able to resolve the problem.

After a defect, the device can only be used again if it is reconditioned under the responsibility of the manufacturer to comply with the general safety and performance requirements.

13.2. Out-of-Use

The D45 is deactivated when the maintenance interval has expired. Follow the information on the display or contact your local reseller in case you were not able to resolve the problem.

13.3. Broken Glass

Please follow these steps in case a glass part breaks:

1. Identify which part is broken.
2. Switch off the D45.
3. Close the door manually.
4. In case of broken lamps, transport the D45 to a well-ventilated area.
5. Contact your local reseller.

13.4. Overheating

In case of the D45 overheating, unplug the power cable from the mains power. In case of a fire, extinguish it with a fire extinguisher. Call UV Smart or your local reseller to report and resolve any issue.

14. Technical Specifications

Type of unit	D45 UV-C Medical Disinfection Device
Classification (acc. to IEC/EN 61010-1)	Medical Disinfection Device
Class (according to MDR)	IIa
Ingress Protection	IP 20
Voltage rating, overvoltage category	120-250 VAC (±10%), OVC II
Frequency	50/60Hz
Amperage rating	2A
Max. power rating	200W
UV-C range	100-280nm (peak at 253.7nm)
Fuse value	2 x 2A time-lag fuse (ø5x20mm)
EMC	IEC 61326-1/61000-3/4 (A1, CISPR 11)
Product Service Life	10 years
Operating conditions	
Temperature	5°C - 40°C
Relative humidity	20% - 85% (without condensation)
Atmospheric pressure	800hPa - 1060hPa
Transport and storage conditions	
Temperature	-25°C - 60°C
Relative humidity	20% - 85% (without condensation)
Atmospheric pressure	800hPa - 1060hPa
Weight	Approximately 25kg
Dimensions (W x H x D)	390mm x 525mm x 200mm (closed)
Pollution degree	PD2
IT connection	USB, Ethernet
Track and trace	Yes
Technical inspection (service/ maintenance)	Every 12 months

15. Symbols

Keep dry
Protect the medical device from moisture.

GS1 Data Matrix
Data Matrix containing the unique Device Identification.

IP20

Ingress Protection Classification
Degree of protection of electrical appliances: Protection against touch by fingers and objects greater than 12 millimeters and no protection against ingress of water.

Temperature limits
Indicates the lower and upper temperature limits.

CE
2696

CE Marking + Notified Body number
The product is CE-certified

REF

REF-number
Catalogue reference number.

SN

SN-number
Serial number symbol.

MD

Medical Device
The product is a medical device.

Alternating current input
The equipment is suitable for alternating current only.

Fuse value
Value of the fuse(s) present in the product.

Optical radiation
Warning of optical radiation.

General warning sign
Take care regarding the hazard specified by the supplementary sign

Mandatory to read the Instructions for Use
The Instructions for Use must be read.

Operating instructions
Operating instructions should be considered when operating the device.

Caution
Consult the Instructions for Use for important information.

Date of Manufacture
Indicates the date on which the product was manufactured.

Legal Manufacturer
Entity responsible for design & manufacturing of the product.

Atmospheric pressure limits
Indicates the lower and upper atmospheric pressure limits.

Protective earth (ground)
Protection against electrical shock in case of a fault.

Humidity limits
Indicates the lower and upper humidity limits.

Non-ionizing
The product emits non-ionizing radiation.

WEEE-symbol
Waste Electrical and Electronic equipment.

Maintenance
Maintenance should be performed. Contact your local reseller.

Dangerous voltage
Indicates hazards arising from dangerous voltages.

Hot Surface
Warning of potential hot surface.

16. Warranty

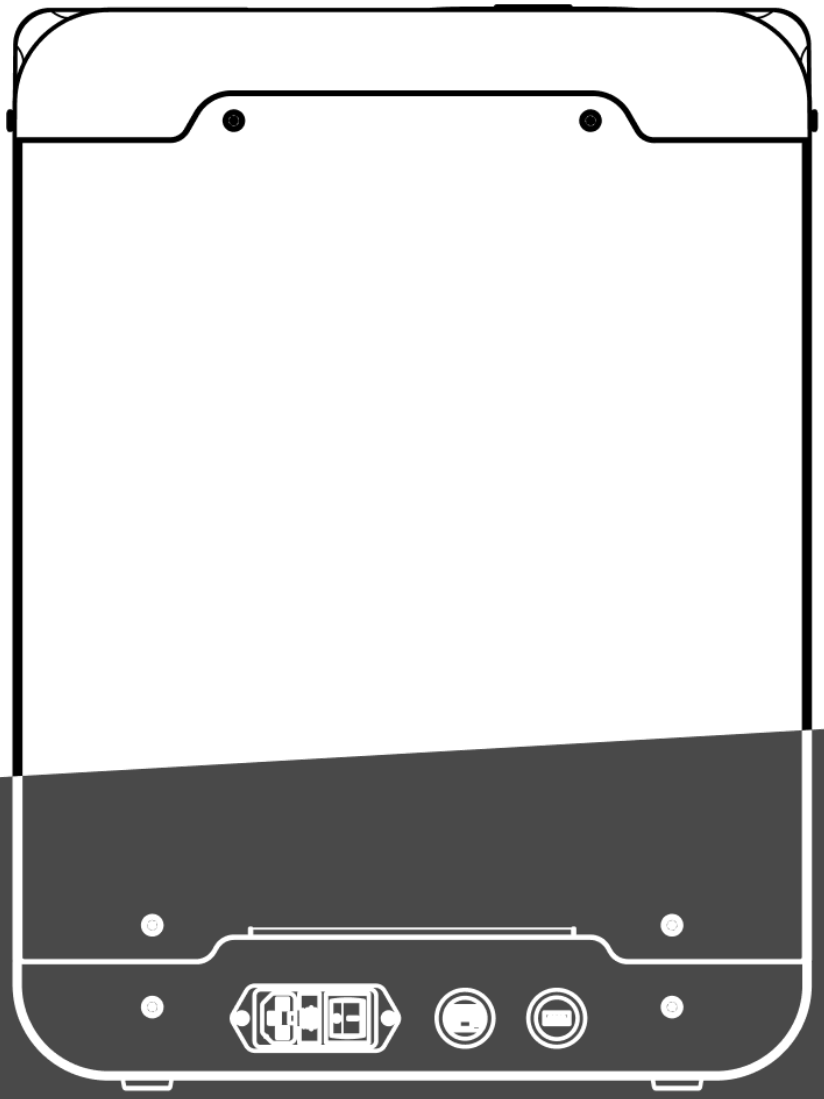
UV Smart offers a 24-month manufacturing failure warranty, encompassing the repair or replacement of parts damaged due to design/manufacturing errors or material defects. It is strictly prohibited to undertake any modifications or repairs at the customer's discretion. Any modifications or repairs carried out by the user/operator or third parties will result in the invalidation of the warranty.

The warranty does not cover the following:
Elimination of faults attributable to incorrect/unauthorized handling, or to abnormal wear and tear.

17. Contact Details

For any problems or questions please contact UV Smart or your local reseller.

UV Smart Technologies B.V.
Phone: +31 850 609 800
Email: info@uvsmart.nl
Adres: Patrijsweg 74
Zip: 2289EX Rijswijk
Country: The Netherlands



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UV Smart
Technologies B.V.
Patrijsweg 74
2289EX Rijswijk
The Netherlands

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Tel. +31 850 609 800
www.uvsmart.nl

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Approved By:

Michiel van Schelven - Author

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