



UV 222 Booth

New solutions for contamination prevention in the pharmaceutical industry

Contents

Summary	3
Introducing the UV222 Booth	4
Specifications	5
UV222 Booth Efficacy	6
Compliance.....	7
Ozone Generation.....	8
Measurements of Far UV-C Transmission through gowning materials	10
UV222 for microbial decontamination of gowned operators	14
Appendix 1 FAT and SAT Protocols	20
Appendix 2 Manuals UV222 Booth Solution 1	51
Appendix 3 Manuals UV222 Booth Solution 2	60
Appendix 4 CE Declaration of Conformity	69

Summary

The UV222 Booth is a novel product utilizing Far UVC technology to provide an added line of protection against contamination in cleanrooms.

The technology behind the UV222 Booth is a newly discovered shade of UVC light that exhibits unprecedented levels of human safety, as the emission wavelength at 222 nanometres does not penetrate our skin and eyes, being thus suitable for direct human exposure. This wavelength also exhibits the well-known antimicrobial properties of UVC, as the light at 222 nanometres can deactivate any microorganism, even antibiotic resistant bacteria, making the UV222 Booth a universal tool in mitigating biological contamination in cleanrooms.

This document presents features, specifications, applications, and compliance of the UV222 Booth, as well as key measurements that support its safety and efficacy. This includes measurements showing that the generated ozone levels remain low, even upon heavy use of the UV222 Booth. Measurements of light transmission show that the light emitted by the UV222 Booth is not transmitted by standard cleanroom gowning materials, which allows for an elevated light-intensity, ensuring efficient disinfection within seconds. Finally, the regulatory conformity of the product is presented along with user manuals and test protocols to showcase how the product functions and how its validated upon installation.

Introducing the UV222 Booth

Personnel entering classified areas such as cleanrooms are important sources of microbial contamination. This constitutes an important challenge to pharmaceutical production lines.

UV Medico has developed a revolutionary solution for the next generation of cleanrooms: The UV222 Booth.

Using UV222 technology, the UV222 Booth has been designed specifically for eliminating microbial contamination on worker uniforms and protective gear before entering classified cleanrooms or other working environments that must be kept free of microbial pathogens.

Several parameters make the UV222 Booth unique. Using the versatile UV222 patented filtered Far UV-C, which has been proven to be safe for use in occupied spaces, the UV222 Booth offers disinfection in seconds. It is chemical free and decontaminates the entire body



UV222 Booth Characteristics:

- Care222® patented filtered Far UV-C.
- Decontamination cycle programmable.
- Touchless ON/OFF interface.
- Built-in safety features (emergency stop, self-diagnostics).
- High efficacy against bacteria, spores, and fungi.
- No impact on gloves, uniforms and gear.
- Easy installation and use.
- Made with high-grade stainless-steel surfaces to comply with cleanroom interior standards.

The UV222 Booth is an advanced addition to current contamination control measures in cleanrooms. It eliminates any residual microorganisms present on protective equipment, ensuring a higher grade of cleanliness and a lower risk of product contamination. The time required to eliminate different viruses and bacteria is indicated in the section UV222 Booth Efficacy, page 20.

The UV222 Booth uses intuitive touchless operation and has built-in safety features to offer a complete solution for areas where disinfection was not fully achievable up until today. It can be customised with operating cycles adapted to individual needs for disinfection, and can be delivered as a standalone solution, or encased in a stainless-steel frame from floor to ceiling fully integrable in any cleanroom.



Audio and visual indication of disinfection cycle.



Operation status indication.

Specifications

Microorganism	Type
Wavelength	222 nm
Average irradiance (at centre)	388.5 $\mu\text{W}/\text{cm}^2$ †
Dose in 30 sec. (at centre)	11.66 mJ/cm^2 †
Input voltage	90 ~ 264 AC
Mode	30 sec. duty cycle†
Max power consumption	3 kW
Weight	430 kg (948 lbs)†
Dimensions	110 x 140 x 224 cm (3.60 x 4.59 x 7.35 ft)†
Operating temperature	0° to + 50° C (32° to 122° F)
Ambient humidity	5–90% RH

† Values based on a standard booth with 121 Far UV-C light sources.
The UV222 Booth can be customised upon request.

UV222 Booth Efficacy

The following table shows the time required to deactivate different microorganisms using the UV222 Booth:

Microorganism	Type	Time for disinfection in UV222 Booth (sec.)*
Arthrobacter nicotinovorans	Bacteria	15.37
Bacillus subtilis	Bacteria	10.53
Clostridium sporogenes	Bacteria	7.39
Enterococcus faecalis	Bacteria	19.54
Escherichia coli	Bacteria	5.41
Listeria monocytogenes	Bacteria	9.21
Pseudomonas aeruginosa	Bacteria	5.10
Salmonella Typhimurium	Bacteria	5.07
Staphylococcus aureus	Bacteria	8.34
Streptococcus pyogenes	Bacteria	53.82
Yersinia enterocolytica	Bacteria	5.66
Candida albicans	Fungi	25.28
Penicillium expansum spores	Fungi	35,57
Bacillus subtilis spores	Spores	16,32
Influenza virus	Virus	3,29
Rotavirus	Virus	11,71
SARS-Cov-2	Virus	3,09

*Calculated taking as reference the values from [Hessling M, 2021, The impact of far-UVC radiation \(200-230 nm\) on pathogens, cells, skin, and eyes - a collection and analysis of a hundred years of data](#); and the standard UV222 Booth with 121 light sources.

Compliance

In compliance with:

- ROHS Directive 2011/65/EU and amendments
- EMC Directive 2014/30/EU
- LVD 2014/35/EU
- ISO 15858 UV-C Devices – Safety information – permissible human exposure.*

*In agreement with article 5.3 of ISO 15858; personal protective equipment according to the product manual must be used by the operator inside the active UV Booth since instantaneous irradiance exceeds the UVC exposure for unprotected skin and eyes.



Ozone Generation

Background information

Light with wavelengths below 240 nm generate ozone from interacting with the oxygen in the air. This interaction is relatively weak in the 190 to 240 nm region. Some ozone-generation is inevitable with all 222 nm disinfection solutions, and since ozone is potentially poisonous, the generation rate should be monitored. Ozone is present in outdoor environments, typically at a concentration ranging from 10-50 parts per billion (ppb). For extended exposure, limits have been set by various regulators (WHO, EU, FDA etc.) ranging between 50 and 100 ppb. Ozone has a very distinct smell and can be smelled already from ~20 ppb.

Literature

From scientific literature some insight can be found on ozone generation from filtered KrCl excimer lamps like the ones used in the UV222 Booth.

Claus, H., 2021. "Ozone generation by ultraviolet lamps." *Photochem. Photobiol.* 97, 471–476.

- <https://doi.org/10.1111/php.13391>.

"However, low-power (<15W) 222 nm lamps and modules are not expected to generate any significant ozone amounts that would lead to—or even approach—the recommended (and legal) limits for ozone concentrations in rooms."

Ma, B., 2023. "Reflection of UVC wavelengths from common materials during surface UV disinfection: Assessment of human UV exposure and ozone generation." *Science of The Total Environment*, Vol 869,

- <https://doi.org/10.1016/j.scitotenv.2023.161848>.

"The ozone concentrations from the KrCl excimer devices were lower than 3 ppb for all the locations measured, which is much lower than ACGIH TLV of 100 ppb and the FDA limit for extended exposure (50 ppb)"*

Ozone testing the UV222 Booth

Since ozone concentration in a room is inherently dependent on room size and ventilation properties the most meaningful measure of ozone production is done at the installation site. Upon installation the UV222 Booth is tested on a range of parameters, ozone generation being one of them.

Detector

A handheld ozone-detector is mounted on the bottom part of the booth (ozone is heavier than air). The detector used is a EZ-1X from EcoSensors. This device has a NIST traceable calibration and has a detection range of 20-140 ppb.

Procedure

The UV222 booth is tested with 20 full cycles in row while monitoring the ozone detector.

Results

No reading was given at any point through the test of the UV222 booth. Hence the concentration remains under the detection limit of 20 ppb.

Conclusion

The measurement done on the UV222 Booth on-site shows that the ozone concentration remains low even upon heavy use of the UV222 Booth. In extension to this it should be noted that ozone decay naturally upon reacting with the air and surfaces in the room, since ozone is a highly reactive chemical compound. In addition, the ventilation in the room will gradually dilute the small amount of ozone generated. All together this ensures that there is no expectation of an ozone build-up to occur over time.

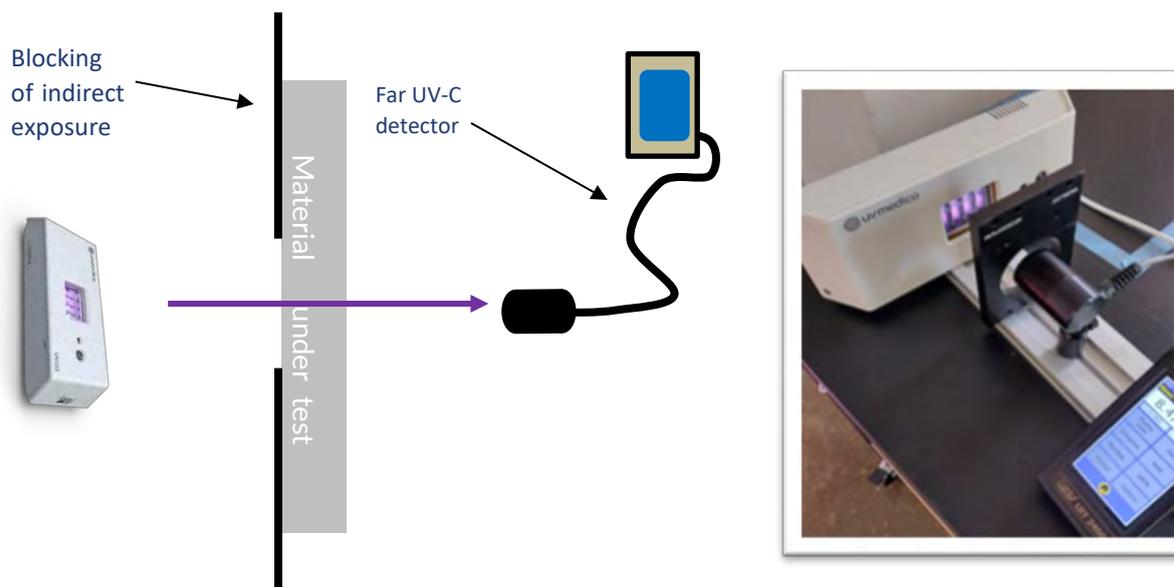
Measurements of Far UV-C Transmission through gowning materials

Background information

The purpose of this experiment is to determine the transmission of Far UV-C 222 nm light through different materials. When working with Far UV-C for safe disinfection the transmission properties of Far UV-C through the materials used in the intended application space are crucial to both the safety and efficacy of the lamps. Since Far UV-C technology is still a rather new field, the knowledge on material properties at these wavelengths is still lacking. Hence, in many cases measurements on specific materials are needed.

Setup With a simple setup we can measure the transmission through a given material. In the following picture the setup is sketched, as explained in the next paragraph.

Figure 1: Measuring transmission through material samples. The insert shows a photo of the setup assembly at UV Medico's facilities.



Detector

To measure the transmission properties specifically for the Far UV-C wavelengths the detector used needs to be capable of picking out the relative change in Far UV-C intensity. This can be achieved in several ways; a few suggestions are listed below in preferred order.

- Solar blind power meter: a device made for measuring light quantities in the UVC range and hence practically blind to the visible wavelengths.
 - Model: Ushio UIT2400
- UV spectrometer: from spectral data the intensity specifically at 222 nm can be compared for relative intensity.
 - Model: Ibsen Freedom UV-vis

Recommendations for the setup planning

- Lamp, detector, and mount for material under test should be secured in their position.
- Make sure that no highly reflective materials are situated close to the setup. Far UV-C is highly reflected by Aluminum, PTFE/Teflon and to a lesser degree by other metals, most other materials have low reflection of Far UV-C.
- Materials should not be stretched unless clearly intended as this will greatly influence the transmission.

Quantification of reflection

The property recorded is the optical intensity transmitted through the material. This is related to the optical intensity measured with no obstruction of the light path to find a relative transmission factor. The transmission factor can be expressed in either a logarithmic suppression or as a transmission percentage as defined below.

- Suppression [dB]:

$$10 \cdot \log \left(\frac{I_{MUT}}{I_{REF}} \right)$$

- Transmission [%]:

$$\frac{I_{MUT}}{I_{REF}} \cdot 100\%$$

Here I_{MUT} denotes the optical intensity through the material under test (MUT) while I_{REF} denotes the reference intensity without any material in the light path.

Results

- Distance lamp to sample: 10 cm
- Distance lamp to detector: 20 cm

Powermeter measurements

- Background reading (Lamp off): 0.0005 $\mu\text{W}/\text{cm}^2$
- Reference intensity (No material mounted): 405 $\mu\text{W}/\text{cm}^2$

Material transmission of UV222 light			
Material	Optical intensity [$\mu\text{W}/\text{cm}^2$]	Suppression [dB]	Transmission [%]
Aseptic production suit Elis	0.2	-33.05	0.04953%
Protective goggles DOTCH Puru Vision 1.0	0.0006	-58.28	0.00015%
Face mask Elis	0.168	-33.81	0.04160%
Gloves Shieldskin Extreme Nitrile 400 DI	0.0017	-53.76	0.00042%
Gloves Shieldskin Extreme Nitrile 300 D	0.0007	-57.61	0.00017%

Spectrometer measurements:

With the UV spectrometer the probe is much more confined as the light is collected with an optical fibre (core $\varnothing 600\mu\text{m}$). This allows an investigation of both the spectral dependency of the transmission as well as a search for local variation of transmission.

- Reference intensity (222 nm peak): 32000 counts

Material transmission with UV222			
Material	222nm peak counts	Suppression [dB]	Transmission [%]
Face mask	-	-	-
Position A	70	-26.60	0.21875%
Position B	44	-28.62	0.13750%
Position C	10	-35.05	0.03125%
Position D	28	-30.57	0.08772%
Stretched	449	-18.53	1.40351%

Conclusion

All materials tested show very little optical transmission for 222 nm light. For ample materials the transmission is below 0.3%, while stretching the material could induce slightly elevated transmission. The effect of the effective blocking of UVC is key in ensuring the safety of the UV222 Booth. With the standard dose of 20 mJ/cm² the UV222 Booth is close to the current daily TLV of 23 mJ/cm² within a single cycle.

The added protection of the gowning ensures that an operator can go through 20 cycles but only be exposed to less than 5% of the daily allowed dose.

UV222 for microbial decontamination of gowned operators



Cleanrooms are spaces with controlled contamination levels. These classified areas are necessary in various fields, including the pharmaceutical industry, and are subjected to a strict monitoring of air and surface pollutants. Microbial contamination represents a risk to product quality, patients, or consumers, and are thus controlled in these spaces.

Personnel monitoring and microbial contamination limits

Microbial contamination limits vary depending on the classification of the cleanroom.

According to EU GMP, the following microbial limits, expressed in colony forming units (CFU), are permitted in cleanrooms during qualification.

EU GMP Grade	Maximum permitted level during qualification		
	air sample cfu/m ³	settle plates (diameter 90 mm) cfu/4 hours	Contact plates (diameter 55 mm) cfu/4 hours
A		No Growth	
B	10	5	5
C	100	50	25
D	200	100	50

Where aseptic operations are performed, microbial monitoring should be performed frequently. It should include monitoring of personnel at periodic intervals during critical interventions, and on each exit from the grade B cleanroom. The microbial load of gloves and gowns is measured using swabs or contact plates.

The microbial limits applicable to personnel gowns and gloves correspond to the contact plate limits within the grade A (no growth) and grade B (5 cfu) areas. Routine gown monitoring is not normally required for grade C and D areas. Consequently, samples taken from operators garments in grade A, must result in “no growth”, while the samples from operators exiting grade B areas must not exceed 5 cfu.

UV222 germicidal efficacy

UV light at 222 nm is highly effective for inactivation of microorganisms [\[1\]](#).

Antimicrobial effect of UV222 lamps has been measured and verified. The fixture was installed in the ceiling at 2 meters from the table surface. An irradiance of 5 $\mu\text{W}/\text{cm}^2$ was delivered from this distance. During the experiment, the lamp was ON for 2 hours. Tests were performed with HygiCult TPC (Aidian), to determine the number of live bacteria (cfu) on the table surface before and after exposure to the UV222 light. After sampling, HygiCult TPC test specimens were stored in a heating cabinet (37°C) for 24 hours. Results showed a reduction on the number of live bacteria (cfu) on the table surface with more than 100-fold. Results are represented on the figures here below.

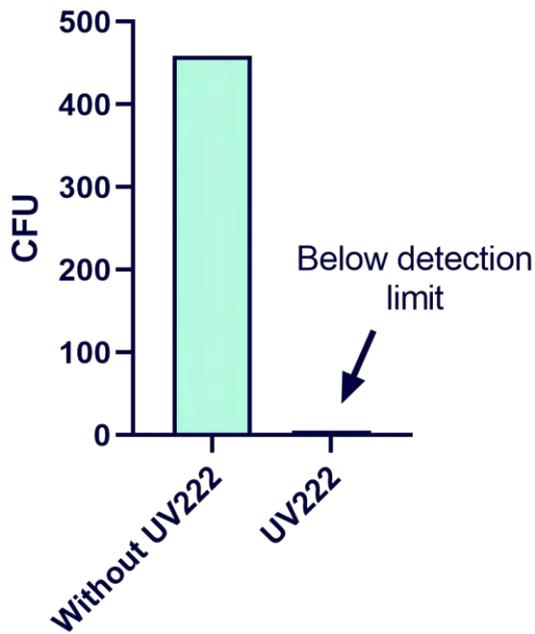


Figure 2. Bacterial count testing with Hygicult stripes.

Figure 1. Bacterial reduction on surface using a UV222 lamp.

Cleanroom garment decontamination

The data available about the effect of UV light on fabrics and, in particular, cleanroom garments, is very limited. However, it has been observed that most of operator monitoring deviations in the cleanroom have less than 10 cfu [2]. The UV222 Booth has been developed to reduce operator microbial deviations in controlled environments. The antimicrobial performance has been tested on personal protective equipment, validating a high efficacy in the decontamination of gowned personnel.

➤ Experimental setup

Cleanroom gown

Living bacteria of the species *Staphylococcus epidermidis* in buffer were transferred to pieces of cleanroom gown fabric (20 x 25 cm). *S. epidermidis* is a part of the human bacterial flora and can often be found on surfaces touched by humans. Figure 1 A. The contaminated fabric was dried in an incubator at 37 ° C and irradiated with a UV Medico UV222 lamp. Sampling was done using Hygicult TPC (Aidian) before and after irradiation.

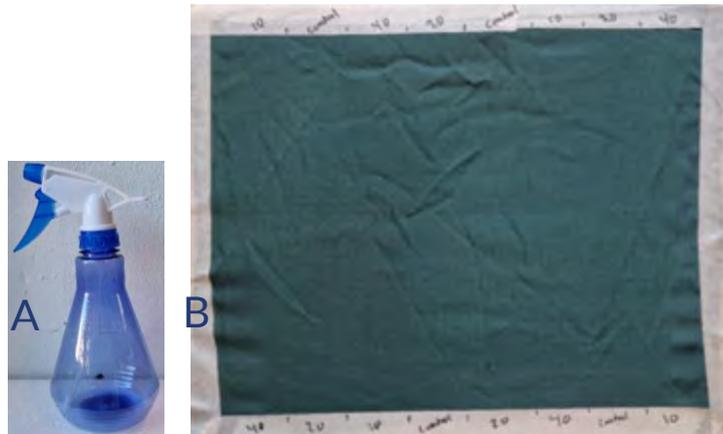


Figure 3. Spray bottle for distributing bacteria evenly on surfaces (A). Distribution of sampling areas on gown fabric (B).

Cleanroom face masks

Living *S. epidermidis* in buffer were transferred onto the surface of the mask. A spatula was used to evenly distribute the solution on the water repellent surface. The mask was dried in an incubator at 37 ° C (approximately 20-30 minutes). Sampling areas were distributed randomly on the mask surface (Figure 52). The mask was decontaminated using UV222 lamp and sampling was done as described above.



Figure 4. Distribution of sampling areas on mask.

Cleanroom goggles

Living *S. epidermidis* in buffer were transferred onto the surface of the goggles using a spray bottle. The goggles were dried in an incubator at 37 ° C (approximately 20-30 minutes) and sampling areas were randomly distributed on the goggles (Figure 3). The goggles were decontaminated using UV222 lamp emitting at 222 nm. Sampling was done as described above.



Figure 5. Distribution of sampling areas on goggles.

➤ Results

The testing revealed that UV222 light has high anti-microbial efficacy on cleanroom garments. Using a UV dose of 10 mJ/cm^2 , the number of bacteria eliminated was more than 100 cfu. This is ten times more than what is observed in real cleanroom testing, less than 10 cfu as mentioned previously [2]. The time required to achieve the dose of 10 mJ/cm^2 in the UV222 Booth is 20 seconds.

The pictures here below show the microbial reduction obtained in different garments in only 20 seconds (10 mJ/cm^2).

Cleanroom gown

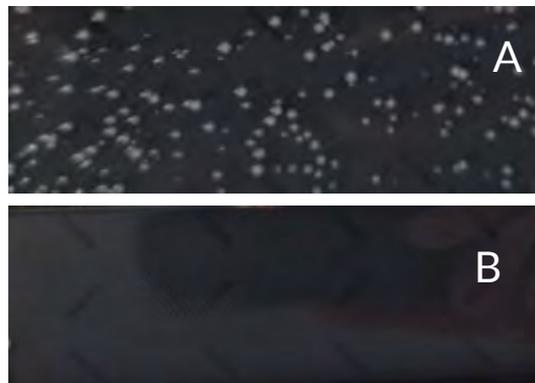


Figure 6. Gown sample before irradiation (A), Gown sample after a dose of 10 mJ/cm^2 (B).

Cleanroom masks



Figure 7. Mask sample before irradiation (A), Mask sample after a dose of 10 mJ/cm^2 (B).

Cleanroom goggles

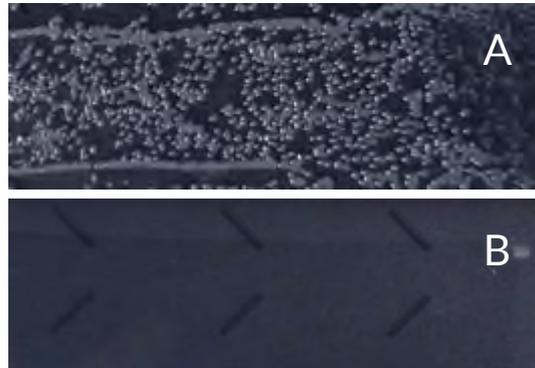


Figure 8. Goggles sample before irradiation (A).
Goggles sample after a dose of 10 mJ/cm² (B).

Conclusion

In this report, we tested the decontaminating efficacy of UV222 on gowns, masks and goggles, worn in high-grade classified cleanrooms. Microbial load on the garments is efficiently reduced.

UV222 efficiently decontaminates gowns, masks, and goggles. Thus, the UV222 Booth can facilitate decontamination of fully gowned operators before they enter production areas.

References

1. Hessling, M. The impact of far-UVC radiation (200-230 nm) on pathogens, cells, skin, and eyes - a collection and analysis of a hundred years of data. *GMS Hyg Infect Control*, 2021. DOI: [10.3205/dgkh000378](https://doi.org/10.3205/dgkh000378)
2. Smith, L. (2020). Gender Influences Bacterial Contamination of Reusable Cleanroom Operators' Garments following Wear. *EJPPS*. DOI:[10.37521/ejpps25202](https://doi.org/10.37521/ejpps25202)

Appendix 1

FAT and SAT

Protocols

Factory Acceptance Test (FAT) Test Plan for UV Booth		
Document No: FT.TP.BA.601015.	Version Number: 01	

Test No.	Prerequisite	Test Method	Observations	Pass/Fail	Date / Signature
Baseline before test					
A	Measuring equipment that are used for measuring dosage and ozone level must be in a calibrated state.	Document calibration performed before test.	The measuring equipment is in calibrated state Yes [<input type="checkbox"/>] No [<input type="checkbox"/>] The uncertainty is: Dosage: _____ Ozone: N/A		
B	Baseline before the test	Identify and reference 1. Firmware version number of UV booth before start of test 2. Design Documentation name and version number	Firmware version number: _____ Design Documentation: _____		

Factory Acceptance Test (FAT) Test Plan for UV Booth		
Document No: FT.TP.BA.601015.	Version Number: 01	

Test No.	URS Ref	Acceptance Criteria	Test Method	Observations	Pass/Fail	Date / Signature
DK.BA.CLA.URS.00094.01						
1	URS.1	<p>1. 1 All materials on the outer surfaces are linked to either a material certificate, a declaration of conformity, or a specification</p> <p>1.2 The exposed surfaces must be made from the following materials:</p> <ul style="list-style-type: none"> - At least 304 stainless steel - Aluminium EN AW-6082 - Coated aluminium - PMMA (Poly(methyl methacrylate))/acrylic/acrylic glass/plexiglass) - Silicone - Plastics - Glass 	<p>Find documentation and specify reference under 'observations' for the following materials:</p> <ul style="list-style-type: none"> - Stainless Steel - Quartz Glass - Glass - Plastics on buttons - Silicone <p>Evaluate the materials, based on the acceptance criteria and determine whether they pass or fail.</p>	<p>Stainless Steel type: _____</p> <p>Stainless Steel reference: _____</p> <p>Quartz Glass type: _____</p> <p>Quartz Glass reference: _____</p> <p>Glass type: _____</p> <p>Glass reference: _____</p> <p>Plastics on buttons type: _____</p> <p>Plastics on buttons reference: _____</p> <p>Silicone on joints type: _____</p> <p>Silicone on joints reference: _____</p> <p>_____</p>		

Factory Acceptance Test (FAT) Test Plan for UV Booth		
Document No: FT.TP.BA.601015.	Version Number: 01	

Test No.	URS Ref	Acceptance Criteria	Test Method	Observations	Pass/Fail	Date / Signature
2	URS. 1	<p>Anchoring 1.3 The UV booth is anchored to the walls/ceiling prior to sealing</p> <p>Sealed joints 1.4 The exposed joints are sealed with silicone and are cleanable as they are smooth and accessible. It is possible to wipe the joints with a dry cleaning rag (simulating cleaning).</p>	<p>Anchoring NA – Anchoring will be tested in SAT</p> <p>Sealed joints NA – Sealing of joints will be tested in SAT</p>	<p>Anchoring NA</p> <p>Sealed joints NA</p>	<p>Anchoring NA</p> <p>Sealed joints NA</p>	<p>Anchoring NA</p> <p>Sealed joints NA</p>
3	URS. 1	<p>Surfaces 1.5 The exposed surfaces of the UV booth are cleanable as they are smooth and accessible. It is possible to wipe all the surfaces on the UV booth with a dry cleaning rag (simulating cleaning).</p> <p>Sealed joints 1.6 All gaps are sealed with silicone</p>	<p>Surfaces Visually assess the surfaces. Thereafter wipe surfaces with a dry cleaning rag and observe smoothness</p> <p>Conclude whether or not the acceptance criteria are met, and hence if this test is passed or failed.</p> <p>Sealed joints NA – Sealing of joints will be tested in SAT</p>	<p>Surfaces Surfaces are cleanable as they are smooth and accessible.</p> <p>Yes []</p> <p>No []</p> <p>Sealed joints NA</p>	<p>Surfaces</p> <p>Sealed joints NA</p>	<p>Surfaces <i>By 2 persons</i></p> <p>Sealed joints NA</p>
4	URS. 2	<p>Footprints 2.1 There are foot prints on the floor to guide the positioning of the operator</p> <p>Malfunction 2.2 In case of malfunction the signal light lights up indicating "service"</p>	<p>Footprints NA -</p> <p>Malfunction Simulate malfunctions, by detaching the stop motion sensor. Simulate malfunction, by detaching the start motion sensor. Observe the operating signal light.</p> <p>Conclude whether or not the acceptance criteria are met, and hence if this test is passed or failed.</p>	<p>Footprints NA</p> <p>Malfunction The signal light indicates "service" in both cases.</p> <p>Yes []</p> <p>No []</p>	<p>Footprints NA</p> <p>Malfunction</p>	<p>Footprints NA</p> <p>Malfunction <i>By 2 persons</i></p>

Factory Acceptance Test (FAT) Test Plan for UV Booth		
Document No: FT.TP.BA.601015.	Version Number: 01	

Test No.	URS Ref	Acceptance Criteria	Test Method	Observations	Pass/Fail	Date / Signature
5	URS. 2	<p>Minimum Dosage (Decontamination) 2.4 When all lights are on, the UV Booth achieves a minimum dose of 5 mJ/cm² at 222 nm UV light within a UV cycle on the following "targeted positions" on gowned operator</p> <ul style="list-style-type: none"> - Forehead - Wrists - Chest - Stomach 	<p>See Appendix 1</p> <p>Conclude whether or not the acceptance criteria are met, and hence if this test is passed or failed</p>	<p>See Appendix 1 - Observations</p>		By 2 persons
6	URS. 3	3.3 The backside of the UV Booth is sealed to ensure pressure cascade	NA - Included in SAT	NA - Included in SAT	NA	NA
7	URS. 4	<p>Dimensions 4.1 The dimensions of the UV booth accommodate use (entering, turning, and exiting) without touching any surfaces.</p> <p>Touchless control 4.2 The cycle is touchlessly controlled (start and stop)</p>	<p>Dimensions Enter, stand in position, turn around, stand in position, exit. Evaluate dimensions; pass if any surface was not touched, fail if any surface was touched.</p> <p>Touchlessly controlled See test 14</p>	<p>Dimensions The dimensions of the UV booth accommodate use (entering, turning, and exiting) without touching any surfaces.</p> <p>Yes []</p> <p>No []</p> <p>Touchless control NA</p>	<p>Dimensions NA</p> <p>Touchless control NA</p>	<p>Dimensions By 2 persons</p> <p>Touchless control NA</p>
8	URS. 5	<p>UV Cycle 5.1 It is possible to initiate a UV cycle</p> <p>5.2 There are different and dedicated visual and audible cues given to the operator when (1) cycle starts, (2) cycle is in progress, (3) cycle is completed, and (4) in case of cycle malfunction.</p>	<p>UV Cycle See test 13</p>	<p>UV Cycle See Test 15</p>		

Factory Acceptance Test (FAT) Test Plan for UV Booth		
Document No: FT.TP.BA.601015.	Version Number: 01	

Test No.	Desired Outcome	Test Method	Observations	Pass/Fail	Date / Signature
Other Design Aspects that must be tested, based on DD.BA.601510					
9	<p><u>LED Light</u> The LED Lighting supplies light to support cleaning activities and in case of emergency.</p>	<p>Tester must push the emergency button and observe active LED light. Tester must push cleaning button and observe active LED light.</p> <p>Conclude whether or not the acceptance criteria are met, and hence whether the test is passed or failed.</p>	<p>The LED light remains active when both emergency and cleaning mode is activated.</p> <p>Yes []</p> <p>No []</p>		<i>By 2 persons</i>
10	<p><u>Emergency button</u> Activating the emergency button must force the UV booth to power off.</p>	<p>Tester must enter the booth and initiate a cycle. Before completing the cycle, the tester must press the emergency button. The cycle must stop and the booth shut down. The LED light must remain active. Thereafter the emergency button must be released and the booth must go back to idle state.</p> <p>Conclude whether or not the acceptance criteria are met, and hence if this test is passed or failed.</p>	<p>The UV booth turns off all UV light sources and the LED light remains active.</p> <p>Yes []</p> <p>No []</p>		<i>By 2 persons</i>
11	<p><u>Cleaning button</u> Activating the cleaning button must force all UV light sources to be turned off, and only the LED light to be turned on.</p>	<p>Tester must, prior to stepping into the booth, activate cleaning mode by pressing the cleaning button. The tester must then enter the booth and try to start and stop cycle (via motion sensors). It must be ensured that only the LED light remains active, and the UV light sources remain inactive whilst cleaning-button is activated.</p> <p>Conclude whether or not the acceptance criteria are met, and hence if this test is passed or failed.</p>	<p>The UV booth turns off all UV light sources and the LED light remains active. It is impossible to start and stop a cycle, whilst the cleaning mode is active.</p> <p>Yes []</p> <p>No []</p>		<i>By 2 persons</i>

Factory Acceptance Test (FAT) Test Plan for UV Booth		
Document No: FT.TP.BA.601015.	Version Number: 01	

Test No.	Desired Outcome	Test Method	Observations	Pass/Fail	Date / Signature
12	<p><u>Operating Signal Light</u> Green: Klar til brug Yellow: Service Red: I brug</p>	<p>The tester must notice the functional operating signal, before a cycle, during a cycle and in events of malfunction.</p> <p>Malfunctions are tested in test 4</p> <p>Conclude whether or not the acceptance criteria are met, and hence if this test is passed or failed.</p>	<p>The operating signal correctly depicts the state of the UV Booth.</p> <p>Green: Klar til brug Red: I brug</p> <p>Yes [] No []</p>		By 2 persons
13	<p><u>States of the UV Cycle</u> All states of the cycle are clearly conveyed according to design documentation.</p>	<p><u>See Appendix 2</u> Conclude whether or not the acceptance criteria are met, and hence if this test is passed or failed</p>	<u>See Appendix 2: Observations</u>		
14	<p><u>Start Cycle</u> The motion sensor module to the right is to START to cycle: The operator waves their hand in front of the module, 5 cm. away from the module for a couple of seconds and the UV222 Booth starts the cycle.</p> <p><u>Stop Cycle</u> The motion sensor module to the left is to STOP the cycle before the cycle is completed: The operator waves their hand in front of the module, 5 cm. away from the module for a couple of seconds and the UV222 Booth stops the cycle.</p>	<p>Operator must enter the booth, initiate the cycle through the start motion sensor, stop the cycle before the cycle is completed through the stop motion sensor.</p> <p>Conclude whether or not the acceptance criteria are met, and hence if this test is passed or failed.</p>	<p>The UV booth starts the cycle immediately after activating the start motion sensor. The booth stops the cycle immediately after activating the stop motion sensor.</p> <p>Yes [] No []</p>		By 2 persons
15	<p><u>Maximum Dosage (Gowning components)</u> Determine maximum dosage for gowning components.</p>	<p><u>See Appendix 1</u> Conclude whether or not the acceptance criteria are met, and hence if this test is passed or failed.</p>	<u>See Appendix 1 - Observations</u>		By 2 persons

Factory Acceptance Test (FAT) Test Plan for UV Booth		
Document No: FT.TP.BA.601015.	Version Number: 01	

Test No.	Prerequisite	Test Method	Observations	Pass/Fail	Date / Signature
Additional Safety and Performance Requirements					
16	Power cut off Power up and shut down the UV Booth with no consequences for the UV Booth	Initiate the cycle, through the start sensor. Shortly into the cycle: Cut power on main switch in control box and observe the booth shutting down immediately. Switch on the power in the control box and observe the booth power up and ready for use – “Green: Klar til brug”. Conclude whether or not the acceptance criteria is met, and hence if this test is passed or failed.	The UV Booth shuts down immediately after the power plug is pulled. The UV booth starts up in “Klar til brug” mode, after inserting the power-plug. Yes [] No []		<i>By 2 persons</i>
Additional Safety and Performance Requirements					
17	Stress test Perform a System Stress Test with no consequences for the UV Booth	Repeat test 14 50 times Repeat test 16 50 times Conclude whether or not the acceptance criteria is met, and hence if this test is passed or failed.	Repeating the tests sequentially has no impact on the UV Booth. Yes [] No []		<i>By 2 persons</i>

Test No.	Prerequisite	Test Method	Observations	Pass/Fail	Date / Signature
Baseline after test					
C	Baseline after the test	Identify and reference 1. Firmware version number of UV booth after test 2. Design Documentation, name and version number	Firmware version number: _____ Design Documentation: _____		<i>By 2 persons</i>

	Factory Acceptance Test (FAT) Test Plan for UV Booth		
	Document No: FT.TP.BA.601015.	Version Number: 01	

Appendix 1: Measurement protocol for UV dose in UV booth

Equipment:

- UIT2400 optical power-meter. Calibrated (NIST traceable) to 222 nm. With this power-meter the irradiance is measured directly. The power-meter is “Solar Blind” and hence does not pick up light from ceiling lights or other sources outside of the far UV.
- Measurement tape

Procedure:

- Measurements are taken at the following positions: the forehead, the wrists, the outer wrist of the right hand, middle of the chest and the stomach.
- These positions translate into the coordinates in below table (from the ground in the center of the UV Booth). These coordinates are based on a standard person.
- The maximum dosage is also determined 10 cm away from a UV light source for the duration of a UV cycle.

	Height [cm]	Width [cm]	Depth [cm]
Forehead	185	0	0
Wrists	170	±50	+10
Outer right wrist	170	+50	+10
Chest	160	0	+15
Stomach	125	0	+15
Maximum dosage	Center of a UV light source	NA	10 cm away from a UV light source

Factory Acceptance Test (FAT) Test Plan for UV Booth		
Document No: FT.TP.BA.601015.	Version Number: 01	

Appendix 1: Observations

Location of measurement	Dosage - Test 1 $\left[\frac{mJ}{cm^2} \right]$	Dosage - Test 2 $\left[\frac{mJ}{cm^2} \right]$	Dosage - Test 3 $\left[\frac{mJ}{cm^2} \right]$	Date / Signature
Forehead Height: 185 cm, Width: 0 cm, Depth: 15 cm				By 2 persons
Wrist (right) Height: 170 cm, Width: ±50 cm, Depth: 10 cm				By 2 persons
Outer Writs (right) Height: 170 cm, Width: ±50 cm, Depth: 10 cm				By 2 persons
Wrist (left) Height: 170 cm, Width: ±50 cm, Depth: 10 cm				By 2 persons
Chest Height: 160 cm, Width: 0 cm, Depth: ±15 cm				By 2 persons
Stomach Height: 125 cm, Width: 0 cm, Depth: ±15 cm				By 2 persons
Maximum Dosage 10 cm away from a UV light source				By 2 persons
Duration of UV cycle				

Factory Acceptance Test (FAT) Test Plan for UV Booth		
Document No: FT.TP.BA.601015.	Version Number: 01	

Appendix 2: States of the UV Cycle

Procedure:

All states of a cycle must be observed. For any state, the visuals (countdown bar), audible and the LED lights must be observed. The test is a three-part test. The tester must note down all observations in 'Appendix 2: Observations'.

1. The regular cycle
The tester must observe idle state. Thereafter the tester must enter the booth, start the cycle, stand in the UV booth until the cycle is complete, and finally exit the booth. All observations must be noted down
2. The interrupted cycle
The tester must enter the booth, initiate a cycle and shortly after interrupt the cycle (stopping the cycle manually) and observe the booth
3. A malfunction on the UV booth
 - 3a) The start sensor must be detached, and the tester must observe the UV booth
 - 3b) The stop sensor must be detached, and the tester must observe the UV booth

Acceptance Criteria

State of the Cycle	Acceptance Criteria
Idle state when operator enters UV222 Booth:	There are no lights in the countdown bar.
Operator starts cycle:	Two short beeps, follow two quick purple light flashes of all pixels in countdown bar to indicates UV cycle starts.
During cycle:	There will be an audible signal for every second, follow countdown bar shots off purple lights and operator has a visual indication on how long time remaining the cycle.
Completed cycle:	A long beep follow all pixels lights up fully up with green lights to indicates cycle is completed.
Interruption of cycle:	If operator stopes cycle with STOP motion sensor module before cycle is completed, multiple short beeps follow red lights flashing in all pixels in countdown bar will indicate UV cycle is not completed.
Malfunction on the UV222 Booth:	All pixels are lighted up with a deep yellow light.

	Factory Acceptance Test (FAT) Test Plan for UV Booth		
	Document No: FT.TP.BA.601015.	Version Number: 01	

Appendix 2: Observations

State of the Cycle	LED light [On/Off]:	Countdown bar - according to acceptance criteria [Yes/No]	Audible cues - according to acceptance criteria [Yes/No]	Comment (if any otherwise N/A)	Date / Signature
Idle State					By 2 persons
Starting the Cycle					By 2 persons
During the Cycle					By 2 persons
Completed Cycle					By 2 persons
Interruption of Cycle					By 2 persons
Malfunction of Cycle					By 2 persons

	Factory Acceptance Test (FAT) Test Plan for UV Booth		
	Document No: FT.TP.BA.601015.	Version Number: 01	

Appendix 3: Elaborations table, observations and explanations

Test No.	Observation and/or Explanation	Date / Sign

	Factory Acceptance Test (FAT) Test Plan for UV Booth		
	Document No: FT.TP.BA.601015.	Version Number: 01	

--	--	--

Site Acceptance Test (SAT) Test Plan for UV Booth		
Document No: ST.BA.TP.601510	Version Number: 01	

Test No.	Prerequisites	Test Method	Observations	Pass/Fail	Date / Signature
Baseline before test					
A	Measuring equipment that are used for measuring dosage and ozone level must be in a calibrated state.	Document calibration performed before test.	The measuring equipment is in calibrated state Yes [<input type="checkbox"/>] No [<input type="checkbox"/>] <u>Date of calibration:</u> Dosage: _____ Ozone: _____ <u>The uncertainty is:</u> Dosage: _____ Ozone: _____		<i>By 2 persons</i>

Site Acceptance Test (SAT) Test Plan for UV Booth		
Document No: ST.BA.TP.601510	Version Number: 01	

Test No.	Prerequisites	Test Method	Observations	Pass/Fail	Date / Signature
B	Baseline before the test. Ensure that the firmware versions are the same as the firmware versions of ended FAT test.	Identify and reference <ol style="list-style-type: none"> 1. Firmware version number of UV booth before start of test 2. Design Documentation, file- and version number 	Firmware version numbers <u>UV Light Sources:</u> FAT (end) Firmware version: 2.01 SAT (start) Same version: Yes [] No [] <u>Start & Stop Motion Sensors:</u> FAT (end) Firmware version: 2.01 SAT (start) Same version: Yes [] / No [] <u>Operator Signal Light:</u> FAT (end) Firmware version: 2.01 SAT (start) Same version: Yes [] / No [] <u>Countdown-bar:</u> FAT (end) Firmware version: 2.02 SAT (start) Same version: Yes [] / No [] <u>Display (in control box):</u> FAT (end) Firmware version: 2.01 SAT (start) Same version: Yes [] / No [] Design Documentation: _____		<i>By 2 persons</i>

Test No.	URS Ref	Acceptance Criteria	Test Method	Observation	Pass / Fail	Date / Signature
----------	---------	---------------------	-------------	-------------	-------------	------------------

Site Acceptance Test (SAT) Test Plan for UV Booth		
Document No: ST.BA.TP.601510	Version Number: 01	

DD.BA.CLA.URS.00094.01-03						
1	URS.1	<p>All materials on the outer surfaces are linked to either a material certificate, a declaration of conformity, or a specification</p> <p>The exposed surfaces must be made from the following materials:</p> <ul style="list-style-type: none"> - At least 304 stainless steel - Aluminium EN AW-6082 - Coated aluminium - PMMA (Poly(methyl methacrylate)/acrylic/acrylic glass/plexiglass) - Silicone - Plastics - Glass 	<p>Find documentation and specify reference under 'observations' for the following materials:</p> <ul style="list-style-type: none"> - Stainless Steel - Quartz Glass - Glass - Plastics on buttons - Silicone <p>Evaluate the materials, based on the acceptance criteria and determine whether they pass or fail.</p>	<p><u>Stainless steel for cabinet:</u> Type: 304L/304 Ref. 0186668 – 1, DKMTR-000059616_SO1104418 Yes [] No []</p> <p><u>Stainless steel for service hatches and skirts:</u> Type: AISI 304/304L Ref. F21MC25-1, DKMTR-000049034_SO01107610 Yes [] No []</p> <p><u>Front glass UV light source:</u> Type: Quarts SiO₂ Ref. ntjs-5-010, 20221111 Yes [] No []</p> <p><u>Front glass bar, LED, traffic light:</u> Type: Warm heated sodalime glass Ref. 01535, doc00627220221125113748 Yes [] No []</p> <p><u>Emergency stop:</u> Type: Plastic Ref. DS.BA.0900766b8162d01f Yes [] No []</p> <p><u>Cleaning button:</u> Type: Plastic Ref. DS.BA.37500053 Yes [] No []</p> <p><u>Silicone joints prior to installation:</u> Type: Ljungdahl Byg & Sanitet Ref. DS.BA.Silikone.60151000 and Faktura_1231 Yes [] No []</p>		

Site Acceptance Test (SAT) Test Plan for UV Booth		
Document No: ST.BA.TP.601510	Version Number: 01	

2	URS.1	<p><u>Anchoring</u> The UV booth is anchored to the walls/ceiling prior to sealing</p> <p><u>Sealed joints</u> The exposed joints are sealed with silicone and are cleanable as they are smooth and accessible. It is possible to wipe the joints with a dry cleaning rag (simulating cleaning).</p>	<p><u>Anchoring</u> Observe and assess the anchoring of the UV booth to the walls/ceiling.</p> <p>Conclude whether or not the acceptance criteria are met, and hence if this test is passed or failed.</p> <p><u>Sealed joints</u> Wipe the joints with a dry cleaning rag, and observe the smoothness</p> <p>Conclude whether or not the acceptance criteria are met, and hence if this test is passed or failed.</p>	<p><u>Anchoring</u> The UV Booth has been properly anchored to the walls/ceiling</p> <p>Yes [<input type="checkbox"/>]</p> <p>No [<input type="checkbox"/>]</p> <p><u>Sealed joints</u> Exposed joints are cleanable as they are smooth and accessible.</p> <p>Yes [<input type="checkbox"/>]</p> <p>No [<input type="checkbox"/>]</p>	<p><u>Anchoring</u></p> <p><u>Sealed joints</u> <i>By 2 persons</i></p>	<p><u>Anchoring</u> <i>By 2 persons</i></p> <p><u>Sealed joints</u> <i>By 2 persons</i></p>
3	URS.1	<p><u>Surfaces</u> The exposed surfaces of the UV booth are cleanable as they are smooth and accessible. It is possible to wipe all the surfaces on the UV booth with a dry cleaning rag (simulating cleaning).</p> <p><u>Sealed joints</u> All gaps are sealed with silicone</p>	<p><u>Surfaces</u> Visually assess the surfaces. Thereafter wipe surfaces with a dry cleaning rag and observe smoothness</p> <p>Conclude whether or not the acceptance criteria are met, and hence if this test is passed or failed.</p> <p><u>Sealed joints</u> Visually observe all the sealed joints have been sealed properly with silicon.</p> <p>Conclude whether or not the acceptance criteria are met, and hence if this test is passed or failed.</p>	<p><u>Surfaces</u> Surfaces are cleanable as they are smooth and accessible.</p> <p>Yes [<input type="checkbox"/>]</p> <p>No [<input type="checkbox"/>]</p> <p><u>Sealed joints</u> All the sealed joints are properly sealed with silicone.</p> <p>Yes [<input type="checkbox"/>]</p> <p>No [<input type="checkbox"/>]</p>	<p><u>Surfaces</u></p> <p><u>Sealed joints</u></p>	<p><u>Surfaces</u> <i>By 2 persons</i></p> <p><u>Sealed joints</u> <i>By 2 persons</i></p>

Site Acceptance Test (SAT) Test Plan for UV Booth		
Document No: ST.BA.TP.601510	Version Number: 01	

4	URS.2	<p><u>Footprints</u> There must be footprints on the floor to guide the positioning of the operator</p> <p><u>Malfunction</u> If malfunction occur the signal light must indicate "service".</p>	<p><u>Footprints</u> NA</p> <p><u>Malfunction</u> Simulate malfunctions, by detaching the stop motion sensor. Simulate malfunction, by detaching the start motion sensor. Observe the operating signal light.</p> <p>Conclude whether or not the acceptance criteria are met, and hence if this test is passed or failed.</p>	<p><u>Footprints</u> NA</p> <p><u>Malfunction</u> The signal light indicates "service" in both cases.</p> <p>Yes [<input type="checkbox"/>]</p> <p>No [<input type="checkbox"/>]</p>	<p><u>Footprints</u> NA</p> <p><u>Malfunction</u></p>	<p><u>Footprints</u> NA</p> <p><u>Malfunction</u> <i>By 2 persons</i></p>
5	URS.2	<p><u>Minimum Dosage (Decontamination)</u> The UV Booth must achieve a minimum dose of $5 \frac{mJ}{cm^2}$ at 222 nm UV light during a cycle on the following "targeted positions" on gowned operator</p> <ul style="list-style-type: none"> - Forehead - Wrists - Chest <p>Stomach</p>	<p><i>See Appendix 1</i></p> <p>Conclude whether or not the acceptance criteria is met, and hence if this test is passed or failed</p>	<p><i>See Appendix 1 - Observations</i></p>		
6	URS.3	<p>The backside of the UV Booth is sealed to ensure pressure cascade</p>	<p>Asses the sealing of the backside first visually and thereafter by feeling the sealings.</p> <p>Conclude whether or not the acceptance criteria are met, and hence if this test is passed or failed.</p>	<p>The backside of the UV Booth is properly sealed.</p> <p>Yes [<input type="checkbox"/>]</p> <p>No [<input type="checkbox"/>]</p>		

Site Acceptance Test (SAT) Test Plan for UV Booth		
Document No: ST.BA.TP.601510	Version Number: 01	

7	URS.4	<p><u>Dimensions</u> The dimensions of the UV booth accommodate use (entering, turning, and exiting) without touching any surfaces.</p> <p><u>Touchless control</u> The cycle is touchlessly controlled (start and stop)</p>	<p><u>Dimensions</u> NA - Included in FAT</p> <p><u>Touchlessly controlled</u> See test 14</p>	<p><u>Dimensions</u> NA - Included in FAT</p> <p><u>Touchless control</u> See test 14</p>	<p><u>Dimensions</u> NA - Included in FAT</p> <p><u>Touchless control</u> See test 14</p>
8	URS.5	<p><u>UV Cycle</u> There must be a start sensor to initiate UV cycle.</p> <p>There must be different and dedicated visual and audible cues given to the operator when (1) cycle starts, (2) cycle is in progress, (3) cycle is completed, and (4) in case of cycle malfunction.</p>	See Appendix 2	See Appendix 2: Observations	

Test No.	Ref	Acceptance Criteria	Test Method	Observation	Pass / Fail	Date / Signature
Other Design Aspects that must be tested, based on DD.BA.601510						

Site Acceptance Test (SAT) Test Plan for UV Booth		
Document No: ST.BA.TP.601510	Version Number: 01	

9	NA	<p>LED Light The LED Lighting supplies suitable light to support cleaning activities inside the UV booth</p>	<p>Adjust the intensity of the LED light to support cleaning activities.</p> <p>Conclude whether or not the acceptance criteria are met, and hence whether the test is passed or failed.</p>	<p>The LED supplies suitable light and remains active when both emergency and cleaning mode is activated.</p> <p>Yes [<input type="checkbox"/>]</p> <p>No [<input type="checkbox"/>]</p>		<i>By 2 persons</i>
10	NA	<p>Emergency button Activating the emergency button must force all UV light sources to be turned off, and only the LED light to be turned on.</p>	<p>Tester must enter the booth and initiate a cycle. Before completing the cycle, the tester must press the emergency button. The cycle must stop and the booth shut down. The LED light must remain active. Thereafter the emergency button must be released and the booth must go back to idle state.</p> <p>Conclude whether or not the acceptance criteria are met, and hence if this test is passed or failed.</p>	<p>The UV booth turns off all UV light sources and the LED light remains active.</p> <p>Yes [<input type="checkbox"/>]</p> <p>No [<input type="checkbox"/>]</p>		<i>By 2 persons</i>
11	NA	<p>Cleaning button Activating the cleaning button must force all UV light sources to be turned off, and only the LED light to be turned on.</p>	<p>Tester must, prior to stepping into the booth, activate cleaning mode by pressing the cleaning button. The tester must then enter the booth and try to start and stop cycle (via motion sensors). It must be ensured that only the LED light remains active, and the UV light sources remain inactive whilst cleaning-button is activated.</p> <p>Conclude whether or not the acceptance criteria are met, and hence if this test is passed or failed.</p>	<p>The UV booth turns off all UV light sources and the LED light remains active. It is impossible to start and stop a cycle, whilst the cleaning mode is active.</p> <p>Yes [<input type="checkbox"/>]</p> <p>No [<input type="checkbox"/>]</p>		<i>By 2 persons</i>

Site Acceptance Test (SAT) Test Plan for UV Booth		
Document No: ST.BA.TP.601510	Version Number: 01	

12	NA	<p><u>Operating Signal Light</u> Green: Klar til brug Yellow: Service Red: I brug</p>	<p>The tester must notice the functional operating signal, before a cycle, during a cycle and in events of malfunction. Malfunctions must be simulated through malfunction of the start or stop motion sensor module.</p> <p>Conclude whether or not the acceptance criteria are met, and hence if this test is passed or failed.</p>	<p>The operating signal correctly depicts the state of the UV Booth.</p> <p>Green: Klar til brug Red: I brug</p> <p>Yes [] No []</p>		<i>By 2 persons</i>
13	NA	<p><u>States of the UV Cycle</u> All states of the cycle are clearly conveyed according to design documentation.</p>	See Appendix 2	See Appendix 2: Observations		

Site Acceptance Test (SAT) Test Plan for UV Booth		
Document No: ST.BA.TP.601510	Version Number: 01	

14	NA	<p>Start Cycle The motion sensor module to the right is to START to cycle: The operator waves their hand in front of the module, 5 cm. away from the module for a couple of seconds and the UV222 Booth starts the second cycle.</p> <p>Stop Cycle The motion sensor module to the left is to STOP the cycle before the cycle is completed: The operator waves their hand in front of the module, 5 cm. away from the module for a couple of seconds and the UV222 Booth stops the cycle.</p>	<p>Operator must enter the booth, initiate the cycle through the start motion sensor, stop the cycle before the cycle is completed through the stop motion sensor.</p> <p>Conclude whether or not the acceptance criteria are met, and hence if this test is passed or failed.</p>	<p>The UV booth starts the cycle immediately after activating the start motion sensor. The booth stops the cycle immediately after activating the stop motion sensor.</p> <p>Yes [<input type="checkbox"/>]</p> <p>No [<input type="checkbox"/>]</p>	<i>By 2 persons</i>
15	NA	<p>Worst Case: Maximum Dosage (Gowning components) Determine maximum dosage for gowning components. Ensure that is does not exceed $20 \frac{mJ}{cm^2}$</p>	<p>See Appendix 1</p> <p>Conclude whether or not the acceptance criteria are met, and hence if this test is passed or failed.</p>	<p>See Appendix 1 - Observations</p>	<i>By 2 persons</i>

Site Acceptance Test (SAT) Test Plan for UV Booth		
Document No: ST.BA.TP.601510	Version Number: 01	

Test No.	URS Ref	Acceptance Criteria	Test Method	Observation	Pass / Fail	Date / Signature
Additional Safety and Performance Requirements						
16	NA	Power cut off Power up and shut down the UV Booth with no consequences for the UV Booth	Initiate the cycle, through the start sensor. Shortly into the cycle: pull the plug and observed the booth shutting down immediately. Insert power-plug into outlet and observe the booth power up and ready for use – “Green: Klar til brug”. Conclude whether or not the acceptance criteria is met, and hence if this test is passed or failed.	The UV Booth shuts down immediately after the power plug is pulled. The UV booth starts up in “Klar til brug” mode, after inserting the power-plug. Yes [] No []		<i>By 2 persons</i>
17	NA	Stress test Perform a System Stress Test with no consequences for the UV Booth	Repeat test 14 50 times Repeat test 16 50 times Conclude whether or not the acceptance criteria is met, and hence if this test is passed or failed.	Repeating the tests sequentially has no impact on the UV Booth. Yes [] No []		<i>By 2 persons</i>
18	NA	Operator Functionality Test based on SOP	Tester must be a trained operator. The tester must simulate usage of the UV booth, following the designated JI/SOP. If the tester successfully uses the booth, completing a cycle, the test passes. Otherwise, the test fails.	The trained operator successfully completed a UV cycle. Yes [] No []		<i>By 2 persons</i>
Other Tests						
19	NA	Ozon level must not exceed 0,1 ppm during peak-hour.	Ozon meter will measure the level of ozon, simulating peak-hour, 20 sequential and completed UV cycles. Conclude whether or not the acceptance criteria are met, and hence if this test is passed or failed.	The ozon level is acceptable, since it did not exceed 0,1 ppm during the simulated peak-hours Yes [] No []		<i>By 2 persons</i>

Site Acceptance Test (SAT) Test Plan for UV Booth		
Document No: ST.BA.TP.601510	Version Number: 01	

20	NA	<p>Determine amount of undesired UV outside of the UV booth.</p>	<p>Determine worst case location of undesired UV light outside the UV booth</p> <p>Measure the level of UV detected outside the UV Booth. Set up power-meter outside the UV Booth where unintended UV exposure is not desired Start a cycle Note down the measurements.</p> <p>Conclude whether or not the acceptance criteria are met, and hence if this test is passed or failed.</p>	<p>The worst case location of undesired UV light has been photo documented. Yes [<input type="checkbox"/>] No [<input type="checkbox"/>]</p> <p>Observation 1 $\left[\frac{mJ}{cm^2} \right]$ _____</p> <p>Observation 2 $\left[\frac{mJ}{cm^2} \right]$ _____</p> <p>Observation 3 $\left[\frac{mJ}{cm^2} \right]$ _____</p>	<p><i>By 2 persons</i></p>
-----------	----	--	---	---	----------------------------

Test No.	Prerequisites	Test Method	Observations	Pass/Fail	Date / Signature
Baseline after test					

Site Acceptance Test (SAT) Test Plan for UV Booth		
Document No: ST.BA.TP.601510	Version Number: 01	

Test No.	Prerequisites	Test Method	Observations	Pass/Fail	Date / Signature
C	Measuring equipment that are used for measuring dosage and ozone level must be in a calibrated state.	Document calibration performed after test.	<p><u>The measuring equipment has been verified.</u></p> <p>Yes [<input type="checkbox"/>]</p> <p>No [<input type="checkbox"/>]</p> <p><u>Verification Reference:</u></p> <p>Dosage: _____</p> <p>Ozone: _____</p> <p><u>The equipment has drifted out side tolerance</u></p> <p>Yes [<input type="checkbox"/>]</p> <p>No [<input type="checkbox"/>]</p>		<i>By 2 persons</i>

Site Acceptance Test (SAT) Test Plan for UV Booth		
Document No: ST.BA.TP.601510	Version Number: 01	

Test No.	Prerequisites	Test Method	Observations	Pass/Fail	Date / Signature
D	Baseline after the test	Identify and reference <ol style="list-style-type: none"> 1. Firmware version number of UV booth before start of test 2. Design Documentation, file- and version number 	<p>Firmware version numbers</p> <p><u>UV Light Sources:</u> SAT (end) same version as SAT (start): Yes [] No []</p> <p><u>Start & Stop Motion Sensors:</u> SAT (end) same version as SAT (start): Yes [] No []</p> <p><u>Operator Signal Light:</u> SAT (end) same version as SAT (start): Yes [] No []</p> <p><u>Countdown-bar:</u> SAT (end) same version as SAT (start): Yes [] No []</p> <p><u>Display (in control box):</u> SAT (end) same version as SAT (start): Yes [] No []</p> <p>Design Documentation:</p> <p>_____</p>		<i>By 2 persons</i>

Site Acceptance Test (SAT) Test Plan for UV Booth		
Document No: ST.BA.TP.601510	Version Number: 01	

Appendix 1: Measurement protocol for UV dose in UV booth

Equipment:

- UIT2400 optical power-meter. Calibrated (NIST traceable) to 222 nm. With this power-meter the irradiance is measured directly. The power-meter is “Solar Blind” and hence does not pick up light from ceiling lights or other sources outside of the far UV.
- Measurement tape

Procedure:

- Measurements are taken at the following positions: the forehead, the wrists, middle of the chest and the stomach.
- These positions translate to the coordinates in below table (from the ground in the center of the UV Booth). These coordinates are based on a standard person.
- The maximum dosage is also determined 10 cm away from a UV light source for a complete cycle.

-	Height [cm]	Width [cm]	Depth [cm]
Forehead	185	0	+15
Wrists	170	±50	+10
Chest	160	0	+15
Stomach	125	0	+15
Maximum dosage	Center of a UV light source	NA	10 cm away from a UV light source

Site Acceptance Test (SAT) Test Plan for UV Booth		
Document No: ST.BA.TP.601510	Version Number: 01	

Appendix 1: Observations

Location of measurement	Dosage - Test 1 $\left[\frac{mJ}{cm^2} \right]$	Dosage - Test 2 $\left[\frac{mJ}{cm^2} \right]$	Dosage - Test 3 $\left[\frac{mJ}{cm^2} \right]$	Date / Signature
Forehead Height: 185 cm, Width: 0 cm, Depth: 15 cm				By 2 persons
Wrist (right) Height: 170 cm, Width: ±50 cm, Depth: 10 cm				By 2 persons
Wrist (left) Height: 170 cm, Width: ±50 cm, Depth: 10 cm				By 2 persons
Chest Height: 160 cm, Width: 0 cm, Depth: ±15 cm				By 2 persons
Stomach Height: 125 cm, Width: 0 cm, Depth: ±15 cm				By 2 persons
Maximum Dosage 10 cm away from a UV light source				By 2 persons
Duration of Cycle				

Site Acceptance Test (SAT) Test Plan for UV Booth		
Document No: ST.BA.TP.601510	Version Number: 01	

Appendix 2: State of the Cycle

Procedure:

All states of a cycle must be observed. For any state, the visuals (countdown bar), audible and the LED lights must be observed. The test is a three-part test. The tester must note down all observations in 'Appendix 1: Observations'.

1. The regular cycle
The tester must observe idle state. Thereafter the tester must enter the booth, start the cycle, stand in the UV booth until the cycle is complete, and finally exit the booth. All observations must be noted down
2. The interrupted cycle
The tester must enter the booth, initiate a cycle and shortly after interrupt the cycle (stopping the cycle manually) and observe the booth
3. A malfunction on the UV booth
 - 3a) The start sensor must be detached, and the tester must observe the UV booth
 - 3b) The stop sensor must be detached, and the tester must observe the UV booth

Acceptance Criteria

State of the Cycle	Acceptance Criteria
Idle state when operator enters UV222 Booth:	Light turned off when not in use .
Operator starts cycle:	Two short beeps along with all pixels flashing purple twice.
During cycle:	Every second, several pixels will turn off accompanied by a short beep, which gives the operator both visual and audio indication of how much time is left for the cycle to finish.
Completed cycle:	A long beep while all pixel's flash green.
Interruption of cycle:	If the operator stops cycle using the STOP sensor module before the cycle is completed, there will be multiple short beeps while all pixels will flash red.
Malfunction on the UV222 Booth:	All pixels flash deep yellow and multiple short beeps will be heard.

Appendix 2: Observations

Site Acceptance Test (SAT) Test Plan for UV Booth		
Document No: ST.BA.TP.601510	Version Number: 01	

State of the Cycle	LED light [On/Off]:	Countdown bar - according to acceptance criteria [Yes/No]	Audible cues - according to acceptance criteria [Yes/No]	Comment (if any, otherwise N/A)	Date / Signature
Idle State					By 2 persons
Starting the Cycle					By 2 persons
During the Cycle					By 2 persons
Completed Cycle					By 2 persons
Interruption of Cycle					By 2 persons
Malfunction of Cycle					By 2 persons

Appendix 2

Manuals UV222 Booth

Solution 1

UV222 Booth™

(Filtered Far UV-C)

User manual



Table of Contents

1. Using this manual - General	3
2. Before decontamination.....	3
3. The display.....	4
4. Decontamination	6
5. Stop and blockage	7
6. Cleaning	8

1. Using this manual - General

This manual (“Manual”) is intended as reference for authorised users to be able to safely use the UV222 Booth (“Product”) from UV Medico (“Supplier”).

The observation of the Manual does not dispense the user from the observance of the local safety instructions and regulations other than provided by the Manual. Such safety instructions and regulations must be observed at all times.

For information about adjustments and maintenance not mentioned on this Manual, please contact the Supplier.

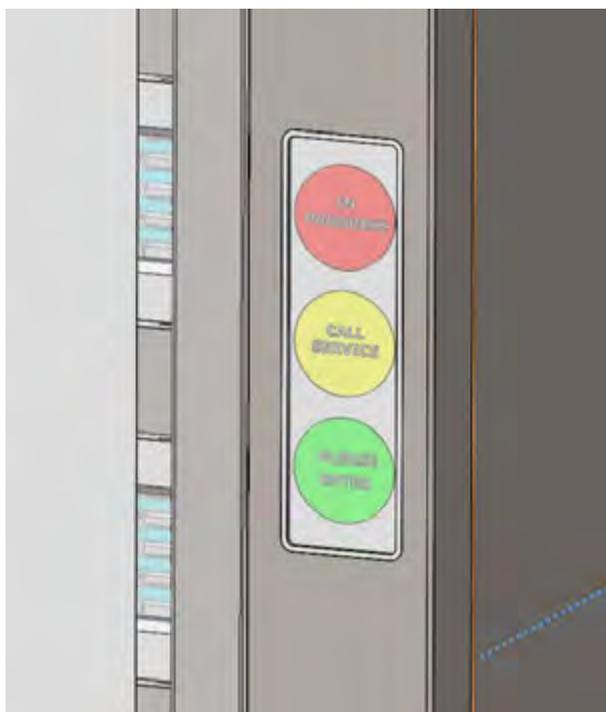
If you suspect that the Product is damaged or detect a potential or actual danger when using the Product, immediately discontinue use of the Product and contact the Supplier.

2. Before decontamination

Personal protective equipment (PPE) must be used by the operator inside the active Product. PPE shall consist of full cleanroom gown covering the skin as well as goggles that comply with EN270 / EN166 3 S.

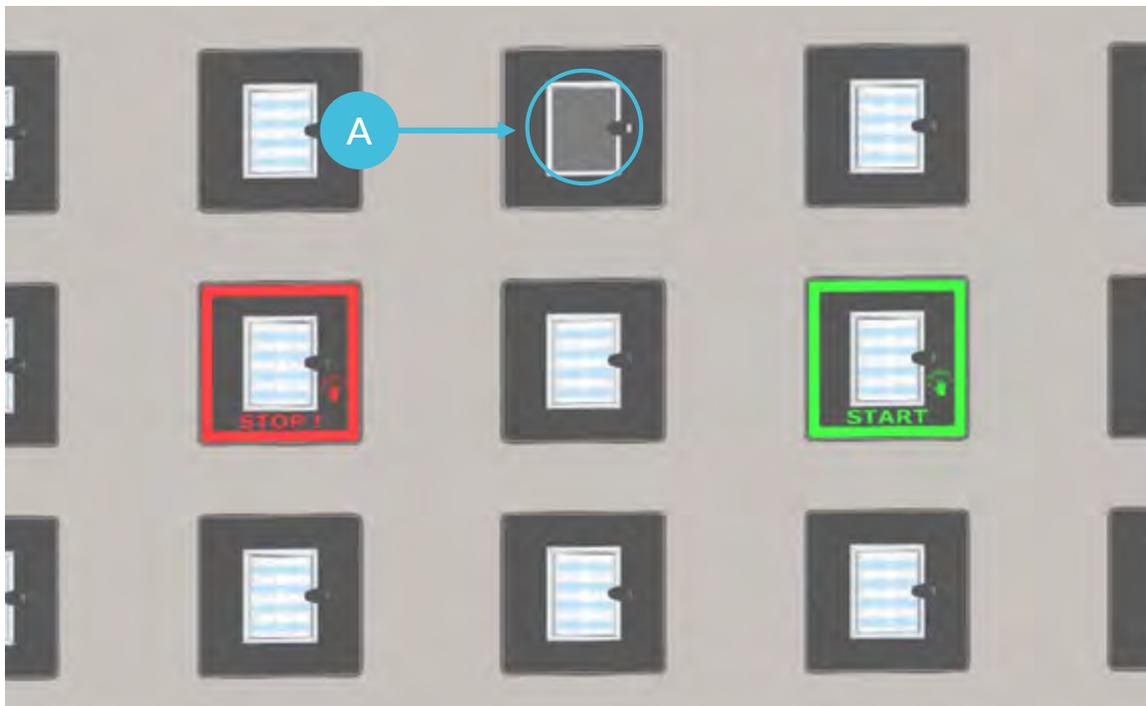
On the outside of the booth, there is a traffic light display:

- In progress (red): The booth is occupied.
- Call service (yellow): There is an error on the booth. Contact the Supplier for service.
- Please enter (green): The booth is free and ready for use.



3. The display

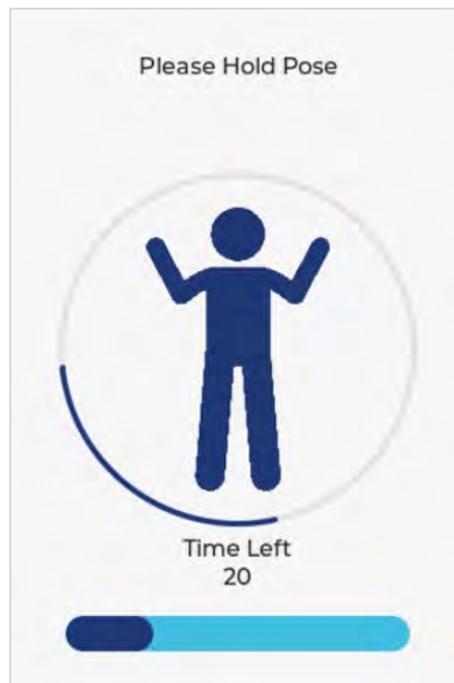
Inside the booth, there is a display module that serves as visual aid during use, as well as to assist identifying different errors: **A**



The below images show all possible screens during correct functioning:



Before decontamination



During decontamination



After decontamination



Doors are open

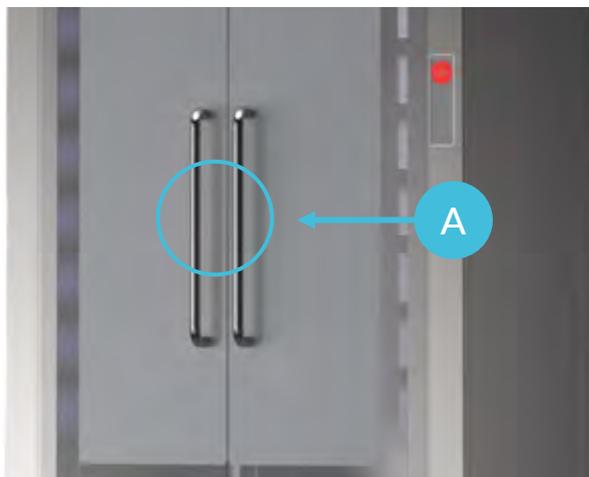
Finally, in case of failure, a fifth screen will show the message **ERROR** with one of the below messages briefly describing the issue:

- Missing module
- Decontamination not done

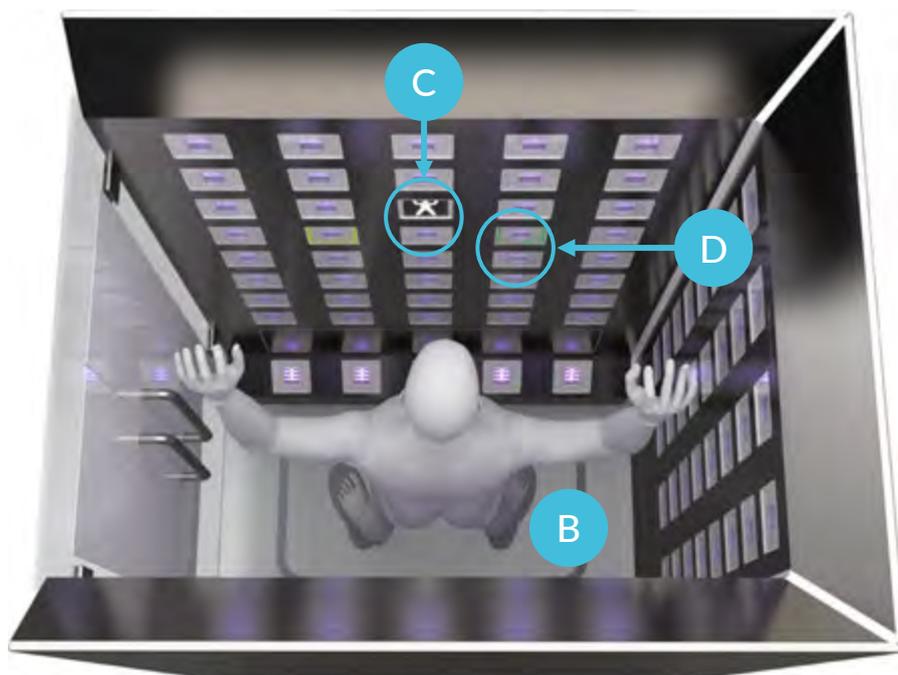
In case any of the above appears on the display, please refer to the **Service Manual**.

4. Decontamination

1. Use the handles to pull the doors to enter. **A**



2. When going in, enter sideways, without touching any surfaces.
3. Close the doors using the handles.
4. Place your feet on the markings on the floor **B** (if available).
5. Adopt the position displayed on the screen in front of you **C**, and once ready, hover a hand over the light source framed in green with the word **START**. Do not touch the surface. **D**
6. Two short beeps will indicate the beginning of decontamination. Adopt final pose.

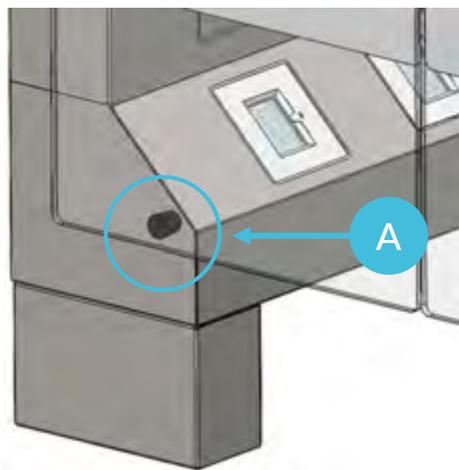


7. Wait 30 seconds. During decontamination, there will be an audible signal every second, and the Far UV-C light sources will light up in pale violet.
8. A long beep will indicate the end of decontamination.
9. Exit the booth by using the handles.

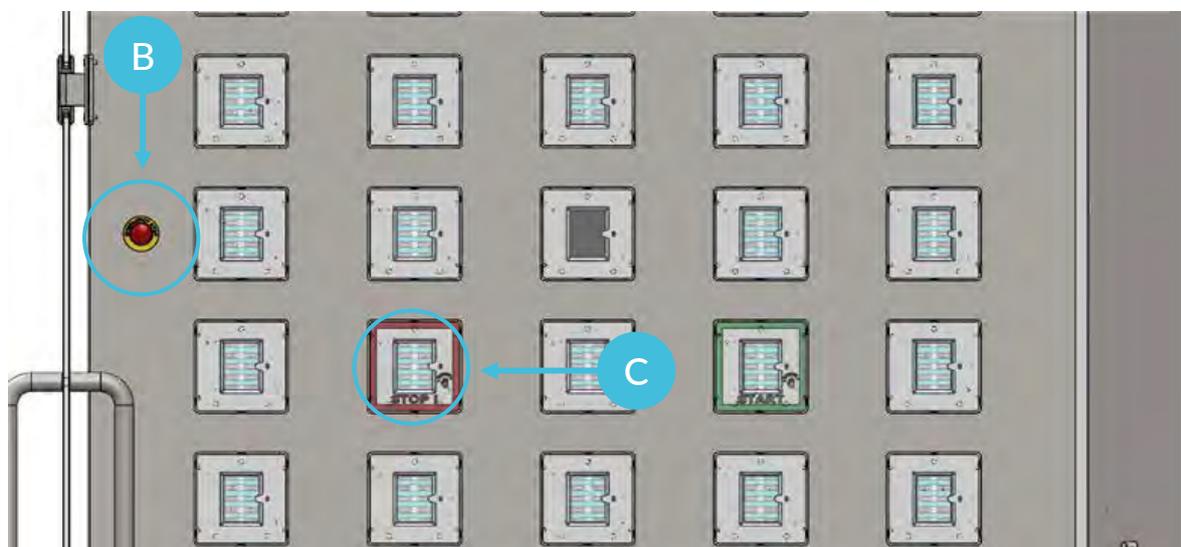
5. Stop and blockage

The UV Booth has three different stop systems. When activated, all Far UV-C light sources will turn off and the decontamination cycle will be cancelled.

- Doors: Magnetic sensors on the doors will interrupt decontamination if the doors are opened. **A**



- Emergency stop button. **B**
- Stop sensor: Hover your hand over the module framed in red with the word **STOP**. **C**



6. Cleaning

Keep the doors open while cleaning. A magnetic sensor on the door will prevent the booth from functioning while open.

If the doors need to be closed while cleaning, use the emergency stop button if the lights turn on.

UV222 Booth and its logo are registered trademarks of UV Medico A/S. All rights reserved. No part of this manual may be copied or published by means of printing, photocopying, microfilm or otherwise without the prior written consent of the manufacturer. This restriction also applies to the corresponding drawings.

The information given in this manual has been collected for the general convenience of our customers. It has been based on general data pertaining to construction material properties and working methods known to us at the time of issue of the manual and is therefore subject at any time to change or amendment, and the right to change or amend is hereby expressly reserved. The instructions in this manual only serve as a guideline for installation, use, maintenance, and repair of the Product mentioned on the cover page of this document. This manual is to be used for the standard model of the Product of the type given on the cover page. Thus, the manufacturer cannot be held responsible for any damage resulting from the application of this manual to any other product.

This manual has been written with great care. However, the manufacturer cannot be held responsible, either for any errors occurring in this manual or their consequences.

Appendix 3

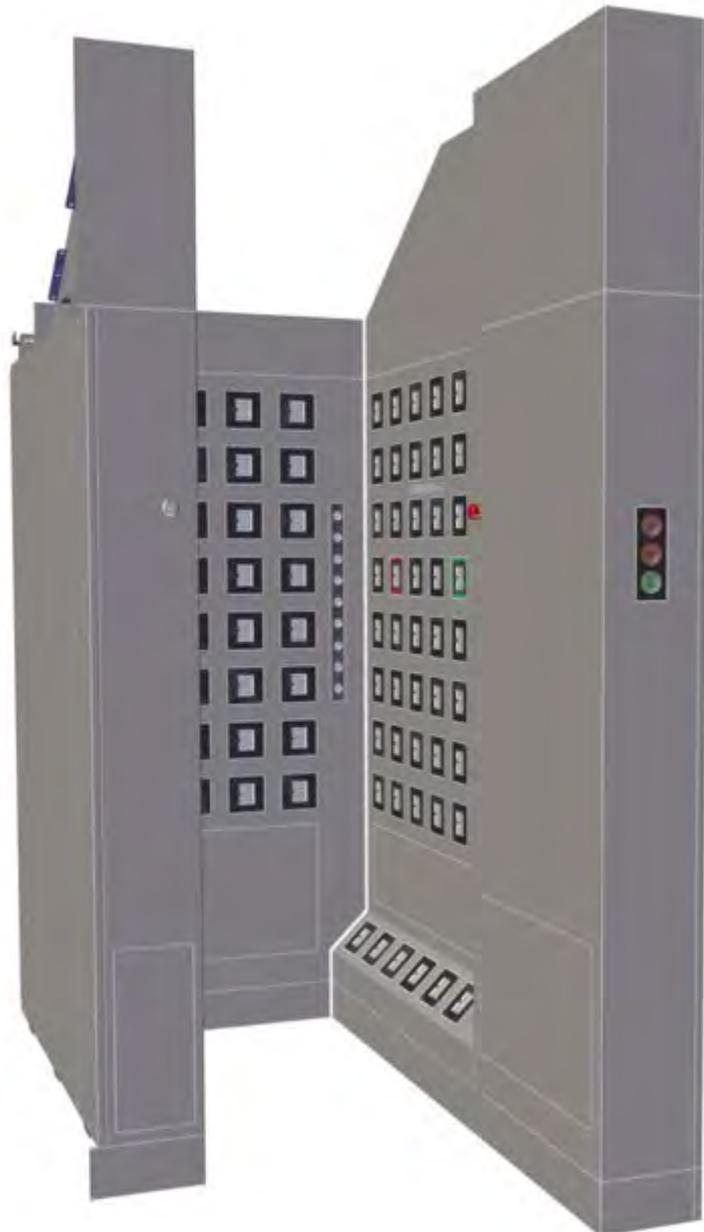
Manuals UV222 Booth

Solution 2

UV222 Booth™

(Filtered Far UV-C)

Operation manual



Operation manual – UV222 Booth, 60151000		
Document No.: OM.BA.601510.	Rev. 01	

Table of Contents

1. Using this manual - General	2
2. Operator training.....	3
3. Before decontamination.....	3
4. The countdown bar with audio.....	4
5. Decontamination	5
6. Stop and blockage.....	6
7. Cleaning	7

1. Using this manual - General

This manual (“Manual”) is intended as reference for authorised users to be able to safely use the UV222 Booth (“Product”) from UV Medico (“Supplier”).

The observation of the Manual does not dispense the user from the observance of the local safety instructions and regulations other than provided by the Manual. Such safety instructions and regulations must be observed at all times.

For information about adjustments and maintenance not mentioned on this Manual, please contact the Supplier.

If you suspect that the Product is damaged or detect a potential or actual danger when using the Product, immediately discontinue use of the Product and contact the Supplier.

Operation manual – UV222 Booth, 60151000



Document No.: OM.BA.601510.

Rev. 01

2. Operator training

Operators using the Product must be trained and be familiar with this manual. They must always ensure their PPE is placed correctly before entering the Product. They must be trained to be extra careful concerning skin exposure. When they verify their gowning before entering the Product, it is essential that they verify there are not any openings exposing the skin or eyes to the Far UV-C light. Note that more than two cycles of disinfection will be needed to exceed the limits of exposure (23 mJ/cm²) in the areas of the body with the highest irradiation.

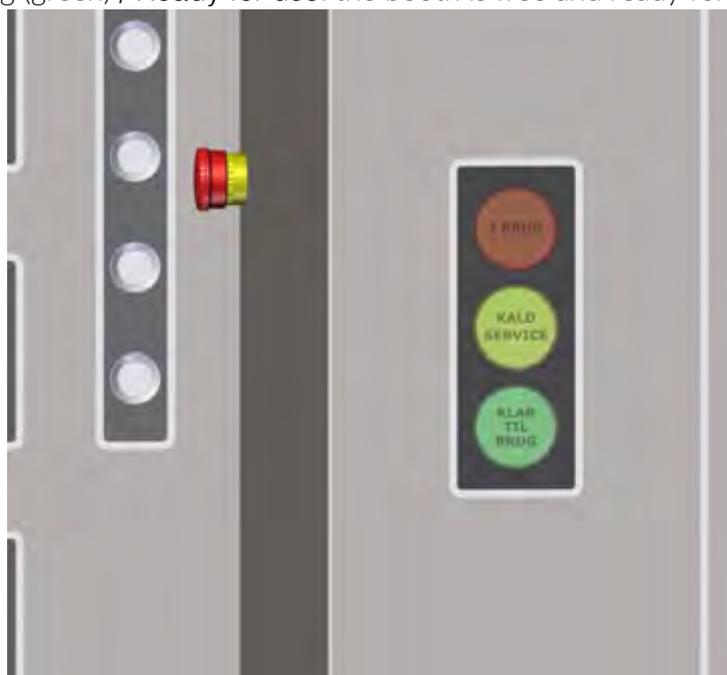
The Product must be powered off from the control box if untrained personnel must access the surroundings of the Product. In the circumstances that the Product cannot be turned off, untrained personnel must be accompanied by trained staff. Warning stickers are not allowed on the surface of the Product due to cleanroom classification requirements, therefore, it is strongly advised to add a visual warning stating "Far UV-C light. Entry of only trained personnel properly gownned" before entering the Product room.

3. Before decontamination

Personal protective equipment (PPE) must be used by the operator inside the active Product. PPE shall consist of full cleanroom gown covering the skin as well as goggles that comply with EN270 / EN166 3 S.

On the outside, on the right panel of the booth, there is a traffic light display:

- I brug / In use (red): the booth is occupied.
- Kald service / Call service (green): there is an error on the booth. Contact the Supplier for service.
- Klar til brug (green) / Ready for use: the booth is free and ready for use.



4. The countdown bar with audio

Inside the booth, there is a LED bar **A** with multiple pixel lights that serves as visual aid during use, as well as to signal malfunction on Start and Stop Sensor and Light source modules:



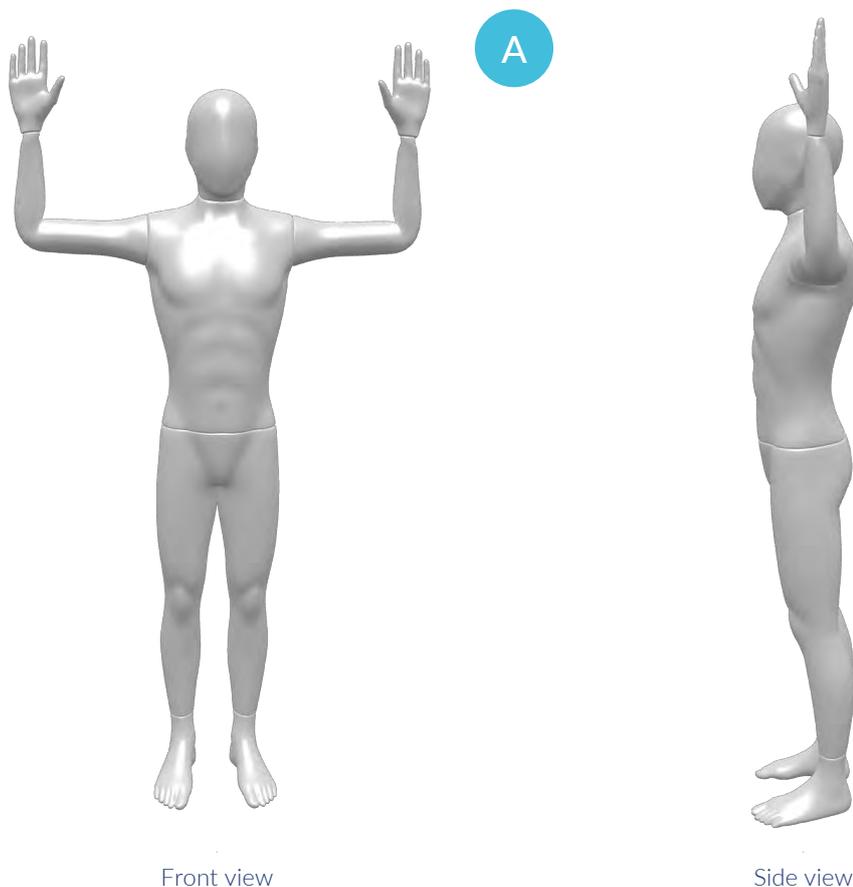
Below are all possible statuses during correct functioning:

- Idle: light turned off when not in use.
- Operator starts cycle: two short beeps followed by two purple flashes.
- During the cycle: every second, several pixels will turn off accompanied by a short beep.
- Cycle finished: a long beep followed by all pixels flashing green.
- Interruption of cycle: if the operator stops the cycle using the **STOP** sensor, there will be multiple short beeps and all pixels will flash red to indicate 30 second cycle is not completed.

Finally, in case of malfunction, the countdown bar will flash deep yellow and multiple short beeps will be heard. See the **Service Manual** for what to do in the case of malfunction.

5. Decontamination

1. Verify that the booth is available by looking at the traffic light display.
2. Enter without touching any of the Product's surfaces.
3. Adopt the position displayed below **A**, and once ready, keep your hand in front of the green module with the word **START** for 2 seconds at a distance of 5 cm.
4. Two short beeps followed by two purple flashes of the countdown bar will indicate the beginning of decontamination. Adopt pose **A**.

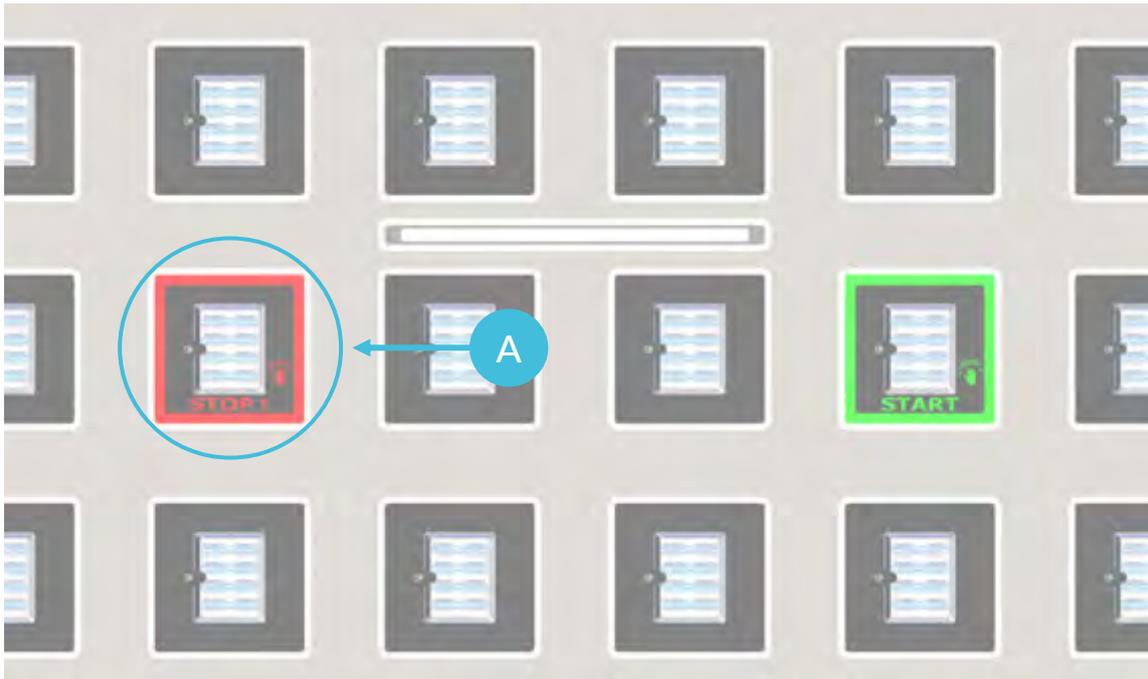


5. Wait 30 seconds. During decontamination, the Far UV-C light sources will light up in pale violet. There be an audible signal every second, and at the same time, several pixels will turn off on the countdown bar to mark the process.
6. A long beep and all pixels on the countdown bar will flash green to indicate the end of decontamination.
7. Exit the booth without touching any surfaces.

6. Stop and blockage

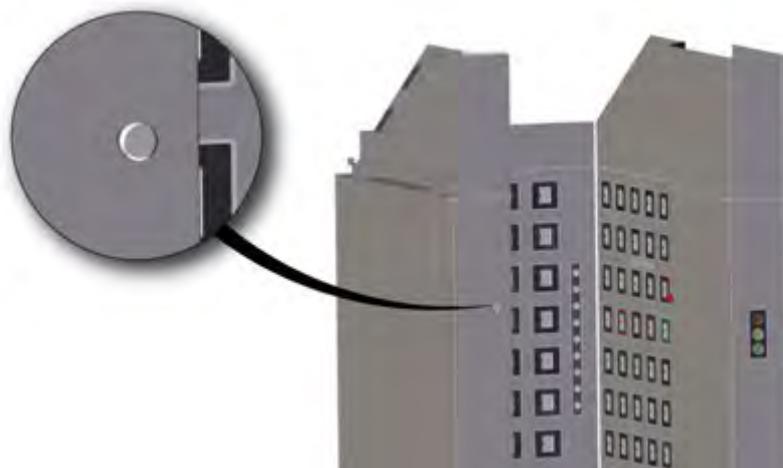
The Product has three different stop systems, but the room lights will be kept on allowing for better visibility.

- a) Stop sensor: keep your hand in front of the red module with the word **STOP** for 2 seconds at a distance of 5 cm. **A**



- b) Cleaning stop: a grey stop button on the left side of the booth can be pushed when cleaning is needed.

To reactivate the Product, turn the button clockwise. The booth will automatically power up and be ready for use within a few seconds.



Operation manual – UV222 Booth, 60151000

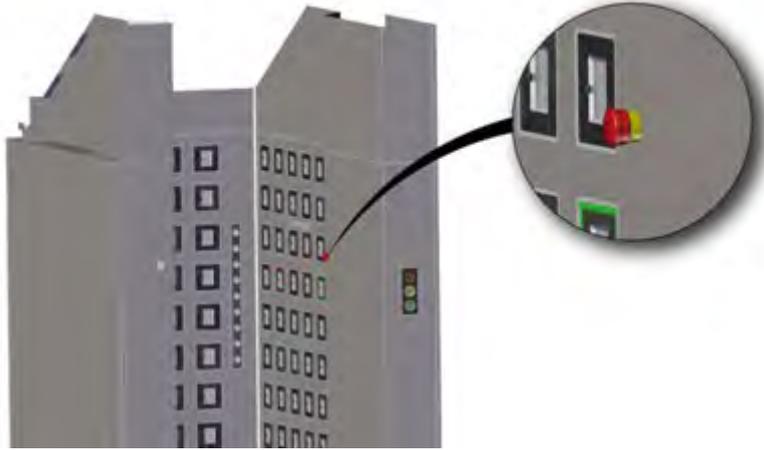


Document No.: OM.BA.601510.

Rev. 01

- c) Emergency stop button: in case of emergency, press the red stop button located inside the booth, on the right-side panel.

To reactivate the Product, turn the button clockwise. The booth will automatically power up and be ready for use within a few seconds.



7. Cleaning

Press the cleaning stop button for cleaning (see [5. Stop and blockage](#)). This will prevent the Product from working.

Operation manual – UV222 Booth, 60151000		
Document No.: OM.BA.601510.	Rev. 01	

UV222 Booth and its logo are registered trademarks of UV Medico A/S. All rights reserved. No part of this Manual may be copied or published by means of printing, photocopying, microfilm or otherwise without the prior written consent of the manufacturer. This restriction also applies to the corresponding drawings.

The information given in this Manual has been collected for the general convenience of our customers. It has been based on general data pertaining to construction material properties and working methods known to us at the time of issue of the Manual and is therefore subject at any time to change or amendment, and the right to change or amend is hereby expressly reserved. The instructions in this Manual only serve as a guideline for installation, use, maintenance, and repair of the Product mentioned on the cover page of this document. This Manual is to be used for the standard model of the Product of the type given on the cover page. Thus, the manufacturer cannot be held responsible for any damage resulting from the application of this Manual to any other product.

This Manual has been written with great care. However, the manufacturer cannot be held responsible, either for any errors occurring in this Manual or their consequences.



UV Medico A/S
Søren Frichs Vej 40E
8230 Åbyhøj
Denmark

+45 20 90 71 30

info@uvmedico.com
www.uvmedico.com

Appendix 4

CE Declaration of Conformity

EU Declaration of Conformity

Manufacturer	UV Medico A/S Søren Frichs Vej 40E, st 8230 Åbyhøj Denmark CVR: 42602582
Object of the declaration	Germicidal Compact Far UV light Type: UV222 Booth FAR UVC disinfection booth

The described product is in conformity with the relevant Union harmonisation legislations

ROHS Directive 2011/65/EU and amendments Directive of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

LVD 2014/35/EU Directive of the European Parliament and of the Council of 26 February 2014 on the harmonization of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits.

EMC Directive 2014/30/EU Directive of the European Parliament and of the Council of 26 February 2014 on the harmonization of the laws of the Member States relating to electromagnetic compatibility.

Directive 2006/42/EC DIRECTIVE 2006/42/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 17 May 2006 on machinery, and amending Directive 95/16/EC.

The conformity of the designated product with the provisions of European Directives is given by the compliance with the following European Standards or other specifications. It not elsewhere/otherwise indicated the edition/amendment as referenced below applies.

RoHS EN 50581 :2012
Technical documentation for the assessment of electrical and electronic product with respect to the restriction of hazardous substances

EMC EN 62233:2008
Measurement methods for electromagnetic fields of household appliances and similar apparatus about human exposure.
EN 61000-3-2: 2014
Electromagnetic compatibility (EMC) - Part 3-2: Limits - Limits for harmonic current emissions (equipment input current: 16 A per phase).

EN 61000-3-3: 2013

Electromagnetic compatibility (EMC) - Part 3-3: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low voltage supply systems, for equipment with rated current: 16 A per phase and not subjected to conditional connection.

EN 55014-1 :2017

Electromagnetic compatibility - Requirements for household appliances, electric tools, and similar apparatus - Part 1: Emission.

EN 55014-2:2015

Electromagnetic compatibility - Requirements for household appliances, electric tools, and similar apparatus - Part 2: Immunity - Product family standard.

List of additional Standards the product is compliant to:

ISO 15858

UV-C Devices – Safety information – Permissible human exposure.

*In agreement with article 5.3 of ISO 15858; personal protective equipment according to the product manual must be used by the operator inside the active UV Booth since instantaneous irradiance exceed the UVC exposure for unprotected skin and eyes.

This declaration conformity is used under the sole responsibility of the manufacturer UV Medico A/S.

Signature on behalf of UV Medico A/S, 17/08/2022, Aarhus, Denmark.



Anders Samuelson
CEO



Peter Johansen
Chairman