PDA Parenteral Drug Association

Midwest Chapter

Microbial Contamination and Control Conference

May 13th & 14th

Autonomous UV-C Robot Disinfection in Cleanrooms: Application & Qualification Case Study

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Agenda

- The Challenge: Effective Contamination Control
- Robotics in Pharma
- Ultraviolet Germicidal Irradiation
- UV-C Autonomous Robot: Background, Benefits, Use-Cases
- Qualification Case Study
- Overall Qualification Process
- Take Aways

The Challenge

The Challenge: Effective Contamination Control

Contamination Control Strategy (CCS):

A documented, risk-based strategy that defines the overall approach to identify, assess, control, and continuously review risks of microbial, endotoxin/pyrogen, and particulate contamination

"A CCS should be implemented across the facility in order to define all critical control points and assess the effectiveness of all the controls (design, procedural, technical and organisational) and monitoring measures employed to manage risks to medicinal product quality and safety. The combined strategy of the CCS should establish robust assurance of contamination prevention."

– Annex 1 Manufacture of Sterile Medicinal Products

The Challenge: Contamination Control

PDA Technical Report No. 90: Contamination Control Strategy Development in Pharmaceutical Manufacturing (2023)

Personnel: Our Greatest Asset…and our Greatest Risk

- **Properly trained personnel are the foundation of pharmaceutical manufacturing quality & contamination control, however:**
  - Despite training, humans remain a primary source of contamination
  - Humans continuously shed microorganism (“mobile contamination sources”)
  - Human error: deviations from procedures, poor aseptic technique or behavior, etc
  - A robust CCS must therefore assume human fallibility and compensate through facility design, **automation (where feasible)**, procedural controls, and effective monitoring

Robotics in Pharma

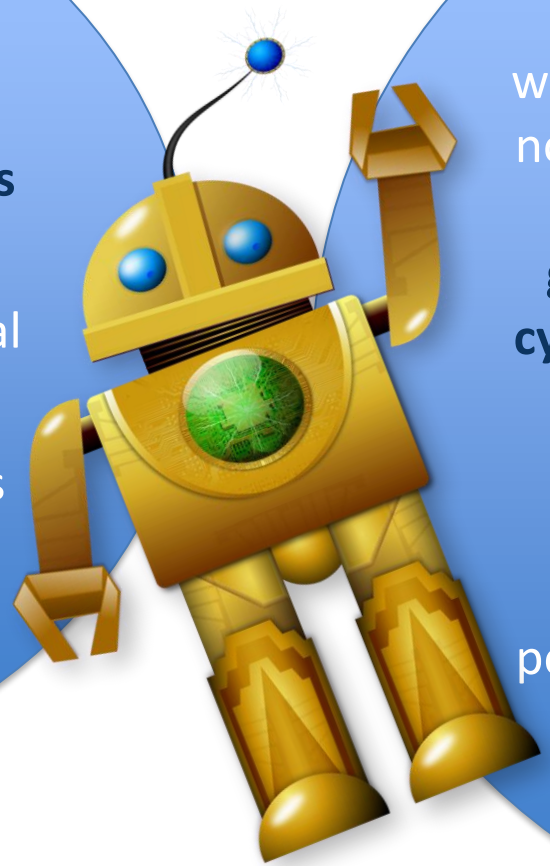
Regulatory Position on Automation & Robotics

FDA Guidance for Industry – cGMP (2014): Automation of other process steps, **including the use of technologies such as robotics**, can further reduce risk to the product.

EU GMP Annex 1:(2022): The use of appropriate technologies (e.g. […] **robotic systems**) should be considered to increase the protection of the product from potential extraneous sources of endotoxin/pyrogen, particulate and microbial contamination such as personnel…
[…] Robotics and automation of processes can also be considered to eliminate direct human critical interventions

Industry Position on Automation & Robotics

ISPE GPG Pharma 4.0:
Robotics directly support Pharma 4.0's goal of **minimizing manual operations** where human presence a contamination risk.
Robots natively generate digital records, supporting Pharma 4.0's **data-centric** model.
Automated execution reduces ALCOA+ risks associated with **manual documentation.**



PDA Letter 2023[1]: By having a robot performing a given operation, whether in an aseptic environment or not, one can assume that the robot is going to **repetitively execute the given instructions exactly in every cycle**. (…) we can say that the robot is the perfect solution for having the **certainty of having a selected standard operating procedure respected in every step**, with the possibility of **fully automatic tracking of operations performed** directly stored in the batch record.

[1]PDA Letter Robotics and Automation in Pharmaceutical Production: A paradigm shift led by EU GMP Annex 1, Andrea Tanzini (2023)

The Pharmaceutical Manufacturing Robot Landscape

Industrial Robotic Arms

Aseptic Processing, Filling & Packaging

Collaborative Robots (Cobots)

Flexible Small-Batch Operations

Autonomous Mobile Robots (AMRs & AGVs)

Material Transport & Logistics

Cleanroom-Specific Robots

Sterile & Isolator Environments

UV-C Disinfection Robots

Automated Bioburden Reduction

Inspection & QC Robots

High-Speed Visual Inspection

Inspection & QC Robo

High-Speed Visual Inspection

AI Alert

Laboratory & API Robots

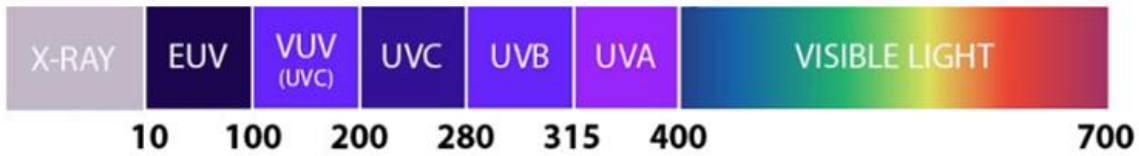
R&D & Analytical Automation

Human Intervention ↓ | Sterility Assurance ↑ | Data Integrity ↑ | Contamination Control ↑

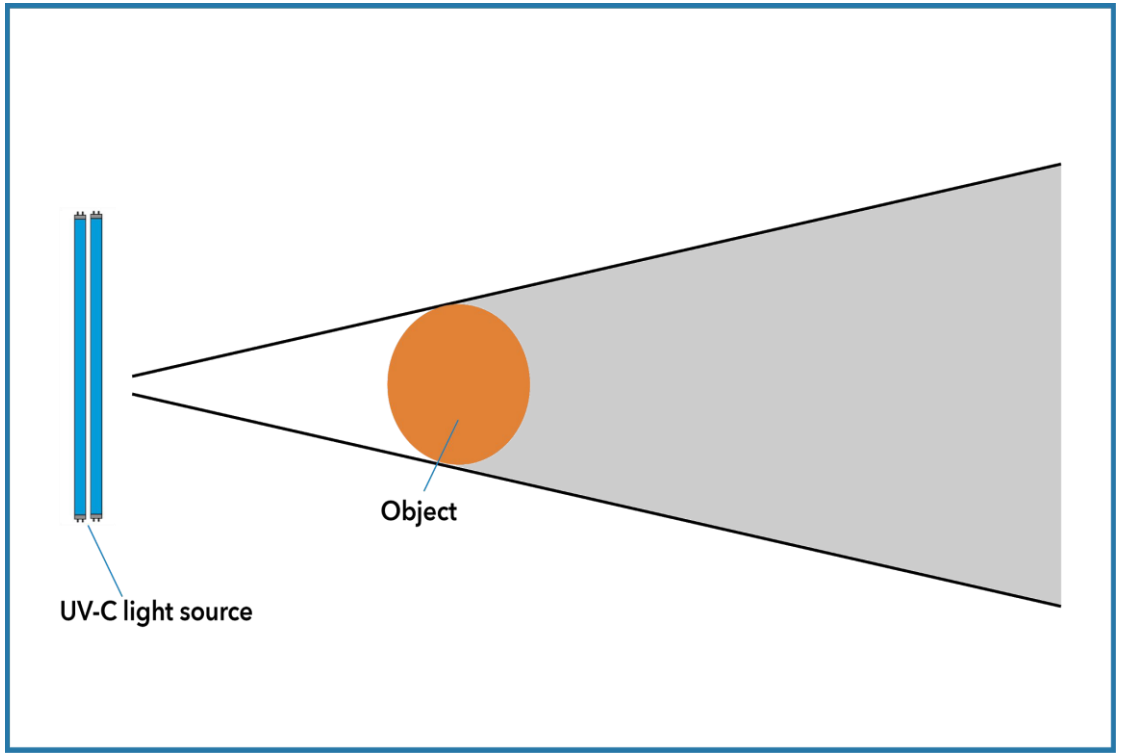
Ultraviolet Germicidal Irradiation (UVGI)

Ultraviolet Germicidal Irradiation (UVGI)

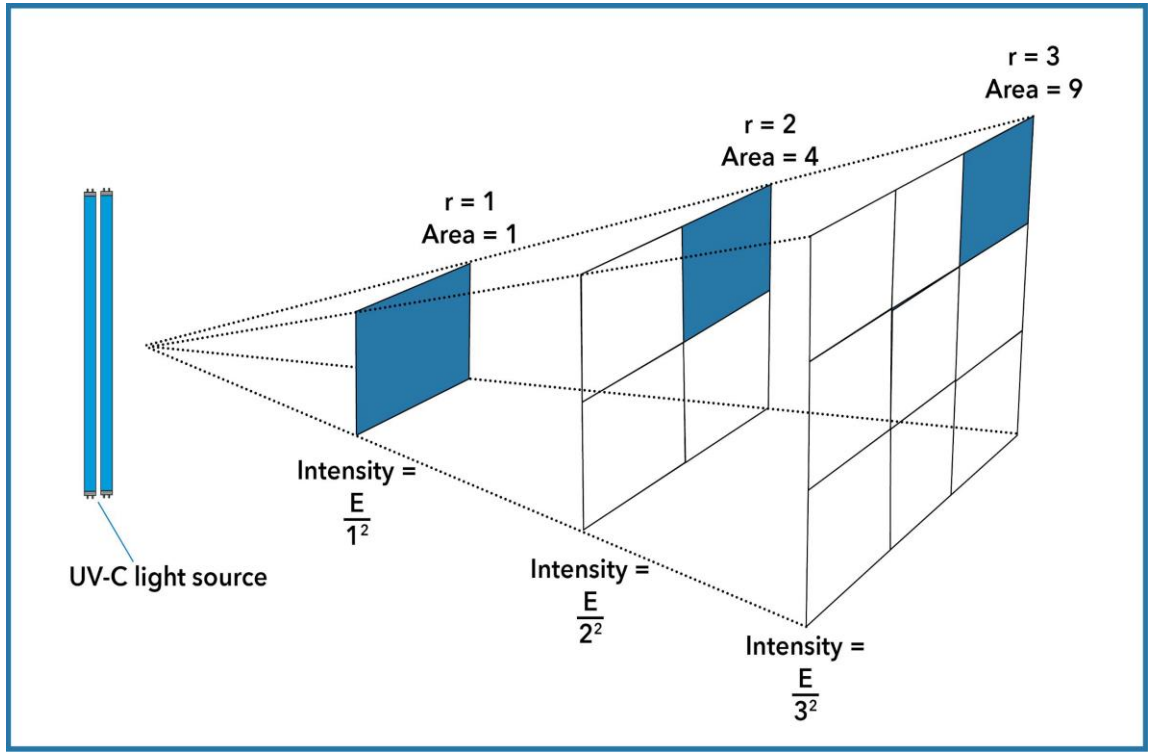
- UV-C light is a short-wavelength band of ultraviolet radiation, typically between 200 - 280 nm, with high photon energy
- UV kills cells because of the accumulation of DNA / RNA damage. If the damage is too extensive, a protein directs the **cell to apoptosis, or programmed cell death**
- Peak germicidal wavelength **~260 nm.** Mercury vapor lamps emit **~90-95% of energy at 253.7 nm,** optimizing germicidal effectiveness



Ultraviolet Germicidal Irradiation (UVGI)



Light travels in a straight line - causing shadowing

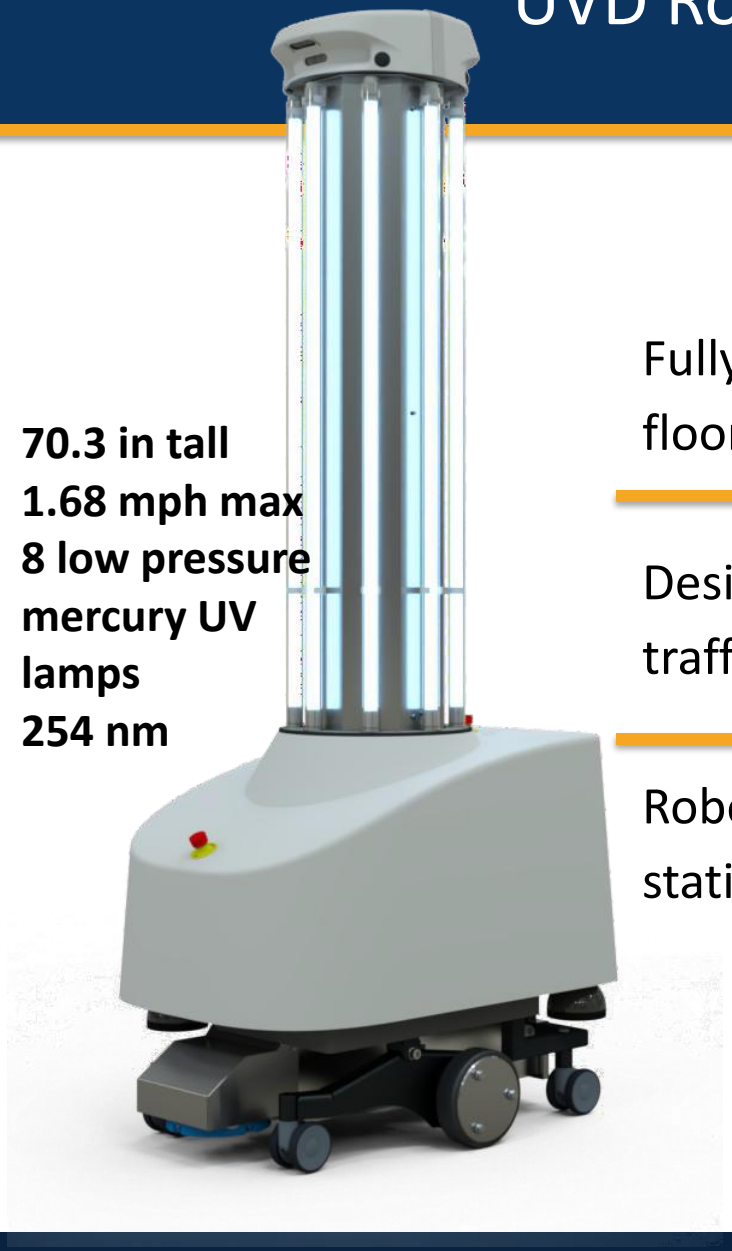


Inverse Square Law and distance from light source

UV-C autonomous robot motility overcomes shadowing and reduced intensity due to distance

UVD Robot Pharma Background

UVD Robot Pharma – Blue Ocean Robotics



- **70.3 in tall**
- **1.68 mph max**
- **8 low pressure mercury UV lamps**
- **254 nm**

Fully self-driving UV-C solution for whole room disinfection of cleanrooms – floor to ceiling

Designed to effectively and efficiently disinfect high-touch surfaces and high-traffic areas, reducing environmental bioburden

Robot mobility overcomes shadowing issues that are a major limitation of stationary UV-C systems

UVD Robot Pharma – Safety

3 x3D Cameras

2 front and 1 rear-facing for detecting and avoiding objects in the vicinity

2 Emergency stop buttons

Stops disinfection immediately

Audio warnings

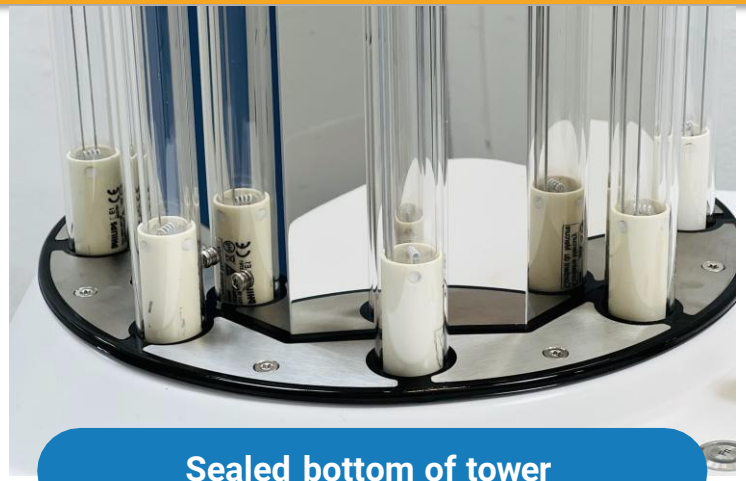
Informs on safety information

2 Lidar, safety laser scanners

1 front-facing and 1 rear-facing for walk and obstacle detection

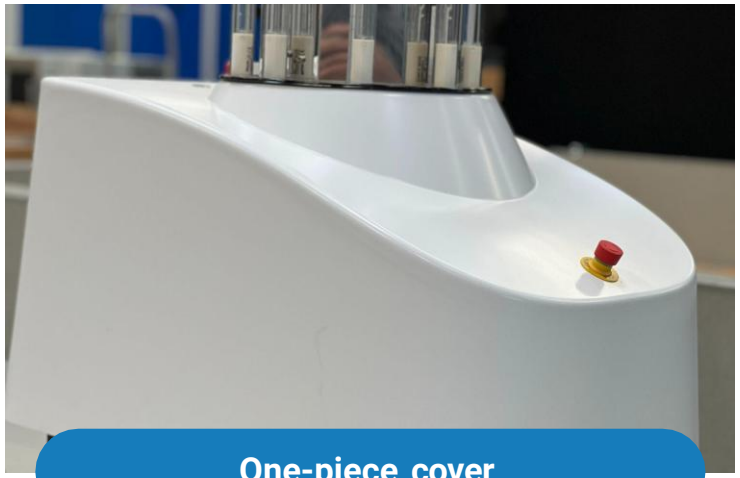
GMP Compliant Materials and Construction

Cameras



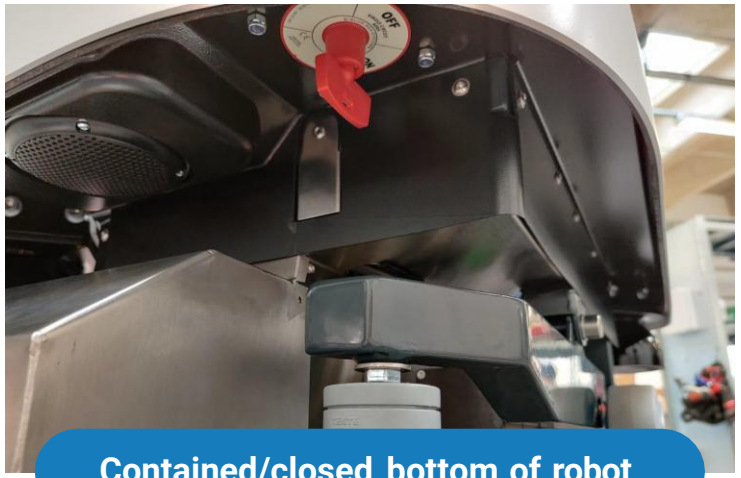
Sealed bottom of tower

Sealed construction



One-piece cover

Stainless steel components



Contained/closed bottom of robot

Benefits of Autonomous UV-C Robots for Cleanroom Disinfection

Chemical-Free

- Dry process: reduce water & chemical disinfectant use
- No consumables
- Less residues
- Less material damage
- Helps meet sustainability goals

Efficiency

- Quicker disinfection than manual (50-90% reduction in time)
- Automatic generation of documentation

Quality

- Effective disinfection
- Repeatable & validated process
- Elimination of human error
- Frequent whole-room disinfection, reducing environmental bioburden
- Dosimeters verify target dose is achieved

Compliance

- Traceability via 21 CFR Part 11 compliance (logs, audit trail, reports)

Typical Pharma Use-Cases

1 Part chemical replacement

Objective: Faster C&D & higher production output

- High-speed disinfection for high-value manufacturing - boost efficiency with automation

2 Add-on large areas

Objective: Risk mitigation & business continuity

- Automated, repeatable disinfection - minimizing risk & ensuring compliance confidence

Real-World Applications in Industry

- **European Fill-Finish Facility, Grade B Suite**
  - Using UV as primary daily disinfection
  - Risk Based supplemental disinfection is required, i.e. for shadowed areas
  - Target dose 100 mJ/cm^2 to focus on vegetative bacteria
  - Manual chemical disinfection reduced 60%-80% (~6 hrs to 1 hr)
  - Reduced sporicidal disinfection frequency from weekly to monthly
- **European Drug Substance Facility, Grade D Corridors**
  - Daily supplemental disinfection
  - Reduced EM excursions by 50%
- **US Fill-Finish CMO, Grades B – D (implementation in progress)**
  - Aim to use UV daily as primary mode of disinfection
  - Supplemented by manual disinfection as needed
  - Reduce the frequency of sporicidal disinfection based on daily whole-room daily disinfection

Robot in Action

UV Robot in Action - Video

Qualification Case Study

Qualification Case Study

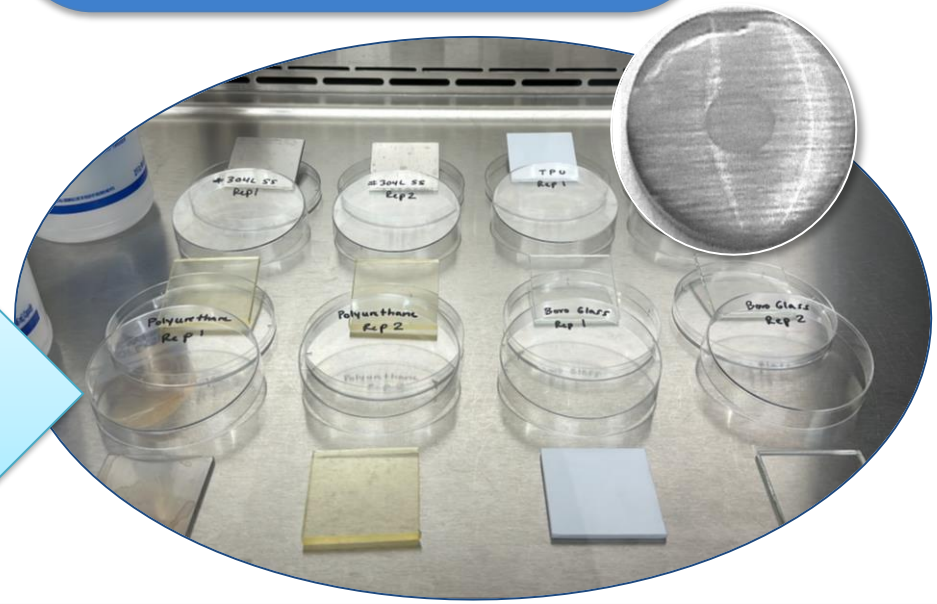
Disinfectant Efficacy Testing Expectations

ANNEX 1 – Section 4.34

The disinfection process should be validated. Validation studies should demonstrate the suitability and effectiveness of disinfectants in the specific manner in which they are used and on the type of surface material, or representative material if justified, and should support the in-use expiry periods of prepared solutions

Standards:
USP <1072>
ASTM E2197
EN 1276, EN 1650, EN 13697, EN 13704, EN 16615

Efficacy testing is required for any modality of disinfection



Qualification Case Study

- Evaluated the efficacy of a UV-C disinfection robot intended for use on various cleanroom surfaces in the company's manufacturing facilities against a panel of compendial and environmental microorganisms
- Based on USP <1072> and Surface Challenge Test Method (EN 13697)
- Microorganisms were inoculated onto coupons made of glass, stainless steel, and vinyl
- Coupons were exposed to UV at multiple dose-levels (mJ/cm^2) and LRV was calculated

Test Set-Up

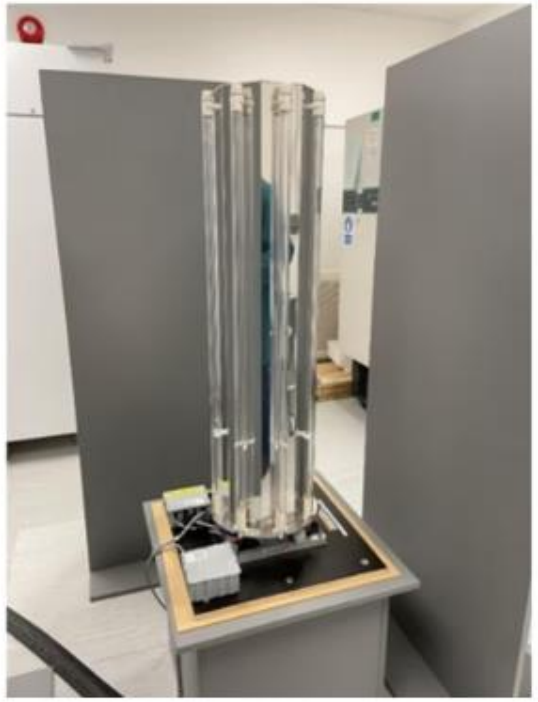


Figure 1a. UVC Tower set up in the laboratory. The boards in the room were to attach the coupons two metres distance from the light Figure 1b. The black cloth was used to protect the control coupons from the light.

Figure 4. Coupons of vinyl, glass and steel with Aspergillus brasiliensis spores inoculated. The UVKEY and ILT2400 dose meter are in place and set to zero prior to start.

UV Doses Tested (mJ/cm^2)

Vegetative Organisms	Bacterial Spores	Mold Spores
0	0	0
5	20	20
10	40	40
15	60	80
20	80	100
25	100	200
50	200	500
100		700

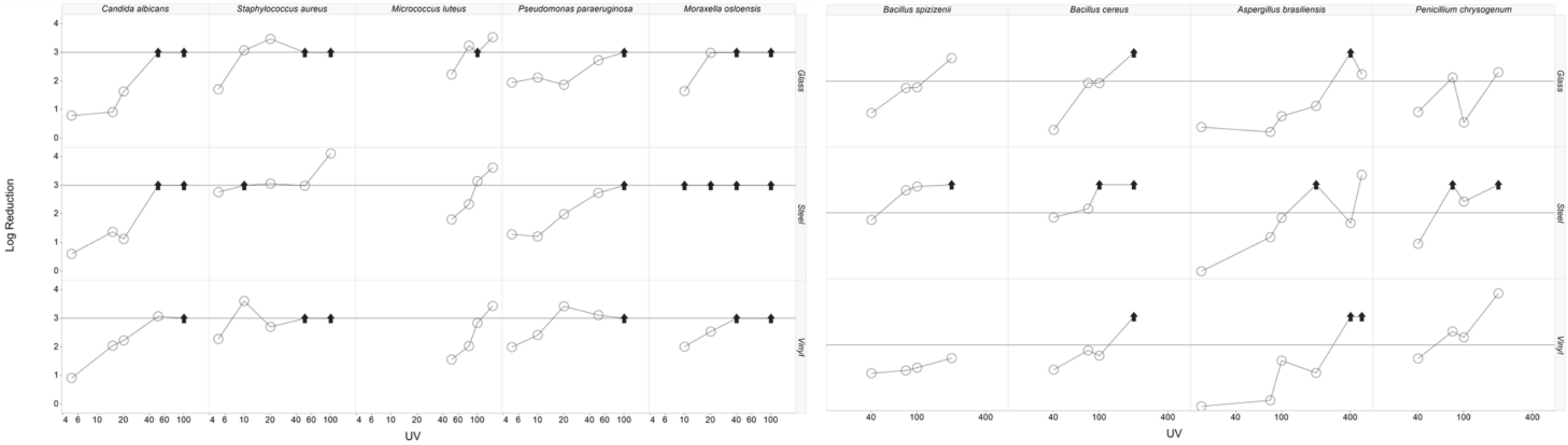
Dose Needed for Required LRV Across All Surfaces

Organism	Type	Target Log Reduction	Dose mJ/cm^2
Aspergillus brasiliensis	Fungal spores	2-log	500
Bacillus subtilis (spizizenii)	Bacterial spores	2-log	>200
Penicillium chrysogenum (En.I.)	Fungal spores	2-log	200
Bacillus cereus (En.I.)	Bacterial spores	2-log	200
Micrococcus luteus (En.I.)	Gram + cocci	3-log	150
Staphylococcus aureus	Gram + cocci	3-log	100
Pseudomonas aeruginosa	Gram - rods	3-log	100
Candida albicans	Yeast	3-log	50
Moraxella osloensis (En.I.)	Gram - cocci	3-log	40

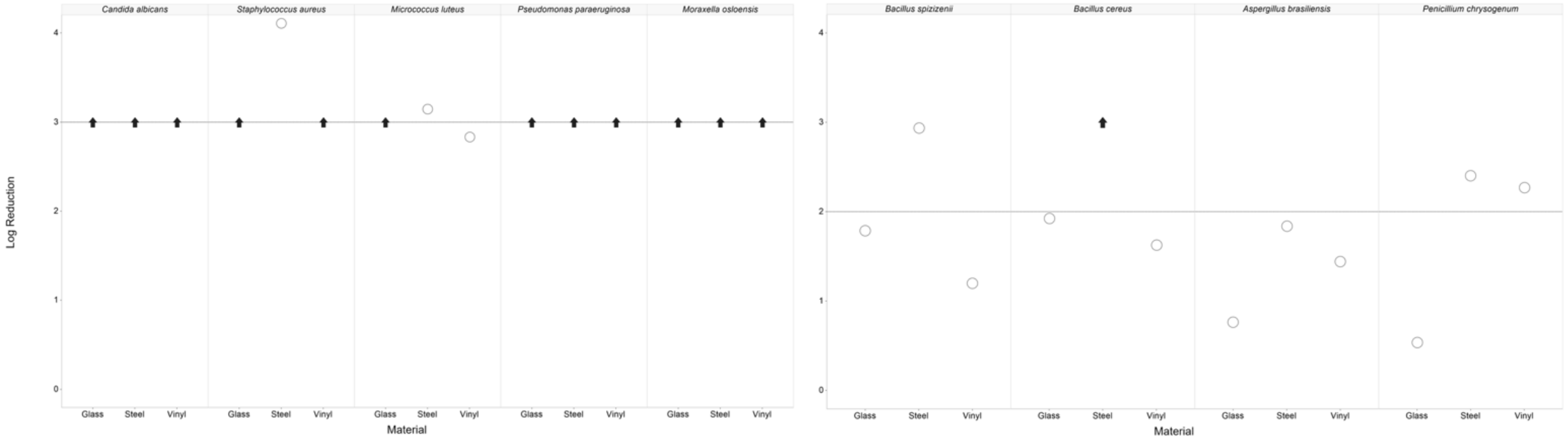
LRV Achieved at 100 mJ/cm^2

Organism	Type	Surface type (worst case)	Target Log Reduction	Log Reduction Achieved
Penicillium chrysogenum (En.I.)	Fungal spores	Glass	2-log	0.3 - 0.9
Aspergillus brasiliensis	Fungal spores	Glass	2-log	0.5 - >2.0
Bacillus subtilis (spizizenii)	Bacterial spores	Vinyl	2-log	1.1 - 1.3
Bacillus cereus (En.I.)	Bacterial spores	Vinyl	2-log	1.4 - >2.0
Micrococcus luteus (En.I.)	Gram + cocci	Vinyl	3-log	2.6 - >3.0
Candida albicans	Yeast	All	3-log	>3.0
Staphylococcus aureus	Gram + cocci	All	3-log	>3.0
Pseudomonas aeruginosa	Gram - rods	All	3-log	>3.0
Moraxella osloensis (En.I.)	Gram - cocci	All	3-log	>3.0

Death Curves



Surface Material Comparison



Exposure Times

Organisms	Dose for 2 or 3 LRV	UV-C Exposure Time (sec) at 1 m distance
Fungal Spores:		
• *Aspergillus brasiliensis*	500 mJ/cm^2	74 sec
• *Penicillium chrysogenum (En.I.)*	200 mJ/cm^2	185 sec
Bacterial Spores:		
• *Bacillus subtilis (spizizenii)*	200 mJ/cm^2	74 sec
• *Bacillus cereus (En.I.)*	200 mJ/cm^2	
Gram-Positive Bacteria:		
• *Micrococcus luteus (En.I.)*	150 mJ/cm^2	56 sec
• *Staphylococcus aureus*	100 mJ/cm^2	37 sec
Yeast		
• *Candida albicans*	50 mJ/cm^2	18 sec
Gram-Negative Bacteria:		
• *Pseudomonas aeruginosa*	100 mJ/cm^2	37 sec
• *Moraxella osloensis (En.I.)*	40 mJ/cm^2	15 sec

Qualification Case Study Conclusions

- **100 mJ/cm^2** was chosen for normal operation based on effective inactivation of vegetative bacteria and yeast
- **Higher doses (>200 mJ/cm^2)** are required for remediation of spore-forming organisms and a sporicidal cycle can be implemented in reaction environmental monitoring results
- **Material degradation determined to be minimal** (data not shown) and identified UV-sensitive materials will be replaced at defined frequencies
- **UV will be part of an overall cleaning and disinfection program, with periodic manual disinfection**

Overall Qualification Process

Overall Qualification Process

Equipment and Software Qualification

- C&Q Plan
- URS
- Quality Risk Assessment
- Design Qualification
- Factory Acceptance Testing
  - UV light intensity
- Installation and Operating Qualification
  - Cleanroom mapping
  - Configuration verification
  - Dosimeter (UV dose verification) test
- Disinfection cycle development per cleanroom
- Requalification
  - UV light intensity
  - Verification of room layouts

Disinfection Efficacy Testing

- Compendial organisms
- Site specific organisms
- Cleanroom materials
- Log reduction - USP <1072>

Site Implementation

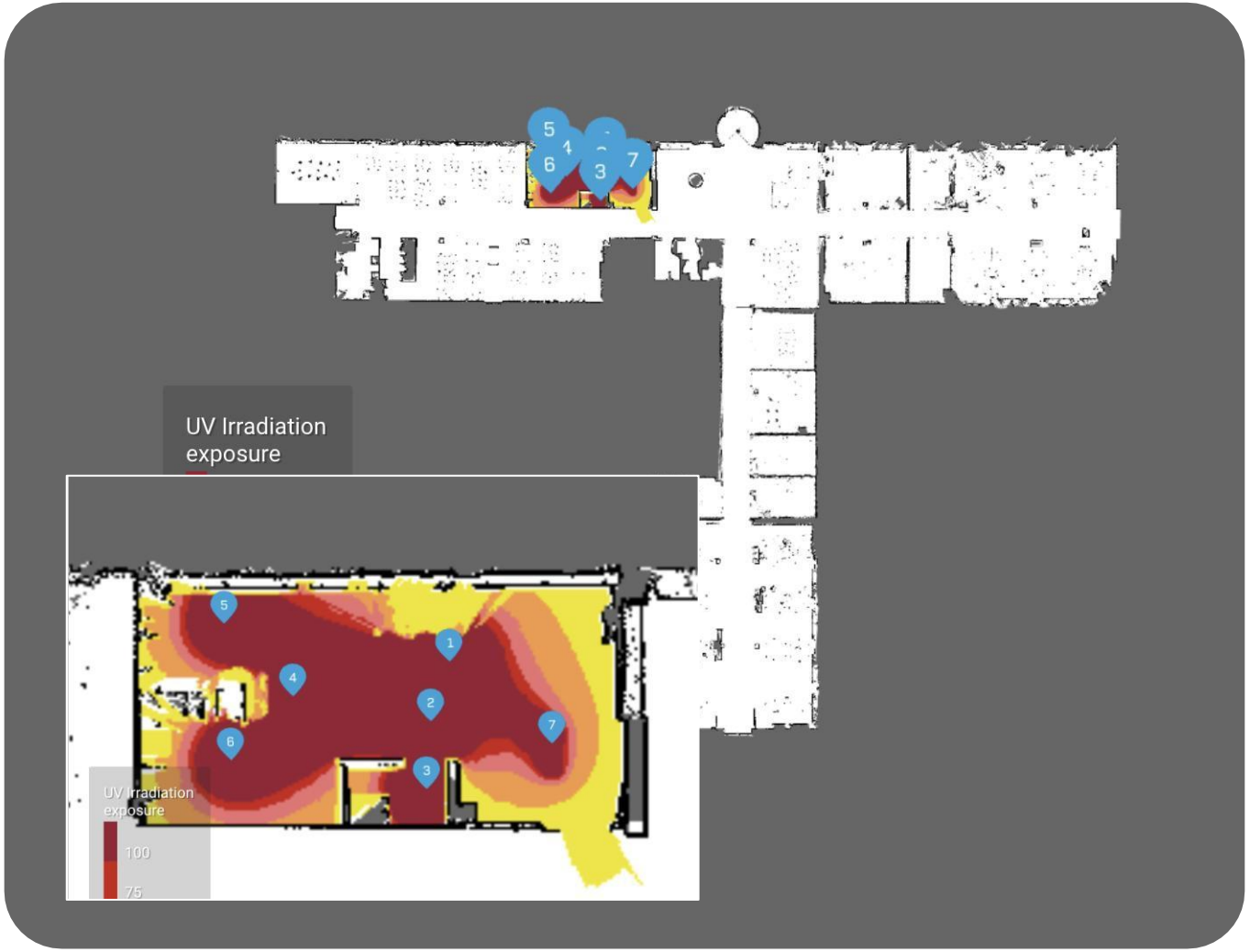
- SOP development / updates to include UV disinfection into disinfection program
  - Cleanrooms / zones
  - Frequency
  - Integration with chemical disinfection

Performance Qualification

- Verify efficacy of cleaning & disinfection program in operation with implementation of UVD Robot
- Daily environmental monitoring sampling over a time frame
- Dependent on application of the UVD Robot / site specific

Installation & Cycle Development

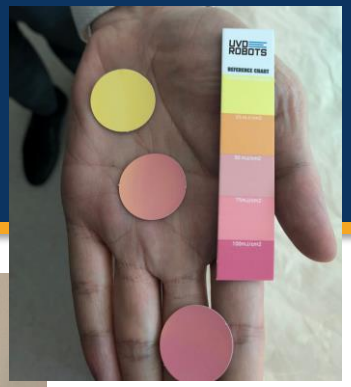
1. Scanning (mapping) of the entire area
2. Input for “master setup” of area(s)
3. Create disinfection run(s) / room(s)
4. Test and validation with dosimeter stickers



Dosimeter Test

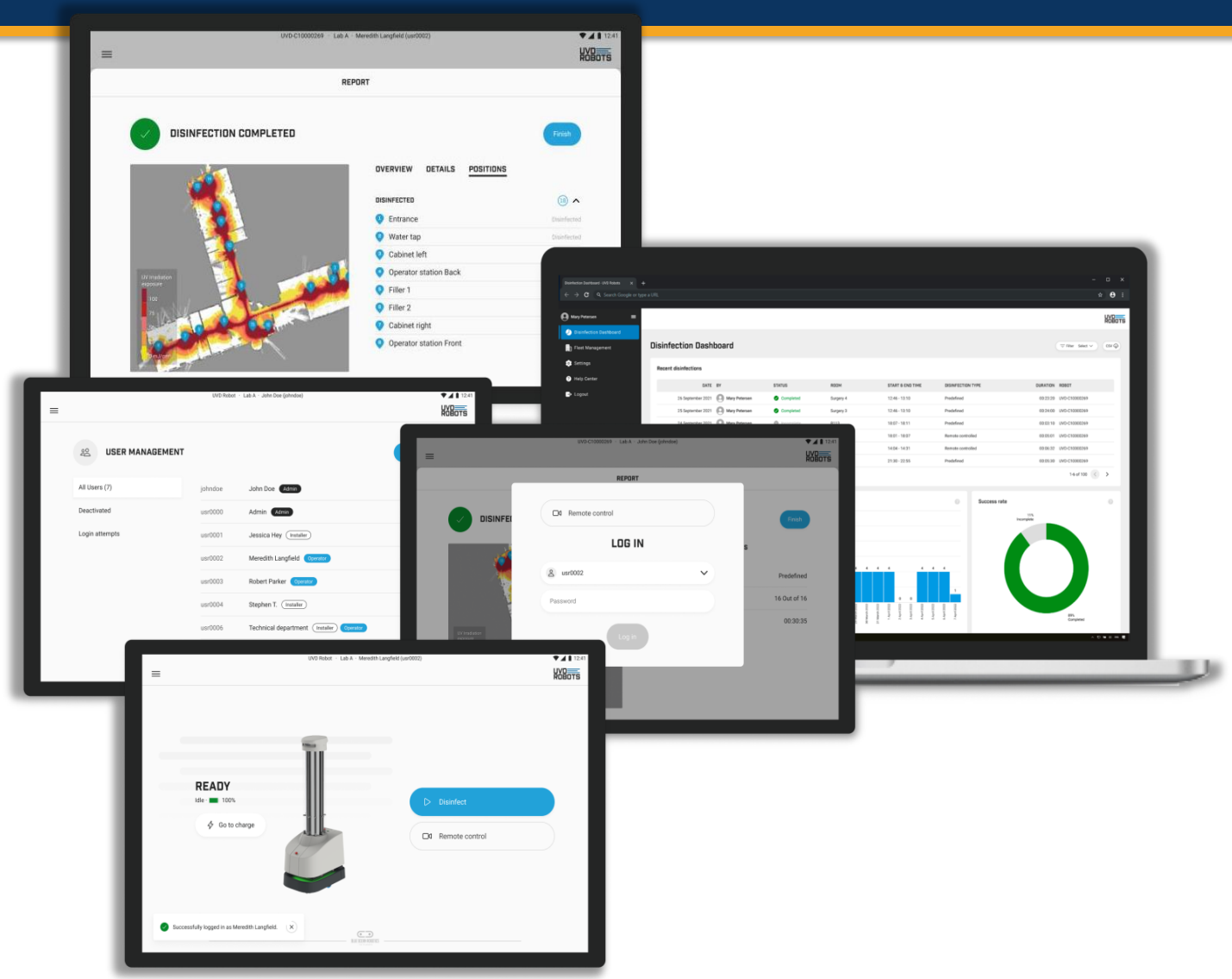
Dosimeter sticker - Before

Dosimeter sticker - After



No UV	25 mJ/ cm2	50 mJ/ cm2	75 mJ/ cm2	100 mJ/ cm2

Electronic Report



Electronic Report

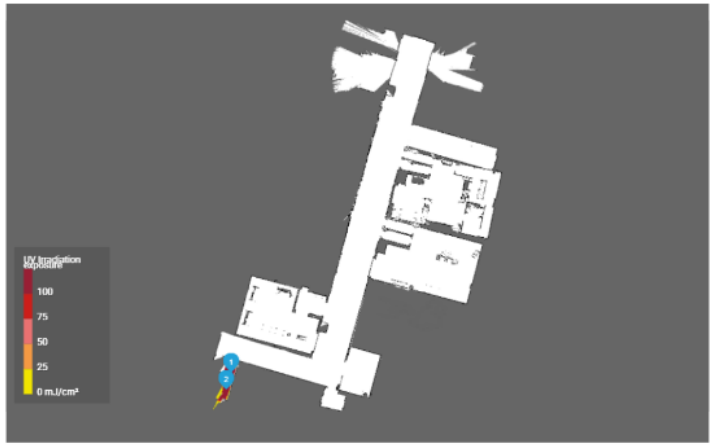
Disinfection Report

UVD ROBOTS

DISINFECTION COMPLETE

Room: RM A-1500B Jan.
Department: -
Robot name: 10000606

Date: 09 Apr 2026
Report exported from timezone: UTC-04:00
Disinfection ID: 69d7e5b4f4c368cc1d3250d0



DETAILS

Disinfection mode	Predefined
Start time	09 Apr 2026 - 13:45
Started by	NathanB
Disinfection finished	09 Apr 2026 - 13:56
Finished by	NathanB
UV-C light duration	00:03:18
Total duration	00:10:45
Positions disinfected	2
Positions remaining	0
Positions failed driving to	

INTERRUPTIONS

Walk detected	2

Disinfection Report

UVD ROBOTS

DISINFECTION COMPLETE

Room: RM A-1500B Jan.
Department: -
Robot name: 10000606

Date: 09 Apr 2026
Report exported from timezone: UTC-04:00
Disinfection ID: 69d7e5b4f4c368cc1d3250d0

DISINFECTION LOG

13:45	Disinfection preparation started	NathanB
13:46	Disinfection started	NathanB
13:49	Warmup complete	
13:50	Disinfection interrupted: Walk detected.	
13:50	Safe conditions restored.	
13:51	Disinfection interrupted: Walk detected.	
13:51	Safe conditions restored.	
13:53	Disinfection resumed.	
13:53	Warmup complete	
13:55	Disinfection completed	
13:56	Disinfection report submitted	NathanB

Take Aways

Take Aways

- **Regulatory Alignment:** EU GMP Annex 1 and FDA guidance actively encourage automation and robotics to reduce human-derived contamination risk as part of a comprehensive CCS
- **Proven UV-C Efficacy:** UV-C germicidal irradiation at ~254 nm delivers effective microbial inactivation; robot mobility overcomes shadowing and distance limitations of stationary UV-C systems
- **Chemical-Free:** Dry process, consumable and residue free, supporting sustainability goals and reducing personnel exposure to chemicals
- **Operational Impact:** Real-world implementations demonstrate 60–80% reduction in manual disinfection time, 50% fewer EM excursions, and reduced sporicidal disinfection frequency

Take Aways

- **Efficacy Qualification Results:** A standard dose of 100 mJ/cm² achieves ≥3-log reduction for vegetative organisms on common cleanroom surface materials and higher doses can be applied for sporicidal cycles targeting bacterial and fungal spores

- **Best Practice – Integrated Disinfection Program:** Daily autonomous UV-C disinfection as the primary mode, supplemented by manual chemical disinfection, delivers frequent, comprehensive whole-room coverage of floors, walls, ceilings, and touchpoints

- **Defined Qualification Pathway:** Equipment qualification, disinfection efficacy testing (per USP <1072>/EN 13697), and dosimeter-verified cycle development provide a robust, risk-based framework adaptable to any cleanroom environment

Thank You!

Questions?