# CMC UV-C technical validation ICU1

# OMNIA UV-C robot

Product version 1.0

**Review & Approval**

| Name | Role | Function | Date (`YYYY-MM-DD`) | Signature |
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## 1 Scope

The purpose of this test report is to be able to communicate the following metrics, as part of a proof of concept (POC), to Clemanceau Medical Center (CMC) in Dubai, UAE:

- Identify high-touch surfaces in the hospital intensive care unit (ICU).
- Obtain the fluence ($mJ/cm^2$) achieved by the Omnia UV-C disinfection robot in a variety of high-touch locations.
- Correlate the achieved fluence to log reduction for selected bacteria/viruses.
- Validate the disinfection algorithm of the Omnia robot by verifying that the desired fluence (set before disinfection in the user interface (UI)), is achieved.
- Determine if the ATP test is a suitable measure for expected disinfection severity as a result of UV-C light.
- Determine if the Omnia robot is compatible with the facilities present at CMC.
- Determine if the Omnia robot adheres to and provides additional benefit to the standards, guidelines and protocols implemented by CMC.

In addition, the following items are showcased to CMC in the process:

- Understanding the use-case and limitations of the Omnia UV-C disinfection robot.
- Usage of the Omnia UV-C disinfection robot in a variety of test environments.
- Creating safety related awareness amongst personnel of CMC by means of demonstrations, training sessions and competency tests.
- Interpreting disinfection results.

The timeline to perform this proof of concept is in week 10 of 2024. The technical UV-C disinfection validation was performed on the 6th of March.

## 2 Method

This section describes the method which was followed for the proof of concept study. The Omnia robot used for the proof of concept is type OMNIA.UVC.GEN1.BSE1.21.01 with hardware version version 1.00 beta 1 and software version 1.00 beta 4. The robot in the room to be disinfected is shown in Figure 1. The room is part of Clemenceau Medical Center Hospital located in Dubai.

A schematic overview of the 2D layout of the room (ICU1) is shown in Figure 2. The room consists, among other things, of a hospital bed, windows and curtains, moving cabinets, a chair, sink and cabinets (for simplicity but wrongly referred to as the kitchen), blood

Figure 1: Omnia UV-C disinfection robot in room ICU1.

cuff device, dialysis machine, respirator and a sliding door. There are a variety of overhanging devices. Also low objects such as movable stands are present.

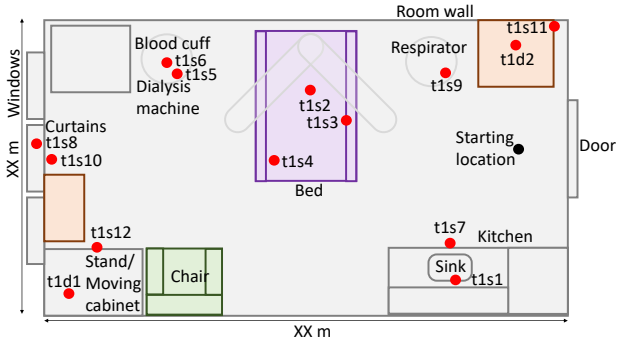



Figure 2: ICU1 room schematic layout (not to scale).

The high-touch areas in the isolation control unit 1 (ICU1) were identified by hospital personnel, in particular the infection control officer. A variety of these locations were chosen to measure the total UV-C fluence as a result of the Omnia robot, in $mJ/cm^2$. The test locations were given a unique number and are listed in Table 1 with a short description of what the location entails. Also, the locations are classified according to the type of UV-C dosimeter used, the spatial orientation of the dosimeter and whether or not the dosimeter was exposed or in shadow areas. There are a total of 14 test locations throughout the room, of which 11 have a vertical orientation, 2 horizontal and one in between the two former. The classification for exposure of the dosimeters is from best to worst as follows: direct exposure, partial exposure, partial shadow and full shadow. A direct exposure location is almost always in direct line of sight with the robot throughout the disinfection. Partial exposure for more than half the time.

Partial shadow less than half the time. Full shadow is not in line of sight during the majority of the disinfection. There are 5 direct exposure locations, 4 partial exposure locations, 4 partial shadow locations and one full shadow location chosen.

The original UV-C sticker dosimeters without received UV-C exposure, which are to be used as a reference, are shown in Figure 3.

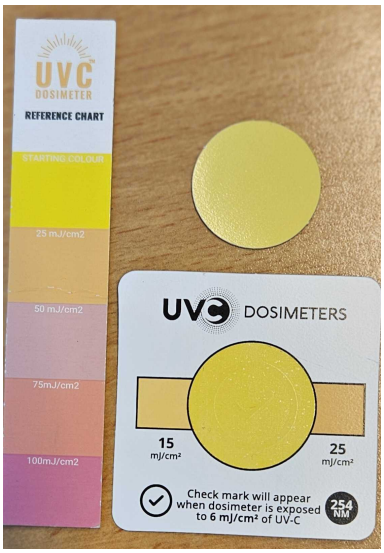



Figure 3: Reference cards UV-C dosimeters.

The Hygiena SystemSure Plus ATP luminometer (shown in Figure 4) is used for adenosine triphosphate (ATP) measurements. Normal 'acceptable' ATP values are between 10 and 30 relative light units (RLU). More than 30 RLU is not acceptable to CMC hospital. In principle the ATP measurement is always kept lower than 30 RLU if the protocols are followed in CMC.


Figure 4: Hygiena SystemSure Plus ATP luminometer used for ATP measurement.

Now that the setting and layout of the room and test locations are explained, the following steps will have to be followed in chronological order to conduct the proof of concept:

1. The UV-C stickers and UV-C dosimeters are to be placed in the designated areas in the correct orientation. The unique ID's will be noted on the stickers too. Quick Check stickers[1] are placed in shadow locations, since the expected exposure is less than in direct exposure areas, where the UV-C Dots stickers[2] are placed. Also the digital UV-C dosimeters are placed and reset to 0.
2. An ATP test will be performed for the specified locations, shown in Table 1. Results will be noted down immediately.
3. The room to be disinfected will be mapped.
4. A disinfection with setting 'C.Diff 2-log' will be performed, taking into account the prescribed safety precautions. Warming up time of the lamps is taken as 30 seconds.
5. After disinfection, the report is saved for later review.
6. First, only the infection control officer will enter the room to take ATP measurements and surface culture swabs.
7. Then, each UV-C dosimeter is taken a picture of, with the color scale in frame.
8. The stickers are left in place, after which another disinfection is started with the same settings.
9. After the 2nd disinfection is completed, the former 3 points are repeated.
10. The color change in the UV-C dosimeters are interpreted by a minimum of two non color blind people.

For interpretation of the results, Table 2 is used. This table shows for the relevant types of microorganisms the required amount of fluence in $mJ/cm^2$ according to literature.

Equation 1 can be used to calculate the log reduction value from the amount of fluence a dosimeter received. This equation should be used in conjunction with Table 2, as the results are interpolated on a logarithmic scale. The equation is derived from the more standard linear interpolation.

$$y(x) = 10^{\left(\frac{\log_{10}\left(\frac{x}{x_1}\right)\cdot\log_{10}\left(\frac{y_2}{y_1}\right)}{\log_{10}\left(\frac{x_2}{x_1}\right)}+\log_{10}(y_1)\right)}, \qquad (1)$$

where:

- y = log reduction value

[1] https://uvcdosimeters.com/uvc-254-quick-check/
[2] https://uvcdosimeters.com/uvc-254-dots/
[3] https://doi.org/10.6028/jres.126.021

Table 1: Fluence per UV-C sticker dosimeter after one- and two disinfections.

| ID | Type | Orientation | Test location description | Classification |
|---|---|---|---|---|
| T1S1 | UV-C sticker & ATP & surface culture | Vertical | Sink crane/faucet | Direct exposure |
| T1S2 | UV-C sticker & ATP & surface culture | Horizontal | Bed center | Partial exposure |
| T1S3 | UV-C sticker & ATP & surface culture | Vertical | Bed handle inside | Partial exposure |
| T1S4 | UV-C sticker | Vertical | Under the bed knob | Partial shadow |
| T1S5 | UV-C sticker & surface culture | Vertical | Dialysis machine | Partial shadow |
| T1S6 | UV-C sticker & ATP & surface culture | Horizontal | Blood pressure cuff | Partial shadow |
| T1S7 | UV-C sticker | Vertical | Clauset inside handle | Partial exposure |
| T1S8 | UV-C sticker | Vertical | Behind curtains | Full shadow |
| T1S9 | UV-C sticker | 45 degrees | Respirator | Partial shadow |
| T1S10 | UV-C sticker | Vertical | Curtains | Direct exposure |
| T1S11 | UV-C sticker | Vertical | Corner of wall near ceiling | Direct exposure |
| T1S12 | UV-C sticker | Vertical | Stand / moving cabinet | Partial exposure |
| T1D1 | UV-C digital dosimeter | Vertical | Stand / moving cabinet | Direct exposure |
| T1D2 | UV-C digital dosimeter | Vertical | Table top near the bed | Direct exposure |

Table 2: Required fluence per log reduction for common relevant micro-organisms found[3].

| Micro-organism | | | Disinfection severity ($mJ/cm^2$) | | | | |
|---|---|---|---|---|---|---|---|
| Name | Type | Host | Log 1 | Log 2 | Log 3 | Log 4 | Log 5 |
| Murine norovirus CW3 | Virus | RAW 264.7 macrophags ATCC TIB-71 OR: E. coli C | 10 | 15 | 22 | 27 | 30 |
| Sars-cov-2 (2019) | Virus | VeroE6 cells | 0.8 | 1.6 | 2.5 | 3.3 | 28 |
| Clostridioides difficile (C.Diff) | Bacterium | VeroE6 cells | 11 | 23 | | | |
| Staphylococcus aureus | Bacterium | | 4.4 | 5.8 | 6.4 | 7.3 | 9 |
| Methicillin-resistant Staphylococcus aureus (MRSA) | Bacterium | | 1.2 | 2.4 | 3.7 | 4.9 | |
| Escherichia Coli (E. Coli) | Bacterium | | 3.7 | 5.5 | 6.7 | 7.3 | 9.7 |
| MERS-CoV | Virus | Vero 81 cells | 0.8 | 1.7 | 2.5 | 3.4 | 4.2 |
| Klebsiella terrigena | Bacterium | | 3.6 | 6.4 | 9.3 | 12 | 15 |
| Rotavirus | Virus | Monkey kidney cell line MA 104 | 7.5 | 15 | 25 | 38 | 48 |
| Enterococcus faecium Vancomycin-resistant (VRE) | Bacterium | | 7 | 9 | 11 | 13 | 15 |
| Pseudomonas aeruginosa | Bacterium | | 3.8 | 6.5 | 10 | 17 | |
| Legionella pneumophila | Bacterium | | 3.0 | 5.0 | 7.2 | 9.3 | |
| Enterobacter cloacae | Bacterium | | 6.4 | 12.8 | 19.2 | 25.6 | |

- x = fluence in $mJ/cm^2$
- x1 = lower bound interpolation fluence in $mJ/cm^2$, corresponding to y1
- y1 = lower bound log interpolation value
- x2 = upper bound interpolation fluence in $mJ/cm^2$, corresponding to y2
- y2 = upper bound log interpolation value

To summarize, for each performed disinfection, the following findings should be included in the results section:

- 2D disinfection map of the disinfection performed.
- Total time for the disinfection.
- Relevant disinfection settings and parameters. E.g. selected disinfection severity.
- Image of each dosimeter after disinfection.
- A table and/or graph with a summary of the interpreted UV-C fluence per dosimeter.
- Calculated log reduction for the relevant micro-organisms.
- ATP measurement results.
- If applicable, the results of the surface culture test.

## 3 Hypotheses

The expected achievable fluence value for the setting 'C.Diff 2-log', should be in the order of magnitude of 25 $mJ/cm^2$. This is worst case for horizontal surfaces. Therefore, the dosimeters should indicate a higher dosage than this, except if there is a full shadow case. The expected corresponding log reduction can then be determined based on this value. Figure 5 shows the expected log reduction values for a variety of micro-organisms when using the setting 'C.Diff 2-log' in the webapp of the Omnia robot. These values are based on an emperical data model in combination with the current software disinfection algorithms. It is important to note that the maximum expected or predicted log reduction is limited by literature. The black line represents the limit on most reputable papers with regards to finding a correlation between log reduction and UV-C fluence value. This is therefore taken as the limit on calculating log reduction values. The total disinfection time is expected to be in the order of magnitude of 15 minutes.

The ATP measurements should be negative if the hospital adheres to its own cleaning and disinfection protocols and regulations. Negative means the RLU value of the luminometer should be less than 30.

The surface culture tests should be negative, following the same reasoning as the ATP tests.

## 4 Results

The results for both the metrics mentioned in the method section will be described below. Two disinfections were performed for ICU1, after one another. The setting chosen for both disinfections is 'C.Diff 2-log'. The total disinfection time for disinfection 1 was: 11 minutes. Disinfection 2 took in total 13 minutes.

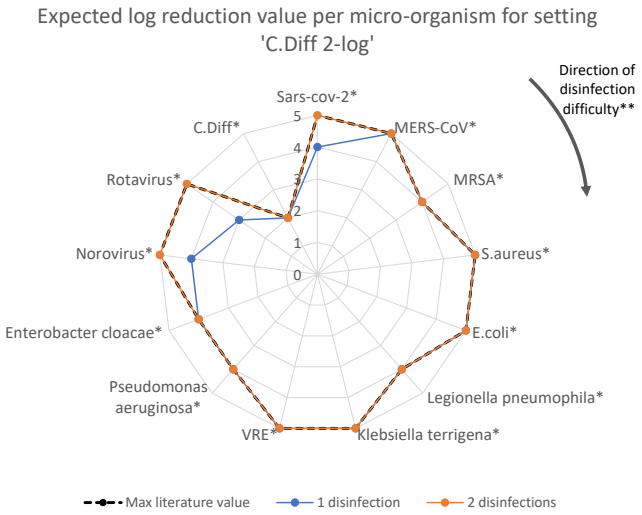



Figure 5: Expected UV-C fluence in $mJ/cm^2$ after disinfection.

The 2D disinfection report (or map) for disinfection 1 is shown in Figure 6. For disinfection 2, it can be seen in Figure 7.

The dosimeter results after the first disinfection are shown in Figure 8. This figure shows for each of the 14 dosimeters either the color change or fluence value in $mJ/cm^2$. The results for the second disinfection, which was performed at maximum an hour after disinfection 1, are presented in Figure 8.

After interpreting the color change for each of the dosimeters, the summary as shown in Table 4 can be constructed. This table shows the fluence value in each of the test locations for both disinfections.

The results from Table 4 can be visualised too, to indicate more intuitive potential correlations. This is done in Figure 10. Note that the maximum UV-C exposure value for the UV-C dosimeters is 100 $mJ/cm^2$.

Calculating the log reduction values for each fluence value, results in the estimated reduction per micro-organism per test location. Figure 11 shows a 2D radar type figure, with on the radial axis the log reduction value calculated based on available literature, different types of micro-organisms on the discrete perpendicular bisector axes and for a variety of test locations indicated by color and line type. The black line indicates the maximum log reduction value found in literature. The current robot model is not designed with the intentions to go beyond this theoretical limit.

Figure 12 shows the resulting radar graph after two disinfections performed consecutively.

The results of the ATP measurements before disin-

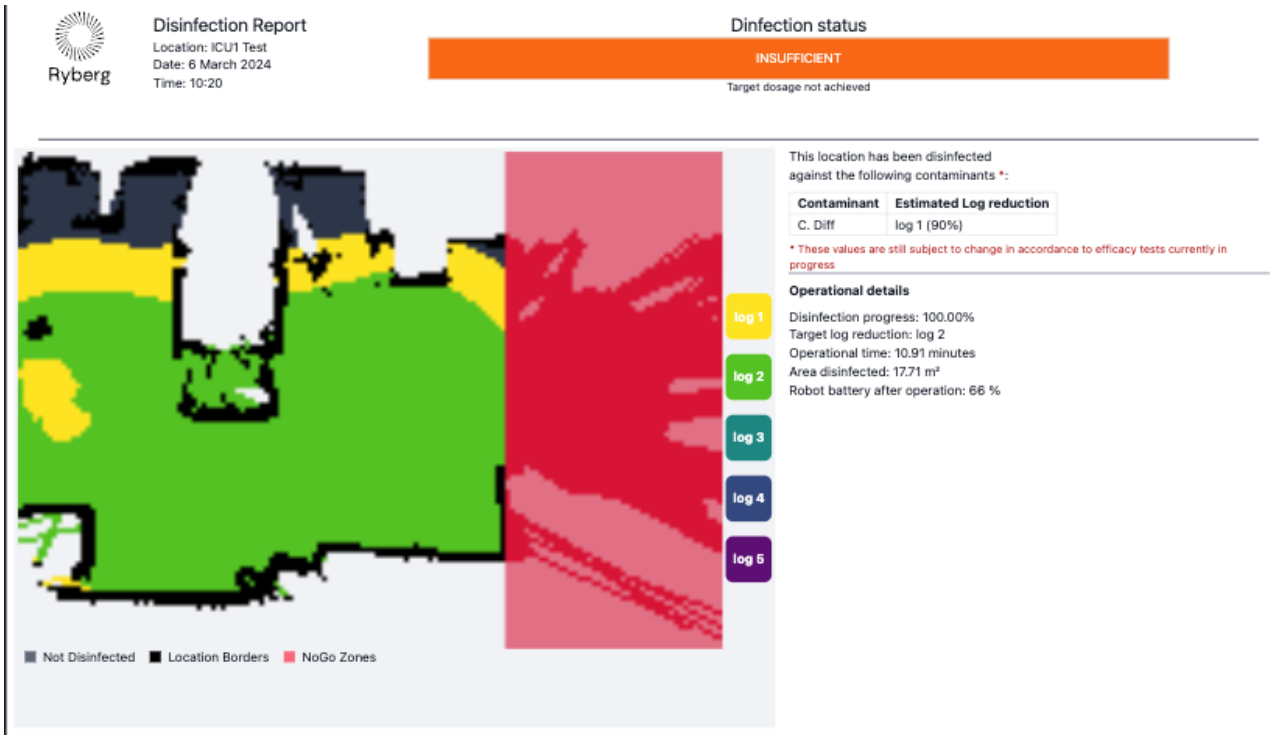



Figure 6: 2D disinfection map indicating log reduction values after disinfection 1 for the selected micro-organisms.

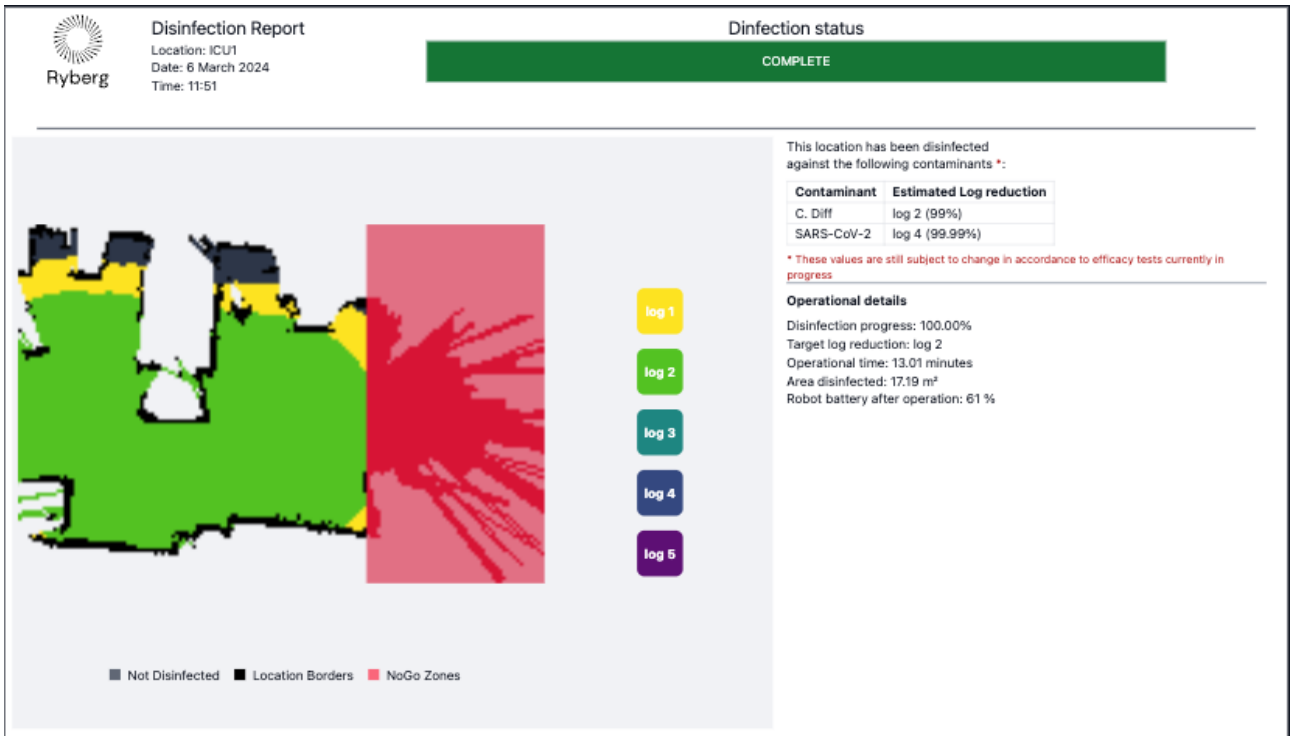


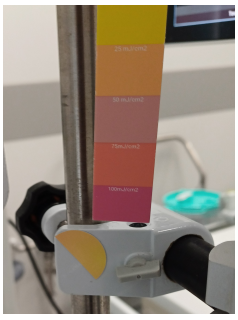

Figure 7: 2D disinfection map indicating log reduction values after disinfection 1 for the selected micro-organisms.

(a) T1S1: sink crane vertical.

(b) T1S2: bed center horizontal.

(c) T1S3 bed handle inside vertical.

(d) T1S4: under the bed vertical.



(e) T1S5: dialysis machine vertical.

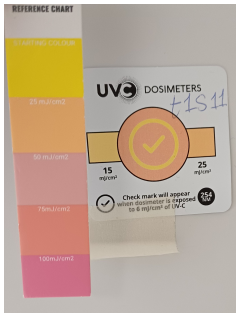
(f) T1S6: blood cuff horizontal

(g) T1S7: inside closet handle vertical.

(h) T1S8: behind curtains vertical.

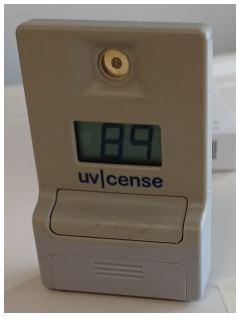
(i) T1S9: respirator 45 degrees angle.

(j) T1S10: in front of curtains vertical.



(k) T1S11: wall corner near ceiling vertical.

(l) T1S12: stand / moving cabinet vertical.




(m) T1D1: table top stand / moving cabinet vertical.


(n) T1D2: table top bedside corner vertical.

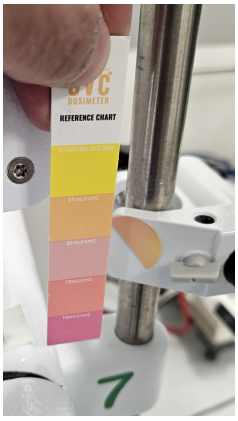
Figure 8: UV-C sticker dosimeters post-disinfection 1.


(a) T1S1: sink crane vertical.


(b) T1S2: bed center horizontal.

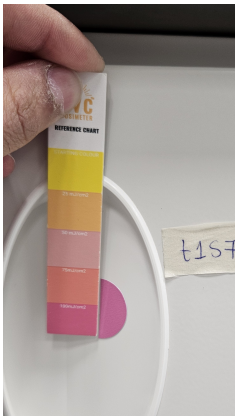

(c) T1S3 bed handle inside vertical.


(d) T1S4: under the bed vertical.




(e) T1S5: dialysis machine vertical.

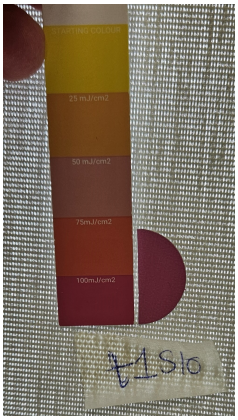
(f) T1S6: blood cuff horizontal




(g) T1S7: inside closet handle vertical.

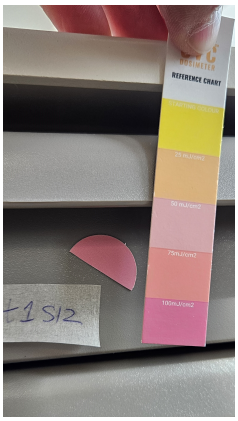

(h) T1S8: behind curtains vertical.


(i) T1S9: respirator 45 degrees angle.

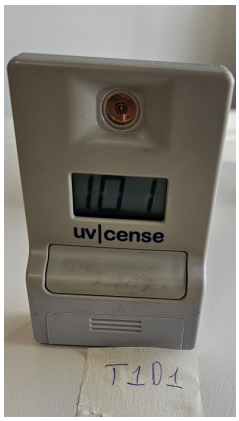



(j) T1S10: in front of curtains vertical.

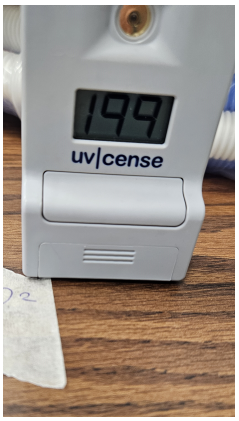

(k) T1S11: wall corner near ceiling vertical.




(l) T1S12: stand / moving cabinet vertical.




(m) T1D1: table top stand / moving cabinet vertical.




(n) T1D2: table top bedside corner vertical.

Figure 9: UV-C sticker dosimeters post-disinfection 2.

Table 3: Fluence per UV-C sticker dosimeter after one- and two disinfections.

| ID | Fluence 1 ($mJ/cm^2$) | Fluence 2 ($mJ/cm^2$) |
|---|---|---|
| T1S1 | 70 | >100 |
| T1S2 | 25 | 50 |
| T1S3 | 25 | 55 |
| T1S4 | 25 | 50 |
| T1S5 | 20 | 25 |
| T1S6 | 25 | 45 |
| T1S7 | 100 | >100 |
| T1S8 | 10 | 15 |
| T1S9 | 65 | >100 |
| T1S10 | 100 | >100 |
| T1S11 | 40 | 90 |
| T1S12 | 40 | 95 |
| T1D1 | 89 | 101 |
| T1D2 | 105 | >199 |

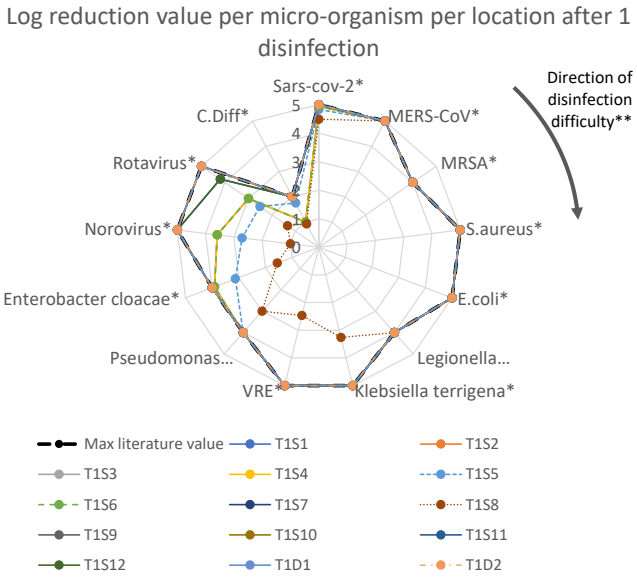



Figure 11: Calculated log reduction values based on available literature.

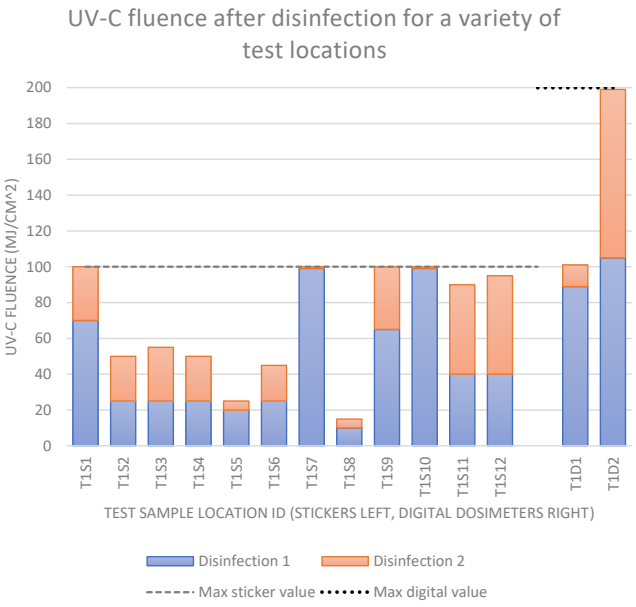



Figure 10: UV-C fluence in $mJ/cm^2$ after disinfection for a variety of test locations.

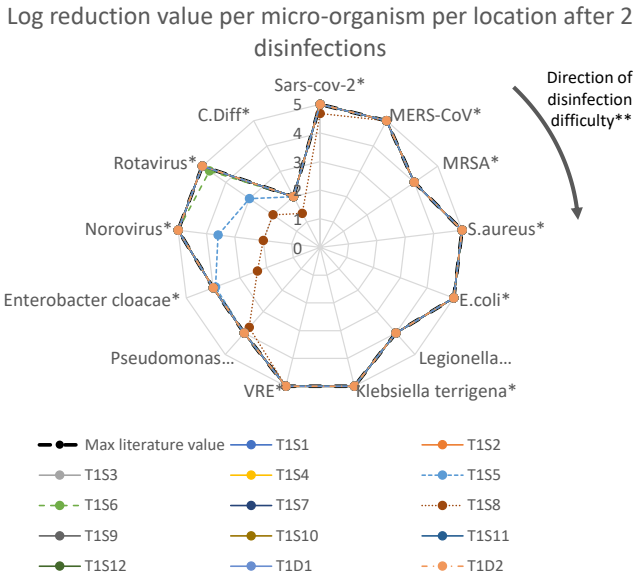



Figure 12: Calculated log reduction values based on available literature.

fection, after disinfection 1 and after disinfection 2, are listed in Table 4. A visual representation is also shown in Figure 13.

Table 4: ATP measurement before-, after one- and after two disinfections.

| ID | ATP 1 (RLU) | ATP 2 (RLU) | ATP 3 (RLU) |
|---|---|---|---|
| T1S1 | 6 | 4 | - |
| T1S2 | 3 | 3 | 5 |
| T1S3 | 62 | 19 | 2 |
| T1S6 | 26 | 40 | 12 |

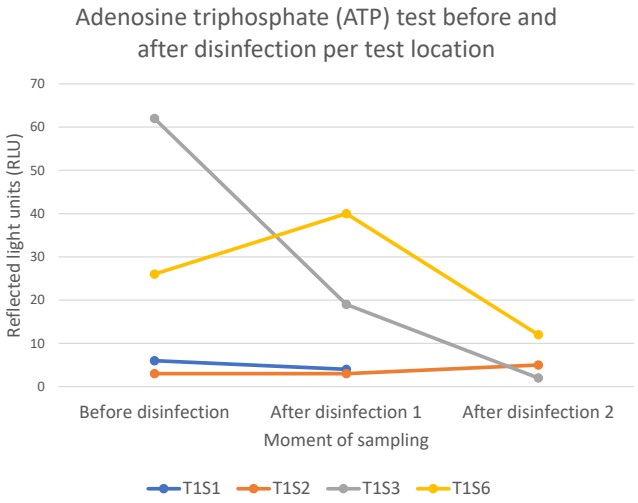



Figure 13: ATP tests performed before and after disinfection.

The surface culture tests, which were performed after the first disinfection, came back negative. Meaning, the microbial count present on the surfaces was accepted by the hospital.

## 5 Discussion

The low sample size of $n = 1$ for the disinfections performed can result in a large uncertainty of the results.

Also, since a visual inspection is used to determine the fluence values, there is some interpretation of the exact amount of fluence. The amount of subjectivity differs per test, but this should be reflected in the resulting standard deviation of the test in question.

The resolution of the UV-C stickers is $\pm 6 mJ/cm^2$ for the quick reference cards and $\pm 13 mJ/cm^2$ for the UV-C dots stickers, this should be taken into account as well.

Even though the Quick Reference dosimeters use the same color scale as the Dots variant, the manufacturer does not recommend to use the color card from the UV-C Dots. This however was done for these tests, as from experience, the color change and dosage do match.

A limitation of using the sticker UV-C dosimeters, is that the influence of surface roughness is not taken into account. Soft or more porous surfaces are harder to disinfect than hard non-porous materials. This could be reflected in the achievable log reduction values.

From empirical knowledge, there is a discrepancy noticeable between the digital- and sticker dosimeters, as the stickers consistently showed a lower UV-C fluence value with respect to the digital dosimeters. The sticker manufacturer Intellego claims their stickers are "Validated by RISE: Research Institute of Sweden"[4]. The digital dosimeter manufacturer, UVCense, stated their devices are calibrated and have an accuracy of "$\pm 4\% \pm 1 mJ/cm^2$ (NIST-traceable calibration meter)"[5].

It should also be noted that the achieved disinfection severity was optimized for speed. The Omnia UV-C disinfection robot can disinfect more thorough than reflected in this study, if severity is given more priority over speed.

According to the auto-generated reports shown earlier, the first disinfection was insufficient and the second one was completed for a 2-log reduction of C.Diff. This is the estimated UV-C dosage using the current software algorithms. It could be that the robot was standing still for some time in disinfection 1 (yellow spot in left hand side of the map). Also, since there was a lot of equipment in the room, the area behind the objects was difficult to reach (seen in the top part of the the maps).

The study was limited due to lack of available literature on UV-C fluence levels of certain relevant micro-organisms. Also the lack of data on higher log-reduction UV-C fluence levels was noticeable. In general, research papers only went to a 4-log or 5-log reduction at maximum. One example which is reflected heaviliy in the results, was the disinfection severity for C.Diff, as data only up to a 2-log reduction was available at the time.

The ICU1 room at CMC was last cleaned 2 days ago and they had a patient in the room prior to cleaning. Touching surfaces or even human presence in the room could have an influence on the ATP and surface culture test results.

The influence of shadows on the test locations can be predicted quite accurately before starting the disinfection. This is shown in Figure 14, where the test sample locations were grouped according to the method explained earlier. The graph shows a linear relation between four categories of exposure values. This relation holds true for both disinfections. Also from figures 11 and 12 is can be concluded that there were some shadow areas present, based on the fluence value

[4] https://uvcdosimeters.com/uvc-254-dots/
[5] https://mm.digikey.com/Volume0/opasdata/d220001/medias/docus/2580/UVD200BLE%20Datasheet.pdf

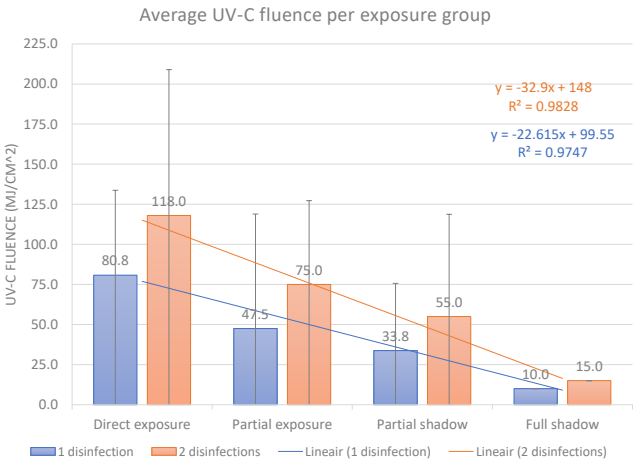



Figure 14: UV-C fluence in relation to sample location expected exposure.

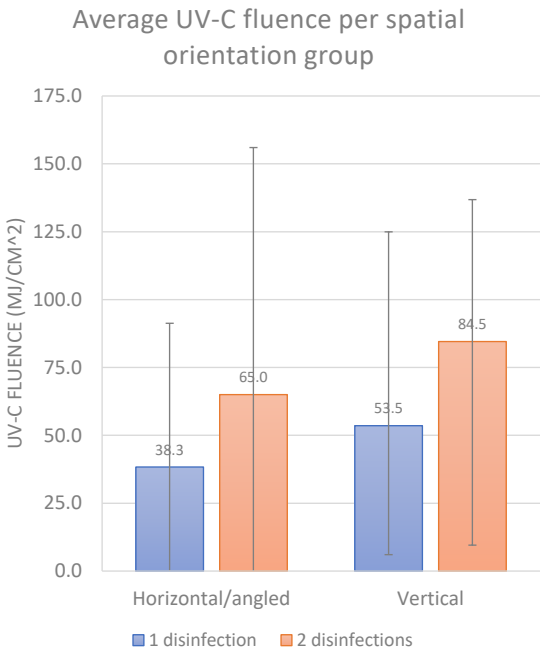



Figure 15: UV-C fluence in relation to sample location orientation.

per dosimeter. However, this sometimes was also reflected on the dosimeters itself as a color gradient (e.g. T1S5). After attending a manual (chemical) cleaning and disinfection routine of a patient room at CMC, it became apparent that every piece of furniture or equipment is moved or was flipped upside down. This principle could also be applied in the UV-C disinfection routine. For example, two UV-C disinfections could be performed (same as was done now), where the furniture or equipment is moved/rotated slightly before the 2nd disinfection. The previous shadow areas can then be counteracted. And since this is already done in the daily routine, it should not disrupt the workflow of personnel.

The influence of test surface orientation can be investigated too. Two classifications were made: vertical and horizontal and/or angled orientation of the dosimeters. Figure 15 indicates that the vertical surfaces get more exposure than horizontal and/or angled surfaces, although too little data is used to indicate any statistical significance. In the current robot software state, worst-case horizontal surfaces are always assumed even if in reality the test surface is vertical. This is due to the 2D map used for estimating log reduction. It is recommended to take this into account in newer software models, such that a (partial) 3D can be created.

According to literature, an ATP measurment does not prove to be the best choice for measuring UV disinfection severity. Since the cell's internal DNA is damaged, preventing the micro-organism from replicating, instead of damaging its cell wall which is the case with chemical disinfectants, the amount of ATP is not reduced significantly immediately after disinfection. This was also supported by the findings in our ATP tests, although on average there was a reduction visible, but the statistical significance remains questionable[6]. If the cell dies immediately, there can be a small reduction, but there may be a larger reduction in ATP values a couple hours after disinfection, up to 24 hours according to some studies, after the cells die[7].

An observation relating the use of Clinell Universal Wipes [8] for cleaning and disinfection at CMC and the relative effectiveness against the Corona virus could be made. The effectiveness of Clinell wipes was found to be a 4-log (i.e. 99.99%) reduction against both SARS-CoV-2 [9] and MERS-CoV [10]. For these two viruses, the log reduction observed across all sample locations throughout the intensive care unit (ICU1), was a 4.5-log and >5-log reduction respectively.

The target disinfection time of 15 minutes for ICU1 was achieved: 11 and 13 minutes of disinfection time resulting in an average duration of 12 minutes.

The intentions for CMC were to use the Omnia UV-C disinfection robot for terminal disinfection. The device will be an addition to the current disinfection protocol. As a comparison, manual cleaning and disinfection of ICU1 takes two trained people of housekeeping one hour. If additionally, terminal fogging is applied, this takes 10 minutes to set up and about 2 hours of fog-

[6]https://www.researchgate.net/publication/318458346_Mechanisms_of_ultraviolet_disinfection_and_chlorination_of_Escherichia_coli_Culturability_membrane_permeability_metabolism_and_genetic_damage

[7]https://www.gl-biocontrol.com/en/how-to-assess-the-efficacy-of-uv-disinfection-using-atp-testing

[8]https://gamahealthcare.com/products/universal-wipes-200/

[9]https://gama.getbynder.com/m/394cae9c796e6464

[10]https://gama.getbynder.com/m/626f1fe9d80dc1f8

ging, evaporating and ventilating afterwards. In comparison, the current Ryberg UV-C disinfection adds only 12 minutes to this.

As an acknowledgment, this proof of concept study was performed by Ryberg in close collaboration with CMC. The results were interpreted and reported by engineers from Ryberg and medical staff from CMC.

At last a couple of recommendations for follow up studies which could be performed. First of all, it would be interesting to compare a static UV-C device to an autonomous moving UV-C robot. Total disinfection time, usability as well as disinfection severity taking into account shadow forming should be part of this study. Also, the repeatability of the disinfection should be identified. Since the robot is not moving with a predetermined path, the starting location is different and the objects may have moved slightly, it would be interesting to investigate the disinfection coverage for varying parameters. At last, it is imperative to do a validation study with micro-organisms with the help of a medical (research) lab. The disinfection routine, workflow and environment (i.e. the use-case) should reflect the robot being used by hospital personnel in a hospital environment.

# 6 Conclusion

The proof of concept performed at Clemanceau Medical Center (CMC) in Dubai, showed that the usage of the Omnia UV-C disinfection robot has the potential to provide an additional means of infection prevention. The technical validation with digital- and sticker-type UV-C dosimeters, ATP measurements and surface culture test, indicated the achievable log reduction values for a variety of test locations in the intensive care unit (ICU).

The total disinfection time for ICU1 was 12 minutes on average and the target UV-C dosage of 25 $mj/cm^2$ on horizontal surfaces was achieved on 86% of sample locations. The results are based on and supported by scientific literature.

Furthermore, the usability of the Omnia UV-C disinfection robot in the CMC environment was investigated and the potential of implementation in the existing cleaning and disinfection standards and protocols was explored. Demonstrations and training sessions among hospital staff was performed as well.