

Test Report Disinfection Wheelchair Cushion



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Test Report

Vicair – Wormer

Test Runs Disinfection Wheelchair Cushion

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| | Responsibility | Name and Title | Date | Signature |
|----------|-----------------------|--------------------------------------------------------------------|-------------|------------------|
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| Approval | Document Approval | Jasper Rogmans Sales & Marketing Manager Vicair | | |



1 Introduction

1.1 Purpose

This document describes the results of the disinfection tests executed on the Vicair Adjuster 02, Vector 02 and Vicair 4 wheelchair cushions, to demonstrate disinfection capabilities using a washing program on a common household washing machine together with laundry detergent.

1.2 Scope

Disinfection tests were performed on the Vicair Adjuster 02, Vector 02 and Vicair 4 wheelchair cushions. During the tests, the following characteristics were verified:

- » System settings (temperature and time conditions)
- » Determination of log reduction, using biological indicators

A detailed description of the performed tests can be found in test protocol 2022_WORMVICA_WD_TP1.0. After completion of the protocol, a third cushion (Vicair 4) was introduced into the test setup. This is described in section 2 Change during testing. The results of the tests are described in section 3 Results.

2 Change during testing

Originally only the Adjuster and Vector cushions would be tested, as described in the protocol. During testing, the decision was made to also include the Vicair 4 cushion into the test setup as it has “hidden” zippers which might hold possible contamination more easily. The cushion consists of 4 compartments, containing ‘Smartcells’. As opposed to the two other types that were tested, the top and bottom side of the Vicair 4 are both made of the same polyester fabric with a polyurethane coating. There are no Velcro strips on the bottom side. A picture of the cushion can be found in Figure 1.



Figure 1. Vicair 4.

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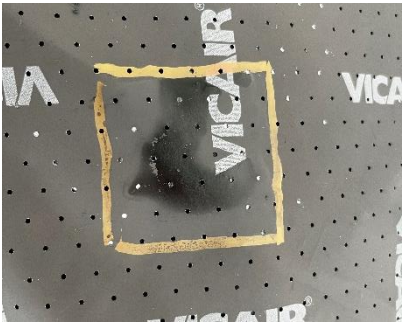
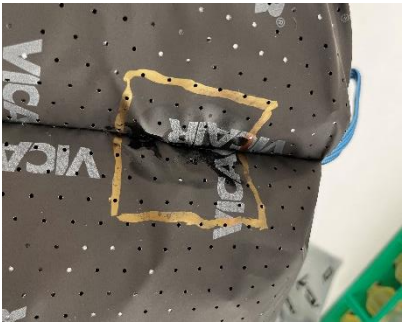
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Three disinfection tests were performed as described in the protocol, but alternating between the three types of cushions:

- Run 1: Vector and Adjuster (Osmaflux Profi)
- Run 2: Vector and Vicair 4 (Ariel Color)¹
- Run 3: Adjuster and Vicair 4 (Ariel Color)

Eleven different test locations on the cushions were identified as being worst-case. These can be found in the protocol for the Vector and Adjuster cushions. An overview of the locations for the Vicair 4 and a rationale behind the choice, can be found below:

Table 1. Overview of test locations on the wheelchair cushions and rationale behind the choice

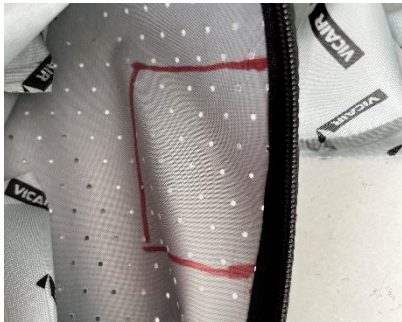
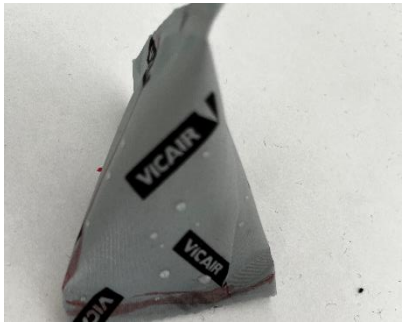

| Location ID | Location Description | Rationale | Sample Image |
|-------------|----------------------|----------------------|--------------------------------------------------------------------------------------|
| 1 | Outside | Material composition |  |
| 2 | Grooves (outside) | Difficult to reach |  |

¹ A different detergent than described in the protocol was used. Because Ariel is also a common household product, it is still representative for testing.



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| Location ID | Location Description | Rationale | Sample Image |
|-------------|-----------------------------|------------------------------------------|--------------------------------------------------------------------------------------|
| 3 | Zipper 1 (inside) | Possibilities to retain contamination |  |
| 4 | Zipper 2 (inside) | | |
| 5 | Air pocket 1 | Material composition, difficult to reach |  |
| 6 | Air pocket 2 | | |
| 7 | Air pocket 3 | | |
| 8 | Air pocket 4 | | |
| 9 | Air pocket 5 | | |
| 10 | Compartment wall 1 (inside) | Material composition, difficult to reach |  |
| 11 | Compartment wall 2 (inside) | | |

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3 Test results

3.1 Technical specifications

| Technical specifications | |
|--------------------------|--------------------|
| Type washing machine | Miele PW6080 LP ED |
| Program | 60°C (1:02h) |

3.2 Test 1

3.2.1 Microbiological analysis

| Location ID | Microbiological Analysis (<i>Enterococcus F.</i> / mL) | | |
|-------------|---------------------------------------------------------|-----------|------------------|
| | Adjuster 02 | Vector 02 | Positive control |
| 1 | <10 | <10 | 7.000.000 |
| 2 | <10 | 50 | 28.000.000 |
| 3 | <10 | <10 | 20.000.000 |
| 4 | 50 | 110 | 15.000.000 |
| 5 | 230 | 170 | 19.000.000 |
| 6 | 380 | 2.000 | 20.000.000 |
| 7 | <10 | <10 | 52.000 |
| 8 | <10 | <10 | 300.000 |
| 9 | <10 | <10 | 20.000 |
| 10 | <10 | <10 | 6.000.000 |
| 11 | <10 | <10 | 12.000.000 |

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3.2.2 Log reduction¹

| Location ID | Log reduction | | | |
|-------------|---------------|-------------------|---------------|-------------------|
| | Adjuster 02 | | Vector 02 | |
| | Log reduction | Percent reduction | Log reduction | Percent reduction |
| 1 | 6,85 | 99,99999 | 6,85 | 99,99999 |
| 2 | 7,45 | 100,00000 | 5,75 | 99,99982 |
| 3 | 7,30 | 100,00000 | 7,30 | 100,00000 |
| 4 | 5,48 | 99,99967 | 5,13 | 99,99927 |
| 5 | 4,92 | 99,99879 | 5,05 | 99,99911 |
| 6 | 4,72 | 99,99810 | 4,00 | 99,99000 |
| 7 | 4,72 | 99,99808 | 4,72 | 99,99808 |
| 8 | 5,48 | 99,99967 | 5,48 | 99,99967 |
| 9 | 4,30 | 99,99500 | 4,30 | 99,99500 |
| 10 | 6,78 | 99,99998 | 6,78 | 99,99998 |
| 11 | 7,08 | 99,99999 | 7,08 | 99,99999 |

3.2.3 Temperature measurement

| Logger | Measured Maximum Temperature |
|--------|------------------------------|
| T1 | 60,50 |
| T2 | 60,59 |
| T3 | 60,48 |
| T4 | 60,58 |

¹ Log reduction is calculated with the following formula:

$$\text{Log reduction} = \log_{10} \frac{N_0}{N}$$

Where N is the amount of CFU (colony forming units) left after disinfection and N₀ the amount of CFU on the corresponding location of the positive control cushion.

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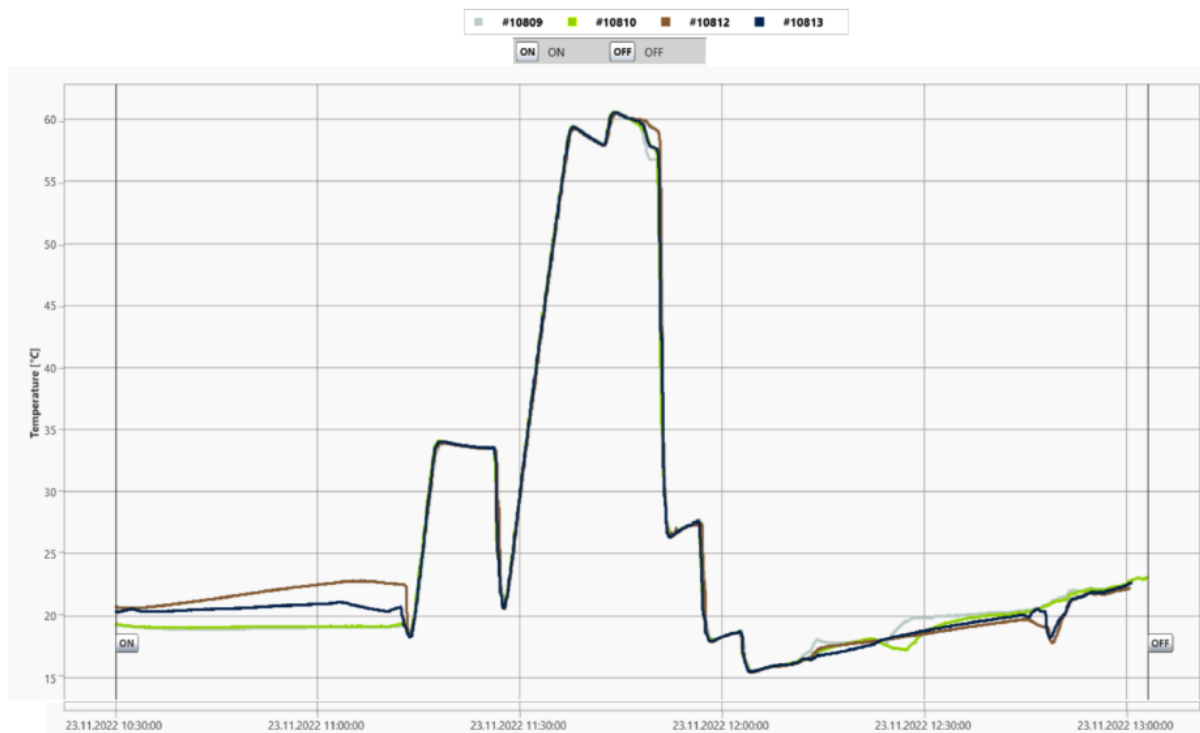


Figure 2. Temperature profile – Run 1.

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3.3 Test 2

3.3.1 Microbiological analysis

| Location ID | Microbiological Analysis (<i>Enterococcus F.</i> / mL) | | |
|-------------|---------------------------------------------------------|-----------|------------------|
| | Vector 02 | Vicair 4 | Positive control |
| 1 | <10 | <10 | 4.600.000 |
| 2 | <10 | <10 | 560.000 |
| 3 | <10 | <10 | 8.000.000 |
| 4 | 240 | <10 | 13.000.000 |
| 5 | 150 | <10 | 16.000.000 |
| 6 | 50 | <10 | 18.000.000 |
| 7 | <10 | <10 | 110.000 |
| 8 | <10 | <10 | 500.000 |
| 9 | <10 | <10 | 300.000 |
| 10 | <10 | No result | 14.000.000 |
| 11 | <10 | <10 | 6.000.000 |



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3.3.2 Log reduction¹

| Location ID | Log reduction | | | |
|-------------|---------------|-------------------|------------------------|-------------------|
| | Vector 02 | | Vicair 4 | |
| | Log reduction | Percent reduction | Log reduction | Percent reduction |
| 1 | 6,66 | 99,99998 | 6,66 | 99,99998 |
| 2 | 5,75 | 99,99982 | 6,90 | 99,99999 |
| 3 | 6,90 | 99,99999 | 7,26 | 99,99999 |
| 4 | 4,73 | 99,99815 | 7,26 | 99,99999 |
| 5 | 5,03 | 99,99906 | 5,04 | 99,99909 |
| 6 | 5,56 | 99,99972 | 5,70 | 99,99980 |
| 7 | 5,04 | 99,99909 | 5,48 | 99,99967 |
| 8 | 5,70 | 99,99980 | 5,04 | 99,99909 |
| 9 | 5,48 | 99,99967 | 5,04 | 99,99909 |
| 10 | 7,15 | 99,99999 | No result ² | No result |
| 11 | 6,78 | 99,99998 | 6,78 | 99,99998 |

3.3.3 Temperature measurement

| Logger | Measured Maximum Temperature |
|--------|------------------------------|
| T1 | 60,55 |
| T2 | 59,89 |
| T3 | 60,46 |
| T4 | 60,66 |

¹ Log reduction is calculated with the following formula:

$$\text{Log reduction} = \log_{10} \frac{N_0}{N}$$

Where N is the amount of CFU (colony forming units) left after disinfection and N₀ the amount of CFU on the corresponding location of the positive control cushion.

² During analysis of this sample an error occurred and no result could be determined. Since this location (compartment wall) was tested twice during this run and twice during run 3 resulting in no growth after disinfection, this does not have a critical impact on the test results.

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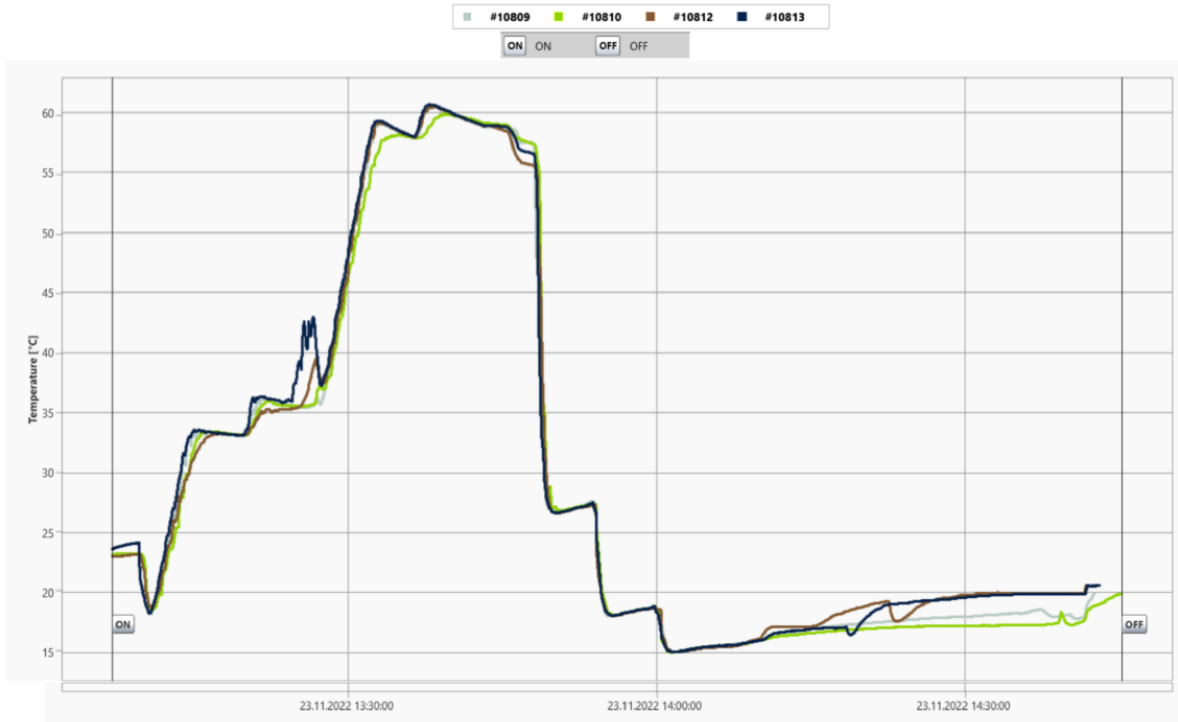


Figure 3. Temperature profile – Run 2.

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3.4 Test 3

3.4.1 Microbiological analysis

| Location ID | Microbiological Analysis (<i>Enterococcus F.</i> / mL) | | |
|-------------|---------------------------------------------------------|----------|------------------|
| | Adjuster 02 | Vicair 4 | Positive control |
| 1 | <10 | <10 | 9.800.000 |
| 2 | 70 | <10 | 16.000.000 |
| 3 | <10 | 50 | 26.000.000 |
| 4 | 80 | 90 | 33.000.000 |
| 5 | 190 | <10 | 40.000.000 |
| 6 | 1.200 | <10 | 10.000.000 |
| 7 | <10 | <10 | 720.000 |
| 8 | <10 | <10 | 700.000 |
| 9 | <10 | 500 | 560.000 |
| 10 | <10 | <10 | 37.000.000 |
| 11 | <10 | <10 | 24.000.000 |



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3.4.2 Log reduction¹

| Location ID | Log reduction | | | |
|-------------|---------------|-------------------|-------------------|-------------------|
| | Adjuster 02 | | Vicair 4 | |
| | Log reduction | Percent reduction | Log reduction | Percent reduction |
| 1 | 6,99 | 99,99999 | 6,99 | 99,99999 |
| 2 | 5,36 | 99,99956 | 7,20 | 99,99999 |
| 3 | 7,41 | 100,00000 | 5,72 | 99,99981 |
| 4 | 5,62 | 99,99976 | 5,05 | 99,99910 |
| 5 | 5,32 | 99,99953 | 7,52 | 100,00000 |
| 6 | 3,92 | 99,98800 | 7,60 | 100,00000 |
| 7 | 5,86 | 99,99986 | 5,86 | 99,99986 |
| 8 | 5,85 | 99,99986 | 5,85 | 99,99986 |
| 9 | 5,75 | 99,99982 | 3,05 ² | 99,91071 |
| 10 | 7,57 | 100,00000 | 7,57 | 100,00000 |
| 11 | 7,38 | 100,00000 | 7,38 | 100,00000 |

3.4.3 Temperature measurement

| Logger | Measured Maximum Temperature |
|--------|------------------------------|
| T1 | 60,62 |
| T2 | 60,78 |
| T3 | 60,73 |
| T4 | 60,83 |

¹ Log reduction is calculated with the following formula:

$$\text{Log reduction} = \log_{10} \frac{N_0}{N}$$

Where N is the amount of CFU (colony forming units) left after disinfection and N₀ the amount of CFU on the corresponding location of the positive control cushion.

² Because no growth was observed after analysis of the other smart cells and there is sufficient evidence that they can be properly disinfected, this analysis is not taken into account in the discussion of the results.

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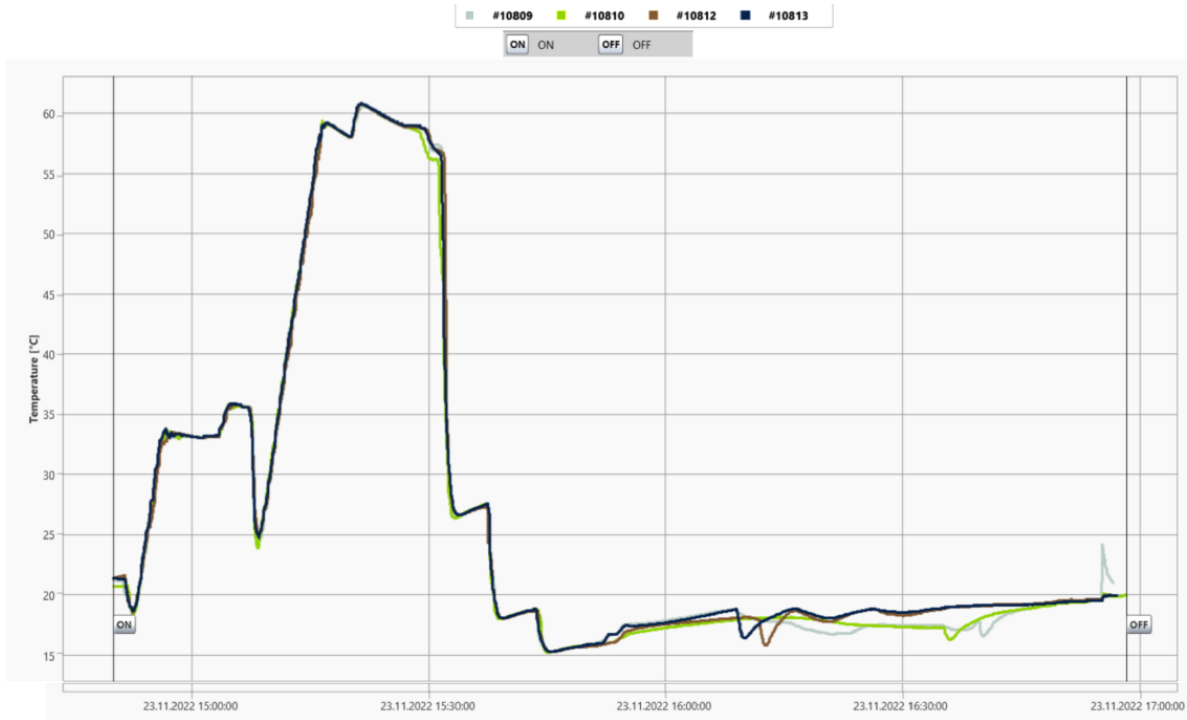


Figure 4. Temperature profile – Run 3.

4 Test Conclusion

An informal survey of several of the Vicair customers shows that a log reduction of 4 is generally considered as being sufficient for Class 1 (low risk) medical devices. Except for the zipper of the Adjuster during run 3, this reduction is achieved on every test location of all cushions during the three runs.

The open design of the cushions ensures that the water and detergent can easily reach the walls of the compartments and 'Smartcells' inside. In general it seems that the zipper and velcro (test locations 4, 5 and 6) of the Adjuster 02 and the Vector 02 cushions are the most difficult to disinfect. Here a higher number of colonies remained after disinfection.

It can also be stated that the outer material of the 'Smartcells' might have anti-microbiological properties, resulting in a lower number of colonies on the positive controls (positions 7, 8 and 9) compared to the other locations. This also has an impact on the log reduction calculation since the N_0 value is lower to start with.

Furthermore the tests suggest that there is no clear difference between the professional detergent and the common household detergent. The log reduction of all three runs was similar for all test locations. The temperature curves of the 3 tests are comparable. On average, the duration of the disinfection phase is 10 minutes with a temperature ranging between 57°C and 61°C.

These tests give a good first insight regarding the hardest to disinfect locations of the cushions and the level of microbiological reduction that can be achieved using a washing program on a common household washing machine together with laundry detergent.

5 Appendices

Appendix 1: Completed test protocol (2022_WORMVICA_WD_TP1.0)

This appendix contains 15 pages.

Appendix 2: Overview of microbiological analysis results

This appendix contains 3 pages.