

Optapad® hygiene & cleaning

Validation report with test results



VALIDATION & TESTS



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Knivsta den 4 september 2019

Table of Contents

1.	BACKGROUND	3
2.	DESCRIPTION OF OPTAPAD®	3
3.	VALIDATION REQUIREMENTS	3
4.	MEASURING METHODS AND HYGIENE THRESHOLDS.....	4
4.1	ATP MEASURING	4
4.2	MICROBIOLOGICAL ANALYSIS.....	4
5.	EXECUTION	5
5.1	CLEANING METHOD.....	5
5.2	CONTAMINATION	5
5.3	TESTING	5
6.	RESULTS & SUMMARY	6
7.	CONCLUSION	6
8.	APPENDICES	6
	APPENDIX 1: CLEANING INSTRUCTIONS OPTAPAD®.....	6
	APPENDIX 2. TEST PROTOCOL ATP.....	6
	APPENDIX 3. TEST PROTOCOL TOTAL PLATE COUNT.....	6

1. Background

Hygiene Diagnostics AB is an independent Swedish consulting firm that performs cleaning validation commissions.

2. Description of OPTAPAD®

OPTAPAD® is a touchpad manufactured by Optapad Nordic AB that can be connected to any computer of choice with a USB port. The product sports a functional design, which offers the user ergonomic benefits and an improved working environment. The touchpad is made of glass and has a soft wrist rest made from smooth polyurethane. The wrist rest is held in place with magnets and is removable for easy access during cleaning.

The product has two variants: OPTAPAD® Original and OPTAPAD® Extended (with wider and softer wrist rests).

For more information on OPTAPAD® contact:

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3. Validation requirements

OPTAPAD® can be effectively cleaned and disinfected in accordance with the cleaning instructions (Appendix 1) in order to achieve:

- A cleaning effect of at least 90% and/or an ATP level less than or equal to 500 RLU per 100 cm² in line with SS 8760014.¹
- A level for the Total Plate Count less than or equal to 500 CFU per 100 cm² in line with SS 8760014.²

¹ Swedish cleaning standard for hospitals SS 8760014:2017 (Cleaning in order to reduce the spread of infection in health care), Appendix E.

² Ibidem

4. Measuring methods and hygiene thresholds

The cleaning evaluation was carried out by measuring ATP (adenosine triphosphate) and by microbiological analysis of the total amount of aerobic bacteria on OPTAPAD®.

4.1 ATP measuring

ATP is formed in all types of living cells and is, for instance, found in microorganisms, loose skin cells, blood and food residue. This validation used the 3M ATP system Clean-Trace™ with its surface swab test to measure ATP levels on surfaces. The test results are conveyed in relative light units (RLU) and provide a measurement of the amount of cellular organic dirt. Low amounts of RLU indicate a lower risk of bacterial growth and contamination. A recommended hygiene threshold for hand touch surfaces in Swedish health facilities is 50 femtomoles of ATP per 100 cm² or lower, depending on the level of cleaning quality.³ When converted to the Clean-Trace™ system's ATP scale, this threshold is equal to 500 RLU per 100 cm².⁴

Highly contaminated hand-touch surfaces can have 3,000 – 5,000 RLU or more. To pass the hygiene threshold this requires a cleaning effect of at least 90%.

4.2 Microbiological analysis

3M Petrifilm™ agar plates with surface swabs (Swab-Sampler, 1ml) were used to measure the Total Aerobic Plate Count. The measuring unit for the analysis is colony-forming units (CFU). High levels of bacteria on cleaned surfaces indicate that the cleaning and disinfection are not sufficiently effective.

A microbiological hygiene threshold has been suggested on similar grounds as for ATP and is less than or equal to 5 CFU per cm².⁽⁵⁾

³ SS 8760014:2017, Appendix E.

⁴ The RLU-scale for the Clean-Trace™ ATP-meter utilizes 1 femtomole ATP equal to 10 RLU.

⁵ SS 8760014:2017, Appendix E.

5 Execution

5.1 Cleaning method

The cleaning of OPTAPAD® was carried out in accordance with the cleaning instruction included with the product (Appendix 1). A regular alcohol-based surface disinfecting solution (DAX Surface Disinfectant Plus™) was used which contained 45 vol% and a cleaning detergent.

5.2 Contamination

A dirty cleaning cloth was used as a source of bacteria to ensure that the control surfaces on OPTAPAD® were highly contaminated before cleaning. The dirty cloth was pressed against the control surfaces.

The dirty cloth was prepared by using it to wipe down work surfaces in a regular office. The cloth was then placed in a bowl with 30 ml of tap water and left in an incubator for 48 hours at 37°C. After the incubation the total amount of aerobic bacteria on the surface of the dirty cloth was >250 CFU/cm² (3M Dipslide). An ATP swab test pressed against the cloth gave an ATP value of 16,395 RLU.

5.3 Testing

ATP and microbiological testing were carried out by swabbing two control surfaces on the OPTAPAD® Extended: the left wrist rest (10 x 10 cm) and the whole touchpad (10 x 10 cm) (Image 1).

In order to prepare for every test round the OPTAPAD® was contaminated with the dirty cleaning cloth by pressing it against the control surfaces for a few seconds. The control surfaces were then left to air-dry for three minutes before the surfaces were swabbed, cleaned with a microfiber cloth, and then swabbed again. The same microfiber cloth was used during every test round.

Negative controls of ATP and Total Plate Count was taken by testing, but without swabbing the surfaces. ATP and microbiological analyses were performed in accordance with 3M's instructions.



Image 1. Control surfaces. A: Wrist rest left side, 10 x 10 cm. B: Touchpad including buttons, 10 x 10 cm

6 Results & summary

Hygiene thresholds for the cleaning of the OPTAPAD® were determined with the help of the Swedish standard SS 8760014. The standard is used to evaluate the quality of cleaning in health care and specifies the recommended thresholds for ATP and the Total Plate Count in order to lower the risk of infection.

Altogether, twenty test rounds with surface swabs before and after cleaning were performed. Two control surfaces were tested, each the size of 100 cm² (A: Wrist rest and B: Touchpad). In total there were 20 ATP tests and 20 microbiological analyses carried out. All test results are presented in the test protocols (Appendix 2 and 3).

The contamination level of ATP was measured to be around 4,000 RLU. The average cleaning effect was 93%. ATP levels for the control surfaces after cleaning had an average of 187 RLU for Wrist rest (Std.Dev 10 RLU) and 228 RLU for Touchpad (Std.Dev 80 RLU). All test results passed the ATP threshold of 500 RLU per control surface.

The contamination level of the Total Plate Count was calculated to be >3,000 CFU per control surface. The bacteria level after cleaning was on average 10 CFU for both control surfaces (Std.Dev 5 CFU Armrest and 9 CFU Touchpad). All test results passed the bacteria threshold of 500 CFU per control surface.

7 Conclusion

No deviations were noted during the validation. All hygiene control requirements were met in all the test rounds.

The validation has shown that OPTAPAD® hygiene design and cleaning instructions work as intended and render a cleaning result, which is in line with the Swedish standard SS 8760014.

8 Appendices

Appendix 1: Cleaning instructions OPTAPAD®

Appendix 2. Test protocol ATP

Appendix 3. Test protocol Total Plate Count

Appendix 1: Cleaning instructions OPTAPAD®

A. Materials

- Disinfecting solution with detergent in liquid or gel form with an alcohol level of at least 45 vol% but less than 70 vol%.
- Microfiber cloth.

B. Instruction

Disconnect your Optapad® before cleaning.

- 1: Spray the cleaning solution 3-4 times on the microfiber cloth.
- 2: Remove the wrist rests.
- 3: Wipe on and around the glass surface with the damp cloth.
- 4: Wipe the wrist rests with the damp cloth.
- 5: Put the wrist rests back.

Appendix 2. Test protocol ATP

Test method: Clean-Trace ATP surface test.

Negative control: 2 RLU.

ATP-values OPTAPAD® Wrist rest (Control surface A)

Round#	Before cleaning: contaminated surface (RLU/100 cm ²)	After cleaning (RLU/100 cm ²)	Cleaning effect	Validation requirements* (Pass/Fail)
1	2261	195	91.4%	Pass
2	1869	197	90.4%	Pass
3	1994	189	90.5%	Pass
4	5687	183	96.8%	Pass
5	6689	171	97.4%	Pass
Average Std.Dev.	3700 2303	187 10	93% 4%	

*ATP reduction \leq 90%, ATP value \leq 500 RLU/100 cm²

ATP-values OPTAPAD® Touchpad (Control surface B)

Round#	Before cleaning: contaminated surface (RLU/100 cm ²)	After cleaning (RLU/100 cm ²)	Cleaning effect	Validation requirements* (Pass/Fail)
6	3389	333	90.2%	Pass
7	3126	258	91.7%	Pass
8	1551	117	92.5%	Pass
9	5671	236	95.8%	Pass
10	5792	194	96.7%	Pass
Average Std.Dev.	3906 1809	228 80	93% 3%	-

*ATP reduction \leq 90%, ATP value \leq 500 RLU/100 cm²

Std.Dev = standard deviation

Appendix 3. Test protocol Total Plate Count

Test method: 3M Petrifilm rapid Aerobic Count Plate.

Cultivation in incubator 24 hours 30°C.

Negative control: 0 CFU.

Total Plate Count OPTAPAD® Wrist rest (Control surface A)

Round#	Before cleaning: contaminated control surface (CFU/100 cm ²)	After cleaning (CFU/100 cm ²)	Surface disinfectant effect	Validation requirements** (Pass/Fail)
11	TNTC*	17	>99%	Pass
12	TNTC*	14	>99%	Pass
13	TNTC*	7	>99%	Pass
14	TNTC*	9	>99%	Pass
15	TNTC*	4	>99%	Pass
Average Std.Dev.	-	10.2 5.3	-	-

*TNTC: Too numerous to Count, estimation >3 000 CFU per 100 cm²

** Approved bacteria level ≤ 500 CFU per 100 cm²

Total Plate Count OPTAPAD® Touchpad (Control surface B)

Round#	Before cleaning: contaminated control surface (CFU/100 cm ²)	After cleaning (CFU/100 cm ²)	Surface disinfectant effect	Validation requirements** (Pass/Fail)
16	TNTC*	9	>99%	Pass
17	TNTC*	6	>99%	Pass
18	TNTC*	27	>99%	Pass
19	TNTC*	5	>99%	Pass
20	TNTC*	5	>99%	Pass
Average Std.Dev.	-	10.4 9.4	-	-

*TNTC: Too numerous to Count, estimation >3 000 CFU per 100 cm²

** Approved bacteria level ≤ 500 CFU per 100 cm²

Std.Dev = standard deviation