



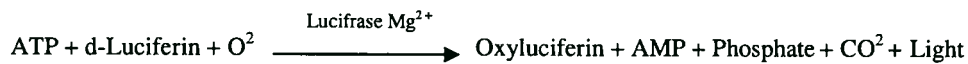
Investigation into the Effectiveness of Tristel Pre Clean Wipes at Removing Applied Soiling from an Olympus Scope Surrogate Device

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1.0 Introduction

- 1.1 The first part of the decontamination process of medical devices is the thorough cleaning of the surface of medical devices to remove any soiling prior to the instrument being put through the disinfection / sterilisation process. This study was carried out to determine the effectiveness of the Tristel Pre Clean wipes to remove soiling present on endoscopes.
- 1.2 The surrogate test device was loaded with endoscope washer disinfectant test soil as per described in the HTM 2030 guide lines section 17.34, batch number 1-267 diluted 1:10 using purified water.
- 1.3 The surrogate device was cleaned as per described in the protocol and then swabbed and analysed using the Hygiena SystemSure Plus system. This device detects residual levels of Adenosine Triphosphate (ATP) which is the universal energy molecular found in all living cells.



The above equation shows how the assay works. The reaction is based on the enzyme Luciferase from Fireflies that catalyses the reaction of Adenosine 5 Triphosphate (ATP) with d-Luciferin and oxygen to produce light which is detected by the instrument, generating a numerical value in Relative Light Units (RLU).

1 RLU is approximately equivalent to 1 fmol of ATP.

HTM 2030 guide lines state that any detection method used must be able to detect at least 2mg protein/m² the Hygiena SystemSure Plus has a detection limit of <0.2mg blood protein this is 100 times more sensitive than the traditional ninhydrin swab method.

- 1.4 The swabs used for the analysis carried out in this study supplied by Hygiena part number US2020 lot number 79409 expires 26 Aug 2010.
- 1.5 The Hygiene ATP Monitoring System was used in the default mode. Here values of 0 – 10 are considered to be “clean” values of 11 – 29 indicate the surface has not been adequately cleaned. Values of 30 or greater indicate the surface is “dirty”.
- 1.6 The surrogate device consisted of a section of an Olympus scope.

2.0 Results

- 2.1 Before any swabbing took place the surrogate device was visually inspected and photographed to record the appearance.
- 2.2 Prior to any work being performed using the surrogate device it was initially cleaned using isopropanol wipes to remove any residual dirt or grease from the surface, it was then allowed to air dry. Once dry it was wiped down using purified water to remove any residue from the isopropanol wipes.
- 2.3 The surrogate device was then photographed to show the initial clean state of the surface of the surrogate device. See the following page for the images.



The above images show the condition of the surrogate device before the study was commenced but after the initial cleaning had taken place. The second image shows a more detailed view.

2.4 The table below shows the results from the swabbed and tested cleaned surrogate device prior to any further work being carried out. The surrogate device has the following dimensions diameter 1.3cm and a length of 89cm, thus having a total surface area of 181.7cm. 2cm lengths of the surrogate device were swabbed and analysed (total surface area 4.08cm) along the length of the surrogate device to gain information on the back ground noise from the surface material.

	RLU Value	Average RLU
Swab 1	2	2.5
Swab 2	2	
Swab 3	3	
Swab 4	3	

2.5 The back ground noise level from the wipes themselves was also determined. This allowed the amount of residual protein left behind by the wipes themselves to be determined; all values are in RLU's.

2.5.1 The surrogate device was allowed to air dry prior to being swabbed.

Time Sampled	Replicate 1	Replicate 2	Replicate 3
5 minutes	1	2	1
10 minutes	1	0	1
20 minutes	3	2	3

As can be seen the Tristel Pre Clean Wipes alone have given similar RLU values to the cleaned unsoiled surrogate device.

2.6

2.6.2 The following image shows the surrogate device post wiping. As can be seen there is no visible soiling remaining on the surrogate device (the test soil having a red colouration).



2.7 The following results show the RLU values observed for the 1:10 diluted test soil load of the surrogate device. To produce the soiling 1mL of stock soil and 9mL of purified water were mixed together to generate the stock soiling. The soiling was applied to the surface of the surrogate device using a brush ensuring an even coating to the surface of the surrogate device this was then allowed to air dry vertically for 30 minutes before being wiped clean using a single Pre Clean Wipe.

Time Sampled	Replicate 1	Replicate 2	Replicate 3	Average
5 minutes	4	0	0	1.3
10 minutes	8	5	0	4.3
20 minutes	1	1	1	1.0
30 minutes	5	8	4	5.7
1 hour	3	3	1	2.3
1 ½ hours	3	4	1	2.7
2 hours	3	3	1	2.3
2 ½ hours	4	2	3	6.0
3 hours	6	11	1	6.0

2.7.1 As can be seen from the results above the single Pre Clean Wipe has removed effectively the applied soiling, with all bar one value being above the threshold of 10 RLU indicating the surrogate device can be classified as “clean”.

2.7.2 The low RLU values also show that the Pre Clean Wipes do not leave any residual protein on the surface of the surrogate device.

3. Conclusion

- 3.1 The Tristel Pre Clean wipes are effective at removing visible soiling from the surrogate device.
- 3.2 The Tristel Pre Clean wipe has reduced the residual soiling (protein) levels present on the surrogate device to expectable levels and would meet the acceptance criteria as stated by the System Sure Plus system and could be classified as being “Clean”.

Appendix 1

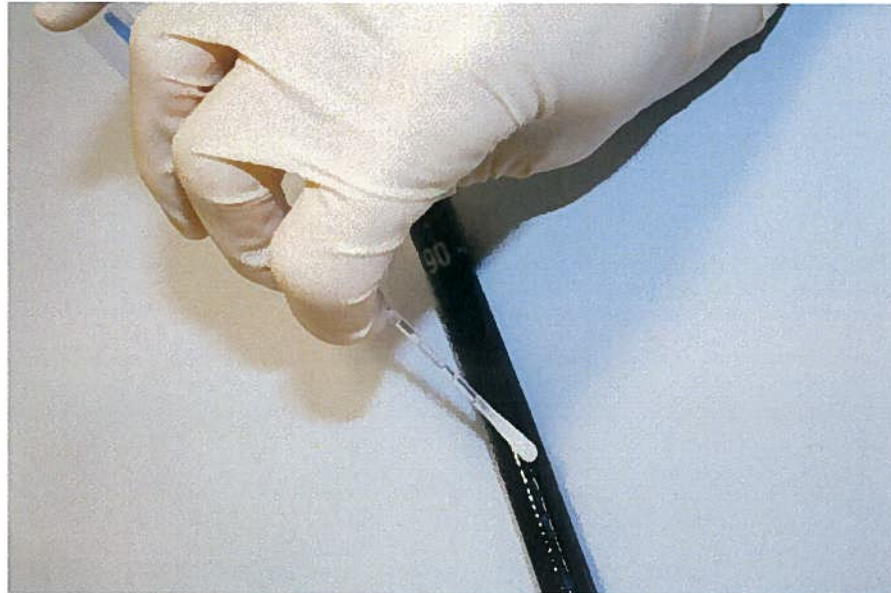
The image below shows the Tristel Pre Clean wipes used, lot number 9174 expires June 2012.



The following image shows the Hygiena SystemSure Plus and an example swab used within the study.



The below image shows how the swabs were taken, all the surface of the swab was used to collect any residual soiling present on the surface of the surrogate device.



The above shows the certificate supplied by the manufacture for the System Sure Plus system