2022

Uv-Smart research report

ETZ - OUTPATIENT CLINIC ENT - INFECTION PREVENTION
DEPARTMENT LOCATION ELISABETH
KIM VAN DEN BERG, INFECTION PREVENTION EXPERT

Research report UV-Smart, ENT scopes
ETZ, location Elisabeth

Introduction

At the end of 2020, the organizational head of the ENT specialism of the ETZ indicated the wish to disinfect ENT scopes by means of UV disinfection in the UV Smart (UVC light). To date, no cleaning and disinfection method is carried out for used ENT scopes within the ETZ that complies with national guidelines.

The Infection Prevention Department was asked to look into the safe use of the UV Smart disinfection device, which is new to the ETZ. Determining and minimizing the risk of infection for the patient is one of the tasks of the Expert Scopes Cleaning and Disinfection (DSRD). This is the infection prevention expert in the ETZ with a focus area "Flexible endoscopes".

During a consultation between the manufacturer of UV Smart, Medical Technology, ENT doctor, organizational head of ENT, Purchasing and Infection Prevention, it was decided to organize a trial placement of the UV Smart, during which it was assessed whether the UV Smart disinfection method is a safe method. Within a trial period of 13 days, the used ENT scopes were manually cleaned and disinfected in the UV Smart in an unambiguous manner.

The DSRD has obtained information about the method of cleaning based on data from the manufacturer of the ENT scopes. From the manufacturer of UV Smart, information about disinfection of the ENT scope has been shared.

Based on the above data, the following research question has been defined:

Does the method of cleaning specific to ENT scopes in combination with disinfection in the UV Smart lead to a disinfected ENT scope that can be used responsibly for safe patient care in the field of Infection Prevention?

In order to arrive at an answer to the research question, the Infection Prevention Department, together with the ENT specialism, has chosen to carry out the UV Smart disinfection method under controlled conditions within the ENT department in the ETZ, for a fixed period of time. How this has been achieved is described below under "method".

The objective of the research is to collect data on the quality of the cleaning and disinfection of ENT scopes in order to be able to give advice to entrenchment specialists based on the results on whether or not UV Smart disinfection method for ENT scopes in the ETZ can be safely used .

Method

Below is an overview of the activities / interventions.

Preparation

During the preparation, the manufacturer of the ENT scopes, the company Pentax, shared a cleaning protocol with the DSRD about the method of cleaning OF ENT scope after the examination of the patient. The theoretical information from Pentax's regulations has been approved by the DSRD as a method for employees of specialism ENT during the period of the test placement. See Annex A for the requirements.

The manufacturer of the UV Smart has explained the instructions for use and operation of the UV Smart.

After the manual cleaning of the ENT scope and the disinfection process in the UV Smart, the ENT scopes are still offered to the Central Scopes Cleaning and Disinfection (CSR), since the UV Smart process is not yet validated and approved.

Use ENT scopes in patient care

In order to be able to monitor the quality of cleaning and disinfection at the ENT scopes, after use in a patient, a number of measurement methods have been defined. These measurement methods were carried out during this research after the cleaning and disinfection process.

It concerns the following methods:

ATP meting

After each use of the ENT scope in the patient, 2 ATP measurements were performed;

- Immediately after the examination of the patient
- After the manual cleaning of the ENT scope

By means of an ATP measurement, organic contamination on surfaces is measured with .b.v. a surface swab) of the outside of the scope.

IN addition to microbiological cultures of the ENT scope, ATP measurements have been used as an additional measurement and provide additional information about the degree of contamination of the ENT scope immediately after use and after cleaning. The result is expressed in Relative Light Units (RLU).

The standard for a manually cleaned object or surface is defined in the ETZ as follows:

●	RLU <1000	= schoon
●	RLU ≥1000 en < 3000	= intermediair
●	RLU ≥3000 en < 10.000	= vuil
●	RLU ≥ 10.000	= extreem vuil

Within this research, it was decided, in consultation with the manufacturer of UV Smart, not to carry out ATP measurements after the disinfection process in the UV Smart. The reason for this is that uv disinfection (UVC light) does not remove proteins, so no microorganisms are removed, but is rendered harmless.
With an ATP measurement, these proteins would then still be measured after disinfection.

See Appendix C for the procedure of performing an ATP surface measurement at ENT scopes.

A total of 26 ATP measurements were made of the ENT scopes during the period of the trial placement, immediately after use with the patient. After cleaning, 26 ATP measurements were also carried out.

Microbiological cultures

According to the specific method below, microbiological cultures have been taken from the patient after each use of the ENT scope.

Method of growing collection:

When taking the cultures, the employee wears unsterile examination gloves and a surgical mouth-nose mask type IIR.

1. For the purpose of taking a culture of an ENT Scoop, a sterile gauze was completely moistened with NaCl 0.9%. With this mesh, the flexible part of the ENT scope was removed, rubbing three consecutive times with the same mesh from the wheelhouse to the tip of the scope. With the mesh, the control buttons on the wheelhouse and the wheelhouse itself were first removed, after which the tip was removed with the mesh around the shaft of the scope.
2. The gauze was immediately placed in a container containing 15 ml of liquid Tryptic Soy Broth (TSB broth).
3. The cultivation (TSB broth with gauze) was started after collection and developed by Microvida, Department of Bacteriology.
    a. The culture was pretexted after which 20µl was inoculated.m by the InoqulA on a blood agar plate.
    b. The blood agar plate was incubated for 48 hours at 35°C in the incubator.
    c. During the incubation period, after 24 hours and 48 hours, it was assessed whether microorganisms had grown on the blood agar plate.
        i. When microorganisms grow, these were determined with the Maldi-TOF and the result was then passed on to the Infection Prevention Department.
        ii. In case of no growth of microorganisms after 48 hours, the result was passed as "no growth" to the Infection Prevention Department.

The standard for microbiological cultures is <1000 CFU micro-organisms per liter, in accordance with ETZ policy. At the end of the UV Smart disinfection process, a microbiological culture was taken 15 times.

Results

Microbiological cultures

Microbiological growth has not been demonstrated in any culture in this study. In all cases, the ENT scopes (used in the patient) were free of microorganisms after the disinfection process in the UV Smart.

ATP metingen

Overall, the results of the ATP measurements show that the RLU values after cleaning are much lower than the RLU values immediately after use with the patient. By cleaning, there is a significant reduction in the RLU value.

In Figure 1 the results of the ATP measurements (in RLU) are shown graphically; immediately after use with the patient and after manual cleaning according to Pentax regulations.

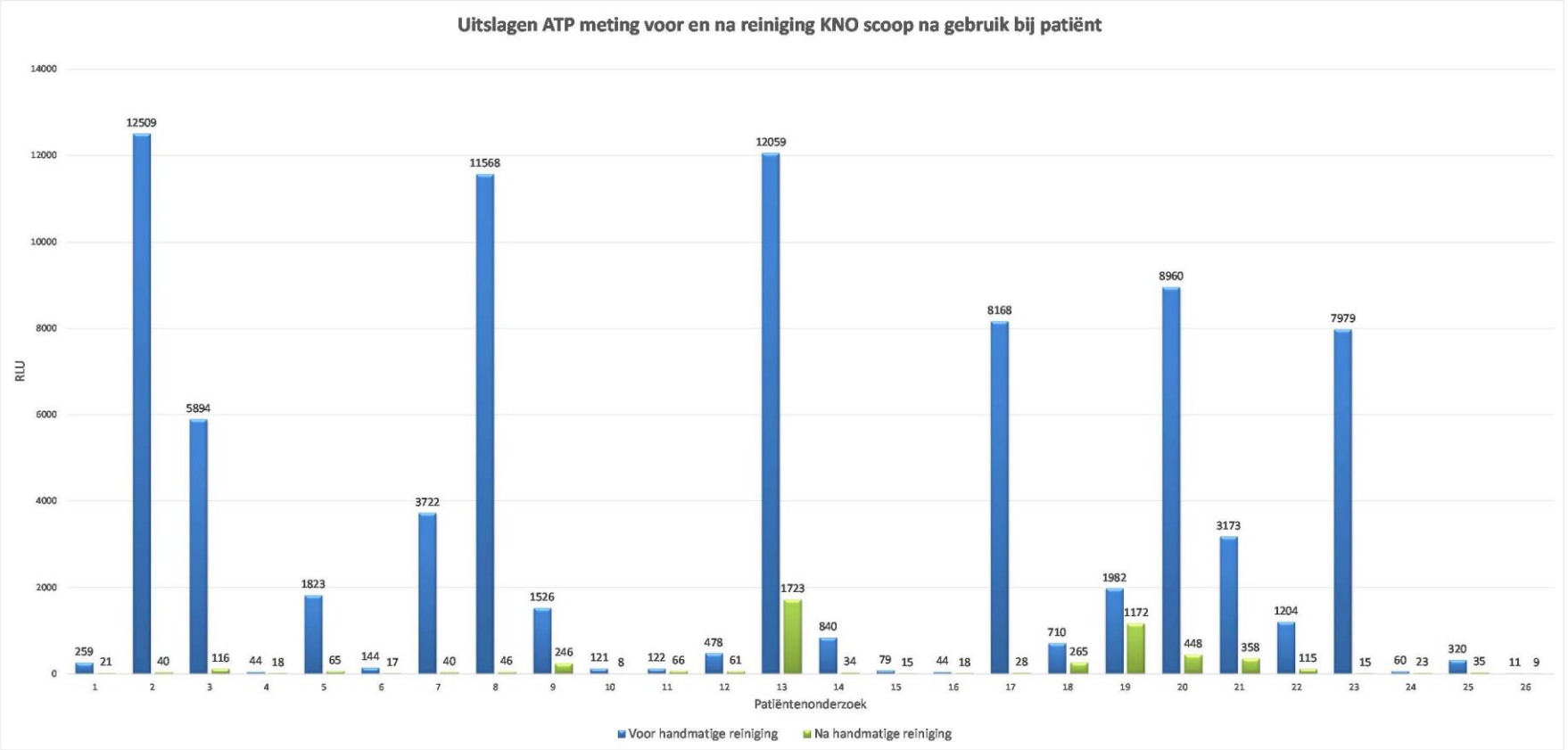


Figure 1: RLU values of ENT scopes after immediate use with the patient and after cleaning

FromofdispersionfromofreinigingsresultatenisShownthatheinsidethisresearchbarelyto nonecorrelationisShownbetweenofmate frompollutionfromofscoopdirectonusebeethe patientinhow"Clean"ofscooponcleaningisbecome.Oncleaningis,in24fromof26 cases, theRLUvalue<500RLU,regardlesshowdirtythiswasdirectonitresearch.Thisisspaciousunderthe standard from<1000 RLU before Cleaned objects. This is visible in Figure 2, See hereunder.

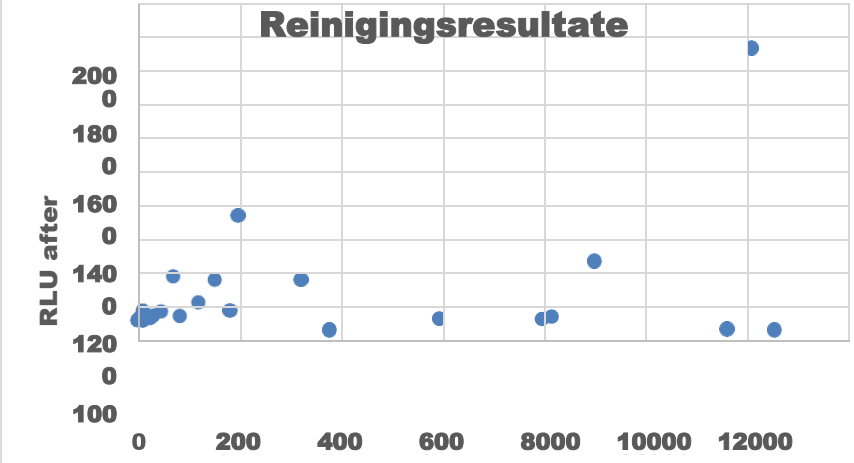


Figure 2: cleaning results ENT scopes

Discussion

In carrying out this research, a number of remarkable points can be mentioned.

Due to the relatively short period of the test placement of the UV Smart, the number of measurements is limited. As a result, the research is small in size. In order to be able to achieve a good comparison of the results, it is preferable to be able to measure for a longer period of time and to collect more data in this way.

During the time of this research, the UV Smart disinfection device has not yet been assigned CE marking by a notified body. This CE marking is necessary for the legal application of the UVC disinfection method d.m.v. the UV Smart. However, since 4-apr-2022 the D60 has received it's CE-mark.

The ETZ will wait with the actual application of the UV Smart disinfection method for ENT scopes until the CE marking has been formally granted. This is expected by the manufacturer to be realized in the course of 2022.

If ent specialism, based on the conclusion of this research, opts for disinfection by means of UV Smart in the future, it should be investigated whether periodic cleaning and disinfection of ENT scopes by the department "Central Scopes Cleaning and disinfection" is still necessary, in addition to the UV Smart disinfection method. The DSRD will consult national and/or ENT guidelines and investigate what is advised about this.

Conclusion

The aim of this research was to investigate whether the method of cleaning specific to ENT scopes in combination with disinfection in the UV Smart leads to a disinfected ENT scope, which can be used responsibly for safe patient care in the field of Infection Prevention.

The results showed that no microbiological growth was detected once after the manual cleaning and the mechanical disinfection process in the UV Smart.
This shows that the quality of the cleaning and disinfection process carried out is good.

Furthermore, the additional information from the results of the ATP measurements carried out shows that manual cleaning prior to the disinfection process is necessary. In all cases, a significant reduction in pollution was achieved through cleaning. In 24 of the 26 cases, the RLU values after cleaning were well below the standard of 1000 RLU for a cleaned object.

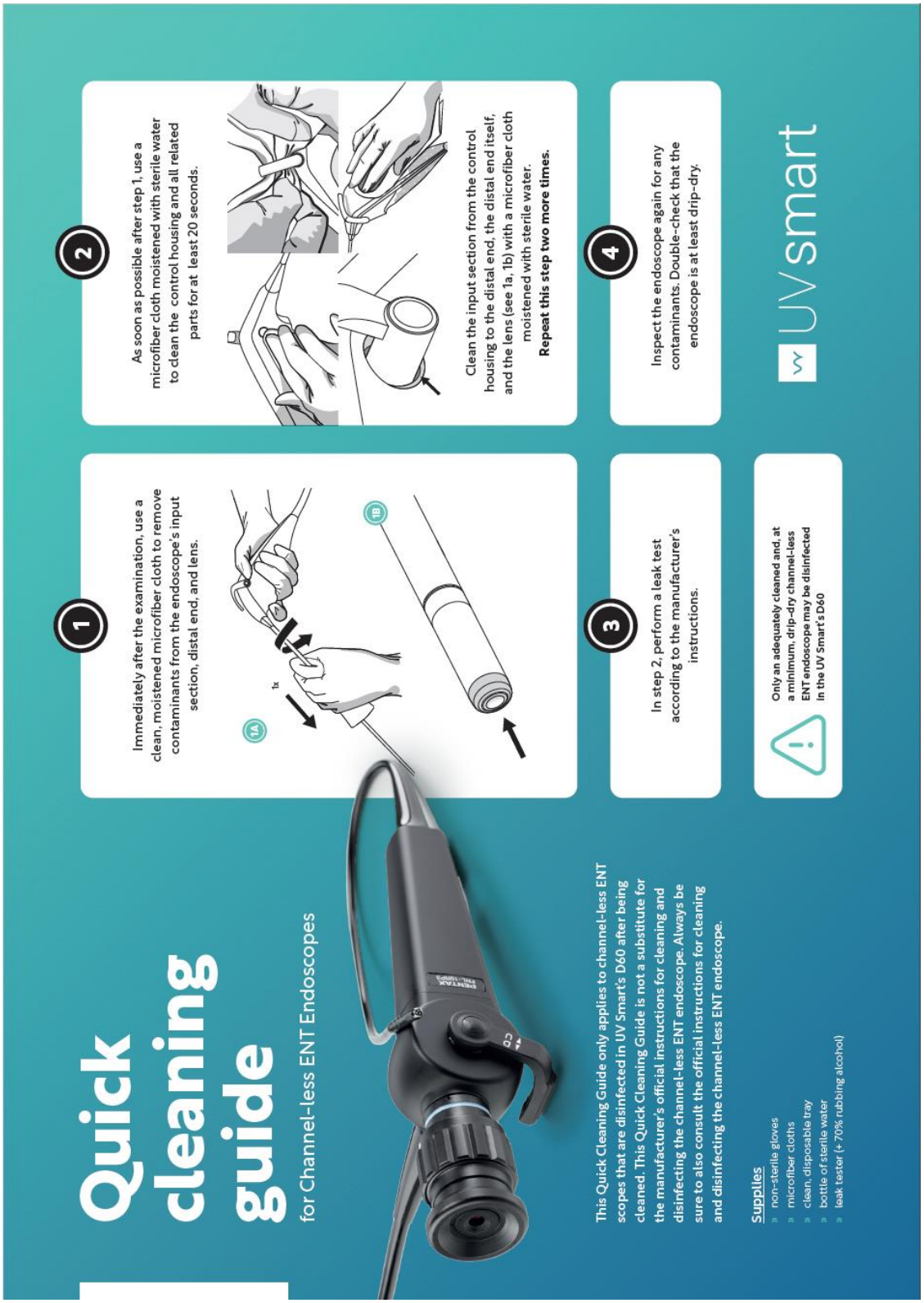
The conclusion is therefore that the disinfection method with the UV Smart, if combined with a thorough manual cleaning of the ENT scopes, can be safely used in patient care by the ENT specialty.

The UV disinfection method is only effective if the ENT scope is manually cleaned according to instructions after each use. Cleaning is, as can be seen in the results of the ATP measurements carried out, the most important step in the reduction of organic pollution and microorganisms.

The ent specialism will have to describe the cleaning instructions of manufacturer Pentax in an ETZ procedure, which will be assessed by the DSRD.
If manual cleaning of the ENT scope is not carried out or is not carried out consistently after use, the entire surface of the scope cannot be reached properly by the UVC light due to the organic contamination. Disinfection cannot then take place optimally, resulting in a scope that cannot be safely used in patient care.

In the future, the ATP measurements and microbiological cultures will be continued when using the UV Smart, according to a periodic schedule to be determined. In this way, the quality of the cleaning and disinfection process is monitored and patient safety is guaranteed.

Appendix A "Cleaning protocol" company Pentax.



Appendix B – Data ATP measurements and microbiological cultures

breeding NR	Date	Scoopnummer	ATP for cleaning in RLU	ATP na reiniging in RLU	Reduction RLU	Culture after UV disinfection	Micro-organisms
1	6-4-2021	402832-1	259	21	92%	And	No growth
2	6-4-2021	402832-5	12509	40	100%	And	No growth
3	6-4-2021	402832-4	5894	116	98%	And	No growth
4	7-4-2021	402832-3	44	18	59%	And	No growth
5	12-4-2021	402833-2	1823	65	96%	And	No growth
6	12-4-2021	402832-4	144	17	88%	And	No growth
7	12-4-2021	402832-5	3722	40	99%	And	No growth
1	13-4-2021	402832-5	11568	46	100%	And	No growth
2	13-4-2021	402832-3	1526	246	84%	And	No growth
3	13-4-2021	402832-1	121	8	93%	And	No growth
4	13-4-2021	402832-4	122	66	46%	And	No growth
12	15-4-2021	402832-4	478	61	87%	And	No growth
13	15-4-2021	402832-5	12059	1723	86%	And	No growth
14	15-4-2021	402832-3	840	34	96%	And	No growth
15	15-4-2021	402832-2	79	15	81%	And	No growth
16		402832-3	44	18	59%		
17		402832-5	8168	28	100%		
18		402832-1	710	265	63%		
19		402833-2	1982	1172	41%		
20		402832-2	8960	448	95%		
		402832-1	3173	358	89%		
Individual ATP measurements		402832-5	1204	115	90%		
	7-4-2021	402832-2	7979	15	100%		
	8-4-2021	402832-4	60	23	62%		
	8-4-2021	402832-5	320	35	89%		
	8-4-2021	402832-1	11	9	18%		
	8-4-2021						
	9-4-2021						
	9-4-2021						
	13-4-2021						
	16-4-2021						
	16-4-2021						
	16-4-2021						

Appendix C - Method ATP surface measurement at ENT scopes

Check in advance whether the battery of the ATP meter is sufficiently charged and there are enough swabs.

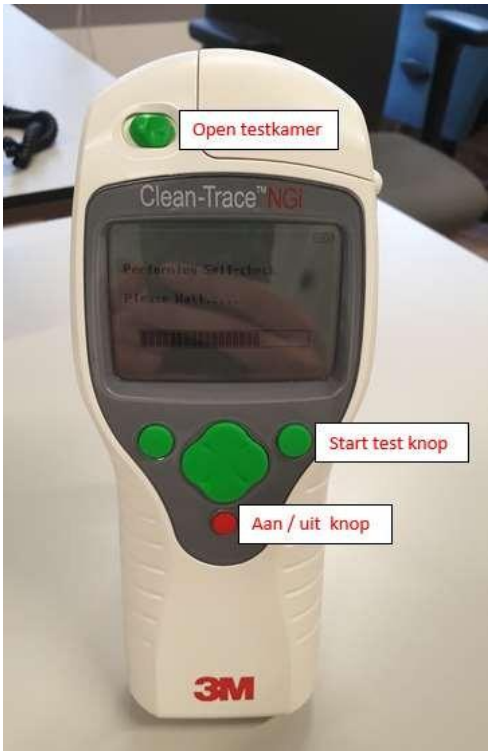


Figure 3: ATP meter

- Zet de ATP meter aan door de AAN/UIT knop (rode knop) dri e seconden ingedrukt te huuden.
- Make sure the cotton swab is at room temperature at least ten minutes before use and turn on the ATP meter.
- Remove the cotton swab from the package immediately before use. Make sure it does not become contaminated beforehand.
- Move the cotton swab over the surface test area:
    - Entire flexible part of the scope (shaft, NOT the wheelhouse).
    - Rub with sufficient pressure from left to right and at the same time turn the cotton swab around.
- Place the cotton swab back in the package and press until the top of the cotton swab is the same as the top of the package.
- Shake the package with cotton swab quickly, for at least 5 seconds, from left to right to mix the sample with the reagent (Luciferase).
- Immediately afterwards open the measuring chamber of the ATP meter, place the package with cotton swab in the measuring chamber with the cap facing up. Place the ATP meter VERTICALLY in the corresponding

standard on a flat surface.

- Close the measuring chamber and then press the right round green button on the control panel.
- The result in RLU appears on the screen.
- Remove the package with cotton swab immediately afterwards. (Do not leave behind, leakage risk).

The ATP meter is fully charged in 2 hours. (indicator at the top right of the screen).