SystemSURE Plus
ATP Cleaning Verification System

System Implementation Guide

Contents

This guide is designed to assist users in setting up and operating an ATP cleaning verification program using the SystemSURE Plus within healthcare facilities. For instructions on how to operate the SystemSURE Plus ATP Cleaning Verification System please reference the Operators Manual included with the system.

The contents of this guide include:

The SystemSURE Plus ATP Cleaning Verification System

Hygiena's SystemSURE Plus ATP Cleaning Verification System is a tool used to monitor and improve the cleanliness levels of surfaces in healthcare facilities. Additionally the system acts as a tool to educate cleaning staff and other hospital personnel on proper cleaning techniques for terminal cleaning. The Centers for Disease Control and Prevention (CDC) encourages all hospitals to develop preventative programs to optimize and monitor the thoroughness of high touch surface cleaning*. With the SystemSURE Plus ATP Cleaning Verification System hospitals can standardize the assessment of surface cleaning throughout one or multiple facilities and monitor cleaning on a continuous basis.

The SystemSURE Plus ATP Cleaning Verification System enables healthcare organizations to:

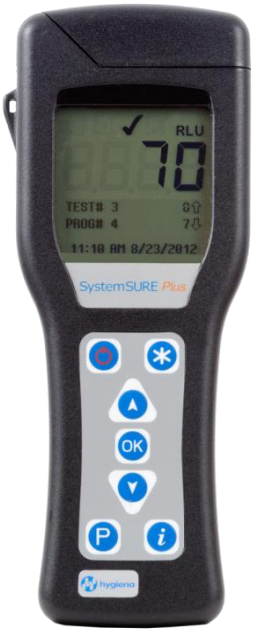
- Instantly assess the cleanliness of surfaces, allowing immediate corrective action to be taken
- Reduce or eliminate variation in surface cleaning performance by standardizing acceptable cleaning levels
- Improve and enhance the training of cleaning personnel
- Provide insight into whether current cleaning processes and tools are sufficient or below adequate
- Reduce the use of conventional microbiological testing methods that are slow, labor intensive, and costly
- Record and track test results to identify problem areas, make improvements, and show due diligence to auditors and compliance with regulations
- Enhance environmental cleaning programs which helps to prevent the spread of harmful bacteria and viruses that are associated with healthcare associated infections
- Ensure patient safety and increase patient satisfaction

Using Hygiena's SystemSURE Plus Cleaning Verification System, healthcare facilities are able to create a standard by which to measure cleaning effectiveness.

*http://www.cdc.gov/HAI/toolkits/Evaluating-Environmental-Cleaning.html

Components of the SystemSURE Plus ATP Cleaning Verification System

The SystemSURE Plus ATP Cleaning Verification System includes three components:



SystemSURE Plus Luminometer – a user-friendly, handheld, light-reading unit that provides precise, on-site test results. Used with the UltraSnap testing device, extremely low levels of contamination can be detected in just 15 seconds. (Catalog # SS3)

UltraSnap Testing Device – a convenient, all-in-one ATP test device. Simply swab, snap and squeeze and the test is ready to be measured in the SystemSURE Plus. Packaged 100 tests per box. (Catalog # US2020)

SureTrend Data Analysis Software – a powerful software program that allows users to upload test results to a database, analyze trends and generate reports for management and record-keeping. (Catalog # DS201)

Hygiena's luminometer, testing devices and software are designed to be easy-to-use enabling both technical and non-technical staff to operate the SystemSURE Plus.

Section I: Overview of SystemSURE Plus ATP Cleaning Verification System

The SystemSURE Plus ATP Cleaning Verification System is a rapid cleaning monitoring system used to help hospitals and other healthcare organizations achieve optimal standardized cleaning levels. The SystemSURE Plus ATP Cleaning Verification System uses bioluminescence technology to identify and measure **adenosine triphosphate**, commonly known as **ATP.**

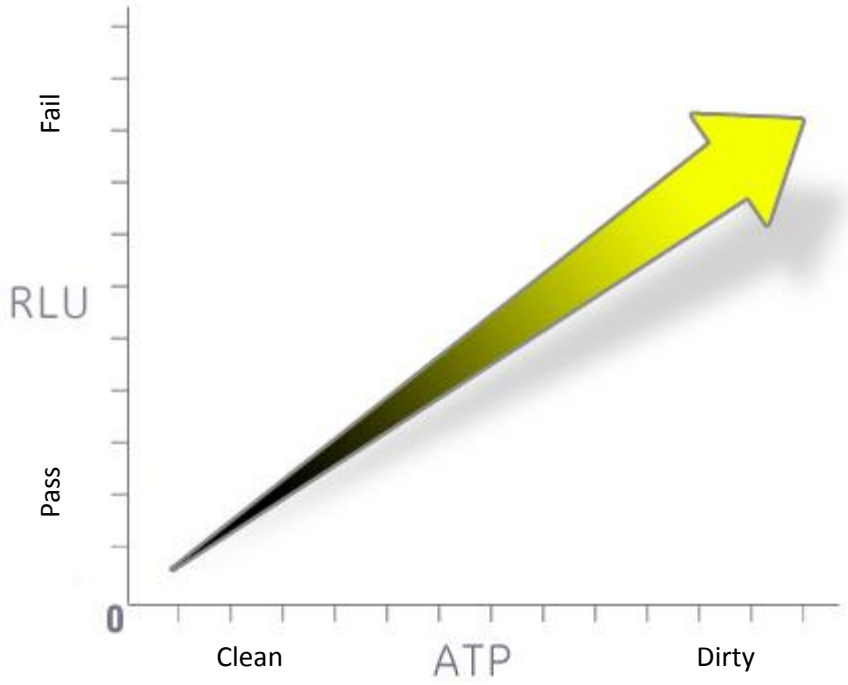
1.1 What is ATP?

ATP is an energy molecule found in all living cells that allows cellular metabolism to take place. All organic matter contains ATP, including blood, saliva, and bacteria. In healthcare facilities, organic matter such as bodily fluids, blood and specific bacteria left on surfaces can become a point of cross contamination between patients and staff leading to infections if not properly cleaned. Therefore the detection of ATP on a surface after cleaning is an indication of improper cleaning and that bacteria or bioburden that can support bacterial growth is still present on the surface.

1.2 Measuring ATP with Bioluminescence Technology

UltraSnap ATP surface tests contain an enzyme called luciferase which produces a bioluminescence (light-producing) reaction when it comes into contact with ATP. Using bioluminescence technology, the SystemSURE Plus luminometer can measure low levels of ATP collected with the UltraSnap test device.

ATP presence and RLU measured



Measuring the amount of light produced by the ATP reaction provides a good indication of surface cleanliness because the quantity of light generated by the reaction is directly proportional to the amount of ATP present in the sample. The bioluminescence reaction is immediate, allowing results to be processed in real-time. Results are then expressed numerically on the SystemSURE Plus screen as Relative Light Units (**RLU**).

1.3 Additional Uses of SystemSURE Plus

In addition to routine ATP cleaning verification in environmental service departments, the SystemSURE Plus ATP Cleaning Verification System can be used for:

Central/Sterile Services – Used for verifying the cleanliness of flexible endoscopes and other reusable medical devices. Improper cleaning of equipment before sterilization can lead to non-sterile equipment.

Food Service/Cafeteria Food Safety – Can be used to verify food preparation surfaces have been cleaned properly.

Training – An effective tool for teaching new staff proper cleaning procedures.

Hand Hygiene Compliance – Can be used to measure levels of ATP present on personnel's hands before and after hand washing to demonstrate efficacy and thoroughness of hand washing efforts.

For more information on implementing the SystemSURE Plus in these areas, visit www.hygiena.com/healthcare

SECTION 2: Implementing an ATP Cleaning Verification System

2.1 Establishing Test Locations and Limits

Before testing begins, it is necessary to identify areas within the facility that will be tested and establish appropriate Pass/Fail limits for each location. The CDC provides a list of recommended locations to test in hospitals *(see exhibit 1.0 on page 22)*. Locations typically tested are high touch point surfaces where the chance of spreading infectious bacteria is high. Monitoring of low risk surfaces on a less frequent basis is also essential to verifying the facility is being thoroughly cleaned. Prepare the list of locations on a piece of paper or Microsoft Excel worksheet. (*For a spreadsheet of test locations typical for health care facilities, contact 1-888-HYGIENA or visit www.hygiena.com*)

Once locations to be tested have been identified, Pass/Fail limits for each location can be established by assigning the locations to broad risk categories (listed on page 23) or by collecting samples. **Before collecting initial samples, it is essential to master proper sampling procedure as detailed on page 24.**

There are three ways to determine custom limits for locations:

1. Standard Deviation Method

Implementation Time: 2-4 weeks
Complexity: Moderate

The SystemSURE Plus comes with a preset Upper Limit of 30 RLU and Lower Limit of 10 RLU. These limits are based on actual limits used in sterile services departments of healthcare facilities. They are a starting point from which custom limits can be refined depending on initial results.

Pass	<10 RLU
Caution	11-29 RLU
Fail	>30 RLU

Over a 2-4 week period sample each location a minimum of 10 times after cleaning. If locations are the same from room to room, it is acceptable to test the same location from different rooms. Record RLU measurements on a spreadsheet (Example 1).

Example 1:

Tests	1	2	3	4	5	6	7	8	9	10
Location	**RLU measurement**									
Bedrail	48	49	50	38	38	35	73	118	36	15
IV Pole	10	25	67	35	8	5	50	47	32	24
Bedside Table	45	27	0	2	51	5	0	2	10	6
Remote	112	215	78	45	89	86	95	148	62	71
Panel	0	0	10	9	15	12	0	10	5	5

Once the data points have been collected, Pass/Caution/Fail limits can be customized for each test location. To determine the lower (Pass) limit of each location, calculate the average RLU score from the samples collected.

Note: If the average RLU is less than 10, add one standard deviation to the average. If the average RLU is 0, use system defaults of 10 (pass) and 30 (fail).

To determine the upper (Fail) limit, calculate the standard deviation of the samples collected and multiply by 3.* Add that value to the average. Statistically, this calculation indicates with 99.6% confidence that any RLU reading above this level is an indication of failure to properly clean that area.

(Data from Example 1)

Location	Average	Ave+ (3 * Standard Deviation)
Bedrail	50	134
IV Pole	30	91
Bedside Table	15	73
Remote	100	248
Panel	~~7~~ 12**	23

*For calculations using Microsoft Excel:

- For lower limit (Pass), use the function "=AVERAGE"
- **If Average is below 10, use the function "=STDEV" and add to "=AVERAGE"
- For upper limit (Fail) use the function "=3*STDEV and add to "=AVERAGE"

The range between the Pass and Fail values is the Caution range. Thus, for Example 1 data, the limits for the locations using the standard deviation method are as follows:

Location	Pass	Caution	Fail
Bedrail	50	51-133	134
IV Pole	30	31-90	91
Bedside Table	15	16-72	73
Remote	100	101-247	248
Panel	12	13-22	23

This option could give different Pass, Caution and Fail levels for each location. This is typical when different surface types (plastic, stainless steel, etc) are being tested and when the age of equipment varies.

2. **Band Method**

Implementation Time: 2-4 weeks
Complexity: Moderate

The Band Method categorizes results into different limit bands.

Band	Pass	Caution	Fail
4	150	151-299	300
3	100	101-199	200
2	50	51-99	100
1	25	26-49	50

Collect results the same way as in the Standard Deviation method (see page 7).
To determine the band that is most appropriate for the test point, calculate where 80% of the results fall.

E.g. if 80% or more of the results collected for a given test point are below 100 RLU, band 3 would be the appropriate band for this location. Here is an example applying results from Example 1.

Location	**Total Samples**	**<150 Band 4**	**<100 Band 3**	**<50 Band 2**	**<25 Band 1**
Bedrail	10	100%	90%	70%	10%
IV Pole	10	100%	100%	80%	40%
Bedside Table	10	100%	100%	90%	70%
Remote	10	90%	70%	10%	0%
Panel	10	100%	100%	100%	100%

Test Points	**Band**
Bedrail	3
IV Pole	2
Bedside Table	2
Remote	4
Panel	1
Overall (Average)	**2**

2. **Simple Clean Method**
   Implementation Time: 1-2 days
   Complexity: Easy

   With this method, the manager overseeing the ATP cleaning verification program should clean each location that will be tested the way the manager wants the location to be cleaned each time. Ten samples should be taken from the same locations in different rooms to ensure that no site is tested more than once. For example, the light switches in ten different rooms could be sampled after the cleaning of these sites. Testing the same location, but in different rooms is acceptable. Input the results into the Standard Deviation Method to calculate upper and lower limits for each location (see page 7).

   If the average for a location is "0 RLU" then the limits should be set to the system defaults of 10 RLU for Pass and 30 RLU for Fail. Occasionally blank UltraSnap devices may emit up to 2 RLU of naturally occurring light. A pass limit of 10 RLU is a reasonable sensitivity for hospital surfaces and equipment.

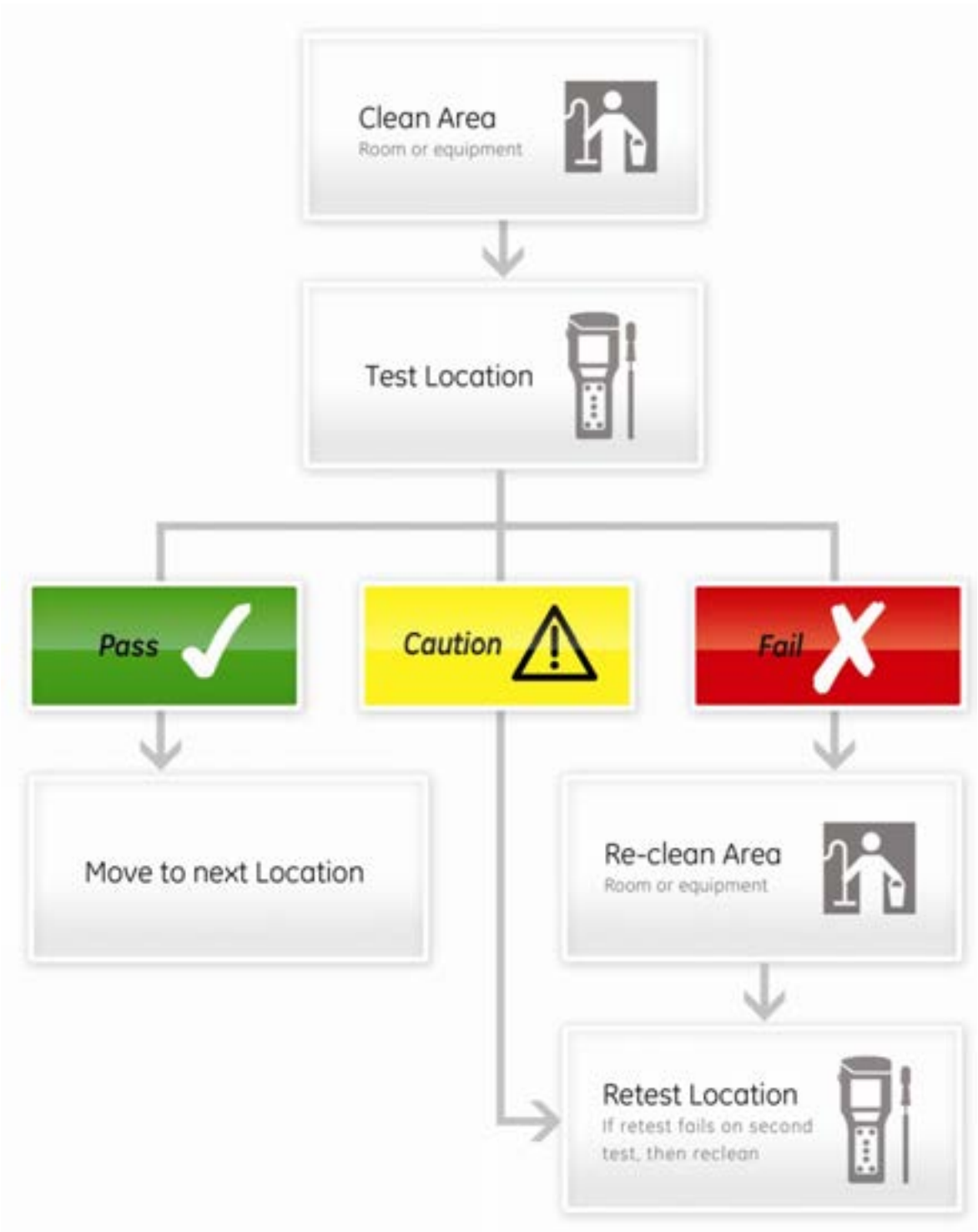
2.2 Corrective Action Procedures

Corrective action procedures provide clear instructions for what steps should be taken following Pass, Caution, or Fail results.

Recommended corrective action procedures are as follows:

ATP TEST RESULT	CORRECTIVE ACTION
✓ ***(Pass)***	The surface has been adequately cleaned.
! ***(Caution)***	The surface may not have been adequately cleaned. You may choose to proceed to the next test or have the area re-cleaned and re-tested. A control point with a *Caution* reading should be noted and monitored for future problems.
✗ ***(Fail)***	The surface has not been cleaned to the cleaning standard and must be cleaned again and re-tested.

2.3 Suggested Cleaning, Testing, and Corrective Action Procedure Flowchart



2.4 Programming Location Pass/Fail Limits into Software

Once the locations have been identified and the limits determined, they must be entered into the SureTrend software and synced with the SystemSURE Plus luminometer.

For instructions on how to install SureTrend software and add locations see the installation guide and manual included with the SureTrend CD. See section 8.3 in the SureTrend User Manual for steps on entering locations and limits.

If you would like assistance programming locations and limits in the SureTrend software, please contact your Hygiena representative.

By default the SureTrend software assigns a Lower limit of 10 and an Upper limit of 30 when you add a new location. Assign the correct limits to each location based on the processes used in Section 2.1.

Group information can also be entered at this time. Group information is used for grouping locations together for reporting purposes. For example, groups can allow users to compare the performance of departments, wings, or facilities.

Below is an example of the location setup in SureTrend software.

Prog #	Location	Group	Lower	Upper
1	Bedrail – East	St. Jude - East	50	100
2	Remote Control - East	St. Jude – East	25	50
3	Sink – East	St. Jude - East	15	30
4	Bedrail - West	St. Jude – West	50	100
5	Remote Control - West	St. Jude – West	25	50
6	Sink - West	St. Jude - West	15	30

2.5 Setting Up Test Plans

Once location and limits have been input into SureTrend software, test plans may then be set up. See section 8.4 in the SureTrend Users Manual for steps on setting up Test Plans.

Test Plans are groups of locations that are tested one after each other, grouped together, or tested on a specific day.

Here are some examples of test plans:

Nurses' Station
Keyboard
Phone
Countertop
File cabinet handle
Light switch

ICU Patient Room
Ventilator control panel
IV Pole
Monitor cables
Call button
Door handle

Public areas
Handrails
Door levers
Waiting area chair
Telephone
Water cooler

ER Mobile Workstations
Crash cart
ECG cart
Laceration cart
Bedside cart
Trauma cart
IV cart
IV medication cart
Cast cart

West Wing Patient Room
Bed tray table
Patient phone
Call button
Bed rail
Main light switch
Sink handles
Toilet flush handle
Bathroom light switch
Bathroom handrail
Television remote

Monday
Bedrails
IV Pole
Bedside Table
Remote
Panels

2.6 Testing Frequency

Once test plans are programmed into the SureTrend software, SystemSURE Plus may be synced with the software and testing may begin. The frequency of testing will be determined by:

- Budget
- Size of facility
- Importance of the cleaning standard
- Logistical and staff constraints
- Compliance with CDC environmental monitoring recommendations or other auditing bodies' recommendations

The CDC has a recommended formulation for sample size determination. It is broken out in two segments: Baseline Monitoring and Ongoing Monitoring

1. Baseline Monitoring

   This is the initial testing regiment that should be conducted to accurately assess the current level of cleanliness and compliance to the current cleaning processes. This initial testing will become the baseline to gauge improvements or deterioration of the thoroughness of cleaning and determine the number of points which must be monitored on a regular basis.

   While it would be ideal to identify small fluctuations in practice accurately (e.g., 10% relative change), such an approach takes slightly more time and testing. Instead, a meaningful change in cleaning practice (e.g., 20% relative change) can be detected without having to evaluate a substantial number of surfaces. The CDC recommends sampling all available surfaces identified in Section 2.1 or Exhibit 1.0 (page 22) in a 10-15% sample of representative patient rooms in hospitals with over 150 beds. In hospitals with less than 150 beds, all available surfaces should be tested in a minimum of 15 rooms for a baseline and ongoing monitoring.

The following is an example of a baseline evaluation (to measure levels of cleanliness):

For a 250 bed hospital with 10 locations in each room, 100 OR locations, and 100 equipment and sterile services locations, there are 2700 total locations to be tested. To monitor 10-15% of locations, a total of 270-405 locations will need to be tested three times per year (a total of 810-1215 tests per year).

Hospital A	Patient Room Locations	OR Locations	Equipment & Sterile Service Locations	Total Locations to be Tested	Total Tests per Year (3 baseline evaluations per year)
250 Rooms	2,500*	100	100	2,700	
10%	250	10	10	270	810
15%	375	15	15	405	1,215

*10 locations per room x 250 rooms = 2,500

The CDC recommends baseline monitoring is conducted at least three times per year. This is the minimum amount of testing that can be done to show a 20% relative change in cleaning levels. If pass levels decline, then more testing should be done in order to determine what is causing deterioration. (i.e. inefficient sanitizer, insufficient cleaning process, poor employee performance, etc).

2. Ongoing Monitoring

When hospitals have achieved more than 80% or higher pass results from routine testing, the number of surfaces to be monitored can be decreased to those available in a 5% sample of rooms per evaluation cycle unless there is deterioration in practice.

The following is an example of ongoing monitoring (once 80% or more of test results are "Passing"):

For a 250 bed hospital with 10 locations in each room, 100 OR locations, and 100 equipment and sterile services locations, there are 2700 total locations to be tested. To monitor 5% of locations, a total of 135 locations will need to be tested three times per year (a total of 405 tests per year).

Hospital A	Patient Room Locations	OR Locations	Equipment & Sterile Service Locations	Total Locations to be Tested	Total Tests (3 times per year)
250 Rooms	2,500*	100	100	2,700	
5%	125	5	5	135	405

*10 locations per room x 250 rooms = 2,500

Daily Monitoring

More and more hospitals are moving to daily or monthly ATP cleaning verification. Daily monitoring only requires a few tests per day, yet holds cleaning staff accountable for achieving an optimal level of cleanliness each and every day. Creating a rewards system based on daily results can be a very powerful program that brings staff together and improves overall hospital cleanliness.

Daily monitoring does take more time and requires more consumables, so a hospital should make sure this type of testing is within resources and budget. Below is a chart breaking down the time and consumable use associated with a daily ATP cleaning program in a 250 bed hospital.

Total Test Locations to Monitor in the Hospital	Test to do Daily	Total Time to Take Tests (1 minute per Test)	Test per Month (30 days)	Total Time Allotted For Testing per Month	Test per Year	Total Time Allotted per Year
2,700	5	5 minutes per day	150	2.5 hours	1,800	30 hours
2,700	10	10 minutes per day	300	5 hours	3,600	60 hours
2,700	15	15 minutes per day	450	7.5 hours	5,400	90 hours

Source: CDC Toolkit for Evaluating Environmental Cleaning, Appendix C, http://www.cdc.gov/HAI/toolkits/Appendices-Evaluating-Environ-Cleaning.html

2.7 Additional Testing

ATP cleaning verification can also be integrated into a hospital's emergency cleaning procedures as a final step to confirm thorough cleanliness.

In the event of patient accidents, bio-waste spills, flood, new construction, outbreak, or other accidental contaminations involving blood, urine, or fecal waste, cleaning staff should perform an emergency cleaning of that area. To confirm thorough cleaning of the site, an ATP test can be taken. This will ensure that the spill site has been properly cleaned.

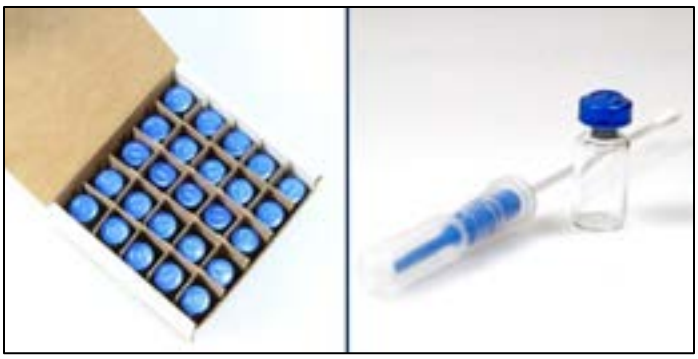
2.8 Calibration

To verify instrument calibration, Hygiena offers two calibration kits that are recommended for periodic use with your SystemSURE Plus System.

Calibration Control Rod Kit (Catalog# PCD4000)

It is recommended that calibration of the SystemSURE Plus luminometer is verified with the Calibration Control Kit once a month for audit record-keeping purposes. Incorporating the Calibration Control Kit into a cleaning verification program will confirm that the instrument is within specifications and operating correctly.

Each kit contains a positive rod and negative rod. The positive rod emits a very low level of constant light output that can be measured in RLUs to verify proper calibration of the unit. The negative rod produces zero (0) RLU and is used to check that background light is not entering the instrument, while ensuring that the light detector is calibrating correctly. The Calibration Control Rod Kit is good for five years of repeated use.



Positive Control Kit (Catalog # CK25)

The Positive Control Kit is used for validating the efficacy and quality of the UltraSnap ATP Testing Device. It comes with 25 sealed glass vials, each of which contain a certain amount (approx. 5×10^{-13} moles) of freeze-dried ATP and sugars to provide a predictable result if UltraSnap devices are used and stored correctly.

Exhibit 1.0 CDC Recommended Test Locations

High Touch Objects:

- Bed control
- Phone and call button
- Chair
- Light switch
- Sink top
- Flush handle
- TV remote

Patient Area:

- Bed rails
- Tray table
- Call boxes
- Telephones
- Bedside tables
- Patient chair
- IV Pole

Toilet Area:

- Sinks
- Bathroom light switch
- Door knobs and levers
- Bathroom handrails
- Toilet seat
- Toilet handles
- Bed pan cleaning equipment

Where applicable:

- IV pump control panel
- Monitor control panel
- Monitor touch screen
- Monitor cables
- Ventilator control panel
- Mobile workstations (carts)

For an expanded list of recommended testing locations for health care facilities, contact Hygiena at 1.888.HYGIENA or visit www.hygiena.com

** Source: CDC Environmental Checklist 10-28-2010 available at*
http://www.cdc.gov/HAI/toolkits/Environmental-Cleaning-Checklist-10-6-2010.pdf

Broad Risk Categories and Limits

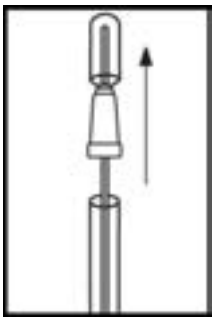
These general guideline limits are based on samples collected from hospital wards. Facilities that do not wish to establish custom limits (page 7) may assign these general limits to the appropriate testing locations.

Application	General Recommended Limits	
	Pass (RLU)	Fail (RLU)
Hospital public areas Examples: Elevator call buttons Hallway handrails Waiting room areas	<60	>80
Near patient areas Examples: Call button Bed rails Patient restroom Monitor panels IV pole	<25	>50
Sterile services	<10	>30
Washer disinfector	<5	>10
Food preparation and catering	<10	>30

Proper Sampling Procedure

The SystemSURE Plus luminometer is designed to detect contamination that cannot be seen by the naked eye. Before collecting a sample for testing, the surface should be visibly clean. If any soiling or residue is apparent, re-clean the area before testing.

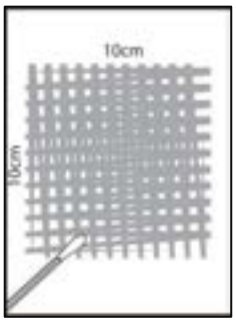
1. Turn on the SystemSURE Plus luminometer. The system will run through a 60 second automatic calibration. Once calibration is complete, scroll through the program numbers (PROG) to find the programmed test location that correlates to the location being tested. This action should be taken prior to swabbing.



2. Remove the individual UltraSnap device from the package. Next, remove the outer tube by holding onto the double ring base of the Snap-Valve while pulling down on the tube. The swab tip comes pre-moistened. Condensation may be visible on the inside of the swab tube. This is normal. **Do not touch the swab tip or shaft with fingers or anything else, as this will contaminate the test.** Discard any swabs that accidentally get tainted or activated.

3. *NOTE**:** For optimal performance, swabs that have been removed from cold storage should stand for 10 minutes at room temperature before use.*

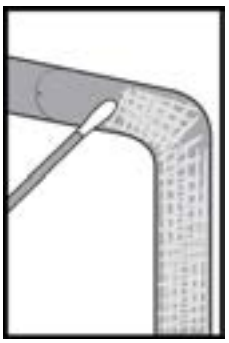
4. Collect a sample with the UltraSnap device using the guidelines below. The UltraSnap device is designed to detect trace amounts of contamination. An excessive amount of sample may interfere with the bioluminescence reaction and produce an inaccurate test result, which is why it is important to remove all visible soil from a surface before swabbing.



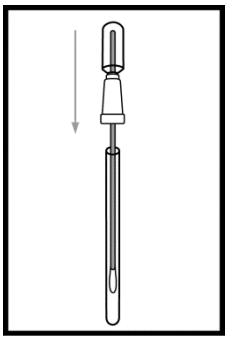
   a. ***Regular surfaces:*** Swab a 10 x 10 cm (4 x 4 in) square on the test surface. Rotate the swab as the sample is collected, while applying firm pressure. This will create a slight bend in the swab shaft.

b. ***Irregular surfaces:*** Where 10 x 10 cm square sampling is not feasible, swab as much of the surface as possible. Be sure that a slight bend in the shaft is achieved and an adequate sample is collected.

Note: Consistent sampling pattern on irregular surfaces is necessary to ensure reliable and repeatable results. All individuals responsible for performing swab tests should agree on similar sampling pattern.



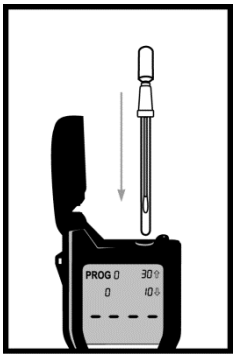
5. Re-insert the swab into the tube. UltraSnap is now ready to be activated, or it can be left inactive for up to 4 hours in this state.



6. Holding the device upright, activate the UltraSnap by bending the bulb at the top until the plastic Snap-Valve breaks, then bend once more in the opposite direction. Squeeze the bulb twice to expel the liquid-stable reagent contained in the bulb and allow it to flow to the bottom of the tube.

7. Gently shake the device with a side-to-side motion for 5-10 seconds, bathing the swab bud in the liquid-stable reagent. The test is now activated and the bioluminescence reaction is taking place. For optimal results, the reading should be taken on the SystemSURE Plus luminometer within 60 seconds of activation.

8. Open the lid on the SystemSURE Plus luminometer, and insert the activated UltraSnap device into the reading chamber. Close the lid, making sure to keep the machine upright for an accurate reading.



9. Continuing to hold the unit upright, press "OK" on the SystemSURE Plus to initiate measurement. Results are displayed on the screen in 15 seconds.

Notes

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