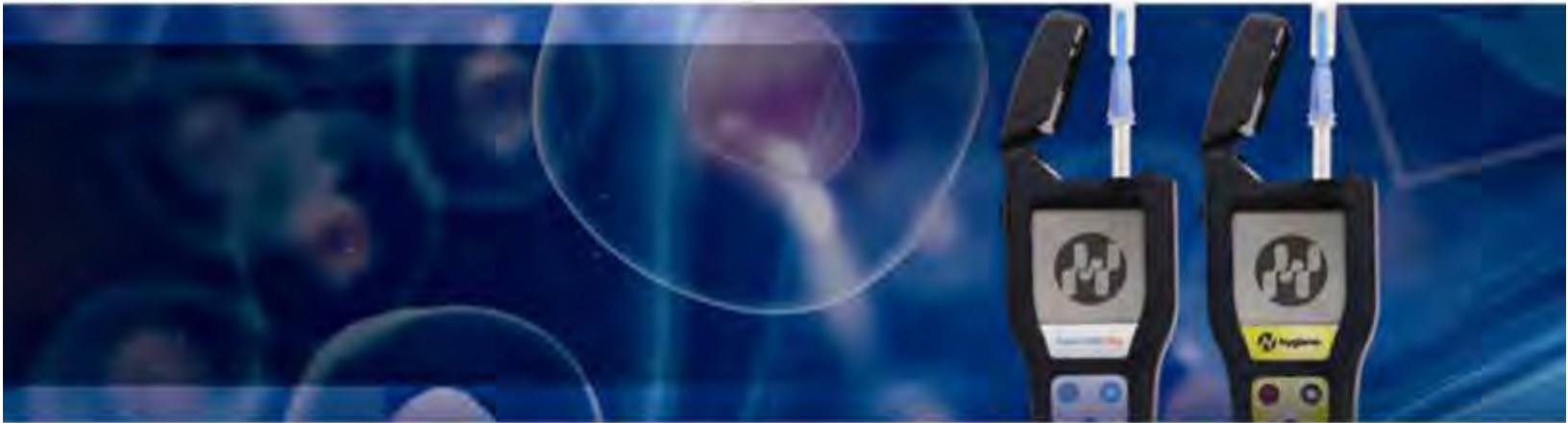


A Guide to ATP Hygiene Monitoring





1430 West McCoy Lane
Santa Maria, CA 93455

Website: www.HardyDiagnostics.com
Email: Sales@HardyDiagnostics.com

Distribution Centers: California | Washington | Utah
Arizona | Ohio | Texas | New York | Florida

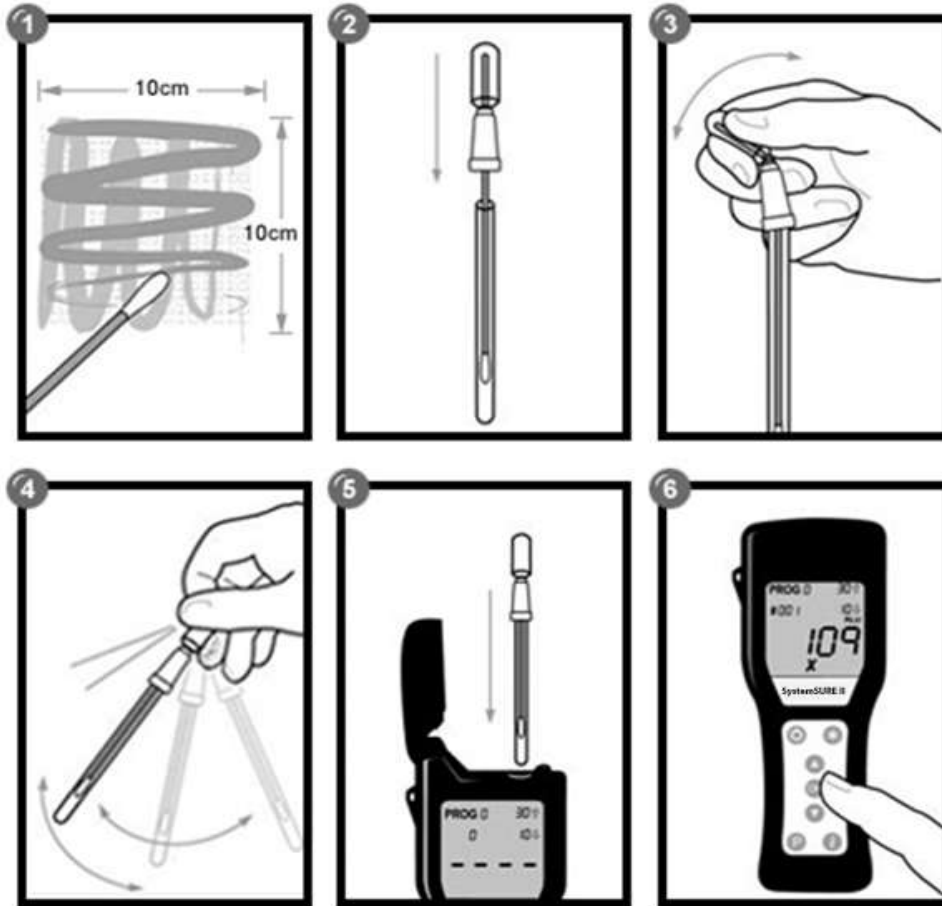


TABLE OF CONTENTS

<u>QUICK START GUIDE</u>	<u>4</u>
<u>INTRODUCTION</u>	<u>5</u>
<u>SECTION 1: An Overview of ATP Monitoring Systems</u>	<u>7</u>
1.1 What is ATP?	7
1.2 Measuring ATP with bioluminescence technology	7
1.3 Interpreting results on the luminometer	8
1.4 Other uses for ATP monitoring systems	9
<u>SECTION 2: Using Your ATP Monitoring System</u>	<u>10</u>
2.1 Proper sampling technique and activation procedure	10
2.1.1 Collecting samples with the testing device.....	10
2.1.2 Measuring ATP with SystemSURE Plus and EnSURE	13
2.1.3 Ensuring correct results with calibration controls.....	14
2.2 Where to do ATP testing	15
2.2.1 Establishing your facility’s test locations (control points).....	15
2.2.2 Types of contact areas	15
2.2.3 Diagram of typical production floor control points.....	17
2.2.4 Monitoring individual control points.....	18
2.2.5 Setting up test plans.....	19
2.3 Determining RLU limits for your facility	20
2.3.1 Setting up RLU limits.....	20
2.3.2 General Pass/Caution/Fail limits	22
2.3.3 Storing and viewing RLU limit data.....	23
2.4 Testing frequency	24
2.5 Corrective action procedures	25
2.6 Continuous improvement.....	27
<u>SECTION 3: Further Help</u>	<u>28</u>
3.1 Glossary	28
3.2 Typical RLU limit guidelines.....	29
3.3 Contact Hygiena	30
Hygiena - Americas	30
Hygiena International.....	30
Hygiena China.....	30
Hygiena Online	30
<u>Notes</u>	<u>31</u>

QUICK START GUIDE

Proper Sampling Procedure



1. Identify the location to be tested and turn on the luminometer. Select the test location from the programmed locations. Remove the ATP testing device from the outer tube. If conducting a surface test, press firmly down on the swab tip and collect a sample from a 10 x 10 cm (4 x 4 in) area. Use a side-to-side and up-and-down motion while rotating the swab tip.
2. Place the swab back into the swab tube. The ATP testing device is now ready to be activated or can be left inactive for up to 4 hours. Once activated, the test must be read within 60 seconds.
3. To activate, break the plastic valve at the top of the device by bending the bulb backward and forward. Squeeze the bulb twice to expel the liquid in the bulb to the bottom of the tube.
4. Bathe the swab bud in the liquid by shaking gently in a side-to-side motion for 5-10 seconds.
5. Place the entire test device into the luminometer and close the lid.
6. Holding the luminometer in a vertical position, press 'OK' to initiate reading. The test result will appear on the screen in 15 seconds.

INTRODUCTION

Hygiena ATP Monitoring Systems

In today's market, impeccable hygiene control is an increasingly critical issue for industries involved in the manufacturing and distribution of consumable products. Hygiena's ATP monitoring systems offer a state-of-the-art solution for organizations seeking to monitor and improve cleanliness.

Recognized worldwide for accuracy, ease-of-use and affordability, the SystemSURE Plus and EnSURE ATP monitoring systems are used extensively by food and beverage processors, hospitals, pharmaceutical manufacturers, restaurants, supermarkets, janitorial/sanitation services and other industries where cleanliness is critical.

The following are some of the benefits experienced by companies using ATP monitoring:

Instantly assess the cleanliness of production surfaces, allowing immediate corrective action to be taken before production begins

Reduce the use of conventional microbiological testing methods that are slow, labor intensive and costly

Enhance cleaning and sanitation training with immediate performance feedback

Optimize cleaning chemicals, equipment and labor so that the plant can maintain a high cleanliness level without an excessive amount of waste

Standardize the level of cleanliness and verify efforts of sanitation personnel

Ensure product quality and avoid recalls which will protect brand image and reputation

Increase product quality and extend shelf-life by preventing product residues and other contamination from coming in contact with new product

Record and track test results to identify problem areas, make improvements and show due diligence and compliance with HACCP, Sanitation Standard Operating Procedures (SSOPs) and industry regulations

Components of ATP Monitoring Systems

Hygiena ATP monitoring systems are comprised of three core components:

- (1) Luminometer
- (2) Test devices
- (3) Data tracking software



SystemSURE Plus



EnSURE

SystemSURE Plus is compatible with:

- UltraSnap – surface ATP
- AquaSnap – liquid ATP

EnSURE offers twice the sensitivity of SystemSURE Plus.

EnSURE is compatible with:

- UltraSnap – surface ATP
- AquaSnap – liquid ATP
- SuperSnap – allergen prevention/protein residue
- MicroSnap – microorganism detection
- ZymoSnap – alkaline phosphatase (ALP)
- CrossCheck- acid phosphatase (ACP)



SureTrend Data Analysis Software

SureTrend is a powerful software program that allows users to upload test results to a database, analyze trends, and generate reports.

Hygiena's luminometer, sample testing devices and software are all designed to be easy-to-use and reliable, enabling both technical and non-technical staff to operate the monitoring systems without difficulty.

SECTION 1 : An Overview of ATP Monitoring Systems

A key feature of ATP monitoring systems is the use of 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 plant, animal and microbial cells. It fuels metabolic processes such as cellular reproduction, muscle contraction, plant photosynthesis, respiration in fungi, and fermentation in yeast. All organic matter (living or once-living) contains ATP, including food, bacteria, mold and other microorganisms. The detection of ATP on a surface or in water therefore indicates the presence of biological matter that may not otherwise be visible to the eye. In industries where plant hygiene control or cleanliness is crucial, ATP testing is an excellent tool for detecting and measuring biological matter that should not be present after cleaning.

1.2 Measuring ATP with bioluminescence technology

Hygiene ATP testing devices contain a natural enzyme found in fireflies. This enzyme, called luciferase, produces a simple bioluminescence (light-producing) reaction when it comes into contact with ATP. Using bioluminescence technology, the SystemSURE Plus and EnSURE luminometers can measure extremely low levels of ATP collected with testing devices. Measuring the amount of bioluminescence from an ATP reaction provides an excellent indication of surface cleanliness or water quality 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 so results can be processed at the testing site in seconds. Results are expressed numerically on the luminometer screen in Relative Light Units (RLU).

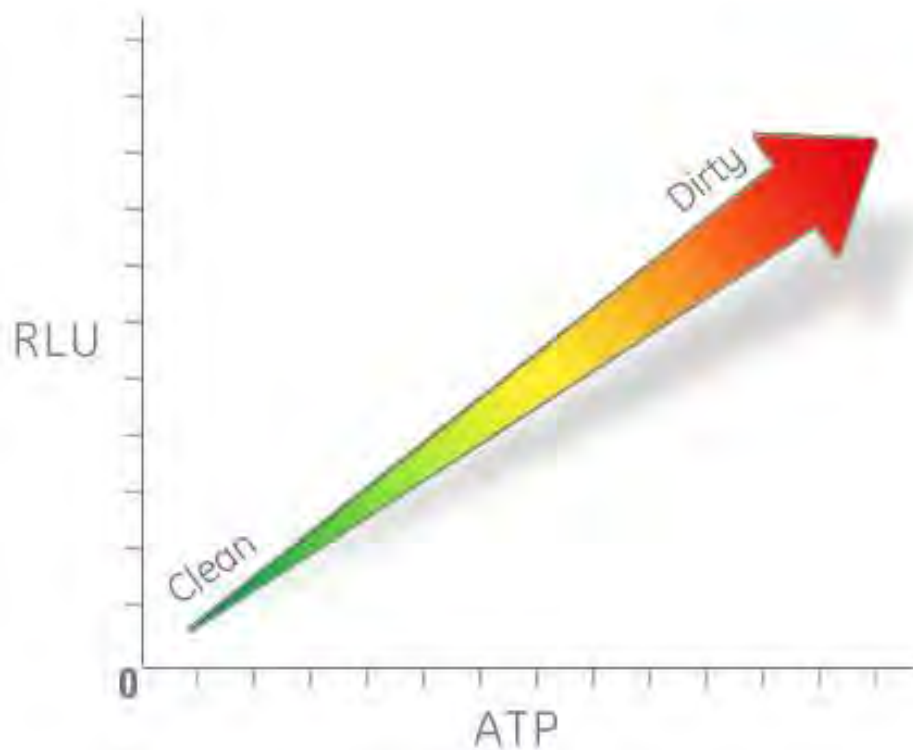


1.3 Interpreting results on the luminometer

The relationship between the amount of ATP collected in a sample and the RLU result displayed on the luminometer is linear, which makes understanding the technology very easy.

The RLU reading is directly proportional to the amount of ATP collected from the sample. A high RLU reading indicates a large amount of ATP at the test location. This in turn indicates improper cleaning and the presence of potential contaminants.

Cleaning properly results in less ATP at the location. Lower ATP levels produce smaller amounts of light output during the bioluminescence reaction and consequently, a lower RLU reading.



1.4 Other uses for ATP monitoring systems

In addition to routine ATP monitoring, other useful applications for ATP monitoring systems include:

Troubleshooting – ATP testing provides a way to expose microbial contamination and other issues that might be causing higher than normal plate counts in environmental testing.

New equipment cleaning verification – When a new piece of equipment is added, new cleaning processes are usually required. An ATP system helps determine the optimal process and chemicals.

Training – New cleaning and sanitation staff requires extensive training. Showing a trainee proper and improper processes and the effect on equipment cleanliness is invaluable.

Validation of hand cleanliness – ATP testing can be used to verify proper hand-washing techniques and cleanliness of employees' hands when used directly on skin. When doing this type of testing, it is important to identify appropriate pass/fail levels taking into account naturally occurring ATP levels from skin cells. To learn more about using ATP testing to verify hand cleanliness, contact a Hygiena representative.

Additional rapid quality tests – Hygiena's EnSURE monitoring system does more than just ATP testing. With same day tests for specific and indicator organisms, allergens, and more, EnSURE can deliver a full picture of plant hygiene on one handheld system. EnSURE is easy-to-use so it's not necessary to be a microbiologist or lab technician. Additionally, all tests measured on the EnSURE monitoring system are recorded and tracked with SureTrend software. For information on all tests available for EnSURE, visit www.hygiena.com.

SECTION 2: Using Your ATP Monitoring System

Proper sampling, correct use of luminometer and testing devices, and accurate data management are crucial components of a successfully implemented ATP monitoring program.

This section will explain how to:

- ☒ Collect a sample using UltraSnap, SuperSnap, or AquaSnap tests
- ☒ Use the SystemSURE Plus or EnSURE luminometer
- ☒ Determine where and when to test control points
- ☒ Set Pass/Caution/Fail limits
- ☒ Determine corrective action procedures

2.1 Proper sampling technique and activation procedure

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.

If testing occurs in real-time at the sampling location, turn on the luminometer and scroll through the program numbers (PROG) to find the program that correlates to the location being tested. This action should be taken prior to activating the test.

2.1.1 Collecting samples with the testing device

1. Remove the testing device from the pouch. 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 with an extractant that breaks through biofilm on test surfaces. 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 contaminated or activated.

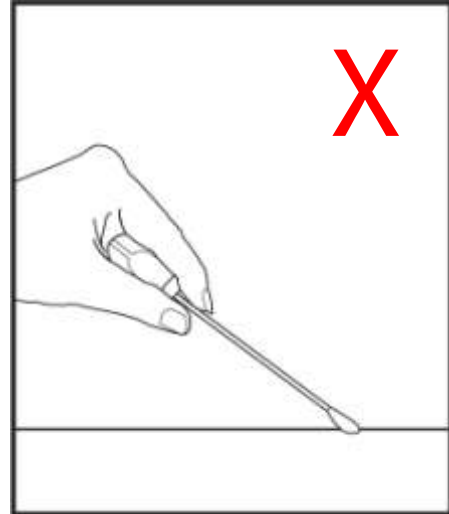


NOTE: For optimal performance, swabs that have been removed from cold storage should stand for 10 minutes at room temperature before use.

2. Collect a sample using the guidelines below. The test device is designed to detect trace amounts of contamination. Collecting a sample on a visibly dirty surface may interfere with the bioluminescence reaction and produce an inaccurate test result.

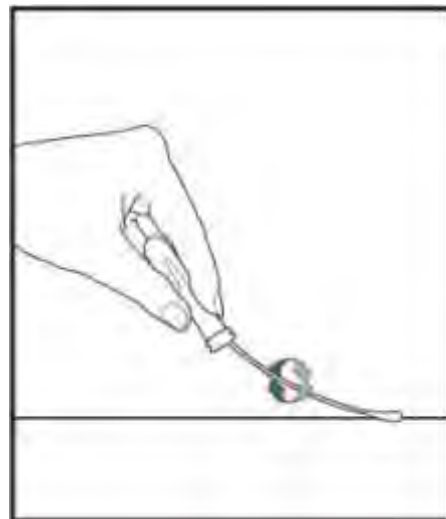
Incorrect swabbing technique:

- Touching the swab shaft with your finger.
- Lightly touching the swab to the sample area .
- Collecting sample on only one side of swab tip.
- Swabbing an inadequate surface area .



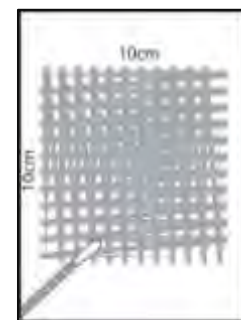
Correct swabbing technique:

- No contact with the swab shaft.
- Sufficient pressure to create flex in the swab shaft . This helps to break through any biofilm.
- Rotate the swab to collect sample on all sides of swab tip.
- Swabbing a 10x10 cm (4x4 in) area (where possible).



a) Regular surfaces

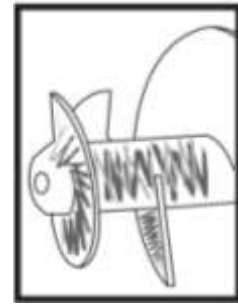
Swab a 10 x 10 cm (4 x 4 in) square on the test surface , making a criss -cross pattern as shown .



b) Irregular surfaces

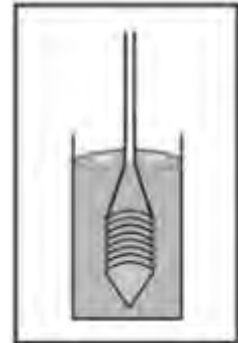
Where 10 x 10 cm square sampling is not feasible, swab as much of the surface as possible. Be sure that a bend in the shaft is achieved and an adequate sample is collected.

Note: Consistent swabbing pattern on irregular surfaces, such as a mixing blade, is necessary to ensure reliable and repeatable results over time. All individuals responsible for performing swab tests should be trained on correct swabbing pattern for irregular and regular surface test sites.

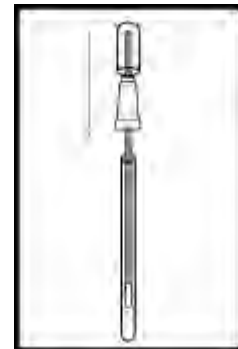


c) Liquid sampling – Use Aqua Snap

Dip AquaSnap honeycomb dipper in sample of water being tested. If the water is not homogenous or contains sediment, mix thoroughly before sampling.



3. Re-insert the swab into the tube. The test device is now ready to be activated. A test with an active sample on it can be left inactivated for up to 4 hours in this state. In some facilities, users prefer to sample each location, write the sample location on the swab tube, and run all tests in a laboratory rather than at the test location. The most common process is to activate and read the test immediately after collecting the sample.



4. Holding the device upright, activate the test device by bending the bulb at the top until the 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.



5. 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 test should be run on the luminometer as soon as possible, and within 60 seconds of activation.

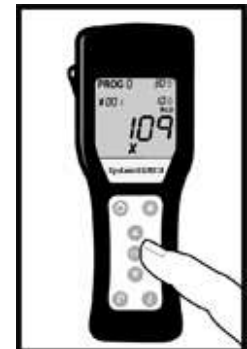


2.1.2 Measuring ATP with SystemSURE Plus and EnSURE luminometers

1. Open the lid on the luminometer and insert the activated testing device into the reading chamber. Close the lid, making sure to keep the machine in an upright position.



2. Press "OK" to initiate measurement. Results are displayed on the screen in 15 seconds.



2.1.3 Ensuring correct results with calibration controls

To help ensure the accuracy of test results, the luminometer automatically self-calibrates every time the instrument is turned on. In some facilities, a quality or risk assessment program such as ISO or HACCP might require additional calibration checks of the system. Hygiena offers two calibration kits that are recommended for periodic use with your system: the Calibration Control Rod Kit for testing the luminometer and the Positive Control Kit for testing ATP test devices.



Calibration Control Rod Kit (Catalog# PCD4000)

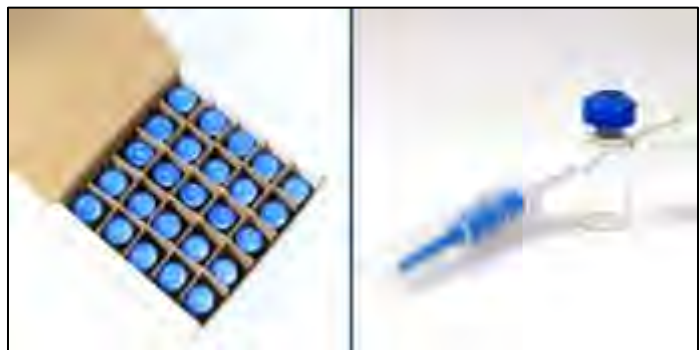
It is recommended that calibration of the luminometer is verified with the Calibration Control Kit once a month for audit record-keeping purposes. Incorporating the Calibration Control Kit into an ATP monitoring program will confirm that the instrument is within specifications and operating correctly.

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 test devices are used and stored correctly.

Each vial provides a sample which produces a positive result within a range. Positive controls should be used whenever there is concern about the product's storage temperature or shelf life. Incorporating the Positive Control Kit into the quality program will validate results of the luminometer and ATP testing devices.



2.2 Where to do ATP testing

2.2.1 Establishing your facility's test locations (control points)

Test areas within your plant should be designated as “ATP control points” in your ATP hygiene monitoring plan. By monitoring these control points you will have reliable, real-time feedback on the cleanliness of a particular piece of equipment or areas being tested. It's important that ATP testing be routinely performed on all important control points. This will ensure product quality, identify issues immediately, and allow valuable trending data to be used to improve plant hygiene.

If you currently have HACCP or sanitation standard operating procedure (SSOP) programs in place, you will most likely have identified your control points that are contact and non-contact surfaces. Verification of cleanliness for these control points is sometimes done visually or by environmental microbiology samples. Start with these control points. Control points can be added or subtracted as your program develops.

If you haven't previously established control points, you need to determine areas where poor cleaning could affect product quality. This can be done by swabbing multiple areas on equipment and production line surfaces after routine cleaning. ATP levels will be higher in those spots that are harder to clean, spots that are missed in your current cleaning procedure, and spots that have developed biofilm. These areas should be established as control points for routine testing and monitoring.

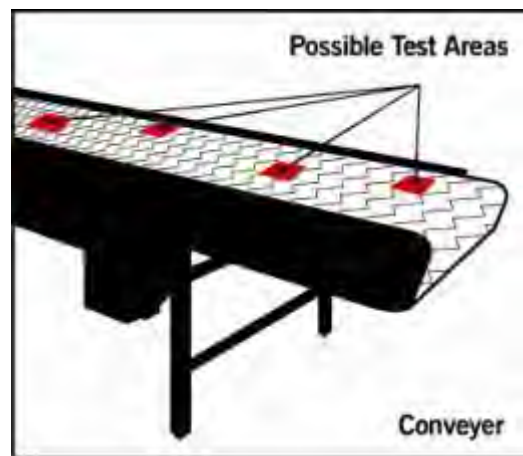
2.2.2 Types of contact areas

a) Direct contact areas

Direct contact areas are surfaces that come in contact with product being processed. These are high-risk areas that should be tested frequently to verify cleanliness. They will typically have a low RLU limit.

Examples: conveyor belt, cutting board, slicers, grinders, moving bins or totes, utensils, etc.

A direct contact surface, such as a conveyor, could be tested in a few

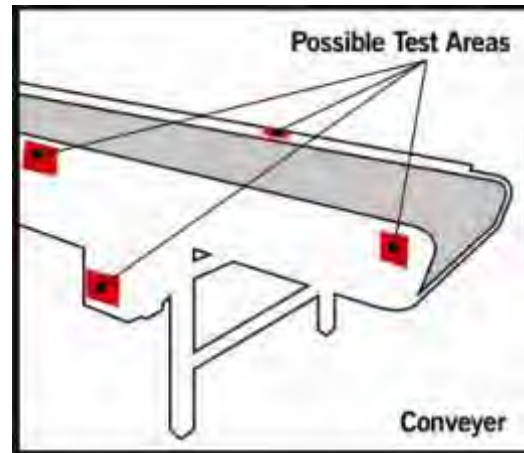


different places of to verify total cleanliness. One test device could be used on multiple spots. If the test fails, then re-cleaning of the entire piece of equipment is required.

b) Indirect contact areas

Indirect contact areas are locations where splashed product or contaminants can be dropped, drained, or transferred onto the product. These areas are often overlooked as sources of contamination and should be routinely tested.

Examples: drain, side walls, machine buttons/controls, and additional machine parts that don't directly contact product but if contamination is allowed to build, could cause microbial contamination that could then spread.



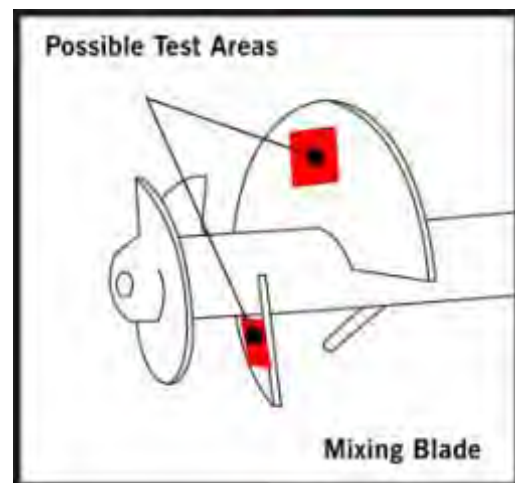
An indirect contact area, such as the side of a conveyor belt, should be tested in a few different spots to verify total cleanliness.

c) Hard-to-clean contact areas

Hard-to-clean areas have a high potential to harbor bacterial growth and should be tested regularly.

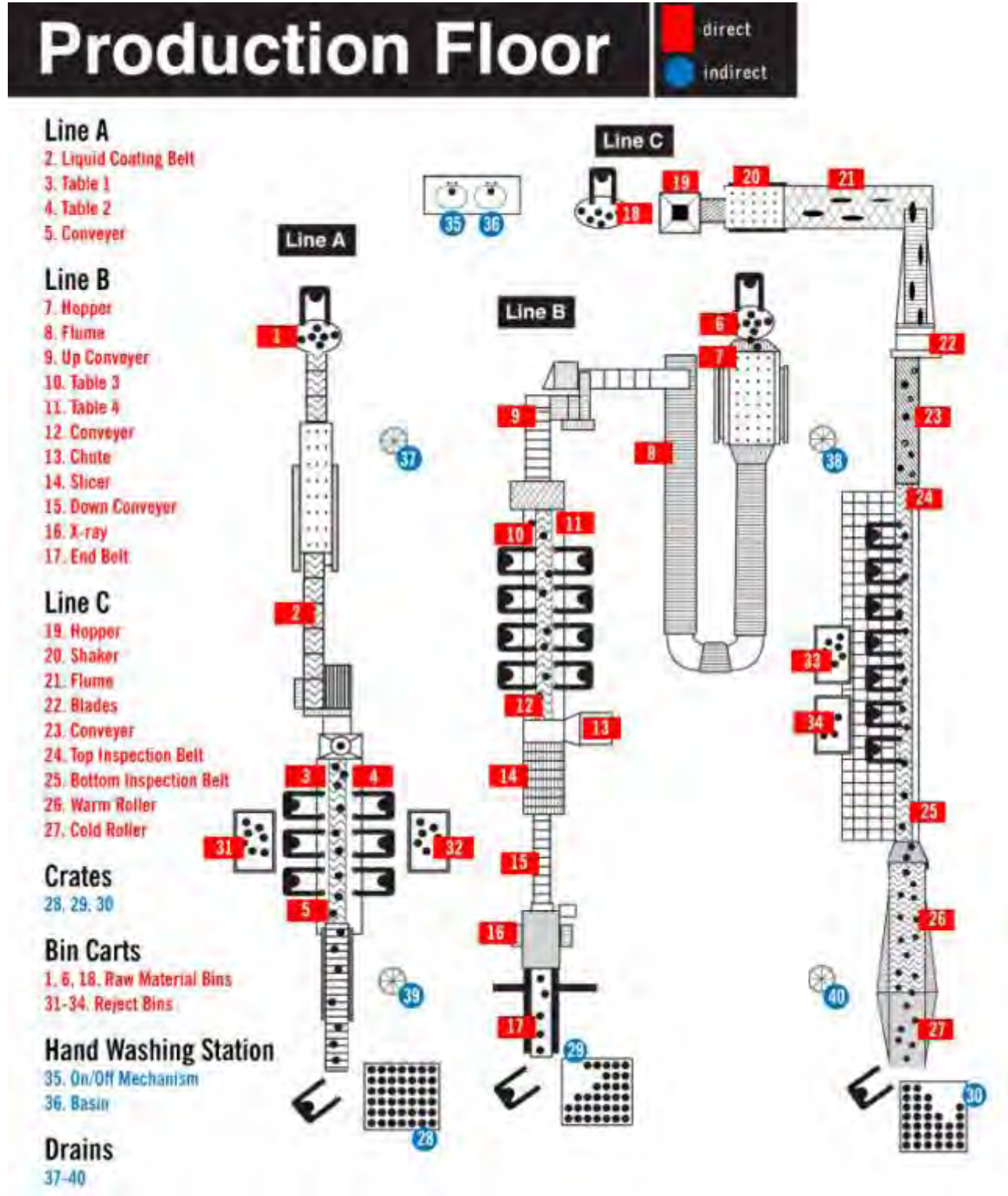
Examples: mixing blades, hoses, O-rings, nozzles, corners, grooves, cracks, joints or areas with irregularly shaped surfaces,

A hard-to-clean area, such as a mixing blade, should be tested in a few different places to verify total cleanliness.



2.2.3 Diagram of typical production floor or control points

Below is an example of a production floor plan. Direct contact surfaces are indicated with a red rectangle, and indirect contact areas with a blue circle.



2.2.4 Monitoring individual control points

Once control points have been identified, this information should be entered into SureTrend software. In SureTrend software, locations may be identified by assigning an alphanumeric name, group category, surface type, and additional notes. Group and surface information is only displayed in the software and not displayed on the handset. Locations may be assigned to test plans according to when they will be tested or which locations should be tested together.

Below is an example of a spreadsheet created with SureTrend software.

Prog #	Location	Group	Surface	Lower	Upper
0	Calibration Control	Calibration Control			
1	Line A Raw Mat. Bin	Bin Carts	Plastic	10	30
2	Liquid Coating Belt	Line A	Plastic	10	30
3	Table 1	Line A	Stainless	10	30
4	Table 2	Line A	Stainless	10	30
5	Conveyer	Line A	Plastic	10	30
6	Line B Raw Mat. Bin	Bin Carts	Plastic	10	30
7	Hopper	Line B	Stainless	10	30
8	Flume	Line B	Stainless	10	30
9	Up Conveyer	Line B	Plastic	10	30
10	Table 3	Line B	Stainless	10	30
11	Table 4	Line B	Stainless	10	30
12	Conveyer	Line B	Plastic	10	30
13	Chute	Line B	Stainless	10	30
14	Slicer	Line B	Stainless	10	30
15	Down Conveyer	Line B	Plastic	10	30
16	X-Ray	Line B	Plastic	10	30
17	End Belt	Line B	Plastic	10	30
18	Line C Raw Mat. Bin	Bin Carts	Plastic	10	30
19	Hopper	Line C	Stainless	10	30
20	Shaker	Line C	Stainless	10	30
21	Flume	Line C	Stainless	10	30
22	Blades	Line C	Stainless	10	30
23	Conveyer	Line C	Plastic	10	30
24	Top Insp. Belt	Line C	Plastic	10	30
25	Bottom Insp. Belt	Line C	Plastic	10	30
26	Warm Roller	Line C	Stainless	10	30
27	Cold Roller	Line C	Stainless	10	30
28	Line A Crate	Crates	Plastic	10	30
29	Line B Crate	Crates	Plastic	10	30
30	Line C Crate	Crates	Plastic	10	30
31	Reject Bin 1	Bin Carts	Plastic	10	30
32	Reject Bin 2	Bin Carts	Plastic	10	30
33	Reject Bin 3	Bin Carts	Plastic	10	30
34	Reject Bin 4	Bin Carts	Plastic	10	30
35	On/Off Mechanism	Hand Washing	Stainless	10	30
36	Basin	Hand Washing	Stainless	10	30
37	Drain 1	Drains	Stainless	100	300
38	Drain 2	Drains	Stainless	100	300
39	Drain 3	Drains	Stainless	100	300
40	Drain 4	Drains	Stainless	100	300

2.2.5 Setting up test plans

Once locations and limits have been input into SureTrend software, test plans may then be set up. See 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 using the production floor on page 17:

Tables
Table 1
Table 2
Table 3
Table 4

Conveyors
Line A Conveyer
Line B Up Conveyer
Line B Conveyer
Line B Down Conveyer
Line B End Belt
Line C Conveyer
Top Insp. Belt
Lower Insp. Belt

Bins and Crates
Line A Raw Mat. Bin
Line B Raw Mat. Bin
Line C Raw Mat. Bin
Line A Crate
Line B Crate
Line C Crate
Reject Bin 1
Reject Bin 2
Reject Bin 3
Reject Bin 4

Line A
Liquid Coating Belt
Table 1
Table 2
Conveyer

Line B
Hopper
Flume
Up Conveyer
Table 3
Table 4
Conveyer
Chute
Slicer
Down Conveyer
X-Ray
End Belt

Line C
Hopper
Shaker
Flume
Blades
Conveyer
Top Insp. Belt
Bottom Insp. Belt
Warm Roller
Cold Roller

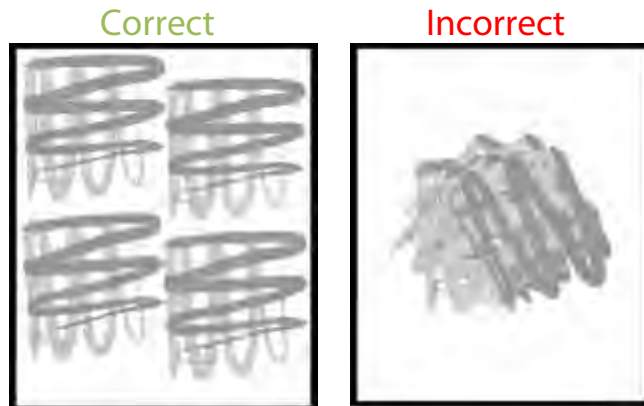
2.3 Determining RLU limits for your facility

Setting correct Pass, Caution and Fail levels is a fundamental part of running a successful ATP monitoring program. RLU limits may vary depending on the type of product being manufactured as well as the surface being checked. However, the formulas used to determine Pass, Caution and Fail levels are always the same.

Hygiena also provides general recommended RLU limits, which meet most manufacturers' hygiene standards. Examples of some typical limit guidelines specific to the food and beverage industry can be found in Typical RLU limit guidelines, in Section 3.2.

2.3.1 Setting up RLU limits

1. Clean product surfaces to the level that daily cleaning procedures should achieve.
2. Conduct an ATP test at each location. Take 5 -10 replicate tests at each cleaned location, being sure not to swab the same exact surface area more than once.



All replicate tests can be done on the cleaned surface or equipment after one cleaning or over the course of several days.

3. To determine the Pass limit: Calculate the average RLU for each location based on the 5-10 test results. To do this, add all test results, and then divide the sum by the number of tests taken. The resulting number is your average RLU. This number is your Pass limit.

4. To determine the Fail limit:

1. Multiplication method: Multiply the Pass limit by 3.
2. Standard deviation method: Determine the standard deviation of test results, multiply the standard deviation by 3, and add this to the Pass limit.

The resulting number is your Fail limit. If the Fail limit is zero (0), it is acceptable to set the Pass limit to the system default of 10 RLU. Occasionally, blank ATP test devices may emit up to 2 RLU.

5. To determine the Caution * limit: The area between the Pass and Fail limits is the Caution range.

*NOTE: The Caution range is sometimes useful for trend analysis and eliminating an excessive amount of re-cleans when an ATP program is implemented. Caution results can be viewed as a warning and more attention should be given to this location the next time cleaning is done. Often, a caution one day will be a Pass the next day. However, users may opt to forgo the Caution range and set the Fail limit to the same RLU as Pass limit. Any result over the Pass limit is then considered a Fail result.

The following table uses example data to illustrate average RLU and Pass/Caution/Fail limits using the multiplication method:

Test	1	2	3	4	5	6	7	8	9	10	Average RLU
Routine cleaning	10	15	8	19	10	13	17	14	15	11	13.2

The data in this example would then yield the following RLU limits:

Pass	Caution	Fail
0-13	14 - 35	36+

If a user chose to eliminate the Caution zone, RLU limits for Pass and Fail would both be set to 13 to yield the following RLU limits:

Pass	Fail
0-13	14+

NOTE: Different surfaces have different levels of risk, and therefore may require different RLU limits. For example, porous plastic or rubber surfaces may be more difficult to clean than stainless steel surfaces, and therefore produce higher ATP test results. In this case, the user may choose to: 1) set RLU limits higher for those harder- to-clean areas; or 2) intensify cleaning to bring ATP test results on those surfaces in line with other control points.

2.3.2 General Pass/Caution/Fail limits

For facilities that opt not to set their own RLU limits, Hygiena offers general guidelines. These are common limits used for ATP hygiene monitoring, and are based on plate count and ATP correlation studies.

RLU	Pass	Caution	Fail
SystemSURE Plus	10	11 – 29	30
EnSURE	20	21 – 59	60

For more information on these general limits, contact a Hygiena representative.

2.3.3 Storing and viewing RLU limit data

Once RLU limits are established, they can be programmed into SureTrend software and then uploaded from the software to the luminometer. For information on how to do this, refer to the SureTrend User's Manual. RLU limits can also be manually entered in to the luminometer (consult the Luminometer Operator's Manual for details).

Once limits have been entered into the luminometer, upper () and lower () limits are displayed numerically on the screen for each PROG location.



After running an ATP test, Pass/Caution/Fail results will display on the luminometer as follows:

- ✓ (Pass) - For any RLU reading that is less than or equal to the Pass limit. A Pass result indicates the surface is clean.
- ! (Caution) - For any RLU reading that is greater than the Pass limit and less than the Fail limit. A Caution result indicates the surface may not have been adequately cleaned.
- ✗ (Fail) - For any RLU reading that is greater than the Fail limit. A Fail result indicates the surface is dirty or contaminated.

For information on what steps should be taken after obtaining Pass, Caution or Fail results, see Corrective action procedures in Section 2.5.

2.4 Testing frequency

Once control points have been established and ATP RLU limits have been set, a sampling frequency plan should be developed.

Sampling frequency should be based on the level of risk associated with the control point being tested. Factors determining the level of risk include:

- surface robustness and susceptibility to contamination
- how often the piece of equipment is cleaned
- age and wear of equipment
- degree of difficulty to clean
- level of contact with product
- for food processors, number of types of food being processed on a machine, which increases the potential for cross-contamination and allergens

Critical (high-risk) control points should be tested on a daily basis, after each cleaning. You may also choose to test after product line changes, after shift changes, and or any time prior to start-up. Lower-risk control points may not need to be tested as frequently.

NOTE: ATP testing should be done prior to the application of a sanitizer if possible.



Testing should be done after cleaning a surface, but prior to the application of a sanitizer if possible. Product residue left on the surface after cleaning inhibits sanitizers from working correctly. Sanitizer is most effective when surfaces are free of all residues. Following this Clean-Test-Sanitize procedure prevents wasting sanitizer and time it takes to re-apply sanitizer.

NOTE: Some sanitation procedures may require ATP testing to be done after sanitizing, because of equipment turnover time. In such cases, follow sanitizer's proper dwell time and concentration levels before ATP testing. Commonly used sanitizers at working strength should not affect Hygiena's ATP tests. Some acid-based sanitizers at high concentrations could slightly reduce output signal. For a list of sanitizers that could affect the ATP bioluminescence reaction, contact Hygiena.

2.5 Corrective action procedures

Implementing a corrective action plan is an essential part of an ATP monitoring program. Corrective action procedures provide clear instructions for what steps should be taken following Pass/Caution/Fail results.

Recommended corrective action procedures are as follows:

TEST RESULT	CORRECTIVE ACTION
(Pass)	The control point has been properly cleaned. Proceed to sanitizing.
! (Caution)	The control point may not have been adequately cleaned. You may choose to proceed to sanitizing, or re-clean and re-test as if the result is a Fail . A control point with a Caution reading should be monitored for future problems.
X (Fail)	The control point was not cleaned properly , and must be cleaned again and re -tested until a Pass or Caution result is achieved. A control point with a Fail reading should be noted and monitored for future problems.

According to the needs of the facility, the user has the option of setting up a more extensive corrective action plan. For example, users may decide that control points which produce Fail results should be re- tested until 3 consecutive days of Pass results are achieved. If the control point does not successfully achieve 3 consecutive days of Pass results, cleaning procedures , personnel, or RLU limits should be re-evaluated.

A flow chart on the next page illustrates general recommended cleaning and corrective action procedures.

Flow Chart: Suggested Cleaning, Test and Correction Action Procedures



2.6 Continuous improvement

Hygiene ATP monitoring systems are designed to aid organizations striving for continuous improvement of standards. Continuous improvement ensures excellence in product quality, while reducing inefficiencies, avoiding recalls, and showing due diligence and compliance to auditors and customers.

Analysis of results is key to the evaluation and ongoing improvement of the cleaning programs. Using SureTrend software, users can monitor and assess ATP test results, perform trend analysis, identify trouble zones, correct improper cleaning procedures and eliminate risk.

If trends show high numbers of Caution and Fail results, standard sanitation operating procedures (SSOP's) should be reviewed for ways to improve protocols. If low numbers of Caution and Fail results are obtained, Pass/Fail limits could be reviewed and potentially lowered, creating a higher cleaning standard which would create a cleaner facility.

Pass, Caution, and Fail limits should also be re-evaluated every year and whenever procedural or equipment changes are made. As cleaning procedures become more efficient and effective, limits should be adjusted to ensure your facility is operating to its maximum potential.

SECTION 3: Further Help

3.1 Glossary

ATP (adenosine triphosphate)

ATP is a chemical compound used by all living organisms to fuel metabolic processes such as muscle function and reproduction. ATP is found in living organisms (including bacteria and other microorganisms) as well as once -living material (such as food). Detection of ATP on a surface indicates the presence of either microbial contamination or food residue that has the potential to support microbe growth.

Bioluminescence

Bioluminescence is a chemical reaction that produces light when ATP comes into contact with the enzyme luciferase. Hygiene's ATP testing devices use bioluminescence technology (combining ATP with luciferase) to produce a light output that can be detected and measured by the luminometer.

RLU (Relative Light Units)

RLU is the unit of measurement for light output during a bioluminescence reaction. Luminometers express ATP test results in RLU. RLU numbers are directly proportional to the amount of ATP on the test sample, therefore a high RLU indicates a large amount of ATP present, which in turn indicates a high degree of contamination. Low RLU indicates low levels of ATP and low level of contamination.

Biofilm

Biofilm occurs when microorganisms work together as a population and secrete a sticky polymer to form a solid matrix attached to a surface. Once a biofilm is established it is very difficult to eliminate. Biofilm can cause poor product quality and/or lost product due to contamination.

HACCP (Hazard Analysis and Critical Control Points)

HACCP is a widely accepted systematic approach to the identification, evaluation and control of significant food safety hazards in the food manufacturing and processing industries.

SSOP (Sanitation Standard Operating Procedures)

Sanitation procedures in food production plants. They are considered a basic requirement in a HACCP program.

Control Points (CP)

Control points within an ATP program are direct and indirect contact areas where potential contamination hazards can be identified, controlled and monitored.

3.2 Typical RLU limit guidelines

The following guidelines are typical of those found in food and beverage manufacturing. For recommended RLU limits in other environments, such as food service, hospitality, restaurants, and food manufacturing, contact Hygiena.

Typical RLU Limits by Product Type

		PASS	CAUTION	FAIL	PASS	CAUTION	FAIL
Product	Surface	SystemSure Plus			EnSURE		
Dairy Products	Stainless Steel	< 5	6 – 7	> 8	<10	11-15	>16
Juice products	Stainless Steel	< 10	11 – 29	> 30	<20	21-59	>60
Water bottling	Stainless Steel	< 5	6 – 9	> 10	<10	11-19	>20
Brewing equipment	Stainless Steel	< 15	16 – 29	> 30	<30	31-59	>60
CIP Rinse Water	Stainless Steel	< 5	N/A	> 5	<10	N/A	>10
Raw meat Slaughter Butchery	Porous Plastic	< 100 < 50	101 - 199 51-99	> 200 > 100	< 200 < 100	201 - 399 101-199	>400 >200
Cooked meat	Stainless Steel	< 25	26-49	> 50	< 50	51-99	>100
Fish products	Stainless Steel	< 30	31 - 59	> 60	< 60	61 - 119	>120
Shellfish	Stainless Steel	< 100	101 - 199	> 200	< 200	201 - 399	>400
Cheese processing	Stainless Steel	< 5	6 - 9	>10	< 10	11 - 19	>20
General food processors	Stainless Steel	< 10	11-29	> 30	< 20	21-59	>60
Vegetable	Stainless Steel	< 10	11-29	> 30	< 20	21-59	>60
Vegetable	Porous Plastic	< 100	101 – 149	> 150	< 200	201 – 299	>300
Cooked products	Stainless Steel	<10	11-29	>30	< 20	21-59	>60

3.3 Contact Hygiena

For any questions about ATP monitoring systems, or more information about Hygiena products, please contact Hygiena at:

Hygiena - Americas

941 Avenida Acaso
Camarillo, CA
USA 93012
Tel: +1-805-388-8007 x300
Fax: +1-805-388-5531
info@hygiena.com

Hygiena International

Unit 11 WENTA Business Centre
Colne Way, Watford, Hertfordshire
WD24 7 ND. UK
Tel: +44 (0)1923 818821
Fax: +44 (0)1923 818825
enquiries@hygiena.com

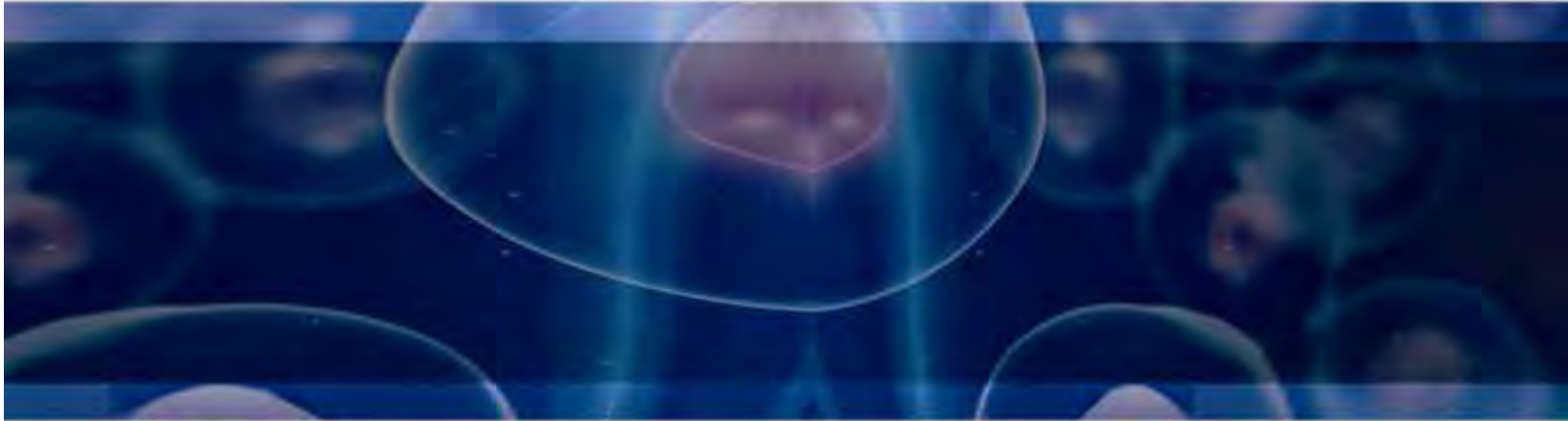
Hygiena China

Neiwailain Building Suite 21A3
No. 518 Shangcheng Road
Pudong New District, Shanghai, China
Tel: +86-21-51321081
Fax: +86-21-51321081
enquiries@hygiena.com

Hygiena Online

For additional information about Hygiena as well as interactive product demos, visit www.hygiena.com and www.youtube.com/HygienaTV

Notes



Hygiena - Americas

941 Avenida Acaso
Camarillo, CA
USA 93012
Tel: +1-805-388-8007 x300
Fax: +1-805-388-5531
info@hygiena.com

Hygiena International

Unit 11 WENTA Business Centre
Colne Way, Watford, Hertfordshire
WD24 7 ND. UK
Tel: +44 (0)1923 818821
Fax: +44 (0)1923 818825
enquiries@hygiena.com

Hygiena China

Neiwailain Building Suite 21A3
No. 518 Shangcheng Road
Pudong New District, Shanghai, China
Tel: +86-21-51321081
Fax: +86-21-51321081
enquiries@hygiena.com