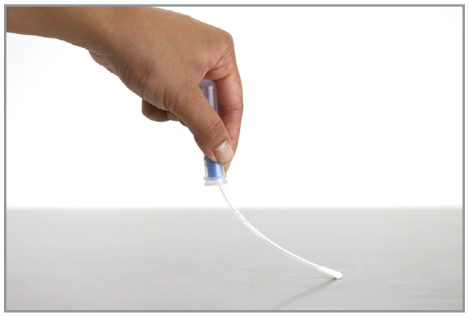

Lower and Upper RLU Limits for ATP Monitoring Programs: What are Lower and Upper RLU limits?

Lower and Upper RLU limits are set values used to easily evaluate and categorize ATP test results in real time.

Lower Limit: The maximum allowable RLU for a result to pass the ATP test for cleanliness. A surface that reads at or below the lower limit is categorized as a Pass result and considered acceptable. Passing results are indicated with a check mark (**√**) on the screen.
Upper Limit: A surface that reads above the upper limit is categorized as a Fail result and considered not adequately cleaned. Fail results are indicated with an (**X**) on the screen.
Caution Area: A surface that reads above the lower limit and at or below the upper limit is categorized as a Caution result. Caution results tell the user there could be something on the surface, but not enough to cause a Fail result. Caution areas can also show a surface is trending towards unclean and may require additional attention during the next cleaning. Caution results are indicated with an exclamation point (**!**) on the screen. Some facilities elect to eliminate the Caution range. To do this, the lower and upper limits are set to the same RLU value. With this setting, a surface that reads at or below the limit is categorized as a Pass result (**√**) and a surface that reads above the limit is categorized as a Fail result (**X**).

Hygiena's SystemSURE *Plus*™ and EnSURE™ luminometers come pre-programmed with a lower limit of 10 RLUs and an upper limit of 30 RLUs. The Pass, Caution, and Fail ranges are as follows:

RLU	0-10	11-30	31+
	Pass (**√**)	Caution (**!**)	Fail (**X**)

To eliminate the Caution area, set 10 RLU as the lower and upper limit. The Pass and Fail ranges are as follows:

RLU	0-10	11+
	Pass (**√**)	Fail (**X**)

Why are the default limits 10 and 30?

Hygiena™ recommends that Pass and Fail limits be determined by the facility and documented as to how they were determined. The default limits of 10 (Pass) and 30 (Fail) RLUs on the SystemSURE *Plus* are based on years of food & beverage processing experience and third-party studies. (See data below). Hygiena recommends users validate these recommendations and adjust them to meet the needs of each facility's unique needs.

Because Hygiena's EnSURE and EnSURE™ Touch luminometers are twice as sensitive to light as SystemSURE *Plus*, users may program limits of 20 (Pass) and (60) Fail RLU on the EnSURE luminometer to match these default recommendations. EnSURE Touch is already pre-programmed at 20 and 60 RLUs for Pass and Fail, respectively.

The following guidelines are typical of those found in the food and beverage industry and are based on clean stainless steel surfaces. Other surfaces may be more difficult to clean and consequently may require higher Pass/Fail limits to be set if complete bio-burden removal is not necessary. *(Refer to the following page for details on establishing custom RLU limits.)*

The data below is extracted from *Performance Evaluation of Various ATP Detecting Units*, a report prepared by the world's largest third-party reference laboratory[1]. The report provides the mean result for two products tested at various dilutions dried on stainless steel surfaces as well as serial dilution detection levels of other food stuff. The process and results for both methods are described below.

Detection of ATP from Food Soiled Stainless Steel Surfaces

Process:

To replicate the scenario of detecting residue on an unclean surface in a food and beverage processing facility, food suspensions were created and 10 replicates of 500 µl were added to a stainless steel 4 x 4 inch square and allowed to dry. An UltraSnap™ ATP test device was used to collect a sample and the device was activated. The RLU output was measured with SystemSURE *Plus*. The RLU limit in the right column is Hygiena's recommendations based on historical data from clean surfaces used in various types of food processing (pass limits are different for different food types if a facility is dedicated to one product type). This is verified with the data obtained at the 1:1000 dilution levels - mimicking low levels of residue which are close to 'clean' in a beef processing facility vs a dairy processor, which has strict CIP standards.

Results

SystemSURE *Plus* with UltraSnap Dry Soiled Stainless Steel Surfaces				
Products	**Dilution**	**Results Mean (RLU)**	**Range**	**Limit (RLU)**
Raw Ground Beef	1:10	2954	2540 - 3644	Fail: 2000
	1:1000	147	116 - 205	Pass: 100
2% Milk	1:1	173	145 - 195	Fail: 100
	1:1000	8	2 - 16	Pass 2

Detection of ATP from Food: Serial Dilutions Pipetted onto Swabs

Process:

Liquid food samples (orange juice and milk) were diluted using sterile water in various dilutions. Solid food samples (ground beef and salad greens) were first stomached using 10 g of sample in 90 ml sterile water and then diluted using sterile water in various dilutions. All test samples were homogenized by hand. Ten replicates of each food suspension were then analyzed using an UltraSnap ATP detection device by pipetting 10 µL of food suspension dilution directly onto the swab bud, activating the device, and measuring RLU results with the SystemSURE *Plus* luminometer. The RLU limits in the right column are recommendations based on the data from the report. The data reinforces the concept that different foods have differing amounts of baseline ATP in them.

Note: The Pass values seen at a 1:1,000 dilution or greater are similar to what would be seen on clean surfaces in various types of food processing facilities. Pass values should be established based on RLU results obtained after normal cleaning for each facility type. Efficient cleaning regimes may be able to remove 99.9% - 99.99% of soil which would equate to a 1:1,000 to 1:10,000 dilution; this is how we should interpret these tables. Again, dairy processing facilities typically have very low RLU values as product is thermally processed and surfaces are cleaned in place to minimize the presence of any contamination.

Results

SystemSURE *Plus* with UltraSnap Serial Dilutions Pipetted onto Swabs				
	Dilution	**Results Mean (RLU)**	**Range (RLU)**	**Limit (RLU)**
Bagged Mixed Salad Greens	1:10	164	129 - 195	Fail: 100
	1:100	36	3.1 - 43	Fail: 30
	1:1000	13	10 - 15	Pass: 10
	1:10000	2	1 - 2	Pass: 2
2% Milk	1:1	301	217 - 366	Fail: 200
	1:10	72	59 - 84	Fail: 50
	1:100	13	11 - 15	Fail: 10
	1:1000	3	3 - 4	Pass: 5
	1:10,000	2	2 - 2	Pass: 2
Pasteurized Orange Juice, no pulp	1:1	5617	5531 - 6220	Fail: 5000
	1:10	3958	3563 - 4448	Fail: 3000
	1:100	437	294 - 541	Fail: 250
	1:1000	56	39 - 70	Pass: 30
	1:10,000	5	2 - 8	Pass: 2
2% Milk	1:10	639	453 - 788	Fail: 400
	1:100	70	54 - 86	Fail: 50
	1:1000	0	0 - 1	Pass: 2
	1:10,000	0	0 - 1	Pass: 2

[1]Kupski, Brian, et al. "Performance Evaluation of Various ATP Detecting Units." Silliker, Inc., Food Science Center Report RPN: 13922, (2010).

Note
ATP tests are not organism tests, thus RLU values cannot be directly correlated to CFU values, nor can ATP tests be a replacement for microbiological tests. UltraSnap tests detect any organic material that contains ATP, which may include microorganisms. Refer to the full copy of the study for details on methodology and limit of detection for microorganisms.

For a full copy of *Performance Evaluation of Various ATP Detecting Units* by Silliker, Inc., please contact Hygiena.

If you have any questions about the information provided, please contact your Hygiena sales representative.

Can I use the same RLU limits for every location?

In some cases, the same RLU limits may be set for several locations. Optimal RLU limits will depend on a variety of factors such as surface variation and risk level. See examples below.

Surface Variations:

- Surfaces which are easy to clean, such as stainless steel or other flat, non-porous surfaces may have stricter, lower limits. Surfaces which are hard to clean, such as porous, grooved, creviced or irregular surfaces like conveyor belts, may have higher limits.

Risk Level:

- Environment: An environment with more stringent cleaning requirements, like a clean room, may have stricter, lower limits compared to a food processing environment with less stringent volatility.
- Contact Risk: Surfaces which come into direct contact with products require stricter RLU limits than non- contact areas, especially when dealing with higher risk products like meat, dairy, and/or produce.

Determining Custom RLU limits

The method for determining and validating custom lower and upper RLU limits is outlined below. In some cases, test results from different control points within a facility consistently fall in a similar range. In this case, RLU limits may be set to the same value for all control points in the facility. Likewise, test results from similar surfaces may consistently fall in a similar range. In this case, the RLU limits may be set to the same values for control points with the same surface type. Hygiena's SureTrend Data Analysis Software allows users to take note of the surface type of each test location.

- **Identify** control points in the facility. These are often outlined in the SSOP/HACCP programs.
    a. Control points can be programmed into the luminometer before testing so that results are saved with the control point location name, date, and time of test.
- **Clean** surfaces to the desired level of cleanliness.
    a. This may include a total production line breakdown.
    b. Future cleanings will be held to this level of clean as a standard.
- **Perform** an ATP test at each control point, taking 5-10 replicate tests. Use one of two methods.
    a. Perform tests over several days.
    b. Or for control points with sufficient surface area, perform multiple tests from different spots at that test location. (e.g. conveyor belt, tank, tabletop, etc.)

- **Calculate** the lower and upper RLU limits
  - **a. Lower RLU limit (Pass limit):** Calculate the average RLU for each location based on the 5-10 test results. The average result will be the lower RLU limit (Pass limit). It will be used to determine the upper limit (below).
  - **b. Upper RLU limit (Fail limit):** There are two options for determining the upper limit.
    - i. Multiply the lower limit by 3.
    - ii. Determine the standard deviation from the lower RLU limit test results, multiply the standard deviation by 3, and add this to the lower limit. This is the recommended method as it encompasses the 95% upper confidence limit of the higher RLU "clean" values.

CONTINUOUS IMPROVEMENT: *Monitoring and assessment of trends is crucial to finding trouble zones, correcting improper cleaning procedures and decreasing risk. Continuous improvement provides brand protection, avoids recalls and shows due diligence to auditors. If high frequencies of Caution and Fail results are obtained with ATP monitoring, SSOP should be reviewed for ways to improve cleanliness. If low frequencies of Caution or Fail results are obtained, RLU limits could be reviewed and potentially lowered to maintain high standards and generate useful management data.*

Feuille de calcul des limites RLU

(Conseil : photocopier ou imprimer des copies de cette page si vous souhaitez enregistrer les données manuellement. Enregistrer ces documents pour vos dossiers.)

Remarque :
Pour calculer la moyenne de vos résultats de test, additionner tous les résultats de test et les diviser par le nombre de tests. L'écart-type est un calcul de la variabilité de vos résultats, ou de la quantité qui diffère de la moyenne. L'écart-type est mieux calculé à l'aide d'un tableur, comme Microsoft Excel, pour minimiser les erreurs de calcul. Si vous souhaitez qu'un document Excel soit formaté pour permettre la saisie des résultats et le calcul automatique des moyennes et des écarts-types, veuillez communiquer avec votre représentant Hygiena ou avec le service à la clientèle au 888-HYGIENA (494-4362) ou à info@hygiena.com

Point de prélèvement	Exemple					
Type de surface	Inoxydable					
Répétition 1	5					
2	9					
3	9					
4	6					
5	4					
6	13					
7	7					
8	9					
9	8					
10	9					
Moyenne	7.9					
Écart type (optionnel)	2.6					
Seuil Supérieur	8					
Seuil Inférieur	24 or 16					

Point de prélèvement	Exemple					
Type de surface	Inoxydable					
Répétition 1	5					
2	9					
3	9					
4	6					
5	4					
6	13					
7	7					
8	9					
9	8					
10	9					
Moyenne	7.9					
Écart type (optionnel)	2.6					
Seuil Supérieur	8					
Seuil Inférieur	24 or 16					