

Hygiena Photodiodes vs. Photomultiplier Tubes (PMTs)



Hygiena's Photodiode

Photodiodes (PDs) are modern solid-state light reading devices first developed in the 1970s. Technological advances in PDs mean they are now used in all new high-end cameras and phones to capture images. Their durability and cost-effectiveness make them preferable over traditional fragile glass PMTs. The use of PDs is preferred in food manufacturing and other areas because they give a direct measurement of light signal rather than amplifying light which is less accurate.

Benefits:

- Robust
- Small, lightweight
- Requires low voltage (<5 volts)
- Stays in calibration
- No yearly maintenance
- Low cost
- Solid state



Photomultiplier Tubes

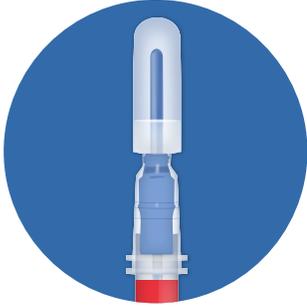
Photomultiplier tubes (PMTs) are vacuum tube devices that detect and amplify low levels of light. They are custom-made, fragile glass tubes that contain several metal plates and a phosphor screen. The alignment of the metal plates is vital for reliable results and the phosphor screen will degrade, giving the PMTs a limited shelf-life and requiring yearly calibration which can be expensive and inconvenient.

Benefits:

- Sensitive to low levels of light
- Detects multiple frequencies – suitable for bioluminescence and chemiluminescence

Bioluminescence Chemistry

Chemistry in test devices is the most critical element of system performance, as it facilitates the bioluminescent reaction that is measured by the instrument. The more reliable the chemistry, the more reliable the results.



Hygiena's Liquid-stable Chemistry

Hygiena test devices utilize a liquid-stable chemistry that eliminates costly manufacturing steps and extraneous device components, enabling more reproducible results and better accuracy. Fewer manufacturing steps also reduces potential for manufacturing variation.



Charm's Lyophilized Pellets

Lyophilization has historically been the technology used to stabilize enzymes prior to use. Water is quickly evaporated out of the sample, leaving a pellet that can be reconstituted with a liquid. The pellet requires complex, expensive manufacturing, dry storage, and rehydration. The evaporation process also leaves behind impurities in the pellet that produce background noise once rehydrated. Background noise interferes with test readings and causes greater variability in results.

Hygiena vs Charm Safety Data Sheet Comparison for ATP Detection Devices

Category	Hygiena UltraSnap™ Surface ATP Test	Charm PocketSwab® Plus
Hazard Identification	Nonhazardous - UltraSnap does not qualify as a hazard due to the low concentrations of chemicals in the mixture. This is verified by both OSHA (USA) and ECHA REACH (EU). Hygiena devices are deemed nonhazardous because the Sodium Azide content in the devices is below the hazardous threshold per Directives 67/548/EEC and 199/45/EC.	No health hazards are expected under normal use. Reagents in the unit may cause irritation of the eyes, skin or gastrointestinal system.
Handling/Personal Protection	UltraSnap does not qualify as a hazard due to the low concentrations of chemicals in the mixture. This is verified by both OSHA (USA) and ECHA REACH (EU). No personal protective equipment required under normal use.	No personal protective equipment required under normal use.
Disposal	No hazardous components and 100% recyclable.	Plastic device is recyclable. Recycle or dispose of by landfill or incineration.
Toxicological Information	No acute or long-term effects from exposure are expected from normal use.	No acute or long-term effects from exposure are expected from normal use.

Comparison of Charm's PocketSwab® with Hygiena's UltraSnap™-original and modern formulations

The table below shows third-party test results of both Charm's novaLUM™ and Hygiena's SystemSURE™ Plus. The study compares both the first-generation and second-generation UltraSnap swab to Charm's PocketSwab. Charm published comparison data using the outdated first-generation UltraSnap swab to justify claims of equivalent performance. The first-generation UltraSnap swab was replaced by the second-generation UltraSnap swab in 2010. The table below shows a comparison of all three test devices. Both of Hygiena's UltraSnap swabs show superior performance over Charm's swab.

Table 1

fmoles	Charm PocketSwab (mean RLU/CV%)	Hygiena UltraSnap pre 2010 (mean RLU/CV%)	Hygiena UltraSnap post 2010 (mean RLU/CV%)
1,000	229,017 (55)	1,155 (7)	1,421 (8)
100	20,849 (24)	108 (6)	150 (11)
10	89 (214)	9 (6)	14 (10)
5	0	3 (29)	3 (20)
1	0	1 (53)	1 (105)
0	0	0	0

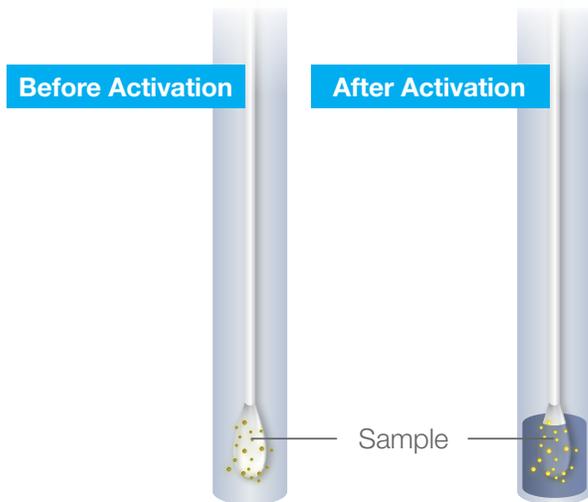


Hygiena's liquid-stable chemistry *eliminates* the need for lyophilization and *stabilizes* the enzymes in a liquid format. This *eliminates* costly manufacturing steps and reconstitution of the enzyme giving more reproducible and accurate results.

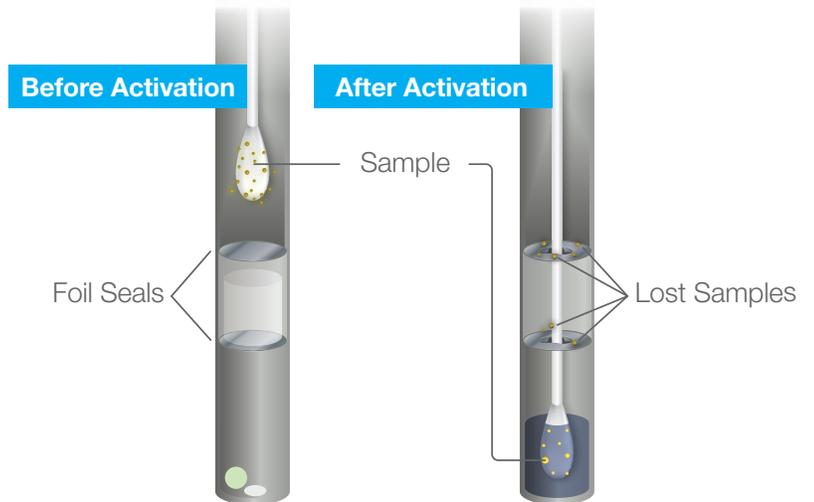
Hygiena instruments use advanced PD sensors and electronics, giving them the ability to detect lower levels of light than PMT based instruments.

Test Device Design

Hygiena UltraSnap™



Charm PocketSwab® Plus



PocketSwab Plus test devices contain two foil seals that the swab tip must pierce before the sample can mix with the chemistry in the tube. When puncturing these seals with the swab tip, sample is left behind due to friction. Thus, less sample makes it into the test device for detection. This can cause inaccurate and variable reading, as the system detects less ATP than was present on the surface. Hygiena's UltraSnap surface ATP test is designed so that 100% of the collected sample is measured, leading to superior sample recovery and more accurate, repeatable results.

Foam vs Fiber:

Another integral component of the test device design is the device bud or tip. Hygiena test devices utilize a fiber device bud in their proprietary design while Charm utilizes a foam device bud. Studies and evaluations have been conducted with both foam and fiber - no differences in results. Swab technique is the most important factor for results.

All Components Combined

Sensitivity: Smallest Detectable Amount of Sample

Hygiena System

femtomoles ATP
ATP (mol)

SystemSURE Plus

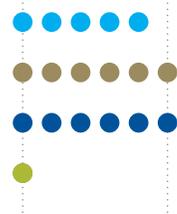
EnSURE

EnSURE Touch

Charm novaLUM

UltraSnap™ Detection Limit

10 fmol 1 fmol .1 fmol .01 fmol
 1×10^{-14} 1×10^{-15} 1×10^{-16} 1×10^{-17}



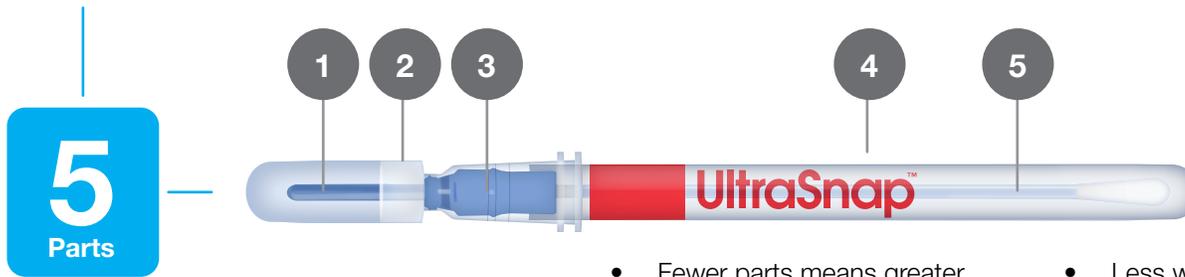
Advanced Sensor:

Hygiena's advanced sensor technology, device design, and liquid-stable chemistry enables greater sensitivity than Charm's novaLUM™ and PocketSwab® Plus system, allowing you to detect lower levels of ATP. By using EnSURE Touch coupled with SuperSnap High-Sensitivity ATP Tests, customers can benefit from extremely low levels of detection down to .1 fmole ATP.



The AOAC Research Institute, one of the world's most recognizable product certification organizations, issued its *Performance Tested Method*™ certificate to UltraSnap™ Surface ATP Tests for use with the EnSURE™ Touch.

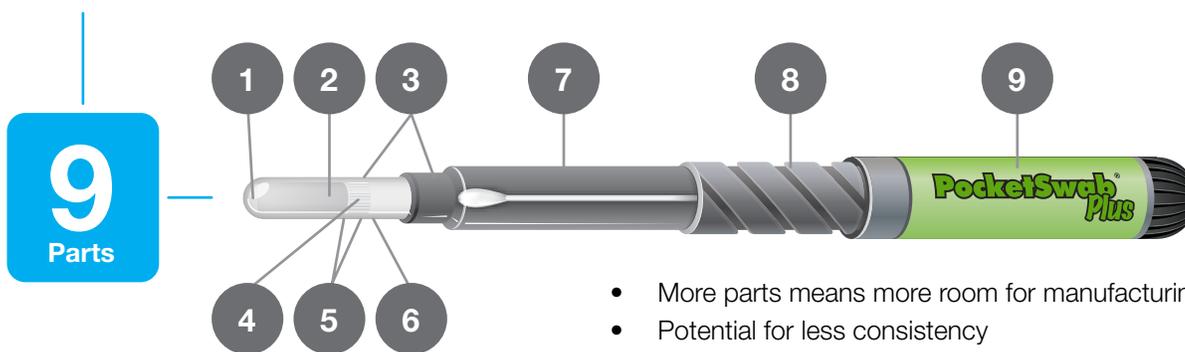
Hygiena UltraSnap™



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Parts

- Fewer parts means greater consistency and control in manufacturing
- Shelf-stable for 30 days at room temperature
- Less waste (more ecological)
- More repeatable tests
- 100% recyclable
- No foil seals

Charm PocketSwab® Plus



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Parts

- More parts means more room for manufacturing error
- Potential for less consistency
- More waste (less ecological)
- 2 foil seals

Conclusion:

Sensor: Hygiena instruments use advanced PD sensors and electronics, giving them the ability to detect lower levels of light than PMT based instruments.

Chemistry: Hygiena's liquid-stable chemistry eliminates the need for lyophilization and stabilizes the enzymes in a liquid format. This eliminates costly manufacturing steps and reconstitution of the enzyme giving more reproducible results and better accuracy.

Formulation Comparison: Charm's previous comparison between UltraSnap and PocketSwab were based on first-generation UltraSnap rather than the current second-generation UltraSnap.

Device Design: Hygiena test devices are designed without foil seals so 100% of the sample is measured, leading to superior sample recovery and more accurate, repeatable results.

Device Design: Hygiena test devices are also designed with fewer parts for greater consistency and manufacturing control.

All Components Combined: Hygiena's ATP Monitoring System outperforms Charm on the basis of sensitivity, test device formulation, sample collection, and manufacturing consistency.

- Charm system cannot detect below 10 femtomoles of ATP as seen in Table 1. Hygiena can consistently detect below this level.
- The RLU per femtomole for Hygiena is 1 - 2, the RLU per femtomole for Charm is 250 - 350.
- Charm's > 0 RLU cut-off for interpreting ATP results is not supported by ATP detection data. Hygiena's method of using the amount of ATP extracted for interpreting ATP results is correct and supported by ATP detection data.