BioHawk LF®

Integrated detection, collection, & bioidentification

Fully automated from threat detection to test result

Features

- Toxins, bacteria, spores, fungi, multi-cellular pathogens
- Up to 8 simultaneous bioassays on collected samples
- Low operating cost: No unnecessary testing
- Automatic confirmatory sample
- 325 liter/minute air sampling rate
- Weeks-long air sampling times
- Uses widely available lateral flow immunoassay tickets
- Room temperature storage of consumables
- Machine vision-based assay protocol
- 10 - 25 minutes total time from detection to result
- Auto-flush protocol for decontamination and cleaning
- Flash memory retains data for over 6,000 assays

Application Areas

- Mailrooms
- Agriculture & air quality
- Medical facilities & public health
- Homeland security & military

The BioHawk LF® is an automated system for detecting, collecting, and identifying airborne pathogens. It integrates three patented Research International technologies: UV-C based biofluorescent detection, wet cyclonic sample collection, and machine-vision lateral flow immunoassay identification.

Low operating costs Why run expensive assays when no threat is present? The BioHawk LF's built-in biodetector initiates identification testing *only* when a credible biothreat has been detected. Testing frequency is reduced to a fraction of traditional fixed-interval testing protocols.

Flexible modes of operation The BioHawk LF can operate in fully automatic mode or in a lower-cost semi-manual mode depending on the requirements of your application.

Long unattended sampling periods A targeted air stream can be sampled for long periods, even several months, without human intervention. Detection of a suspicious aerosol will launch the assay protocol automatically.

The ultimate in automated long-term bio-surveillance Bioassay tickets can be optionally provided in hermetically sealed carriers that preserve viability for several months. This is ideal for long-term, unattended bio-surveillance.

Rapid results Using commercial, off-the-shelf bioassay tickets, the presence of up to eight biothreat agents may be simultaneously determined within 10 to 25 minutes.

Machine vision ensures accuracy Assays are evaluated inside the instrument by patented machine vision. There is no ambient light interference, and no need to educate users on assay interpretation.

Automatic confirmation sample A transfer vial is standard for after-assay storage of sample fluid for use with an alternative confirmation method.

The bioassay ticket advantage Bioassay ticket testing is perhaps the most widely used and mature technology available for the identification of biothreats at trace levels. Tickets have a long shelf life, typically 12 to 18 months, and require no special storage conditions. They are available for a variety of threats from multiple sources, and tests for new threats are commonly developed as the need arises. The BioHawk LF is obsolescence-resistant in that regard.

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Technical Discussion

The BioHawk LF is particularly well-suited for use as part of a complete CBRN monitoring program. It is cost-competitive, reliable, and user-friendly. Its high degree of automation results in ease of use by less experienced personnel.

The biodetector and automated ticket assay module are patented technologies that are also used in other Research International products – notably the AnCam 6100 and VBAD 3600 – systems that are currently in use by world governments to determine the presence of airborne pathogens. More detailed discussions of each subsystem follow.

Biodetector

The biodetector is a third-generation product based on photon-counting technology as licensed from the U.S. Army in 2010. In this device, all aerosol particles in sampled air pass through a beam of UV-C excitation light with a center emission wavelength of 280nm. Each particle in the sample stream passes through the beam and is binned according to its light scattering, fluorescence emission intensity, and physical size. This information is examined every 15 seconds to determine whether a suspicious event has occurred that is not characteristic of the expected aerosol background.

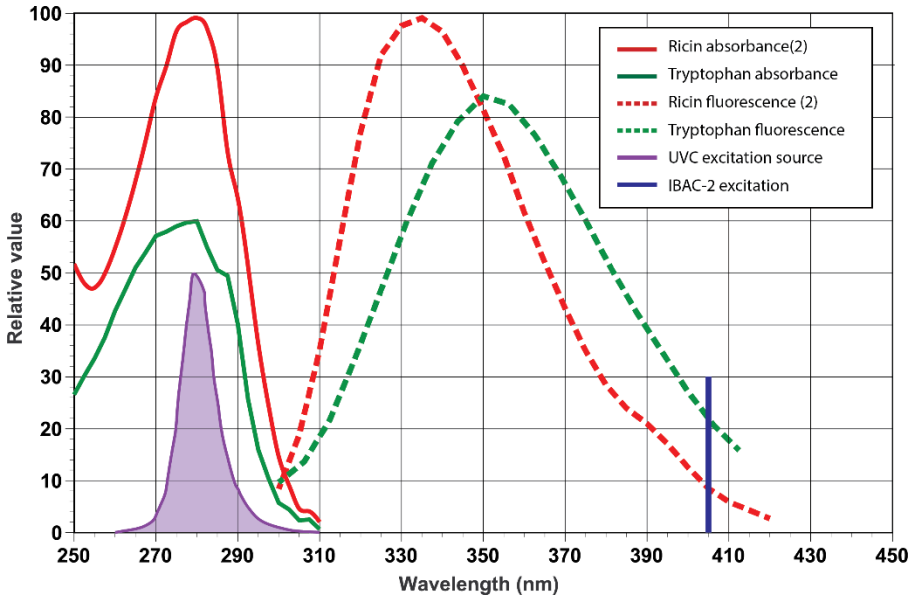

Figure 1. Absorbance and fluorescence spectra of ricin toxin and the protein tryptophan in relation to the BioHawk LF's excitation spectrum. The BioHawk LF is optimally designed to excite bio-fluorescence.

Many proteins found in toxins, viruses, and bacteria peak in fluorescence emission when excited at 280nm (Figure 1) and pulse bursts from those fluorescent photons are used to identify and characterize individual bioaerosol particles. Some non-biological aerosol materials also fluoresce at UV wave-lengths, but yields are typically low with UV-C excitation.

A common problem with bioaerosol triggers has been a high level of false alarms. This issue is dealt with in the BioHawk LF by requiring that a trigger event simultaneously satisfy four different alarm criteria involving: the rate at which the bioaerosol level changes; the fraction of all particles that are biological; the intensity of the fluorescence; and the background particle concentration. The likelihood that all trigger values exceed their limits at the same time is low, thereby significantly reducing false alarms. Alarm parameters may also be adjusted for local conditions by expert users. Software supplied with the product allows collected historical data to be used to determine optimum alarm parameter values.

This leading-edge biodetector subsystem has been granted several patents, including US 10267723 B1; US 10274410 B1; US 10444137 B2; US 10794815 B2; and US 11340153 B2.

Wet Sampler

The BioHawk LF uses a novel wetted-wall cyclone method of aerosol collection. This is the same sampler technology that was used successfully in 2019 to collect the first Covid-19 aerosol samples in Wuhan, China at the start of the pandemic. This work was recognized in a U.S. CDC publication[1].

In this device, aerosol particles in the BioHawk's 325 liter/min airflow are collected into distilled water using a combination of centrifugal and droplet impaction. The typical collection volume of 4.5 ml means that the aerosol air-to-water concentration ratio is about 72,000/min.

Most wet samplers are incapable of continuous operation since evaporation of water by the flowing sample air rapidly diminishes sample volume. This cyclone incorporates a novel patented recirculation circuit that monitors liquid volume

and adds water as needed to maintain a constant liquid inventory. A 5-minute collection time is typical without water replenishment. With the Research International cyclone, sampling can continue uninterrupted for days at a time.

A potential problem with wet samplers is that droplets containing infectious particles may be created during the sampling process. If discharged with sampled air, they may cause illness, which is of significant concern in medical facilities. The Research International sampler employs a droplet separator that reduces emission of droplets to near-zero.

The wet cyclone module has been granted the following patents: US 6484594 B1; US 6532835 B1; and US 7261008 B2.

Bioanalyzer

The BioHawk LF bioanalyzer module is based on fully robotic immunoassay principles, including machine-vision reading of bioassay tickets. The time from alarm to result ranges from 10 to 25 minutes, depending on the threat's concentration.

An immunoassay approach leverages the wide availability of tickets targeting different medical and public safety threats. While less sensitive than PCR, immunoassays require no sample preparation and can be accomplished in half the time required for PCR. In addition, a first step in the assay protocol is production of a confirmatory sample so that users can quickly examine the sample using an alternative assay method of choice.

Alternative technologies often incur significant consumables costs due to a periodic sampling mindset. With the BioHawk LF, there is no interruption to work in progress until an unusual bio-event is detected.

Using the BioHawk LF for Long-Term Unattended Monitoring

Some users need to operate the BioHawk LF in a long-term unattended setting, such as airport security areas, with a ticket loaded and ready to run an automated assay upon threat detection. But while the shelf life of immunoassay tickets ranges from 12-18 months at room temperature, assay tickets must normally be used within 48 hours of removal from their foil packaging to prevent deterioration from issues such as humidity exposure.

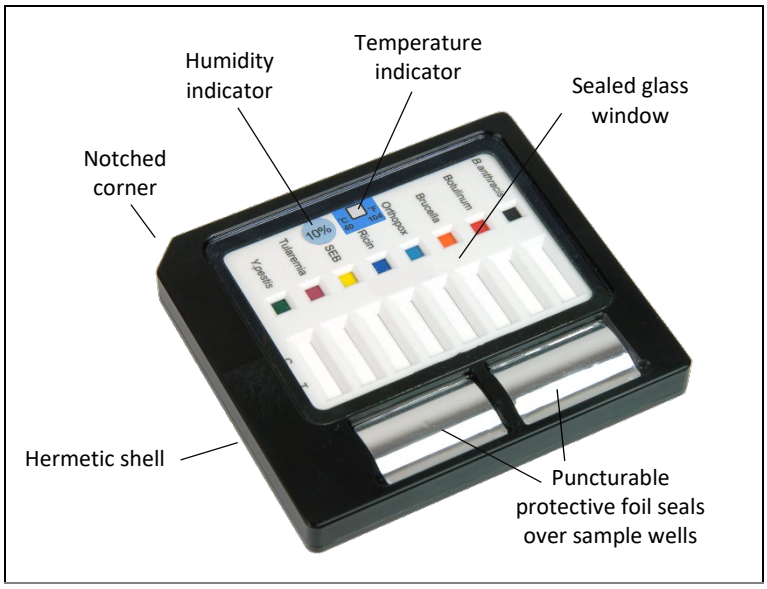

Figure 2. Hermetically sealed 8-channel immunoassay ticket.

To solve this viability problem, Research International has developed a patent-pending hermetic shell to preserve the ticket while allowing it to remain loaded in the BioHawk LF for extended periods – even weeks or months – until it is needed for an assay.

The shell features puncturable foil seals over the sample wells for sample delivery, a large window for machine vision monitoring of the assay development process, a small desiccant pack, and passive humidity and temperature sensors to confirm ticket viability (Figure 2).

The BioHawk's robotic transport system can accept either bare tickets with one to eight channels, or those same tickets encased in this proprietary shell. The shells are reusable; once a ticket is exhausted, a new one may be mounted.

The bioanalyzer module is covered by the following patents: US 10318845 B2; US 11023773 B2; US 10192144 B2; US 11543405 B2; and US 10197558 B1; and US 10690660 B2.

Refs.

1. *Aerosol and Surface Distribution of Severe Acute Respiratory Syndrome Coronavirus-2 in Hospital Wards, Wuhan, China, 2020*, Zhen-Dong Guo et.al., Emerging Infectious Diseases • www.cdc.gov/eid • Vol. 26, No. 7, July 2020.
2. https://docslib.org/doc/13005863/ultraviolet-visible-reference-spectra

Detection & Sampling Specifications

Exterior aerosol sampling rate	>300 liters/min. delivered to trigger and continuously operating wet collector.
Targeted aerosol threats	All toxins, viruses, bacteria and spores in the 1 to 15 micron size range.
Threat detection method	UVC-excited single particle biofluorescence and optical scattering. A multi-parameter threat calculation is performed at 15 sec. intervals.
Detector statistics	Detection limit is 1 sampled particle (U.S. patent 10267723 B1). Will alarm on 20 ACPLA bioaerosol with 90% probability at a background alarm rate of 1 per month. Natural background aerosol statistics may affect field performance.
Sample preparation after trigger event	Wetted wall cyclone. 72,000/min. air/water concentration ratio. Liquid sample volume is unaffected by time, temperature or humidity.
Bioidentification strategy	Automatic robotic lateral flow immunoassay plus confirmatory sample. Minimum/maximum total elapsed times to assay result are 10/25 mins., typ.
Simultaneously identifiable biological agents	Up to 8 agents in a single test cassette. Compatible with lateral flow immunoassay tickets provided by most manufacturers.
Confirmatory assay sample after trigger event	A confirmatory sample filling station can be instructed to automatically fill a vial immediately after an alarm or after a positive assay result. The confirmatory sample may also be transferred to the system waste bottle.
Alarm events performed before system requires service	Unlimited if only used to detect and notify threat event occurrences. If the bioassay option is selected, the assay ticket must be replaced after each test.
Bioassay ticket life	Ready-to-run hermetically sealed tickets installed in the instrument are viable for 6 months and 12-18 months in as-supplied foil pouch.
Output upon alarm or positive assay	Immediate light and sound alerts on initial alarm and if assay results are positive. Electronic signals transmitted as appropriate to a connected remote monitor.

Research International reserves the right to change specifications without prior notice.

Physical Specifications

Power	37 W at 28 VDC
Temperature range	Operating: 5°C to 40°C; instrument storage: -29°C to 66°C
Environmental standards, shock, and vibration	Appropriate sections of MIL-STD-810
Dimensions	47.0 W x 24.8 D x 36.5 H (cm)
Weight	13 kg
Exterior noise level	Less than 70 dBA
Consumables	1) Bulk deionized water; 2) buffer; and 3) wash fluid. Buffer and wash fluid are available in convenient single use bottles.

Software & Communications

Process control	Industrial PC-based control/protocol software. Touch screen control. Fully automated and integrated sampling, sample preparation, bioassay, and cleaning protocols. Immediate operator alert upon any detected operating fault.
Data preservation	All raw biodetector data and bioassay photos are time-stamped and stored.
Ethernet connectivity	Standard RJ-45 connection to onboard computer.

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