

BioHawk®

**8-Channel
Air Sampler
and Biodetection System**

Introduction

The portable BioHawk® is an 8-channel bioassay system integrated with an aerosol collector. It is suitable for the high-sensitivity monitoring of biological agents, toxins, explosives, and chemical contaminants. Assay results are typically available in 10 to 20 minutes. BioHawk can be programmed to monitor surrounding air for aerosol threats with the built-in air sampler, and to periodically transfer a wet concentrate from the air sampler to the biodetector portion.

Alternatively, a Sample Port may be used to introduce liquid samples for analysis from external sources, either manually or under software control. A built-in microcomputer provides unparalleled operating flexibility and sophistication.

Bioassays are performed within a small disposable credit card-sized plastic assay coupon. Unlike other assay technologies that are based on a "use once and discard" philosophy, this coupon and the reagents stored within it may be used for up to 10 assay procedures before being discarded. Since a single assay coupon can handle up to eight different analytes simultaneously, this means that up to 80 individual assays may be performed before discarding or removing the coupon. This capability simplifies field use and substantially reduces life cycle cost.

Assay results may be transmitted to users through the touch panel LCD display, an audible alarm, a pulsating light, or by wireless or RS-232 link to personnel at a remote location. System operation may also be remotely controlled in real time- virtually every fluid or air handling function is capable of being controlled remotely.

Although sophisticated and versatile, the unit is still very easy to use. Most global functions such as air sampling and biodetection are performed using multi-step recipes developed by Research International and stored in the system's computer memory. Users need only the most fundamental level of training since the internal processes and steps are preset through the built-in computerized recipes. For more professional users, bundled Windows-based software allows the user to develop their own customized sample collection and detection protocols.

The system is truly portable at a field weight of only 12.1 kg and volume of 17 liters. The system is capable of 14 to 42 hours of operation on the standard BA5590/U primary battery: Specific operating times will depend on climatic conditions and use profile. A rechargeable battery option is also available.

In the following sections, the air sampler and biodetector technologies are described in greater detail.

Air Sampler Features

The air sampler is a highly effective multi-stage wetted-wall cyclone that continuously processes air at a 325 LPM rate, extracting particulates and transferring them to a liquid phase of 4 to 6 cc volume (see Figure 1). Distilled water is typically the liquid of choice; no additives or surfactants are required for maximum efficiency. This condensed liquid sample may be periodically transferred in part or in whole to the biodetector using a built-in peristaltic pump.

A dropper bottle filling station is also integrated into the BioHawk so that a portion or all of the sample may be dispensed into an 8 cc dropper bottle for archiving and/or application of an alternative analysis method. For example, the dropper bottle feature allows the BioHawk to be used as a sample collection and preparation system for lateral flow tickets.

A unique feature (US patent 6,532,835) of the air sampler is its ability to operate unattended for a long period of time and to amplify trace analyte concentrations by maintaining a constant sample fluid volume in the device that is independent of collection time, air temperature or relative humidity. This is accomplished by monitoring liquid inventory continuously with a proprietary sensor attached to the cyclone body. When the sample water inventory falls below the desired set point, the sensor initiates clean water transfer into the cyclone body from an onboard 1 liter water supply. Water inventories are maintained within a preferred range of about 4 to 6 cc with an accuracy of a few tenths of a cubic centimeter.

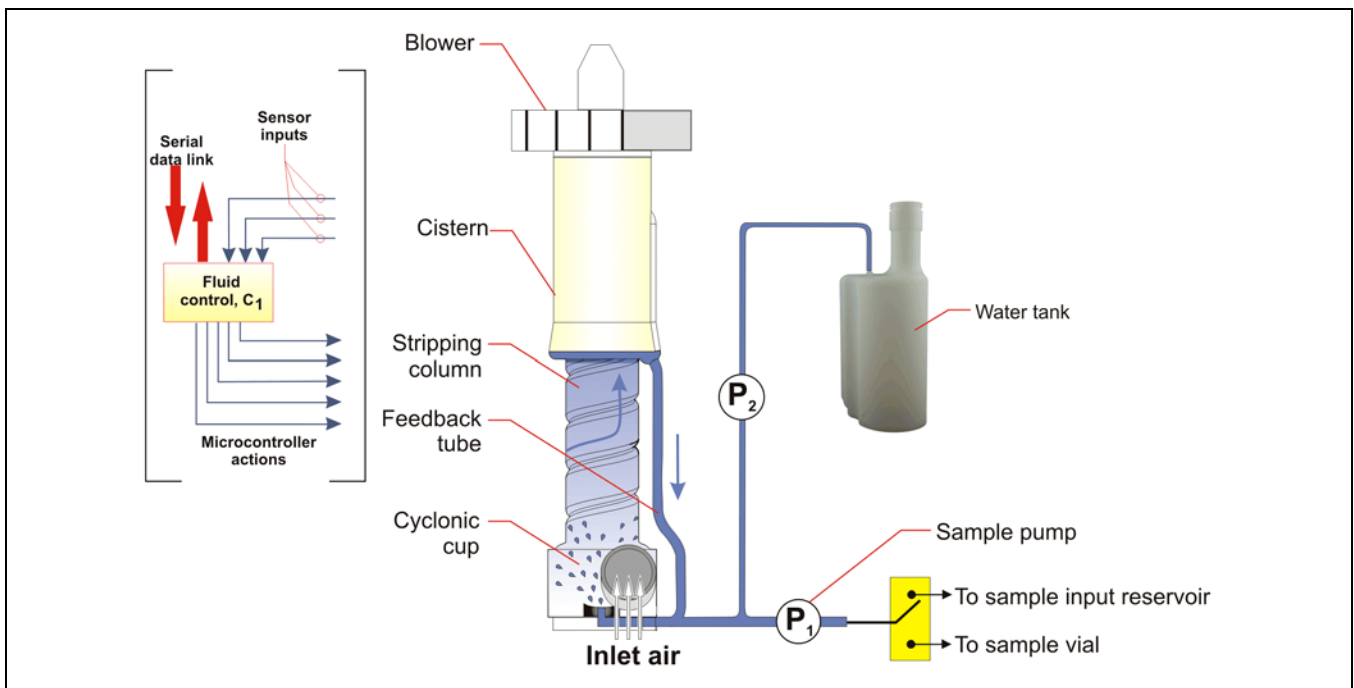


Figure 1: Air sampler flow schematic.

Biodetector Description

The instrument's biodetector section consists of a disposable 8-channel fluorometric assay coupon (see Figure 2) suitable for the high-sensitivity detection of biological agents, toxins, explosives, and chemical contaminants. All target-specific reagents needed to perform an assay are contained within the coupon. The only fluid not carried in the coupon is a saline buffer used to wash the system between assays. It is stored within a refillable reservoir in the instrument. All waste water is also stored in an onboard reservoir- no fluids are discharged from the system during either air sampling or the assay process.

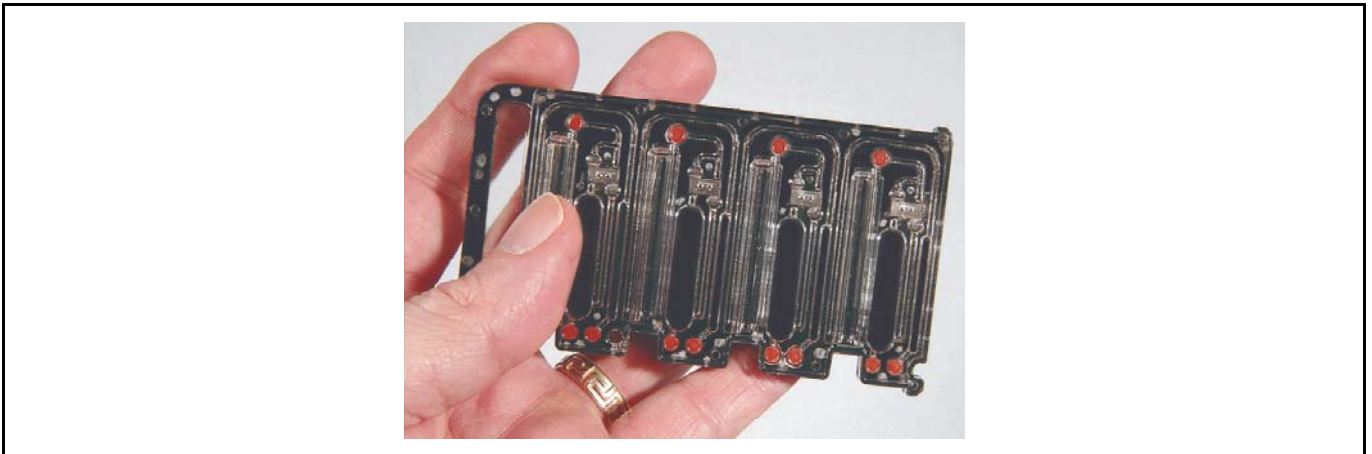


Figure 2: BioHawk bioassay coupon.

Upon coupon insertion into the instrument, an optical bar code on the coupon is automatically interrogated for assay recipe information. Highly reliable computer-controlled peristaltic and syringe pumps are used to move reagents, sample fluids and wash buffer within the coupon, as directed by the assay recipe. Automation of the assay process in this way ensures repeatable behavior from test to test. No user intervention or evaluation is required.

Targeted agents are detected by monitoring fluorescently-tagged chemical reporter reactions taking place on optical waveguide surfaces within the coupon (see Figure 3). These reactions typically use antibodies to bind targeted pathogens to the waveguide surfaces, and fluorophore-tagged secondary antibodies to create a fluorescent signal when the waveguides are irradiated with 635 nm solid state laser light.

Assay data is automatically stored in the system's non-volatile EEPROM with a date and time stamp, and can be downloaded to a remote computer using an RS-232 or wireless link. The BioHawk has the capacity to save up to 6,000 data sets.

Auxiliary Windows-based software allows the user to graphically monitor data recovery while an assay is running. It also provides sophisticated users with the ability to customize the various steps involved in running an assay.

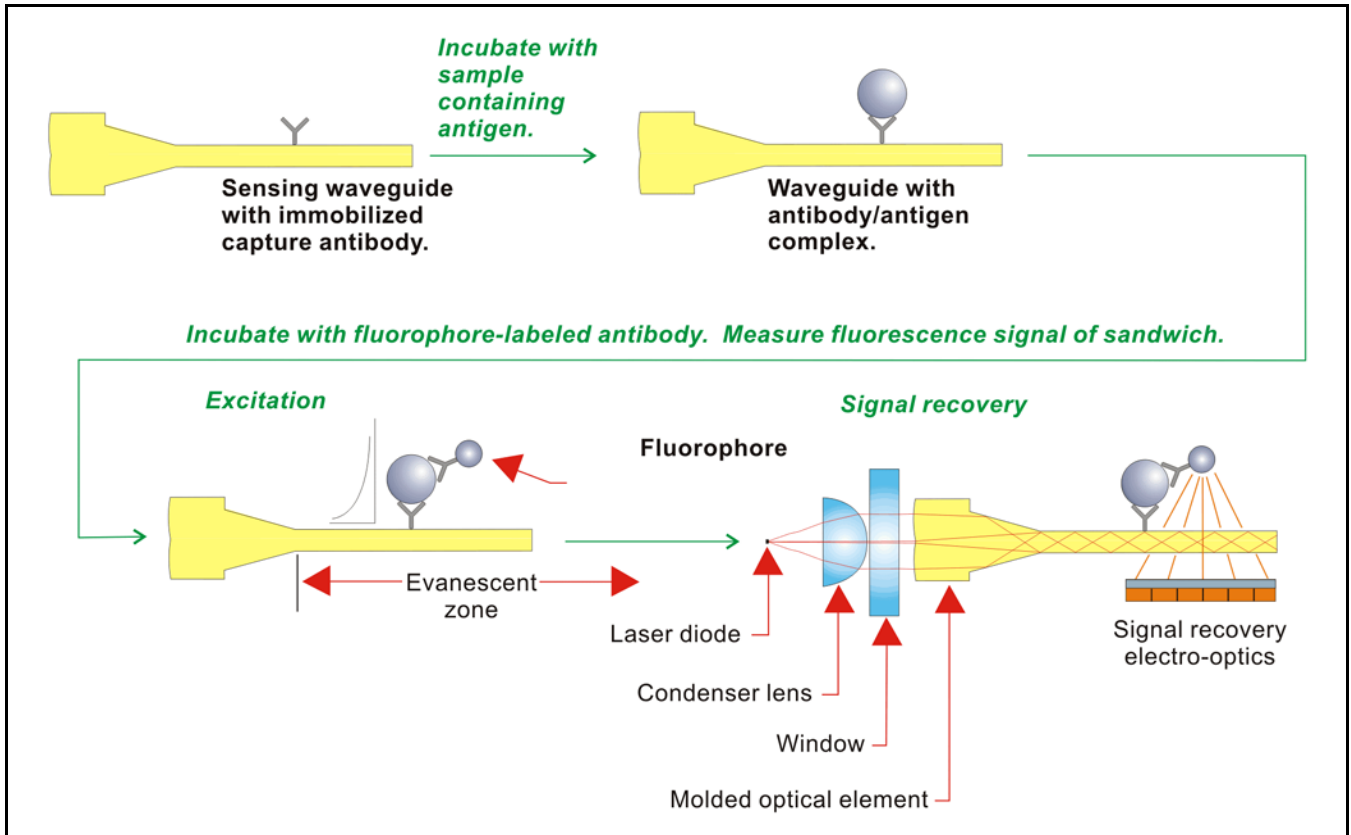


Figure 3: Schematic of two-step identification process.

This product is covered by one or more of the following patents: U.S. Patents No. 6,136,611; 5,430,813; 6,082,185; 6,532,835; 5,061,857; and Japanese Patents No. 3,429,282 and 3,754,440.

For More Information

For further details concerning specific system characteristics, please contact Research International directly.



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BioHawk General Specifications

| Characteristic | Description |
|------------------------------------|--|
| Use profile | Indoor/outdoor sample collection, transfer, and assay; storage of 255 assay recipes; user in full MOPP gear either walking or in moving vehicle. |
| Collection principle | Multi-stage wetted-wall cyclone with enhanced particulate collection. |
| Assay method | Disposable wet assay coupon is re-useable up to 10 times. Eight simultaneous software-based assays. Antibody or nucleic acid. Coupon reseals on removal for archival storage. |
| Fluid Handling | Fluids manipulated under microprocessor control using peristaltic and syringe pumps; sample may be oscillated to lower assay time; reagent is recovered for reuse. |
| Fluids storage | Snap on 3-section fluid pack. Clean water: 1 liter; Buffer: 250 ml. Waste: 500ml. Assay samples may be optionally stored in a detachable 8cc vial for later analysis. |
| Human interface | Day/night Touchscreen LCD display. Usable in MOPP gear. |
| Digital communication | RS-232 bi-directional serial link |
| Physical size | 35.6 cm W x 36.5 cm H x 17.1 cm D |
| Weight | 21.7 lbs. dry; 26.7 lbs. with battery and fluids (9.8/12.1 kg). |
| Operating/storage | 1 to 66°C and -29 to 66°C. Reagent deterioration can reduce upper limit significantly |
| Humidity | 10% and above. May be operated in rain. |
| Survivability | MILSPEC 810F; MTBF of about 30,000 hours is determined by air sampler fan |
| Data storage | Flash memory retains raw/processed data for over 6000 assays. |
| Power Consumption | 6.2 W at idle; 17.8W with fan operating and one assay performed each 30 minutes |
| Power source | Primary battery BA-5390A/U, 1.05 kg (2.3 lb); lifetime 14 to 45 hours. Rechargeable battery UBI-2590; lifetime is approximately 56% of the BA5390A/U primary battery. Universal lump-in-cord power supply, 82-265 Volt (47-63 Hz). |
| Alarm | Visual LED and 103 dB @0.6m waterproof horn; adjustable. RS-232 data link. |
| Decontamination | Auto-flush protocols using onboard water, or manual flush with detergent and/or disinfectant. High-performance pull-through fan easily remove if contaminated. |
| Sound level | 60 dB (A). |
| Ancillary equipment | Heavy-duty hard-shell transport case with wheels. |
| Bioassay Specifications | |
| Analyte range | Toxins, viruses, bacteria, spores, fungi, multicellular pathogens |
| Sensitivity | Analyte dependent, 1 to 10 ppb typical for toxins, 100 to 100,000 CFU/ml for bacteria. |
| Assay time | Dependent on assay; 10 to 20 minutes typical. |
| Reagent storage | Reagent stored onboard assay coupon; may be reused up to 15 times depending on assay protocol. |
| Confirmatory sample | Confirmatory sample may be stored in assay coupon or 8cc sample vial. |
| Air Sampling Specifications | |
| Air collection rate | 325 LPM, nominal. |
| Particulates collection range | 0.5-10 µm |
| Concentration ratio | 65,000/min., nominal. |
| Liquid inventory | 4 to 5cc. Factory set but adjustable under computer control. Patented control process maintains a constant liquid volume in the sampler, independent of collection time, temperature, or humidity; useful for concentrating trace airborne analytes. |
| Air inlet | Screened rectangular opening. Hose adapters available. |
| Sample extraction | On-board 12 cc/min peristaltic pump under manual or remote computer control. Vial filling also supported. Air sampling may continue during extraction. |