

ENVIRONMENTAL DATA EXCHANGE (EDX)

SYSTEM OVERVIEW

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INTRODUCTION AND EDX OVERVIEW

Relative humidity and temperature considerations are critical control parameters in the processing, manufacturing, storage and distribution of pharmaceuticals, food and many other products on the market today.

More and more, industries are requiring specialized monitoring, and the recording of selected environmental conditions, to support quality, regulatory, and accreditation requirements through all facets of the cold chain. 'Key' requirements for these systems include:

- Prompt access to real-time temperature and humidity data, to ensure "in-spec" performance.
- Notifications when 'out-of-range' conditions occur.
- Reliable historical records to support quality reviews and audits.
- The integration of system components to provide a complete and comprehensive temperature profile across the entire cold chain.

Only **Integrated Monitoring Solutions (IMS)** offers an affordable and fully integrated solution across the entire cold chain, providing customers with comprehensive temperature results, and linked information.

IMS' solutions comprise portable, electronic temperature and humidity data loggers, for 'long-haul' transport and remote monitoring, and license-free wireless sensors for warehouse and manufacturing facilities. Utilizing the **Environmental Data Exchange (EDX)** platform, temperature and humidity information is collected from each device, linked, and stored in a centralized information repository. Datalogger information is collected at appropriate intervals, subject to system accessibility, while wireless system components transmit their temperature and humidity results in real-time intervals.

The unique **EDX** portal provides secure, on-line access to current environmental conditions, as well as historical reports for audit purposes. In addition, user-defined alarm notifications can be set up to alert personnel if environmental conditions go 'out-of-range'.

EDX is a user customizable system, designed to provide a robust and fully redundant solution to monitor temperature and humidity conditions 24 hours a day, 7 days a week, and 365 days a year, in a variety of storage conditions.

The **EDX** platform provides a structured environment in which temperature and humidity data is collected and linked from multiple locations, and devices, which are integrated to provide a comprehensive database of environmental conditions, across the complete cold chain.

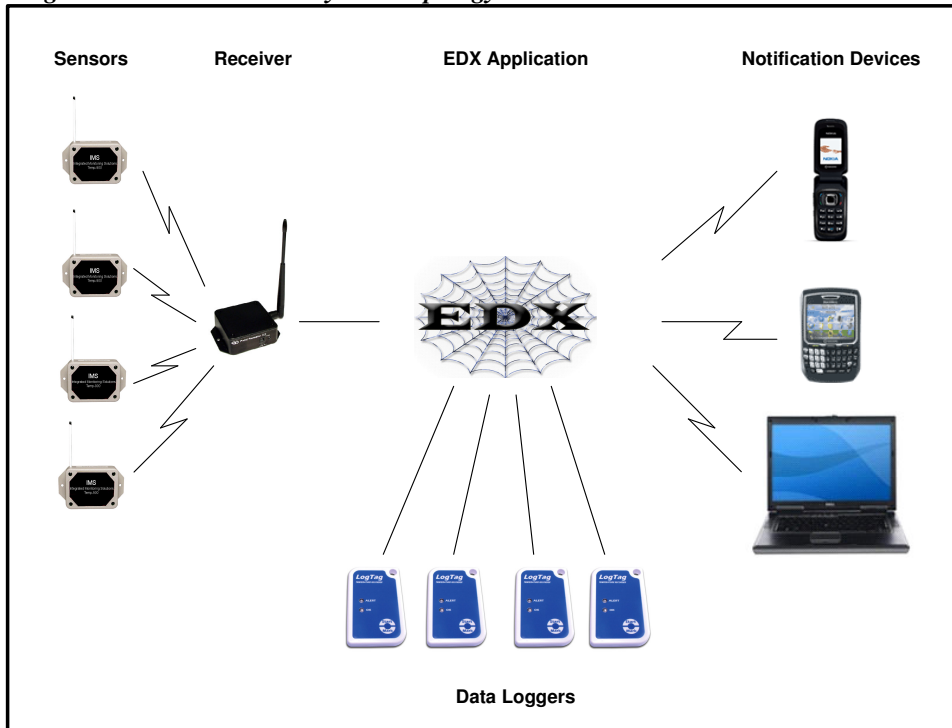
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EDX systems can be easily and securely accessed by users, on-line, and from anywhere in the world.

Diagram 1 outlines a typical topology for an **EDX** system. Hardware and software specifications are available upon request.

Diagram 1 – EDX Wireless System Topology



EDX BENEFITS

The **EDX** solution provides a number of unique benefits, including:

Real-time Monitoring - **EDX** provides the means to easily retrieve temperature and humidity information from the linked database, and to view current and historical conditions from across the entire cold chain. The **EDX** system provides concise reports showing historical data, alarms and current state information.

Historical Monitoring – **EDX** historical reports are designed to support audit and quality assurance activities. Users can view historical information summarized from a single minute to once every 7 days.

Variation Monitoring – ‘Key’ temperature and humidity changes in temperature or humidity readings can be defined by users to trigger an alert and/or for summary as part of historical records.

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‘Out-of-Range’ Event Notifications - Each sensor and datalogger can be configured by users to trigger an alert, and/or an electronic notification, for ‘out-of-range’ conditions. **EDX** alerts have been designed to include a tiered series of notifications to multiple respondents to ensure a prompt response. As well, the **EDX** application includes an audit system for the recording of user responses, which cannot be altered, once entered.

Sensor and Data Logger Settings - Each sensor and datalogger can be given a label name, and setup with information for each point being monitored, such as location, alarm trigger information, notification and escalation protocol, etc.

Linked Information – Only the **EDX** system provides a cost-effective solution to linking environmental conditions across multiple facilities, and all cold chain environments. Whether your environment spans in-storage and in-transit conditions, and includes ambient rooms, refrigerators or freezers, **EDX** has a sensor for your requirements; all of which are integrated as part of a single on-line system.

Fully Customizable and Scalable – The **EDX** application is a fully customizable system, allowing users to e.g., set alarm notifications, determine to whom the notifications will be sent, temperature and humidity threshold values, and many other parameters. In addition, **EDX** systems are designed to allow users to easily and inexpensively add or subtract monitoring components to address their changing needs.

Regulatory Requirements and Guidelines – The **EDX** system, and its components, have been designed to assist users comply with, and meet, various regulations and guidelines, including:

- CFR 21 Part 11
- Health Canada 0069 Requirements
- HAACP Friendly

In addition, our electronic dataloggers have been recognized by the World Health Organization. All of our components are manufactured in accordance with applicable ISO guidelines.

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