GE
Sensing

Kaye Validator ITMS® (Ion Trap Mobility Spectrometer) is a portable instrument that measures both positive and negative ion mobility for rapid and reliable API detection for validating pharmaceutical cleaning processes.

- Minimize production line downtime attributed to analytical lab sample processing
- Improve equipment utilization and increase production capacity

Features

- Rapid sample analysis
- Minimal operator training required
- Low sample analysis cost
- Portable design for at-line use
- Rapid method development
- User-programmable detection level sensitivity

Kaye Validator® ITMS

Cleaning Validation System

Kaye Validator ITMS is a Kaye product. Kaye has joined other GE high-technology sensing businesses under a new name– GE Industrial, Sensing.

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The Kaye Validator ITMS is an at-line instrument for identifying trace levels of pre-determined pharmaceutical compounds. Using ion mobility spectrometry, the instrument can analyze a swab sample for the presence of small molecule API residues or cleaning agents in seconds. Rather than sending samples off to an analytical lab for evaluation, where sample turnaround time can range from hours to days, operators can assess system cleanliness at-line with no delay. Equipment utilization, and production capacity benefit directly from the drastic reduction in process downtime.

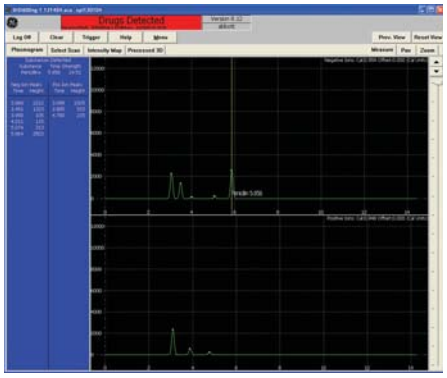
Detect the Broadest Range of Materials with Simultaneous Dual-Mode Detection

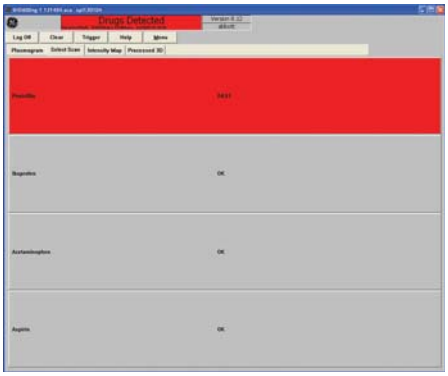
The Kaye Validator ITMS, with GE patented Ion Trap Mobility Spectrometer® (ITMS) technology, delivers simultaneous positive and negative ion detection from a single sample for the most comprehensive rapid trace detection available. It achieves this through a proprietary ion "trap" that increases ionization efficiency, the main factor determining detection sensitivity. Combining ITMS with a unique membrane filter that blocks contaminants, Kaye Validator ITMS delivers uninterrupted performance and provides cleaning verification results quickly and easily. No more costly delays waiting for analytical lab results.

Easily Transported and Flexible Desktop Trace Detection

Particle Swipe
Sample traps are swiped across a surface and then inserted into the Kaye Validator ITMS for analysis. Samples are processed and results displayed in about 10 seconds.

Easy-to-Use Operator Interface
Results require minimal interpretation, so operators can concentrate on obtaining a good sample. The Kaye Validator ITMS has an onboard computer that handles all data logging automatically, including time, date and analysis for each sample. A complete history of saved data and alarm files can be recalled and printed at any time.





Colored highlights indicate substance detected. Material "libraries" are easily customized to include unique and proprietary customer compounds.

A versatile history export feature allows the exporting of history files to a PDA or laptop computer via infrared port; network of file location; or to an internal floppy drive. Any application that reads .csv files (such as Excel) can open exported files. Files can also be set to export to a network or file location at a specified time of day.

Comprehensive Validation Support

Detailed and easy to follow IQ/OQ guidelines are available, as well as thorough Performance Qualification (PQ) documentation to help streamline the instrument validation process.

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Features and Benefits

Sensitivity/Selectivity
- Patented ITMS technology increases ion population, enabling user configurable detection sensitivity
- Patented switching mechanism simultaneously detects positive and negative ions, enabling the detection of the broadest range of APIs and cleaning agents
- Advanced detection algorithm increases selectivity and minimizes false positives

Speed
- Quick analysis and results in as little as 7 seconds

Versatility
- Simultaneous dual-mode operation increases detection sensitivity over traditional IMS technology
- Semi-permeable membrane excludes airborne particulates
- Expandable libraries accommodate unique user requirements
- Three default user levels (operator, maintenance and administrator) provide access control

Economical
- Self contained instrument requires no external gas or reactant supplies
- Patented regenerative dryer eliminates the need for monthly dryer replacement, reducing maintenance downtime, and consumables cost

Reliability
- Rapid, automated calibration assures operational accuracy
- Maintains a low, stable, humidity level in the detector allowing for consistent and reliable detection results
- Automatically saves test results, preventing intentional or unintentional modification or deletions
- Robust internal solid-state flash drive for reliable data storage

Ease of Use
- Touchscreen menus on a graphical user interface are easy to learn and operate
- Built in printer for fast hard copy results or printing at a later date for use for record keeping
- Software upgrades easy to install

Ease of Implementation
- Easy to follow IQ/OQ protocols are available for instrument validation
- Comprehensive validation support including PQ protocols also available

Portability
- Lightweight 26.5 lbs (12 kg) with built-in handles makes it easy to transport
- Internal, one hour battery allows instrument relocation without having to shut it off, eliminating warm up time

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ITMS Specifications

Detector Type
Ion Trap Mobility Spectrometer

Selectivity
<1% typical false positive rate on surface wipes, 0.1% on air samples

Analysis Time
10 to 30 seconds depending on compound

Sample Acquisition
Surface wipe

Warmup Time
Allow 30 minutes minimum for system to stabilize

Operating Temperature
30°F to 104°F (0°C to 40°C)

Storage Temperature
30°F to 122°F (0°C to 50°C)

Power
AC Input
100 to 120 VAC, 200 to 240 VAC, 47 to 63 Hz, 150 W

DC Input
11 to 18 VDC input, 10 A (150 W) maximum

Battery Backup
Up to 60 minutes of standby time daily for transport

Computer
Pentium-based, industrial-grade, single-board computer, solid-state hard disk

Display
10.4 in (264.2 mm), 640 x 480 pixel, 300 nits brightness, TFT-LCD monitor with resistive touchscreen

Signal Processing
- Recognition on multiple peaks spacing and amplitude
- Output to four different display types, including bar graph display or time-of-flight plasmagram display

Detection Modes
Dual (positive and negative ion mode)

Substance Libraries
Generic APIs included. Examples: ibuprofen, acetaminophen and penicillin. Full documentation provided with each API including characterization, quantification data, saturation and detection limits. Documentation meets typical "Validation Protocol for Cleaning Methods" standards.

Additional substances can be added to the standard libraries. It is strongly recommended that this only be done with the assistance of GE.

Dimensions
Kaye Validator ITMS (with display opened)
- Height 14.9 in (378.5 mm)
- Display clearance 16.3 in (414 mm)
- Width 18.9 in (480.1 mm)
- Depth 19.8 in (503 mm)
- Weight 26.5 lbs (12.02 kgs)

Kaye Validator ITMS (with display closed)
- Height 7.1 in (180.3 mm)
- Width 18.9 in (480.1 mm)
- Depth 18 in (457.2 mm)

920-130B

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