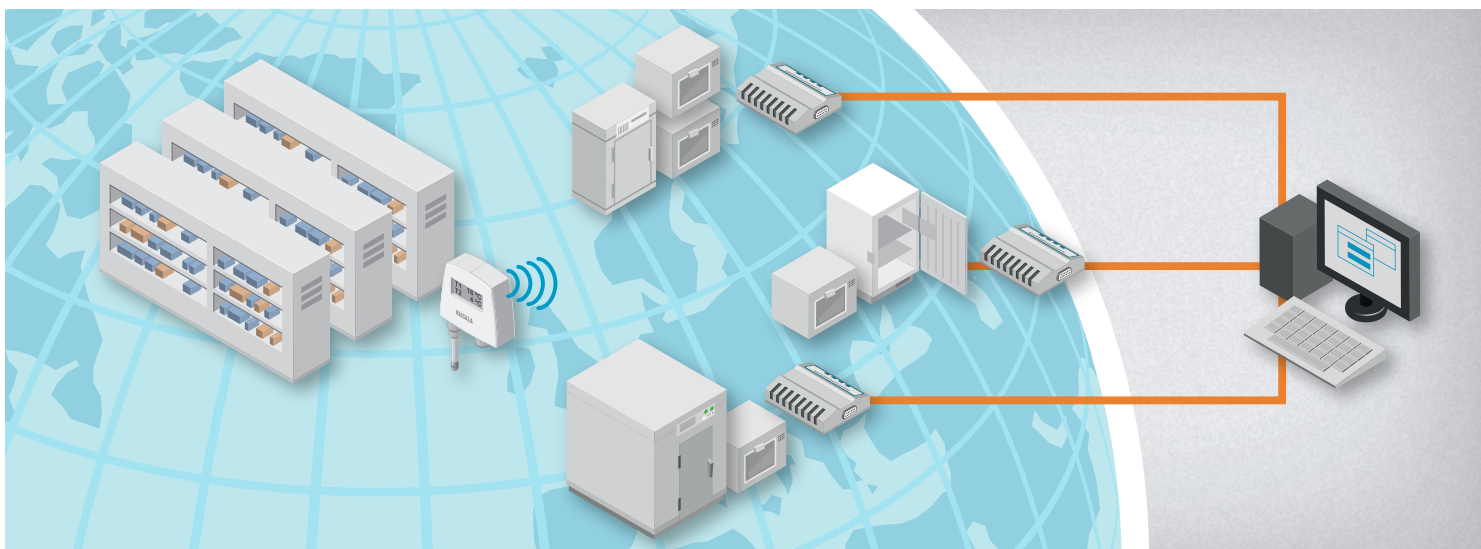


# Continuous Monitoring System

/ REDUCE THE RISKS OF NON-COMPLIANCE & LOST PRODUCT IN GxP ENVIRONMENTS



**VAISALA**

# Continuous Monitoring System (CMS) Overview

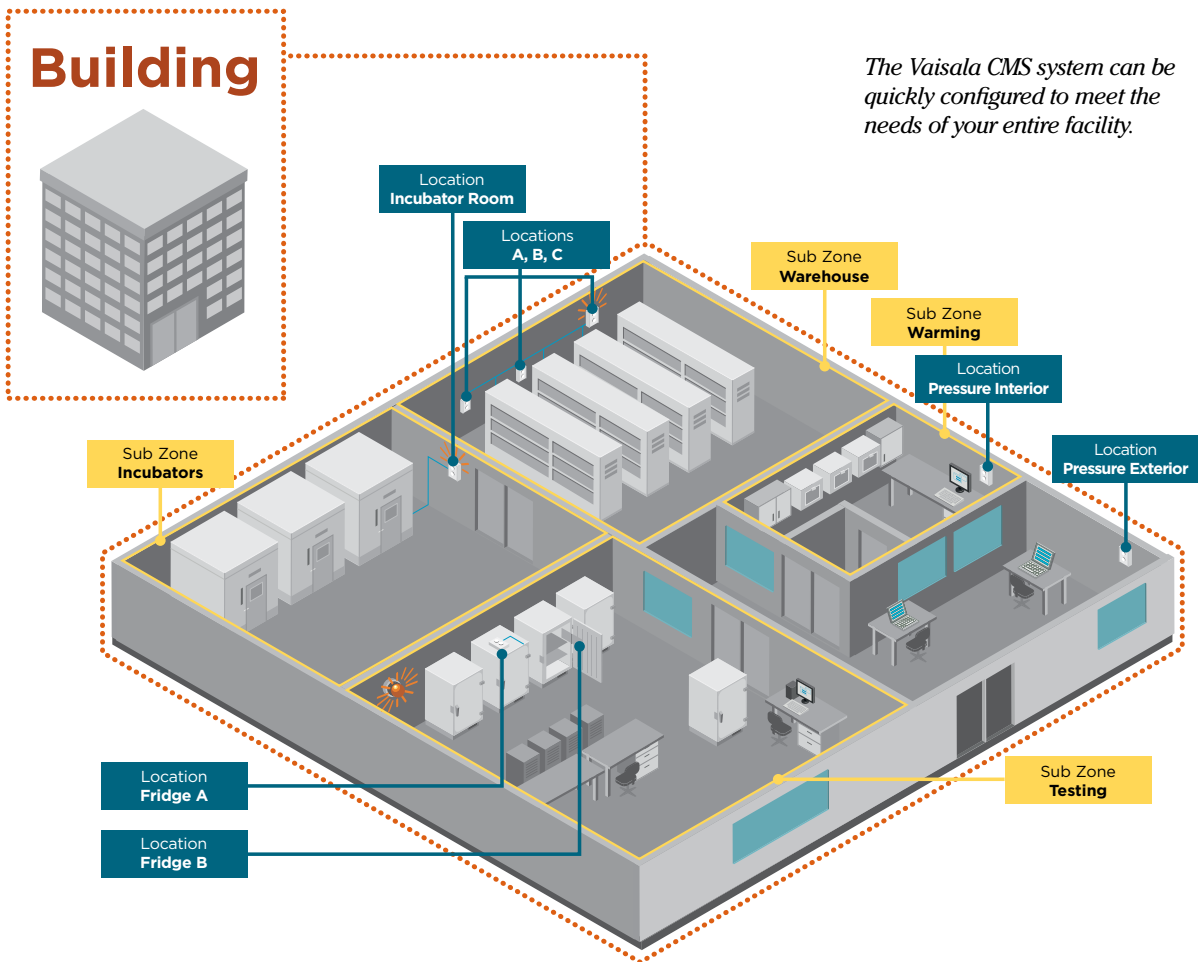
## A Scalable Solution

Vaisala has been a global leader in environmental measurement technologies for over 75 years resulting in an in-depth understanding of the life science arena. The combination of world-class sensing technology and user-friendly software allows the Vaisala Continuous Monitoring System to help life science companies meet regulatory requirements and ensure against product loss or adulteration.

Vaisala's Continuous Monitoring System is a total solution, complete with data loggers, software, service and documentation including IQOQ validation. The system features

viewLinc software, which provides a user friendly interface and intuitive monitoring features. The CMS does not require users to configure multiple sensors from varied manufacturers. Most importantly, the system was designed for life science environments. It can be customized for your entire operation and installs easily on any standard network. Connectivity options include Wi-Fi, Power over Ethernet with the PoE connectivity cradle, standard or multiport Ethernet interface, or direct to PC via USB. By connecting with your existing network, users can set up an easily scaled monitoring system that displays real-

time data, automatically backs up data history, and sends alarms through a variety of notification methods such as email, SMS text and on screen alarms. Easy deployment to existing networks saves on the costs of expensive and disruptive hard-wiring and cabling. There is no dedicated network to maintain. In addition, data loggers can be easily relocated to suit multiple applications and changing needs. Truly a global system, a server in France can monitor a sensor in Singapore. viewLinc software, IQOQ protocols and support documents are available in French, English, Chinese, German, Portuguese, Spanish and Japanese.



# viewLinc Software - The Safe Choice for Environmental Monitoring, Alarming, & Reporting in the Life Science Industries



## Best-in-class Sensors, Powerful Software

The viewLinc system features triple-redundant data retention ensuring that data is immune to power outages, network interruptions, and human error. That is why the world's largest pharmaceutical, biotechnical and critical manufacturing organizations rely on viewLinc to comply with international GMP regulations and guidance, including those from the FDA, EMA, SFDA, PDMA, ICH and others.

We understand the challenges faced in the life science industries and have created a monitoring solution to mitigate risk through reliable measurement for stringent GxP environments. Not only does Vaisala reduce the risks of non-compliance and adulterated product, we provide practical knowledge and education to make deployment and use of the system simple and easy. With Vaisala's continuous monitoring software viewLinc, best-in-class instruments, and reliable service behind you, you can be confident that your environmental monitoring methods and documentation will receive a stamp of approval during the most stringent audits and inspections.

*"[The system] performed flawlessly — I really appreciate Vaisala's expedient service and quality product."*

**- Jason Corrao,  
New Technology Project Manager**

## Fail-safe Performance

- **Complete Data Protection**  
Months of data can be retained in the on-board memory of each data logger. Automatic data backfill to the viewLinc server and client PCs ensure gap-free data.
- **Flexible Alarming**  
Remote and local alerts — via text, phone, pager, PC, buzzer, lights, third party responders — send notice of out-of-tolerance conditions.
- **Easy, Automated Reporting**  
Browser-based access lets users create custom reports on demand. Frequently run reports can be automatically generated and delivered by email on a pre-set schedule.
- **Browser-based Access**  
No software needs to be installed on client PCs.
- **Time Zone Specific Management**  
The system can span time zones, yet still report in the time zone required by the local facility. All data is collected and keyed to one time zone but reportable to all.
- **Low Cost of Ownership**  
viewLinc can be deployed using an existing network and leverage your server infrastructure, saving the expense of maintaining a dedicated network.

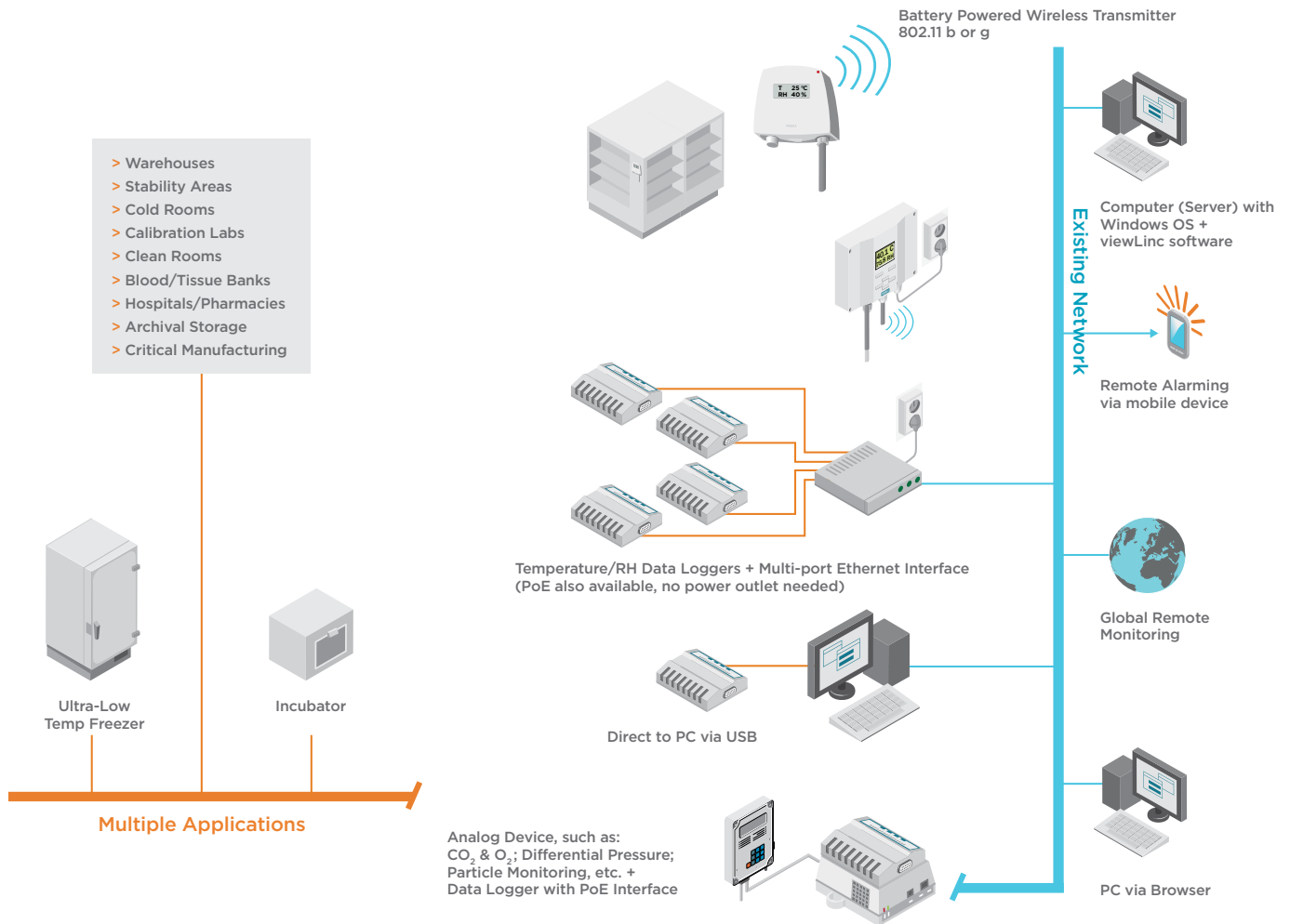
# Monitoring, Alarming, Reporting

## Controlled Environments

With non-disruptive installation on existing networks via PoE, Wi-Fi or Ethernet connectivity, viewLinc significantly reduces total cost of ownership. The system provides alarming and reporting that can be easily configured and automated. Vaisala's variety of sensor options meet and exceed industry standards for accuracy and reliability, providing extra assurance between calibration intervals.

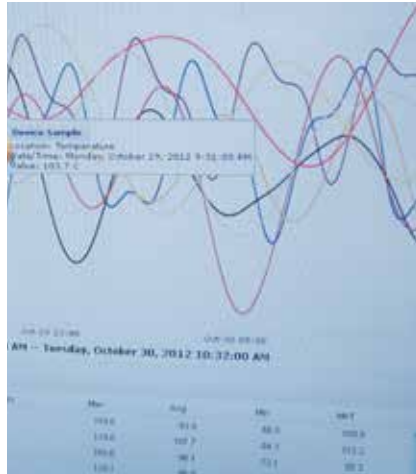
Ideal for GxP/FDA-regulated applications and environments that contain high-value products, viewLinc is flexible, fully validatable, and easy to deploy. Using Vaisala's industry-best data loggers and sensing devices, environmental data are recorded and monitored in real-time, then backed up with triple redundancy so that no data is lost during catastrophic failures. viewLinc software maintains all

historical data in a secure format for review and reporting. A single recorder can monitor temperature, relative humidity, and the analog sensor of your choice; external channels can take either current or voltage inputs for recording differential pressure, CO<sub>2</sub> level, light, particles, conductivity, and more. Optional Boolean channels allow you to monitor door switches or alarm contacts.



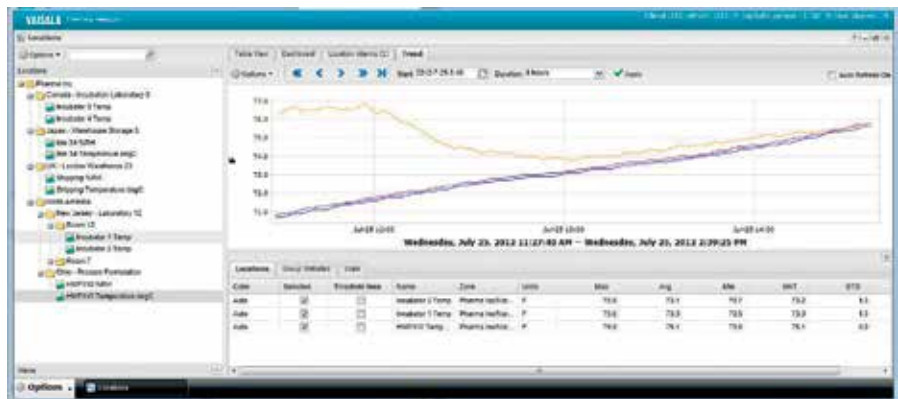
# Real-Time Data Accessibly

- Users can securely log into the application on a smart phone or client PC and view monitored environments from anywhere in the world. An unlimited number of users can monitor and report from any standard Web browser and view real-time data, historical trends and alarm reports in graphical and tabular formats.
- Monitored areas are organized into secure “Zones” that allow you to logically organize monitored locations and grant access to authorized personnel. Users can create preconfigured comments for alarm notifications for specific monitored areas, saving time and standardizing common comments.
- Start with a single monitored point and scale up as you need – from one data location to thousands distributed across a wide geographical area, viewLinc can accept throughput > 5000 location inputs.
- Add viewLinc’s data recorders to any OPC-compatible monitoring system. Interoperability provides added flexibility to your existing monitoring infrastructure.
- viewLinc’s audit trail records all interactions with the system, providing a complete record for compliance with 21 CFR Part 11 and other regulatory and accreditation requirements. viewLinc Administrators can assign permission to restrict users’ access to data, configuration rights and alarm acknowledgment to the user’s areas of responsibility.



*“We are ecstatic with the viewLinc Monitoring System! It helps us meet FDA 21 CFR Part 11 and AATB accreditation requirements and we can monitor multiple sites from any location.”*

**- Brad Bayette,  
Tissue Services Manager**



Watch a brief online demo: [www.vaisala.com/viewlinc-demo](http://www.vaisala.com/viewlinc-demo)



# Reporting and Alarming

## Compliant, Audit-ready, Configurable

viewLinc software's flexible reporting capabilities keep your monitored environments compliant with FDA, SFDA, EMA and other recognized international regulatory agencies. Users can create a wide variety of detailed and summary reports and alarms that include values, locations, alarm duration, acknowledgements and corrective actions. Detailed naming of recorders and channels allows for complete descriptions of monitored locations, making it easy to find, monitor and report on select areas. Frequently generated reports, such as alarm history reports, can be pre-configured and automatically delivered by email on a schedule to relevant personnel. With viewLinc's reporting options, automation, and security, your internal Quality or customer-required records are always available, gap-free, and audit-ready.

The viewLinc CMS software is also designed to recognize multiple time zone installations.

viewLinc's fail-safe alarming is easy to configure, customize, and automate. With escalating multi-threshold alarms, viewLinc triggers a notification at the first sign of a problem, sending alerts to mobile device, desktop display, SMS text or email. Zone security permits scheduling of notification by day, time, and user. System administrators can set alarming functions according to shift schedules, escalation procedures, and user permission-level. The viewLinc system's security settings can be used alone or in conjunction with Windows authentication to allow easy management of permissions.



The interface facilitates easy access to product data in a more familiar Windows-type navigation. viewLinc is compatible with Microsoft Windows Server 2003 (32), 2008, 2012 (64) and win 7 32/64 bit.

### Flexible Reporting

- Review specific monitored points over selected time periods.
- Quick summary and detailed alarm history: values, locations, duration, acknowledgements and corrective actions.
- User-defined limit lines give a quick visual reference on graphic reports.
- Reports are formatted and presentation-ready, including data, statistics, and graphs.

## VAISALA

### viewLinc Alarm Report

Alert events from 2013-01-13 12:26:25 to 2013-01-14 12:26:25  
 Report generated on 2013-01-14 12:26:27 (UTC-08:00) Pacific Time (US & Canada)  
 Include zones and locations: All Locations  
 Include alarm details: No

Summary					
TOTAL active alarms:	60				
Activated alarms:	58				
Deactivated alarms:	57				
Acknowledged alarms:	0				

Activation	Location(s)	Duration	Source	Description	Acknowledgment
2013-01-03 14:48:29		10 days, 21 hours, 41 minutes, 57 seconds	Device Port 1 (08121326) on Host view,incDevel.uniserve.com	Device Calibration Reminder: Default Device Calibration Alarm for Device Port 1 (08121326) on Host view,incDevel.uniserve.com. Affected locations: Temperature (1036),Ext probe (1034)	Acknowledged on 2013-01-07 12:49:00 by admin: -, comment: 123 Acknowledged on 2013-01-07 12:48:41 by admin: 'topping', comment: Known issue with logger
2013-01-03 14:49:27		10 days, 21 hours, 39 minutes, 59 seconds	Device Room 10 (08121264) on Host view,incDevel.uniserve.com	Device Calibration Reminder: Default Device Calibration Alarm for Device Room 10 (08121264) on Host view,incDevel.uniserve.com	Acknowledged on 2013-01-07 12:49:00 by admin: -, comment: 123 Acknowledged on 2013-01-07 12:48:44 by admin: -, comment: Known issue with logger
2013-01-14 09:51:30	2013-01-14 09:51:40	10 seconds	Threshold Alarm: Default Threshold Alarm for Threshold location value greater than 28.00 C for SystemRoom 10(E): Probe	Threshold Alarm: Default Threshold Alarm for Threshold location value greater than 28.00 C for SystemRoom 10(E): Probe Affected location: SystemRoom 10(E): Probe (1054)	
2013-01-14 09:53:30	2013-01-14 09:53:40	20 seconds	Threshold Alarm: Default Threshold Alarm for Threshold location value greater than 28.00 C for SystemRoom 10(E): Probe	Threshold Alarm: Default Threshold Alarm for Threshold location value greater than 28.00 C for SystemRoom 10(E): Probe Affected location: SystemRoom 10(E): Probe (1054)	
2013-01-14 09:54:00	2013-01-14 10:00:40	6 minutes, 40 seconds	Threshold Alarm: Default Threshold Alarm for Threshold location value greater than 28.00 C for SystemRoom 10(E): Probe	Threshold Alarm: Default Threshold Alarm for Threshold location value greater than 28.00 C for SystemRoom 10(E): Probe Affected location: SystemRoom 10(E): Probe (1054)	
2013-01-14 10:11:10	2013-01-14 10:11:20	10 seconds	Threshold Alarm: Default Threshold Alarm for Threshold location value greater than 28.00 C for SystemRoom 10(E): Probe	Threshold Alarm: Default Threshold Alarm for Threshold location value greater than 28.00 C for SystemRoom 10(E): Probe Affected location: SystemRoom 10(E): Probe (1054)	

The time (UTC-08:00) Pacific Time (US & Canada) Page 1 of 7

# Comprehensive Support

## Installation, Maintenance, Warranties

We offer full support for the life of our products. You can depend on responsive service from our technical support team. We ensure that your system is maintained at a level that meets the most stringent standards of your compliance requirements.

### Service Packages: Training, Installation, Validation

As a standard part of every viewLinc system, we offer comprehensive support plans that provide prioritized technical support by phone, email and web, instructor-led administrator and user training, access to eLearning content and free software upgrades. All Vaisala Veriteq data loggers come with a 2-year warranty with extended warranties and support plans available.

Vaisala offers comprehensive services to help you get the most out of your system.

- Full system installation, configuration and training by our certified technicians to ensure that the system is set up to meet your business needs with minimal effort on your part.
- Rigorous validation services and GxP-based qualification documentation to assist you in complying with regulatory and quality requirements.
- Extensive support plans that provide prioritized technical support by phone, email and web, instructor-led administrator and user training, access to eLearning content and free software upgrades.

Vaisala's team of engineers, metrologists and technical support experts are committed to ensuring your system functions flawlessly for years.

### World-class Support

- Onsite or remote support - worldwide
- User/Admin Training - onsite or remote
- Extended Warranties & pre-paid Calibration Plans

### Calibration: On-site or Service Center

To maintain the high accuracy measurement of the viewLinc system, we perform calibrations and complete functional testing in our own ISO 17025 accredited lab, which meets the standards of ISO/IEC 17025 & ANSI/NCSL Z540-1-1994.

Calibrations include:

- Verification of specifications against the original calibration
- Battery check and replacement if necessary
- Update firmware if necessary

When sending devices in for recalibration is impractical, we offer onsite calibration for most devices. On-site calibration includes a NIST-traceable certificate and reminders of recalibration due dates. To reduce the costs of calibration, we offer optional 3 or 5-year pre-paid plans that not only provide protection from price increases, but also offer significant savings on calibration costs. For your convenience, we also offer rental devices while units are being recalibrated.



*"The Vaisala IQ/OQ protocol is very nicely done... [it's] very complete and saved us 2-3 weeks of work."*

*- Stephan Montag, Head of IT*

### Learn More

The Vaisala Continuous Monitoring System is available and supported worldwide. For further information visit [www.vaisala.com/service](http://www.vaisala.com/service).

# Data Loggers, Instruments & Transmitters\*



## HMT140

The Vaisala HUMICAP® Humidity and Temperature Wireless Transmitter HMT140 measures relative humidity and temperature using probe and analog signals - RTD, voltage, current loop and Boolean contacts. The HMT140 connects easily to your existing Wi-Fi network and is battery powered, with an optional 9-30VDC power supply. Other options

include LCD display, multiple signal measurements, and fixed probe directly attached to the transmitter housing or a remote probe with different (3/5/10m) cable lengths. Connecting wirelessly to your existing network will allow you to easily move monitored chambers, or move the device where needed.



## HMT330

The Vaisala HUMICAP® Humidity and Temperature Transmitter Series HMT330 is designed for demanding applications where stable measurement and wide customization is important. Featuring warmed probe technology for superior performance in condensing environments and an IP65 corrosion resistant housing, the HMT330 has an option for integrated data logging, with over four years of measurement history.



## vNet

The vNet PoE network interface provides easy connectivity between Vaisala data loggers and your existing network. The snap-in design streamlines logger connectivity into a small footprint, eliminating wires between normally separate loggers and PoE

devices as well as the cost of installing an AC power source.



## DL4000

The DL4000 data loggers are a simple solution for monitoring pressure, flow, level, PH, electrical properties and gas concentrations. Ideal for standalone or networked applications, this Universal Input logger connects to a PC via USB or installs to your existing network via Ethernet, vNet PoE or Wi-Fi.



## DL1016/1416

These multi-application temperature data loggers can monitor temperatures in up to four applications across a wide range of temperatures - from ultra-low temperature freezers, freezer/refrigerators and incubators. The DL1016 or

1416 data loggers eliminate the need to purchase and install additional hardware - no extra loggers or added network access points are required to simultaneously monitor up to four environments.



## DL2000

Vaisala Veriteq DL2000 precision temperature and humidity data loggers are compact, powerful and easy-to-use recorders for monitoring critical and humidity-sensitive products and processes in

labs, cleanrooms, and stability chambers. The DL2000 also features an optional external channel with current or voltage inputs to record parameters such as differential pressure, CO<sub>2</sub>, level, particles, or conductivity. An optional Boolean channel connects to door switches or alarm contacts.

\* The products listed are a small sample of the options available on the Vaisala CMS. See a complete selection of Vaisala devices at [www.vaisala.com/lifescience](http://www.vaisala.com/lifescience)

# VAISALA

[www.vaisala.com](http://www.vaisala.com)

Please contact us at  
[www.vaisala.com/requestinfo](http://www.vaisala.com/requestinfo)



Scan the code for more information

Ref. B211046EN-D ©Vaisala 2014

This material is subject to copyright protection, with all copyrights retained by Vaisala and its individual partners. All rights reserved. Any logos and/or product names are trademarks of Vaisala or its individual partners. The reproduction, transfer, distribution or storage of information contained in this brochure in any form without the prior written consent of Vaisala is strictly prohibited. All specifications — technical included — are subject to change without notice.