Efento Cloud - system description, security, privacy and data integrity

Efento Cloud is a server platform that collects and processes data from Efento loggers. The platform is designed for facilities where from a dozen to several hundred measurement points are monitored, e.g. pharmaceutical wholesalers, cold stores or warehouses. Data can be sent to the platform from any location, and the user has access to it via a web browser.

The system consists of Efento loggers that measure and log various physical values including temperature, humidity, water presence and atmospheric pressure, Efento Gateway, which collects and sends the measurement data, and the Efento Cloud platform.

The server platform is the "brain" of the entire system, that collects and analyses the data, informs users about any abnormalities by SMS or e-mail and allows users to access the data via web browser or mobile application. The platform architecture and hosting are based on Amazon Web Services, which enables flexible scaling of the solution. Every day, the platform receives and processes over 1.5 million measurements from loggers working at our clients' sites.

www.efento.pl
+48 574 753 980
efento@efento.pl

Key features

Alarm rules

You can define any number of alarm rules and assign loggers to each rule. The rule consists of an input, condition and action, for example: if the temperature rises above 10 degrees, the platform will send an SMS notification to selected recipients. The rules can be configured in any way, e.g. sending notifications to different recipients depending on the threshold being exceeded.

SMS and e-mail notifications

The platform allows you to send notifications to any number of users, both in the form of e-mails and SMS.

Data storage

All measurements from Efento loggers are saved in the Efento Cloud platform. You can access them 24 hours a day from anywhere in the world via a web browser or mobile application. Measurements are stored in the platform for two years.

Locations

Thanks to Efento Cloud, you can easily organise the locations and assign the loggers to them. The platform enables mapping the structure of an organisation in the form of a tree and assigning individual sensors to its branches. The method of grouping is not subject to any restrictions, you can use a geographical division (e.g. Country -> States -> Cities -> Facilities), functional (e.g. Type of facility -> City -> Exact location) or other, better suited to your organisation.

Permission levels

For organisation users, you can create accounts for administrators who can configure the system (e.g. edit alarm rules, transfer sensors between locations, add new users), managers who have access to

www.efento.pl
+48 574 753 980
efento@efento.pl

data and the ability to edit some settings (e.g. alarm rules) and analysts, who only have access to the data without the possibility to edit any settings.

Access to your locations

In addition, the rights may be granted to individual locations, thanks to which a person from the Krakow branch does not have access to data from the loggers working in the Warsaw branch.

Maps / floor plans

You can assign a map or a room plan to each location and place loggers on it. Thanks to this, you can quickly see where the logger that measured the high temperature is located. The map also shows the status of the loggers with the possibility of filtering them.

Reports

Measurements from a selected period of time can be exported at any time in the form of a report (pdf and csv). What's more, Efento Cloud allows you to automatically send reports to any email address with a selected frequency (e.g. once a day, once a week, once a month).

Charts

Data from any period of time can be displayed in the form of a graph, so you can quickly check whether the set alarm thresholds have not been exceeded

History of events

All events such as the occurrence of alarms caused by exceeding the alarm thresholds, loss of communication with the logger, return of measured values to safe ranges are saved in the system and after logging in, you can quickly restore the list of events along with the dates and times of their occurrence.

www.efento.pl
+48 574 753 980
efento@efento.pl

Loggers statuses

Efento Cloud enables quick and convenient filtering and sorting of loggers. You can filter loggers by name, serial number, measurement type or location. In addition, you can quickly filter out inoperative loggers, loggers with low battery level or loggers turned off.

Audit trail

All changes and operations performed by users in the system are recorded in the audit trail. Thanks to this, administrators can see all changes within the system (including adding / removing a logger, changing alarm rules, adding / changing user permissions) along with information when they were made and what user made them.

Data security and integrity

Data completeness

- Each Efento logger is equipped with the memory of the last 40,000 measurements. Efento gateway has a memory of 1,000,000 measurements, shared equally between the loggers it works with. In the event of a temporary loss of connectivity or power, the missing measurements will be automatically resent to the platform from the gateway or loggers' memory.
- In critical situations, it is possible to directly read data from the loggers or Efento Gateway memory.

Security of data transmission

- At each stage of communication, the data transmission is encrypted, which makes it impossible to capture and / or modify them ("man in the middle" attack).
- Communication between the loggers and Gateway is encrypted using AES 128.
- Communication between Efento Gateway and the Efento Cloud platform is based on the HTTPS protocol with TLS / SSL. TLS ensures the confidentiality and integrity of data transmission as well as server and client authentication. It is based on asymmetric

www.efento.pl
+48 574 753 980
efento@efento.pl

encryption and X.509 certificates.

- The server-browser communication (access to the platform by the user) takes place using the HTTPS protocol

Security of data storage

- The Efento Cloud platform is hosted on Amazon Web Services servers (data centre in Frankfurt and Dublin). All data of the platform users are stored in the territory of the European Union
- Data and settings backup is performed automatically once a day and is stored for 30 days from the date of execution
- The data is stored in the Cassandra database cluster, which ensures its consistency. Data on the platform is collected for a minimum of two years.
- The stability of Efento Cloud's work is supervised by a team that watches over the correctness of the platform's operation 24/7.
- AWS servers are GxP (Good Laboratory Practices (GLP), Good Clinical Practices (GCP), Good Manufacturing Practices (GMP) compliant. More information: https://aws.amazon.com/compliance/gxp-part-11-annex -11 /

Data access security and data integrity

- The Efento Cloud platform provides 3 levels of access:
  - Administrator - access to data, the ability to change settings, the ability to edit users,
  - Manager - access to data, the ability to change settings,
  - Analyst - access to data.
- Users (regardless of the authorization level) have no access to the database and cannot edit the measurement data.
- In the process of transmitting measurements and saving them on the platform, the security mechanisms introduced (encryption and identification of the device they come from) make it impossible to edit measurement data or send them via an unauthorised device.
- Measurement reports can be generated as non-editable files (PDF). It is possible to verify the reports by the re-generation of a report from a selected period of time by the inspection body

www.efento.pl
+48 574 753 980
efento@efento.pl

Certificates of compliance with EU requirements (CE)

In the attachment CE certificates confirming the compliance of the devices with the requirements included in the relevant Community standards.

GxP compliance

Efento Cloud is compliant with the requirements of GxP (Good Laboratory Practices (GLP), Good Clinical Practices (GCP), Good Manufacturing Practices (GMP). All its parts of the system meet the regulatory requirements in the fields of security, data integrity and have the features required by the GxP regulations.

The system has been validated according to the requirements and the guidelines of GxP.On customer's request, Efento can provide the description of the test cases (IQ, OQ, PQ) for self validation after the implementation of Efento Cloud system in customer's premises.

www.efento.pl
+48 574 753 980
efento@efento.pl