



Case Study:

Temperature Monitoring and Control Thermolabile Pharmaceutical Products



Executive Summary

All entities that stock thermolabile pharmaceutical products is to ensure that these **products are stored in optimal environmental conditions to preserve quality**. The fridges or cold rooms used for storing these products must be constantly monitored to ensure that the temperature is always maintained **within the range specified by the South African Pharmaceutical Council (SAPC)** i.e., WHO **international standards**. The historical data must be logged and retained for compliance and validation purposes.

Argility is able to ensure that this goal is achieved by deploying an IoT management solution, Skydata. The Skydata platform will:



Monitor the fridge temperatures



Log historical data



Alert when thresholds are breached



Generate reports and dashboards available to authorised users

Business Challenges

The procurement, storage and distribution of thermolabile pharmaceutical products in South Africa are strictly governed by SAPC in accordance with the WHO specifications. It is **essential that the cold chain is preserved** throughout the process.

Entities that store and distribute thermolabile pharmaceutical products must ensure that the products are stored in a fridge or cold room at a temperature of between 2°C and 8°C. It is imperative that the temperature continues to be **constantly monitored and kept within the optimal range, to ensure that the efficacy of the product is not compromised**. If the prescribed temperature range is breached, an alert must automatically be raised so that immediate corrective action may be taken to rectify the situation.

In addition to the fridge temperatures, the **SAPC Good Pharmacy Practice (GPP) regulations specify** that the ambient temperature where other pharmaceutical products are stored must be in the range of 15°C to 25°C.

The entity must also ensure that **any compliance requirements, such as keeping temperature records, are strictly adhered to and tracked**.

Proposed Solution

Argility will supply the **IoT remote monitoring devices** for installation into all the designated fridges that require monitoring.

In the pharmaceutical use case the platform monitors devices that are connected to the fridge **monitoring the internal temperature** and the **external ambient**. The recommended devices are powered by batteries.

Using a **defined communications network** the IoT monitoring devices will communicate temperatures to Argility's Skydata cloud platform, every 60 minutes.

Data can be logged and sent to Skydata at a minimum once a day and maximum once every 10 minutes. Sending data every 60 minutes will **ensure that the batteries drain slowly and last for a period of at least three years** on a single battery, as well as **keeping network costs low**. For that reason we recommend that a logging interval of 30 or 60 minutes be used for this use case.

Once data is communicated from the IoT devices, the **Skydata platform** will take care of **device management, business rules, security, alerts, notifications, dashboards and reporting**, as well as the **storing and managing of historical data**.

Given the device agnostic nature of the Skydata IoT platform, **any future business monitoring needs** can be satisfied by **deploying additional IoT devices and sensors** into the physical environment which can **feed additional data points** into the platform, without requiring another software platform. For example these could be humidity, pressure, CO2/air quality, gas, water and electricity usage, GPS location and more.



Business Rules

Based on our understanding of the business case and goals, we propose the following business rules. Rules are configured on the Skydata IoT backend application and can be tweaked and improved to suit your specific requirements.

General rules

- Battery low alert (*high severity*)
- Not reporting for six hours alert (*high severity*)

Ambient rules

- Temperature over 25°C for more than one hour (*high severity*)
- Temperature under 15°C for more than one hour (*high severity*)

Fridge rules

- Temperature over 8°C for more than one hour (*high severity*)
- Temperature under 2°C for more than one hour (*high severity*)
- Temperature over 8°C for more than two hours (*critical severity*)
- Temperature under 2°C for more than two hours (*critical severity*)



Critical severity - rules to send notifications via SMS and email



High severity - rules to send notification via email



Medium severity - rules to send notification via email

Reporting

Access to real-time dashboard and daily/monthly exception reports will be made available to designated people.

Three reports will be sent by email daily:

- **Exception summary report** – provides a summary of min, max, average temperature per asset, including any recent alarms raised.
- **Alarm report** – provides a list of any threshold breaches as per the threshold rules defined
- **Daily temperature report** – provides a list of the temperature readings for the preceding 24 hours – compliance report for inspectors.

The three reports will be scheduled and emailed every morning to each Store. If appropriate, also to each regional. They will contain data about any stores or devices under the regionals management.

All data will be kept on Skydata for a period of three years and will be made available if and when required.

Key Features and Benefits

- Web based administration, configuration dashboard and third party device management
- Secure user and role based authentication and notifications
- Scheduled and automated extracts and reports
- Multiple pre-integrated wireless and wired devices and sensors
- Communicate wirelessly via long range battery powered device
- No connection required to electrical circuit – fridge can be moved without affecting the device
- Cross platform mobile friendly data visualisation dashboards (Android and iOS)
 - Dashboard summaries and drill down features
 - Ability to view data across multiple stores
 - Ability to view detailed data points within a specified store/location

Use Cases

Pharmacies

Clinics

Hospitals

Veterinary Clinics



Value Adding Services

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- Customised Solution
- Development and Support
- System and 3rd Party Application Integration
- Infrastructure and Middleware Management
- Service Delivery Management and Helpdesk
- Professional Services
- Procurement and Configuration
- Technology Consulting (Virtual CTO/CIO)

For further information - www.argility.com/skydata-iot/

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