Renesas Healthcare Solutions



In-Transit Medication Management Solution for Improved Supply Chain Visibility

Renesas has developed a reference solution for in-transit medication management (ITMM) that enables data logger manufacturers to achieve quick time to market. This solution can be thought of as an advanced data logger, which enables the supply chain to be compatible with the Drug Supply Chain Security Act (DSCSA). This ITMM solution is backward compatible to traditional handheld scanning systems.

The Renesas ITMM solution has multiple sensors that can track temperature, humidity, GPS location, tampering, shock and pressure. These parameters are displayed on the onboard display in both human-readable and barcode formats. A primary cell battery powers the ITMM module, and Bluetooth[®] low energy technology is used to communicate to a mobile phone. A USB port is provided for data transfer or a firmware upgrade. Push buttons and LEDs provide HMI functionality to the solution.



Data logger with mobile app enables tracking of sensitive medications

Feature	Benefit
Fuel Gauge	Accurate measure of the battery charge to avoid shutdown
USB	Standard micro-USB for data transfer and firmware upgrade
Alert	Out-of-range event in transit
Push Buttons	Toggle between human-readable and barcode format on display; scan through different parameters displayed on the screen
LEDs	Power and battery level status; Bluetooth® connection and activity status; general ITMM solution status
Bluetooth	Secure, reliable and low power method for communicating to the mobile device
GPS	Track location history of the medicine

Medication management expands beyond cold-chain monitoring

Transporting medicine from the pharmaceutical factory to pharmacies is a \$78.8 billion industry, globally. Traditionally, only the cold-chain (refrigerated) portion of the total biopharma/supply chain – estimated to be a \$12.6 billion market – was monitored for temperature and humidity.

However, with the introduction of biologic-based drugs, expansion of the international drug trade, and new regulations requiring stricter oversight of drugs during transportation, both the cold-chain portion and the non-cold-chain (ambient) \$66.2 billion part of that supply chain will have to be monitored closely in the coming years.

This new reality gives companies great opportunities to provide highly integrated, more carefully controlled drug supply chains. Fortunately, the electronic technology that enables the Internet of Things (IoT) can implement very effective tracking and environmental regulation systems.

Feature	Benefit
Temperature/ Humidity/ Pressure/ Shock Sensor	Ensures medicine has not been subjected to extreme conditions
Tamper Sensor	Ensures medicine has not been tampered with
E-ink Screen	Displays various sensor data in bar code format which can be read by traditional handheld scanner
NFC Tag or Barcode Reading	Mobile app enables the mobile device to read NFC tag or barcode so that information at the medicine- package level can be combined with data logger data (GS1-GTIN format)
Mobile App	Forms database of medicine information from labels, GPS history, and sensors data and has capability to report suspicious drugs to FDA

On the mobile phone side, the user has the ability to scan the NFC tag, linear, or 2D barcode on a medicine package. This would help identify the medicine being tracked. When the medicine package is ready to be shipped, the user has to *arm* the ITMM solution via the mobile app. At the destination, the user can *disarm* the solution via the mobile app and be alerted of any tampering. The data log from onboard sensors can be transferred to the mobile app via Bluetooth[®] low energy technology. Additionally, alert levels for different sensors can be set, the sensor data log displayed, and the medicine-package's identity and location history tracked. The "Contact FDA" button is provided to report suspicious activity.

This solution showcases the Renesas Synergy[™] Platform, featuring the Synergy S3 MCU, the RL78/G1D MCU, and

the USB Charger IC. Renesas Synergy is a complete and qualified platform that accelerates embedded development, inspiring innovation and enabling differentiation. The RL78/ G1D is an industry-leading, true low power MCU featuring Bluetooth low energy technology (v4.1). Renesas also has a portfolio of power management ICs.

Customers have the option to use Wi-Fi, LoRa or cellular technology for connectivity instead of the provided Bluetooth low energy technology. The mobile app can be further enhanced by providing back-end connectivity to a cloud platform and building a dashboard on the cloud. This dashboard can be a single point of interaction between the manufacturers, third-party logistics providers, distributors, and dispensers.



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