

# In-Transit Visibility and Total Asset Visibility for Cold Chain Supply Logistics

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## ABSTRACT

This innovative wireless monitoring solution will provide In Transit Visibility (ITV) and Total Asset Visibility (TAV) and material condition reporting throughout the Cold-Chain distribution system for perishable, temperature sensitive and high priority cargos, providing situational awareness and accountability information to cargo owners.

In accordance with multiple policies and regulations, this capability will assist in ensuring the delivery of viable vaccines/pharmaceuticals in quantity and provide historical data logging to identify any significant environmental/material condition variation events.

## 1 BACKGROUND

For many years, the Cold Chain industry has utilized manual data loggers to monitor temperature sensitive cargo during the storage and transport processes. However, these older types of manual loggers are generally ineffective because they are unable to provide real-time alerts should an exception occur and users are unable to determine when and where the compromise occurred.

And furthermore, the sensor data of these manual data loggers needs to be manually recorded or uploaded at the end of every shipment. This leads to human errors, especially when a large amount of monitored items are being processed at the same time.

With the latest radio and MEMS sensor technologies, it is now possible to provide constant monitoring of products in real-time and to receive alert messages via email or text should an exception occur anywhere in the world.

## 2 APPLICATIONS

The latest M2M and IoT technologies are now enabling many market segments to incorporate the latest monitoring technologies for the monitoring of their products. Whether the products are in storage, or in transit by air, rail or ocean, shippers have to ensure that their temperature sensitive products are continually monitored from the manufacturer to the end-user and provide real-time situational awareness to Integrated Logistics Management teams.

All sectors of industries have implemented strict regulations and guidelines for the handling of temperature sensitive products. The following are just a few of these regulations that require :

- BUMEDINST 3500.5 [i] dated Sept 7 2010: "Pandemic Influenza Planning Policy"
- BUMEDINST 5450.1H [ii] dtd 27 Apr 2012 "Mission, Functions and Tasks of Naval Medical Logistics Command"
- BUMEDINST 6230.15B [iii] dtd 17 Oct 2013 "Immunization and Chemoprophylaxis for the Prevention of Infectious Diseases"
- SECNAVINST 4000.37A [iv] "Naval Integrated Logistics" (Technology); OPNAVINST 4030.1B "Packaging of Navy Material"
- NAVFACINST 4081-1A [v] "Acquisition Logistics Manual" (Packaging, Handling, Storage and Transportation)
- MIL-STD- 2073-1E [vi], "DoD Standard Practice for Military Packaging"
- The FDA's DSCSA [vii] and FSMA[viii] regulations have implemented new serialization coding controls that will be applicable to all pharmaceutical products and food products from November 2018.

The DHS Border Control Posts process almost 11 million Intermodal containers annually and an improved monitoring procedure for monitoring the contents of these containers is urgently desired by DHS and industry.

## 3 HOW MYCONI FUNCTIONS

The Myconi monitoring solution is particularly designed for Total Asset Visibility for all cargo that is sensitive to temperature, humidity, light, harsh handling and geo-locational challenges. Industries and applications involved with the storage and transportation of vaccines and serums, pharmaceutical products and equipment, processed and perishable foods and even HAZMAT all require their products to be actively monitored on a 24/7 basis, and should any exception event occur, an alert message should immediately be forwarded to the relevant people.

When an alert message is received, the user can determine if remedial action can be immediately

implemented, or alternatively, proactive action can be introduced to ensure that future exceptions do not occur. Because of the detailed reporting, the data can also be used for accountability purposes to hold those responsible for the compromise and loss of products.

## 4 EMBEDDED SENSING TECHNOLOGY

Myconi Technologies has considered the requirements needed for the real-time monitoring of products and, using the IEEE 802.15.4 standard, have developed a proprietary wireless, ad hoc, peer-to-peer, self-healing mesh network protocol and transceives data on the internationally license-free ISM 2.4GHz bandwidth.

Myconi has incorporated their mesh wireless technology into five ultra-low powered mobile monitoring devices and three wireless gateway configurations. All the monitoring devices and gateways utilize the latest MEMS sensors that constantly monitor environmental conditions and wirelessly transmits data to the IoT based network management platform via the wireless gateways.

The Myconi MB monitoring tag is as compact as a FitBit monitoring device (the Myconi MB Tag) is like a Fitbit and is placed into boxes of products that require constant monitoring.

The MB Tag device is easily configured by the shipper and based on the type of product being shipped, predetermined threshold limits for various environmental conditions are automatically downloaded over-the-air to the device. The device immediately begins logging and storing sensor data and will only transmit data at pre-selected intervals, and in the event of an exception occurring.

Should an exception occur, an alert message is immediately transmitted to selected users by email or text and notifies them of when, where, why and how the exception occurred.

The proprietary Myconi Mesh technology enables each device to determine its own optimal data transmission path to the gateway which then forwards the data onto the internet based Data Management Platform.

Myconi Gateways can function as either “fixed gateways” (for warehouses, offices or marshalling yards), or “mobile gateways” for trailers, containers, aircraft, trains, forklifts, pallets etc.

Myconi networks can function with a single gateway, but for ultimate redundancy and latency, multiple gateways can function in each network.

Myconi monitoring devices can move freely between fixed and mobile networks from anywhere in the world.

## 5 FEATURES AND BENEFITS

Cellular based monitoring devices do exist and can provide real-time alerts but these can never be mass deployed mainly because they require expensive SIM card contracts and if the device is shipped to other countries, the international roaming costs are also expensive. And cellular communication requires a lot of battery power to operate and typical cellular devices have a limited battery life of only 7 days which is inadequate for an A-to-Z monitoring solution.

The very nature of mobile monitoring requires the device to be as compact as possible and with sufficient battery power to ensure the device can remain active for as long as possible, in the region of 6 to 12 months.

Myconi has achieved this extended battery life for all devices, and offers the following features:

- Based on the IEEE 802.15.4 standard
- Operates globally on the 2.4GHz ISM bandwidth
- Every device is configured over-the-air
- Every device determines its own optimal data path
- Low unit cost, compact size and low weight.
- Ultra-low power circuitry; > 6 months battery life
- Devices are reusable.
- Self-healing mesh network for max. redundancy
- Highly scalable networks for millions of devices
- High data through-put per network
- Secure data storage with 256 bit AES encryption
- Devices can move freely between networks
- Networks can have multiple gateways.
- Gateways can be fixed or mobile.
- Detailed audit trails can be wirelessly downloaded.

## 6 INTELLECTUAL PROPERTY

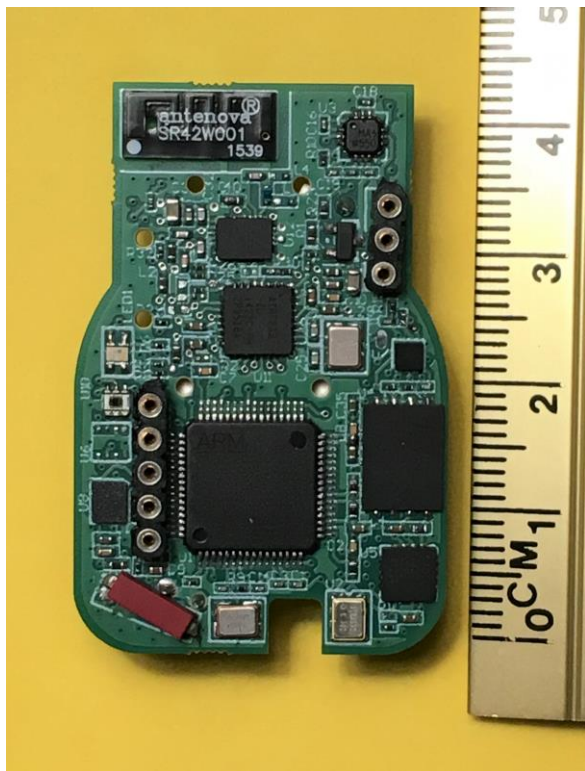
In order to protect the Myconi technology that is incorporated into the monitoring solution, several utility patents have been obtained as follows:

- Patent US 9,059,906: Data Communications interface
- Patent South Africa 2015/04550: Barcode ID for portable device
- Patent US 9,628,876: Network & method for associating a mobile monitoring device in a network based on comparison of data
- Patent US 9,133,019: Sensor Probe & related systems
- Patent US 9,832,547: Association functionality in a mobile monitoring device for continual remote monitoring
- Patent US 9,942,629: MEMS Sensor Probe multiplexer

Several other published patents in the USA and Germany are pending.

## 7 MYCONI MB TAG

The Myconi MB Tag is the most compact wireless monitoring device available and constantly monitors environmental conditions with a battery life of greater than 6 months.



The Myconi MB Tag is powered by a coin cell battery and can operate at temperatures as low as -40 F.

If a MB Tag and a mobile gateway move in unison on the same platform, an association is formed (patented) which confirms to users that the MB Tag is either on a particular pallet, or on a certain trailer, forklift, aircraft etc. While the MB monitoring tags do not have GPS, the location is derived from the GPS within the associated gateway (patented).

## 8 STATUS

Current Limited Rate Production (LRP) for Myconi MB Tags/Gateway and data management platform.

Current TRL Level 8, capability ready for operational test and evaluation

This secure TRL 8 (Technology Readiness Level 8) system is comprised of 5 different wireless monitoring devices (with optional probes), 3 wireless gateway

configurations, and includes a secure internet-based data management platform.

The current Myconi solution can provide an innovative monitoring solution to US Navy logistics commands to enable In Transit Visibility (ITV)/Total Asset Visibility (TAV) and material condition monitoring of perishable/sensitive/high priority products/cargo (food/medicines/vaccines) and other end items to reduce the number of compromised products during the transportation and storage processes of Cold Chain Supply Logistics.

Considerable cost savings can be achieved from in-transit intervention of environmental conditions and where possible improve accountability and responsibility

## 9 CONCLUSION

The need for Cold Chain management for a variety of products has existed for many years and industry has used manual temperature data loggers. These loggers in reality are ineffective mainly because they are unable to provide real-time alerts and the sensor data has to be manually uploaded at the end of every shipment, which is labor intensive and can lead to human errors.

The Myconi solution can assist users to conform to these latest FDA DSCSA and FSMA regulations.

With the advancement of electronics and wireless M2M technologies, it is now possible to provide continual monitoring from A to Z throughout the entire Cold Chain process and provide real-time exception reports to assist in the reduction of compromised products, and potentially saving industry billions of dollars.

## REFERENCES

[<sup>i</sup>] <http://www.med.navy.mil/directives/ExternalDirectives/3500.5.pdf>

[<sup>ii</sup>] <http://www.med.navy.mil/directives/ExternalDirectives/450.1H.pdf>

[<sup>iii</sup>] <http://www.med.navy.mil/directives/ExternalDirectives/6230.15B.pdf>

[<sup>iv</sup>] <https://standards.globalspec.com/std/1403913/navy-secnav-4000-37a>

[<sup>v</sup>] <https://www.navfac.navy.mil/content/dam/navfac/Expeditionary/PDFs/NAVFACINST4081-1A-Encl1.pdf>

[<sup>vi</sup>] <https://www.mfg.com/sites/default/files/MIL-STD-2073-1D-Pckg-Cheat-Sheet.pdf>

[<sup>vii</sup>] <https://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/>

[<sup>viii</sup>] <https://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm>