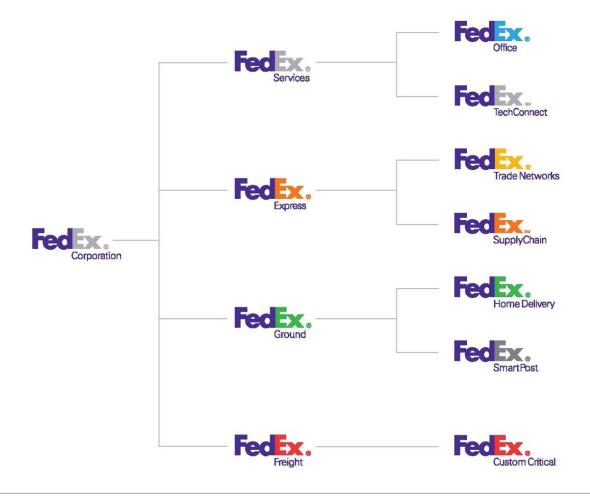




FedEx for the Supply Chain Global Network, Visibility, and Cold Chain Solutions

Karl Kussow
Manager, Quality
FedEx Custom Critical

FedEx is a family of interconnected companies





Operational Controls across the OpCo's are a key strength for FedEx

Case Study: Thermal blankets and aircraft conditioning meet product requirements at a sustainable cost.

SOPs for transport match the product's and thermal covering's capabilities

- Product and packaging
- Blankets
- Trucks
- Aircraft
- Route/seasonal weather
- · Visibility and monitoring that enables active control



Strategy for Thermal Blankets in Transportation

- Consider product temperature requirements
- Take advantage of seasonally achievable ambient profiles
- Plan for heating vs. cooling
- Chose appropriate technologies for in transit temperature protection
 - Weather Conditions
 - Protective covering(s)
 - blankets, insulated boxes
 - Transport temperature controls
 - Process controls, visibility, and enroute intervention capability
- Apply controls and best practice procedures
 - Balance capabilities of technology and process
- Align Quality system objectives with transport provider



Controlled Room Temperature Transportation using Thermal Blankets

HYD to MEM 15-40°C case Study - Summer

- Cargo without blankets
- Thermal Blankets used as a device to reduce the effects of hot weather during mode transfer and hub operations
- Summer 2010





Thermal Blanket for temperature protection

- Cargo loaded onto Blanket spread out on each Airplane pallet.
- Blankets cover each built up load.
 One blanket for each airplane pallet.
- Blanket sealed around pallet and netted to secure for aircraft loading pallets





Blanket-protected pallets in the plane



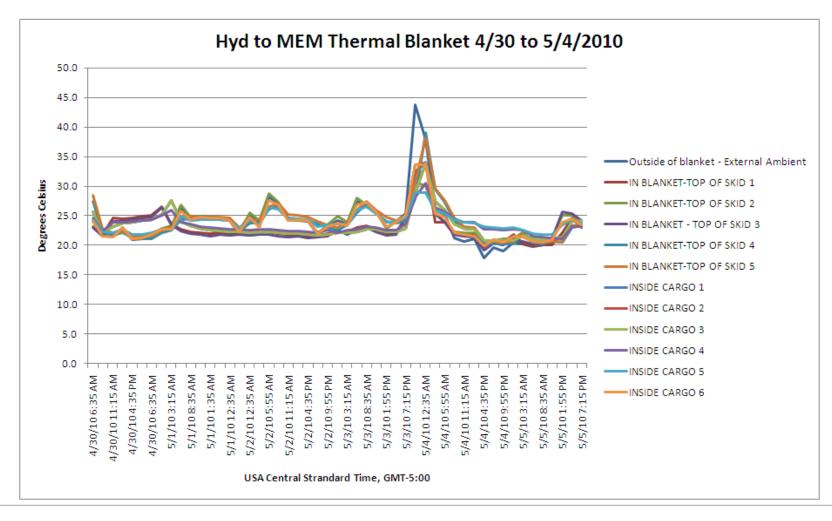


Blanket covered pallets unloaded



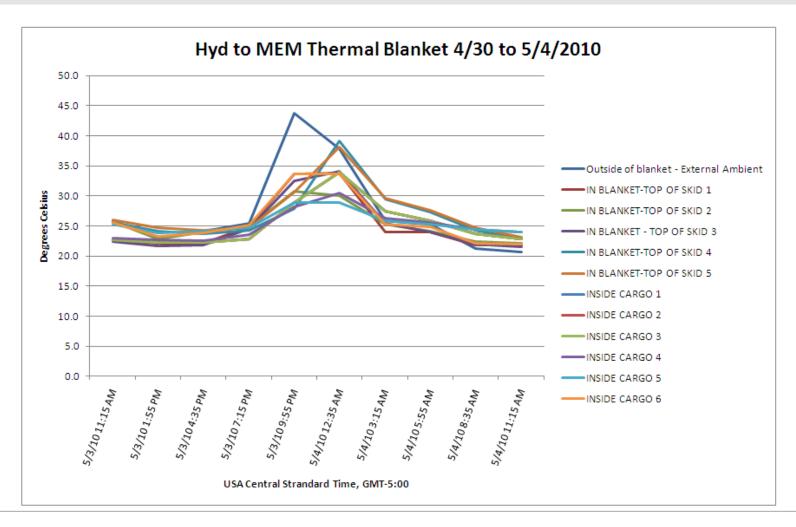


Temperature record – door to door





Hot Weather (DXB) – Effect of Blanket





FedEx

Portfolio of **Solutions**

Global Access



Peace of Mind And Quality Mgmt

Leading Edge Technology



FedEx Operating Companies



FedEx Express invented express distribution and remains the industry's global leader, providing rapid, reliable, time-definite delivery to more than 220 countries and territories, connecting markets that comprise more than 90 percent of the world's gross domestic product within one to three business days.



FedEx Ground is a leading provider of ground small-package delivery services, providing service to the U.S. and Canada.



FedEx Freight is the market leader in providing less-than-truckload (LTL) freight services across all lengths of haul.



FedEx Office (formerly FedEx Kinko's) provides access points to printing and shipping expertise with reliable service when and where you need it.



FedEx Operating Companies



FedEx Trade Networks is the global freight forwarding arm of FedEx and keeps supply chains moving for customers of all sizes by providing flexible end-to-end services that include international air and ocean freight forwarding, customs brokerage, warehousing and distribution and trade facilitation solutions.



FedEx Custom Critical provides businesses with customized solutions for their critical shipping needs, with services ranging from expedited to temperature control and increased security.



FedEx Truckload Brokerage provides full-service brokerage to meet customers' freight shipping needs, including brokerage solutions for truckload, flatbed, intermodal and LTL.



Global Cold Chain Capabilities Catalog: Interactive Website (Keyword: coldchain)





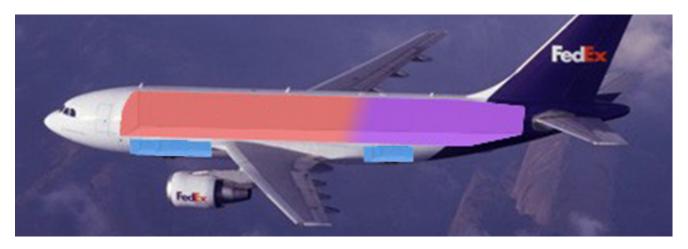
Innovation and capability: FedEx Aircraft Can Maintain Cold and CRT Ranges

Thermal mapped FedEx aircraft

 B777F capable of temperature control including Cold (2-8°C) and Room Temp (15-30°C) ranges, and can do both simultaneously in different parts of the aircraft

Based on temperature data FedEx knows:

- Best area to place cargo containers within aircraft
- Best temperature setting for maximum cargo container performance





Innovative Technologies + FedEx = HealthCare Solutions

Monitoring, Event Notification and Intervention Capabilities:





Specialized Packaging and Container / Airfreight Options:





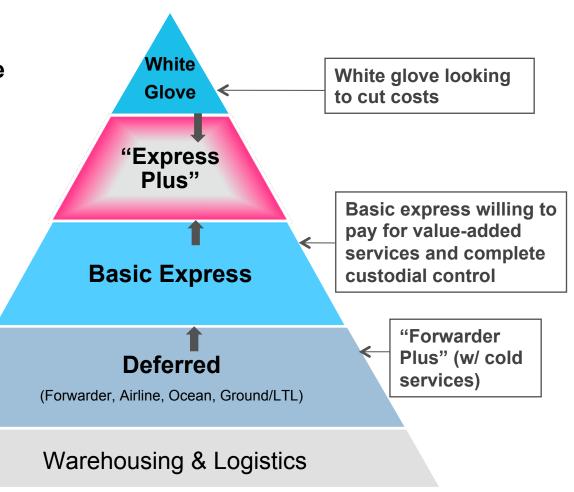






Cold Chain Logistics at a Glance

- FedEx underlying transportation capabilities are highly competitive and becoming more targeted and systematized in this market
- FedEx opportunity lies in cost-effective, scalable "Express plus" services leveraging our secured air network





Trends Effecting Transportation

Increase in global pharmaceutical shipments

Rising need for temperature-controlled transport

- Molecules becoming more complex
- Biotech community on the rise
- Increase in regulatory controls

Increasing Complexity and Costs to Transport Systems

- Federal and state operating authorities, permits, tolls and fees, regulatory compliance costs
- Transport equipment purchase, qualification, maintenance, and modernization
- Smart, Educated, Safe drivers
- Nature: traffic, roads, weather



International Regulations add Complexity

Security issues

Governing regulations and guidance

- <u>EMEA</u>: MHRA, IMB, and others
- <u>The Americas</u>: Health Canada, FDA, U.S. Pharmacopeia and governing agencies (EPA, USDA, DOT, DEA, etc.), Brazil, and others
- APAC: Japan, Australia, and others

Other international regulations and guidance

• PDA, HDMA, WHO,

Current Good Distribution Practices

 Implement effective cold-chain management to ensure a product's safety, efficacy, and pedigree are not affected by the distribution process.



Need for a Qualified Service

Safe Product that meets Regulatory Requirements

 Documented evidence that you met all requirements to ensure your product's identity, strength, quality and purity across the entire distribution channel – from manufacturer to end user.

A cost-effective distribution chain

This presentation focuses on the "transportation" element.



Define the Challenge

How do I...

Effectively leverage my existing situation

Take advantage of new technologies and processes

- New products: clinical trials to production
- Improve the quality and efficiency of current transportation



Decision Drivers

Regulatory compliance: GMP, GDP, TSA rules, Import Rules...

Product filing details

Product sensitivity

Existing distribution infrastructure

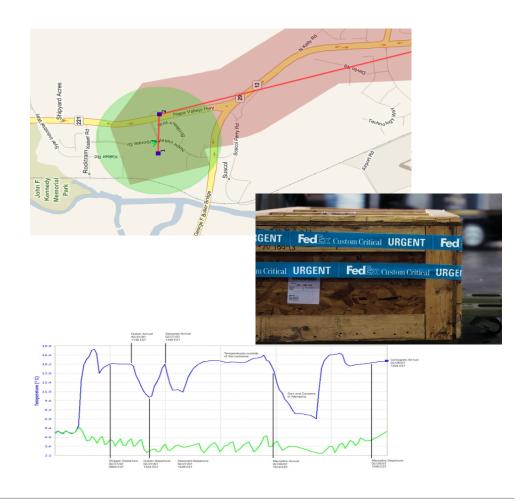
- Warehouses already owned
- Package systems already developed and deployed
- Validations completed
- SOPs developed, trained, and deployed

The transportation environment



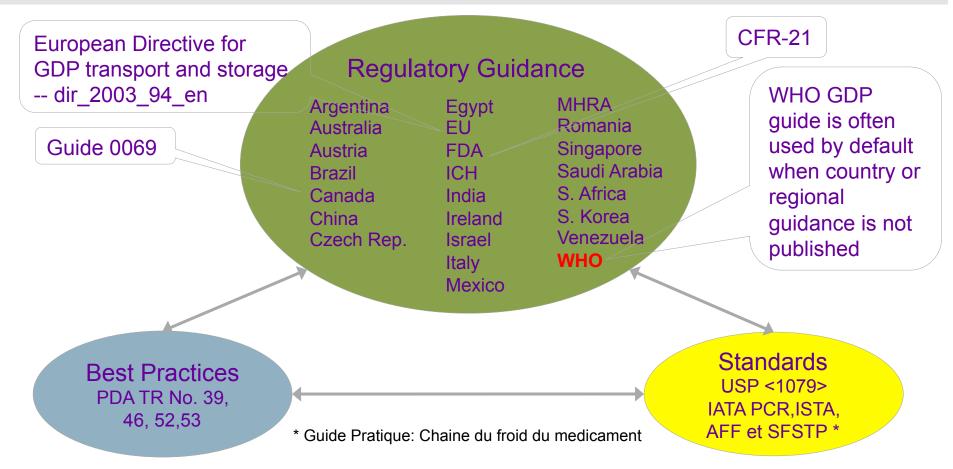
Solid visibility is established with the elements of Good Distribution Practice (GDP)

- Security
- Pedigree
- Environmental monitoring
- Temperature control
- Auditable data record
- Data access (QA/QP release, International Customs)
- Quality systems
 - Procedures for sustainability and continuous improvement
 - Flexibility for individual products





Regulatory and Standards-Based Guidance Driving GDP...



Reference: Rafik H. Bishara, "The Impact of USP <1079> on Cold Chain Management", March 7, 2006 (Sensitech Sponsored Webinar), Revised March 21, 2010



Visibility and Control: Supply Chain GDP Guidance

Implement effective cold-chain management to ensure a product's safety, efficacy, and pedigree are not affected by the distribution process

PDA TR-52

Topics addressed by the guidance

- 3.0 Requirements
- 3.1 Stability
 - 3.1.1 Storage Temperatures
 - 3.1.2 Shipping Temperatures
 - 3.1.3 Stability Testing to Support Distribution
 - 3.2 Distribution Control Management
- 3.3 Performance Management
- 3.4 Supply Chain Partner Management

Table: Seven Pillars of Good Distribution Practices



Source: PDA Technical Report No. 52 , Guidance for Good Distribution Practices (GDPs) For the Pharmaceutical Supply Chain. Purchase online from the PDA at www.pda.org



Guide 0069 - Requirements

Label claim and Transport environmental requirements supported by stability and technical justification. [1.0, 2.0]

Controls and Proof of success required for ANY environmental category

Qualified equipment / environmental controls [3.1, 3.2**, 3.3*]

Calibration, Monitor locations, alarms, recorded [3.1, 3.2, 3.3]

Properly loaded [3.1]

Protect from weather during transfer (load/unload) [3.2, 3.4]

Written agreements / procedures [2.0, 3.1, 3.2, 3.5]

Training [3.1]

Transportation Records including monitoring records [3.5]

Audits [3.2]



FedEx Custom Critical

- Headquarters in Uniontown, Ohio (south of Akron)
- Open 24 hours a day, 365 days a year
- 600+ employees
- 1,400 vehicles through 100% contractor fleet
 - Approximately 400 temperature-control vehicles
- Average shipment = 6,000 lbs; 500 miles;
 Delivers in less than 10 hours





FedEx Custom Critical Overview

- The largest time-specific expediter in North America
 - 24/7 customer service
 - Direct, door-to-door delivery
- Exclusive use vehicles in four sizes
 - Right-sized for your shipment
- Independent Contractor fleet
- Communications and custodial control experts
 - Proactive calls/emails on pickup, delivery and if there are any issues along the way
- · Air solutions to meet any speed, size and/or cost requirements
- Temperature-control services and shipments requiring special care in handling
- Customized secure transport



Temperature-Control Solutions: Air

- Feature FedEx Express network and use of air-cargo containers or customer's packaging
- Three options
 - Temp-Assure Air and Validated Air from Custom Critical
 - FedEx Express International Priority Freight with a container
- Various container technologies are utilized









Temp-Assure Validated: Quality by design

Key Features

- Customer service availability
- Company stability and experience
- Every unit is thermal mapped
- Monitoring and contingency plans
- Global capabilities
- Many security options
- Dedicated quality team
- Quality Agreement (customer specific)
- Quality Management System
- Support cGDP by providing an audit trail for shipments





Sources of Security Guidance

Cargo Screening (TSA and Local Countries)

- 100% screening
- Access Controls
- Chain of Custody

Customs Trade Partnership Against Terrorism (C-TPAT, TAPA)

Supply Chain Security Guidelines

Anti Counterfeiting / Diversion (FDA, CBP)

- Serialization
- E-Pedigree
- PREDICT, Good Importer Practices



New FDA standard for cargo theft reporting in March 2012

Coalition statistics tell the story:

- Dramatic burglary at an Eli Lilly warehouse where rope-rappelling thieves stole cancer, cardiovascular and depression medications. Loss: \$75 million
- Another burglary at a GlaxoSmithKline warehouse. Loss: \$6 million
- 2009 heist of a rig from North Carolina, containing Novo Nordisk drugs, some of which later were tied to adverse reactions from patients who got them from a pharmacy chain. Loss: \$10.9 million

The new FDA standard:

- New expectations for industry and agency responses
 - FDA expects to be immediately notified when there is a theft
 - Details including the quantities, lot numbers, dosages, strengths, expiration dates and storage needs for the hijacked goods are part of the expectation



Security Gaps found in Unexpected Places

Drivers with commercial licenses even though they had other licenses suspended under different names.

Exposed after a tour bus crash in March that killed 15 people while returning to New York City from a Connecticut casino.

Arrests were the result of partnerships with authorities from the New York City Police Department and U.S. Customs, along with prosecutors in suburban Westchester, Rockland, and Nassau counties, and in the New York City boroughs of Queens, the Bronx, and Brooklyn.

Department of motor vehicle facial recognition technology, first used last year, has so far identified more than 3,000 people with multiple licenses. More than 600 have been arrested on felony charges.

Source: CargoNet



Be aware, starting from the first contact

Customer service and dispatch operations training

Operational awareness

Signs of illegal shipping:

- Calling party, pickup, and delivery locations are new and the caller is unwilling to provide detailed contact information
- Customer gives cell phone numbers only for contact numbers, no main phone number.
- Pickups or deliveries in unusual places and at unusual times (hotels, parking lots, etc, picking up at 0300)
- Payment by credit card or requests for multiple payment forms: third party credit cards, multiple prepaid credit cards,
- Very general commodity description or unusual commodity description: affordable commodities that can be purchased locally minus the expense of shipping.
- Requests for the drivers to meet the delivery contact at a location other than the address given.
- No bill of lading from the customer.



Plan to eliminate security gaps

Certified authentic cargo shipped

Secured and Protected during transport

- Chain of custody
- Track and Trace
- Real time monitoring
- Anti-tampering and detection

Authenticated at delivery

Enable verification / detection at all stages of distribution

- Data collection, access, real time,
- Mutual understanding of key quality attributes shared across the supply chain

Make accountability equally strong during product recall or returns



Transport Security Basics

- Scheduling appropriate pickup and delivery times
- Utilize Secure Parking
- Monitor and respond to crime levels along the route
- Cultivate a relationship with law enforcement
- Include law enforcement in your security contingency plan
- Know the personnel with access to cargo
- Use appropriate technology and have backup systems



Visibility and control in several layers

Layers of technology, control, and planning

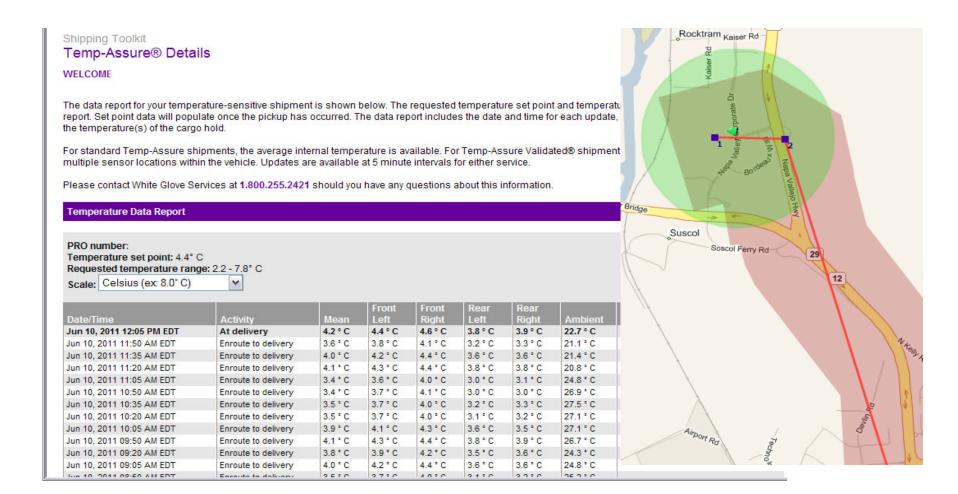
- Exclusive-use vehicles provide direct, door-todoor service
- Continuous and proactive shipment monitoring with two-way, on-board satellite communication
- shipment intervention, notifications and contingency plans
- Driver Identification
 - Know who is making your pickups and deliveries
 - See drivers' photos prior to pickup and delivery
- Command Center tracking and immediate response







Real-Time Shipment Monitoring





Opportunities for increased visibility throughout the supply chain

Temperature-control infrastructure

- Ensure enhanced visibility with controls during transport
- Improved contingency response

Combine data streams into one interface for monitoring and reporting

- Have a command center that centralizes these controls
- Temperature (and other environmental factors as needed)
- Location
- Status (who has custody right now)
- Door-open (and/or light)
- Identity confirmation (enabling authentication at delivery)





Real Time Monitoring + Intervention for Any Cargo

Multi-sensor monitoring devices (e.g., Senseaware)

- Temperature, Pressure, RH, Position, Light as a function of time
- Secure-access for monitoring in near real time: www.senseaware.com

Having the data and being able to do something about it

Custodial Control network = control

Shipment Watch: increase safety and security

Concierge service





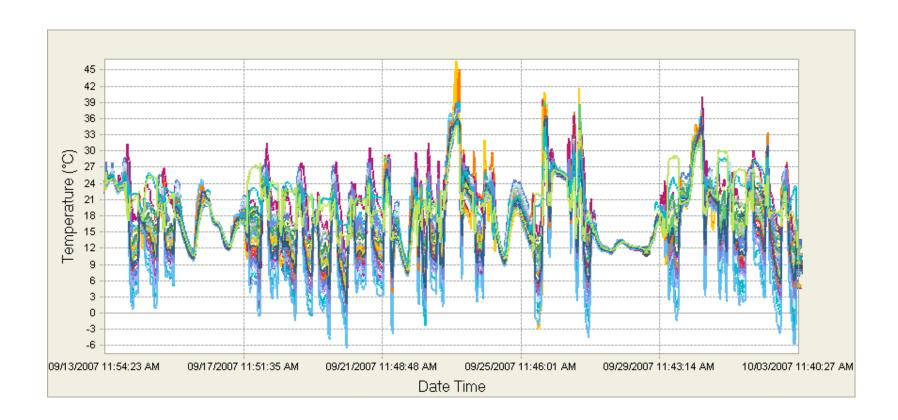
Control Mechanisms for Security and Temperature overlap and support each other

Controls have similar characteristics

- Chain of custody
- Monitoring systems: real time for situational awareness
 - Track and Trace
- Alert mechanisms: overlapping tiers
- Clear instructions with training
- Procedural controls
- Ability to react to protect cargo while enroute



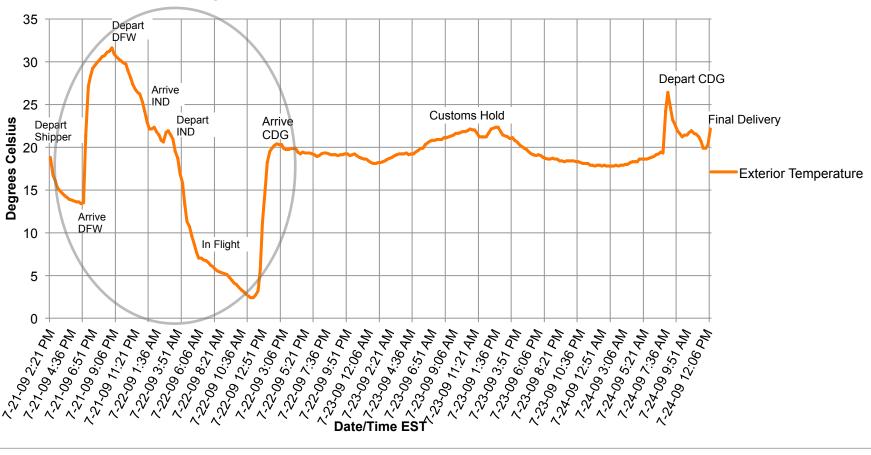
Uncontrolled Aircraft Temp. - International





Case Study: Unregulated Summer Ambient Temp

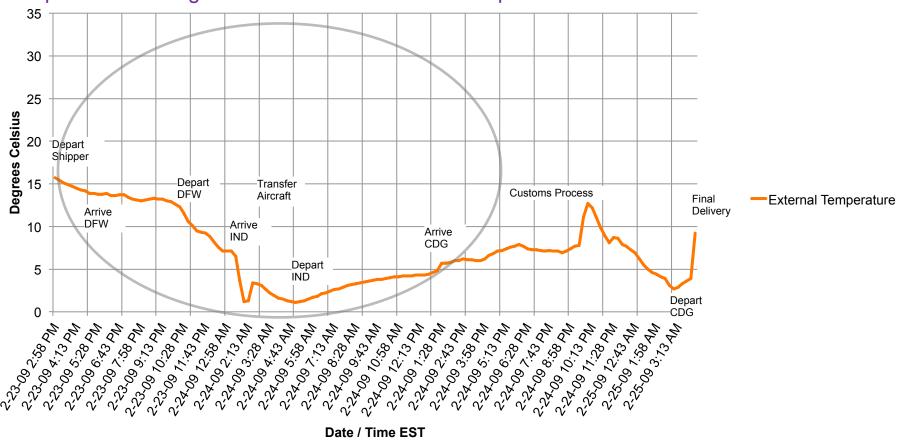
Temperatures during uncontrolled international transportation





Case Study: Unregulated Winter Ambient Temperature

Temperatures during uncontrolled international transportation





Active Temperature Control Systems

Critical Design Parameters:

- Insulation
- Airflow
- · Capacity for heat exchange,
- Control Accuracy
- Monitoring systems and alarms

Performance affected by process:

- Maintenance
- Power Source
- Preconditioning
- · Loading and unloading,
- Temperature immediately outside an open door
- Temperature and amount of the material placed within



Case Study: Compressor-powered Container

Able to heat and cool

- Internal temperature set points between +4°C and +25°C
- Actively maintains internal temperatures
- Withstand external temperatures between -20°C and +49°C
- Just plug it in. No battery or dry-ice replenishment required
- Less need to control temperatures external to the container

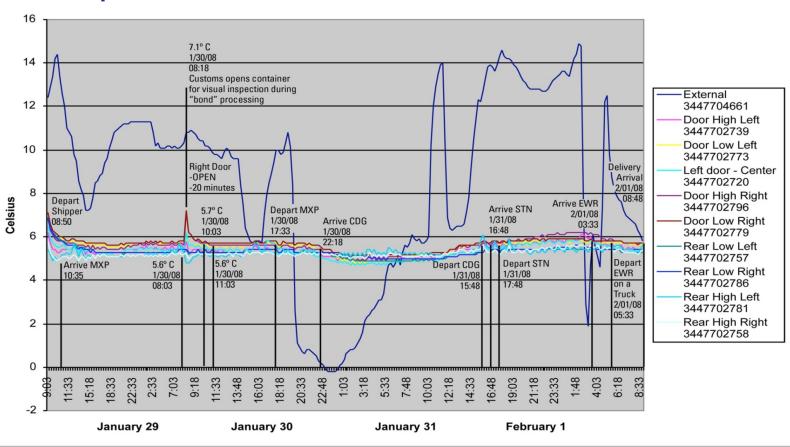
Live Shipment test

- International Lane: Europe to USA
- 72 hours
- 9 monitors spaced within the container
- Customs inspection opened the container



Live Shipment Trial

AcuTemp® RKN: MXP-CDG-STN-EWR: Jan. 2008

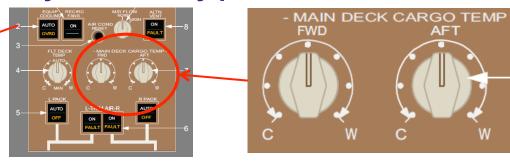




Aircraft Temperature System

Temperatures must be manually selected by pilots





Main deck cargo temperatures are controlled manually:

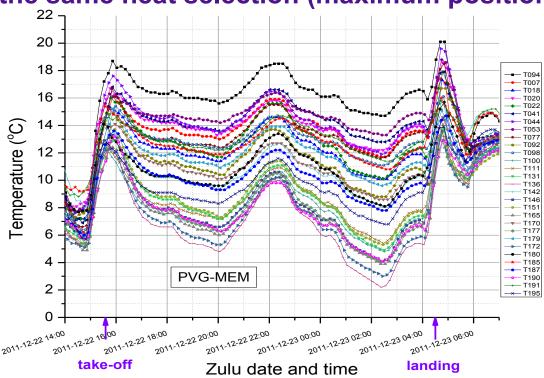
- 2 temperature zones (aft and forward compartments)
- 20 settings or clicks per knob

Temperature reported by Boeing on empty cargo	T (°C)	T (°F)
Cold (C)	4	40
Mid position	16	60
Warm (W)	27	80



Temperatures vary around the cargo

Temperatures can vary by as much as 12°C within the cargo on the main deck at the same height level (70cm from the floor) and for the same heat selection (maximum position)



No negative temperatures are observed on temperature recordings

Outside temperatures	°C
Departure	3
In flight	-50
Arrival	8

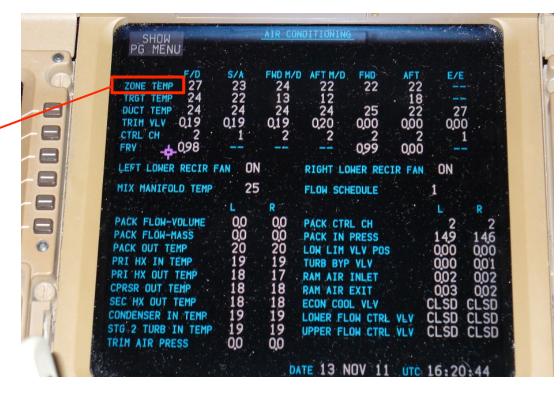


Outcome of study: default temperatures

Temperature instructions (21°C for forward, 26°C for aft) to FedEx pilots ensure more stable reproducible temperatures within B777F



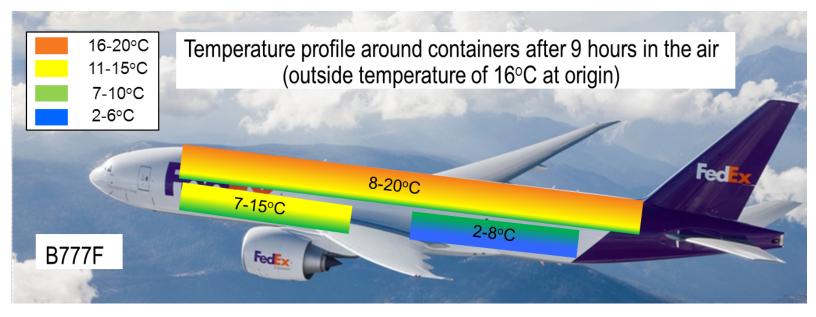
The temperature selectors need to be adjusted to achieve appropriate temperatures on the computer screen





All-Cargo Custodial Control: Aircraft

Default temperature settings implemented for the whole B777F fleet



- Time and temperature sensitive shipments are typically placed on the main deck where the temperature settings are adjusted for shipments to experience more homogeneous temperatures
- Temperature settings in the bellies can be regulated for healthcare shipments
- Charter flights with adjusted flight schedules, aircraft temperature settings and desired routes can
 even be offered to healthcare customers for high volume product launches

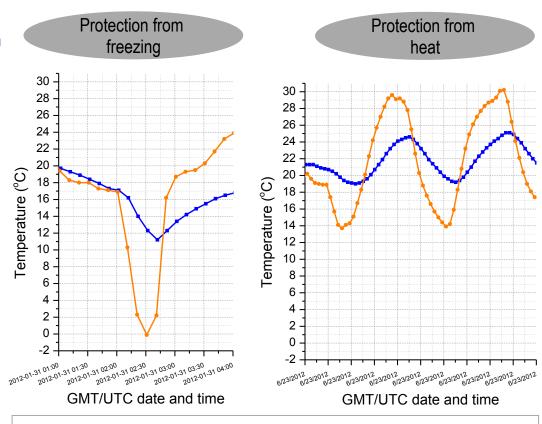


Thermal blankets can protect from temperature fluctuations

- Ideal for room temperature shipments
- Relatively inexpensive and green solution
- Reverse logistics managed by FedEx
- Assigned as FedEx physical assets
- · Protection from rain and dirt







- Temperatures experienced in the FXE network (outside blanket)
- Temperatures under the thermal blanket (on customer shipment)



Ambient Conditions: Ground Transport

Weather

Effects of Warm or Cold weather inside unprotected cargo holds

Temperature Control equipment varies in capability to overcome extreme temperatures

- BTU exchange
- TCU settings
- Insulation
- Maintenance
- Cargo load plan and cargo preconditioning

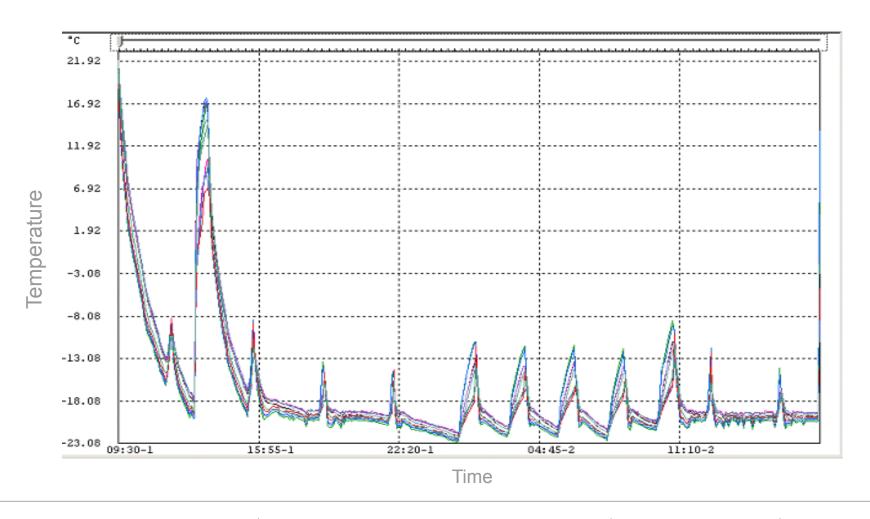
Load/Unload environment

Monitoring and Contingency intervention

Test critical areas of operation to ensure consistent quality results

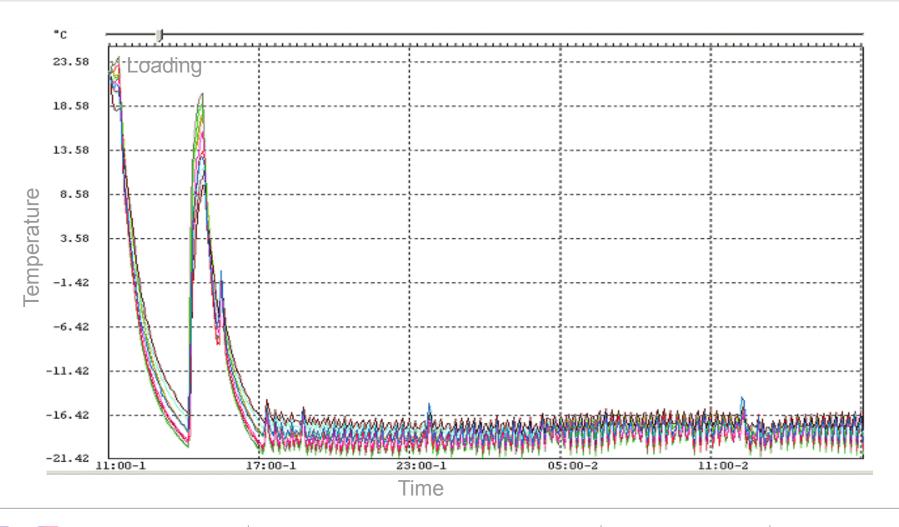


Typical Behavior of a Refrigerated Truck (Unqualified)





Controlled, Qualified Truck

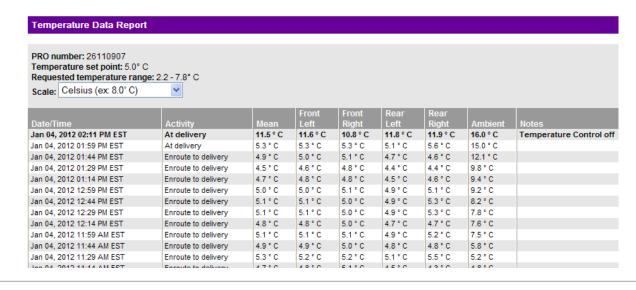




Enroute Monitoring

Custodial Control and Monitoring
Effective pre-shipment preparation checks
Continual monitoring of each shipment
Immediate contact communication with all parties

- Online and Real time shipment monitoring ensures full communication
- Proactive route management
- Effective contingency response
 - Severe weather
 - Breakdown,
 - · Traffic delays,
 - Accident





Enroute Communication

Confirmation of events:

- Pickup/Delivery,
- Geofence targets: pre-arrival alerting

Positive driver identification

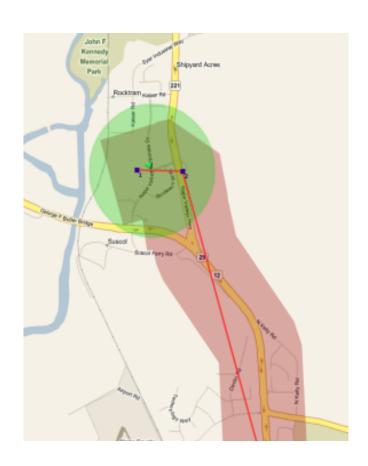
 Shipment summary with driver photo emailed prior to pickup

Shipping toolkit

 Online shipment quoting, scheduling, tracking, and account maintenance

Post shipment record review and analysis

- Temperature Data
- Quarterly Performance Review





Contingency planning

Assessment is part of shipment pre-planning

- Identify contingency events
 - Equipment failure
 - Traffic delay

Contingency intervention planning

- Temp storage enroute
- Tow to destination
- · Backup vehicle door-to-door transfer
- Alternate routing

Security alert procedure – appropriate emergency response

- Monitoring
- Automated alerts
- Driver-activated alarm

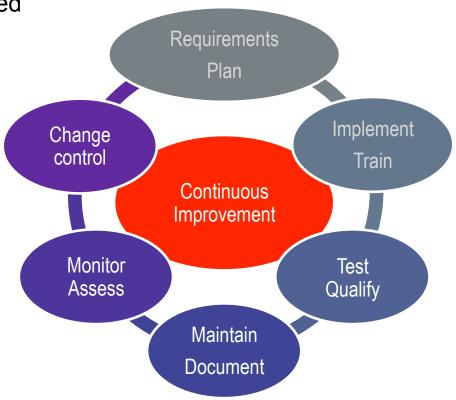


Modern carriers must have quality systems

Quality Systems appropriate to service

System designed for result then tested

- Controlled
- Continuous improvement





Quality Management Results

Door to Door service from one company

Complete access to systems for route, shipment tracking, geo-fence alerts, contingency decision making

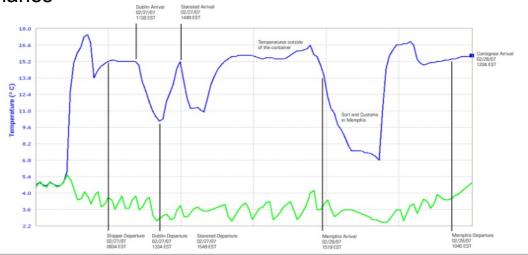
Partnering for improved solutions

- Complete understanding of control systems
- Flexibility to match needs on specific lanes

Compliant audit trail

- Temperature
- Location
- Event

Zero product loss





Carrier-Customer Relationships

Facilitate problem solving

Enable more effective overall solutions

Establish Quality Agreements tailored to transportation

- Promote mutual understanding
- Refrigeration performance standards
- Monitoring methods and results
- Record keeping and communication activities
- Pre-coordinate contingency actions



Carrier Models

Integrator model

- Common Ownership
- Single source
 - Management
 - Control

Traditional model

- Different Ownership
- Multiple
 - Systems
 - Measurements
 - Quality standards



Carrier Models: Traditional Model

Multiple Companies on a single shipment

- Truck from company A
- Warehouse (or Ramp) at company B
- Plane Hub Plane from company C
- Warehouse at company D
- Truck from company E
- Command center by company F



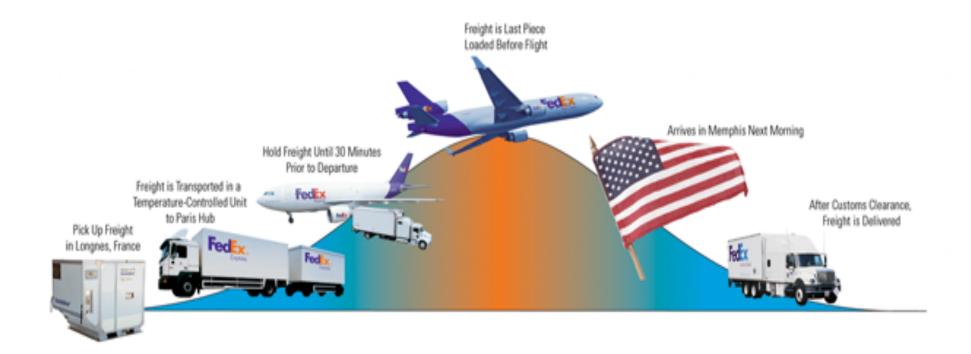
Carrier Models: Integrator Model

Single source of Management and Control

- Container positioning
- Container preconditioning
- Direct service locations
- Ability to force line haul routings
- Monitor live time temperatures enroute
- Effective contingency intervention capability
- Consistent post shipment temperature data
- Auditable temperature and event data trail
- Deviation and CAPA reporting



Multiple Modes in the Integrator Model





FedEx custodial control produces a new paradigm for transportation quality and innovation

- Understands Regulations
- Designed for security and control
- Separate networks for specific purpose:
 - FedEx Ground, Freight, and Express
- Shipment specific, customized care from FedEx Custom Critical
- Innovation for high value and critical care shipments
- Leads development and implementation of best practices
- Safe and dependable: an armored system



Thank You

