



# Investigation and Evaluation of the Distribution Environment for a Medical Device

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# Reason for Investigation

## Packaging Development:

- observe and map distribution channel
- measure distribution environment
- determine if another industry distribution simulation test method is more appropriate

## Smith & Nephew, Inc:

- design package that properly protects product with most cost effective and efficient material configuration possible
- provide documentation of S&N distribution environment as educational tool to S&N employees

# Project Information

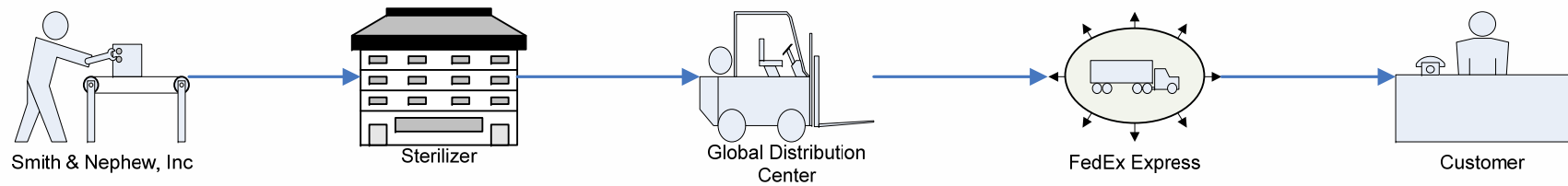
- Timeline
  - Start: August 2007
  - Finish: December 2008
- Data
  - Collection:
    - 10 states (11 cities)
    - 7 countries

# Distribution Channel

Segmented distribution channel into 4 parts:

- Sterilization
- Warehouse (Global Distribution Center)
- FedEx Express Distribution System
- Sales Rep Cycle

# Overview of Product Distribution Life Cycle



# Distribution Environment

Investigation and evaluation of the distribution environment:

- Temperature
- Humidity
- Drop Height / Shock
- Vibration (not analyzed)

Note: Not evaluating the affects on package design

# How we measure the environment?

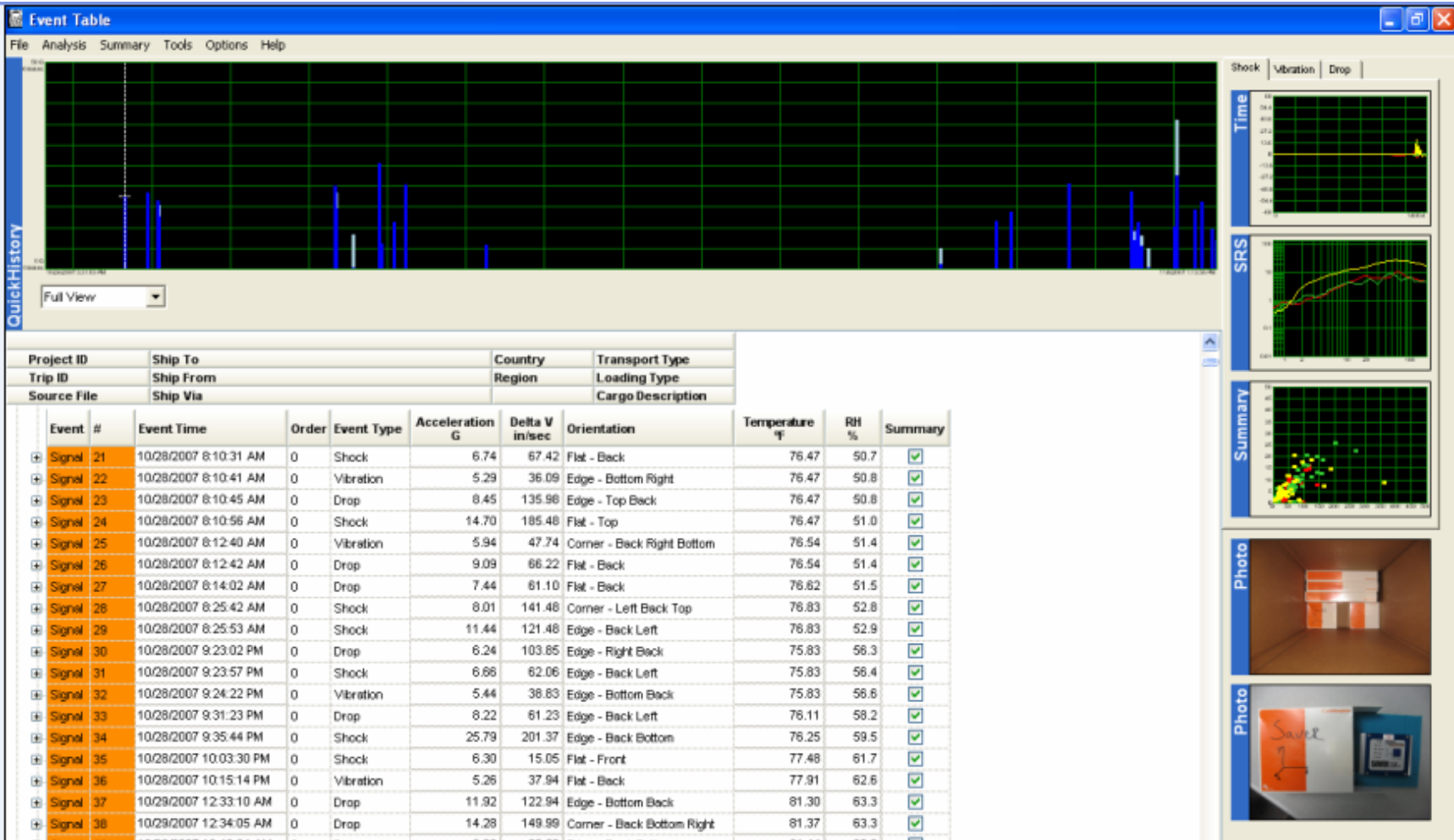
## Data Recorder

- Lansmont Saver<sup>◇</sup> 3X90
  - Internal Temp. & RH Sensor
  - Can record shock, vibration and drops using a tri-axial accelerometer.
  - Records events two ways:
    - Event triggered
    - Timer triggered



# How we measure the environment?

Lansmont SaverXware<sup>◇</sup>





Distribution Study -  
**Distribution Hazards**

# Factors that can Produce Shipping Damage

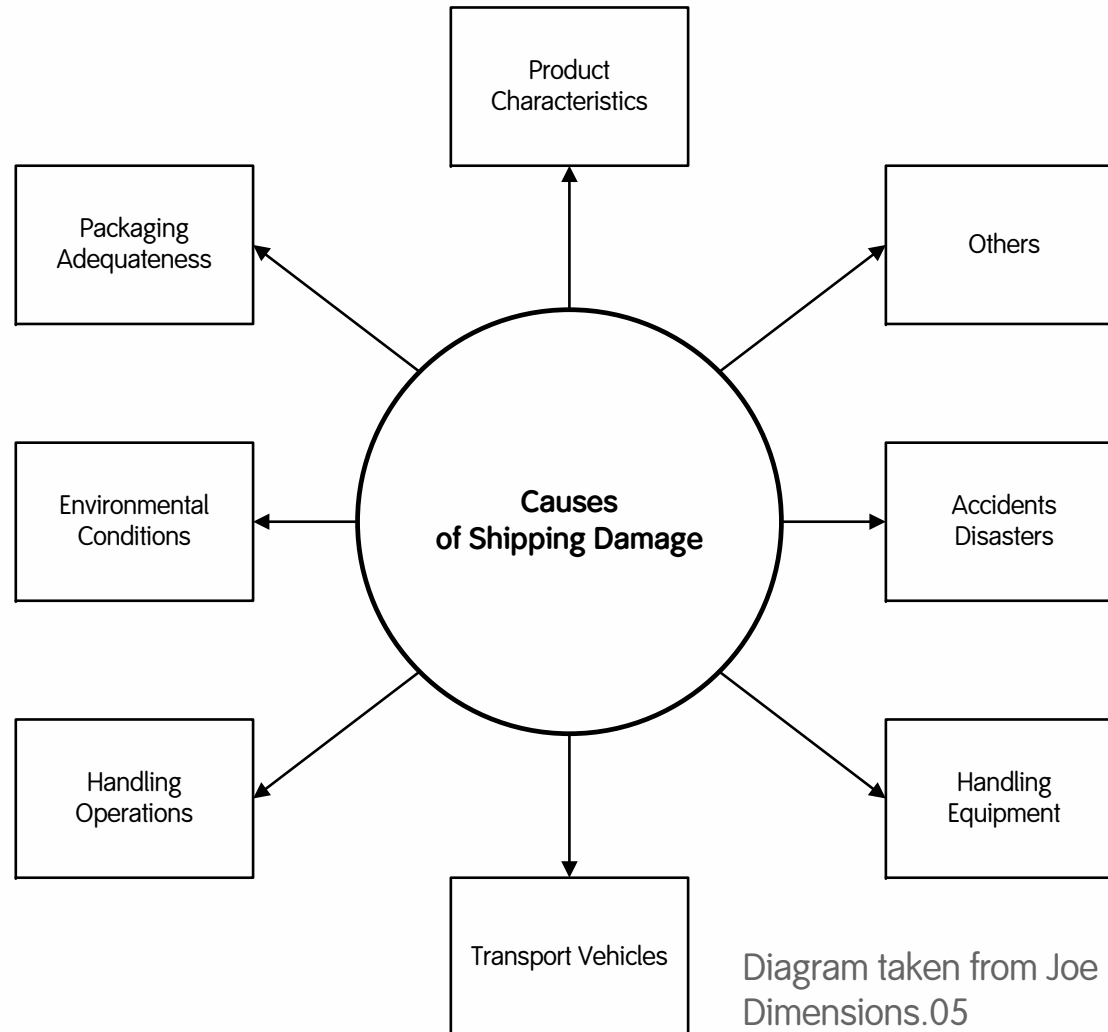


Diagram taken from Joe Zhou presentation at Dimensions.05

Distribution Study -  
Information Gathering

# Information Gathering

- Analyze shipping database to determine most commonly shipped (for both domestic and international):
  - Boxes
  - Weights
  - Shipping method
  - Locations
- Manufacturing floor observations / speaking with packagers:
  - Determine commonly used box and weight for shipments to both sterilizers
- Warehouse observations:
  - Conveyor system
  - Slides
  - How packages were stored before being placed in the FedEx Express truck

# Determining Coefficient of Restitution

- Used similar method to the MADE studies (Measurement and Analysis of the Distribution Environment)
- That method was as follows:
  - Drop package on three surfaces:
    - Steel plate, knocked down corrugated cartons, and foam
  - Drop package at two different heights: 18” and 36”
- Calculate  $e$  by using the following equation:

$$V_r = eV_i$$

- 0.27 was calculated to be our Coefficient of Restitution

## Determining Equivalent Free Fall Drop Height (EFFDH)

- Each event was individually evaluated
- $\Delta V_x$ ,  $\Delta V_y$ ,  $\Delta V_z$ , for each event recorded by SaverXware<sup>◇</sup> was transferred to excel file
- Calculated the EFFDH by using the following equation ( $e = 0.27$ ):

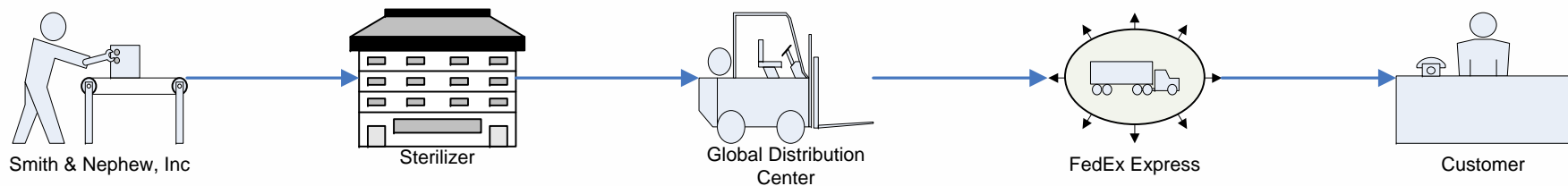
$$h = \frac{\Delta V_x^2 + \Delta V_y^2 + \Delta V_z^2}{2g(1+e)^2}$$

- Once all EFFDH were calculated all drops under 6” were discarded
  - Not determined to be significant
- Any EFFDH over 30” was re-evaluated by examining SaverXware<sup>◇</sup> graph
  - Remove noise (slide or roll) to determine impact velocity

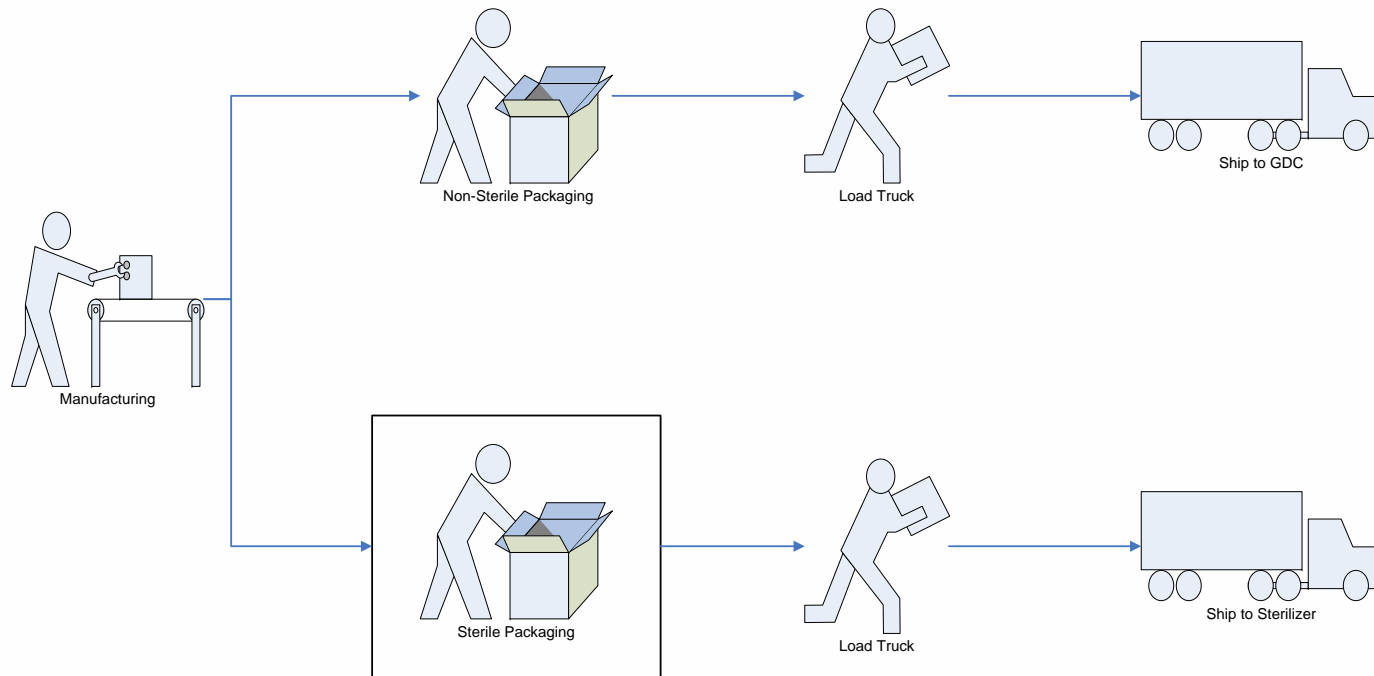
Distribution Study -  
**Data Collection**

# Distribution Channel

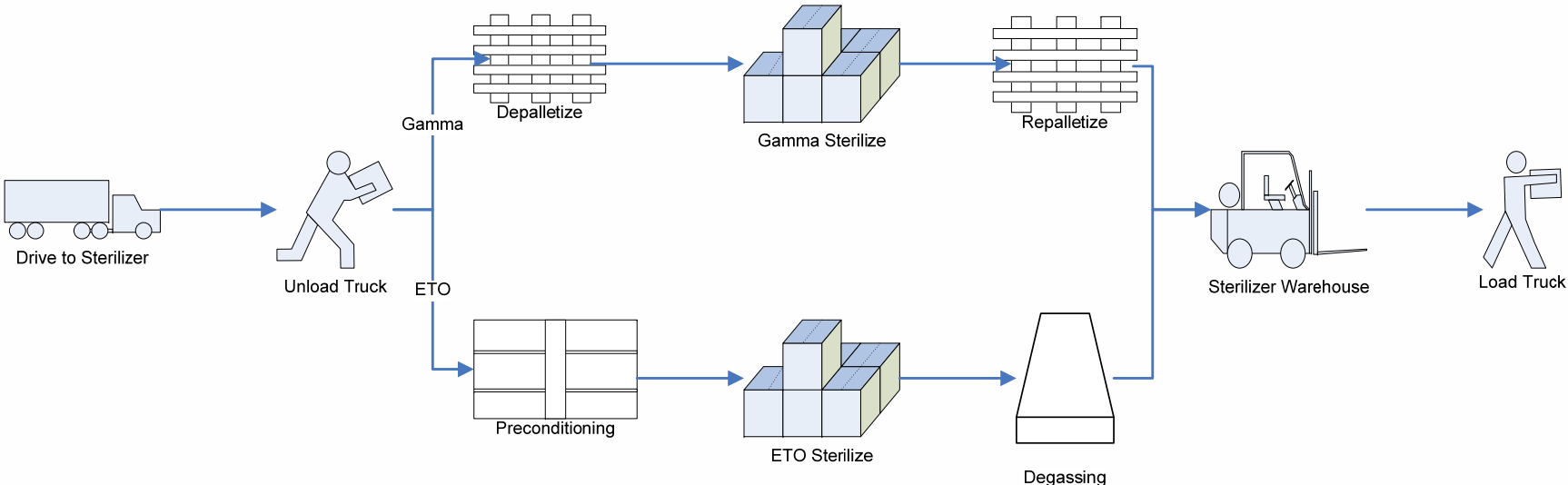
- Mapping S&N's distribution system was completed by analyzing the following:
  - Sterilization
  - Warehouse (GDC)
  - FedEx Express Distribution System
  - Sales Rep Cycle



# S&N Packaging



# Sterilizer



# Sterilizer Hazards



# Sterilizer – Test Purpose and Plan

## Purpose:

- measure distribution environment occurring from point package left S&N dock to delivery of package to warehouse

## Plan:

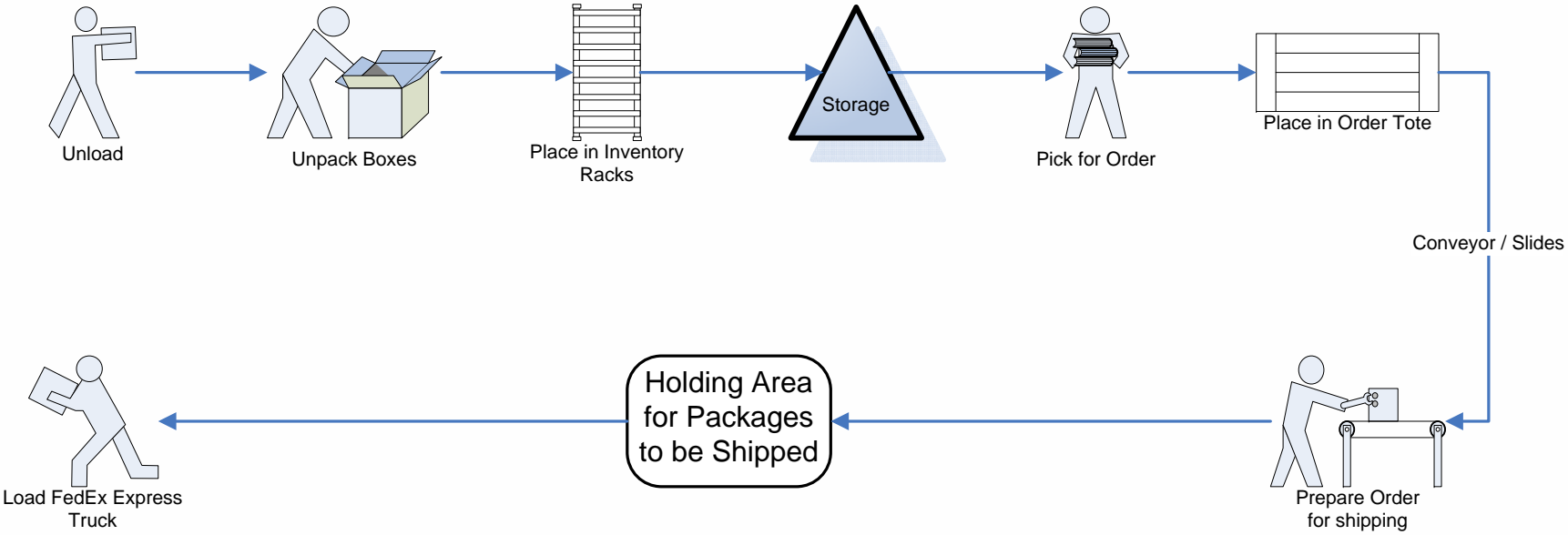
- shipped SAVER<sup>◇</sup> in 14.75” x 11.25” x 30” corrugated box (25 lbs)
- evaluated both Gamma (West Memphis, AR) and ETO (Memphis, TN)
- Four shipments to each facility
  - 1 shipment to each facility was measured (time constraint)

# Sterilizer – Analysis Results

Sterilizer EFFDH Data		
	Gamma	ETO
Average	12.45 in	10.98 in
Minimum	7.03 in	6.22 in
Maximum	17.87 in	14.83 in
95 <sup>th</sup> Percentile	17.32 in	14.54 in
90 <sup>th</sup> Percentile	16.78 in	14.24 in
Orientation		
Corner	0	0
Edge	0	2
Flat	2	1

Temperature and Relative Humidity Data			
		Gamma	ETO
Temperature	Average	60.95°F	55.17°F
	Minimum	46.40°F	46.53°F
	Maximum	76.81°F	62.51°F
Relative Humidity	Average	36%	39.36%
	Min	26.20%	32.09%
	Max	42.99%	50.73%

# Warehouse (Global Distribution Center)



# Warehouse Hazards



# Warehouse – Test Purpose and Plan

## Purpose:

- measure distribution environment occurring from point package arrives at warehouse from sterilizer to point package is placed into shipper for shipment to customer (via FedEx Express).

## Plan:

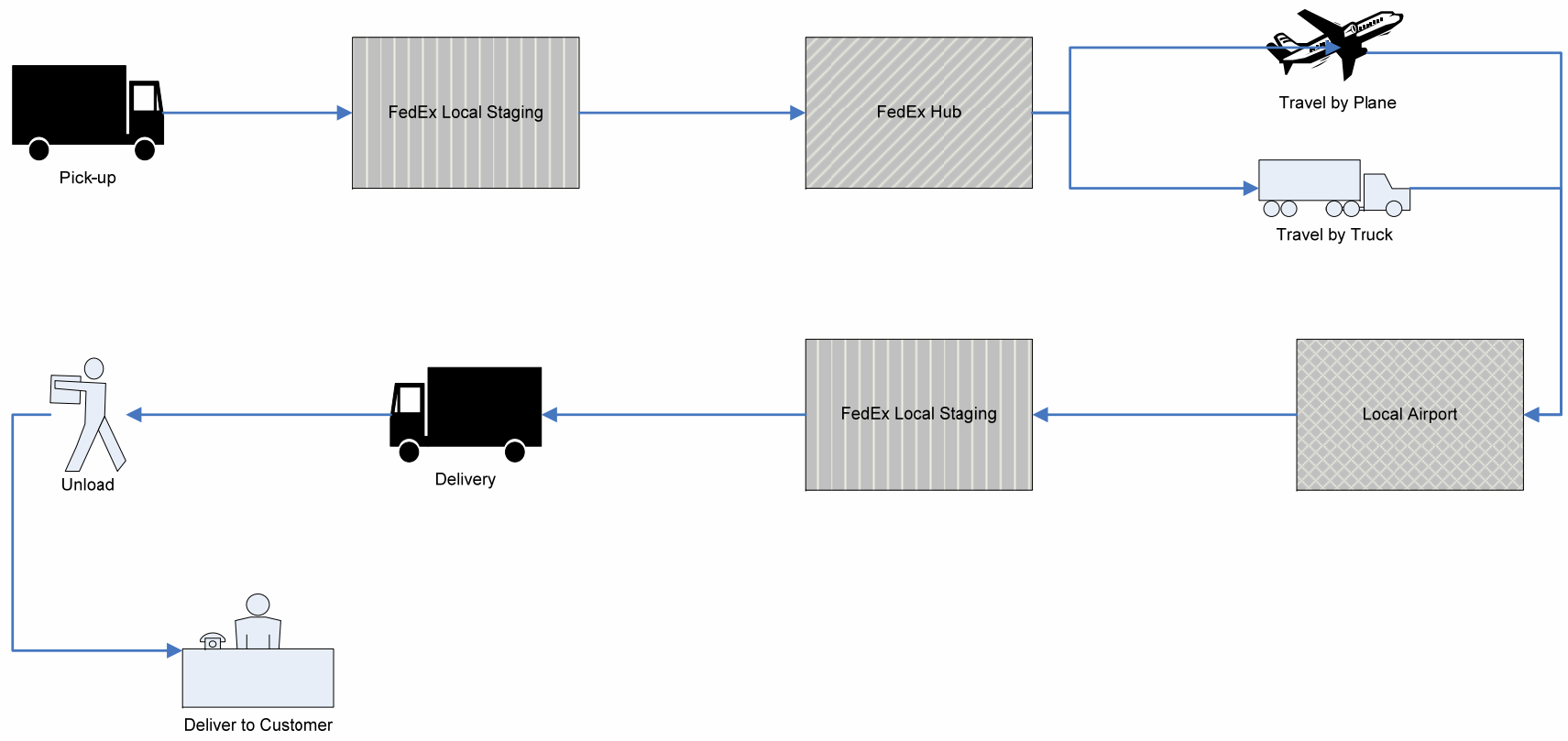
- placed SAVER<sup>◇</sup> in plastic tote and in corrugated shipper
- evaluated conveyors, packing stations, and slide / chutes
- Five shipments through the facility
  - One shipment through the facility measured (moving facilities)

# Warehouse – Analysis Results

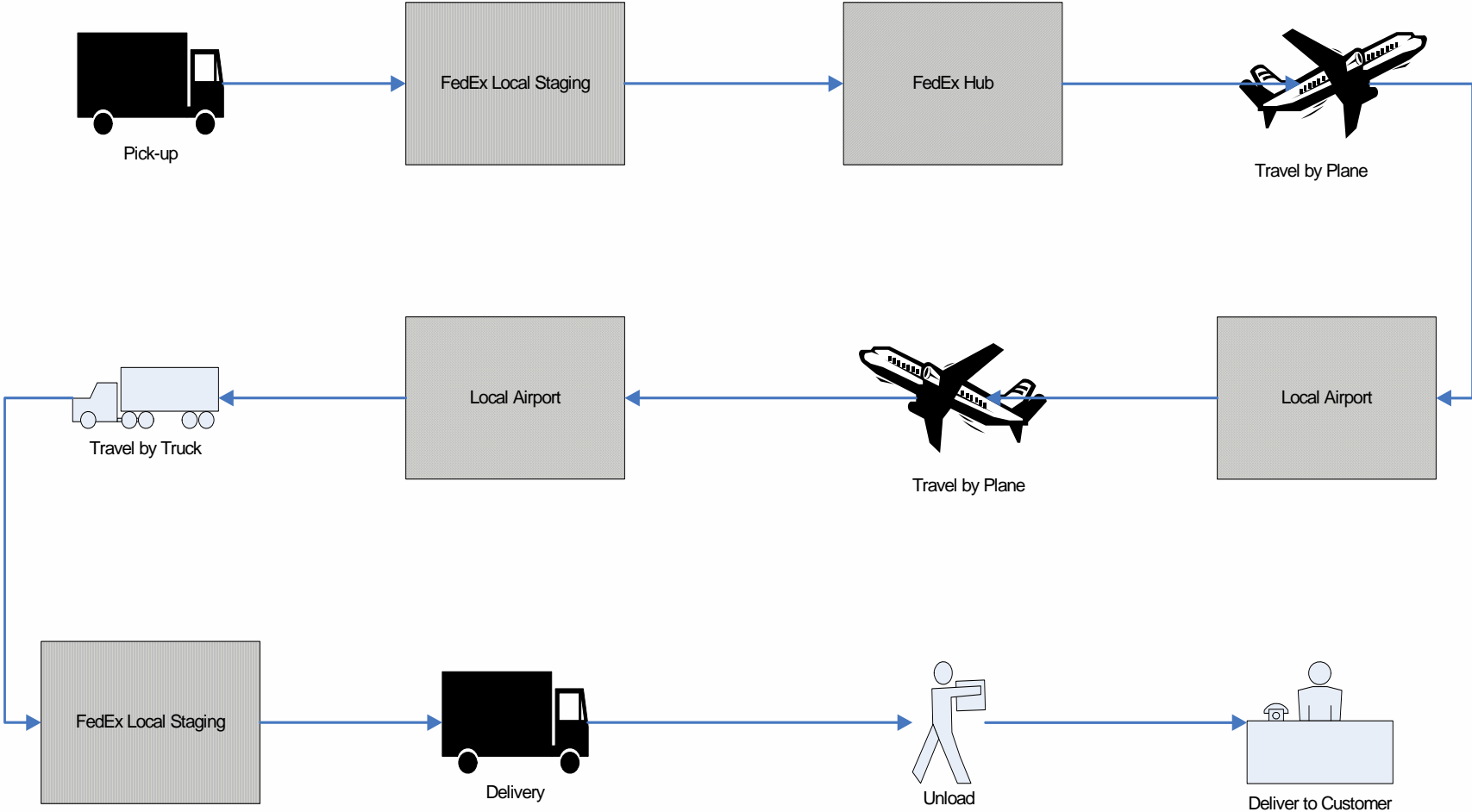
Warehouse EFFDH Data	
	EFFDH
Average	16.5 in
Minimum	6.5 in
Maximum	26.5 in
95 <sup>th</sup> Percentile	25.5 in
90 <sup>th</sup> Percentile	24.5 in
Orientation	
Corner	1
Edge	1
Flat	0

Temperature and Relative Humidity Data		
Temperature	Average	79.16°F
	Minimum	78.92°F
	Maximum	79.43°F
Relative Humidity	Average	44.56%
	Min	41.56%
	Max	50.42%

# FedEx Express Domestic Distribution System



# FedEx Express International Distribution System



# FedEx Express Distribution System Hazards



# FedEx Hub

Memphis, TN



# FedEx Express Distribution System (Domestic) – Test Purpose and Plan

## Purpose:

- measure distribution environment occurring from point package left S&N warehouse to delivery of package to customer

## Plan (domestic):

- Database = box size, box weight, ship method, ship location
- shipped SAVER<sup>◇</sup> in 10" x 10" x 15.5" corrugated box (11 lbs.)
- Outbound: Standard Overnight<sup>®</sup>; Inbound: 2Day<sup>®</sup>
- 24 shipments were measured using 11 cities
  - Boston, Charlotte, Cleveland, LA, Minneapolis, Phoenix (2X), San Antonio, San Francisco, Spokane, St. Louis, and Tampa

# Shipment Study – Domestic



# FedEx Express Domestic Shipping – Analysis Results

FedEx Express Domestic EFFDH Data (Standard Overnight)		
	Standard Overnight	2Day
Average	13.17 in	13.40 in
Minimum	6.00 in	6.02 in
Maximum	49.25 in <sup>1</sup>	62.00 in <sup>2</sup>
95 <sup>th</sup> Percentile	28.12 in	29.61 in
90 <sup>th</sup> Percentile	23.36 in	25.34 in
Orientation		
Corner	52 drops (19.48%)	67 drops (23.84%)
Edge	147 drops (55.05%)	119 drops (42.35%)
Flat	68 drops (25.47%)	95 drops (33.81%)

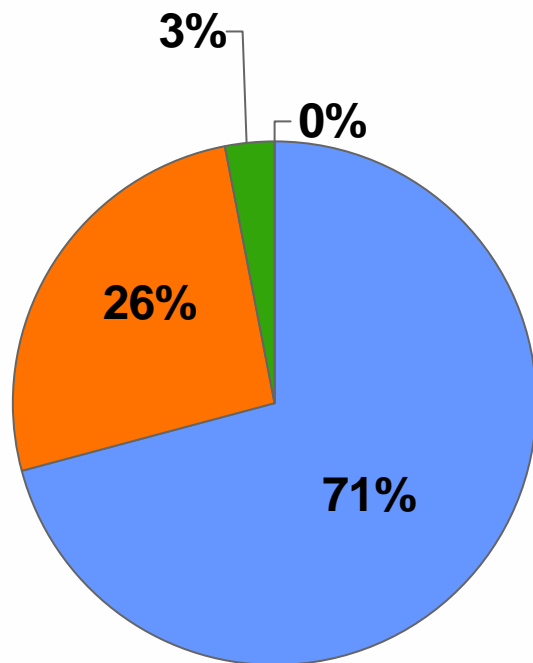
<sup>1</sup>Los Angeles Trip – 10/24/07 @ 6:39 am – At local FedEx facility (Memphis)

<sup>2</sup>Los Angeles Trip – 10/20/07 @ 9:56 am – Arrived FedEx location (Memphis Sortation)

# FedEx Express Domestic Shipping – Analysis Results

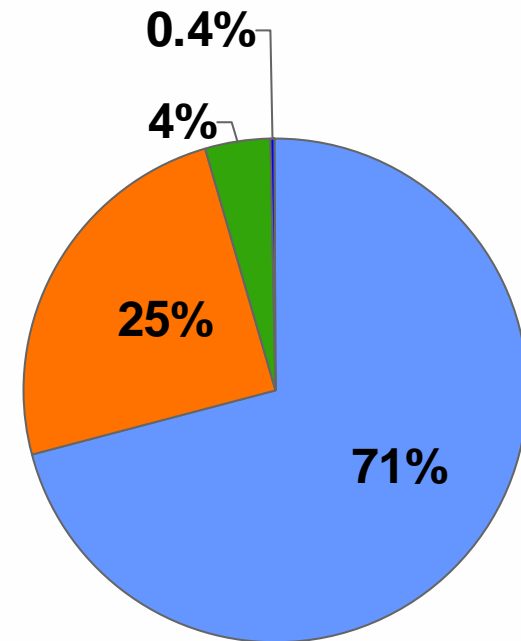
## Number of Events (EFFDH)

Standard Overnight

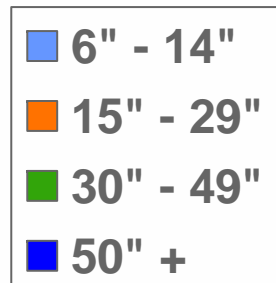


Total = 267 events

2Day



Total = 281 events



# FedEx Express Domestic Shipping – Analysis Results

Temperature and Relative Humidity Data				
		Standard Overnight		
		Value	Time-Date	Location
Temperature	Average	66.92°F		
	Minimum	41.06°F	9:22 am 1/30/2008	Delivery – Minneapolis
	Maximum	85.25°F	10:11 pm 7/14/2008	At FedEx facility - Memphis
Relative Humidity	Average	40.64%		
	Minimum	22.40%	9:13 am 1/30/2008	Delivery – Minneapolis
	Maximum	79.20%	6:41 pm 7/14/2008	Pick-up - Memphis

# FedEx Express Domestic Shipping – Analysis Results

Temperature and Relative Humidity Data				
		2Day		
		Value	Time-Date	Location
Temperature	Average	67.28°F		
	Minimum	15.07°F	9:45 am 1/31/2008	At local FedEx facility – Minneapolis
	Maximum	92.81°F	11:06 pm 7/15/2008	Left FedEx origin facility- Memphis
Relative Humidity	Average	39.61%		
	Minimum	14.80%	3:55 pm 1/30/2008	Pick-up – Minneapolis
	Maximum	74.58%	4:26 pm 10/18/2008	Pick-up – San Antonio

## FedEx Express Distribution System (International) – Test Purpose and Plan

### Purpose:

- measure distribution environment occurring from point package left S&N warehouse to delivery of package to customer

### Plan (international):

- Database = box size, box weight, ship method, ship location
- shipped SAVER<sup>◇</sup> in 10” x 10” x 23” corrugated box (26 lbs)
- Outbound: FedEx Intl Priority®; Inbound: FedEx Intl Priority®
- 11 shipments were measured using 6 locations
  - Australia (sales office), Switzerland (DC), Japan (sales office), Malaysia (mfg/pkg), Germany (mfg/pkg), United Kingdom (mfg/pkg)

# Shipment Study – International



# FedEx Express Intl Shipping – Analysis Results

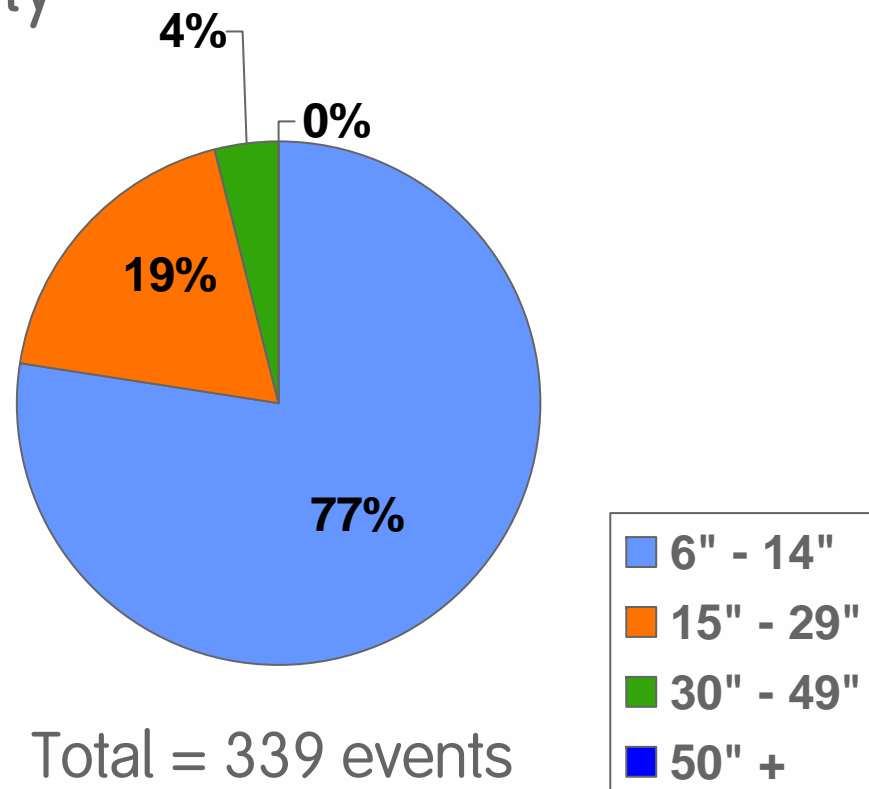
FedEx Express International EFFDH Data	
	EFFDH
Average	12.22 in
Minimum	6.00 in
Maximum	49.31 in
95 <sup>th</sup> Percentile	28.25 in <sup>1</sup>
90 <sup>th</sup> Percentile	22.46 in
Orientation	
Corner	65 drops (19.17%)
Edge	128 drops (37.76%)
Flat	146 drops (43.07%)

<sup>1</sup>UK Trip – 6/24/08 @ 12:19 am – Arrived FedEx Location (Memphis Sortation)

# FedEx Express Intl Shipping – Analysis Results

## Number of Events (EFFDH)

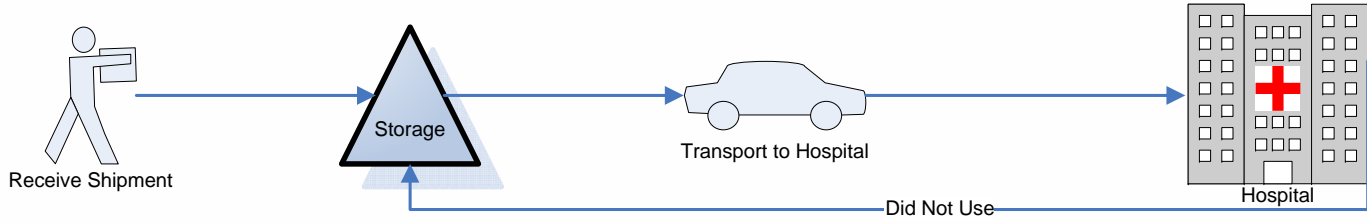
Intl Priority



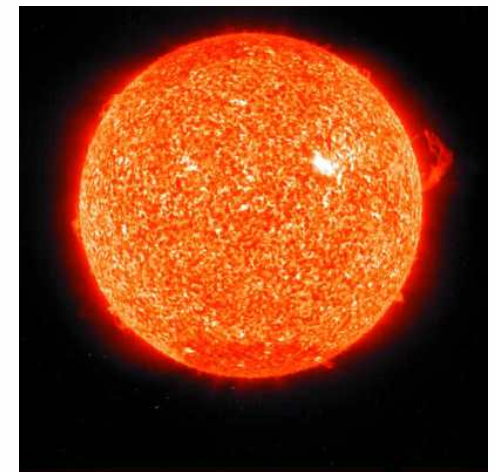
# FedEx Express Intl Shipping – Analysis Results

Temperature and Relative Humidity Data				
		International Priority		
		Value	Time-Date	Location
Temperature	Average	69.80°F		
	Minimum	50.56°F	6:42 am 11/08/2008	At Local FedEx Facility - Memphis
	Maximum	95.62°F	7:51 pm 7/04/2008	Departed FedEx Location - Memphis
Relative Humidity	Average	46.25%		
	Minimum	20.42%	2:46 am 7/3/2008	Left FedEx Origin Facility – Australia
	Maximum	81.64%	1:50 pm 7/06/2008	International Shipment Release – Memphis

# Sales Rep Cycle



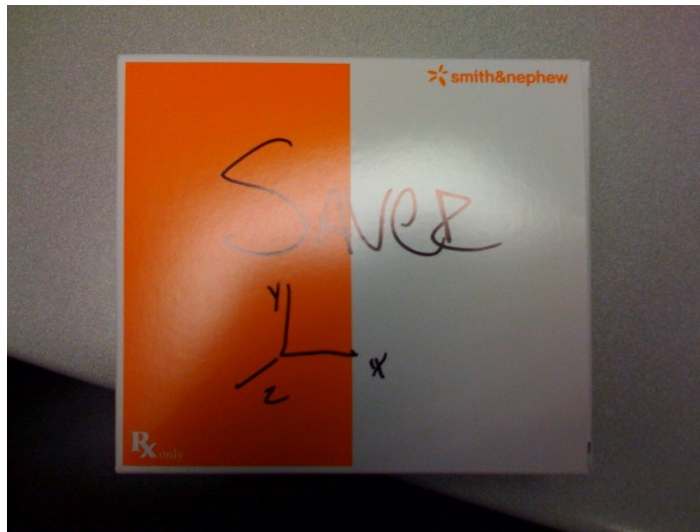
# Sales Rep Cycle Hazards



# How we measure the sales rep. environment?

## Data Recorder

- Typical set-up in carton and tote



# Sales Rep – Test Purpose and Plan

## Purpose:

- measure distribution environment occurring from point package delivered by FedEx Express and in possession of sales rep

## Plan:

- placed SAVER<sup>◇</sup> into plastic tote
- tote placed in trunk of a black car for 8 days (January 2008)
- tote placed in trunk of a white car for 7 days (August 2008)
- tote placed in back of a black SUV for 7 days (August 2008)
- tote carried to and from office several times

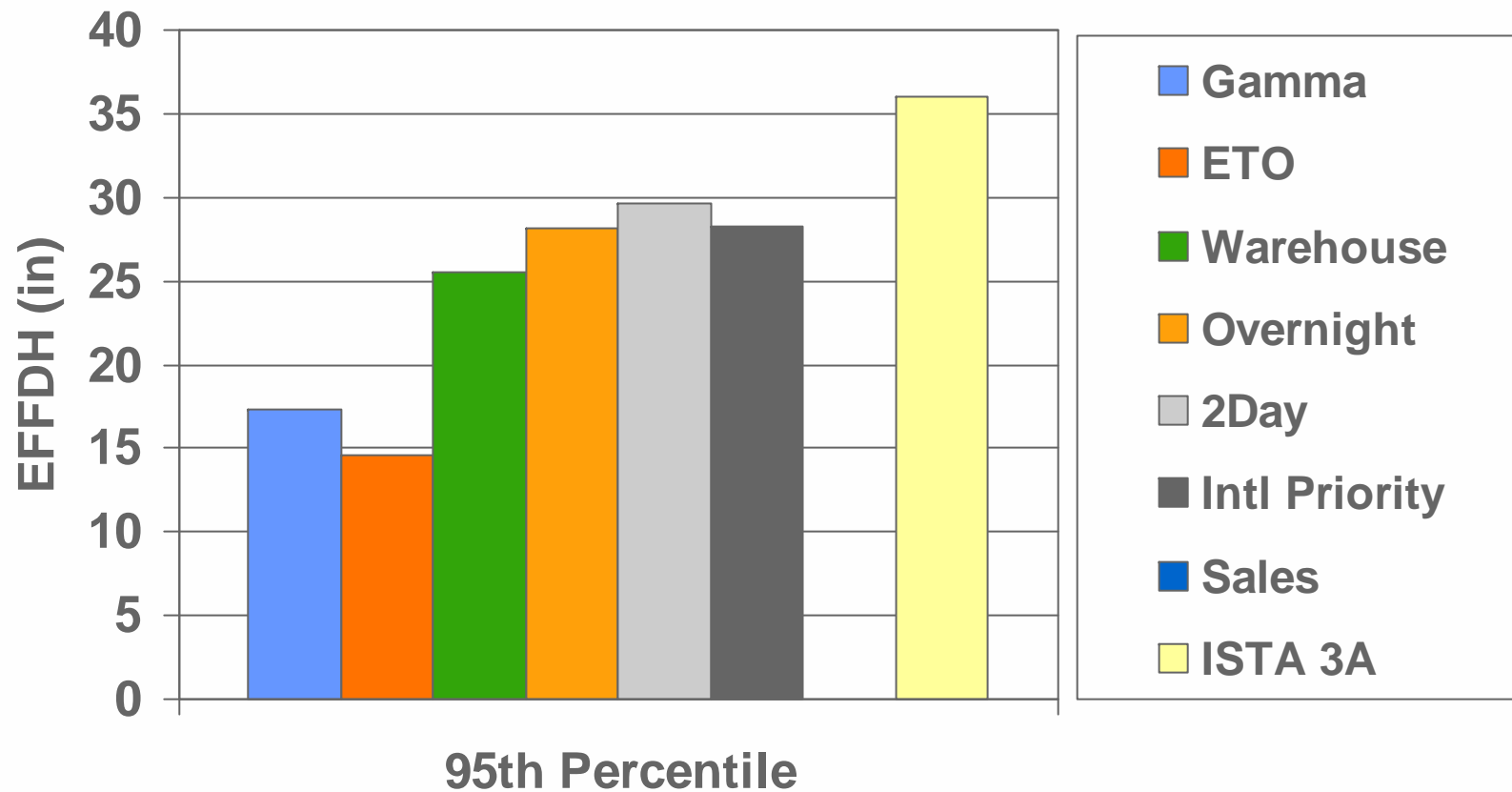
# Sales Rep Cycle – Analysis Results

Temperature and Relative Humidity Data			
		Value	Time-Date
Temperature	Average	84.15°F	
	Minimum	17.37°F	7:16 am 1/03/2008
	Maximum	113.26°F	5:48 pm 8/28/2008
Relative Humidity	Average	41.53%	
	Minimum	13.22%	2:31 pm 1/02/2008
	Maximum	90.45%	12:16 pm 1/09/2008

- +100°F duration of 10 hours
- 113°F duration of 30 min
- SAVER<sup>®</sup> did not record any significant events related to shock or drop

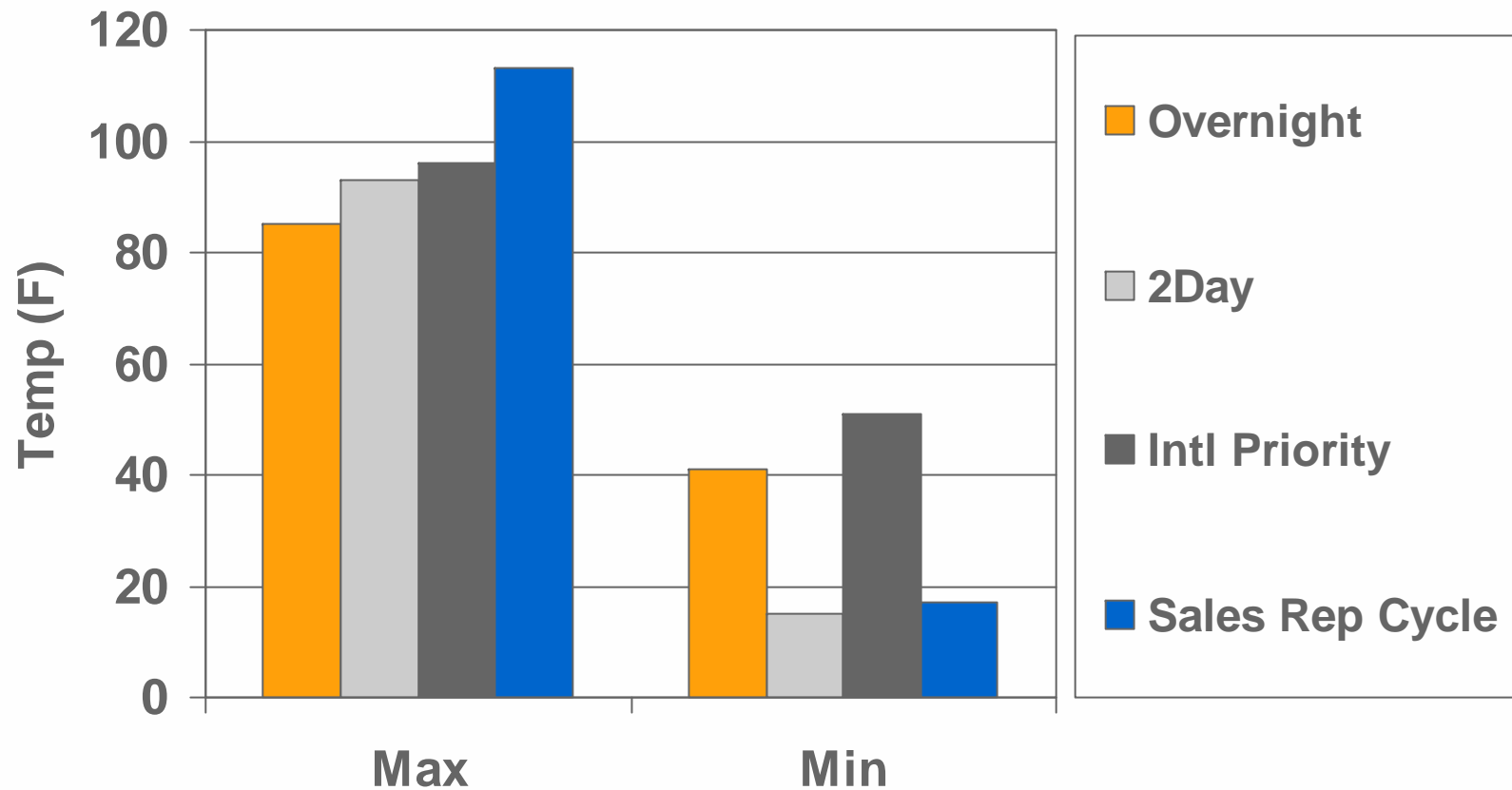
# Conclusion

## Comparison of EFFDH



# Conclusion

## Comparison of Temperatures



# Conclusion

## Comparison of ISTA Test Methods to S&N Distribution Channel

Test Method	ISTA 1G	ISTA 3A	S&N Study
No. of Drops	10	17	24
Average	30 in	20.1 in	13.4 in
95 <sup>th</sup> Percentile of Drop Height	30 in	36 in	29.6 in
Corner Drop	10%	29.4%	23.8%
Edge Drop	30%	47.1%	42.4%
Flat Drop	60%	23.5%	33.8%
Environmental	No	Yes	Yes

\*Used data from 2Day method because it showed to be worst case

**ISTA 3A ~ S&N Distribution Channel**

# Conclusion

## Lessons Learned

- Warehouse conveyors – use of broom handle (impact low)
- Domestic and Intl shipping are the similar (EFFDH, Temp, RH)
  - no need for separate test protocols
- Standard Overnight® has least variation in temperature & RH
- 2Day® contained highest drop heights
- S&N data from FedEx Express evaluation is similar to other industry studies
- Sales Reps can have impact / control temperature exposure

# Next Steps

- Further internal evaluation
  - Sterilizer & Warehouse
- Select one location and ship multiple times
  - Better track temperature over seasons
  - Increase statistical confidence
- Share data / information
  - Shipping Department or other GBU's
  - Use as an educational tool for other functional areas

# References

- Yongquan, Zhou “Joe,” 2005, Dimensions.05 presentation, “Proactive and Systematic Approaches to Reduce Damage and Improve Customer Experience”
- Russell, Paul and Kipp, Bill, 2006, Dimensions.06 presentation, “European Express Shipping Drop / Impact Study”
- Sheehan, Richard L, 2001, Dimensions.01 presentation, “Analysis of Drop Height Data”
- Yongquan, Zhou “Joe,” – Packaging Project Engineer, FedEx
- Darley, Russell – Manager, Global Packaging, Smith & Nephew, Inc

Questions?