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Temperature mapping study of United States distribution systems

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ABSTRACT

The purpose of this one-year temperature mapping study was to determine the extreme temperatures and respective durations commercial pharmaceutical products are expected to be exposed to during routine ambient distribution within the continental United States. Extreme temperature conditions may affect the safety and efficacy of pharmaceutical products during distribution. Knowing the value and duration of the extreme temperatures that products are likely to experience in the ambient (uncontrolled) distribution environment allows for improved product degradation testing, optimized thermal package design and scientifically based determination as to when logistical and environmental controls should be used. Before this study, testing was performed using profiles provided by standards organizations. This study was designed to provide company specific data that may be used to design tests, validate, or modify existing test procedures throughout the organization. To achieve this, packages were shipped to selected locations across the United States from the company's Eastern, Southern, and Western Distribution Centers (DCs) during peak summer and winter conditions. The packages were equipped with data logging instrumentation that recorded the temperature and the time-of-day. As a result of this project, the organization now has first hand knowledge of the expected extremes and durations within its United States distribution environment. This information is now in use for study design, logistical decision-making, and proving that appropriate testing has been performed to regulatory bodies.

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CHAPTER 1: INTRODUCTION

Background of the Problem

Before this study, the company utilized temperature profiles provided by standards organizations for the determination of shipping methods, product robustness testing, and thermal package design without company specific first hand data. Available temperature profiles are nonspecific and highly generalized to fit a wide array of applications. A comprehensive thermal mapping study of the company's commercial distribution systems facilitates optimized study design, better logistical decision-making and proof that appropriate testing has been performed to regulatory bodies.

Problem Statement

Relying solely on profiles published by standards organizations and not comparing product sensitivities to company specific, actual field data leaves the company vulnerable to the questioning of their current practices in regard to study design, logistical decision-making and proving that appropriate testing has been performed.

Objective of the Research

The objective of this study was to map the single parcel commercial ground shipping routes used by the company to distribute commercial Rx products. This was done by shipping time-stamping, temperature sensing data loggers throughout the continental United States using modes and routes representative of the actual commercial shipping lanes.

Scope of the Research

The scope of the research was limited to:

- Single parcel packages.
- The continental United States.
- Year-round data collection with increased data collection during summer and winter seasonal extremes.
- This data was used to:

- Verify or supersede temperature profiles generated by standards organizations currently in use for cold chain package testing.
- Establish minimum and maximum temperatures used to determine shipping methods and design or confirm cycling profiles used in studies to evaluate product sensitivities during formulation.

CHAPTER 2: LITERATURE REVIEW AND BACKGROUND THEORIES

Pharmaceutical product stability has time and temperature dependencies. A temperature mapping study of the pharmaceutical product distribution routes is performed to establish the value and duration of extreme temperatures products are likely to experience in the commercial distribution environment. The information gathered is important for purposes of regulatory compliance, product development and testing, packaging design, and logistics planning. This review of literature therefore proceeds in the topical order below to establish the technical and business-level foundation of temperature mapping studies, as well as best practices for performing such studies:

- Stability issues in pharmaceutical products
  - Technical issues, including degradation characteristics
  - Physical causes, with emphasis on temperature considerations
  - Manufacturing issues
  - Logistics issues
  - Packaging issues
- Regulatory compliance
- Product development and testing
- Temperature mapping study best practices

Pharmaceutical Product Stability – Technical Issues Including Degradation Characteristics

The United States Pharmacopeia is the authority that sets public standards for pharmaceutical products manufactured or sold in the United States. USP <1150> provides the key definitions and parametric boundaries for the study of stability in pharmaceutical products. USP <1150> states that when possible, the dosage unit should be used as the unit of measurement for pharmaceutical product stability, and that the concept of stability applies to product identity, strength, quality, and purity. USP <1150> lists temperature, light, air, humidity, packaging components, and if applicable, microbial contaminations as factors that affect stability. It is noteworthy that the list of factors affecting stability does not include the elapse of time. Instead, USP <1150> makes it clear that concept of time is implicit in the

concept of stability because stability protocols apply to products "from initial preparation to expiration date."

USP <1191> provides a technical discussion of stability and the breakdown in stability in pharmaceutical products. According to USP <1191>: "Stability is defined as the extent to which a product retains, within specified limits, and throughout its period of storage and use (i.e., its shelf-life), the same properties and characteristics that it possessed at the time of its manufacture."

USP <1191> provides Table 1, which characterizes the five types of stability affecting pharmaceutical products.

Table 1 Criteria for Acceptable Levels of Stability

Type of Stability	Conditions Maintained Throughout the Shelf Life of the Drug Product
Chemical	Each active ingredient retains its chemical integrity and labeled potency, within the specified limits.
Physical	The original physical properties, including appearance, palatability, uniformity, dissolution, and suspendability, are retained.
Microbiological	Sterility or resistance to microbial growth is retained according to the specified requirements. Antimicrobial agents that are present retain effectiveness within the specified limits.
Therapeutic	The therapeutic effect remains unchanged.
Toxicological	No significant increase in toxicity occurs.

As can readily be seen from Table 1, when instability occurs, it can increase the possibility of adverse effects for the patient, decrease the therapeutic efficacy, and detract from product appearance and uniformity. USP <1191> also provides specific descriptions of manifestations of instability at the product-type level, as summarized in Table 2:

Table 2

PRODUCT TYPE	TYPICAL MANIFESTATIONS OF INSTABILITY
Gelatin Capsule	Softening or hardening of the shell
Uncoated Tablet	Crumbling (not from breakage), discoloration, swelling, crystal formation, fusion
Coated Tablet	Discoloration, clumping, tackiness
Powders and Granules	Caking, odor
Effervescents	Swelling, development of gas pressure within container
Solutions, Elixirs, Syrups	Precipitation, microbial contamination, gas pressure within container
Emulsions	Permanent oil separation
Suspensions	Non-resuspendable caking, crystal growth
Tinctures, Fluids, Extracts	precipitation
Sterile Liquids	microbial contamination, change in color, cloudiness
Creams	crystal growth, microbial contamination, emulsion breakdown, evaporation
Ointments	change in consistency (grittiness), separation
Suppositories	softening, drying

The negative consequences of product stability changes that result in abnormal product appearance and efficacy are as varied as customer dissatisfaction and product returns, and damaged reputation and court-imposed fines for criminal actions. As an example, Clinard and Yeager (2006) report that "in 1995 Warner-Lambert pled guilty and was given a criminal fine of $10 million for failing to notify the FDA about stability problems with a widely used drug for the treatment of epilepsy."

Pharmaceutical Product Stability – Physical Causes with Emphasis on Temperature Considerations

There are four primary environmental exposure factors affecting pharmaceutical product stability. These factors are temperature, light, humidity, and atmospheric gases. Obviously, temperature mapping studies, which are the focus of this thesis, are concerned with the impact of temperature on stability. As such, it must be remembered that while exposure to excess heat is

often considered the biggest worry, it must also be realized that inappropriately cold temperatures may also affect product safety and efficacy. USP <1191> illustrates effects of low temperatures by citing that inappropriate refrigeration of liquid drugs may cause excess viscosity, and that inappropriate freezing can have adverse effects on dispensability and efficacy.

When performing or interpreting the results of a temperature mapping study, it is useful to understand the magnitude of temperature variations and specific effects that concern pharmaceutical products. USP <1191> characterizes the impact of temperature on stability in terms of the typical effects temperature has on chemical reactions. To this end the document notes that across most drug hydrolysis and many drug oxidation reactions the rate of a chemical reaction increases exponentially for each 10 degree Celsius increase in temperature.

While the actual impact of temperature variation for any individual product will vary depending on such factors as its molecular bonding type and pH value, U.S. Pharmacopeia <1191> provides the general example of a hydrolysable product intended to be refrigerated that is instead exposed at room temperature to a continual 20 degree increase in temperature. In this case the efficacy should be expected to decrease to one-fourth to one-twenty-fifth of its shelf life under refrigeration.

Since this example in USP <1191> covers the affect of continual exposure to an elevated temperature on pharmaceutical products, for the purposes of interpreting variations uncovered in a temperature mapping study it is worthwhile to consider the mathematics applicable to the transient variations experienced in the distribution environment. To this end, in the article "Comparing Ambient Temperature Profiles," O'Donnell (2009) describes a useful method for computing the impact of transient temperature spikes. O'Donnell considers these critical factors when determining a representative ambient temperature profile:

- The cumulative amount of heat exposure during the distribution process (the area under the curve), and
- The assignment of temperature spikes at the appropriate place along the timeline, (the elapsed time during the distribution process capturing day/night exposure and critical touch points).

O'Donnell provides the following method for calculating the cumulative amount of heat exposure: “Simple Calculation for Determining the Heat under the Curve.” During the package design process, it is important to determine the amount of heat exposure the packaged product is likely to be exposed to during the distribution process. Such a calculation is helpful in determining the amount of insulation required for the amount of refrigerant necessary, and the size of the package, which are all necessary elements for maintaining the product within a specified temperature range. A simple process for determining a relative number representing the total amount of heat is by calculating the area under the heat curve. This can be achieved by multiplying the length times the width of the curve.

$$A = L \times W$$

Where A = area, L = temperature and W = (time) and where all widths are broken down to an equal interval… the length, L = (temperature) at each interval is multiplied by the width, W = (time) and where all widths are equal.

$$A = L1 \times W + L2 \times W + L3 \times W + L4 \times W$$

The resulting area... represents all the heat under the curve and can be used to compare other profiles (whose area is determined by the same method), for determining which are more “severe.” This can be critical information to have when determining package design parameters.

O'Donnell's discussion of the computation and impact upon product stability quoted above provides a mathematical foundation for estimating effects of transient and long term exposure of pharmaceutical product to elevated and extreme low temperatures that is especially useful for comparing temperature excursions having different durations and temperature extremes. Such comparisons are useful for extrapolating between test cases with documented results, and cases in which potential or actual results need to be estimated.

The area under the curve described by O'Donnell represents Mean Kinetic Temperature, or MKT. USP <1150> describes the importance of MKT relative to pharmaceutical product stability as providing a single number that represents the cumulative effect of degradation caused by various temperatures to which the product has been exposed. USP <1150> states that data loggers can be used to collect the periodic readings required as input to the calculation of MKT,

and takes special care to point out that MKT "is not a simple arithmetic mean," but, when formally calculated, a value that more highly weights temperature extremes through use of logarithmic functions.

In an earlier work, O'Donnell characterized the role that MKT (mean kinetic temperature) calculations play in regulatory compliance that are useful in avoiding the types of criminal sanctions described by Clinard and Yeager (2006). Citing the FDA, O'Donnell writes:

> The FDA states in its Code of Federal Regulations, Part 203 that manufacturers, authorized distributors of drugs and their representatives shall store and handle all drug samples under conditions that will maintain their stability, integrity, and effectiveness, and ensure that the drug samples are free of contamination, deterioration and adulteration. This is not possible without the application of MKT.

In addition to the steady state MKT example from USP <1191> and the cumulative MKT calculation methodology provided by O'Donnell the International Conference on Harmonization based recommendations for extrapolations to aid in accelerated studies have been widely embraced within the pharmaceutical industry. For example, in "A Stability Program for the Distribution of Drug Products," Lucas, Bishara, and Seevers (2004) provide guidelines for both long term and accelerated stability testing that are compliant with ICH product registration study requirements as summarized in Table 3.

TABLE 3 ICH Compliant Guidelines For Long Term And Accelerated Stability Testing

ICH Q1A Summary of Stability Parameters Study	Storage Condition	Minimum Time Period	Comments
General Case: Long-term	25 °C ± 2°C/60% RH ±5% RH or 30°C ± 2°C/65% RH ± 5% RH	12 months	Must cover retest or shelf life period at a minimum and includes storage, shipment and subsequent use.
General Case: Intermediate	30°C ± 2°C/65% RH ± 5% RH	6 months	Must cover retest or shelf life period at a minimum and includes storage, shipment and subsequent use.
General Case: Accelerated	40°C ± 2°C/75% RH ± 5% RH	6 months	Must cover retest or shelf life period at a minimum and includes storage, shipment and subsequent use.
Refrigeration: Long-term	5°C± 3°C	12 months	Must cover retest or shelf life period at a minimum and includes storage, shipment and subsequent use.
Refrigeration: Accelerated	25°C ± 2°C/60% RH ± 5% RH	6 months	Must cover retest or shelf life period at a minimum and includes storage, shipment and subsequent use.
Freezer: Long-term	-20°C± 5°C	12 months	Must cover retest or shelf life period at a minimum and includes storage, shipment and subsequent use.

Stability Issues in Pharmaceutical Products – Manufacturing Issues

The preceding review of literature regarding salient mathematical calculations for and impacts of temperature extremes on pharmaceutical products above provides a foundation for discussion the literature on stability studies in manufacturing. At the international level, the ICH initially provided technical requirements for the registration of pharmaceuticals for human use across Japan, Europe, and North America. The ICH is currently focusing its attention on the harmonization of the organization of a submission across the three regions. In the United States, The FDA is coordinating its activities for common technical documentation (the "CTD" process)

with ICH specifications, as is illustrated by the FDA's publication "International Conference on Harmonization (ICH) - Guidance for Industry - M4E: The CTD – Efficacy." In addition to its M4E specifications for efficacy, the ICH provides M4Q and M4S specifications for, respectively, quality and safety.

By providing a set of common terminology and measurements for pharmaceutical product efficacy, this coordinated international and national-level work establishes a basis for providing an objective, quantification-based method for stability studies. This level of commonality is vital for establishing and maintaining effective and affordable regulatory, testing, and production processes. For example, while manufacturing methods and products will obviously differ from one company to another, the process for testing stability may be documented as in USP <1150>, Pharmaceutical Stability, which specifies that the formulator of a product typically first determines the effects of temperature, light, air, pH, moisture, trace metals, and commonly used excipients or solvents on the active ingredient(s). From this information, one or more formulations of each dosage form are prepared, packaged in suitable containers, and stored under a variety of environmental conditions, both exaggerated and normal. At appropriate time intervals, samples of the product are assayed for potency by use of a stability-indicating method, observed for physical changes, and, where applicable, tested for sterility and or for resistance to microbial growth and for toxicity and bioavailability. Such a study, in combination with clinical and toxicological results, enables the manufacturer to select the optimum formulation and container and to assign recommended storage conditions and an expiration date for each dosage form in its package.

These guidelines provide a basis for the provision of common services across the pharmaceutical industry, thereby facilitating third-party provision of testing services, including stability studies. For example, in a 2005 white paper "Pharmaceutical Stability Studies," Dr. Kim Baughman, the Director of Development at Microbac Inc., attributes the ability of Microbac to provide pharmaceutical industry-wide preclinical and clinical testing services to the standardization being imposed by ICH guidelines product efficacy, quality, and safety through stability achieved by optimal packaging and storage conditions.

Apart from temperature-related manufacturing protocols for the testing of finished product stability, temperature control is a vital part of the manufacturing process itself. As an

example, Del Cielo (1993) points out in his chapter on biopharmaceutical manufacturing facility design chapter in *Pharmaceutical Dosage Forms: Parenteral Medications*, key processes in the production of biopharmaceuticals require chromatography to take place at 4 degrees centigrade, and if columns cannot be jacketed, the process must occur in a cold room with an appropriate single source of heat transfer between heating and cooling within the same piece of equipment. Temperature controls require sensors to verify that operational controls are functioning properly. Typically, sensors are attached to alarm systems so that the operations staff can be alerted to non-compliant conditions, including variations from accepted temperature conditions in the manufacturing environment. As Hinckley (2009) points out, for alarm systems to be effective, several conditions must hold. Among these conditions are operators that must not be "subject to so many alarms that they cannot prioritize actions," operators must not "know or believe that the sensors generating the alarms are faulty," and must not be "rewarded for ignoring the alarm." This brings forth the important point that compliance is not simply a question of quantification and measurement, but that there is a human component as well which is of particular importance not only in the manufacture, but also in the transport of pharmaceutical products.

Stability Issues in Pharmaceutical Products – Logistics Issues

In view of the cost, compliance, and public relations issues that pharmaceutical companies face regarding product stability, and in view of the role temperature extremes and variations can play relative to product stability, it is easily seen that determining the temperature parameters applying to the (uncontrolled) ambient shipping environment is a critical undertaking for the pharmaceutical industry. One of the key parameters for any such study is defining the expected time product will spend within the distribution environment. In the case of Merck, a key logistics strategy employed to control time within the supply chain outside the company's control is to employ a three-distribution center strategy. This strategy generally limits the transit time for Merck's shipments of products from its distribution centers to its customers' warehouses to 48 to 96 hours, but with need to account for exceptions beyond 96 hours.

Cost is a major consideration in logistics. Reporting on The Council of Supply Chain Management Professionals' annual report, Schultz states that in 2007, "American businesses spent a record $1.4 trillion on logistics… That was equal to 10.1% of the nation's Gross Domestic Product." Breaking logistics costs into transportation and carrying cost components,

Schultz further notes that while transportation costs represent 56% of total logistics expenditures; their current annual rate of increase is a relatively modest 5.9% when compared with the 9% rate for inventory carrying costs. Schultz (2007) attributes the low rate of increase in shipping costs to overcapacity among shippers, and states that the large number of bankruptcies among carriers ("2000 trucking companies have closed in the first quarter alone"), the current overcapacity among shippers, which currently limits shipping cost increases, can be expected to disappear.

The pharmaceutical industry finds itself in an environment in which logistics costs, especially shipping, are a significant and growing concern. And it is expected that the geographic range, technical and regulatory complexity, and cost implications of pharmaceutical product distribution will continue to increase. For example, a variety of public relations, cost pressure, and government agency scrutiny factors are causing pharmaceutical companies to reduce sales force size and, as a direct consequence direct visits to physicians' offices, particularly in remote areas. Regarding sales force reduction at pharmaceutical companies, Quinn (2008) notes that even without direct sales force contact distribution of samples directly to physicians remains a desirable function for the pharmaceutical industry, physicians, and patients. For pharmaceutical companies, it provides education and advertising. For physicians it provides a convenient program for commencing patient therapy rapidly with direct instruction to the patient on dosage and administration. And for patients it provides reduced cost and familiarity with the product and its proper usage.

Among the factors at play in increasing logistics costs is the growing need for refrigerated transport of pharmaceutical products. As new products with new functions are developed, many, especially biopharmaceuticals, tend to have increasingly large molecular structures which render them increasingly sensitive to temperature-induced instability.

A 2005 Novumed study found that approximately 11% of all products from large pharmaceutical companies require refrigeration. With costs a major concern, avoiding need for refrigeration and other special handling is desirable, whenever possible. As Catalano Ruriani (2003) notes, when shipping temperature-sensitive products that require refrigeration it is necessary to plan not only for the end-to-end, across the supply chain cost for refrigeration, but also for the per-truck space reduction capacity that results from extra truck-wall insulation and the payload reduction resulting from the weight of the refrigeration equipment and insulation.

Since products requiring refrigerated shipment incur significantly higher logistics costs, it is important for pharmaceutical companies to understand the temperature ranges in their distribution environments so that products can be packaged and shipped safely without refrigeration, if possible. Examination of the literature shows that looking to the future it is possible that technology breakthroughs may help limit the need for cold chain transport.

In response to the burdensome costs involved in cold chain shipping, proposals for use of industrial protein production techniques within the pharmaceutical industry are starting to appear. As an example, Estell (2006) advocates the use of industrial biotechnology techniques for mass production of highly stable proteins as a means of producing a pandemic flu vaccine. Estell writes:

> An important aspect of industrial protein manufacturing is the development of the production process before the creation of the final product molecule. This is essentially the opposite of the classical pharmaceutical approach in which the product is created, and the manufacturing process is then developed from the research chemistry bench. In industrial protein manufacturing, an initial robust process is developed for a scaffold protein that has many of the desired properties; then a few changes are made in this protein to create the final molecule. The production and purification processes developed for the scaffold protein can then be modified for the final molecule. Industrial protein manufacturing can supply a protein-based product at yields, volumes, and cost levels not possible with the classical pharmaceutical approach.

Estell then describes temperature stability as a key facet of any such protein synthesis:

> Formulation and delivery systems must allow flexibility and end-product stability. Protein-based end products that are transported and stored around the world must be able to withstand the high temperatures and humidity of tropical locations without losing potency, strength, or efficacy, and must remain stable for years with no refrigeration. Finally, the protein scaffold must be engineered to provide the desired properties. In the case of the influenza vaccine, epitopes for the new strain are added to the protein scaffold, which is then introduced to the protein production pathway.

In addition to the scaffold-method for production of proteins, Estell advocates separation of product components to increase stability. The upshot of the combination of scaffolding and compartmentalization, according to Estell, would be a pharmaceutical product that can withstand the temperature ranges experienced in non-temperature-controlled shipping. Estell describes this as follows:

> Temperatures during shipment can be anywhere from below freezing to higher than 40 degrees C, but the performance and stability of the active ingredients remain efficacious for the life of the product, including during shipment and storage, in either solid or liquid form. These protein formulations do not require refrigeration or freezing. Unique properties of solid, multilayer, granular formulations can control the release of active ingredients and delay degradation by humidity, temperature, and other environmental influences. Compartmentalizing the active ingredient against other components of the product may also help maintain its effectiveness and control the release of active ingredients. An example everyone knows is the "tiny little time pills" in Contac cold formulations.

Estell's work points the way to a potential future environment in which ambient temperatures and protective packaging are of less concern than today. However, for now and the foreseeable future, it will be necessary to perform ambient temperature studies to help ensure cost-effective compliance and stability of pharmaceutical products.

Stability Issues in Pharmaceutical Products – Packaging Issues

USP <1079>, Good Storage and Shipping Practices, focuses on the relationship between temperature variations in the distribution environment and packaging. USP <1079> states:

> Operational and performance testing should be parts of a formal qualification protocol that may use controlled environments or actual field testing based on the projected transportation channel. These should reflect actual load configurations, conditions, and expected environmental extremes. Temperature and humidity monitors should be placed into the product or a representative thereof. Testing consists of consecutive replicate field transportation tests using typical loads, according to an established protocol.

After stating the importance of field transportation temperature testing, USP <1079> continues by reemphasizing the importance of temperature, and then relating temperature concerns to protective packaging requirements:

> Shipping of temperature-sensitive articles requiring thermally controlled packaging presents a special challenge. Unlike shock, vibration, and other physical hazards, thermal hazards tend to be unique to a given system. Except for temperature-controlled trucks, the distribution environment is widely variable and depends upon a range of factors, including points of origin and destination, article and container sensitivities to cold, accidental freezing or heat, transit mode (e.g., air, truck, combination), time, weather or season, and carrier type (e.g., small package carrier or integrator, freight forwarder, U.S. Postal Service). The shippers should know and understand the systems they use and should design the protective package accordingly.

Much of the latest literature on package design focuses on cold chain package design. For example in "Cold Chain Logistics Challenges and Trends in a Complex Market," Peter (2004) focuses on the requirements, costs, and need for advanced passive and active packaging technologies. Peter's article focuses on how ambient temperature testing remains vital for (1) defining the parameters for valid laboratory testing of the packaging in temperature extremes of the normal shipping environment, and (2) providing audit support for proving that adequate testing has been performed, thereby providing the cost and ecological benefits of validating least ecological impact, least cost packaging solutions.

Regarding least impact, least cost packaging solutions, it should be pointed out that summer and winter pack outs are being designed and employed in order to address specific seasonal needs. McLean (2008) describes these seasonal pack outs together with all-season pack outs with the clear message that the effort "to maintain temperature range regardless of ambient temperature" can be fine-tuned for the purpose of minimizing cost and impact.

McLean describes the process required for such fine as consisting of the following steps:

Process to Qualify Protective Packaging

1) Identification of Requirements
1a) Identify product, stability data, mode of transportation, and temperature sensitivity
2) Design Qualification
2a) Define ambient temperature profile
2b) Define product shipping configuration
2c) Determine temperature monitoring device location
2d) Determine insulating material.

Especially noteworthy for the purposes of this discussion is the key role (step 2a) that ambient temperature testing plays in effective, efficient, least impact package design.

A developing trend for cost sharing and carbon footprint reduction outside the pharmaceutical industry that bears watching is occurring in the United Kingdom (with participants including Coca Cola and Heinz) and in continental Europe (with participants including Nestle, Carrefour, Wal-Mart, Kraft Foods, and Procter and Gamble) in which the companies are sharing warehouses and trucks. According to the *International Institute of Refrigeration Newsletter* (2008):

> Each warehouse and truck is being used by several competitors, and it is hoped this could potentially save up to 25% emissions per pallet. Participating suppliers would relinquish their own warehouses and deliver directly from the manufacturing facility into a

> collaborative warehouse that is run jointly with other suppliers. From there the goods would be shipped either to city hubs that supply urban stores or regional centres that deliver to rural zones.

Regulatory Compliance Considerations - Product Development and Testing

Within the context of logistics, the reason for concern with time and temperature is their potentially adverse impact on product efficacy. Temperature extremes, especially over time, affect the stability of many products. Decreases in product stability have a negative impact on efficacy, which is the key consideration behind the regulations with which pharmaceutical companies must comply. As was discussed in detail above in the review of USP <1191>, the efficacy and appearance of pharmaceutical products can be impaired by improper temperature extremes, including those experienced during shipping. It is therefore critical that pharmaceutical companies study the impact of temperature variations on products and apply the knowledge gained when designing packaging and planning product transportation.

The literature on logistics tends to focus on issues of costs and compliance. Regarding costs Barakat (2003) lists the specific aspects of logistics that affect costs as: "packaging materials, carrier costs, handling costs, and value of rejected shipments (expired or damaged)." After covering customer satisfaction issues in logistics (notably, replenishment time) Barakat turns his attention to compliance issues in logistics. Regarding compliance, Barakat notes that the FDA requires integrity up to the time when the product is received by customer, which means that quality assurance must be built into packaging and transit. He says, "Testing and validation are minimum steps required to demonstrate that the temperature of the products shipped will remain within the acceptable temperature range in the real world." For this purpose he recommends the use of data loggers to "quantify the transit times and risks relatively inexpensively in the real world within a testing laboratory environment."

In *Temperature Management of Pharmaceutical Distribution: Update 2008* Beard discusses logistics costs relative to industry-wide competitive pressures, and then discusses compliance in terms of being able to document and prove compliance. Specifically, when discussing costs, Beard first focuses on the competitive environment and pressures of research, development, and trial costs across the pharmaceutical industry. After mentioning the additional pressures introduced by increasing competition from manufacturers of generics, Beard turns his attention to regulatory compliance. In this regard, he focuses on the requirement for and

processes for establishing proof of compliance. Beard discusses the steps for proof of compliance as follows:

> ...proof of temperature (POT) from point of origin to point of delivery is required for all pickup and delivery vehicles, line-haul trailers and temperature-managed facilities, as well as the transfer of products between each....A manufacturer's first step in complying with this mandate is to develop categories based upon stability data for all their products. Each category describes modes of transport, approved carriers, temperature limits and allowable excursions. At what temperature is the product stable and when does temperature begin to alter its efficacy over time? Precise lengths of time out of range, plus the severity of temperature excursions themselves, must be established and documented both for in-house production and storage and for out-of facility shipping and distribution.

Beard then covers the temperature mapping aspect of proving compliance:

> For the temperature to remain within precise limits, sensors must be set in both vehicles and warehouse storage rooms. Temperature mapping to show variations throughout each room and trailer should be performed during annual extreme climate fluctuations and when the spaces are full and empty of content. These results will point to the best placement for calibrated monitoring devices and to the manner in which shipments should be stacked to maximize airflow. Temperature mapping and all other temperature management procedures, systems and technologies must be qualified by an experienced quality-assurance and control department, whether in-house or outsourced, that is thoroughly trained in validation activities.

Beard covers the topics of regulatory agencies and compliance as follows:

> *Regulatory Agencies*
>
> In North America, USP <1079?, "Good Storage and Shipping Practices," and Health Canada's "Guidelines for Temperature Control of Drug Products During transportation and Storage" each lay out regulatory expectations and good distribution practices for temperature sensitive deliveries. The Canadian document is expected to be revised later this year.
>
> *Compliance*
>
> What's important in the future is to promote a culture of industry collaboration and to champion the value of information-sharing across all stakeholders. Regulatory bodies in the U.S. and Canada may differ somewhat in their handling of new requirements, but in

> both countries and around the world the safety and quality protection of pharmaceuticals and other health-care products in transit can no longer be left in doubt.

Temperature Mapping Study – Best Practices

Temperature mapping studies are required for product and packaging development and for compliance. Sensitech (2006), a major supplier of data loggers, writes:

> To determine appropriate packaging specifications for a specific product, it is first critical to have an accurate ambient temperature profile for the specific trade lane in question. The only way to develop a temperature profile is to conduct a Shipping Study because there are many factors that contribute to determining the thermal variability of a specific trade lane, including carriers, delivery times, service levels, and routes.

Best practices for temperature mapping start with the equipment that will be employed in performing the study. When considering temperature sensing equipment, Sensitech (2006) recommends use of data loggers, and advises against use of chemical-strip color change temperature indicators in their article entitled "Reconsidering Temperature Indicators."

USP <1118> Monitoring Devices, Time, Temperature, and Humidity provides specific recommendations covering device selection and recording intervals. Regarding device selection, USP <1118> states:

> An inexpensive limit detector may be all that is needed when there is a low probability that excessive temperatures will be experienced. Alternatively, a data logger may be preferred when it would be useful to demonstrate that exposure to the highest temperatures was very brief.

USP <1118> continues by noting that ambient temperatures as recorded in climatic databases are not necessarily indicative of the temperatures experienced within mailboxes, trucks, or shipping containers at those times. For this reason USP <1118> suggests the use of microelectronic devices, such as data loggers, to record time, temperature, and humidity whether at a fixed location such as a warehouse, or to travel with a product during shipment.

When discussing the use of electronic recording devices, USP <1118> is careful to point out the importance of validation, as follows:

> Validation is a process that assures the user of the monitoring device that the device has been tested prior to use either by the manufacturer or the user, to assess the measurement accuracy, measurement responsiveness, and time accuracy, where appropriate. Monitors used in manufacturing, storage, and transport of drugs should be properly qualified by

> their users to ensure that the monitors have been received and maintained in proper working order. Pharmacies and consumers may accept the validation performed by the manufacturer of the device.

Regarding measurement accuracy, USP <1118> states that device calibration should be performed to ensure validity of reported results:

> For temperature and humidity monitoring devices, measurement accuracy refers to the closeness of the value obtained with a particular device to the true value being measured. In practice, this is determined by comparison with a device that has been calibrated against a standard that is obtained from or traceable to the National Institute of Standards and Technology (NIST).

Another validation factor covered by USP <1118> is measurement responsiveness. USP <1118> provides guidelines for frequency of measurement taking and recording appropriate to the likelihood of capturing occurrence of significant changes as follows:

> Any monitor takes time to respond to a change in the temperature or humidity. The more rapid the response, the clearer the picture of the environmental history of a monitored product will be. Measurement responsiveness may be defined as the time, t½, required for a device to read a value of (x + y)/2 after an instantaneous change in the property being measured from x to y. Measurement responsiveness is typically defined for the operating range of a device. Different levels of responsiveness are needed for different monitoring applications. For devices used to monitor storage locations, where the temperature and humidity are unlikely to change rapidly, a t½ 15 minutes may be appropriate. For devices used to monitor transport, where more rapid changes are possible, a t½ 5 minutes may be needed.

Time accuracy is also a validation factor covered by USP <1118>. USP <1118> states: "Most commonly, time accuracy is expressed as a ± percentage of total duration of the recording period. For pharmaceutical applications a ±0.5% time accuracy is adequate."

Since there are alternatives to temperature mapping studies, it is worthwhile to evaluate the plusses and minuses of the different methods. In his discussion of the process for qualifying a new package, Crawford (2003) refers the selection of the alternative to be selected and using "just right" testing. Crawford provides three assessment options; expert knowledge/rigorous logic, actual shipment and stress simulation in the laboratory. Crawford argues that expert knowledge/rigorous logic has the advantage of allowing us to focus our testing to a specific distribution stress, or even to decide that some aspect of stress is not applicable to the case at

hand. Applying this to a temperature mapping study, knowledge and logic might allow us to limit a shipping study to Phoenix, Arizona in August, and Minneapolis, Minnesota in January, while skipping a temperate location such as Atlanta, Georgia altogether.

Crawford says that while the second alternative, actual (or test) shipment "expose[s] test packages to a slice of the actual distribution environment... unfortunately it is only a small slice of the whole distribution reality because there can be large variation in distribution stress from shipment to shipment." Crawford continues by explaining that for such testing, the testing should be instrumented, but that "even with multiple test shipments, the full extent of distribution stress may not be experienced by the test packages due to the large variation (shipment to shipment) of distribution stress." As a result, Crawford appears to prefer laboratory simulation of distribution stress. Crawford cites the following advantages of laboratory testing:

1. Simulated distribution stress is controlled – it is a known, definable stress input.
    a. Package performance is assessed in response to the known stress input.
    b. The type and intensity of the simulated distribution stress can be (and should be) created to replicate, as best as possible, actual distribution environment stress.
2. Simulated distribution stress is repeatable – assuming adequate test equipment and techniques.
    a. Performance of a proposed package can be compared to an existing package.
3. Laboratory testing can be completed more quickly than test shipments.
    a. Package performance assessment can be completed in hours rather than days.
    b. Packages can be modified in response to initial test results and quickly retested.
    c. Lab tests can be quickly adjusted/refocused based on preliminary results.
4. Sometimes fewer test samples can be used than with test shipments (can still get good results).

In evaluating Crawford's reasoning, it must be realized that temperature excursion testing must be performed in order to be able to verify that the parameters chosen for laboratory testing match those that will be experienced in the distribution environment. Thus we might try to apply Crawford's reasoning as follows:

1. Use knowledge and logic to limit test excursion sites (for example, test Phoenix, Arizona in mid-summer, test Minneapolis, Minnesota in mid-winter to determine temperature extremes for testing).

2. Test using temperature logging equipment to ensure that all aspects of temperature variation are captured.

3. Use the resulting data to set temperature parameter values for accelerated laboratory testing.

While this reasoning might be applicable for certain purposes, such as shock and vibration testing, it would not be appropriate for passing an FDA audit. This is because temperature excursion testing that covers the entire distribution geography provides benefits of unanticipated anomaly detection and correction, mutual data confirmation, and average value discovery that are required for proving compliance and assuring proper setting of test parameters. But it is exactly Crawford's point that a reasoned combination of experience, real world observation, and laboratory testing is required for “just right” testing, so that what applies to shock and vibration stress test formulation may not apply to temperature test formulation, and Crawford would almost certainly agree that best practices for establishing and using temperature profiles should include a full test of the entire shipping environment, at least during the mid-summer and mid-winter seasons.

Chapter 3: Methodology

Materials/Equipment Used:

- TempTale4 data loggers
- Ventilated boxes
- Shipping Manifest
- Secure web enabled data warehousing software

The data loggers selected for the test were TempTale4 single use electronic time-stamped temperature recording devices (Figure 1) manufactured by Sensitech Inc. TempTale4s have the outside dimensions of 3.6" L x 2.0" W x 0.67" and weigh approximately 1.6 ounces. The measurement range of the data logger is from -30ºC to +70ºC. The accuracy of the data logger is ±1.1ºC ºfrom -30ºC to -18ºC, ±0.55ºC from -18ºC to +50ºC and ±1.1ºC from +50ºC to +70ºC. The data loggers were configured to take a temperature measurement every ten minutes. The memory type is Non-volatile 16K EEPROM with a storage capacity of 16,000 data points. The data logger has the battery life 1 year run life, 3.0v Lithium Battery.

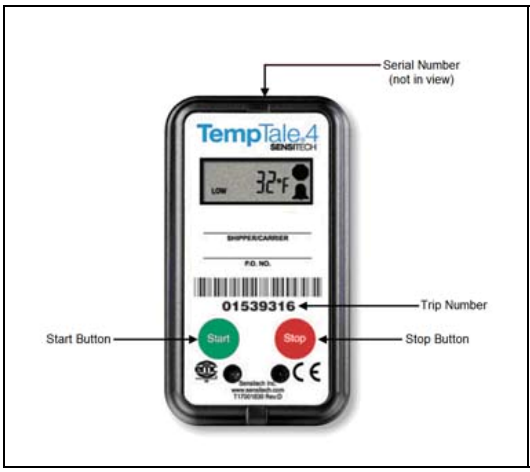
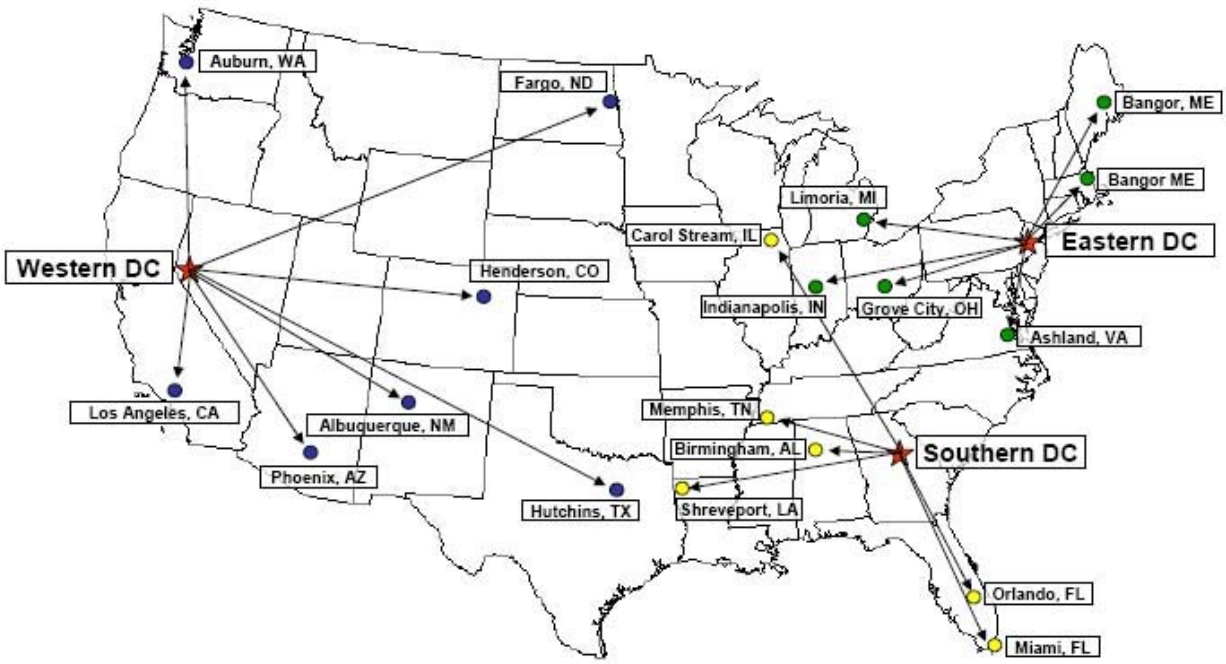


Figure 1 – TempTale4

Figure 2 – Ventilated Box

The TempTale4s (Figure 1) were activated and placed in ventilated boxes (Figure 2). The boxes were mailed out from the company's three United States DCs to specific destinations across the United States. Figure 3 is a map showing the locations of the DCs and destinations to which the

data loggers were shipped. Tracking information on the packages was recorded in the DC's shipping manifest.



Map Key	
Distribution Centers (Red)	**Destination Colors**
Eastern DC	Green
Western DC	Blue
Southern DC	Yellow

Figure 3 – Company Distribution Centers and Ship to Locations – Map and Key

The study utilized 500 data loggers shipped through the United States. Table 4 shows selected destinations that represented worst case shipping routes for that region and the number of monitors sent to each destination. This study was designed to identify minimum and maximum temperatures and durations for each DC.

Table 4 – Origin DC, Destination City and number of monitors shipped		
Origins	**Destination**	**Number of Monitors**
Eastern DC	Ashland VA	33
	Bangor ME	16
	Grove City OH	35
	Indianapolis IN	53
	Livonia MI	17
	Wilmington MA	16
Western DC	Albuquerque NM	18
	Auburn WA	17
	Fargo, ND	17
	Henderson CO	34
	Hutchins, TX	33
	Los Angeles, CA	19
	Phoenix, AZ	36
Southern DC	Birmingham AL	17
	Carol Stream, IL	32
	Memphis TN	36
	Miami FL	35
	Orlando FL	15
	Shreveport, LA	16
	Total*	495

The study was performed following these steps:

1. Company logistics shipped the vented boxes containing TempTales to specific receiving locations from the three DCs that represented extreme geographical climates.
2. The TempTales recorded time-stamped temperature readings every ten minutes throughout the distribution process.
3. The receiving locations, listed in Table 4, forwarded the TempTales to the analyzing laboratory.

4. The analyzing laboratory downloaded the temperature data into its secure web enabled data warehousing software.
5. Time stamped temperature data from the secure web enabled data warehousing software was analyzed for the following attributes:
    a. Actual minimum and maximum temperature.
    b. Mean temperatures by DC.
    c. Number of monitors over 40°C and under 0°C and associated durations.
    d. Statistical minimum and maximum temperatures.
    e. Statically derived temperature boundaries with confidence levels by season.

CHAPTER 4: RESULTS, ANALYSIS, AND DISCUSSION

Of the 500 Monitors shipped from the three DCs to nineteen locations across the continental United States, 495 monitors were successfully returned to the analyzing laboratory. This equates to 99% of the monitors successfully shipped, received and read. Table 5 contains a breakdown of the number of monitors shipped from each DC and lost in transit.

Table 5 – Numbers of Monitors Shipped By Location

Location	Number of Monitors
Eastern DC	170
Western DC	174
Southern DC	151

NOTE: 5 monitors were lost in transit.

Actual Minimum and Maximum Temperature Extremes, Durations at Extremes and Calculated Mean

The maximum temperature seen in the US single parcel commercial ground distribution environment was 60.9°C for 2.3 hours, captured in Reno, NV during the summer season. The lowest temperature seen in the distribution environment was -19.8 °C for 38 hours, also captured in Reno, NV during the winter. Table 6 shows the minimum and maximum temperature extremes experienced within all three DC's shipping lanes.

Table 6– Temperature Extremes and Durations by DC

Origin	Minimum	Duration Below -10°C	Duration Below 0°C	Maximum	Duration Above 40°C	Duration Above 50°C	Duration Above 60°C
Eastern	**-11.5°C**	7.7h	32.3h	**46.0°C**	12.2h	N/A	N/A
Western	**-19.8°C**	38.0h	89.5h	**60.9°C**	39.3h	24.3h	2.3 h
Southern	**-10.8°C**	0.7h	41.3h	**45.9°C**	13.7h	N/A	N/A

The data was further analyzed to derive the minimum, maximum and mean temperature segmented by season, from each DC, see Table 7. With the exception of capturing a maximum temperature in the fall from the Southern DC, all other minimum temperatures were recorded in the winter season and maximum temperatures were recorded during the summer season.

Table 7– Seasonal Summary Analysis of Shipments by Origin

Origin	Number of Shipments	Season	Mean (°C)	Minimum (°C)	Maximum (°C)
Eastern DC	170	Summer	23.3	10.1	**46.0**
		Winter	7.2	**-11.5**	28.1
		Fall	16.4	-7.2	34.7
		Spring	14.9	-1.9	36.4
Western DC	174	Summer	27.4	9.1	**60.9**
		Winter	5.0	**-19.8**	46.1
		Fall	16.6	-6.6	38.9
		Spring	16.2	-3.1	38.3
Southern DC	151	Summer	29.1	17.6	45.6
		Winter	12.7	**-10.8**	29.9
		Fall	20.6	-2.7	**45.9**
		Spring	19.7	3.3	36.4

Total Number of Shipments: **500** (NOTE: 5 monitors were never returned)

Part of the drug product development process involves analyzing how the product will react within the distribution environment to establish the correct shipping methodology. Cycling studies outlined by the ICH are often used for this purpose. The data gathered from this study may be used to design studies representative of the actual distribution environment or to validate profiles generated by standards organizations.

Number of Monitors Over and Under 0°C and Over 40°C and Associated Durations

Temperature cycling studies often utilize temperatures elevated or lowered to key points. For example, elevated temperatures as high as 50°C and as low as -10°C are frequently used in

product fragility temperature cycling studies. For this reason, the data has been analyzed to show the frequency and duration at elevated and low temperatures.

Low temperature exposure:

- **49** shipments were exposed to temperatures below 0°C, with the time of exposure ranging from 0.2 - 97.3 hours.
- **13** shipments were exposed to temperatures below -10°C (min temp -19.8°C), with the time of exposure ranging from 0.2 - 38.0 hours.
- There were **no** shipments exposed to temperatures below -20°C.

Elevated temperature Exposure:

- **22** shipments were exposed to temperatures above 40°C, with the time of exposure ranging from 0.2 - 39.3 hours.
- **3** shipments were exposed to temperatures above 50°C, with the time of exposure ranging from 0.2 - 24.3 hours.
- **1** shipment was exposed to temperatures above 60°C (max temp of 60.9°C) for an exposure length of 2.3 hours.

Statically Derived Minimum and Maximum Temperature Boundaries with Confidence Levels by Season

Tables 6 through 11 contain statically derived minimum and maximum temperatures by confidence level broken down by DC, season and trip length. This data is most valuable to formulators performing product fragility studies who may use this data to compare product sensitivities to the actual distribution environment. By providing the confidence levels, testing may be designed with a better understanding of the probability of an extreme temperature being realized in the actual distribution environment.

Table 8 - Eastern DC Winter Statistical Minimum and Maximum Temperature Ambient Temperature Profiles

Profile Length	Confidence Level / Standard Deviations		Statistical Minimum	Statistical Maximum
48 hours	3.0 SD	99.7%	-7.3°C	31.6°C
	2.57 SD	99.0%	-4.6°C	28.9°C
	2.0 SD	95.4%	-0.9°C	25.2°C
96 hours	3.0 SD	99.7%	-15.4°C	31.2°C
	2.57 SD	99.0%	-11.2°C	27.4°C
	2.0 SD	95.4%	-7.4°C	23.5°C

Table 9 - Eastern DC Summer Statistical Minimum and Maximum Temperature Ambient Temperature Profiles

Profile Length	Confidence Level / Standard Deviations		Statistical Minimum	Statistical Maximum
48 hours	3.0 SD	99.7%	1.1°C	42.6°C
	2.57 SD	99.0%	3.2°C	39.6°C
	2.0 SD	95.4%	8.1°C	35.7°C
96 hours	3.0 SD	99.7%	-4.3°C	44.6°C
	2.57 SD	99.0%	-0.2°C	40.6°C
	2.0 SD	95.4%	3.8°C	36.5°C

Table 10 – Western DC Winter Statistical Minimum and Maximum Temperature Ambient Temperature Profiles

Profile Length	Confidence Level / Standard Deviations		Statistical Minimum	Statistical Maximum
48 hours	3.0 SD	99.7%	-13.5°C	39.1°C
	2.57 SD	99.0%	-9.4°C	34.7°C
	2.0 SD	95.4%	-4.7°C	30.4°C
96 hours	3.0 SD	99.7%	-19.3°C	37.9°C
	2.57 SD	99.0%	-15.3°C	33.8°C
	2.0 SD	95.4%	-9.8°C	28.3°C

Table 11 Western DC Summer Statistical Minimum and Maximum Temperature Ambient Temperature Profiles

Profile Length	Confidence Level / Standard Deviations		Statistical Minimum	Statistical Maximum
48 hours	3.0 SD	99.7%	1.1°C	45.6°C
	2.57 SD	99.0%	4.8°C	42.5°C
	2.0 SD	95.4%	8.5°C	38.2°C
96 hours	3.0 SD	99.7%	-4.1°C	48.7°C
	2.57 SD	99.0%	-0.3°C	44.9°C
	2.0 SD	95.4%	4.7°C	39.9°C

Table 12 Southern DC Winter Statistical Minimum and Maximum Temperature Ambient Temperature Profiles

Profile Length	Confidence Level / Standard Deviations		Statistical Minimum	Statistical Maximum
48 hours	3.0 SD	99.7%	-4.5°C	38.1°C
	2.57 SD	99.0%	1.4°C	35.1°C
	2.0 SD	95.4%	2.6°C	31.0°C
96 hours	3.0 SD	99.7%	-7.0°C	38.6°C
	2.57 SD	99.0%	-3.7°C	35.3°C
	2.0 SD	95.4%	0.5°C	30.9°C

Table 13 Southern DC Summer Statistical Minimum and Maximum Temperature Ambient Temperature Profiles

Profile Length	Confidence Level / Standard Deviations		Statistical Minimum	Statistical Maximum
48 hours	3.0 SD	99.7%	9.0°C	45.5°C
	2.57 SD	99.0%	11.6°C	42.9°C
	2.0 SD	95.4%	15.1°C	39.5°C
96 hours	3.0 SD	99.7%	2.9°C	45.0°C
	2.57 SD	99.0%	5.8°C	41.9°C
	2.0 SD	95.4%	9.8°C	37.9°C

CHAPTER 5: CONCLUSION

The objective of this study was to determine the extreme temperatures and respective durations commercial pharmaceutical products are expected to be exposed to during routine, single parcel, ambient distribution within the Continental United States. This study met the intended objective by capturing extreme seasonal temperatures with durations within the United States. The maximum temperature seen in the distribution environment was 60.9°C for 2.3 hours. The lowest temperature seen in the distribution environment was -19.8 °C for 38 hours.

The study utilized 500 data loggers that were shipped from the company's three United States commercial distribution centers over the course of twelve months. Out of the 500 monitors shipped, 495 were recovered and read. Of the 495 shipments analyzed, one data logger was exposed to temperatures above 60°C. Three data loggers were exposed to temperatures above 50°C. Forty nine data loggers were exposed to temperatures below 0°C. Thirteen data loggers were exposed to temperatures below -10°C. No shipments were exposed to temperatures below - 20°C.

Before this study, the company relied solely on temperature profiles published by standards organizations. This study provided company specific temperature mapping data. This mapping data is now being used throughout the organization for study design, logistical decision making and to verify profiles provided by standards organizations relevant to the United States. Through the use of this company specific first hand data, assurance that appropriate testing is being performed has been realized.

Recommendations for Future Research

This study was limited to the commercial distribution system within the United States. As the company is a global entity, it is recommended that studies similar to this be performed in international distribution lanes such as Europe, Asia and South America.

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APPENDIX A

TempTale - Certificates of Validation

Certificate of Validation

SENSITECH
COLD CHAIN VISIBILITY

Ship To Address

Schering Plough
Keith Holland, PO #0000304772
Eastern Distribution Center
3070 Route 22 West
Branchburg, NJ 08876
USA

Bill To Address

Schering Plough
Accounts Payable
PO Box 377
Memphis, TN 38151
USA

Order: 253843 - 0
Ship Date: May 14, 2007

Unit S/N	Model Number	Validation Date *
3404703401	LS100-01-040	5/14/2007
3404703402	LS100-01-040	5/14/2007
3404703403	LS100-01-040	5/14/2007
3404703404	LS100-01-040	5/14/2007
3404703405	LS100-01-040	5/14/2007
3404703406	LS100-01-040	5/14/2007
3404703407	LS100-01-040	5/14/2007
3404703408	LS100-01-040	5/14/2007
3404703409	LS100-01-040	5/14/2007
3404703411	LS100-01-040	5/14/2007
3404703414	LS100-01-040	5/14/2007
3404703415	LS100-01-040	5/14/2007
3404703421	LS100-01-040	5/14/2007
3404703422	LS100-01-040	5/14/2007
3404703424	LS100-01-040	5/14/2007
3404703426	LS100-01-040	5/14/2007
3404703428	LS100-01-040	5/14/2007
3404703441	LS100-01-040	5/14/2007
3404703452	LS100-01-040	5/14/2007
3404703453	LS100-01-040	5/14/2007
3404703454	LS100-01-040	5/14/2007
3404703455	LS100-01-040	5/14/2007

Sensitech Inc., 800 Cummings Center, Suite 258X, Beverly, MA 01915 USA Tel (978) 927-7033 FAX (978) 921-2112

Certificate of Validation

SENSITECH
COLD CHAIN VISIBILITY

Ship To Address

Schering Plough

Keith Holland, PO #0000304772
Eastern Distribution Center
3070 Route 22 West
Branchburg, NJ 08876
USA

Bill To Address

Schering Plough

Accounts Payable
PO Box 377
Memphis, TN 38151
USA

Order: 253843 - 0

Ship Date: May 14, 2007

Unit S/N	Model Number	Validation Date *
3404703456	LS100-01-040	5/14/2007
3404703457	LS100-01-040	5/14/2007
3404703458	LS100-01-040	5/14/2007
3404703461	LS100-01-040	5/14/2007
3404703463	LS100-01-040	5/14/2007
3404703466	LS100-01-040	5/14/2007
3404703468	LS100-01-040	5/14/2007
3404703470	LS100-01-040	5/14/2007
3404703472	LS100-01-040	5/14/2007
3404703474	LS100-01-040	5/14/2007
3404703475	LS100-01-040	5/14/2007
3404703482	LS100-01-040	5/14/2007
3404703484	LS100-01-040	5/14/2007
3404703485	LS100-01-040	5/14/2007
3404703486	LS100-01-040	5/14/2007
3404703487	LS100-01-040	5/14/2007
3404703488	LS100-01-040	5/14/2007
3404703489	LS100-01-040	5/14/2007
3404703490	LS100-01-040	5/14/2007
3404703491	LS100-01-040	5/14/2007
3404703492	LS100-01-040	5/14/2007
3404703493	LS100-01-040	5/14/2007

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Unit S/N	Model Number	Validation Date *
3404703494	LS100-01-040	5/14/2007
3404703495	LS100-01-040	5/14/2007
3404703496	LS100-01-040	5/14/2007
3404703498	LS100-01-040	5/14/2007
3404703499	LS100-01-040	5/14/2007
3404703500	LS100-01-040	5/14/2007
3404703702	LS100-01-040	5/14/2007
3404703706	LS100-01-040	5/14/2007
3404703707	LS100-01-040	5/14/2007
3404703711	LS100-01-040	5/14/2007
3404703712	LS100-01-040	5/14/2007
3404703713	LS100-01-040	5/14/2007
3404703714	LS100-01-040	5/14/2007
3404703715	LS100-01-040	5/14/2007
3404703716	LS100-01-040	5/14/2007
3404703717	LS100-01-040	5/14/2007
3404703718	LS100-01-040	5/14/2007
3404703719	LS100-01-040	5/14/2007
3404703726	LS100-01-040	5/14/2007
3404703727	LS100-01-040	5/14/2007
3404703728	LS100-01-040	5/14/2007
3404703729	LS100-01-040	5/14/2007

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Unit S/N	Model Number	Validation Date *
3404703730	LS100-01-040	5/14/2007
3404703741	LS100-01-040	5/14/2007
3404703742	LS100-01-040	5/14/2007
3404703743	LS100-01-040	5/14/2007
3404703744	LS100-01-040	5/14/2007
3404703745	LS100-01-040	5/14/2007
3404703746	LS100-01-040	5/14/2007
3404703748	LS100-01-040	5/14/2007
3404703750	LS100-01-040	5/14/2007
3404703751	LS100-01-040	5/14/2007
3404703752	LS100-01-040	5/14/2007
3404703753	LS100-01-040	5/14/2007
3404703754	LS100-01-040	5/14/2007
3404703755	LS100-01-040	5/14/2007
3404703757	LS100-01-040	5/14/2007
3404703761	LS100-01-040	5/14/2007
3404703762	LS100-01-040	5/14/2007
3404703763	LS100-01-040	5/14/2007
3404703764	LS100-01-040	5/14/2007
3404703766	LS100-01-040	5/14/2007
3404703767	LS100-01-040	5/14/2007
3404703768	LS100-01-040	5/14/2007

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Unit S/N	Model Number	Validation Date *
3404703769	LS100-01-040	5/14/2007
3404703770	LS100-01-040	5/14/2007
3404703781	LS100-01-040	5/14/2007
3404703782	LS100-01-040	5/14/2007
3404703783	LS100-01-040	5/14/2007
3404703784	LS100-01-040	5/14/2007
3404703785	LS100-01-040	5/14/2007
3404703786	LS100-01-040	5/14/2007
3404703787	LS100-01-040	5/14/2007
3404703788	LS100-01-040	5/14/2007
3404703789	LS100-01-040	5/14/2007
3404703790	LS100-01-040	5/14/2007
3404704201	LS100-01-040	5/14/2007
3404704203	LS100-01-040	5/14/2007
3404704204	LS100-01-040	5/14/2007
3404704205	LS100-01-040	5/14/2007
3404704206	LS100-01-040	5/14/2007
3404704207	LS100-01-040	5/14/2007
3404704208	LS100-01-040	5/14/2007
3404704209	LS100-01-040	5/14/2007
3404704210	LS100-01-040	5/14/2007
3404704211	LS100-01-040	5/14/2007

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Unit S/N	Model Number	Validation Date *
3404704212	LS100-01-040	5/14/2007
3404704213	LS100-01-040	5/14/2007
3404704214	LS100-01-040	5/14/2007
3404704215	LS100-01-040	5/14/2007
3404704216	LS100-01-040	5/14/2007
3404704217	LS100-01-040	5/14/2007
3404704218	LS100-01-040	5/14/2007
3404704219	LS100-01-040	5/14/2007
3404704220	LS100-01-040	5/14/2007
3404704226	LS100-01-040	5/14/2007
3404704227	LS100-01-040	5/14/2007
3404704228	LS100-01-040	5/14/2007
3404704229	LS100-01-040	5/14/2007
3404704230	LS100-01-040	5/14/2007
3404704241	LS100-01-040	5/14/2007
3404704246	LS100-01-040	5/14/2007
3404704247	LS100-01-040	5/14/2007
3404704248	LS100-01-040	5/14/2007
3404704249	LS100-01-040	5/14/2007
3404704251	LS100-01-040	5/14/2007
3404704254	LS100-01-040	5/14/2007
3404704255	LS100-01-040	5/14/2007

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Unit S/N	Model Number	Validation Date *
3404704256	LS100-01-040	5/14/2007
3404704257	LS100-01-040	5/14/2007
3404704266	LS100-01-040	5/14/2007
3404704267	LS100-01-040	5/14/2007
3404704268	LS100-01-040	5/14/2007
3404704269	LS100-01-040	5/14/2007
3404704270	LS100-01-040	5/14/2007
3404704271	LS100-01-040	5/14/2007
3404704272	LS100-01-040	5/14/2007
3404704273	LS100-01-040	5/14/2007
3404704274	LS100-01-040	5/14/2007
3404704275	LS100-01-040	5/14/2007
3404704276	LS100-01-040	5/14/2007
3404704277	LS100-01-040	5/14/2007
3404704278	LS100-01-040	5/14/2007
3404704280	LS100-01-040	5/14/2007
3404704286	LS100-01-040	5/14/2007
3404704295	LS100-01-040	5/14/2007
3404704306	LS100-01-040	5/14/2007
3404704307	LS100-01-040	5/14/2007
3404704308	LS100-01-040	5/14/2007
3404704309	LS100-01-040	5/14/2007

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3404704310	LS100-01-040	5/14/2007
3404704311	LS100-01-040	5/14/2007
3404704312	LS100-01-040	5/14/2007
3404704313	LS100-01-040	5/14/2007
3404704314	LS100-01-040	5/14/2007
3404704315	LS100-01-040	5/14/2007
3404704325	LS100-01-040	5/14/2007
3404704327	LS100-01-040	5/14/2007
3404704328	LS100-01-040	5/14/2007
3404704329	LS100-01-040	5/14/2007
3404704330	LS100-01-040	5/14/2007
3404704338	LS100-01-040	5/14/2007
3404704339	LS100-01-040	5/14/2007
3404704340	LS100-01-040	5/14/2007
3404704346	LS100-01-040	5/14/2007
3404704347	LS100-01-040	5/14/2007
3404704348	LS100-01-040	5/14/2007
3404704349	LS100-01-040	5/14/2007
3404704350	LS100-01-040	5/14/2007
3404704356	LS100-01-040	5/14/2007
3404704357	LS100-01-040	5/14/2007
3404704361	LS100-01-040	5/14/2007

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Unit S/N	Model Number	Validation Date *
3404704362	LS100-01-040	5/14/2007
3404704363	LS100-01-040	5/14/2007
3404704364	LS100-01-040	5/14/2007
3404704365	LS100-01-040	5/14/2007
3404704366	LS100-01-040	5/14/2007
3404704367	LS100-01-040	5/14/2007
3404704368	LS100-01-040	5/14/2007
3404704369	LS100-01-040	5/14/2007
3404704370	LS100-01-040	5/14/2007
3404704371	LS100-01-040	5/14/2007
3404704372	LS100-01-040	5/14/2007
3404704373	LS100-01-040	5/14/2007
3404704374	LS100-01-040	5/14/2007
3404704375	LS100-01-040	5/14/2007
3404704376	LS100-01-040	5/14/2007
3404704377	LS100-01-040	5/14/2007
3404704378	LS100-01-040	5/14/2007
3404704379	LS100-01-040	5/14/2007
3404704380	LS100-01-040	5/14/2007
3404704386	LS100-01-040	5/14/2007
3404704387	LS100-01-040	5/14/2007
3404704388	LS100-01-040	5/14/2007

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Unit S/N	Model Number	Validation Date *
3404704389	LS100-01-040	5/14/2007
3404704390	LS100-01-040	5/14/2007
3404705501	LS100-01-040	5/14/2007
3404705502	LS100-01-040	5/14/2007
3404705503	LS100-01-040	5/14/2007
3404705504	LS100-01-040	5/14/2007
3404705505	LS100-01-040	5/14/2007
3404705521	LS100-01-040	5/14/2007
3404705522	LS100-01-040	5/14/2007
3404705523	LS100-01-040	5/14/2007
3404705524	LS100-01-040	5/14/2007
3404705525	LS100-01-040	5/14/2007
3404705526	LS100-01-040	5/14/2007
3404705527	LS100-01-040	5/14/2007
3404705528	LS100-01-040	5/14/2007
3404705536	LS100-01-040	5/14/2007
3404705537	LS100-01-040	5/14/2007
3404705538	LS100-01-040	5/14/2007
3404705539	LS100-01-040	5/14/2007
3404705540	LS100-01-040	5/14/2007
3404705541	LS100-01-040	5/14/2007
3404705546	LS100-01-040	5/14/2007

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Unit S/N	Model Number	Validation Date *
3404705547	LS100-01-040	5/14/2007
3404705548	LS100-01-040	5/14/2007
3404705549	LS100-01-040	5/14/2007
3404705550	LS100-01-040	5/14/2007
3404705551	LS100-01-040	5/14/2007
3404705552	LS100-01-040	5/14/2007
3404705553	LS100-01-040	5/14/2007
3404705554	LS100-01-040	5/14/2007
3404705555	LS100-01-040	5/14/2007
3404705556	LS100-01-040	5/14/2007
3404705557	LS100-01-040	5/14/2007
3404705558	LS100-01-040	5/14/2007
3404705559	LS100-01-040	5/14/2007
3404705560	LS100-01-040	5/14/2007
3404705561	LS100-01-040	5/14/2007
3404705562	LS100-01-040	5/14/2007
3404705566	LS100-01-040	5/14/2007
3404705567	LS100-01-040	5/14/2007
3404705568	LS100-01-040	5/14/2007
3404705571	LS100-01-040	5/14/2007
3404705572	LS100-01-040	5/14/2007
3404705576	LS100-01-040	5/14/2007

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3404705577	LS100-01-040	5/14/2007
3404705581	LS100-01-040	5/14/2007
3404705582	LS100-01-040	5/14/2007
3404705583	LS100-01-040	5/14/2007
3404705591	LS100-01-040	5/14/2007
3404705592	LS100-01-040	5/14/2007
3404705593	LS100-01-040	5/14/2007
3404705594	LS100-01-040	5/14/2007
3405702501	LS100-01-040	5/14/2007
3405702502	LS100-01-040	5/14/2007
3405702503	LS100-01-040	5/14/2007
3405702504	LS100-01-040	5/14/2007
3405702505	LS100-01-040	5/14/2007
3405702506	LS100-01-040	5/14/2007
3405702507	LS100-01-040	5/14/2007
3405702508	LS100-01-040	5/14/2007
3405702509	LS100-01-040	5/14/2007
3405702510	LS100-01-040	5/14/2007
3405702511	LS100-01-040	5/14/2007
3405702512	LS100-01-040	5/14/2007
3405702513	LS100-01-040	5/14/2007
3405702514	LS100-01-040	5/14/2007

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Unit S/N	Model Number	Validation Date *
3405702521	LS100-01-040	5/14/2007
3405702522	LS100-01-040	5/14/2007
3405702523	LS100-01-040	5/14/2007
3405702524	LS100-01-040	5/14/2007
3405702525	LS100-01-040	5/14/2007
3405702526	LS100-01-040	5/14/2007
3405702527	LS100-01-040	5/14/2007
3405702528	LS100-01-040	5/14/2007
3405702529	LS100-01-040	5/14/2007
3405702530	LS100-01-040	5/14/2007
3405702542	LS100-01-040	5/14/2007
3405702543	LS100-01-040	5/14/2007
3405702545	LS100-01-040	5/14/2007
3405702546	LS100-01-040	5/14/2007
3405702547	LS100-01-040	5/14/2007
3405702559	LS100-01-040	5/14/2007
3405702560	LS100-01-040	5/14/2007
3405702563	LS100-01-040	5/14/2007
3405702564	LS100-01-040	5/14/2007
3405702565	LS100-01-040	5/14/2007
3405702566	LS100-01-040	5/14/2007
3405702567	LS100-01-040	5/14/2007

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Unit S/N	Model Number	Validation Date *
3405702568	LS100-01-040	5/14/2007
3405702569	LS100-01-040	5/14/2007
3405702570	LS100-01-040	5/14/2007
3405702578	LS100-01-040	5/14/2007
3405702579	LS100-01-040	5/14/2007
3405702580	LS100-01-040	5/14/2007
3405702582	LS100-01-040	5/14/2007
3405702583	LS100-01-040	5/14/2007
3405702584	LS100-01-040	5/14/2007
3405702585	LS100-01-040	5/14/2007
3405702588	LS100-01-040	5/14/2007
3405702589	LS100-01-040	5/14/2007
3405702590	LS100-01-040	5/14/2007
3405702595	LS100-01-040	5/14/2007

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Sensitech Inc. certifies that the item(s) identified previously have been thoroughly tested per Sensitech Quality Assurance procedures and are validated for one year from the date of sale. They have met performance accuracy specifications* over the stated range. Reference instrumentation used to perform validations is certified traceable in accordance with the National Institute of Standards and Technology (NIST). Validation equipment certifications are on file at Sensitech Beverly Massachusetts, USA.

* For complete accuracy specifications of TempTale monitors, please refer to the published Technical Specifications.

Reference Instrumentation

Temperature: Ertco-Hart Thermometer, Model EH850C / 1502A, Serial Numbers; A01978, A02030, A1B608, A14436, A29918, A3A343, A3A347, A39317, A53912, A53913, A53915, 67605, 76924, 84290, 93656, 95718, 95719
Ertco-Hart PRT, Model 5613/5614, Serial Numbers; 504134, 514471, 528707, 562963, 649393, 657206, 657208, 743403, 743413, 743416, 743967, 765842, 778117, 778470
Accuracy: ±0.05° Celcius over a range of -200° to +200° Celcius.

Humidity: Edgetech Dew Point Hygrometer, Model DewPrime II, Serial Numbers 2312x & 1H906DCR
Accuracy: ±0.5% over a range of 10% to 95% RH.

**** It is recommended that the item(s) listed previously be replaced one year from date of sale.**

Total Units for Shipment: 300

Validation Performed / Approved By: _____ Date: *May 14, 2007*

Job Title: *Shipper*

If Applicable:
Customer Commodity Number: _____

Lot Number: _____

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Bill To Address

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Unit S/N	Model Number	Validation Date *
3428718022	LS100-01-040	10/3/2007
3428718024	LS100-01-040	10/3/2007
3428718026	LS100-01-040	10/3/2007
3428718027	LS100-01-040	10/3/2007
3428718033	LS100-01-040	10/3/2007
3428718074	LS100-01-040	10/3/2007
3428718088	LS100-01-040	10/3/2007
3428718090	LS100-01-040	10/3/2007
3428718097	LS100-01-040	10/3/2007
3428718098	LS100-01-040	10/3/2007
3428719601	LS100-01-040	10/3/2007
3428719602	LS100-01-040	10/3/2007
3428719603	LS100-01-040	10/3/2007
3428719604	LS100-01-040	10/3/2007
3428719605	LS100-01-040	10/3/2007
3428719606	LS100-01-040	10/3/2007
3428719607	LS100-01-040	10/3/2007
3428719608	LS100-01-040	10/3/2007
3428719609	LS100-01-040	10/3/2007
3428719610	LS100-01-040	10/3/2007
3428719611	LS100-01-040	10/3/2007
3428719612	LS100-01-040	10/3/2007

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3428719613	LS100-01-040	10/3/2007
3428719614	LS100-01-040	10/3/2007
3428719615	LS100-01-040	10/3/2007
3428719616	LS100-01-040	10/3/2007
3428719617	LS100-01-040	10/3/2007
3428719618	LS100-01-040	10/3/2007
3428719619	LS100-01-040	10/3/2007
3428719620	LS100-01-040	10/3/2007
3428719621	LS100-01-040	10/3/2007
3428719622	LS100-01-040	10/3/2007
3428719623	LS100-01-040	10/3/2007
3428719624	LS100-01-040	10/3/2007
3428719625	LS100-01-040	10/3/2007
3428719626	LS100-01-040	10/3/2007
3428719627	LS100-01-040	10/3/2007
3428719628	LS100-01-040	10/3/2007
3428719629	LS100-01-040	10/3/2007
3428719630	LS100-01-040	10/3/2007
3428719631	LS100-01-040	10/3/2007
3428719632	LS100-01-040	10/3/2007
3428719633	LS100-01-040	10/3/2007
3428719634	LS100-01-040	10/3/2007

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3428719635	LS100-01-040	10/3/2007
3428719636	LS100-01-040	10/3/2007
3428719637	LS100-01-040	10/3/2007
3428719638	LS100-01-040	10/3/2007
3428719639	LS100-01-040	10/3/2007
3428719640	LS100-01-040	10/3/2007
3428719641	LS100-01-040	10/3/2007
3428719642	LS100-01-040	10/3/2007
3428719643	LS100-01-040	10/3/2007
3428719644	LS100-01-040	10/3/2007
3428719645	LS100-01-040	10/3/2007
3428719646	LS100-01-040	10/3/2007
3428719647	LS100-01-040	10/3/2007
3428719648	LS100-01-040	10/3/2007
3428719649	LS100-01-040	10/3/2007
3428719650	LS100-01-040	10/3/2007
3428719651	LS100-01-040	10/3/2007
3428719652	LS100-01-040	10/3/2007
3428719653	LS100-01-040	10/3/2007
3428719654	LS100-01-040	10/3/2007
3428719655	LS100-01-040	10/3/2007
3428719656	LS100-01-040	10/3/2007

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3428719657	LS100-01-040	10/3/2007
3428719658	LS100-01-040	10/3/2007
3428719659	LS100-01-040	10/3/2007
3428719660	LS100-01-040	10/3/2007
3428719661	LS100-01-040	10/3/2007
3428719662	LS100-01-040	10/3/2007
3428719663	LS100-01-040	10/3/2007
3428719664	LS100-01-040	10/3/2007
3428719665	LS100-01-040	10/3/2007
3428719666	LS100-01-040	10/3/2007
3428719667	LS100-01-040	10/3/2007
3428719668	LS100-01-040	10/3/2007
3428719669	LS100-01-040	10/3/2007
3428719670	LS100-01-040	10/3/2007
3428719671	LS100-01-040	10/3/2007
3428719672	LS100-01-040	10/3/2007
3428719673	LS100-01-040	10/3/2007
3428719674	LS100-01-040	10/3/2007
3428719675	LS100-01-040	10/3/2007
3428719676	LS100-01-040	10/3/2007
3428719677	LS100-01-040	10/3/2007
3428719678	LS100-01-040	10/3/2007

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3428719679	LS100-01-040	10/3/2007
3428719680	LS100-01-040	10/3/2007
3428719681	LS100-01-040	10/3/2007
3428719682	LS100-01-040	10/3/2007
3428719683	LS100-01-040	10/3/2007
3428719684	LS100-01-040	10/3/2007
3428719685	LS100-01-040	10/3/2007
3428719686	LS100-01-040	10/3/2007
3428719687	LS100-01-040	10/3/2007
3428719688	LS100-01-040	10/3/2007
3428719689	LS100-01-040	10/3/2007
3428719690	LS100-01-040	10/3/2007
3428719691	LS100-01-040	10/3/2007
3428719692	LS100-01-040	10/3/2007
3428719693	LS100-01-040	10/3/2007
3428719694	LS100-01-040	10/3/2007
3428719695	LS100-01-040	10/3/2007
3428719696	LS100-01-040	10/3/2007
3428719697	LS100-01-040	10/3/2007
3428719698	LS100-01-040	10/3/2007
3428719699	LS100-01-040	10/3/2007
3428719700	LS100-01-040	10/3/2007

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Unit S/N	Model Number	Validation Date *
3428720602	LS100-01-040	10/3/2007
3428720603	LS100-01-040	10/3/2007
3428720604	LS100-01-040	10/3/2007
3428720605	LS100-01-040	10/3/2007
3428720606	LS100-01-040	10/3/2007
3428720607	LS100-01-040	10/3/2007
3428720608	LS100-01-040	10/3/2007
3428720609	LS100-01-040	10/3/2007
3428720610	LS100-01-040	10/3/2007
3428720611	LS100-01-040	10/3/2007
3428720617	LS100-01-040	10/3/2007
3428720618	LS100-01-040	10/3/2007
3428720619	LS100-01-040	10/3/2007
3428720620	LS100-01-040	10/3/2007
3428720621	LS100-01-040	10/3/2007
3428720622	LS100-01-040	10/3/2007
3428720623	LS100-01-040	10/3/2007
3428720624	LS100-01-040	10/3/2007
3428720625	LS100-01-040	10/3/2007
3428720626	LS100-01-040	10/3/2007
3428720627	LS100-01-040	10/3/2007
3428720628	LS100-01-040	10/3/2007

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3428720629	LS100-01-040	10/3/2007
3428720630	LS100-01-040	10/3/2007
3428720633	LS100-01-040	10/3/2007
3428720634	LS100-01-040	10/3/2007
3428720635	LS100-01-040	10/3/2007
3428720636	LS100-01-040	10/3/2007
3428720637	LS100-01-040	10/3/2007
3428720638	LS100-01-040	10/3/2007
3428720639	LS100-01-040	10/3/2007
3428720640	LS100-01-040	10/3/2007
3428720644	LS100-01-040	10/3/2007
3428720645	LS100-01-040	10/3/2007
3428720656	LS100-01-040	10/3/2007
3428720657	LS100-01-040	10/3/2007
3428720658	LS100-01-040	10/3/2007
3428720659	LS100-01-040	10/3/2007
3428720662	LS100-01-040	10/3/2007
3428720663	LS100-01-040	10/3/2007
3428720664	LS100-01-040	10/3/2007
3428720665	LS100-01-040	10/3/2007
3428720671	LS100-01-040	10/3/2007
3428720677	LS100-01-040	10/3/2007

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3428720678	LS100-01-040	10/3/2007
3428720679	LS100-01-040	10/3/2007
3428720680	LS100-01-040	10/3/2007
3428720681	LS100-01-040	10/3/2007
3428720682	LS100-01-040	10/3/2007
3428720696	LS100-01-040	10/3/2007
3428722106	LS100-01-040	10/3/2007
3428722107	LS100-01-040	10/3/2007
3428722108	LS100-01-040	10/3/2007
3428722109	LS100-01-040	10/3/2007
3428722110	LS100-01-040	10/3/2007
3428722116	LS100-01-040	10/3/2007
3428722117	LS100-01-040	10/3/2007
3428722118	LS100-01-040	10/3/2007
3428722119	LS100-01-040	10/3/2007
3428722120	LS100-01-040	10/3/2007
3428722121	LS100-01-040	10/3/2007
3428722122	LS100-01-040	10/3/2007
3428722123	LS100-01-040	10/3/2007
3428722124	LS100-01-040	10/3/2007
3428722125	LS100-01-040	10/3/2007
3428722132	LS100-01-040	10/3/2007

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Unit S/N	Model Number	Validation Date *
3428722137	LS100-01-040	10/3/2007
3428722139	LS100-01-040	10/3/2007
3428722140	LS100-01-040	10/3/2007
3428722142	LS100-01-040	10/3/2007
3428722143	LS100-01-040	10/3/2007
3428722144	LS100-01-040	10/3/2007
3428722145	LS100-01-040	10/3/2007
3428722150	LS100-01-040	10/3/2007
3428722151	LS100-01-040	10/3/2007
3428722152	LS100-01-040	10/3/2007
3428722153	LS100-01-040	10/3/2007
3428722154	LS100-01-040	10/3/2007
3428722155	LS100-01-040	10/3/2007
3428722156	LS100-01-040	10/3/2007
3428722157	LS100-01-040	10/3/2007
3428722158	LS100-01-040	10/3/2007
3428722160	LS100-01-040	10/3/2007
3428722171	LS100-01-040	10/3/2007
3428722172	LS100-01-040	10/3/2007
3428722173	LS100-01-040	10/3/2007
3428722174	LS100-01-040	10/3/2007
3428722175	LS100-01-040	10/3/2007

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Unit S/N	Model Number	Validation Date *
3428722188	LS100-01-040	10/3/2007
3428722189	LS100-01-040	10/3/2007
3428722190	LS100-01-040	10/3/2007
3428722191	LS100-01-040	10/3/2007
3428722193	LS100-01-040	10/3/2007
3428722194	LS100-01-040	10/3/2007
3428722195	LS100-01-040	10/3/2007
3428722196	LS100-01-040	10/3/2007
3428722197	LS100-01-040	10/3/2007
3428722198	LS100-01-040	10/3/2007
3428722199	LS100-01-040	10/3/2007
3428722200	LS100-01-040	10/3/2007

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Sensitech Inc. certifies that the item(s) identified previously have been thoroughly tested per Sensitech Quality Assurance procedures and are validated for one year from the date of sale. They have met performance accuracy specifications* over the stated range. Reference instrumentation used to perform validations is certified traceable in accordance with the National Institute of Standards and Technology (NIST). Validation equipment certifications are on file at Sensitech Beverly Massachusetts, USA.

* For complete accuracy specifications of TempTale monitors, please refer to the published Technical Specifications

Reference Instrumentation

Temperature: Ertco-Hart Thermometer, Model EH850C / 1502A, Serial Numbers; A01978, A02030, A1B608, A14436, A29918, A3A343, A3A347, A39317, A53912, A53913, A53915, 67605, 76924, 84290, 93656, 95718, 95719
Ertco-Hart PRT, Model 5613/5614, Serial Numbers; 504134, 514471, 528707, 562963, 649393, 657206, 657208, 743403, 743413, 743416, 743967, 765842, 778117, 778470
Accuracy: ±0.05° Celcius over a range of -200° to +200° Celcius.

Humidity: Edgetech Dew Point Hygrometer, Model DewPrime II, Serial Numbers 2312x & 1H906DCR
Accuracy: ±0.5% over a range of 10% to 95% RH.

**** It is recommended that the item(s) listed previously be replaced one year from date of sale.**

Total Units for Shipment: 210

Validation Performed / Approved By: _____ Date: *October 03, 2007*

Job Title: *Shipper*

If Applicable:
Customer Commodity Number: _____

Lot Number: _____

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