

MARKEN SMART BOX

A CASE FOR COLLABORATION



INTRODUCTION

Industry has gradually grown together and today the development, manufacture and use of new products have long ceased to be strictly separate industry sectors. Integrated solutions are becoming more and more the standard and decisive factors for success, as a result customers and suppliers have become partners in the development of fully integrated solutions for their users.

Working in partnership with Marken Intelsius designed, developed and delivered an innovative, qualified and connected packaging solution within a project timescale of less than a year from concept to delivery.



INTELSIUS & MARKEN

INTELSIUS

Intelsius are a forward-thinking company that offers a comprehensive and pioneering range of temperature controlled and sample transport packaging solutions to meet the unique and demanding challenges of the global cold chain and life sciences industry.

Since its foundation over 20 years ago, Intelsius has focused on developing innovative products that integrate and simplify multiple work steps and create safe and easy to use solutions.

Intelsius are committed to listening to our clients, whilst anticipating and adapting to their needs to develop technological products and services unavailable elsewhere in the temperature-controlled packaging industry.

MARKEN

Marken is a wholly owned subsidiary of UPS. Marken is the only patient-centric supply chain organization 100% dedicated to the pharmaceutical and life sciences industries.

Marken maintains the leading position for Direct to Patient and Home Health care services, biological sample shipments and offers a state-of-the-art GMP-compliant depot network and logistic hubs in 51 locations worldwide for clinical trial material storage and distribution.

Marken's more than 1,000 staff members manage 80,000 drug and biological shipments every month at all temperature ranges in more than 150 countries. Additional services such as biological kit production, ancillary material sourcing, storage and distribution, shipment lane verification and qualifications, as well as GDP, regulatory and compliance consultancy add to Marken's unique position in the pharma and logistics industry.



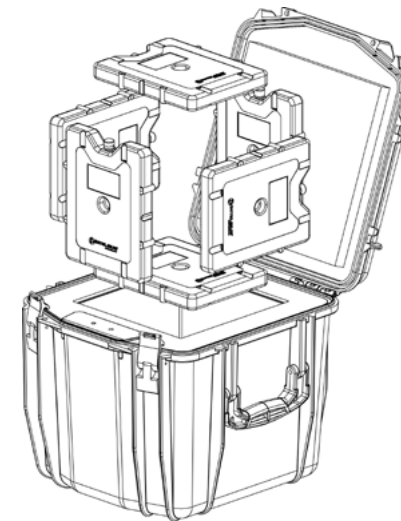
THE CHALLENGE

In an ever-changing Life Sciences Logistics environment, Marken saw the need for high-performance thermal packaging systems with fully integrated temperature monitoring and location tracking capabilities, whilst streamlining the handling of large amounts of data associated with shipments. The solution needed to be a robust, serviceable and safe solution that is flexible enough to support multiple tracking and logging devices while being qualified to the highest standards. Marken also wanted to be able to continue using existing devices and integrate future IoT solutions.

After an in-depth market evaluation Marken selected Intelsius as the partner to develop a proprietary high performance Vacuum Insulation Panels (VIP) and Phase Change Material (PCM), passive packaging solution, capable of being used with a variety of temperature monitoring devices with real time track & trace.

Intelsius were tasked with combining the high performance of their ORCA systems into an easy to use solution in a rigid outer case with discrete and secure integration of the selected logging devices.

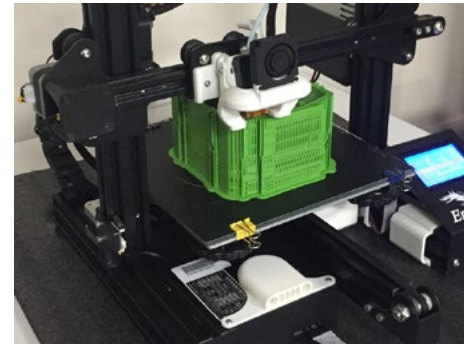
Initial concepts were drawn up along with identifying a comprehensive list of product features, payload sizes, testing requirements and several preferred logging solutions for integration into the final design.



THE COLLABORATION

Intelsius identified all the materials, solutions and processes required to compress development and manufacture times as well as reduce project and tooling costs with the use of key parts from ORCA M and common components from the manufacturers pre-existing product range.

Working in collaboration with Marken, Intelsius managed the design, development and delivery of the project, working closely with key stakeholders from within Marken, as well as meeting with manufacturing partners and IoT solution providers at key stages of the production and approval process.



THE SOLUTION

Intelsius developed a 4L and an 11L adaptive passive packaging solution, utilising the same PCM panels and insulation components from Intelsius ORCA Multi-Use systems. The rigid cases are robust, easy to handle and secure, featuring a dedicated logger housing to mount and protect current and future logging and tracking technologies.

Key features of our Smart Box include:

Connectivity

Real-time location and temperature capable tracking
Bluetooth payload temperature monitoring

Compliance

21 CFR Part 11 compliant – secure data integrity

Performance

ISTA 7D Thermal Qualified 2-8°C, 15-25°C and -20°C and dry ice for 96+ hours

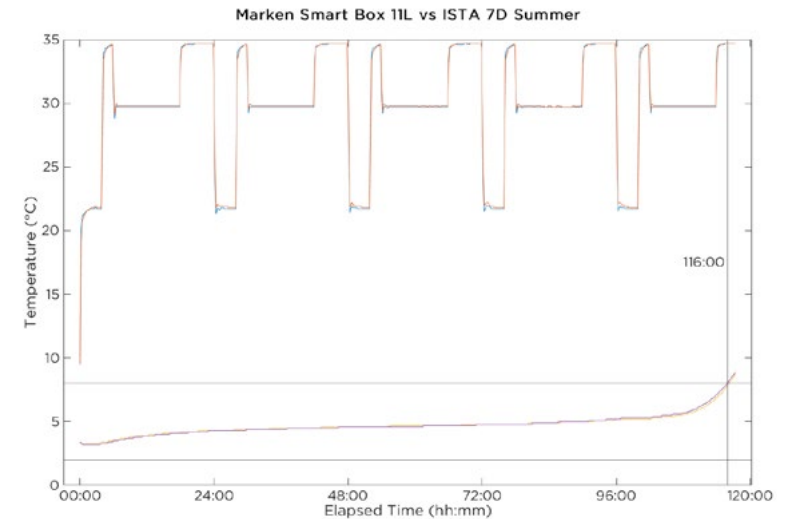


THE QUALIFICATION

Marken Smart Box systems were performance qualified at Intelsius' ISTA certified laboratory for payload temperatures of 2-8°C, 15-25°C, -25°C to -15°C and dry ice, against ISTA 7D temperature profiles.

In addition to this payload systems were developed which are specifically designed for use with Marken Smart Box systems, to maximise payload space as well as meet IATA Dangerous Goods Regulations for packing instruction 650 shipments of UN3373 Biological Substances.

The complete Marken Smart Box range was also tested to meet the requirements of ISTA 3A transport and distribution testing to ensure absolute payload integrity during transit.



THE ASSESSMENT

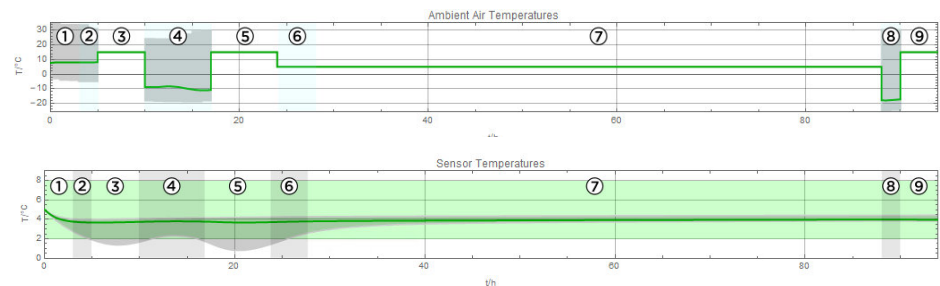
Along with delivering a physical packaging solution qualified in laboratory conditions Intelsius also conducted virtual Operational Qualification testing using Intelsius ATMOS Lane Services for virtual shipments using real life weather data across Marken's 12 most frequently used shipping lanes.

ATMOS Lane is an Intelsius service that offers performance assessments that would not be possible on the basis of physical test shipments alone.

A digital facsimile of the packaging system is built and its performance calibrated to the thermal testing previously conducted. A shipping lane is then created using known transit waypoints and historical temperature data. The combination of the digital packaging model and life like simulated shipping lane gives the end user insight into the external temperature challenges and associated risks that a parcel will be exposed to at any time of year before commencing trial shipments.

This new type of virtual qualification service provides an unprecedented and super-fast packaging performance assessment not available through thermal testing in a climate chamber and the results allow Marken to demonstrate the real life performance capabilities of the brand new Marken Smart Box to customers.

Over 30 thousand shipments have been simulated for the 4 L and 11L, Marken Smart Box systems against over 3 years of historical weather data, with a pass rate equating to 99.59%. This testing and reporting has highlighted the reasons for these potential excursions allowing for Marken to mitigate these in the future ensuring 100% success.



THE RESULTS

Intelsius designed, developed and delivered a user centric, innovative, qualified and connected packaging solution which meets the full gamut of the clinical trials logistics and supply chain market which Marken serves within a project timescale of less than a year from concept to delivery.

“Marken selected Intelsius as their preferred partner for this exciting development because they proposed a truly innovative solution and understand the complex needs of the clinical trials market. When you combine that with the unique offering of ATMOS services, we believe that Marken Smart Box puts us in an unrivalled position in the Healthcare Logistics space.”

Jim Bacon – Director - Technical Operations, Marken



“The excellent cooperation of all parties involved across several companies and the strong focus on developing a solution that meets the requirements of the application has enabled Marken to offer a tailor-made and individual solution in the shortest possible time while achieving an unprecedented level of performance and product safety.”

Jens Mangelsen – Technical Director, Intelsius



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