Temperature-stability validation appraisal: ICEY-TEK coolboxes for the storage and transport of vaccines and temperature-sensitive medications

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Executive Summary

The transport of temperature sensitive medications and vaccines to geographically remote or difficult-to- access areas presents logistic challenges to health providers, especially if externally powered refrigeration units are unavailable or unfeasible. This study seeks to explore the thermal performance of ICEY-TEK coolboxes of varying volumes, in combination with a variety of ice packs and cooling methods. The results indicated that, in ambient temperatures of up to 20 degrees Centigrade, medications could be passively maintained at <10 degrees Centigrade for in excess of 5 days in certain set-ups. In general, ice-cube cooled boxes outperform gel 'cool-pack' cooled boxes, although even with small volume gel 'cool-pack' setups an internal temperature of <10 degrees Centigrade could be maintained for on average in excess of 30 hours. This study suggests that the ICEY-TEK boxes may represent a cost-effective and power-independent method of transporting temperature-sensitive medications for extended periods and to remote locations.

Aims & Objectives

This study aims to investigate the use of a specific technology combination for the short- and medium-term storage of temperature sensitive medications and vaccines. As a provider of pre-hospital clinical care in a variety of settings (including some remote locations, potentially require protracted journeys to difficult-to-access terrain), the cost-effective storage and cold transport of temperature-sensitive medications and vaccines for extended periods of time is of significant importance. This study aims to evaluate the use of a variety of ICEY-TEK brand coolboxes, with various combinations of cooling methods.

Methods

In order to investigate variations in 'real world' conditions, a variety of coolbox sizes and cooling method combinations were investigated. A selection of temperature sensitive medications were placed in each coolbox (pre-filled vaccinations – boxed and unboxed, a selection of medication ampoules and prefilled syringes) along with the chosen cooling method (appropriately sized to minimise dead space within the box as far as possible). To investigate variation in cooling method, a variety of cool pack brands were compared, along with an approximately equivalent amount of bagged water ice-cubes (frozen in a conventional domestic freezer).

The study investigated the performance of the ICEY-TEK Cube Boxes of 25L, 40L and 55L capacity; the ICEY-TEK Long Boxes of 56L and 70L capacity (supplied by www.coolboxesuk.com). The cooling methods included the large 'Aussie Gel' ice packs (30cm x 23cm x 3cm), the small 'Nu-Ice' gel packs (5lbs) and the large 'Nu-Ice' gel packs (10lbs) (supplied by www.CoolBoxes.co.uk). All packs were pre-frozen for a minimum of 48 hours in a standard domestic freezer. Where cubed ice was used, this was contained in polythene bags.

This study appraised the following devices and combinations:

Product	Cooling Method
25L ICEY-TEK Cube Box	1 x large Aussie Gel ice pack
40L ICEY-TEK Cube Box	2 x large Aussie Gel ice packs
55L ICEY-TEK Cube Box	3 x large Aussie Gel ice packs
56L ICEY-TEK Long Box	8Kg cubed ice
56L ICEY-TEK Long Box	2 x small, 1 x large Nu-Ice packs
70L ICEY-TEK Long Box	4 x large Aussie Gel ice packs
70L ICEY-TEK Long Box	10Kg cubed ice

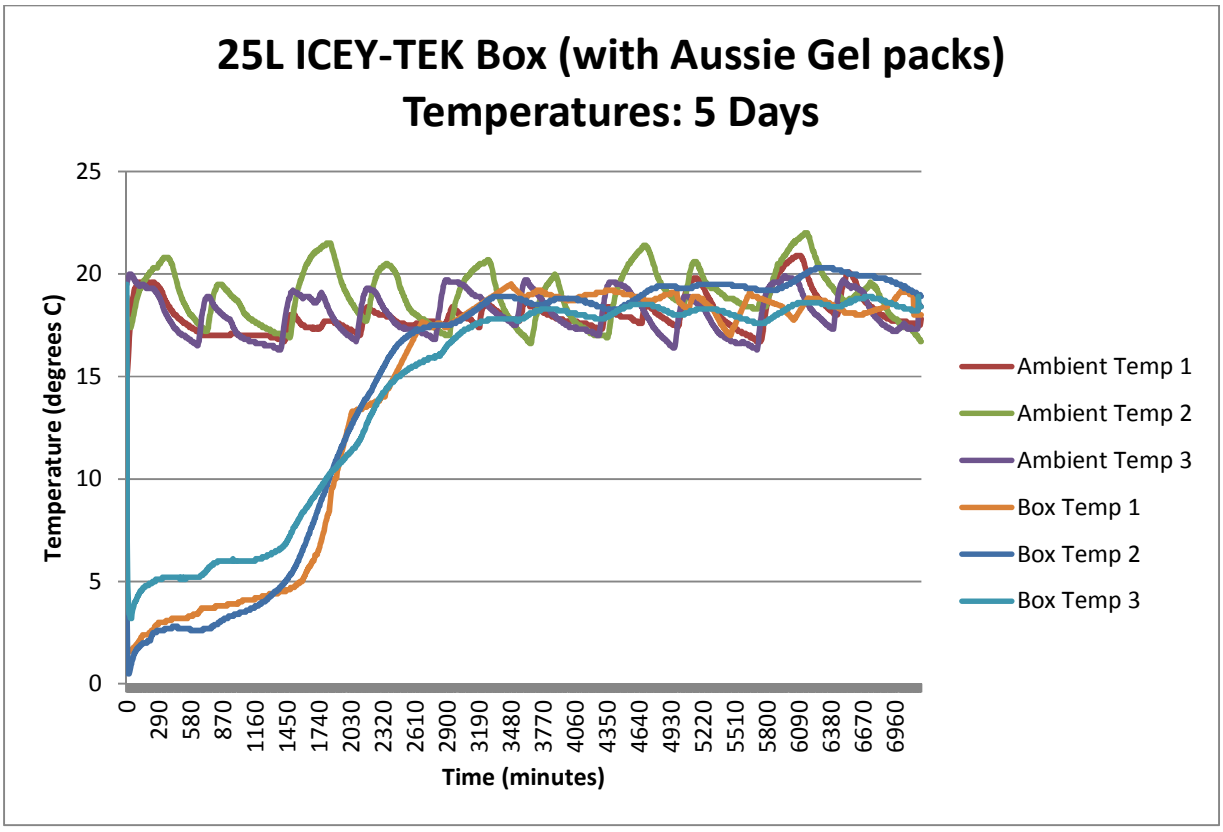
Temperature measurements were recorded using a pair of calibrated LogTag TRIX-8 temperature data loggers (supplied by LS Technology). One data logger was placed in contact with the vaccinations/medications inside the coolbox to record internal medication item temperature, and one data logger was fixed to the outside of the coolbox to record external ambient environmental temperature.

Both loggers were activated simultaneously, and recorded temperatures at 5-minute intervals. The coolbox was not opened until the end of the study period. The TRIX-8 devices comply with EC EMC directives 50081-1:1:1992 and EN 61000-6-1:2001 for performance. The devices are EN12830 compliant for the monitoring of transported chilled, frozen and deep frozen goods, meet the World Health Organisation E06/06 Performance, Quality and Safety standards with respect to vaccine transport, and are certified according to the Food and Drug Administration CFR21 Part 11. In addition, all TRIX-8 devices were calibrated at two temperature points (0 °C and 10°C) using independent United Kingdom Accreditation Service (UKAS) calibrated test equipment, and traceability to national reference standards maintained.

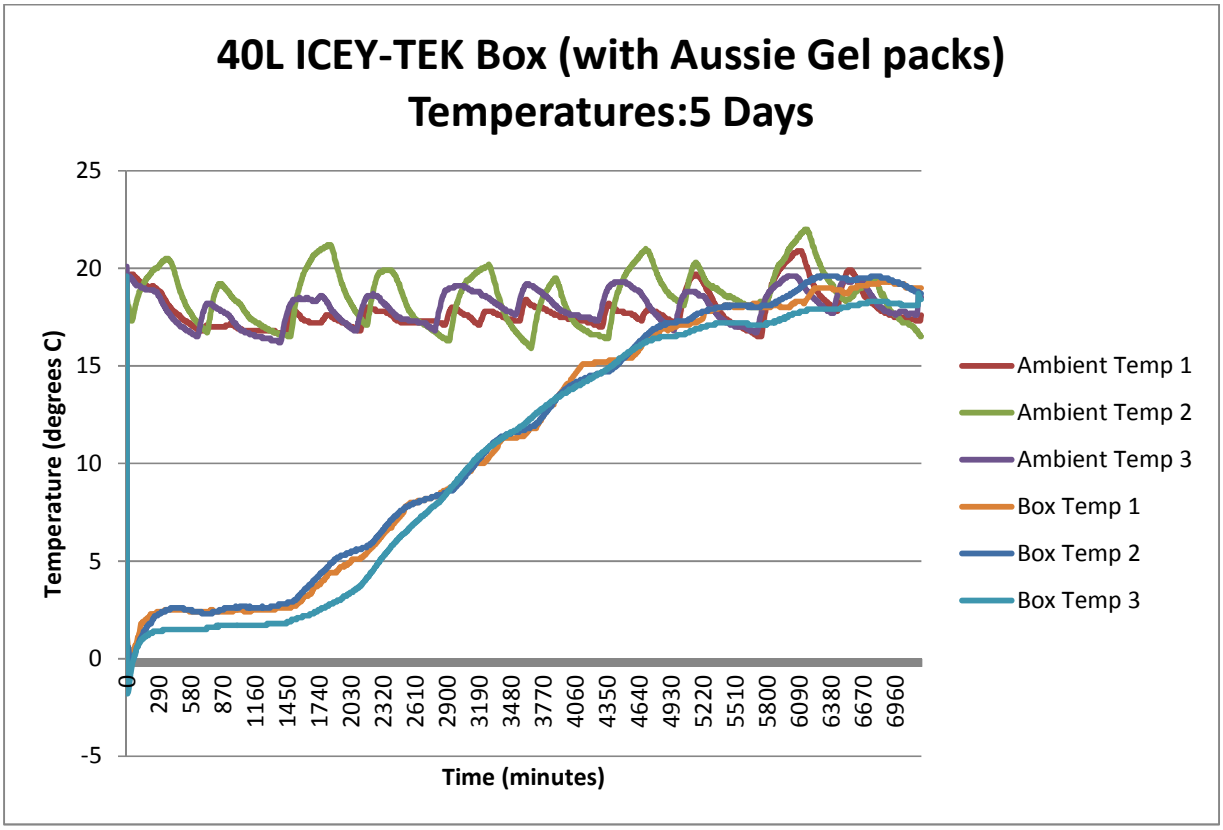
Each experimental set-up was run in triplicate. Data was downloaded using *LogTag Analyzer* Software (available from www.LoggerShop.co.uk) and exported to *Microsoft Excel* for handing and analysis. This methodology has been piloted previously in studies investigating thermo-stability of intravenous fluids during transportation, and has been evaluated to produce consistent and reliable results.

Results

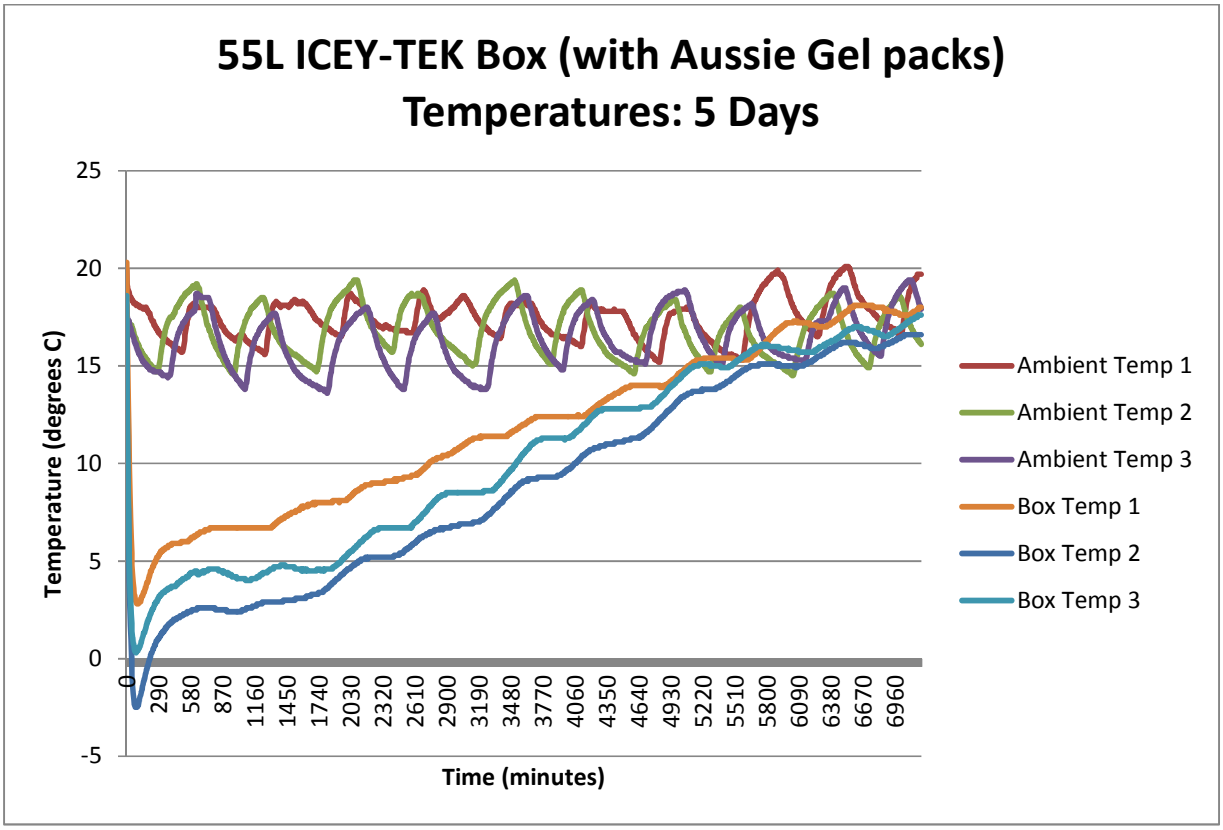
Results are presented for each box size as below. Study configurations were run in triplicate, so the mean time in minutes to reach 10 degrees C (the generally accepted upper temperature limit for storage of 2-8 degree medications and vaccines) is also presented, alongside the mean external temperature. Graphical representations for each configuration are presented for 5 days (120 hours).



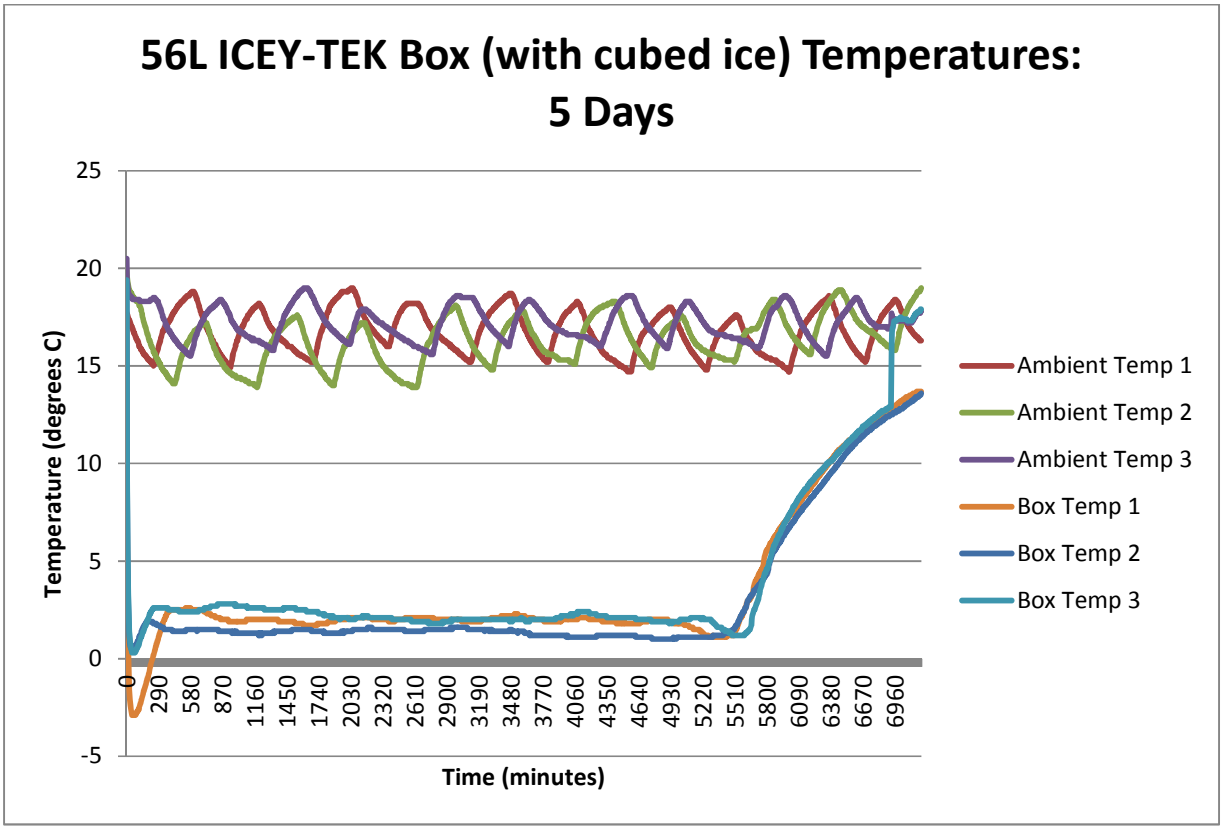
Mean Time to reach 10 degrees C:	1842 mins (30.7 hours)
Mean ambient temperature:	18.4 degrees C



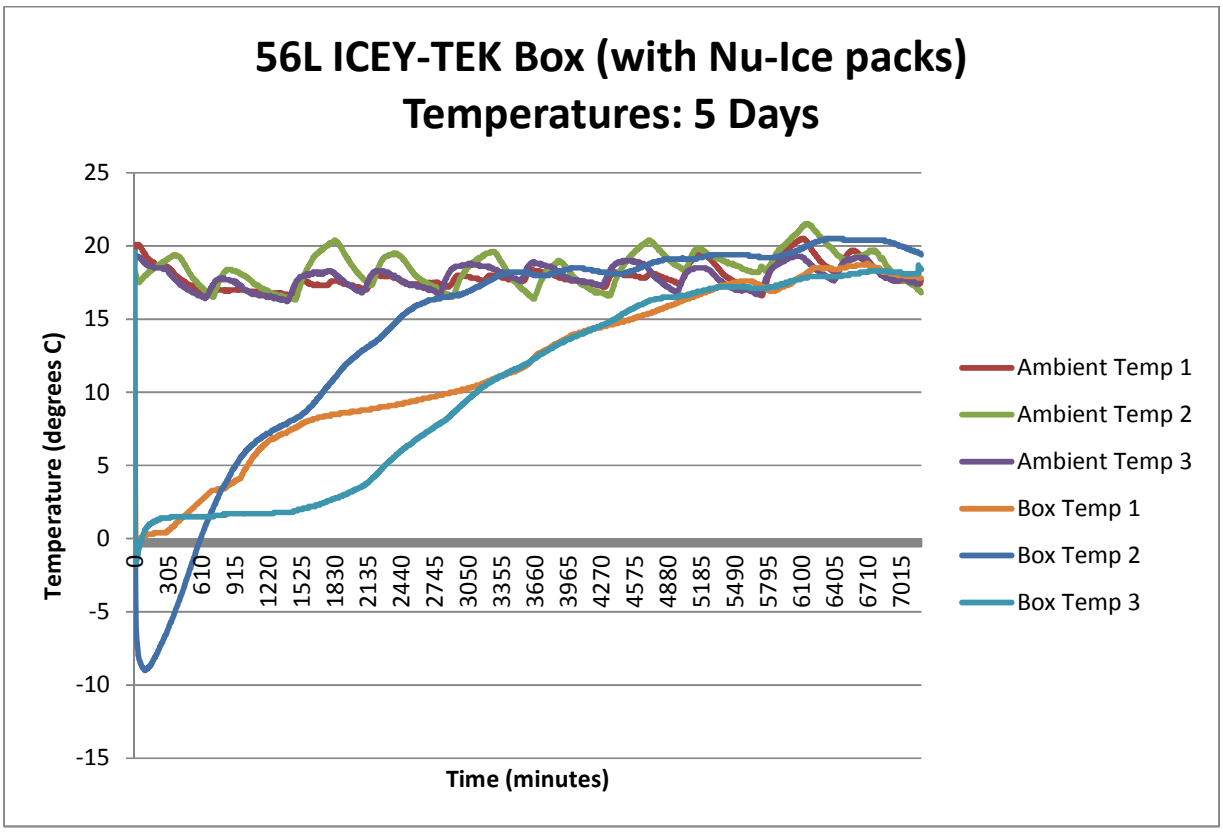
Mean Time to reach 10 degrees C:	3147 mins (52.4 hours)
Mean ambient temperature:	18.2 degrees C



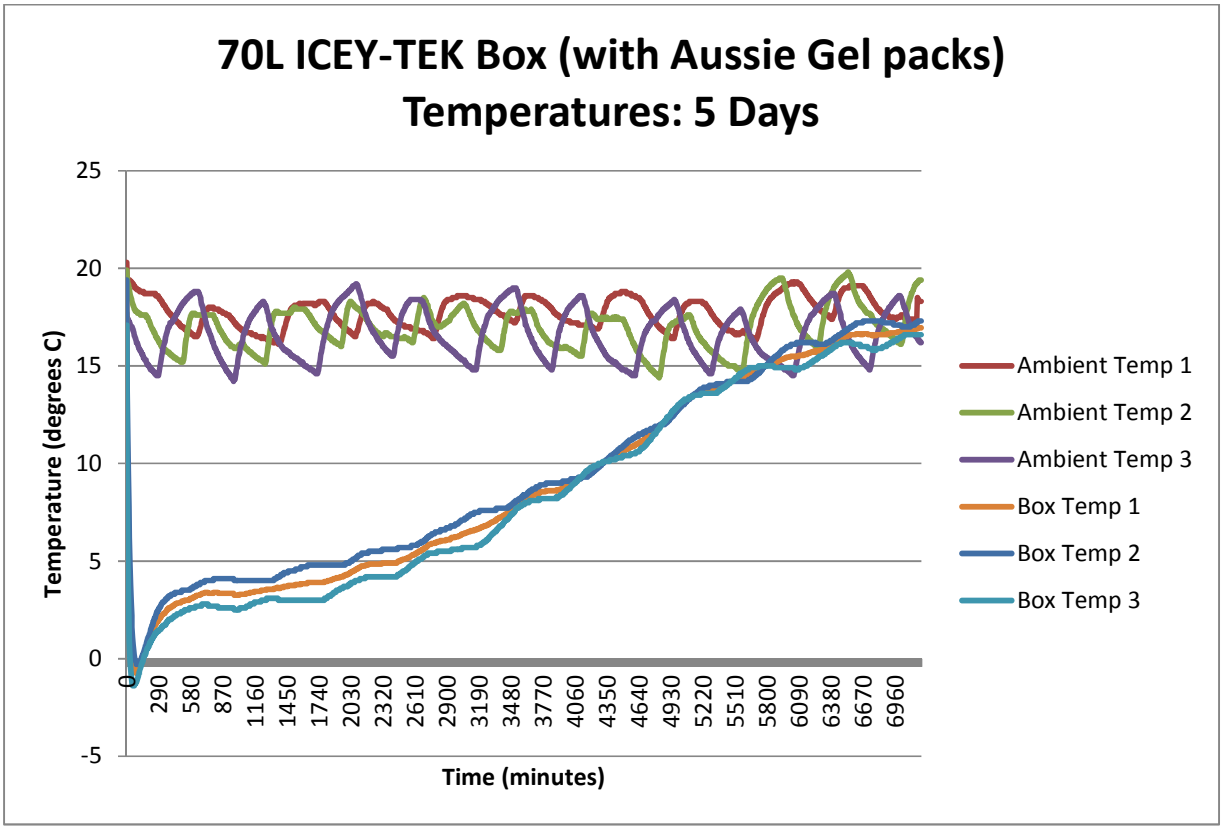
Mean Time to reach 10 degrees C:	3440 mins (57.3 hours)
Mean ambient temperature:	16.9 degrees C



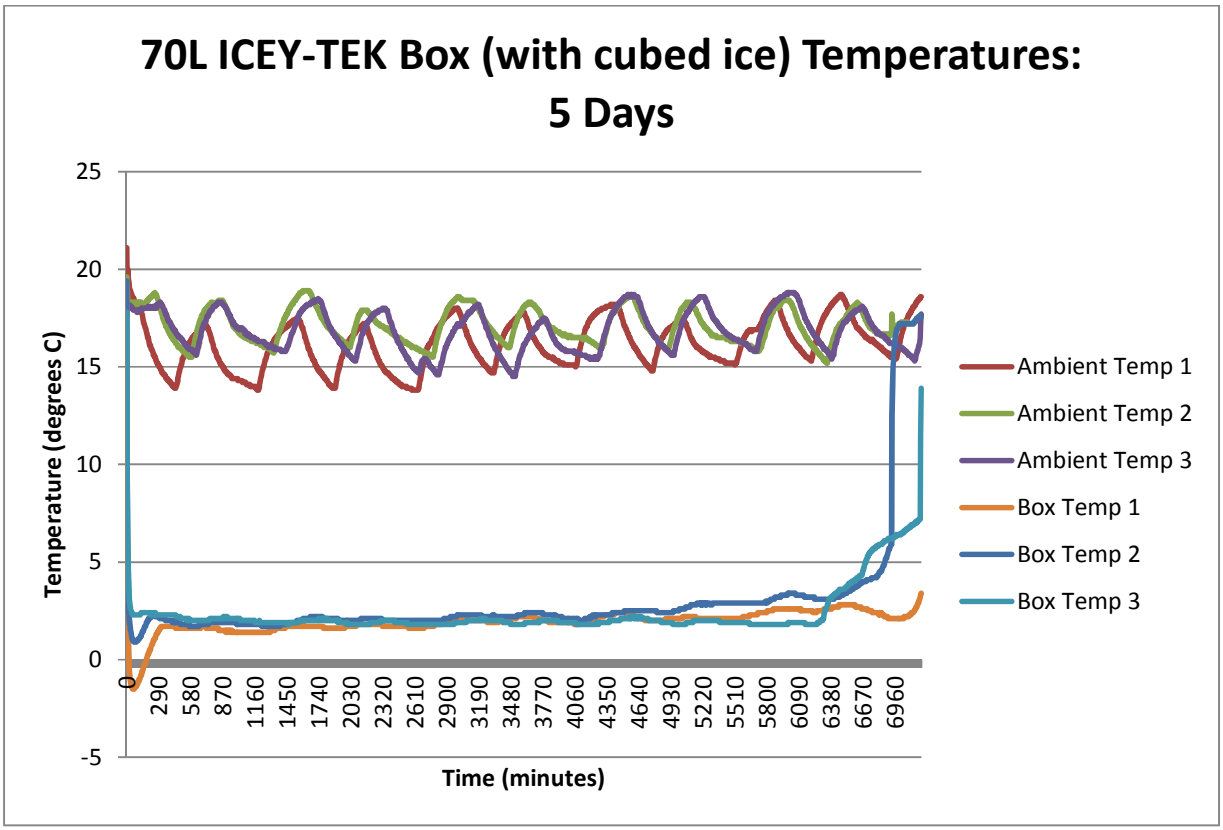
Mean Time to reach 10 degrees C:	6382 minutes (106.4 hours)
Mean ambient temperature:	16.8 degrees C



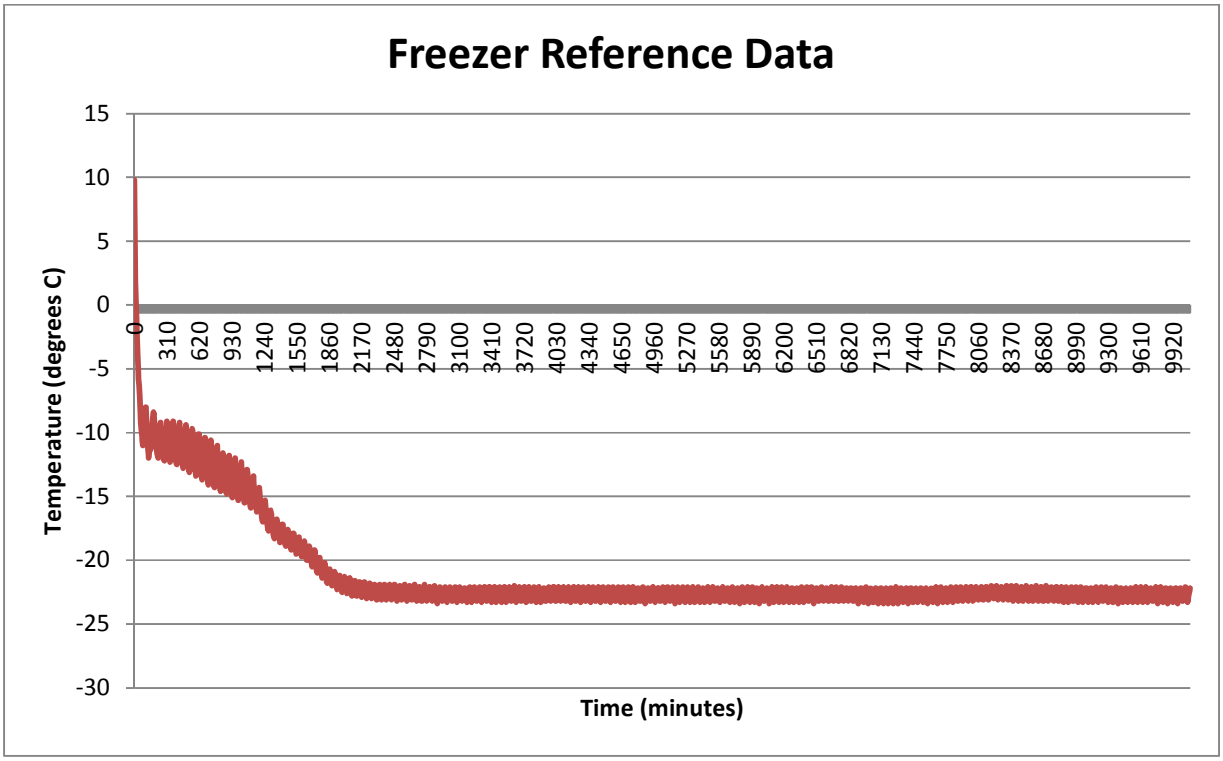
Mean Time to reach 10 degrees C:	2577 minutes (42 hours)
Mean ambient temperature:	18.1 degrees C



Mean Time to reach 10 degrees C:	4295 minutes (71.6 hours)
Mean ambient temperature:	17.1 degrees C



Mean Time to reach 10 degrees C:	7200+ minutes (120+ hours)
Mean ambient temperature:	16.7 degrees C



Discussion

This study indicates that the coolboxes tested have significant scope for maintaining relatively cooled internal temperatures for the storage of temperature-sensitive medications for extended durations.

The larger volume boxes perform better in terms of time below target temperature, and are able to achieve internal temperatures of <10 degrees Centigrade for periods in excess of 5-days in stable conditions. Although untested for repeated opening- and closing, in sealed conditions there is potential for extended transport and transit of temperature sensitive medications.

In this study, standard ice-cube cooled boxes performed better than boxes cooled with 'Aussie Gel' packs, and better than boxes cooled with 'Nu-Ice' packs, with reference to length of maintenance of internal temperature <10 degrees Centigrade. However, there are practical considerations involved in generation of several kilograms of cubed ice that may mean this approach is not practical. Even using the ice-packs and the smallest volume box (25 litres), internal temperatures of <10 degrees Centigrade were maintained for on average greater than 30 hours.

Although in this study, 10 degrees Centigrade has been used as a cut-off point for defining the period of adequate cooling, this is in some ways an arbitrary watershed. All box configurations maintained the internal temperature below ambient for much longer than the time-to-10-degrees period. Where

medications or vaccinates have the potential to be stored at higher temperatures, these configurations could expand the useable envelope of such products beyond the 5-day study period, if appropriately validated.

The external ambient temperatures ranged between approximately 15 degrees Centigrade and just over 20 degrees Centigrade across the experimental set-ups, and all showed approximately 5 degrees Centigrade of diurnal variation. Although these ambient temperatures are not extreme, they are very typical of standard UK environmental averages during the warmer months, and represent – in the author's opinion – an appropriately representative 'real world' environment.

Conflicts of Interests and Provenance

Report jointly internally and externally commissioned.

'Coolboxes' and Ice-packs loaned by coolboxuk.com for the duration of the study. A charitable donation was provided to Severn Ambulance and Medical Services to contribute towards the cost of data acquisition, analysis and write-up of the associated report.