



Step 1.

Place one cold pack in the bottom of the cooler.



Step 2.

Place one corrugated plastic divider over the cold pack.



Step 3.

Place one glycol USB Probe Data Logger that has been chilled to approximately 40°F inside of a cardboard box.



Step 4.

Fill dead space with cellophane packing bags.



Step 5.

Place second corrugated plastic divider over box.



Step 6.

Place second cold pack on top as the last item and close the lid.

Testing Items/Conditions:

1. One HCL® Transport Cooler, 7-Quart #20185 (Ambient air conditioning 68-72°F)
2. One USB Probe Data Logger with Glycol Bottle Probe #19516 (Probe chiller to approximately 40°F.) (Not included)
3. Two 8" x 5" cold packs (Condition-frozen).
4. Two pieces of corrugated plastic (Used to separate cardboard box from cold packs).
5. Cellophane packing bags as fill material. (Not included)
6. One 6½" x 4½" x 3" cardboard box. (Not included)

EasyLog USB	Time	Fahrenheit(°F)	Comments	Serial Number
1	10/14/2019 10:01	40.3		10033654
2	10/14/2019 10:06	45.5		
3	10/14/2019 10:11	46.5		
4	10/14/2019 10:16	45.8		
5	10/14/2019 10:21	44.5		
6	10/14/2019 10:26	43.1		
7	10/14/2019 10:31	41.6		
8	10/14/2019 10:36	40.3		
9	10/14/2019 10:41	39.2		
10	10/14/2019 10:46	38.2		
11	10/14/2019 10:51	37.5		
12	10/14/2019 10:56	36.8		
13	10/14/2019 11:01	36.3		
14	10/14/2019 11:06	36		
15	10/14/2019 11:11	35.7		
16	10/14/2019 11:16	35.5		
17	10/14/2019 11:21	35.4		
18	10/14/2019 11:26	35.3		
19	10/14/2019 11:31	35.3		
20	10/14/2019 11:36	35.3		
21	10/14/2019 11:41	35.3		
22	10/14/2019 11:46	35.3		
23	10/14/2019 11:51	35.4		
24	10/14/2019 11:56	35.4		
25	10/14/2019 12:01	35.5		
26	10/14/2019 12:06	35.6		
27	10/14/2019 12:11	35.6		
28	10/14/2019 12:16	35.7		
29	10/14/2019 12:21	35.8		
30	10/14/2019 12:26	35.8		
31	10/14/2019 12:31	35.9		
32	10/14/2019 12:36	35.9		
33	10/14/2019 12:41	36		
353	10/15/2019 15:21	45.5		

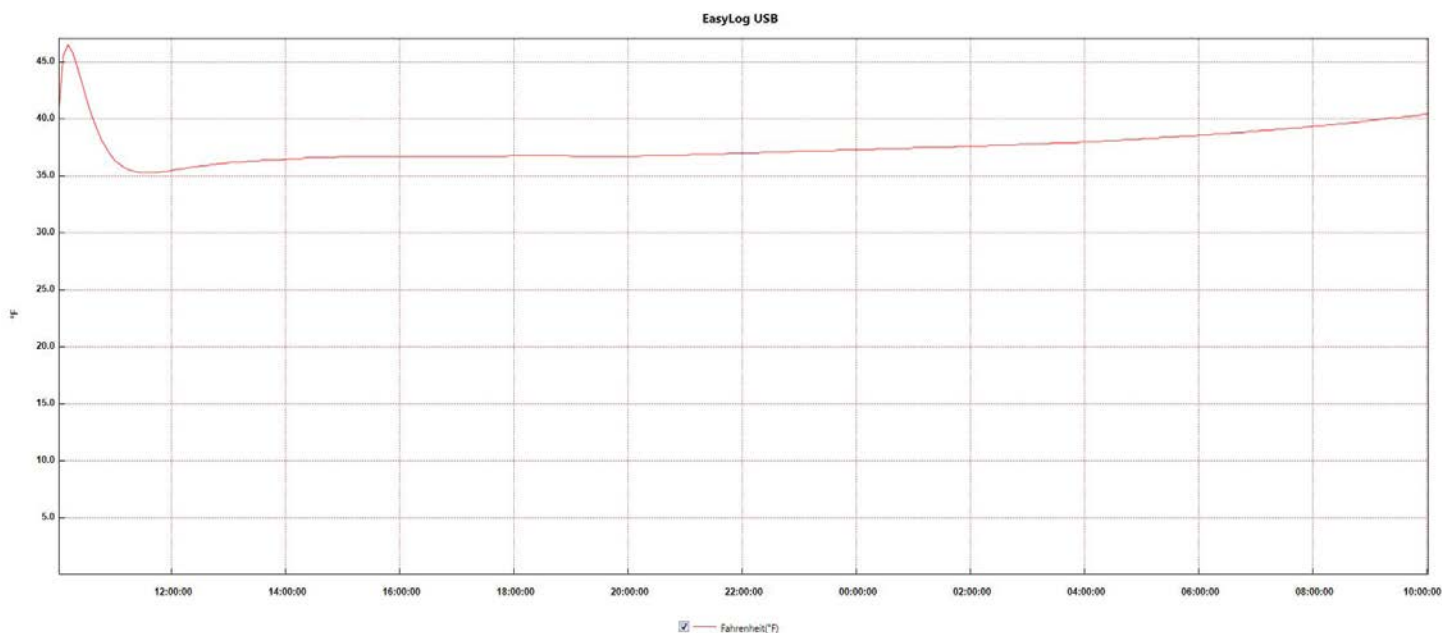
Preferred Packout for the HCL® Transport Cooler, 7-Quart

The plotted curve below does not change when testing the items in a cooler. When the probe is placed inside of the cooler the temperature increases. This is due to the items inside of the cooler using up the cold energy to reach equilibrium. The contents will start to cool down and start to rise to room temperature at the same rate. The temperature stayed within the range below with one glycol probe as payload and ambient conditions between 68-72°F for a period of 24 hours.

USP 10.30.40. Controlled Cold Temperature

“Controlled cold temperature” is defined as temperature maintained thermostatically between 2° and 8° (36° and 46° F), that allows for excursions in temperature between 0° and 15° (32° and 59° F) that may be experienced during storage, shipping, and distribution such that the allowable calculated mean kinetic temperature is not more than 8° (46° F). Transient spikes up to 25° (77° F) may be permitted if the manufacturer so instructs and provided that such spikes do not exceed 24 hours unless supported by stability data or the manufacturer instructs otherwise.

Gradual climb between 36-45.5°F omitted.



From: Monday, October 14, 2019 10:01:18 AM - To: Tuesday, October 15, 2019 10:01:54 AM