

ThermoFisher
S C I E N T I F I C

Responses to EPA E-star Questions from John Clinger & Melissa Fiffer

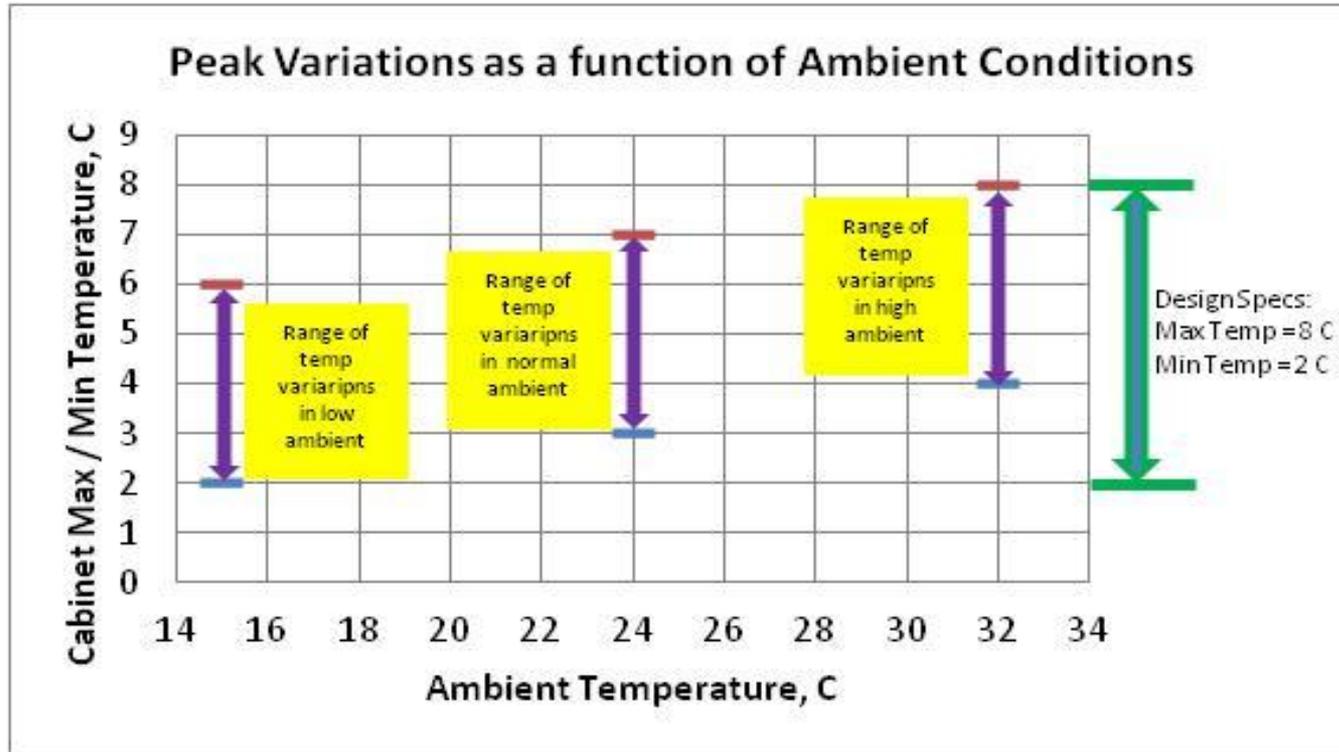
February 16, 2016

Collaboration by Alex Esmon, Qi Wang, Richard Bair, Todd Swift, Joe Arteaga & Jose Bonet

1) List of any ways in which the final DOE test method for Lab Grade wouldn't work for high-performance products (keeping in mind that the test method is final and we do not envision revising it for V 1.0)

Some Suggestions on HP LRF Test Methods:

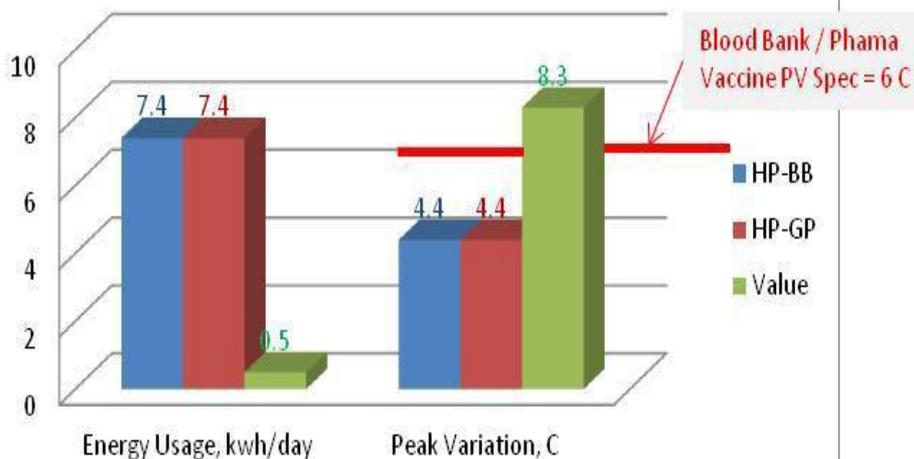
1. Install a significantly large number of temperature sensors, to get a more comprehensive temperature profile inside of cabinet. Suggestion: 5 sensors on each shelf or layer, including 4 corners plus 1 center.
2. Use un-weighted temperature sensors, to make more accurate measurements on cabinet temperature variations, , that allows us to collect the worst values of peak variations;
3. Tests should be conducted in both high and low ambient conditions. In Thermo Fisher's product developments, they are 15C and 32C, respectively. This is because the cross-ambient conditions may have the impact on cabinet peak variations. See below for a detailed examination from the graph. We have to test if the designs meet the requirement for peak variations in all working conditions.



2) Any efficiency data you can share for your current high-perf products (or others on the market), ideally that we could include in our graphs (do you have an Excel file version of the slides you shared with a key to which if any are new high-perf products?)

+4C Refrigerators

+4C Refrigerator

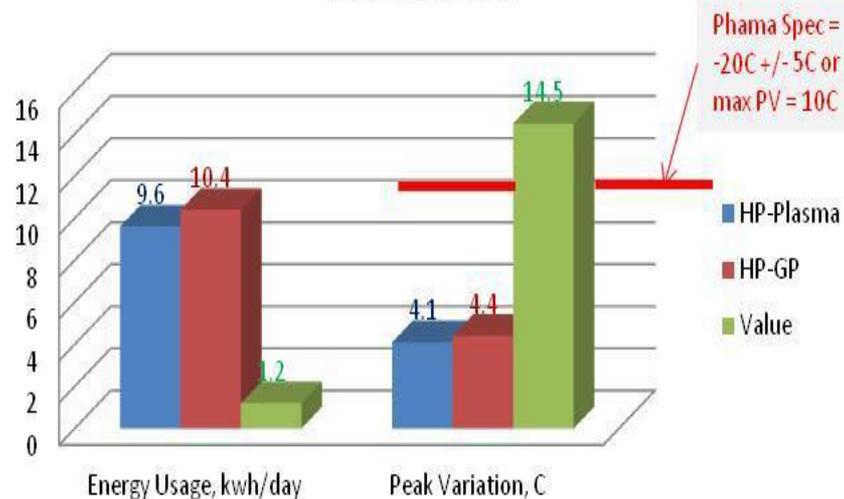


Blue = High Performance Blood Banks
Red = General Purpose (Vaccine / Pharma)
Green = Value / Entry level performance REF

- Value Products Cannot meet the Blood / Pharma / Vaccine Peak Variation (PV) requirements of 2C to 8C or 6C Max PV.
- Value products are more energy efficient but cannot meet the stringent requirements of Critical Pharma & Vaccine Customers

-20C Freezer

-20C Freezer



Blue = High Performance Plasma FZ
Red = General Purpose (Vaccine / Pharma) FZ
Green = Value / Entry level performance FZ

- Value Products Cannot meet the Pharma Peak Variation (PV) requirements of 20C +/- 5C or Max PV of 10C
- Value products are more energy efficient but cannot meet the stringent requirements of Critical Pharma Customers

3. Can your team provide additional detail on what separates a HP refrigerator from a general purpose one (specific non-shared physical/functional characteristics)? The input below is a start, but it isn't sufficient for us to generate a definition to clearly differentiate the two products types. Any additional insight you can share would be greatly appreciated, the more detailed the better.

Question	Response
<p>What bins the high-performance products fall into, relative to the set-up of the draft V 1.0 ENERGY STAR specification: I think I heard Alex say that they could be Lab Grade Refrigerators or Lab Grade Freezers – confirmation of this fact, and also more info on the exact temperature set points, would be helpful</p>	<p>The high performance (purpose-built) products fall into a few different buckets—for refrigerators, there is General Use Lab grade, Blood Bank, Pharmacy and finally Chromatography. Units in each category are built with application specific needs in mind such as drawers, glass doors, chart recorders, access ports, etc. The refrigerators have a set-point from the factory of +4 or +5 C and are designed to maintain tight variation around those points. The high performance freezers fall into three categories: -20 manual defrost general use, -30 auto defrost general use and -30 auto defrost plasma storage. We also have a specific enzyme storage -20 manual defrost unit, again that is specific for application requirements. If it would help, I can provide technical data sheets for respective models.</p>
<p>List of which factors distinguish/define a high-performance product as its own bin (this could include temperature sensitivities, defrost tolerances, etc.)</p>	<ul style="list-style-type: none"> •High performance refrigerators and freezers are designed to maintain very tight peak variation around set point and ensure that under normal use, the expected temperature ranges are met and maintained, these include design aspects such as: •Fan assisted temperature recovery •Directed air flow to maintain cabinet conditions uniformly (in auto defrost units) •Robust refrigeration systems that are designed to maintain tight tolerances •Robust door design •Specific insulation design •On-board alarms •Access ports for 3rd party temp verification modules or wireless monitors •On-board temperature controls, not just temperature displays •Access to defrost cycle control mechanism <p>The following are some examples of application specific ranges that these product are designed to maintain at all times:</p> <ol style="list-style-type: none"> 1)Refrigerated blood products: +1 to +6 C 2)Frozen blood products: below -18 C 3)Vaccines: +2 to +8 C (with no deviations into freezing ranges) 4)Vaccines (frozen): -15 to -50 C (with no thawing) 5)Enzymes: -20 +/- 5C 6)Pharmaceuticals: +2 to +8 C 7)Chromatography columns: +2 to +8 C (no freezing) <p>These requirements are almost always times tied to specific regulatory and compliance or accreditation requirements from bodies like:</p> <ul style="list-style-type: none"> •FDA, USP, AABB, CAP, JCAHO, FACT, NSF, CDC