# Minimizing Temperature Variations in Upright Mechanical Freezers

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## Abstract

Standard practice for storage of blood products such as serum, plasma, etc. is in a *frozen* condition in temperatures at or below -70◦C Although some temperature gradations are expected within a freezer chamber, all points must be able to maintain temperatures at or below -70◦C so that each specimen remains at or below -70◦C, thereby maintaining specimen integrity. In a validation study of upright mechanical -80◦C freezers under full specimen load, we found that temperatures measured within the freezer chamber ranged from -19◦C to -83◦C (>60◦C variation) depending on position within the unit and the freezer rack configuration.

During an ongoing validation, initial data gathered using our Data Acquisition System (DAQS) measured temperatures within upright freezers of one manufacturer between -65◦C and -70◦C at the top freezer box level. The single temperature sensor provided by the manufacturer in each freezer unit is located in the middle back of the freezer chamber. The manufacturer's sensor recorded the temperature of the chamber as -83◦C, differing by as much as 33◦C from the readings on the top shelf of the unit. Subsequently, more detailed temperature mappings revealed that additional points in the top of this freezer demonstrated temperatures as warm as -19◦C Freezers from another manufacturer were also mapped, and the temperature variation on the top shelf of the unit was not as severe, although several points within the freezer did not maintain temperature below -70◦C. A difference in the racking system configuration was noted between the freezers from the two manufacturers. The freezer demonstrating the greater temperature variation contained less space for free airflow within the unit.

Further experiments were conducted to evaluate the effect of increasing airflow within the upright freezer chamber. An inventory rack was removed from the top of the unit; this generated a 10◦C drop in temperature at the warmest point within the unit. Removal of a rack from each shelf resulted in a 49◦C drop in temperature. Adjustment of the shelves within the unit to generate three inches of airspace (without removal of racks) resulted in a 50◦C drop in temperature. A similar series of experiments was conducted on other units from the same manufacturer and a unit from a different manufacturer. In each case, the increase of free airflow space within the unit resulted in a decrease in temperature, bringing all points within the unit at or below -70◦C.

In conclusion, inventory racking systems within an upright freezer must be arranged in a manner that allows for adequate free airflow. Changing the size of the inventory racks used within these freezers and/or changing the original factory-installed shelving configuration will allow for increased airflow without decreasing the number of specimens that can be stored within a unit. Allowing for proper free airflow within a unit decreases the temperature variation to which specimens are exposed during storage and enables the freezers to maintain specimen temperatures at or below -70◦C, thereby maintaining specimen integrity.

## Introduction

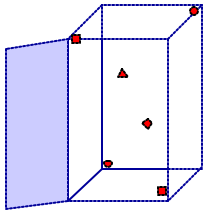
BBI Biotech has designed a Validation Protocol (VP), which is used to ensure that every freezer used for specimen storage is properly installed, operates to its specifications, and performs consistently. The VP is comprised of three parts; 1) Installation Qualification (IQ); 2) Operational Qualification (OQ); and 3) Performance Qualification (PQ). The purpose of the IQ is to verify that a system or equipment item has been installed in a manner that is consistent with design specifications and/or manufacturer's recommendations. This includes, but is not limited to, pre-installation requirements such as assigning the Unit ID, ensuring proper space and electrical configurations are present, and installing the alarm point so that it is ready for use upon the freezer's arrival. The post-installation requirements include labeling the Unit and making the connections to power and the temperature monitoring systems.

An OQ is a list of criteria that must be met in order to determine that the Unit will operate in a manner that is consistent with the design specifications and/or manufacturers recommendations. This is demonstrated by checking all systems on the freezer (i.e., Set Point, Alarm Status, Chart Recorder Operation) and by performing a temperature mapping of the Unit in pre-defined locations.

The PQ is performed to demonstrate that the unit is continuing to operate and perform within the parameters set during the original validation process. The PQ is conducted at BBI Biotech on an annual basis in conjunction with the preventive maintenance performed on each unit. The PQ consists of a temperature mapping of the freezer in pre-defined locations.

During the PQ temperature mapping of the 48 upright mechanical -80ºC freezers housed at BBI Biotech, it was discovered that many of the upright freezers had temperatures readings that do not pass our VP specifications. An in-depth analysis of the results demonstrated that a similar temperature pattern was being displayed in the failing units and that the units from a particular manufacturer (Manufacturer A) had a greater amount of variation within the unit. As a result, more detailed mappings were performed in order to delineate the area where warmer temperatures are present and to determine the cause.

Fig. 1: Summary of Initial Performance Qualification Mapping Results for Upright -80ºC Mechanical Freezers

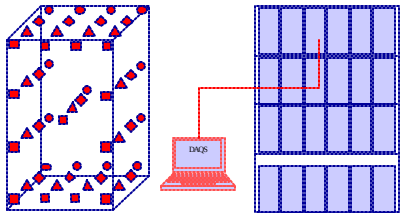


| # of Freezers | Warmest Temperature Within Unit |
|---|---|
| 8 | -50ºC to -55ºC |
| 4 | -56ºC to -60ºC |
| 3 | -61ºC to -65ºC |
| 15 | -66ºC to -70ºC |
| 13 | -71ºC to -75ºC |
| 4 | -76ºC to -80ºC |
| 1 | -80ºC or colder |
| 48 | Total |

## Methods

BBI Biotech utilizes a Data Acquisition System (DAQS), manufactured by Omega Engineering, Incorporated, to measure and record the temperature at various locations throughout the freezer chamber using Type T thermocouples. The DAQS system and each probe on the system were calibrated to a TRACEABLE® National Institute of Standards and Technology (NIST) thermometer prior to and during the validation experiments. The ambient temperature during the validation process was also recorded. The thermocouples were sheathed to avoid direct contact with metal surfaces and secured to the level of the top freezer box within each shelf. The initial mapping scheme (Fig. 1) was designed to record a representative temperature for each area in the freezer chamber. The set point for each freezer is -85ºC. Upon evaluation of the initial mapping results, a detailed mapping scheme was developed (illustrated in Figure 2 below) to determine the exact areas in the freezer that were exhibiting the warmer temperatures. Sixteen points were set at the top freezer box level on the top and bottom shelves of the unit and 20 points were staggered through the middle two shelves and in the center of the unit. The temperature probes were allowed to stabilize in the unit and the temperature of each probe was recorded for a minimum of 24 hours.

Fig. 2: Inventory Configuration and Detailed Mapping Scheme for Upright Mechanical Freezers




Detailed temperature mappings were performed on a total of four units. Initial detailed mappings were performed on each unit with their original inventory configuration. In Manufacturer A's units, there was no free airflow space on top of the racks from the top three shelves of the unit and 4 inches of free airflow space above the racks on the bottom shelf of the unit. The unit from Manufacturer B had only 1.5 inches of air space on top of the racks on the top shelf, but had over 3 inches of airspace above the racks on the bottom shelf. The inventory configuration of each unit was then adjusted in a series of steps to determine the affect of the adjustments on the temperature throughout the unit. The alterations that were performed included a sequential removal of racks from the unit, an adjustment of the shelves within the unit (leaving all original racks in place), and the adjustment of shelves with a sequential removal of racks. Figure 3 shows the resulting inventory configuration after racks were removed from the unit (3A) and after shelves were adjusted in the unit (3B).

Fig. 3: Inventory Configuration and Detailed Mapping Scheme for Upright Mechanical Freezers

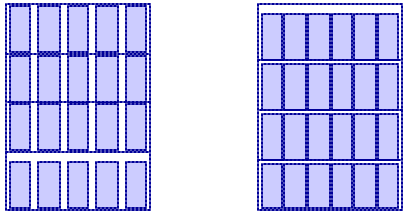


Figure 3A: One rack was removed from each shelf. The remaining racks were evenly dispersed throughout the unit

Figure 3B: Original racks were left in the unit. The shelves were adjusted to allow for three inches of airspace above the top specimen box on the top shelf of the unit and 1 inch above the racks on all other shelves within the unit.

Tables 1 through 4 summarize the temperature data from the top shelf of each unit (16 temperature points) in our series of experiments. All temperature points were mapped at the top specimen box level on the top shelf of the unit unless otherwise noted. The data from the other points mapped within the units (bottom three shelves of the unit) all consistently fell within acceptable range and have not been included in the summary data.

Table 1: Manufacturer A, Unit 1 Temperature Mapping Results

| Description of Experiment | Highest Temperature | Lowest Temperature |
|---|---|---|
| Original 52 Point Mapping | -20ºC | -80ºC |
| Removal of 1 rack from Top Shelf | -30ºC | -78ºC |
| Removal of 4 racks (1 from each shelf) | -69ºC | -83ºC |
| Adjustment of shelf height to increase airflow (shelves lowered to generate 3 inches of air space above the top specimen box level and 1 inch of airspace between each shelf) All racks present. | -70ºC | -77ºC |
| Air Temperature at top of unit (3 inches above top specimen box level) after shelf adjustment | -65ºC | -82ºC |
| Removal of 1 rack after shelf adjustment | -72ºC | -79ºC |
| Removal of 4 racks (1 from each shelf) after shelf adjustment | -76ºC | -83ºC |
| Temperature at 2nd specimen box level (top shelf) after shelf adjustment. All racks present | -74ºC | -80ºC |

Table 2: Manufacturer A, Unit 2 Temperature Mapping Results

| Description of Experiment | Highest Temperature | Lowest Temperature |
|---|---|---|
| Original 52 Point Mapping | -19ºC | -83ºC |
| Removal of 1 rack from Top Shelf | -42ºC | -74ºC |
| Removal of 4 racks (1 from each shelf) | -69ºC | -84ºC |

Table 3: Manufacturer A, Unit 3 Temperature Mapping Results

| Description of Experiment | Highest Temperature | Lowest Temperature |
|---|---|---|
| Original 52 Point Mapping | -55ºC | -86ºC |
| Adjustment of Shelf height to increase airflow (shelves lowered to generate 3 inches of air space above the top specimen box level and 1 inch of airspace between each shelf) | -74ºC | -84ºC |

Table 4: Manufacturer B, Unit 4 Temperature Mapping Results

| Description of Experiment | Highest Temperature | Lowest Temperature |
|---|---|---|
| Original 52 Point Mapping | -62ºC | -84ºC |
| Adjustment of Shelf height to increase airflow (shelves lowered to generate 3 inches of air space above the top specimen box level and 1 inch of airspace between each shelf) | -79ºC | -83ºC |

## Conclusions

- Inventory racking systems within an upright freezer must be arranged in a manner that allows for adequate free airflow space.
- Changing the size of the inventory racks used within these freezers and/or changing the original factory-installed shelving configuration will allow for increased free airflow space without decreasing the number of specimens that can be stored within a unit.
- Allowing for proper free airflow space within a unit decreases the temperature variation to which specimens are exposed during storage and enables the freezers to maintain specimen temperatures at or below -70ºC, thereby maintaining specimen integrity.

## Acknowledgments

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