

# Top considerations for selecting a ULT Freezer – application

From application to environment, there are many aspects for consideration that will impact the type of ultra-low temperature (ULT) freezer to be selected for the given situation. Some of these aspects include: application, performance standards, space constraints and environment, facilities interactions, and service support. The application of the cold storage product is the first concern or stop in the decision tree when deciding on the best ULT freezer for a user's given needs.

## Key takeaways/benefits/separating features

### • Installation

- Install unit in a level area, with a minimum of 8" of space on the top and sides and 6" in the back, 6" standoffs are provided with each unit. Do not install directly under air conditioning ducts or in direct sunlight. Make sure the unit is plugged into a dedicated circuit, with appropriate line voltage and capacity. Supply voltage must be within +/- 10% of freezer rated voltage. Always ensure that the room they are installed in stays within a reasonable range of temperature (15°C – 32°C).

### • What samples will be stored?

- Unrestricted airflow is critical for proper operation of a ULT freezer
- There are two types of products based on the intended use of the product: general purpose storage and medical device.
- See intended use below: main differentiator is the storage and intent of reintroduction of the sample into the human body.
- There are other types of storage considerations. For example, will the freezer store product controlled by the DEA? This would require the samples be "locked" in some fashion. This could impact either exterior door considerations or internal compartment storage and/or locking.

### • How will the samples be stored? What temperature?

- Application can also be considered on the interior of the freezer as well. There are many configurations and storage/racking solutions available. Understanding what type of samples and how they will be stored is important. Will they be stored in cryoboxes and racks? How many users will be sharing the freezer and will this dictate the needed interior compartment configurations?

### • Will the unit be qualified through a validation protocol? Is that qualification part of a large monitoring/audit infrastructure?

- Depending on the validation protocols this could impact the necessary performance of the product.
- This will also impact the type of data storage that comes with the unit. Does the freezer have internal temperature/event logging for audit purposes? (21 CFR Part 11 compliance).
- Is the facility accredited where the ULT will be used? There are different standards that impact accreditation. Examples: Biobanking standards, ISBER best practice, ISO 20387:2018 biobanking standard, CAP Accreditation Standard for Biobanking, etc.).

### • Does the institution provide or require the product to be designed in a certain way to meet Green Standard or Sustainability Initiatives?

## In review

Ultra-low temperature freezers are used in a variety of labs ranging from academic research labs to production environments for the biotech and pharmaceutical industries. While the main purpose of any freezer is to maintain the temperature of the samples stored within,

there are a multitude of variations in freezer configuration and operation which make each ultra-low application unique. To properly fit the freezer in a given situation, we start by understanding some basics:

- What is being stored?
- How will it be used once it is removed from the freezer?
- Who will have access to the freezer and the contents? Will it be restricted?
- How often will the freezer be accessed?
- Are their validation protocols which must be adhered to?

Once we understand these fundamental aspects of the application, we can begin to select the best freezer to meet the needs for the specific situation.

## Intended use

### General purpose models:

The general purpose -86°C freezers described here are high performance units for professional use. These products are intended for use as cold storage in research use and as a general purpose laboratory freezer, storing samples or inventory at operating temperatures between -50°C and -80°C. It is not considered a medical device and has therefore not been registered with a medical device regulatory body (e.g., FDA); that is, it has not been evaluated for the storage of samples for diagnostic use or for samples to be re-introduced to the body. This unit is not intended for use in classified hazardous locations, nor to be used for the storage of flammable inventory.

### FDA Class II models:

The -86°C freezers described in this manual are intended for the storage of Frozen Red Blood Cells in 40% glycerol at -65°C for up to 10 years; Frozen Rejuvenated Red Blood Cells at -65°C for up to 10 years; Fresh Frozen Plasma at -65°C for up to 10 years; and Frozen or Cryopreserved

Tissue for long term storage: Musculoskeletal Tissue at -40°C or colder, Skin at -40°C or colder and Bone at -40°C or colder.

These products should only be used by an authorized and adequately trained personnel. It is considered a medical device and has therefore been listed with medical device regulatory body FDA and is considered a Class II medical device by the FDA. This product is listed under product code KSE, regulation number 864.9700 and is considered 510(K) exempt. This unit is not intended for use in classified hazardous locations, nor to be used for the storage of flammable inventory.

## References

1. AABB - Technical Manual 17th Ed., page 273,274. STANDARDS FOR TISSUE BANKING 14th Ed., Section E, E3.300, E3.310, Table E3.331.

**Note for clarity:** The 'Bone' is the Osteoarticular Graft, a weight bearing allograft with intact articular surfaces, consisting of a joint with associated soft tissue and bone. STANDARDS FOR TISSUE BANKING 14th Ed., Section page 8

Find out more at [thermofisher.com/ult](https://www.thermofisher.com/ult)

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