

**AZENTA**  
LIFE SCIENCES

# Competitive Analysis Case Study

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January, 2024

# Session Topics



- 01 Day One Review
- 02 Competitive Analysis
- 03 Case Study

# DAY ONE REVIEW

# D1

# US System of Weights and Measure

*A Historical Context*



# Cryo-preservation

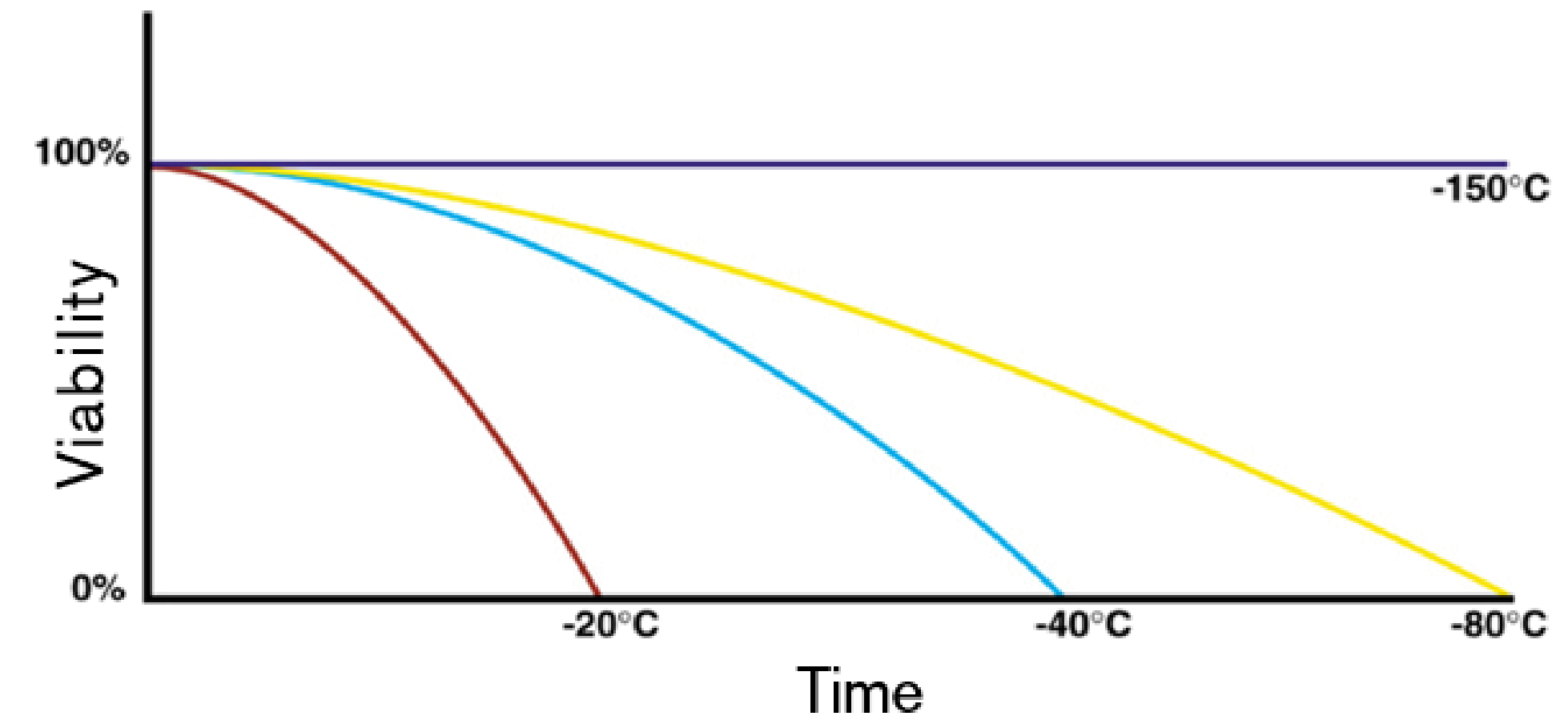
## *Principles and importance*

### **PRESERVATION OF LIVING CELLS AND TISSUES AT VERY LOW TEMPERATURES FOR AN EXTENDED DURATION OF TIME.**

- Glass Transition temperature ( $T_g$ ) =  $-135^{\circ}\text{C}$
- Liquid nitrogen (LN2) provides cooling to  $-196^{\circ}\text{C}$
- Cryo-preservatives (CPAs) used for sample protection at low temperatures.
- Typical samples: Blood cells, stem cells, oocytes, sperm, embryos, forms of medication

### **Significance**

- Sample quality for pharmaceutical research, biotechnological industries or in medical transplantation
- **Sample recovery and viability is imperative**

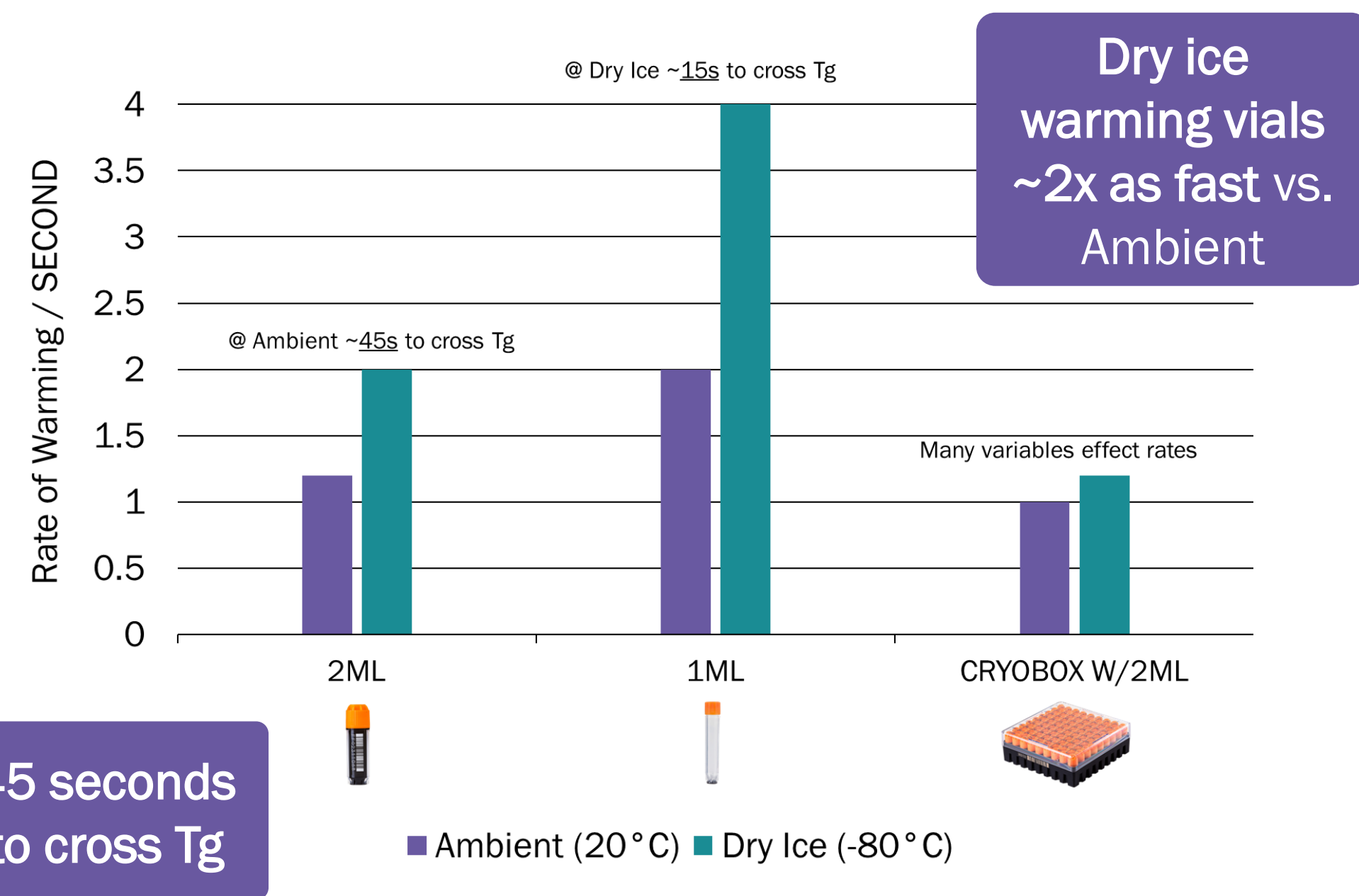


# Transient warming and Sample Viability

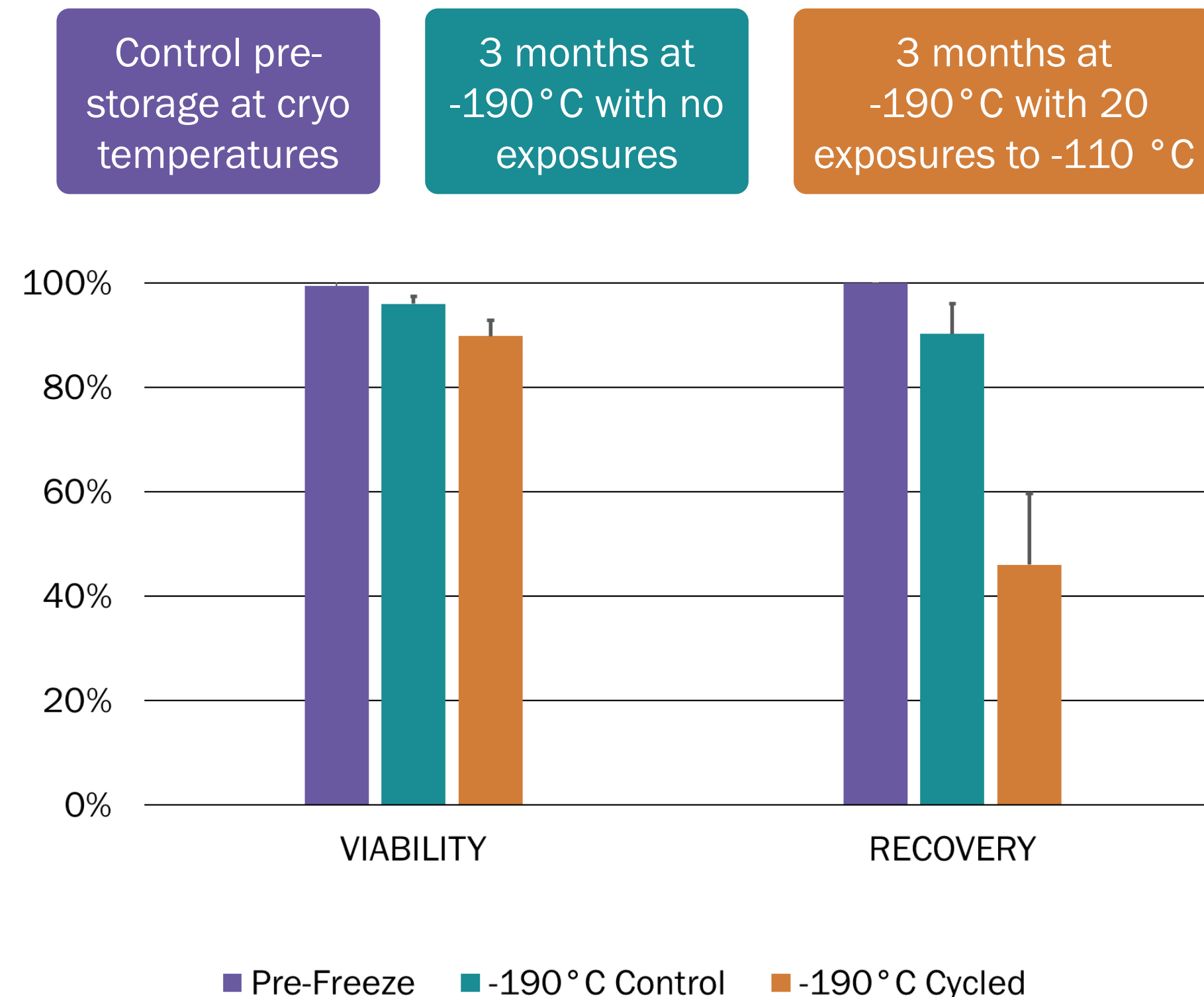
## A BREIF EXPOSURE OF CRYOPRESERVED PRODUCT TO TEMPERATURES ABOVE THE CRITICAL STORAGE TEMPERATURE.

How quick do samples warm? How long is 'Transient'?

- Conduction and Convection








Viability and recovery of mesenchymal stem cells pre-freeze and post-thaw



# Cryo Product Industry Personas



	Biobank 	Discovery Lab 	Cell Line Distribution 	Manufacturer 	Hospital/Clinic 
<b>Typical Location</b>	<ul style="list-style-type: none"> <li>Research Hospitals</li> <li>Government supported research centres</li> <li>Large Pharmaceutical research biobank</li> </ul>	<ul style="list-style-type: none"> <li>BioPharma Discovery Research environment</li> </ul>	<ul style="list-style-type: none"> <li>Laboratory functioning as a stand-alone business or integrated within a research organisation.</li> </ul>	<ul style="list-style-type: none"> <li>Large Biopharma</li> <li>Contract development and manufacturing organisations (CDMOs)</li> </ul>	<ul style="list-style-type: none"> <li>Cell lab facility supported by a Hospital or Clinic.</li> </ul>
<b>Primary Responsibility</b>	<ul style="list-style-type: none"> <li>Support the collection, annotation, storage, retrieval and distribution of research specimens</li> </ul>	<ul style="list-style-type: none"> <li>Discovery and research into new cellular therapies and treatments</li> </ul>	<ul style="list-style-type: none"> <li>Maintain inventory of high-quality cell lines used for research</li> </ul>	<ul style="list-style-type: none"> <li>Receive cells, manufacture autologous therapies or manufacturing allogeneic therapies from multiple cell sources.</li> </ul>	<ul style="list-style-type: none"> <li>Commercial products received from manufacturer which will be maintained by staff until handover for patient infusion</li> </ul>
<b>Challenges</b>	<ul style="list-style-type: none"> <li>Supporting a wide range of labware</li> <li>Documentation requirements</li> <li>Upkeep and maintenance cost</li> <li>Academia – Budget constrictions</li> <li>Pharma – Untrained scientists unnecessary interaction with cryo storage</li> </ul>	<ul style="list-style-type: none"> <li>Training requirements</li> <li>Multiple users within a common infrastructure with shared freezers</li> <li>Inventory management</li> </ul>	<ul style="list-style-type: none"> <li>Sample tracking capability</li> <li>Cell viability during processing</li> <li>Consistent and delicate handling of cells to maximise viability and quality</li> </ul>	<ul style="list-style-type: none"> <li>Scaling the system to meet future demands</li> <li>Manual paper inventory records</li> <li>Documentation and reporting challenges</li> </ul>	<ul style="list-style-type: none"> <li>Co-ordination of multiple staff members to ensure highest quality sample delivery to patients</li> <li>Maintaining cold chain of custody, condition and identity</li> </ul>
<b>Cryogenic Storage Value Proposition</b>	<ul style="list-style-type: none"> <li>Labware agnostic</li> <li>Environmental monitoring and automatic data recording</li> <li>Lowest cost of operation</li> </ul>	<ul style="list-style-type: none"> <li>User friendly user interface</li> <li>Permission and user access capability</li> </ul>	<ul style="list-style-type: none"> <li>Temperature Uniformity throughout storage chamber</li> <li>-190C top temp provides plenty of safety margin</li> </ul>	<ul style="list-style-type: none"> <li>Expansion larger inventory tracking can provide with FreezerPro LIMS</li> <li>Increase capacity without taking up more space</li> <li>Automatic environmental monitoring reports through web page</li> </ul>	<ul style="list-style-type: none"> <li>Diverse automation and supporting portfolio designed to provide optimal cold chain management</li> <li>Tracking of samples in and out of freezer with reporting option (21-CFR-Part 11 compliant)</li> </ul>

**SAMPLE QUALITY | REGULATORY COMPLIANCE | USER SAFETY**

# COMPETITIVE ANALYSIS

Automated Portfolio

02



# Competitive Analysis

## Custom Biogenic Systems (BioLife)

### Product Highlights

- Novel Technology with LN2 Jacket
- Large Opening provides easy view of inventory system
- Wide range of product sizes for many applications

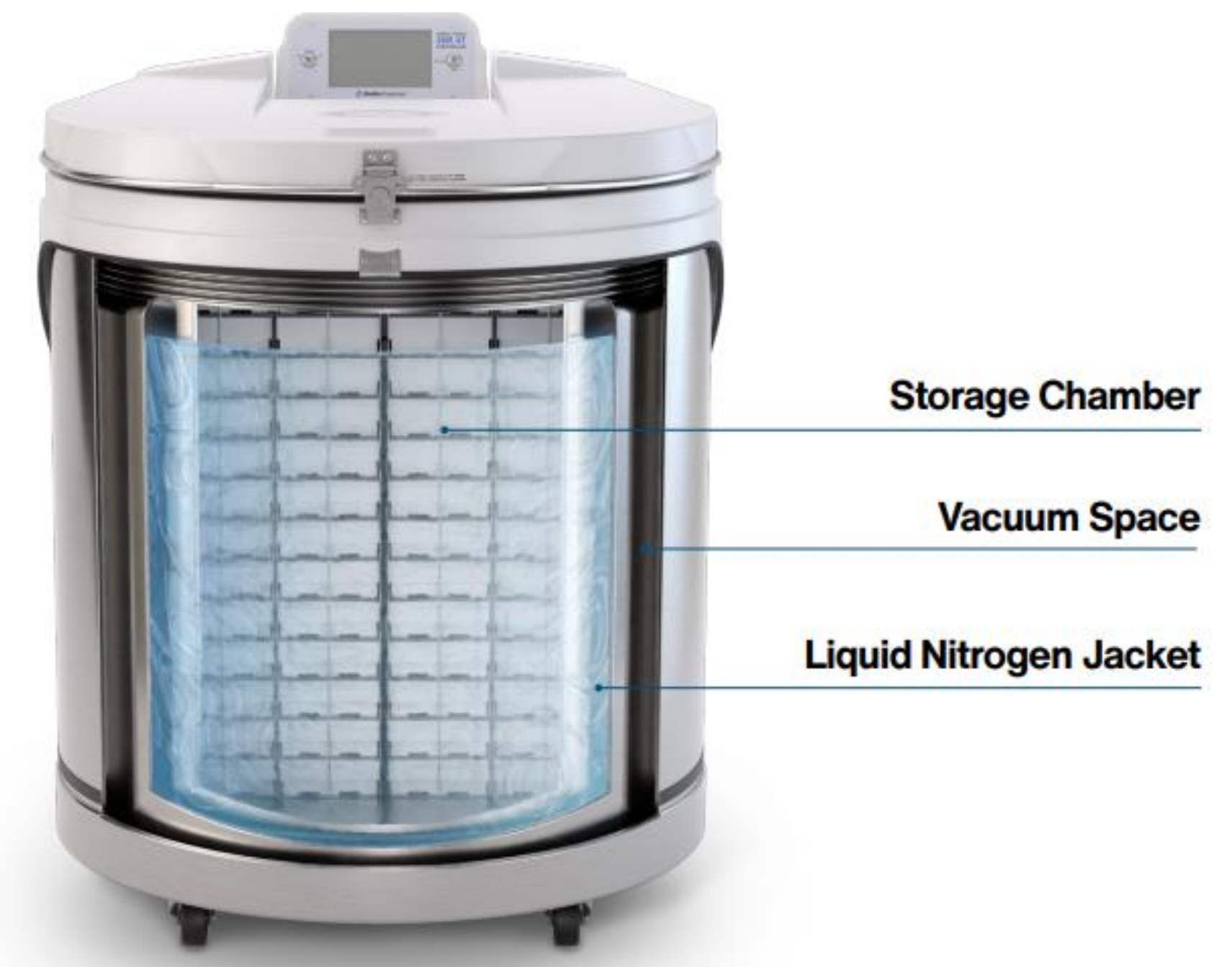
### Company Highlights

- Complete product line from freezing, shipping, storage
- Excellent Penetration into Hospitals, Transplant Labs
- Currently for sale/sale pending

### Cons:

- Poor temperature performance/stability
- Sub optimal ergonomics and storage density
- Low tech controls and monitoring system

## Isothermal Series



# Competitive Analysis

## MVE (Cryoport)

### Product Highlights

- High Efficiency and Thermal Stability
- Large product portfolio (Freezing and Transport)
- High product quality and reliability

### Company Highlights

- Market and Brand Recognition
- Global distribution thru equipment dealers and gas suppliers

### Cons:

- Older designs and controls
- Poor visibility and sub optimal ergonomics
- No remote monitoring/web based connectivity

## MVE HEco Series



# Competitive Analysis

## IC Biomedical (formerly Taylor Wharton)

### Product Highlights

- Most modern design with valuable features
- Motorized Turn Tray
- Internal Light
- Complete product portfolio

### Company Highlights

- New state of the art manufacturing facility
- PE owned, currently seeking sale

### Cons:

- Motorized turn tray adds significant cost
- Web based monitoring / Text and Email alerts require subscription additional cost

## Revolution Series



# CASE STUDY

# 03

# Barnes Jewish Hospital Cancer Center



## Background:

- Cancer center specializes in Childhood Cancer Treatment
- First transplants took place in late 1970's
- Located in Central USA (St. Louis, MO)
- Typically process ~300 transplants per year
  - (about 1500 250ml cassettes per year)
- Bone Marrow repository contained 30 CBS Isotherm V5000 Freezers
- Facility is centrally located within building, expansion not possible

## Problem:

- Needed to increase capacity without moving walls!
- Resolve ergonomic and workflow issues



# Barnes Jewish Hospital Cancer Center



## Capacity

- Increase capacity and reduce footprint
- Significantly better storage density with all samples in vapor

## Performance / Efficiency

- Significantly reduce LN2 usage
- -190°C vapor storage temperature
- 25 day hold time below -135°C
- Temperature does not fluctuate with LN2 level or lid openings

## Ergonomics / Workflow

- Auto fog clear and cryo LED provide full sample visibility
- Reduced lift over and user reach
- Sufficient workspace to maintain cold chain
- Lid access control / chain of custody

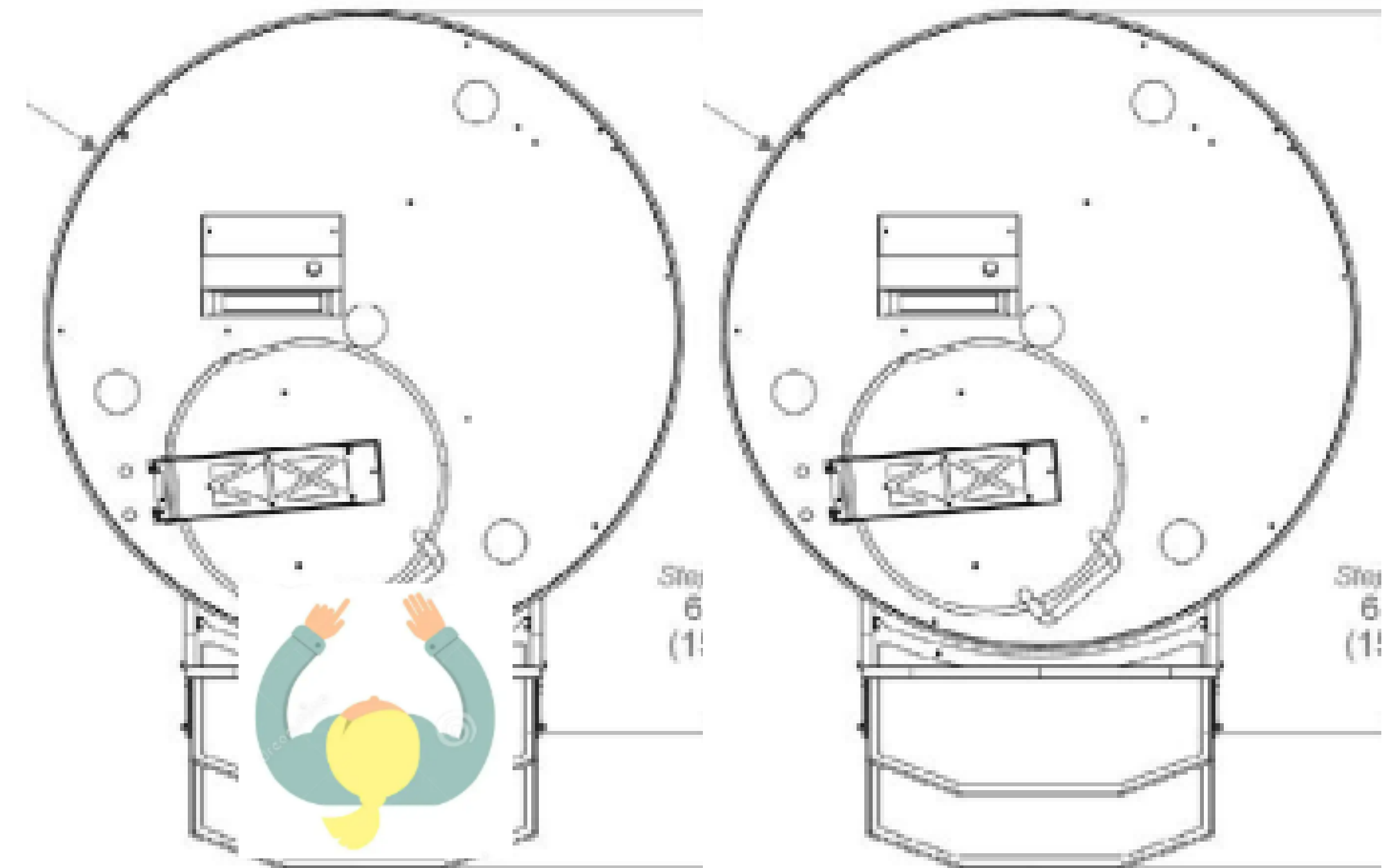
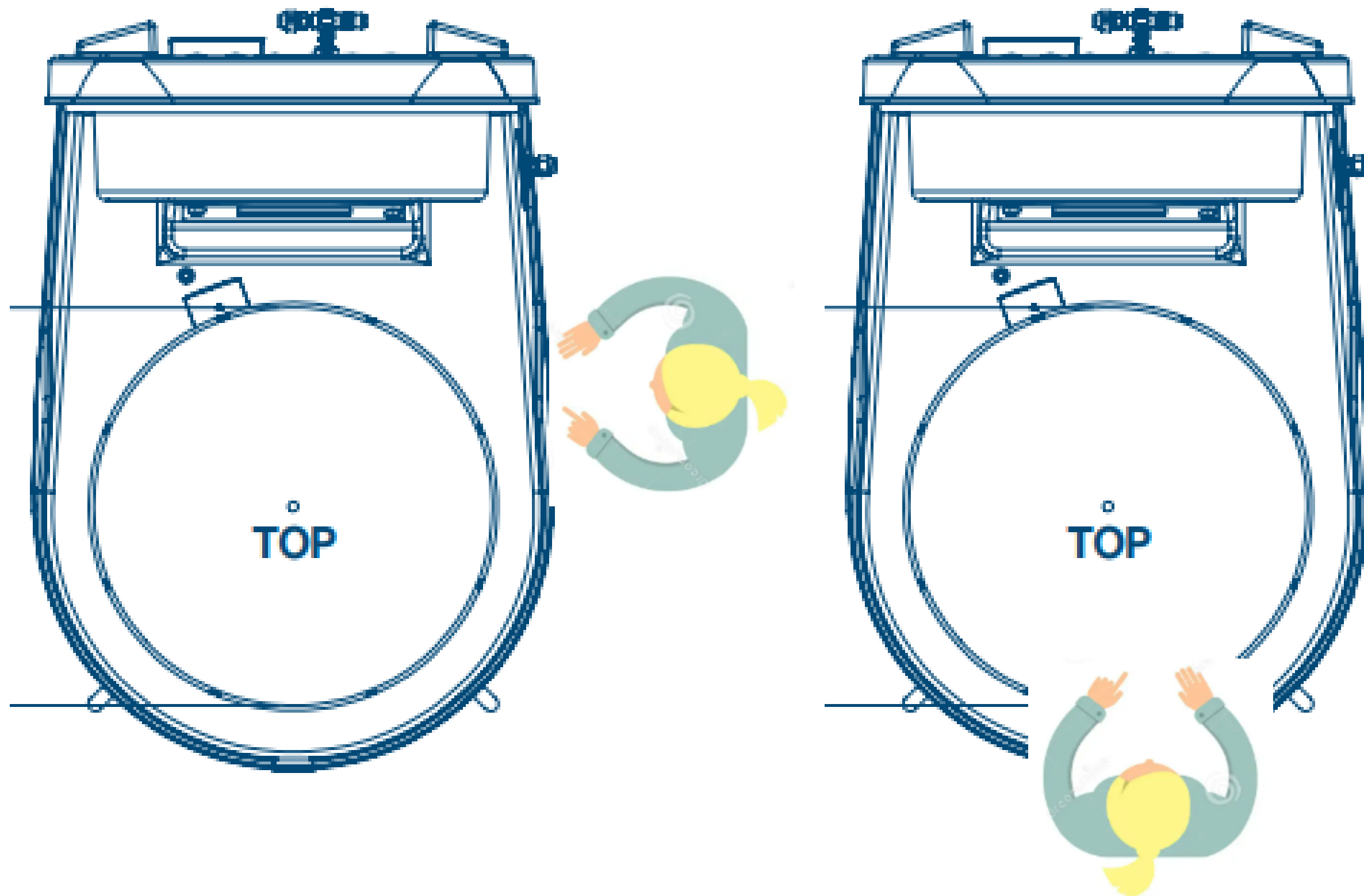
## Connectivity

- Built-in WiFi/LAN
- Text and email alerts
- Cloud backup / redundant remote monitoring



	CBS V5000	Azenta A700	
750ml bags	608	848	
250ml bags	912	1376	50% inc
50ml bags	1936	3080	
Ext Dims	119cm X 137cm	140cm	
Storage Density	559 bags/m2	894 bags/m2	59% inc
Liftover Height	270cm	86cm	>200% dec
Max Reach	112cm	59cm	90% dec

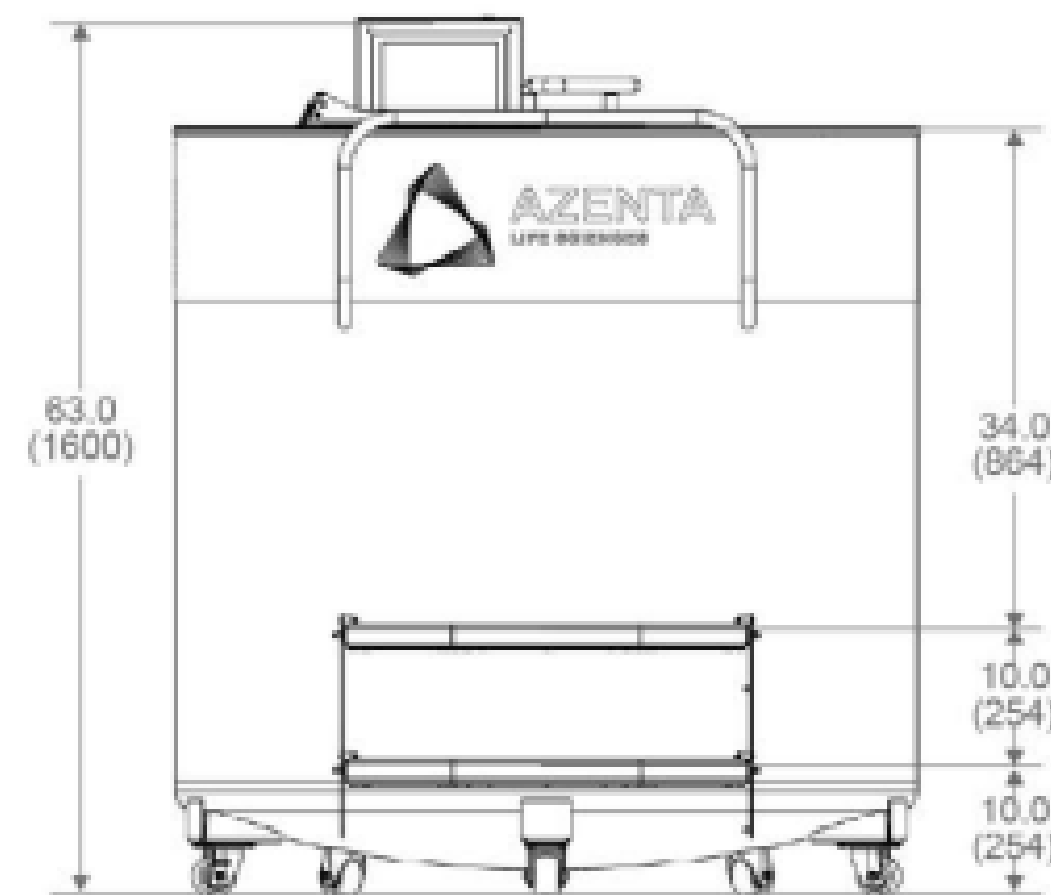
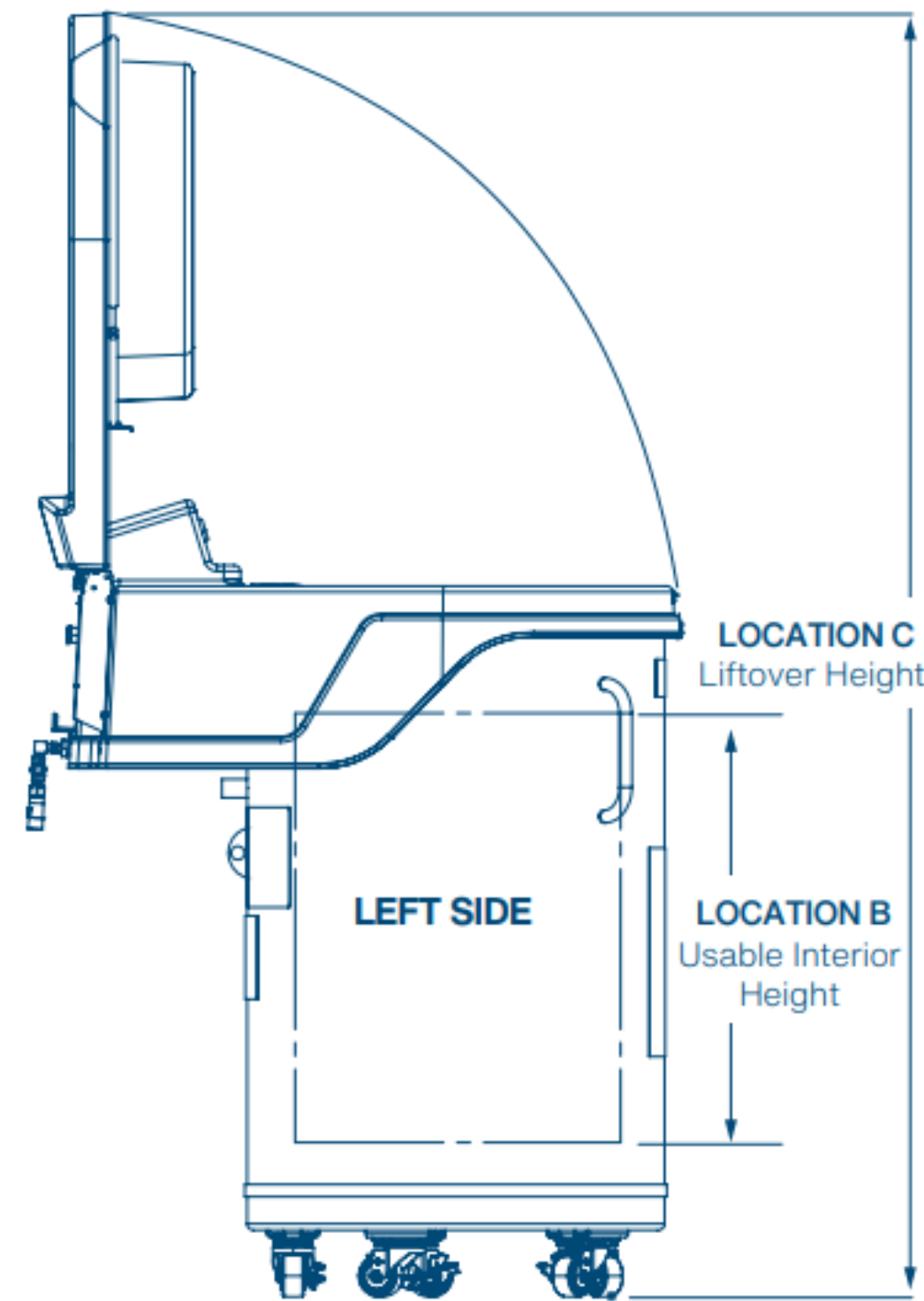
# Barnes Jewish Hospital Cancer Center



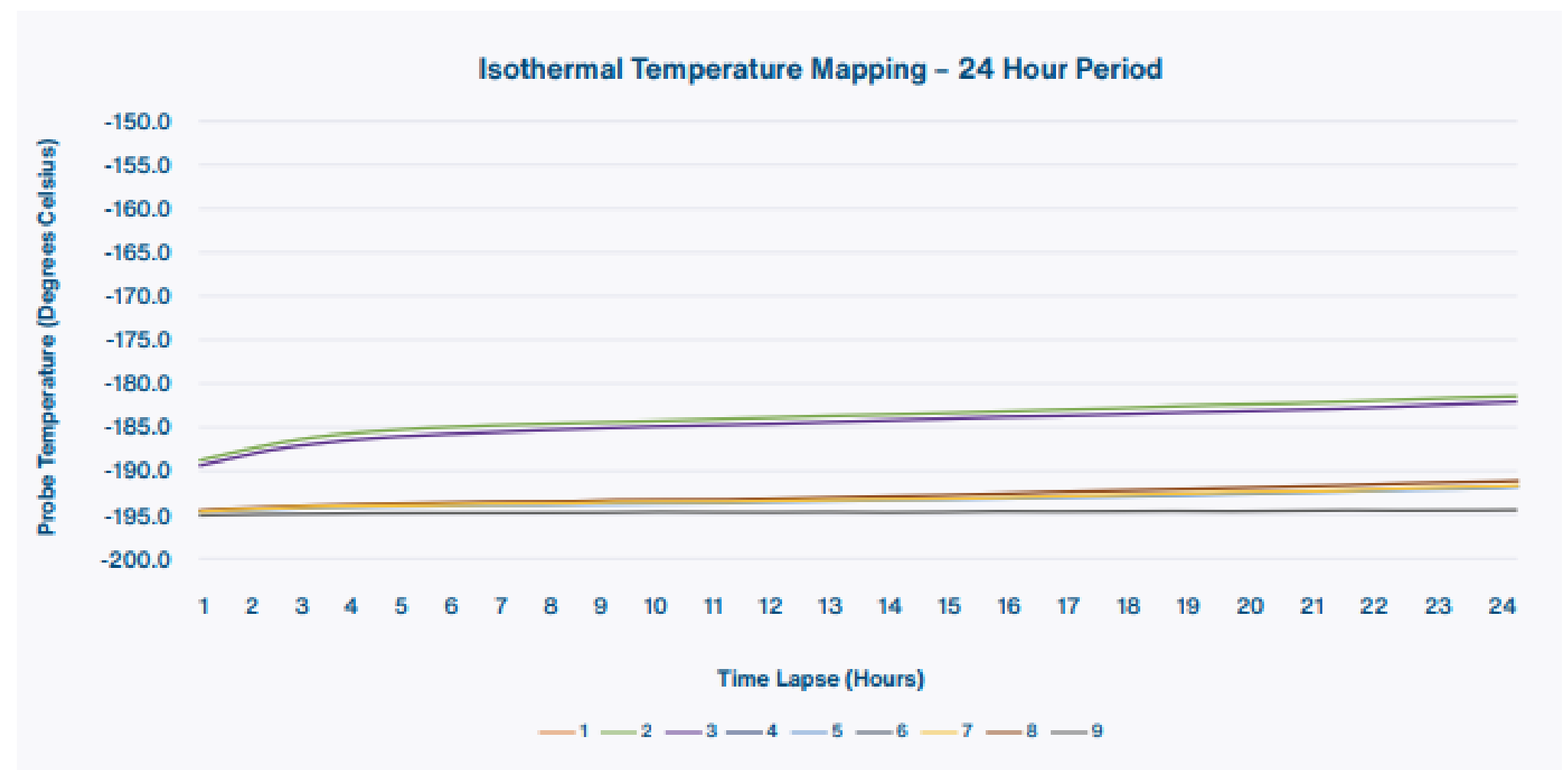
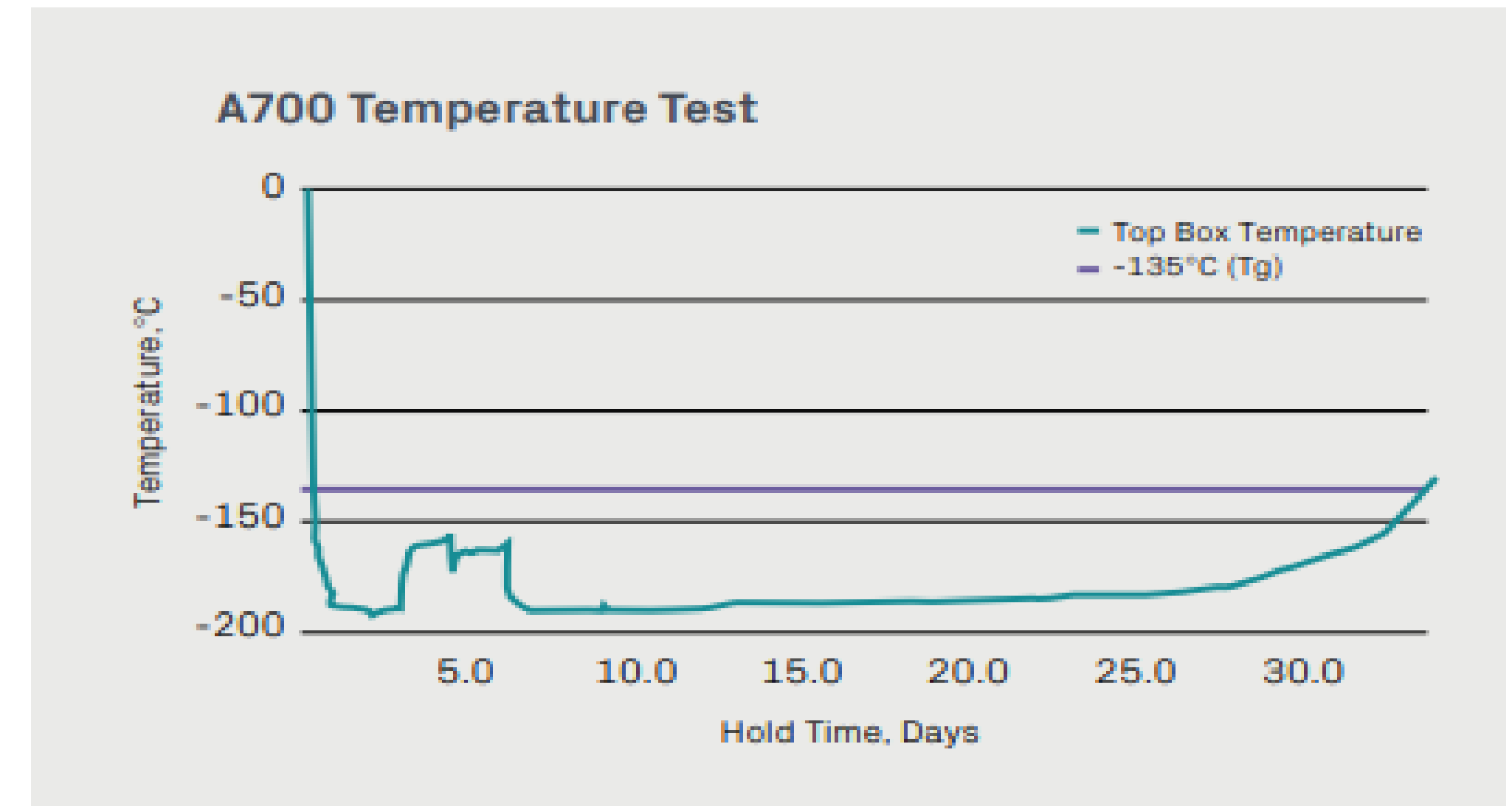
- In order to access frames and cassettes, users must utilize a 2-step rolling ladder
- To access frame toward the back, user must move ladder between units

- Built in two tier folding steps eliminate need for ladder
- Turn tray allows access to entire collection
- Freezers can be moved closer together allowing for more facility capacity

# Barnes Jewish Hospital Cancer Center



- Open top freezers require space on sides and large ceiling height
- Large opening leads to poor temp stability with lid open





# Barnes Jewish Hospital Cancer Center

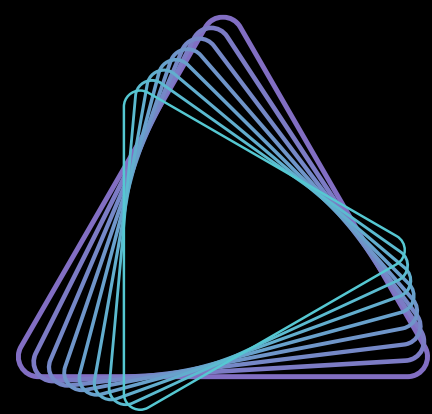


## Summary:

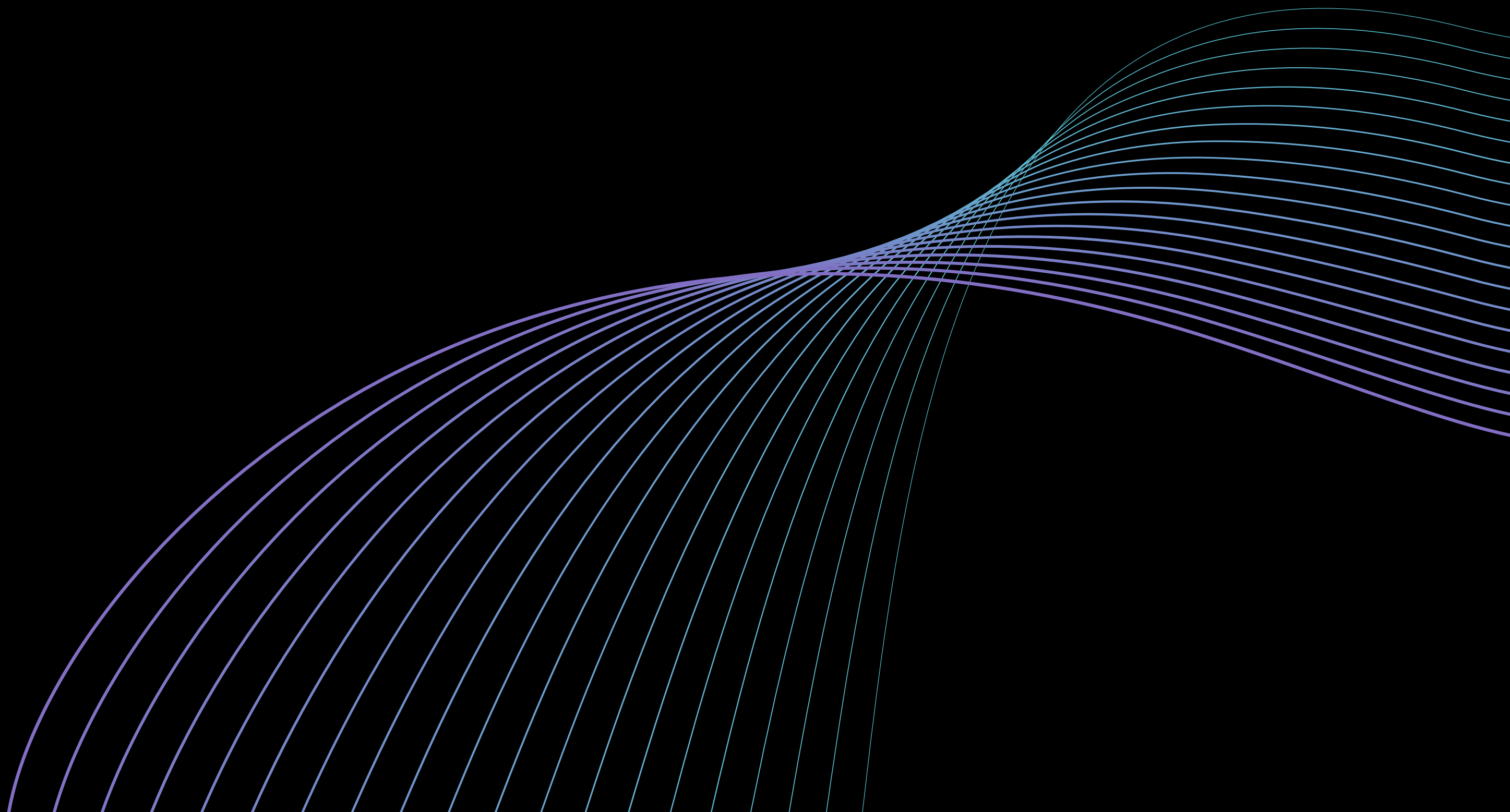
- Stem cell transplant center out of space and could not expand
- Technicians complained about ergonomics and ease of use
- Utilized our storage density and design to increase capacity
  - More bags per square foot
  - More freezers in same facility
  - Nearly doubled capacity without any facility improvements!
- Temperature uniformity potentially produces better outcomes
- Remote monitoring gives PI piece of mind!



Thank you



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# APPENDIX

05

# References



1. John Fink et al, "The Effects of Common Transient Warming Events on Post Thaw Recovery and Viability: Of Human Mesenchymal Stem Cells Stored in -190 °C & -80 °C Environments," 2017, <https://www.azenta.com/resources/effects-common-transient-warming-events-post-thaw-recovery-and-viability-human>.
2. European Medicines Agency Inspection, "Good Manufacturing Practice: An analysis of regulatory inspection findings in the centralised procedure," January 18, 2007, [https://www.ema.europa.eu/en/documents/other/good-manufacturing-practice-analysis-regulatory-inspection-findings-centralised-procedure\\_en.pdf](https://www.ema.europa.eu/en/documents/other/good-manufacturing-practice-analysis-regulatory-inspection-findings-centralised-procedure_en.pdf).
3. "Estimated Costs of Occupational Injuries and Illnesses and Estimated Impact on a Company's Profitability Worksheet," Occupational Safety and Health Administration, accessed December 6, 2023, <https://www.osha.gov/safetypays/estimator>.

# Manual Freezer Solutions

## HIGH EFFICIENCY (HE) FREEZER PRODUCT LINE

### Improved ergonomics

- Cryo LED and Auto Fog Clear
- Full Sample Visibility
- Low lift over height

### Increased capacity

- Highest Storage density
- Optimized footprint
- Lowest LN2 usage per sample

### Sample exposure to harmful transient warming events

- 1,000+ innocent samples per rack
- Searching for sample increases time out of freezer

### Less efficient operation

### Variability in documentation and tracking

### Risk of injury

### Stay connected

- Touchscreen with WiFi/ LAN
- Text & Email alerts
- Remote Monitoring



# Product Pricing



## CryoStore **PICO (A32)**

Cryobox format pricing:  
**\$150,000.00**



## CryoStore **A45**

Cryo-critical Cryobox format pricing:  
**\$167,000.00**

Tall door Cryo-Critical Cryobox format pricing:  
**\$177,000.00**



## CryoStore **M60**

Cryobox format pricing:  
**\$184,500.00**

SBS format pricing:  
**\$208,000.00**

Cryo-critical Cryobox format pricing:  
**\$205,000.00**

Cryo-critical cassette format pricing:  
**\$251,000.00**

Ultralow Cryobox format pricing:  
**\$210,500.00**

Ultralow SBS format pricing:  
**\$237,500.00**

Cryo-critical Ultralow Cryobox format pricing:  
**\$231,000.00**

# Appendix - FreezerPro

FreezerPro is a scalable, fast, reliable and secure Laboratory Information Management Software solution which enables users to know precisely where a laboratory sample is located even before opening the freezer door.

- Track all sample movement and sample information
- Create virtual freezers, customize to emulate the configuration of physical freezers down to box and vial level
- Quick and easy setup with intuitive user interface
- Dedicated menu for reports, providing tracking of all activities and a comprehensive audit trail
- Sample type customization with functionality to store specific metadata
- Easy search feature based on sample data by word or keyword
- Web-based solution providing access to sample information from anywhere in the world

