



**StableClimate®**  
**Stability Chambers**

# Chambers Built for Various Pharmaceutical/Medical Applications



- Pharmaceutical Packaging
- Nutraceuticals
- Drug Products & Substances
- Respirators
- Ventilators
- Inhalers
- Tissue Storage
- DNA Storage
- Environmental Samples
- Medical Electronics
- Catheters
- Adhesives
- Medical Generator
- Ultrasound Equipment
- Defibrillators
- Dialysis Machine Components
- Heart Stents



# Stability Chamber Markets Served

- **Stability Chambers May be Applied to Range of Markets with a Variety of Applications**
  - Consumer
  - Industrial R&D and Test
  - Electronics
  - Automotive
  - Aerospace
  - Pharmaceutical & Biotechnology
    - Drug Stability and Shelf Life Testing  
(meets the ICH & FDA Guidelines for Stability Testing)



# Stability Chamber Approvals



## Stability Chamber Standard Models

- Global Voltages and Agency Approvals: **UL/CUL and CE**
- Designed to meet ICH Q1A Guideline for stability testing

2.1.7.1 & 2.2.7.1	Storage Conditions for Drug Substances or Products	General Case		
		Long Term	25 °C, ±2 °C/60% RH ±5% RH or 30 °C, ±2 °C/65% RH ±5% RH	12 months
		Intermediate	30 °C, ±2 °C/65% RH ±5% RH	6 months
		Accelerated	40 °C, ±2 °C/75% RH ±5% RH	6 months
2.1.7.2 & 2.2.7.4	Drug Substances or Products for Storage in a Refrigerator	Long Term	5 °C, ±3 °C	12 months
		Accelerated	25 °C, ±2 °C/60% RH ±5% RH	6 months
2.1.7.3 & 2.2.7.5	Drug Substances or Products for Storage in a Freezer	Long Term	-20 °C, ±5 °C	12 months
2.2.7.3	Drug products packaged in Semi-Permeable Containers	Long Term	25 °C, ±2 °C/40% RH ±5% RH or 30 °C, ±2 °C/35% RH ±5% RH	12 months
		Intermediate	30 °C, ±2 °C/65% RH ±5% RH	6 months

# StableClimate™ Stability Chambers

CSZ stability chambers are ideal for stability, shelf life, package testing and more. Meets ICH Q1A.

- One Door models are available in 24 or 33 cu. ft.
- Two door models are 52 cu. ft.
- Three door models are 80 cu. ft.
- IQ/OQ/PQ Validation Offered



### *Temperature Range:*

- Temperature Only Models: 4 °C to +70 °C
- Temperature/Humidity Models: 5 °C to +60 °C

### *Optional Humidity Range:*

- 10% to 95% RH

# Stability Chamber Models & Selection

- **Stability Chamber Standard Models**
  - Global Voltages and Agency Approvals
  - **UL/CUL and CE**
  - Meets ICH (International Conference on Harmonization) Guidelines for Temperature and Stability Controls
  - First few units - 2-4 weeks delivery, then will be 1-2 weeks delivery



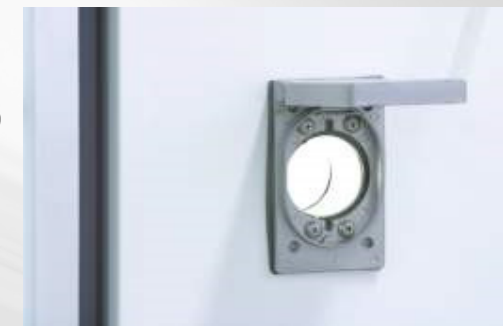
# Stability Chamber Cabinet Design

- **Cabinet Design & Construction**
  - Full Capacity Chamber Space Utilization, 24ft<sup>3</sup>, 33ft<sup>3</sup>, 52ft<sup>3</sup>, 80ft<sup>3</sup> Internal Volume
  - CFC Free Foam Insulation and Refrigerants
  - 3 Poly Coated Wire Rack Shelves per Door, Easily Removable and Adjustable
  - Heavy-gauge Stainless Steel Interior with interior floor drain
  - White Painted Steel Exterior with Solid Door
  - Full Peripheral Magnetic Door Gasket with Self Closing Hinges and Locking Door



# Stability Chamber Cabinet Design

- **Cabinet Design & Construction**
  - Air Distribution System Provides exceptional temperature uniformity
  - Full length door handles
  - Heavy Duty Casters
  - Optional:
    - 2” Access Ports with Covers (fixed location, special locations are custom and would not be UL)
    - Additional Shelves





# Stability Chamber Refrigeration

- **Refrigeration System**
  - Hermetically Sealed Compressor
  - CFC free, Non-toxic and Environmentally safe R134a Refrigerant
  - Coated Evaporator Coil
  - Proportionally Modulated Refrigeration Flow Precisely Controls Temperature
  - Expansion Valve Refrigeration Metering Provides Immediate Response to Added Heat Loads
  - Flush Mounted External Evaporator for 100% Useable Space



# Stability Chamber Humidity Control



- **Humidity Control System**
  - Highly Efficient Atomizing Humidifier Provides Rapid Response
  - Electronic Humidity Sensor
  - Full Humidity Range to 95% RH Obtainable Subject to Ambient and Chamber Temperature
  - High/Low Humidity Alarms
  - RO Water from .05-1 MegaOhm Resistance, 1/8" Male Pipe Thread for Water Supply
  - Easy Inlet and Drain Connections Includes Floor Drain with Silicon Drain Stopper
  - PLC Humidity Level Controls
  - Drain Hose Inside Cabinet- 1/2" ID 18"L
  - Water Usage per hour (estimated min. 0 to 3 lbs. per hr. with current humidifier)
  - Easy Installation, Low Maintenance

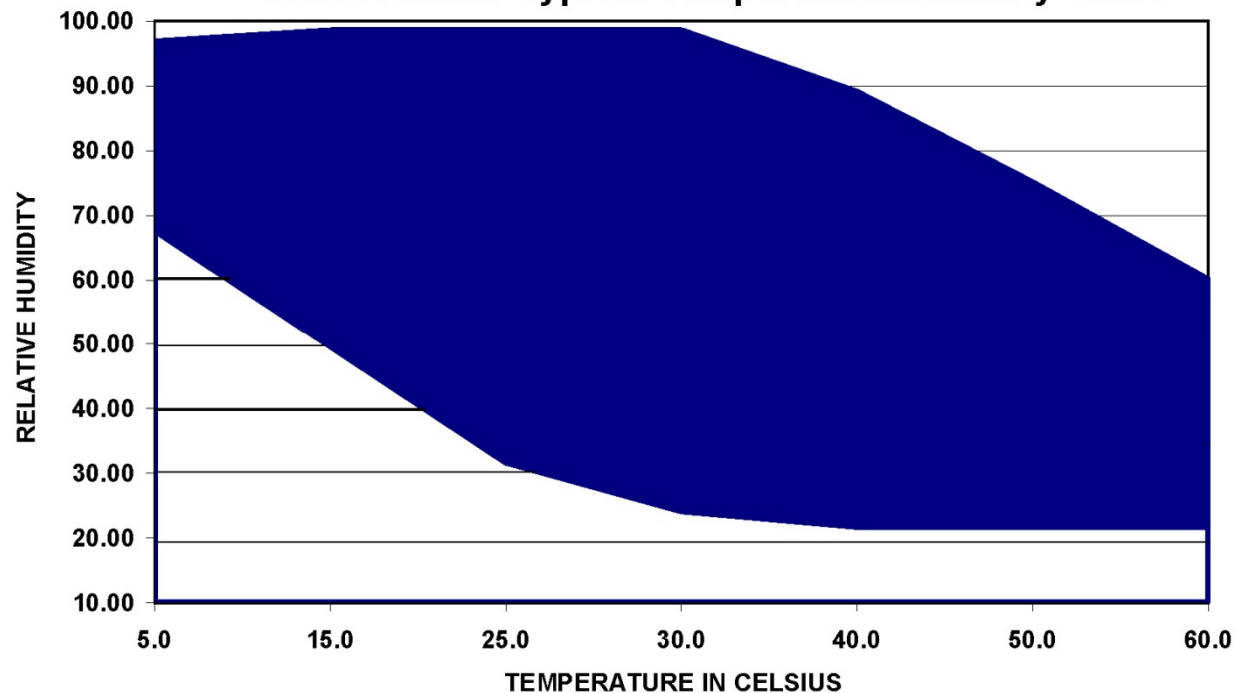
# Humidity Performance

## Humidity Range:

- 25% to 95% RH

Recommended water source reverse osmosis with resistance .5 to 1 MegaOhm Resistance, 1/8" Male Pipe Thread for Water Supply.

StableClimate Typical Temperature/Humidity Chart



# Stability Chamber PLC Control

## Stability Chamber PLC Control Advanced Microprocessor

- Fully Programmable Ramp Soak Functions
- 4x20 Character Liquid Crystal Alphanumeric Message Center
- Hi/Lo Audible and Visual Alarms with Remote Contacts
- Real Time Clock
- Precise Temperature and Humidity Control
- Optional Temperature & Humidity Recorder, RS485 Digital Communications, Duplex Electrical Outlets, Remote Monitoring Software



# Stability Options

## Alarms/Recorders/Electronics

- Chart recorder 6" Temperature (Factory Installed)
- Chart recorder 6" Two Pen Temperature & Humidity (Factory Installed)
- Live Duplex Outlet With Vapor Proof Cover (Factory Installed)
- 4-20MA Output (Factory Installed)
- RS-485 Communication Port (Factory Installed)
- Software Plant Visor (CD) (Requires RS485)

## Shelving/Drawers/Doors

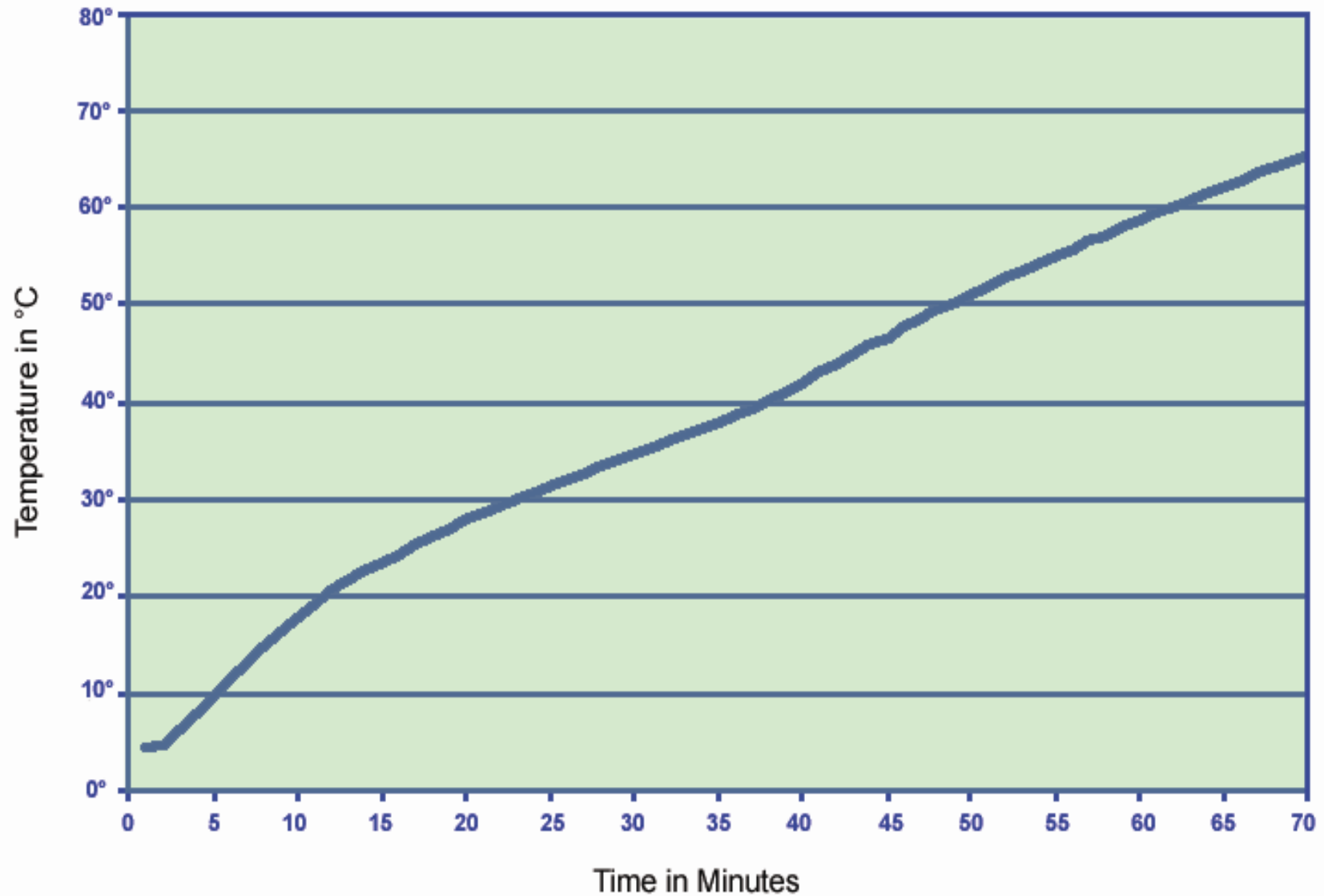
- (1) Standard Wire Shelf
- (1) 1/2 Size Stainless Steel Shelf
- Reverse Hinge door conversion (per door)

## Miscellaneous

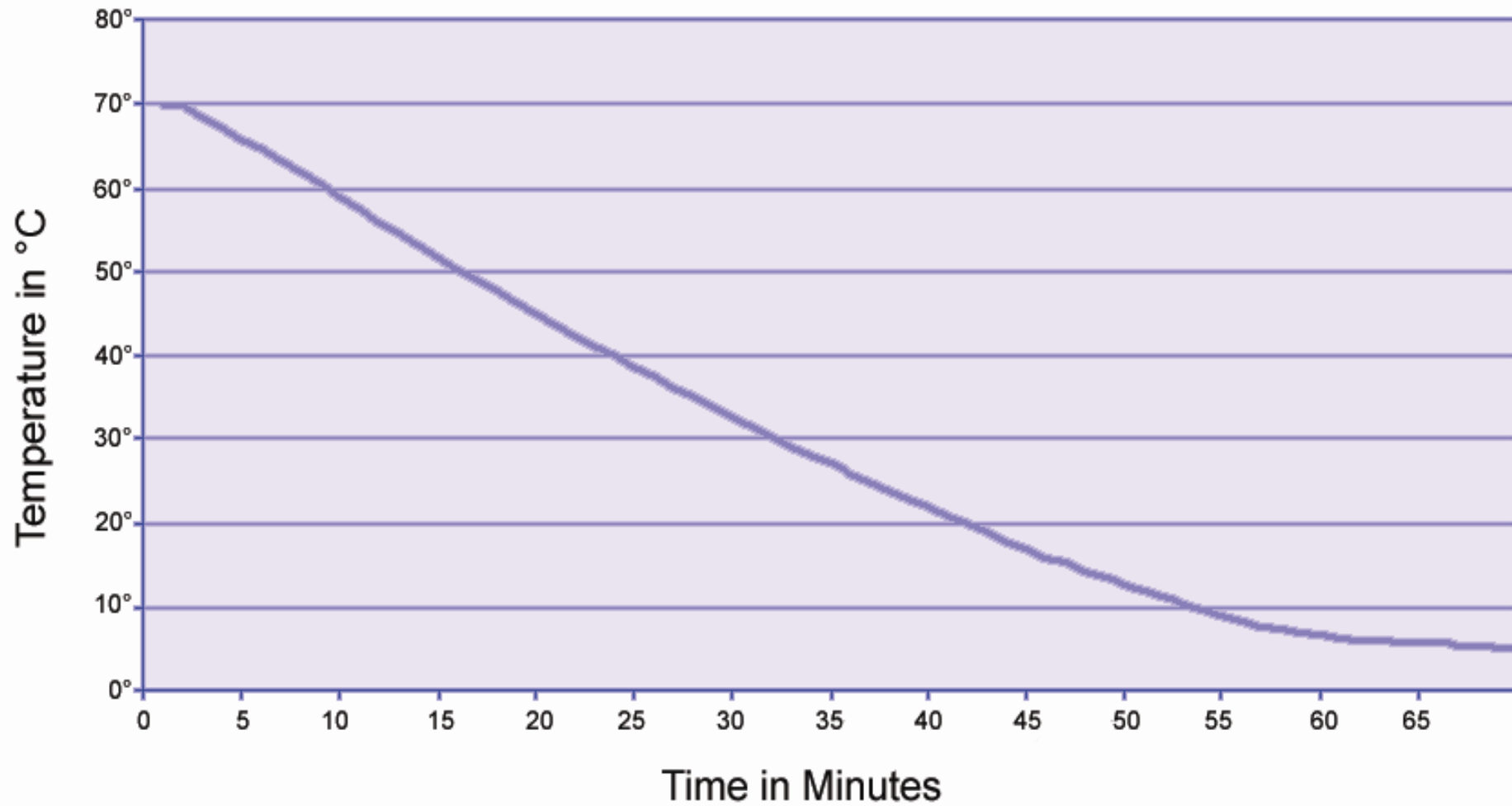
- Demineralizer humidity water filter
- RO System
- 2" Sleeve with Cover (Factory Installed)
- Stainless Exterior
- Validation Data Factory
- Export Crating



## Typical Temperature Heat-Up



## Typical Temperature Pull Down



# Stability Options

## Alarms/Recorders/Electronics

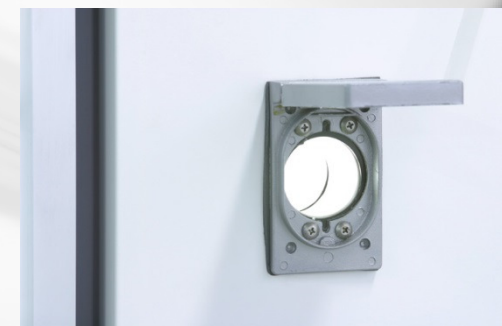
- Chart recorder 6" Temperature (Factory Installed)
- Chart recorder 6" Two Pen Temperature & Humidity (Factory Installed)
- Live Duplex Outlet With Vapor Proof Cover (Factory Installed)
- 4-20MA Output (Factory Installed)
- RS-485 Communication Port (Factory Installed)
- Software Plant Visor (CD) (Requires RS485)

## Shelving/Drawers/Doors

- (1) Standard Wire Shelf
- (1) 1/2 Size Stainless Steel Shelf
- Reverse Hinge door conversion (per door)

## Miscellaneous

- Demineralizer humidity water filter
- 2" Sleeve with Cover (Factory Installed)
- Stainless Exterior
- Validation Data Factory
- Export Crating





# Stability Chamber Service and Support

- **Service & Support**
  - Warranty 18 Months Parts and Labor, 5 Years Compressor, US & Canada
  - Warranty 18 Months Parts (International)
  - Service calls come into CSZ and forwarded to ISO.
  - In-house setup and testing for performance verification of temperature and humidity

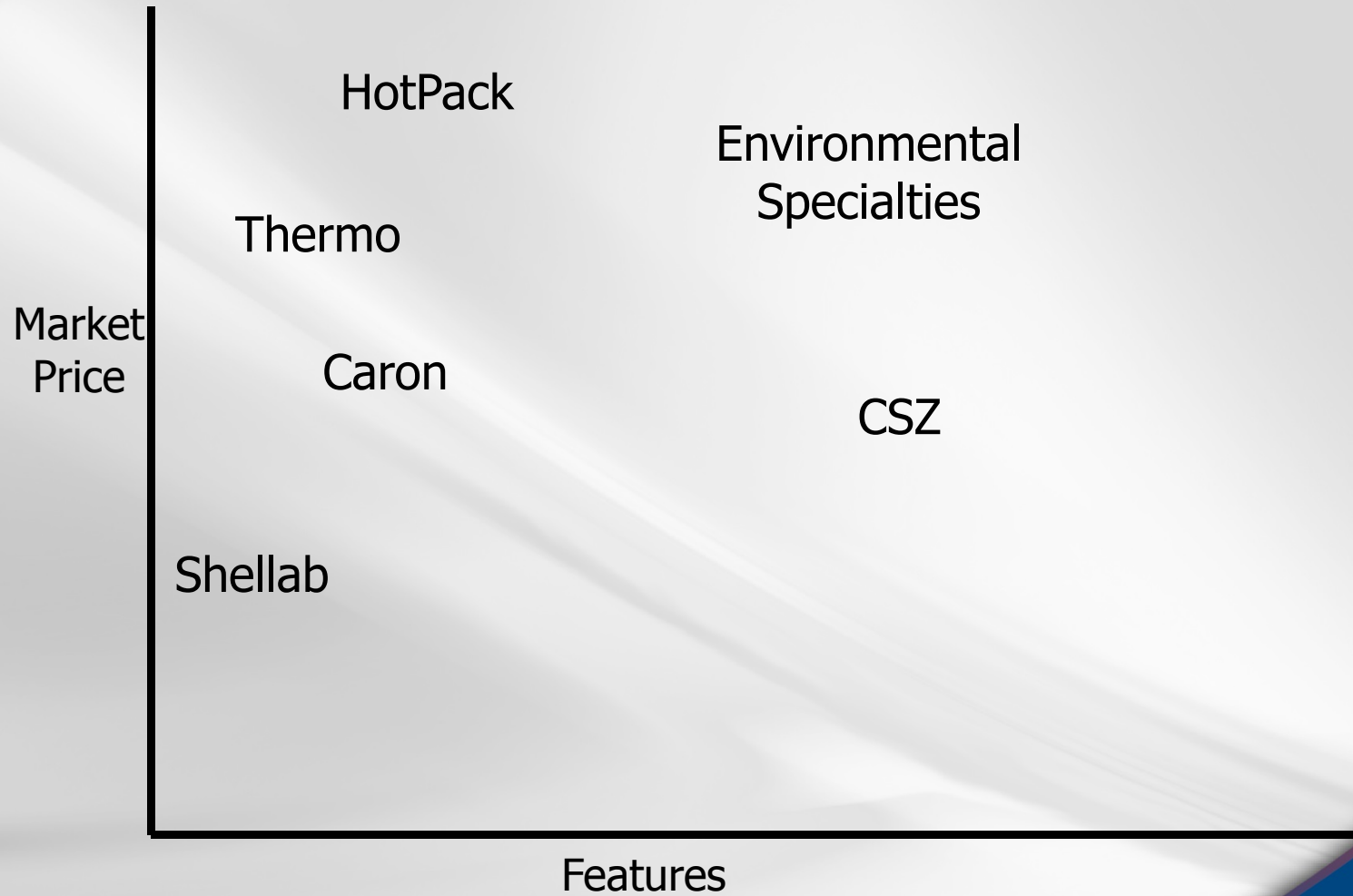
# Overview

- **Competitive Features & Unique Selling Points**
  - Model Selection & Variety
  - Installation and Start-up= Virtual Plug & Play
  - Exclusive PLC Proprietary Control
  - 100 Event Alarm Logging with Date/Time Stamp
  - Password Entry System
  - 18 Months Parts and Labor Warranty
  - Stock Availability of Standard Models
  - Service and Support
  - Value Price

# Competition

- Environmental Specialties
- Thermo
- Hotpack
- Caron
- Shellab
- Darwin

# Stability Chamber Competitive Landscape



## Humidity and Temperature Controlled Stability Chambers

