



Environmentally friendly stability Chamber powered by Meditech Technology for safe testing of specimens

**Meditech technologies India Pvt Ltd** manufactures the most innovative stability chamber series in humidity and temperature applications. These lines of stability chambers has both thermostatic (temperature only) versions and climatic (temperature humidity) versions.

Meditech has more than 25 years of knowledge , experience and expertise in the field along with feedbacks from both customers and distributors. Meditech is highly successful in producing rich features and highly reliable chambers to fulfill customers stability chamber testing needs.

With Meditech stability chamber series, one has the ability to apply the laws of nature temperature and humidity, and allow unknown possible product defects to reveal themselves. There shall be increase in reliability and robustness with every test performed on Meditech stability test Chambers



**Stability Tests** plays an important step in the development of new drugs and pharmaceutical substances. This is an indispensable element in the licensing process defined by federal regulating authorities. However, these tests are just as important for safeguarding the quality of the product within the framework of quality assurance of stability chamber

Together with the help of experts in the pharmacy industry and committees from the pharmaceutical industry and experts from the licensing authorities (such as the FDA) have developed the ICH Guidelines for the harmonization of stability tests. These guidelines define standardized storage and batch evaluation as well as the time sequence of the required analytic tests.

According to the ICH Guideline Q1AR2, stability tests have to be performed under defined climatic conditions in order to provide evidence of the stability of active substances.

MEDITECH offers a range of stability chambers to meet these regulatory requirements as well as stability testing requirements for other industry segments of Pharmacy, Drugs, tablets, Cosmetic, Food, Beverages, etc.

We offer a centralized solution across all ICH conditions of real-time, intermediate, accelerated & semi-permeable study conditions along with a state-of-the-art 21 CFR Part 11 ready software that provide tools for viewing, trending, alarm management, audit trails, MKT and many other such features in the form of stability chamber.



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### Stability Chambers

manufactures by Meditech as a result of intensive Research and Development along with years of experience involved in carrying out Stability Test and Shelf Life Test on drug and drug substances.

The Stability chambers are designed according to the ICH guidelines Q1 A (R2) ICH guidelines, WHO, MCA and USFDA requirements. They are superior in Air Flow Distribution, Temperature and Humidity Recovery, Controlled Technology.

### Cabinet Construction

Accuracy, Uniformity, Reliability and Economy. The chambers are manufactured as per the cGMP Regulations and designed for low electrical and water consumptions

### Low Energy And Low Water

Meditech Chambers are designed for low energy consumption for continues research works. CFC Free insulation material and world class energy efficient materials are used for construction.

Most preferred chambers for USFDA & UK-MHRA approvals. Low RH Chambers now available for conditions of 25°C / 40% RH, 40°C / 25% RH & 30°C / 35% RH

### Technical Data

Standard Model(S): Inside S.S.304 & Outside Galvannealed Powder Coated mild steel.

GMP Model(G): Inside S.S. 316 with mirror polish & outside with SS 304 matt buff.

Temp. Range /Accuracy: 20°C to 60°C /± 0.2°C

Temp Uniformity : ± 2°C

Humidity Range/Accu.: 40% to 95% RH /± 2% RH

Humidity Uniformity : ± 3% RH

### Construction Features

manufactured on fully automatic CNC machines thereby giving consistency in performance and an aesthetic look.

CFC Free PUF insulation on automatic machine for better accuracy of Temperature and Humidity .

Chambers are provided with effective air circulation system, refrigeration system, humidity system, full view observation glass door, chamber illumination and stainless steel perforated trays.

Stand by refrigeration system and stand by humidity system is provided on request

### Safety Features

Stability Chamber is provided with safety cut offs and alarms at centrally located places.

Dedicated Safety system to shut off the humidity system and chamber shut down in case of overshoot or undershoot of temperature or humidity with audio visual alarm.

Thermostatic safety system is provided as an additional safety feature.

Low water level cut off for humidity system.

Door open alarm.

All the alarms and events are logged in the software.

### Software

- 21 CFR part 11 USFDA compliant software with validation documents.
- Secured audit Trail.
- Multi level security password with aging and history.
- Electronic signature.
- Web based (Ethernet) online remote monitoring
- GSM alarm system (mobile alert)
- Data of door access security system in software with remote options.
- All the events, utility, working status, all the alarms are logged in the software.
- Records in graphical and in tabular form.
- Reports of mean Kinetic Temperature Reading.
- Works on 230V AC single phase 50Hz (country specific).
- Complete with extensive DQ, IQ, OQ and PQ protocols as per the International guidelines along with calibration certificates.

### Control Features

Microprocessor-based 4 inch Touch Screen PID controller with auto tuning for accurate control of temperature and humidity conditions and printer interface facility to store data and to print it directly on a printer.

Direct % RH electronic capacitor type humidity sensor.

Online connection of Touch screen to Computer via Ethernet using TCP IP Protocol for online mapping purpose and data logging.

A PLC system for an auto changeover of standby systems and other event logging and monitoring purpose.

GSM mobile alert module to give malfunction SMS on mobiles simultaneously.

Door Access Security System with smart cards / bio-metrics

An Advance PLC system with touch screen display with all the above features incorporated. Network connectivity via Ethernet for web based online remote monitoring.

Utility management system provided for continuous machines operations and cross checks.

### Ultrasonic Humidifier – On Demand

Meditech's patented ultrasonic humidifier **MHumid®** maintains accurate humidity inside the chamber. Within few seconds the humidity is maintained inside the chamber unlike conventional steam heating system. **95% more efficient than steam heating . Thus saving 95% of electricity**

## Web Based Software (SAIFIN53) - Remote Chamber and Room Management

### Access Anywhere Anytime!! Around the Globe

#### Instantly connect and control your Chambers and Rooms without installing software

For more than a decade, Meditech SAIFIN53 software has gained popularity among operators and end users for its reliability and ease. SAIFIN53 is available remotely via a web browser using internet facility. SAIFIN53 is designed to meet the increasing demands for improved efficiencies. This web based software also adds extra capabilities of data logging, user-configuration and features of all alarm notifications via SMS and Email.

#### Features

- Eliminate the need for multiple software installations and Qualifications
- Web based software accessible through browser
- Compatible with server-based OS, android, Windows-7/8/9/10
- Ensure one-time software installation on your plants server and access the software anytime, anywhere through a web browser from any Desktop/Laptop (same LAN Network)
- View Status, take printouts or execute any of your tasks from anywhere
- Department wise segregation of users, equipment & Data
- Harmonization of reporting format (header, footer, etc) and other such operations through the plant

Centralized user defined Alarms, alerts and Notifications through SMS & emails

Configure the type & no. of alarms to be sent via email/SMS & configure delay time too

Running time calculation of MKT and Moving Average Component running hours to determine the shelf-life of major components

Real-time display of all connected equipment in single screen

Automatic data backup facility

System Diagnosis for troubleshooting via Team Viewer

Ethernet communication with chambers

Complying US FDA 21 CFR Part 11

#### Key Features

- A Truly innovative data handling and communication options
- Plug and Play fashion via Ethernet to connect local or plant networked PC or Laptop
- One can view LIVE system parameters and historical graphs as well as receive alarms, reports, data log files over email
- Settings with just a standard browser
- Access live or stored data remotely within the facility (LAN network) or from anywhere in the world



**Secure audit trails**  
 -Audit protection  
 -Provide certified proof of process control

# FEATURES AND FUNCTIONS

## A REVOLUTIONARY MONITORING & ALARM SYSTEM



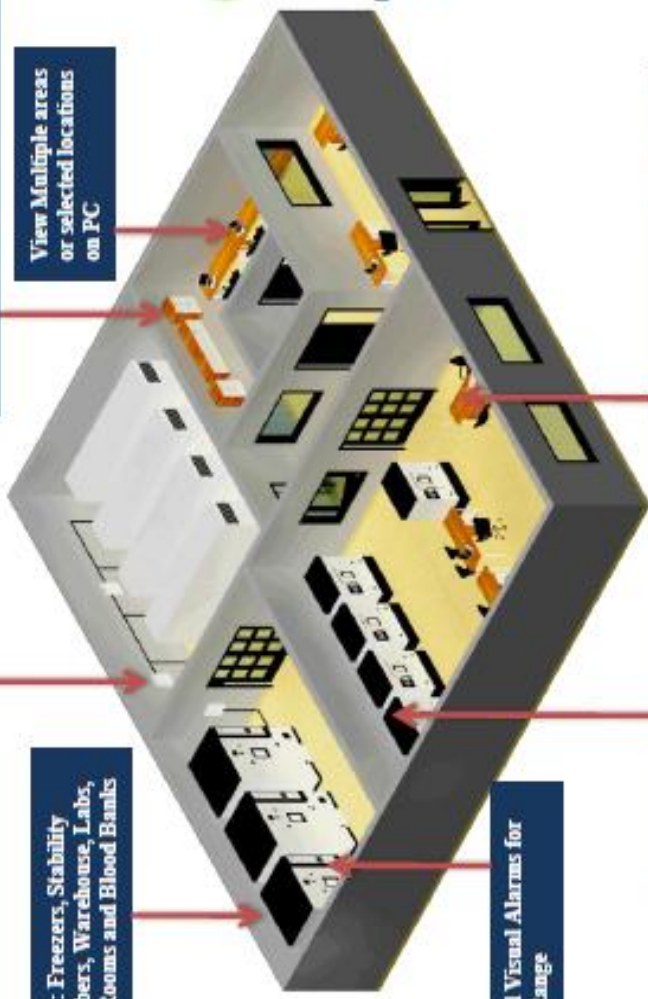
**Say No To Manual Recording**  
 -Error Free  
 -Separate signatures for data reviews & data approval  
 -No mistake in record maintaining  
 -Data analysis  
 -Tabular and graphical data representation

**Wireless Display with Humidity, Temperature CO2 Sensors for Visibility and audit**

**Record and alarm Temperature, Relative Humidity, Flow, Differential Pressure, CO2, O2, LN2, Status and Contacts**

**USES : Freezers, Stability Chambers, Warehouse Labs, Cold Rooms and Blood Banks**

**View Multiple areas or selected locations on PC**



**Audio and Visual Alarms for Settable Range**

**Compact size chart recorders and alarms system**

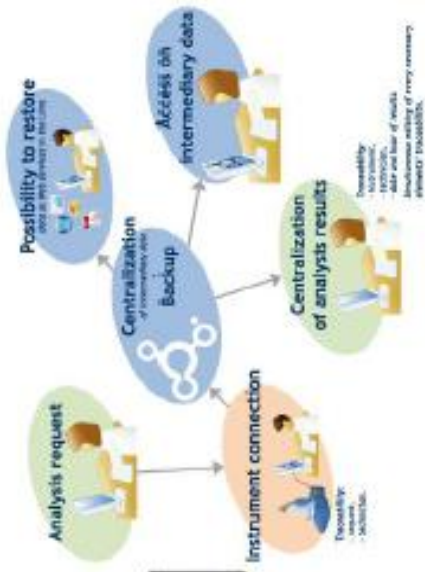
**Data recorders are easy to relocate and swap for service and calibration**



**View Data from Any part of the World**  
 -Browser base application software  
 -view from PC, smart phones and tablets



**Alarms**  
 Alarms for parameter deviation  
 SMS Alerts  
 Alarm log with acknowledgement and user comments  
 Email alerts for supervisor



**Traceability**  
 -Instant response to data request  
 -Continues Data saving  
 -Data Protection and backups



**Supervisor Function**  
 Alerts users for pending activity  
 Escalates unattended issues to higher authority



**Receive SMS and Email alarm notification**

# Stability Chamber

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### COLD ONLY

DIN 40046 Page 3, Test A  
IEC 68-2-1, Test A  
BS 2011, Part 2, Test A  
MIL-STD 810 D, Met.502.2  
MIL-E-5272, Test 4.2

### HOT ONLY

DIN 40046, Page 4, Test 3  
IEC 68-2-2, Test B  
BS 2011, Part 2, Test B  
MIL-STD 810 D, Met.501.2  
MIL-STD 883 C, Met.1008.2  
MIL-E 5272, Met.4.1  
MIL-STD 202 E, Met.108 A

### HOT/COLD

DIN 40046, Page 14, Test Nb  
IEC 68-2-14 Nb  
MIL-STD 311 A, Part 112.1

### VARIABLE CLIMATE

DIN/IEC 68-2-30 DB  
IEC 68-2-38  
MIL-STD 202 E, Met.106 D  
DIN 40046 Page 6 and 31  
IEC 68-2-4, Test D  
BS 2011, Part 2.1, Test Da  
MIL-STD 750 B, Met.1021.1  
DIN 40046 Page 101  
DIN 50016  
MIL-STD 311 A, Part .105.1  
MIL-STD 810, Met.507  
Proc.1-2-3

### CONSTANT CLIMATE

DIN 40046  
DIN 50014  
IEC 68-2-3, Test Ca  
MIL-STD 202 E, Met.103 B  
DIN/IEC 68-2-56

| Model  | W x D x H cm  | W x D x H cm   | Cu.ft | Liters | Trays |
|--------|---------------|----------------|-------|--------|-------|
| MTBBR1 | 45 x 45 x 60  | 65 x 114 x 130 | 4     | 120    | 2     |
| MTBBR2 | 60 x 60 x 60  | 76 x 121 x 130 | 8     | 200    | 2     |
| MTBBR3 | 60 x 60 x 90  | 76 x 121 x 165 | 12    | 324    | 3     |
| MTBBR4 | 60 x 60 x 125 | 76 x 121 x 199 | 16    | 450    | 4     |
| MTBBR5 | 60 x 80 x 125 | 76 x 141 x 199 | 21    | 600    | 5     |
| MTBBR6 | 80 x 80 x 125 | 96 x 141 x 199 | 28    | 800    | 5     |
| MTBBR7 | 80 x 80 x 155 | 96 x 141 x 225 | 34    | 1000   | 5     |
| MTBBR8 | 160x75x170    | 192x126x189    | 70    | 2000   | 8     |
| MTBBR9 | 190x80x200    | 224x131x219    | 105   | 3000   | 12    |

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## Screen Shots of Touch Screen Controller










ISO 9001:2008, ISO 14001, ISO 13485  
WHO-GMP & CE Certified Company

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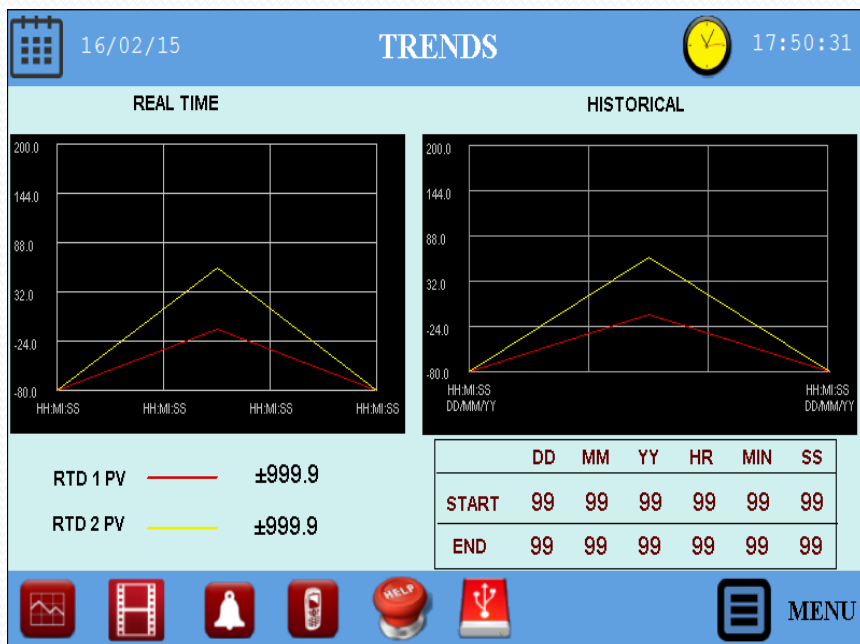
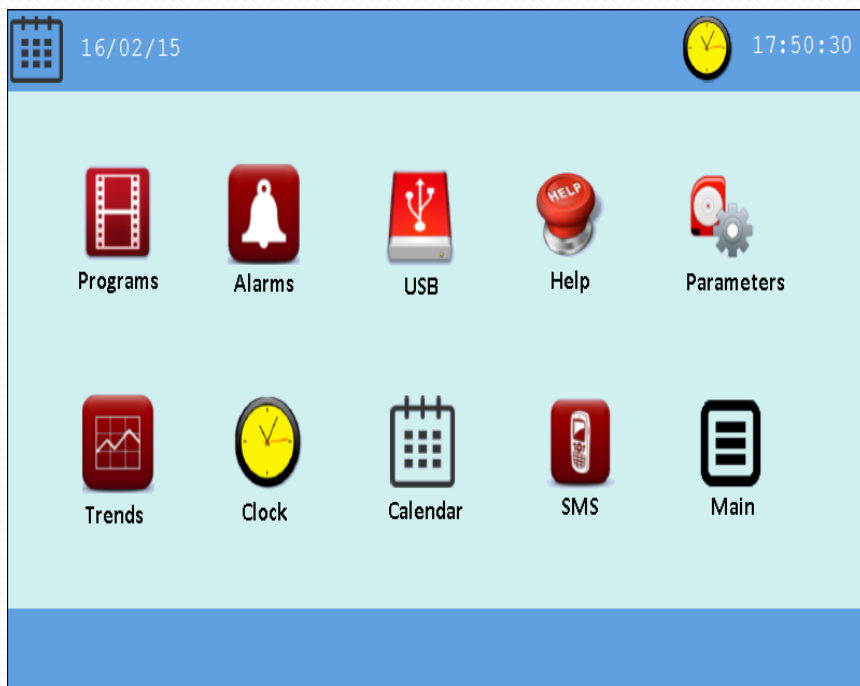
| 16/02/15       |         | PARAMETERS |             | 17:50:31 |      |
|----------------|---------|------------|-------------|----------|------|
| DESCRIPTION    | VALUE   | UNIT       | DESCRIPTION | VALUE    | UNIT |
| Heater On Time | ±99999  | Min        |             |          |      |
| Temp Set RTD1  | ±9999.9 | °C         |             |          |      |
| Temp Set RTD2  | ±9999.9 | °C         |             |          |      |
| Comp. Sel.     | Comp1   |            |             |          |      |
| Comp 1 Time    | ±9999.9 | Min        |             |          |      |
| Comp 2 Time    | ±9999.9 | Min        |             |          |      |
|                |         |            |             |          |      |



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