



photostability chamber



Environmentally friendly Temperature test Chambers powered by Meditech Technology for safe testing of specimens

Meditech technologies India Pvt Ltd manufactures the most innovative chamber series in humidity and temperature applications. These lines of 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 testing needs.

With Meditech 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 test Chambers

Technical Specification

Temp. Range : 20°C to 60°C

Temp. Accuracy : ± 0.2°C

Temp. Uniformity : ± 1°C

Humidity Range : 40% Rh to 90% Rh

Humidity Accuracy : + 2 % Rh

Humidity Uniformity : + 3 % Rh

Fluorescent tube for day light effect and UV tubes for Ultra Violet ray in accordance to the ICH guidelines requirement of a lightning energy mounting to 1.2 mil lux per hours and integrated UV energy share of 200 Watt Hours per meter square.

As per ICH guidelines :

At 25°C : RH = 60%

At 30°C : RH = 65%

At 40°C : RH = 75%

Photostability 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

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 test 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



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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**

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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
MTBBR6	60 x 80 x 125	76 x 141 x 199	21	600	5
MTBBR7	80 x 80 x 125	96 x 141 x 199	28	800	5
MTBBR8	80 x 80 x 155	96 x 141 x 225	34	1000	5
MTBBR9	160x75x170	192x126x189	70	2000	8
MTBBR10	190x80x200	224x131x219	105	3000	12



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



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

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

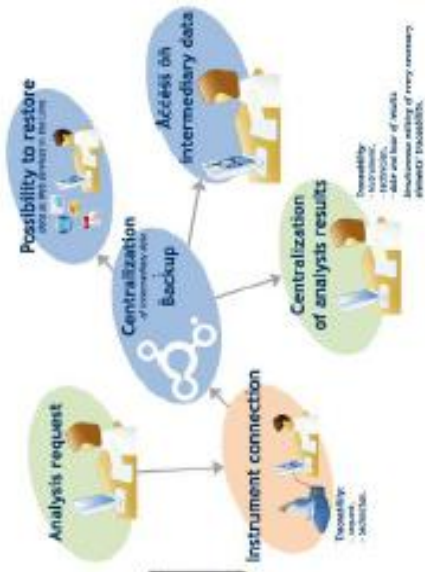
Audio and Visual Alarms for Settable Range

Compact size chart recorders and alarms system

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



Receive SMS and Email alarm notification



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

Humidity Chamber



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

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Screen Shots of Touch Screen Controller










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

Meditech Technologies India Pvt Ltd

No.6 President Terrace.Takli Road, Dwarka
Nashik – 422011, India
Tel No: 0253-6418632
info@newmeditech.com;huzafa@newmeditech.com

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			

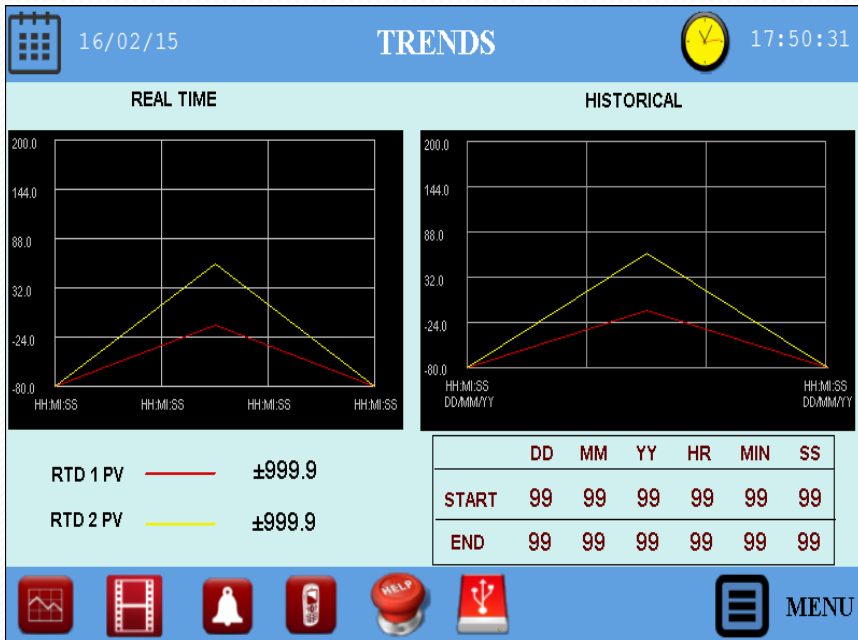
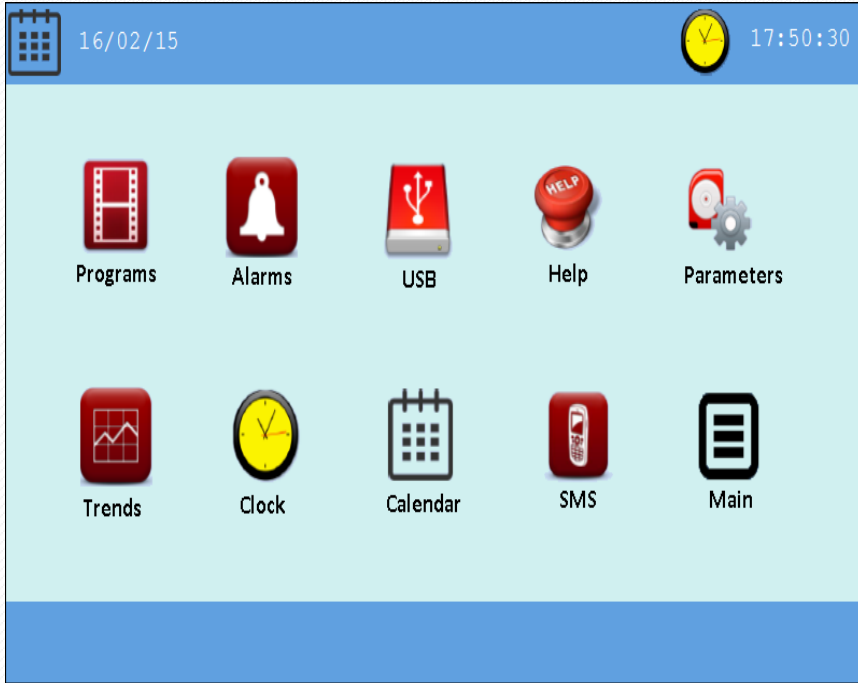








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Screen Shots of Touch Screen Controller



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