

General Information

WALK IN STABILITY CHAMBER

Manufacturer	Osworld Scientific Equipments Pvt. Ltd, Mumbai, India
Product	Walk In Stability Chamber
Brand	OSWORLD
HSN code	84198960
Model	OWISC-Advanced-Touch Screen-PLC(description refer to Annex.II).
Type	Unit assembled at site, available in knock-down conditions.
Application	Stability study meets ICH guidelines and USFDA requirements .
Certification / Registration	ISO 9001 : 2015 audited by BVQI
	GST: 27AABCO0610N1ZK
	SME: 27221200666
	IEC : 0308048806
	Calibration: ERTL Certificate

Product Highlights

Parts	Brand, COO	Salient Features
Stainless steel	Jindal, India.	LAN Connectivity.
Touch screen display (HMI)	Exor, Italy	Ethernet communication.
Program logic control (PLC)	Siemens, Germany	SQL Database.
Temperature sensor	Rotronic, Switzerland.	Licensed Software.
Humidity sensor	Rotronic, Switzerland.	SMS Alert, MKT, Audit Trail, Alarm Log

Key Specifications

For conditions as per ICH guidelines	25°C – 40% RH / 25°C – 60% RH / 30°C – 65%RH / 30°C – 75%RH / 40°C – 75%RH / 40°C – 25% RH / 30°C – 60%RH, any other acceptable conditions.
Temperature range / resolution	20.0°C to 60.0°C / 0.1°C
Temperature accuracy / uniformity	± 0.2°C / ± 2.0°C
Humidity range / resolution	20% to 90% RH / ±1%
Humidity accuracy / uniformity	± 2% RH / ± 3% RH

Technical Specifications

Construction	Modular type construction of PUF Panels and assembled on-site. PUF (Poly Urethane Foam), Density 40 ± 2Kg/m3 PUF blowing agent-Hydro Carbon CycloPentane (CFC/HCFC/HFC) Free). Working chamber made of Stainless steel 304 grade matt finish. Outer cabinet made of stainless steel 304 grade matt finish.
Door	Insulated door having lock and key arrangement and a viewing glass for sample view. View glass window dimension is 300 x 450mm Height.
PLC control. (for description refer to Annexure I)	PLC system made of Siemens, Germany. 7" HMI color touch screen display made of Exor, Italy. 4GB Data storage Password protected user management entries. Tamper proof non-editable audit trail. Set value programmable with date and time. When PC is connected data can be downloaded defining exact period.

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Cooling	CFC Free Copeland (USA) make compressor with R134A eco friendly refrigerant, with condenser, motor, relay complete unit.
Steam Injection	Steam generator bath with reservoir made of thick stainless steel with heater, water inlet control, low water level safeguard and insulation
Heating	U' Shaped Nichrome wire heater in SS sheathing
Temperature sensor	PT100 RTD Class 'A'.
Humidity sensor	Make ROTRONIC made in Switzerland, capacitance type. High reliability and long term stability. Calibrated within +2% RH @ 55% RH
Air circulation	Motorised blower with impeller.
Insulation	Poly Urethane Foam (PUF).
Chamber illumination	Fluorescent light with door switch for auto on/off.
Electrical	Single phase 230V / 50 Hz OR Three Phase 440 volts AC.

Safety Features

Temperature	High temperature safety cut off.
Boiler heater	Low water level steam generator cut off.
Compressor	Electrical overload cutoff relay for compressor. Time delay for compressor start.
Electrical	Short circuit protection

Calibration & Validation Documents

Calibration	Temperature sensor probe calibrated with traceability to ERTL Humidity sensor calibrated with traceability to ERTL Temperature controller calibrated with traceability to ERTL Humidity controller calibrated with traceability to ERTL
Validation Documents	Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ) documentation and protocols shall be provided with the equipment.

Utilities / Preinstallation Requirement

Power supply	Single phase 230V / 50 Hz OR Three Phase 440 volts AC.
Water	DM water continuous supply through pipeling with valve for boiler input of ½" BSP at 3 feet from ground level.
Drain	Water drain line with ½" nozzle to be provided at floor level.
Room Temperature	Room temperature around machine preferably at 25°C with air conditioning or a well ventilated room with exhaust fan. However surrounding temperature should not exceed 30°C.
Computer requirements	Windows-compatible computer with a standard keyboard, a pointer input (i.e., a mouse, trackpad, or touchscreen). Windows 10 or above. RAM 8 GB, Hard disk – 500 GB. Microsoft office 7 or higher (Professional is recommended) Processor: Intel I3 or higher. Comport / LAN port for communication. Acrobat reader (to view PDF files). Ethernet / LAN Connectivity.
Internet connectivity	For remote access through Team Viewer / Any Desk.

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Ordering Information with price

Walk In Stability Chamber						
Capacity Liters	Internal Size (W x D x H) mm	External Size (W x D x H) mm	No. of Racks	No. of Shelves	Shelf size mm (WxD)	Model
4000	2000 x 1000 x 2000	2160 x 1160 x 2160	2	8	860 x 650	OWISC
5000	2000 x 1250 x 2000	2160 x 1410 x 2160	2	8	915 x 800	OWISC
8000	2000 x 2000 x 2000	2160 x 2160 x 2160	4	16	910 x 825	OWISC
10000	2000 x 2500 x 2000	2160 x 2660 x 2160	4	16	1160 x 525	OWISC
15000	2550 x 2950 x 2000	2710 x 3110 x 2160	6	24	915 x 800	OWISC
20000	2860 x 3500 x 2000	3020 x 3660 x 2160	8	32	815 x 955	OWISC
Note: Larger capacities are available based on requirement.						

Optional accessories applicable for Advanced Model

Sr. No.	Descriptions
1	OS / SOFTLOG / FTP/ V15.1. Advanced software with 21 CFR Part 11 features. For details refer to Annexure I.
2	Multipoint Data scanner cum logger: With 4 temperature + 4 humidity sensors of Rotronic / E + E European brand, placed at specific points in chamber.
3	Standby Refrigeration & Humidity system with PLC for autochangeover.
4	GSM Module: Mobile alert through SMS, deviation alarms to 5 mobile nos. Sim card in customer scope.
5	Door access security system – Password on HMI OR Door access security system – PIN type + Finger Printing
6	Temperature & Humidity mapping on site consisting of 24 hours cycle, of loaded and unloaded chamber, at any one condition. Data is collected from eight different points within the chamber. Note: After validation is completed, validation report / certificate along with validation sticker shall be provided.

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Description - Model configuration

Annexure II

Model - OWISC Advanced

HMI Touch screen	<p>Make Exor, Italy.</p> <p>Exor is a fast growing Italian company with extensive experience of industrial automation and data communication. Since its start it has evolved in to a multinational group present worldwide.</p>
PLC (Program Logic Control)	<p>Make: Siemens, Germany.</p> <p>Siemens AG is a German corporation and the largest industrial manufacturing company in Europe.</p> <p>The principal divisions of the corporation are Industry, Energy and Infrastructure and cities, which represent the main activities of the corporation. The corporation is a prominent maker of medical diagnostics equipment. Siemens and its subsidiaries employ approximately 303,000 people worldwide and reported global revenue of around €62 billion in 2021 according to its earnings release.</p>
HMI features	<p>HMI is 21 CFR compliant. User management functionalities</p> <p>Password protected user account. Multiple user level as per user rights</p> <p>Audit Trail + Alarm log. (reflects in the SCADA as well)</p> <p>Tamperproof and non-editable audit trail data format</p> <p>Time stamped records of parameter changes with user name</p> <p>Audit trail records user creation, login / logout attempts, old and new value of parameter change. Electronic record and storage.</p> <p>Review of the reports on the HMI screen for Process data, Alarms and Audit Trail</p>
Software - 21CFR part 11 compliant Password Policy	<p>OS/SOFTLOG/FTP/V15.1 Advanced.</p> <p>Security policy password length, unique Id and password composition.</p> <p>Database on SQL. Ethernet / LAN Connectivity.</p> <p>Wrong password attempts limit.</p> <p>Password validity / expiry. Change of password for the first login.</p> <p>System logs off if kept idle.</p>
User management system and privileges	<p>User level based on functionality and authority user details, user master</p> <p>Privileges like delete, copy, cut, paste, rename not allowed to unauthorised users. Multiple user creation.</p>
Electronic data	<p>Electronic data is human readable and suitable for inspection for review.</p> <p>Contents like: print by date and time, reviewed by with date and time, analysis and system parameter information.</p> <p>Equipment master window, displaying all the equipment's with name and equipment status.</p> <p>Real time summary along with current status of the equipment.</p> <p>Real time and historical trend for analysis</p>

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Model - OWISC Advanced

Annexure II Cont'd

Electronic data storage	Trends, Alarms, Data log
	Back up manual & Auto backup with pre-defined path
	Restore. Report data log with print option and filter
	Report MKT with print option and filter
	Report alarm / event with print option and filter
	Authorised user access. Data logging at predefined interval.
	Printing option PDF.
Audit trail	Report audit trail with print option and filter. User audit trail with filter.
	Critical hardware related errors and warning logged.
	Time and date stamp change automatically, it is locked and cannot be editable apart from an authorised user.
	Reason for any relevant change is recorded along with the user who made the change.
	Deletion and modification is not allowed.
	Comments for alarm occurrence.
Electronic signature	Automatic Electronic signature generation.
	Name of the authority along with the date and time.
	Responsibilities such as review, approval associated.

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