

| General Information | | STABILITY CHAMBER |
|------------------------------|--|-------------------|
| Manufacturer | Osworld Scientific Equipments Pvt. Ltd, Mumbai, India | |
| Product | Stability Chamber | |
| Brand | OSWORLD | |
| HSN code | 84198960 | |
| Model | OSC - Regular-LCD-PID (description refer to Annexure I). OSC - Advanced-Touch Screen-PLC(description refer to Annexure II). | |
| Type | Vertical, front opening, complete assembled unit, plug to start. | |
| 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 |
| Door gasket | GCF- Secure,UK. | |
| Door handle / hinges | Heyritz, Germany. | |

Key Specifications

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|--------------------------------------|---|
| 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 / ± 1.0°C |
| Humidity range / resolution | 20% to 90% RH / ±1% |
| Humidity accuracy / uniformity | ± 2% RH / ± 3% RH |

Technical Specifications

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| Construction | Double wall with Polyurethane (PUF) insulation provided with door having locking arrangement and inner glass viewing door. Working chamber made of stainless steel 304 grade matt / mirror finish. Outer cabinet made of stainless steel 304 grade matt finish. |
| Temperature / Humidity control cum Data storage logging device with option of PID or PLC control. (for description refer to Annexure I & II) | 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. |
| Cooling | CFC Free Copeland Make compressor with R 134A eco friendly refrigerant, with condenser, motor, relay complete unit. |

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| | |
|----------------------|--|
| 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 HUMIREL made in France, 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. |
| Feet | Castor wheels. |
| Shelf | SS wire mesh heavy duty. |
| Electrical | 230V / 15A / 50 Hz. |

Safety Features

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|---------------|--|
| 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

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|----------------------|--|
| 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

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| Power supply | Single phase, 16Amps, 230 Volts AC 50 Hz. |
| Water | DM water continuous supply through piping with valve for boiler input of 1/2" BSP at 3 feet from ground level. |
| Drain | Water drain line with 1/2" 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). Microsoft Windows 10 or above. RAM 8 GB, Hard disk – 500 GB. 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

| Internal Size W x D x H cm | External Size W x D x H cm | Capacity Liters | SS Shelf | GMP Model No |
|-------------------------------|-------------------------------|--------------------|-------------|-----------------|
| 45 x 45 x 60 | 61 x 92 x 122 | 120 | 2 | OSC G 4 |
| 60 x 60 x 60 | 76 x 108 x 122 | 200 | 2 | OSC G 8 |
| 60 x 60 x 90 | 76 x 108 x 157 | 324 | 3 | OSC G 12 |
| 60 x 60 x 125 | 76 x 108 x 192 | 450 | 4 | OSC G 16 |
| 60 x 80 x 125 | 76 x 127 x 192 | 600 | 5 | OSC G 21 |
| 80 x 80 x 125 | 96 x 127 x 192 | 800 | 5 | OSC G 28 |
| 80 x 100 x 125 | 96 x 147 x 192 | 1000 | 5 | OSC G 34 |

* Please confirm room door size (for equipment entry) and ceiling height

Optional accessories applicable for Regular Model.

| Sr. No. | Descriptions |
|---------|---|
| 1 | Data Storage Device (DSD). LED display. Data-logging: (OSLOG- DSD- LCD). LCD 16 x 2 cm yellow display. Password protected with memory for data storage. Printer connectivity through RS 485 communication. PC connectivity through MODBUS protocol. RTC / date / month settable. Log interval selectable. Print period to and from selectable. Printer Interface facility to 24 column or EPSON 80 Col dot matrix Printer only. (Printer not included in price but optional). |
| 1a | OS / SOFTLOG / V20.1. Regular software with 21 CFR Part 11 features. For details refer to Annexure I. |
| 2 | Standby Refrigeration & Humidity system with PLC for autochangeover. (option not applicable for 120Liters). |
| 3 | 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. |

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 II. |
| 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 | GSM Module: Mobile alert through SMS, deviation alarms to 5 mobile nos. Sim card in customer scope. |
| 4 | Standby Refrigeration & Humidity system with PLC for autochangeover. (option not applicable for 120Liters). |
| 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

Model - OSC - Regular LCD

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|----------------------------------|--|
| Temperature and Humidity control | PID control. LED display Data-logging: (OSLOG- DSD- LCD) LCD 16 x 2 cm yellow display Password protected with memory for data storage. Printer connectivity through RS 485 communication PC connectivity through MODBUS protocol RTC / date / month settable. Log interval selectable Print period to and from selectable |
|----------------------------------|--|

Software - OS SOFTLOG V20.1 Regular

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| OS SOFT Data Logging Software. With 21 CFR Part 11 compliant | Database on SQL Microsoft, free version. (SQL download in customer scope). "WHO DID WHAT, WHEN". Multiple Level Passwords. Multi user level / group passwords (Administrator, Super user, Guest) System access to authorized personnel. Each user has individual account. Minimum password length / Auto log out facility. Password expiry. USB Communication with PC. Every menu entered is prompted for password and purpose. Mean Kinetic Temp. (MKT). Date and time stamp Audit Trail. Report, Trends, Graphical user Interface. Report of Alarm condition in alarm report, Remark in Alarm. Electronic Signature. Unique user ID's and individual passwords. Secure data with backup & restore facility. Real time and historical trends for analysis. Export to PDF for printout. Software compatible to Windows 10 and above. |
|---|---|

Caution!

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| This licence software is available with SOFT KEY, once installed on a PC system, it cannot be transferred on to another PC. After installation for any reason the PC is changed then a new licence will have to be purchased. (Applicable for both software). |
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Description - Model configuration

Annexure I

Model - OSC Advanced

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|-----------------------------|--|
| HMI Touch screen | Make Exor, Italy. 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. |
| PLC (Program Logic Control) | Make: Siemens, Germany. Siemens AG is a German corporation and the largest industrial manufacturing company in Europe. 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. |

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Model - OSC Advanced
Annexure II Cont'd

| | |
|---------------------------------------|--|
| HMI features | HMI is 21 CFR compliant. User management functionalities Password protected user account. Multiple user level as per user rights Audit Trail + Alarm log. (reflects in the SCADA as well) Tamperproof and non-editable audit trail data format Time stamped records of parameter changes with user name Audit trail records user creation, login / logout attempts, old and new value of parameter change. Electronic record and storage. Review of the reports on the HMI screen for Process data, Alarms and Audit Trail |
| Software - 21CFR part 11 compliant | OS/SOFTLOG/FTP/ V15.1 Advanced. |
| Password Policy | Security policy password length, unique Id and password composition. Database on SQL. Ethernet / LAN Connectivity. Wrong password attempts limit. Password validity / expiry. Change of password for the first login. System logs off if kept idle. |
| User management system and privileges | User level based on functionality and authority user details, user master Privileges like delete, copy, cut, paste, rename not allowed to unauthorised users. Multiple user creation. |
| Electronic data | Electronic data is human readable and suitable for inspection for review. Contents like: print by date and time, reviewed by with date and time, analysis and system parameter information. Equipment master window, displaying all the equipment's with name and equipment status. Real time summary along with current status of the equipment. Real time and historical trend for analysis |
| 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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