

General Information

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| Manufacturer | Osworld Scientific Equipments Pvt. Ltd, Mumbai, India |
| Product | Photo Stability Chamber (Humidity & Temperature Control). |
| Brand | Osworld |
| HSN code | 84198960 |
| Models | OPSH - Regular-LCD-PID (description refer to Annexure I). OPSH - 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) | Beiger, Sweden. | Ethernet communication. |
| Program logic control (PLC) | Mitsubishi, Japan. | SQL Database. |
| Temperature sensor | IST, Switzerland. | Licensed Software. |
| Humidity sensor | Humirel, France. | SMS Alert, MKT, Audit Trial, 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 – 60% RH / 40°C – 75%RH / 30°C – 65%RH / 25°C – 40% RH / 40°C – 25% RH / 30°C – 60%RH Please specify if other conditions are required. |
| Temperature range / resolution | : 10.0°C to 60.0°C / 0.1°C |
| Temperature accuracy / uniformity | : ±0.2°C / ±1°C |
| Humidity range / resolution | : 20% to 90% RH / ±1% |
| Humidity accuracy / uniformity | : +1% RH / +3% RH |

Technical Specifications

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| Construction | Double wall with Polyurethane (PUF) insulation. Working chamber made of Stainless steel 304 grade 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) | 7" HMI colour touch screen display. Data storage of 1000 / 1500 readings in FIFO mode. 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. |
| Steam Injection | Steam generator bath with reservoir made of thick stainless steel with heater, water inlet control, low water level safeguard and insulation |
| UVA Intensities | 1.8 W/m ² (requires about 111hrs achieving ICH recommendation of 200W-hr/m ²) |
| VIS Intensities | 12 Klux (requires about 100hrs achieving ICH recommendation of 1.2million lux-hr) |
| 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 | Flange motor with impeller. |

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| 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 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 (if software ordered) | Windows-compatible computer with a standard keyboard, a pointer input (i.e., a mouse, trackpad, or touchscreen). "Microsoft SQL 2012 free version" to be provided by customer. Windows 7 or above. RAM 8 GB, Hard disk – 500 GB. Microsoft office 7 or higher (Professional is recommended) Processor: Intel I3 or higher. Com port for communication. Acrobat reader (to view PDF files). Ethernet / LAN Connectivity. |
| Internet connectivity | For remote access through Team Viewer / Any Desk. |

Ordering Information with price

| Model | Internal size | External size | Door open size cm (DO) | Capacity | | Shelves SS | Weight Kg | Shp Wt Kg | Power | | |
|---------|---------------|---------------|------------------------|----------|--------|------------|-----------|-----------|--------|------|-----|
| | W × D × H cm | W × D × H cm | | Cu. ft. | Liters | | | | VAC,Hz | Amps | KW |
| OPSH 4 | 45×45×60 | 62×105×123 | 67 | 4 | 120 | 2 | 105 | 180 | 220,50 | 10 | 2.5 |
| OPSH 8 | 60×60×60 | 77×120×123 | 82 | 8 | 200 | 2 | 105 | 180 | 220,50 | 10 | 2.5 |
| OPSH 12 | 60×60×90 | 77×120×153 | 82 | 12 | 324 | 3 | 135 | 200 | 220,50 | 12 | 3 |
| OPSH 16 | 60×60×125 | 77×120×192 | 82 | 16 | 450 | 4 | 200 | 290 | 220,50 | 12 | 3 |
| OPSH 21 | 60×80×125 | 77×140×192 | 80 | 21 | 600 | 5 | 200 | 290 | 220,50 | 17 | 4.2 |
| OPSH 28 | 80×80×125 | 97×163×193 | 102 | 28 | 800 | 5 | 255 | 350 | 220,50 | 20 | 5 |
| OPSH 34 | 80×100×125 | 97×163×193 | 102 | 34 | 1000 | 5 | 255 | 350 | 220,50 | 20 | 5 |

Optional accessories applicable for Regular Model.

| Sr. No. | Descriptions |
|---------|--|
| 1 | OS / SOFTLOG / V20.1 / Regular software with 21 CFR Part 11 features. For details refer to Annexure I |
| 2 | Digital Light Indicator (Luxmeter with UV Indication). |
| 3 | Standby Refrigeration & Humidity system with PLC for autochangeover. |
| 4 | 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 / V10.1 / 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 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 | Digital Light Indicator (Luxmeter with UV Indication). |
| 5 | Standby Refrigeration & Humidity system with PLC for autochangeover. |
| 6 | Door access security system – PIN type + Finger Printing |
| 7 | 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. |

Description - Model configuration

Annexure I

Model - OPSH - Regular LCD

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

Description - Model configuration

Annexure II

Model - OPSH Advanced

HMI Touch screen

Make Beiger – Sweden
Beiger electronics is a fast growing Swedish company with extensive experience of industrial automation and data communication. Since its start up in 1981, Beiger Electronics has evolved in to a multinational group present in 22 countries and sales of 1,376 MSEK 2013. The company is listed on the NASDAQ OMX Nordic Stockholm Small Cap list.

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| PLC (Program Logic Control) | <p>Make: Mitsubishi – Japan</p> <p>Mitsubishi is a well known brand and global leader in Electric & Electronic equipment for Industrial use. It has operations in 40 countries, more than 1,20,000 employees and consolidated net sales of more than US\$ 38 billion</p> |
| Temperature and Humidity control | <p>Touch screen 7" HMI display cum logger, make Beijer, Sweden</p> <p>PLC make Mitsubishi, Japan.</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> |