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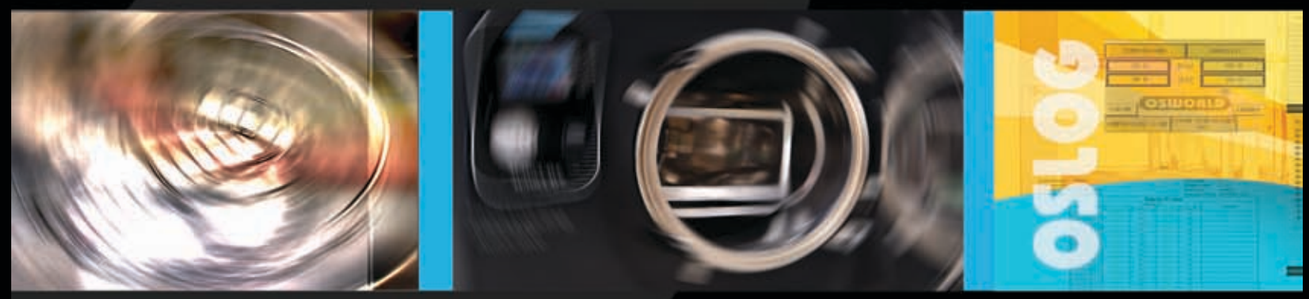
Experiment With The Truth



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Artist impression of
upcoming Osworld factory

Stability Chamber

Stability Chamber

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Stability testing of pharmaceutical products is addressed by the ICH (International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use) and the final guidance on stability testing has been adopted across Europe, Japan and the United States.

Furthermore, the FDA states in 21 CFR part 203 section that manufacturers, authorized distributors of drugs and their representatives shall store and handle all drug samples under "conditions that will maintain their stability, integrity and effectiveness," ensuring that the drug samples are free of contamination, deterioration and adulteration.

Within stability test chambers, parameters such as temperature, humidity and other environmental conditions must be controlled, monitored and documented. To reduce the risk of failed studies, a monitoring system designed for both functionality and compliance is required.

Functions should include data logging, automated date file backup, monitoring and reporting, connectivity options including alarm notifications, multiple levels of data security, which can include digital signatures, and complete event and interaction history and audit trail.

Stability Chamber

ACCESSORIES

- OSLOG Data Storage Device (Oslog-DSD)
- OSLOG software with 21 CFR Part 11 features
- Wireless Module-Connect OSLOG DSD to PC without cables
- GSM Module-Deviation alarm mobile alert through SMS to 5 mobile numbers
- Temperature and Humidity control-PLC-based
- Magnetic door lock facility
- Stand-by refrigeration system
- Stand by boiler system
- PLC for auto changeover to stand-by systems
- Data logger 8 point temperature + 8 point humidity

Stability Chamber

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FEATURES

Components

Chamber: Stainless steel mirror-polished chamber with rounded corners that offer superior air flow and assist cleaning

Temperature sensor: Swiss-make PT 100 RTD class 'A' sensor

Humidity sensor: French-make accurate sensors capacitance type

Temperature/Humidity control: Standard model with digital PID control, CE certified

PLC control: Effective control along with latest touch screen technology, aesthetically appealing HMI display

OSLOG DSD: Meet ICH and GMP regulatory requirements by recording data of chamber conditions against time. Internal memory helps save data up to 5000 readings (For more information refer to page 109)

Refrigeration compressor: Hermetically-sealed Copeland-make compressors utilizing R134a CFC free refrigerant

Over temperature/humidity protection: Protect samples by preventing untoward rise in temperature or humidity

Internal glass door: Samples can be easily viewed from outside without disturbing internal conditions

Access port for external sensor: Multiple sensors can be inserted through port while conducting mapping cycles

Interior lighting: View samples easily as interior lighting switches on automatically when door opens

RS 485 interface: Connect to your PC and manage data with the 21 CFR compliant software (option). (For more information refer to page 108)

Handle: Elegant German handle with firm snap lock

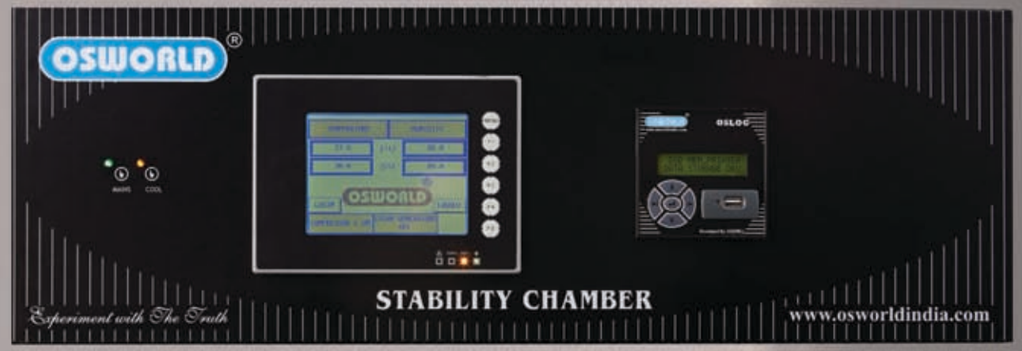
Hinges: Aesthetic German hinge, door sways conveniently

Gasket: Silicon food grade

Shelves: Stainless steel wire shelf designed to maximize air flow

Castor wheels: For easy mobility; conveniently shift equipment and place at desired location

Stability Chamber



SAFETY FEATURES

- High temperature cut-off
- High humidity cut-off
- Low water level sensor
- Compressor thermal cut-off
- Electrical short circuit breaker

ALARMS

- High/low temperature
- High/low humidity
- Low water level

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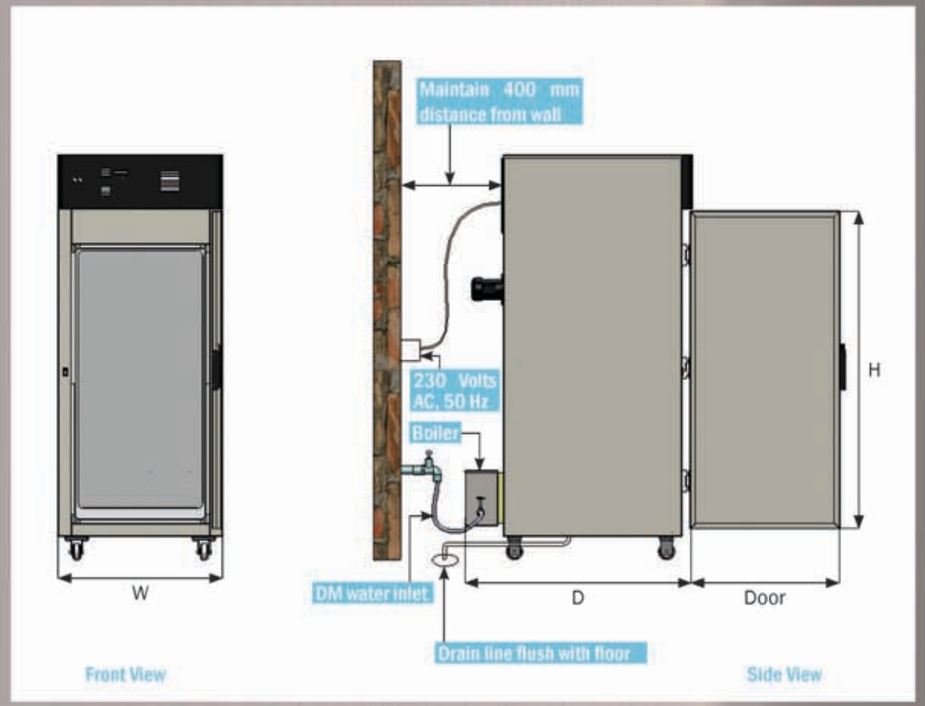
Stability Chamber

Technical Specs

For conditions as per ICH guidelines	25°C – 60% RH / 40°C – 75%RH / 30°C – 65%RH
Construction	Double wall with door having locking arrangement and inner glass viewing door
Temperature range	10.0 °C to 60.0 °C
Temperature resolution	0.1 °C
Temperature accuracy	±0.2° C
Temperature uniformity	±1°C
Temperature Control	Microprocessor-based PID Control. Or PLC-controlled option
Temperature sensor	PT100 RTD type Class 'A', made in Switzerland
Temperature sensor accuracy	±0.25 °C
Humidity range	40% to 90% RH
Humidity resolution	1%
Humidity accuracy	±2% RH
Humidity uniformity	±3 % RH
Humidity sensor	Make: Humirel. Made in France, Capacitance type High reliability and long-term stability Calibrated within +2% RH @ 55% RH Humidity measuring range 0 to 100% Not affected by water immersion
Cooling	CFC-free Copeland-make compressor utilizing R 134A eco-friendly refrigerant, with condenser, motor, relay
Steam Injection	Boiler 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
Air circulation	Flange motor with impeller/blower
Insulation	Poly Urethane Foam (PUF)
Chamber illumination	Fluorescent light with door switch
Trays	Heavy-duty SS wire mesh
Feet	Castor wheels
Electrical	230V/15A/50 Hz



Stability Chamber

Choosing a specific model

While choosing a model the following factors should be considered:

Size: Osworld chambers are available in various capacities. The sample quantity to be tested will determine which capacity of chamber is suitable. While doing this keep in mind that stability test conditions, for long term or accelerated study, are conducted over long duration. It is important to buy bigger than required capacity to ensure that samples have sufficient space. A point to be noted is that chambers can be stuffed with samples only up to 70 per cent of their capacity. Sufficient free space has to be maintained around chamber sides to permit free path for air circulation.

Test Condition: Determine the test condition in terms of temperature and humidity that your sample needs to be tested at. Refer to ICH stipulated guidelines on testing standards for various climatic zones. Osworld chambers are capable of achieving all ICH conditions. However, while ordering it is imperative to specify your desired test condition so that we can test it extensively at the same.

Test condition data record: ICH guidelines makes it mandatory to provide documentary evidence to the auditors by recording the test results. The set values against actual values with respect to time for the entire duration of sample testing need to be preserved and may have to be provided to auditors for inspection. Hence, the OSLOG data storage device should be considered as a must-have accessory.

21 CFR Part 11 compliant software: Electronic records provided to auditors need to be compliant to 21 CFR Part 11 norms. The software also helps in better management of data received from multiple chambers. Storing and reproducing data is made easy with this software. It is advisable to include this in the purchase.

Wireless module: Eliminate lengthy cabling between equipment to the PC. From compliance point of view it is not a necessity, so include this option if budget permits.

GSM Module: Mobile alerts are secondary requirements and this feature can be included depending on the internal protocol or stringency in following compliance levels. From compliance point of view it is not a necessity, so include this if your budget permits. Supplied only if PLC control option is purchased.

Temperature and Humidity control–PLC based: PLC system is the latest technology and is available with an attractive HMI which prominently displays the set and actual parameters. Include this accessory only if your budget permits. Clients located in remote areas, with non-stabilized power input, should usually avoid PLC modules. PLC modules are voltage sensitive and also require trained engineers to attend to any service issues.

Stability Chamber

Magnetic door lock facility: This option is available only if PLC-control option is purchased and the purpose is to restrict unauthorised access. The standard equipment comes with only a lock and key.

Stand-by refrigeration, boiler and auto change over: There is no guideline which stipulates that stand-by systems are necessary. The guidelines simply state that the chambers should function uninterruptedly for the entire test period. However, auditors could insist on failsafe mechanisms for those components which could wear and tear during normal running. It may be necessary to have a proper periodic maintenance plan documented and implemented. As a failsafe measure, the auditors could further insist on having stand-by safety for refrigeration and humidity systems. Include this option on the basis of your experience with the level of audits and the stringent compliance level that the product demands. The PLC changeover option is to automatically switchover to the stand-by system in case the main system fails.

Data logger for temperature and humidity: Records data at multiple points within the chamber and provides documentary evidence of uniformity in conditions throughout the chamber. Generally, if a temperature mapping cycle is conducted as part of PQ during installation then it is sufficient evidence of condition uniformity within the chamber. In most likelihood a data logger is best avoided.

Ordering Information

Model	Internal Size	External Size	Capacity		Shelves	Weight	Shipping weight	Power	
	W × D × H cm	W × D × H cm	Cu. ft.	Litres		Kg	Kg	VAC,Hz	Amps
OSC 4	45 × 45 × 60	60 × 70 × 110	4	120	2	104	150	230,50	10
OSC 8	60 × 60 × 60	75 × 83 × 110	8	200	2	130	190	230,50	10
OSC 12	60 × 60 × 90	75 × 83 × 140	12	324	3	158	244	230,50	12
OSC 16	60 × 60 × 125	75 × 83 × 175	16	450	4	220	340	230,50	12
OSC 21	60 × 80 ×125	75 × 103 × 180	21	600	5	236	384	230,50	17
OSC 28	80 × 80 × 125	95 × 103 × 180	28	800	5	315	512	230,50	20
OSC 34	80 × 80 × 155	95 × 103 × 210	34	1000	5	394	640	230,50	20

PLANNING TO BUY...

A must-read guide to ensure your purchase goes as planned.

If you are ordering a new stability chamber, as an equipment buyer have you done all your homework to make sure that the purchase and installation will go as smoothly as possible, and that the equipment will work properly from the word 'go'? If you think you have everything in check, then take a look at the following list of 'must-do' tasks, to ensure there are no surprises on receiving or while installing the equipment.

Building access: Is the entrance door/delivery door large enough to accommodate the equipment that is being ordered? Is there an elevator with sufficient capacity/size which can accommodate equipment in case it has to be installed on a higher floor? If there is no elevator, is the stairway and hallway wide enough so that equipment can pass through them.

Note: Many clients order equipment of higher capacity and are then surprised to know that the entrance door is not wide enough or high enough to accommodate it. It is important to confirm external dimensions before ordering.

Utilities: Wrong utilities are the chief reason for improperly operating Stability Chambers.

Some things you need to be aware of with respect to utilities and new equipment installation include the following:

Stability Chamber

Water availability: The stability chamber requires water for its basic operation. A key component of any proper installation is to ensure that there is a water source close to it, or preferably, at the point of equipment installation.

Water pressure & quantity: Inlet water should be at normal tap pressure range. Water fed through DM plants could have excessive pressure thus resulting in steam generator inlet valve failure. Quantity of water required is not very high for a chamber of 324 litres capacity per day consumption could be approximately 30 litres. Actual quantity will vary with ambient and operating temperature, humidity and with the frequency and duration of door opening.

Note: Gravity feed systems such as carboys are recommended but ensure the carboys are fitted with automatic water filling/cut-off device. Place carboys above steam generator height to improve pressure.

Water quality: Untreated tap water of drinking quality is acceptable. In hard water areas we recommend treated, single-distilled or single-deionized water or partially demineralised water which is adequately filtered.

Note: DEIONISED OR DISTILLED WATER IS NOT RECOMMENDED. We do not recommend use of ultra-pure water such as triple distilled, triple deionized or high purity reverse osmosis water, because these increase the potential for component corrosion.

Problems that arise due to use of poor quality water: Water quality is the primary cause of steam generator failure, causing heater element and low water level sensor failure (by encrustation with minerals from hard water) or corrosion (by deionized water with excessive resistivity).

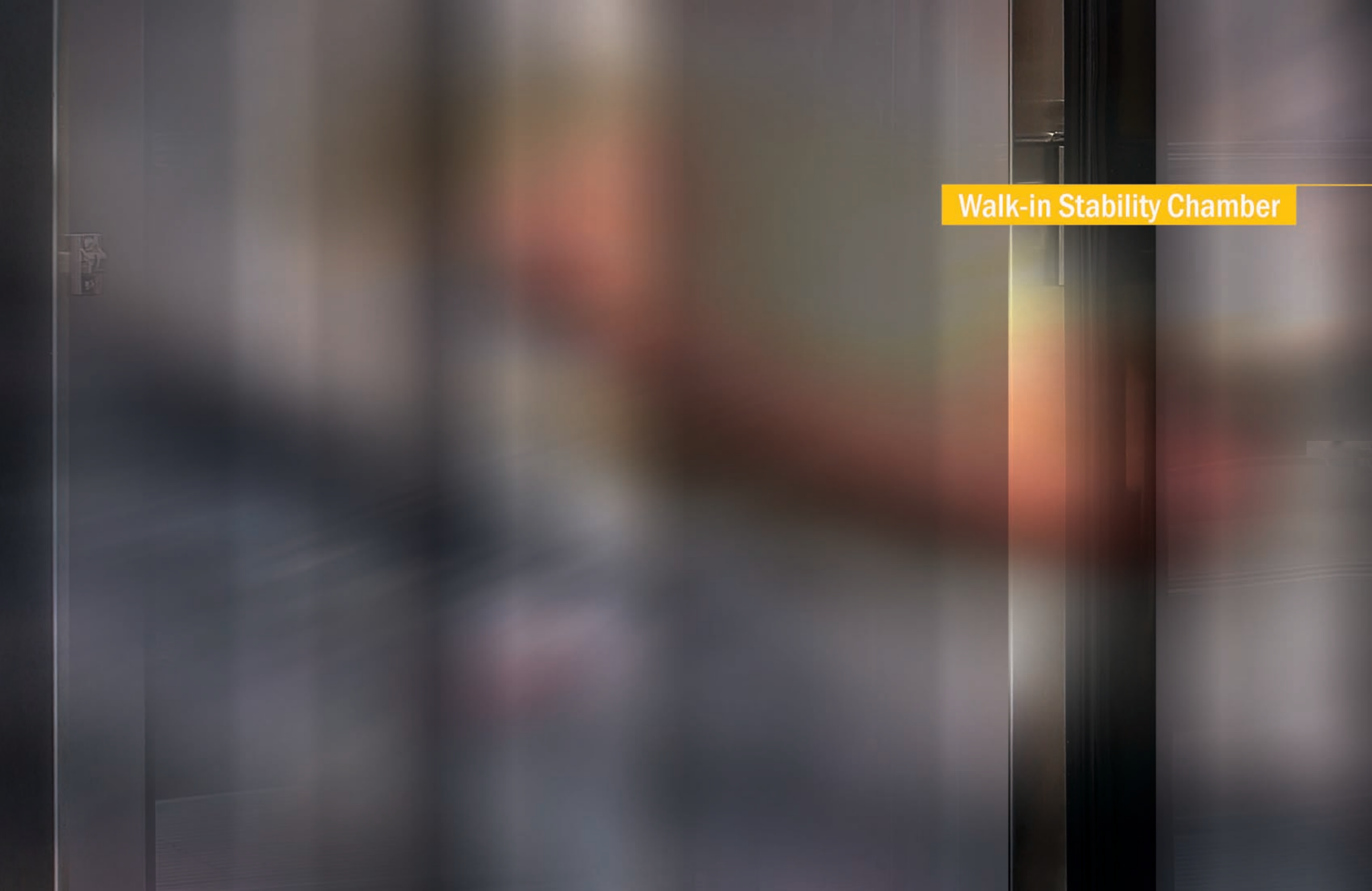
Room/Ambient temperature around equipment: We have observed that pharmaceutical companies which have centralized air conditioned laboratories with room temperatures maintained below 24°C, provide ideal conditions. The chambers installed in these organizations perform better.

Water source and room temperatures are two utilities which are very important. Our records indicate that 80 per cent of all chamber complaints are due to these utilities being improper.

Power supply: Stabilized input power supply of AC 230 volts +/- 10%, 50 Hz is recommended. In areas where the quality of voltage supply is poor, the use of Servo-controlled voltage stabilizer is necessary.

Drain requirements: A free-flowing drain at floor level is required for the equipment to perform properly. The stability chamber has a condensate drain outlet placed 2 inches above floor level. This necessitates the room drain to be at floor level. If you provide a PVC drainage pipe, ensure it does not twist at bends. A copper pipe is recommended.

Note: Providing drain pan can be messy due to overflow, if unattended.


Walk-in Stability Chamber

Walk-in Stability Chamber

Walk-in Stability Chamber

Walk-in Stability Chamber

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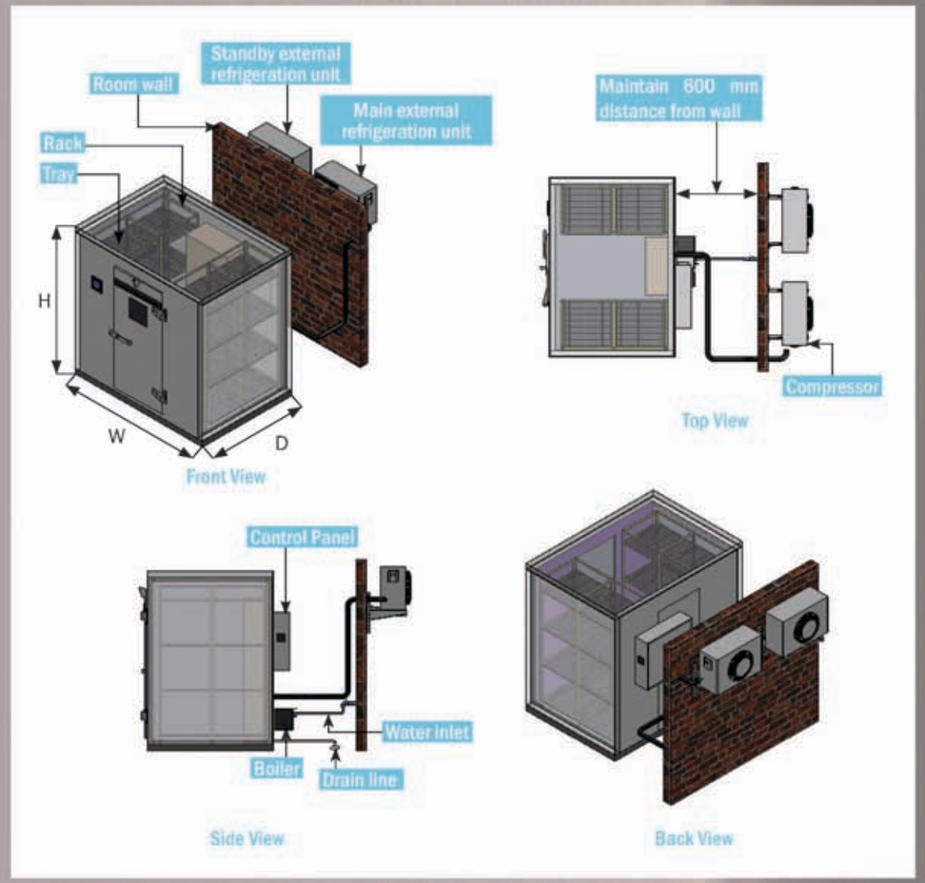
Within stability test chambers, parameters such as temperature, humidity and other environmental conditions must be controlled, monitored and documented. To reduce the risk of failed studies, a monitoring system designed for both functionality and compliance is required.

Functions should include data logging, automated date file backup, monitoring and reporting, connectivity options including alarm notifications, multiple levels of data security, which can include digital signatures, and complete event and interaction history and audit trail.



ACCESSORIES

- OSLOG Data Storage Device (Oslog-DSD)
- OSLOG software with 21 CFR Part 11 features
- Wireless Module - connect OSLOG DSD to PC without cables
- GSM Module. Deviation alarm mobile alert through SMS to 5 mobile numbers
- Temperature and Humidity control - PLC based
- Magnetic door lock facility
- Stand-by refrigeration system
- Stand-by boiler system
- PLC for auto changeover to stand-by systems
- Data logger 8 point temperature + 8 point humidity

Walk-in Stability Chamber

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FEATURES

Components

Chamber: Stainless steel mirror-polished chamber that offers superior air flow and assists cleaning

Temperature sensor: Swiss-make PT 100 RTD class 'A' sensor

Humidity sensor: French-make accurate sensors, capacitance type

Temperature/Humidity control: Standard model comes with digital PID control which is CE certified

PLC Control: Effective control along with latest touch screen technology, aesthetically appealing HMI display

OSLOG DSD: (Refer to page 109)

Meets ICH and GMP regulatory requirements by recording data of chamber conditions against time. Internal memory helps save data of upto 5000 readings

Refrigeration compressor: Hermetically-sealed Copeland-make compressors utilizing R134a CFC free refrigerant

Over temperature/humidity protection: Protect samples by preventing untoward rise in temperature or humidity

Viewing glass door: Samples can be viewed from outside without disturbing internal conditions

Access port for external sensor: Multiple sensors can be inserted through port while conducting mapping cycles

Interior lighting: View samples readily as interior lighting switches on when door opens

RS 485 interface: Connect to your PC and manage data with the 21 CFR compliant software (option). (Refer to page 108)

Handle: Elegant German handle firm snap lock

Hinges: Aesthetic German hinge, door sways conveniently

Gasket: Silicon food grade

Shelves: Stainless steel wire shelf designed to maximize air flow

Ordering Information

Model	Internal Size	External Size	Capacity	Shelves	Weight	Volume packed	Shpg wt	Power	
	W × D × H cm	W × D × H mm	Litres		Kg	Cbm	Kg	VAC, Hz	Amps
OWISC	2000 × 1250 × 2000	2160 × 1510 × 2160	5000	16	104	5	500	230,50	20
OWISC	2000 × 2000 × 2000	2160 × 2360 ×2160	8000	24	130	8	600	230,50	20
OWISC	2000 × 2500 × 2500	2160 × 2960 × 2660	12000	36	158	13	800	440,50	10 × 3

Larger sizes available on request
A suitable size for your application can be designed given particular room dimensions

SAFETY FEATURES

- High temperature cut-off
- High humidity cut-off
- Low water level sensor
- Compressor thermal cut-off
- Electrical short circuit breaker

ALARMS

- High/low temperature
- High/low humidity
- Low water level

PLANNING TO BUY...

- Refer to page 54

CHOOSING A SPECIFIC MODEL

- Refer to page 51

Room size: Osworld Walk-In Chambers are generally erected at site even though they are available in standard sizes. Most situations demand that the chambers be designed to fit in the client's room. Ensure that a proper room drawing is first sent to Osworld, based on which we will work out a suitable size that can be accommodated in your room. We will also suggest the best possible options of placing one or multiple chambers.

Technical Specs

For conditions as per ICH guidelines	25°C – 60% RH / 40°C – 75%RH / 30°C – 65%RH
Construction	Double wall with Poly Urethene Foam (PUF) insulation provided with door having locking arrangement and inner glass viewing door
Temperature range	10.0 ° C to 60.0 ° C
Temperature resolution	0.1 ° C
Temperature accuracy	± 0.2° C
Temperature uniformity	± 1° C
Temperature Control	Microprocessor-based PID Control. Or PLC control option
Temperature sensor	PT100 RTD type Class 'A', made in Switzerland
Temperature sensor accuracy	± 0.25° C
Humidity range	40% to 90% RH
Humidity resolution	1%
Humidity accuracy	± 2% RH
Humidity uniformity	± 3 % RH
Humidity sensor	Make Humirel made in France, Capacitance type High reliability and long term stability Calibrated within +2% RH @ 55% RH Humidity measuring range 0 to 100% Not affected by water immersion
Cooling	CFC-free Copeland-make compressor utilizing R 134A eco-friendly refrigerant, with condenser, motor, relay
Steam Injection	Boiler 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
Air circulation	Flange motor with impeller/blower
Insulation	Poly Urethane Foam (PUF)
Chamber illumination	Fluorescent light with door switch
Trays	Heavy duty SS wire mesh
Feet	Castor wheels
Electrical	230V/15A/50 Hz

LIST OF ESSENTIAL SPARE PARTS

- SSR 25 amps
- Dry heater
- Boiler heater
- Boiler heater connector
- Water inlet float valve
- Low water level sensor
- MCB circuit-breaker
- PLA relay
- Contactor
- RH sensor Humirel
- Temperature PT100 sensor
- Compressor accessories such as relay, capacitor etc.
- Condenser motor
- Chamber circulation motor

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Walk-in Stability Chamber

PARTS REPLACEMENT FREQUENCY

The mean time between failures decreases after a number of years in operation. The main reason is component wear, but operating conditions also play a major role. Based on Osworld's experience, we recommend replacement of certain components during preventive maintenance. Suggested components, if not replaced at specified interval, could result in sudden equipment breakdown during normal operation.

PREVENTIVE MAINTENANCE SPARE PARTS KIT

The Osworld Walk-In Stability Chamber Preventive Maintenance Kits contain the service parts required for a scheduled maintenance, based on recommended replacement intervals.

SERVICE AND MAINTENANCE FREQUENCY

The ideal schedule for periodic maintenance is on a quarterly basis. Tough conditions such as high ambient temperatures or bad water quality can significantly shorten components' life and reduce the interval between maintenance and components' replacement. Have preventive maintenance more regularly if the conditions around the equipment are improper or if the utilities are incorrect. If conditions and utilities provided are excellent then maintenance every six months is acceptable. However, preventive checks can be conducted at regular intervals.

BENEFITS

- Osworld Stability Chamber preventive maintenance kits contain genuine service parts.
- Kits are priced more economically then individually ordered parts.
- Parts are carefully selected and tested for the specific operating conditions.
- Replacing parts on time increases mean time between failures.
- Spare parts reliability and availability are increased. Unplanned shutdowns are prevented and repair costs reduced.

Photo Stability Chamber

Photo Stability Chamber

ACCESSORIES

- OSLOG Data Storage Device (Oslog–DSD)
- OSLOG software with 21 CFR Part 11 features
- Wireless Module: Connects OSLOG DSD to PC without cables
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Photo Stability Chamber

Stability testing of pharmaceutical products is addressed by the ICH (International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use) and the final guidelines on stability testing have been adopted across Europe, Japan and the United States.

Furthermore, the FDA states in 21 CFR part 203 section that manufacturers, authorised distributors of drugs and their representatives shall store and handle all drug samples under "conditions that will maintain their stability, integrity and effectiveness," ensuring that the drug samples are free of contamination, deterioration and adulteration.

Within photo stability test chambers, parameters such as temperature, light and other environmental conditions must be controlled, monitored and documented.

The intrinsic photo stability characteristics of new drug substances and products should be evaluated to demonstrate that, as appropriate, light exposure does not result in unacceptable change.

Light Sources:

The light sources described below may be used for photo stability testing. The applicant should either maintain an appropriate control of temperature to minimize the effect of localized temperature changes or include a dark control in the same environment unless otherwise justified. For both options 1 and 2, a pharmaceutical manufacturer/applicant may rely on the spectral distribution specification of the light source manufacturer.

SAFETY FEATURES/ALARMS

- Refer to page 48

PLANNING TO BUY...

- Refer to page 54

Photo Stability Chamber

Option 1

This includes any light source that is designed to produce an output similar to the D 65/ ID65 emission standard such as an artificial daylight fluorescent lamp combining visible and ultraviolet (UV) outputs, xenon or metal halide lamp. D65 is the internationally recognized standard for outdoor daylight as defined in ISO 10977 (1933). ID65 is the equivalent indoor indirect daylight standard. For a light source emitting significant radiation below 320 nanometers (nm), an appropriate filter(s) may be fitted to eliminate such radiation.

Option 2

For option 2, the same sample should be exposed to both the cool white fluorescent and near ultraviolet lamp. This requires:

1. A cool white fluorescent lamp designed to produce an output similar to that specified in ISO 10977 (1933)
2. A near UV fluorescent lamp having a spectral distribution from 320nm to 400nm with a maximum energy emission between 350 to 370nm; a significant proportion of UV should be in both bands of 310 to 360nm and 360 to 400nm.

Osworld manufacturers two types of photo stability chambers:

1. Photo stability chamber with temperature: Equipment can generate desired amount of light as well as maintain temperature which is essential for the test.
2. Photo stability chamber with light, temperature and humidity: This equipment is necessary in case sample or test demands meeting all three conditions.

Note: In most cases it is preferred to have only light and temperature.

Ordering Information

Model	Internal Size	External Size	Capacity		Shelves	Weight	Shipping weight	Power	
	W × D × H cm	W × D × H cm	Cu. ft.	Litres		Kg	Kg	VAC,Hz	Amps
OPSH - 4	45 × 45 × 60	60 × 70 × 110	4	120	2	104	150	230,50	10
OPSH – 8	60 × 60 × 60	75 × 83 × 110	8	200	2	130	190	230,50	10
OPSH -12	60 × 60 × 90	75 × 83 × 140	12	324	3	158	244	230,50	12
OPSH -16	60 × 60 × 125	75 × 83 × 175	16	450	4	220	340	230,50	12
OPSH -21	60 × 80 ×125	75 × 103 × 180	21	600	5	236	384	230,50	17
OPSH -28	80 × 80 × 125	95 × 103 × 180	28	800	5	315	512	230,50	20
OPSH -34	80 × 80 × 155	95 × 103 × 210	34	1000	5	394	640	230,50	20

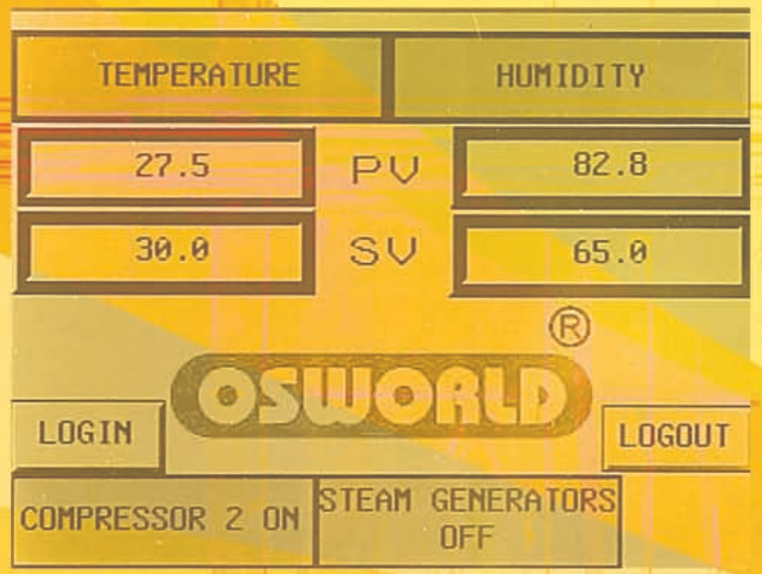
Photo Stability Chamber

OSWORLD

Technical Specs

For conditions as per ICH Guidelines	Designed to meet ICH guidelines for photo stability testing, near UV and visible light testing is performed simultaneously
UVA intensities	1.8 W/m2 (requires about 111 hours to achieve ICH recommendation of 200 W-hr/m2)
VIS intensities	12 K Lux (requires about 100 hours to achieve ICH recommendation of 1.2 million Lux-hr)
Construction	Double wall with door having locking arrangement and inner glass viewing door
Temperature range	10.0 °C to 60.0 °C
Temperature resolution	0.1 °C
Temperature accuracy	± 0.2° C
Temperature uniformity	± 1°C
Temperature Control	Microprocessor-based PID Control. Or PLC control option
Temperature sensor	PT100 RTD type Class 'A', made in Switzerland
Temperature sensor accuracy	± 0.25 °C
Humidity range	40% to 90% RH
Humidity resolution	1%
Humidity accuracy	± 2% RH
Humidity uniformity	± 3 % RH
Humidity sensor	Make: Humirel, made in France, Capacitance type High reliability and long term stability Calibrated within +2% RH @ 55% RH Humidity measuring range 0 to 100% Not affected by water immersion
Cooling	CFC-free Copeland-make compressor utilizing R 134A eco-friendly refrigerant, with condenser, motor, relay
Steam Injection	Boiler 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
Air circulation	Flange motor with impeller/ blower
Insulation	Poly Urethane Foam (PUF)
Chamber illumination	Fluorescent light with door switch
Trays	Heavy-duty SS wire mesh
Feet	Castor wheels
Electrical	230V / 15A / 50 Hz

OSLOG



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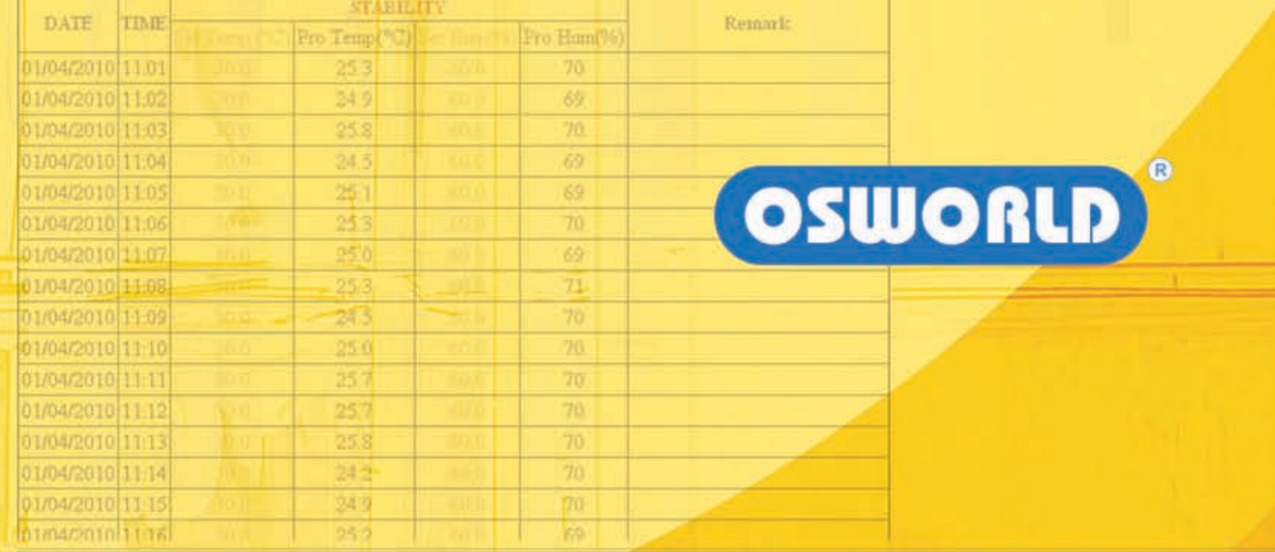
IEA

Equipment Make : Godrej
Equipment Name : oslog2_1
From Date & Time : 01/04/2010 00:00
To Date & Time : 01/04/2010 23:59

Temp Limits : ± 5
Humidity Limits : ± 10
Prepared By : osworld
Print Date & Time : 01/04/2010 17:49

Equipment Id :oslog2

DATE	TIME	STABILITY				Remark
		Set Temp(°C)	Pro Temp(°C)	Set Hum(%)	Pro Hum(%)	
01/04/2010	11:01	30.0	25.3	65.0	70	
01/04/2010	11:02	30.0	24.9	65.0	69	
01/04/2010	11:03	30.0	25.8	65.0	70	
01/04/2010	11:04	30.0	24.5	65.0	69	
01/04/2010	11:05	30.0	25.1	65.0	69	
01/04/2010	11:06	30.0	25.3	65.0	70	
01/04/2010	11:07	30.0	25.0	65.0	69	
01/04/2010	11:08	30.0	25.3	65.0	71	
01/04/2010	11:09	30.0	24.5	65.0	70	
01/04/2010	11:10	30.0	25.0	65.0	70	
01/04/2010	11:11	30.0	25.7	65.0	70	
01/04/2010	11:12	30.0	25.7	65.0	70	
01/04/2010	11:13	30.0	25.8	65.0	70	
01/04/2010	11:14	30.0	24.2	65.0	70	
01/04/2010	11:15	30.0	24.9	65.0	70	



21 CFR Part 11 Compliant Software

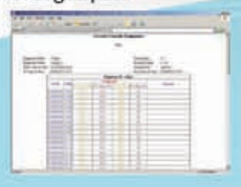
- Mean Kinetic Temperature (MKT), Audit Trail, Graphs, Tabular reports.
- Multiple user passwords
- Minimum, Maximum & Average value at the end of each report.
- Separate alarm report.
- Print/Scan frequency programmable (1 to 240 mins).
- Internal software logging every 1.5 seconds.
- Data acquisition, monitor & control (for PLC based).
- Password protection (Min 3 levels).
- Automatic acknowledgement within specified time with an alarm, log provided readings are logged for that particular alarm.
- Door opening/closing log (Magnetic log with passwords)
- Numeric as well as graphical report (common/individual)
- Roles & privileges for user, operator and administrator
- Electronic signature
- Scanner graph
- Current reading configurable (single/multiple) by user
- Channel-wise scanner alarm report
- Print frequency programmable through software
- Page length programmable
- Controller setting programmable
- Alarm logging with times (Actual high/low readings)

OSLOG Data Acquisition System Software

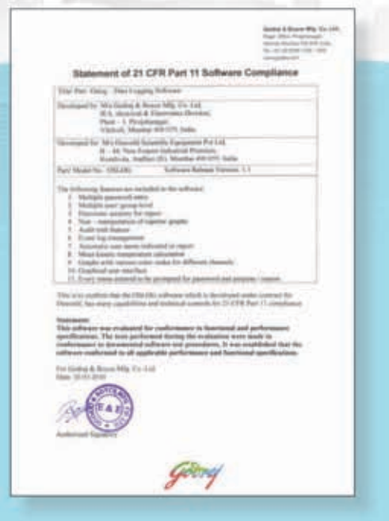
1. Login Screen

2. Security

3. Log Report



4. Log graph


Statement of 21 CFR Part 11 Software Compliance

OSLOG Data Storage Device (Oslog–DSD)

- Online and Offline mode. When online, it also logs data onto a pen drive.
- In offline mode, it stores data in USB pen drive. Pen drive can later be taken to PC and data downloaded using Oslog software.
- In online mode, data is continuously updated on to the PC. For retrieval of data in PC, Oslog–DSD will be connected to PC through RS232 serial port. Oslog software will scan each equipment (every 5 seconds) connected to Oslog–DSD and will store data into database file in the hard drive of the PC.
- Data logging Interval 1 to 240 minutes.
- Pen drive detection and error or USB device full indication.
- At one time max 5 nos. Oslog DSDs and 5 nos. Oscans (Datalogger) can be connected to one single Oslog Software.
- Data Stored in USB Pen drive in ASCII FAT 32 format non manipulative.
- 2 Line, 16 characters LCD display with membrane keypad.
- Oslog–DSD can be placed on front panel of equipment next to the PC for convenience.
- Extremely user-friendly and easy to operate.
- Developed exclusively for Osworld by India's reputed brand M/s Godrej & Boyce Mfg. Co. Ltd., Mumbai.

GSM Module and Internet Connectivity...

1. GSM connectivity: Connect any Osworld equipment to a GSM mobile. The equipment sends deviation alarm of temperature/humidity high/low alarm to 5 designated mobile numbers. To avoid disturbing, spurious/false alarms like door open events from not being sent, the software is programmed to send only deviations which are continuous and need to be attended.

The GSM connectivity is made applicable through our exclusive tie-up with India's most reputed brand, Godrej. Osworld has an exclusive tie-up with Godrej for hardware interfacing and software.

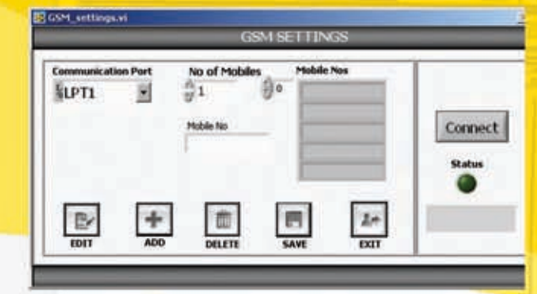
2. Osworld Equipment software connectivity: There are multiple ways to connect Osworld equipments to the Oslog PC software.

A) Online connectivity using Universal Modbus Protocol: In this scenario the Osworld equipment is connected to the PC directly using RS485 Universal Modbus protocol. Multiple Osworld equipments are looped once again using RS485 and finally connected to the PC. The equipment data is downloaded in micro-seconds with in-built software alarm triggers to notify break in connectivity.

This scenario is most widely used in one-on-one connectivity or connecting a few equipments in loop which are located in one room.

B) Ethernet connectivity: Equipments located in multiple rooms in one factory can be monitored/controlled from a single server using the Ethernet connectivity software module. The different computer nodes can be connected to

GSM module



Keeps track of temperature and humidity
Alerts user via SMS on high/low temperature and humidity
Connects up to five mobiles

the equipment using Cat-5 or Cat-6 cables with RJ45 connectors. The Oslog Ethernet software allows maximum 32 nos. Osworld equipment to be connected to ONE computer node in a LAN (Local Area Network) environment.

In a multiple node LAN network where multiple Osworld equipment are connected to multiple nodes, the Oslog software permits 'Unlimited Osworld Equipment to be connected to the server. Currently, the Oslog software is programmed for a Windows platform client-server set-up.

C) Internet Connectivity: A step forward is the connectivity of Osworld equipment to the Internet using the client's IP address. Osworld equipment can be viewed from anywhere in the world using Osworld dedicated Oslog Internet software. Osworld permits its clients to use Osworld web space to monitor their equipment data anytime/anywhere in the world. LIVE Equipment Data or backdated data from the main server of the equipment can be accessed and retrieved.

3) Mobile Connectivity: Osworld provides mobility feature by offering the Osworld Mobile Application on Android handphones for people on the go and who need to keep tabs on the equipment functioning constantly due to important media placed in it. Also view earlier data on the mobile by logging into the mainframe server.

4) Wireless Module: Connect any Osworld equipment wireless (without cables) at 1Km distance line of sight to the PC. Exact data download can be defined as per (from/to... date/time) convenience.

Validation

IQ, OQ, PQ documentation compliant to FDA, GLP and GMP requirement.

Developed for Osworld by Premier Validation Ltd, Europe's leading validation consultants. Their extensive and unparalleled experience in addition to the necessary regulatory knowledge has ensured that all critical parameters are considered.

Installation and Operation Qualification

This Installation and Operation Qualification is designed to validate that the Osworld Stability Chamber is installed correctly and operates according to the functional specifications and the client-user-requirement specifications. For this purpose, a number of predefined verifications and tests will be executed. Successful completion of this protocol will prove that the Osworld Stability Chamber installation was successful and that it operates according to the functional specifications and the client-user-requirement specification.

Performance Qualification

This Performance Qualification is designed to validate that the Osworld Stability Chamber performs according to the functional specifications and the client-user-requirement specifications. For this purpose, a temperature and relative humidity mapping of locations distributed across the working area of the Stability Chamber is executed, using data loggers to measure the local temperatures and relative humidity.

The testing method is based on the principles defined in the French standard NF X15-140. The testing methodology is intended for temperature and humidity-controlled units, located in a controlled environment, with a constant temperature (at one or more set points). Osworld will execute the protocols, analyze and interpret the data collected, resolve any deviations noted during the execution and prepare final Validation report.

Calibration

All measuring devices such as temperature controllers, humidity controllers along with sensors are calibrated prior to use. The quality management system approved calibration plan is implemented by highly skilled personnel.

Sensors are calibrated against master instruments which are calibrated at ERTL which is accredited to NABL, India.

NABL, India, is the signatory of Multilateral Recognition Arrangement (MLA) of International Accreditation Forum (IAF) Inc. The NABL accredited certificates issued by STQC Services are valid worldwide.

Clients: India

Alembic Pharmaceuticals Ltd.

Alkem Laboratories Ltd.

Aurobindo Pharma Ltd.

Bharat Biotech Ltd.

Cadila Healthcare Ltd.

Cipla Ltd.

Concept Pharmaceuticals Ltd.

Dr. Reddy's Laboratories Ltd.

Dr. Sabharwal's Wound Care

E.I.Dupoint Ltd.

Epsilon Laboratories Ltd.

Fresenius Kabi Oncology Ltd.

Glaxo Smithkline Ltd.

Glenmark Pharmaceuticals Ltd.

GVK Biosciences Ltd.

Haffkine Pharmaceuticals Ltd.

Hetero Drugs

Hindustan Unilever Ltd.

Incozen Pharmaceuticals Pvt. Ltd.

Indoco Remedies Ltd.

Ipca laboratories Ltd.

Jubilant Biosys Ltd.

Macleod Pharmaceuticals Ltd.

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Merck Specialities Pvt. Ltd.

MSN Laboratories Ltd.

Mylax Laboratories Ltd.

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Orchid Chemicals & Pharmaceuticals Ltd.

OSWORLD

Pharmasolve Specialities India Pvt. Ltd.

Pfizer Ltd.

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Ranbaxy Laboratories Ltd.

Raptakos Brett & Company Ltd.

RCC Laboratories

Reliance Life Sciences Pvt. Ltd.

Richter Themis Ltd.

S. Kant Healthcare Ltd.

Sandoz Private Ltd.

Sanzyme Ltd.

Saraca Laboratories Ltd.

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Silicon Life Sciences Pvt Ltd.

Stanex Drugs and Chemicals Pvt. Ltd.

Sun Pharmaceuticals Industries Ltd.

Themis Meidicare Ltd.

Torrent Pharmaceuticals Ltd.

Unichem Laboratories Ltd.

US Vitamin Ltd.

Unilever Industries (P) Ltd.

Vasudha Pharma Chem Ltd.

Vet India Pharmaceuticals

Virchow Biotech Ltd.

Wallace Pharmaceuticals Ltd.

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Zydus Cadila Ltd.

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MAHARASHTRA, INDIA.

Bureau Veritas Certification certify that the Management System of the above organisation has been audited and found to be in accordance with the requirements of the management system standard detailed below

Standard

ISO 9001:2008

Scope of certification

MANUFACTURE AND DESPATCH OF OSWORLD BRAND OF ELECTRICAL EQUIPMENT USED FOR TESTING IN QUALITY CONTROL AND R & D LABORATORIES IN PHARMACEUTICAL INDUSTRIES.

Certification cycle start date: **08 May 2013**

Subject to the continued satisfactory operation of the organisation's Management System, this certificate expires on: **07 May 2016**

Original certification date: **08 May 2004**

Certificate No. **IND13.6255N** Version : 1 Revision date: **07 May 2013**

Certification Authority
R. K. SHARMA-Director

NABCB

QM 063

Local office: *"Marvah Centre" 6th Floor, Kitaphanlal Marwah Marg, Opp. Arya Industrial Estate, Off Saki Vihar Road, Andheri (East), Mumbai – 400 072. India*

Further clarifications regarding the scope of this certificate and the applicability of the management system requirements may be obtained by consulting the organization. To check this certificate validity please call +91 22 6695 6300.