

## Guide to choosing accessories which best suit your application

When you're in the process of purchasing one of our products, you will be able to select between several accessories that will be added to the quotation. While all these accessories are optional, it is important to define your requirements and select the appropriate additions. To help customers understand the benefits of certain accessories, follow the basic guide below.

First, it's important to ask yourself some basic questions:

Is the incubator to be used for general application, where audits are not critical, or do you need it for more stringent needs? Or is the incubator required to adhere to FDA audits?

Information below will aid you when deciding which accessories to select, and for more details you can email us on [info@osworldindia.com](mailto:info@osworldindia.com).

When choosing accessories for a product, the following factors should be considered:

**Size / Capacity:** Osworld manufactures incubators in various capacities. The sample quantity to be tested will determine which capacity of incubator is suitable. When you do the sample, keep in mind that test conditions, for long term or accelerated study, are conducted over prolonged time durations. Customers are always advised to buy a bigger capacity than required to ensure samples have sufficient space. It is worth noting that incubators can only be filled with sample sizes up to 70 per cent of their overall capacity. Ensure your chosen incubator size has enough free space around the sides to allow air to flow freely.

*Caution: Restricting or blocking air could result in some samples not getting desired exposure to set climatic conditions; this could call for a retest by an auditor.*

**Test Condition:** Before purchasing, determine the temperature that your sample needs for its test. To find the optimum test condition, check the ICH guidelines to see testing standards across climatic zones. While Osworld incubators can match all ICH conditions, it is important to specify your test conditions when ordering a product. Only with this information can we test the incubator extensively based on your conditions.

**PLC Control with HMI Touch Screen:** Osworld incubators can be configured with PLC control, which is cutting edge technology that boasts an attractive HMI sporting a 7" colored display. With this display, customers can view parameters in clear user interfaces. Through an HMI, information such as audit trails and alarms are shown, as well as a complete data rundown. Use of the PLC control with HMI is password protected to allow access to only authorized personnel, while data is directly linked to a computer.

While the PLC control is an excellent tool, it is admittedly only necessary in specific circumstances. With that in mind, it should only be added as an accessory if your budget allows. For example, customers in remote areas with unstable power input should typically avoid adding a PLC module to an incubator. That's because PLC control systems are voltage sensitive, so some infrastructure may not be able to handle the module. Also of note is the fact PLC modules require trained engineers to handle any service issues that may arise. If you cannot provide these necessities, a conventional PID system is more useful and recommended.

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**Single Point Data Logger:** ICH guidelines mandate the presentation of documented evidence for all incubator test cycles. All information must be retained, including the difference between set values and actual values during the duration of a test cycle. With this information, auditors can inspect the data properly. For many customers, data storage and logging devices become a vital accessory that avoids plenty of time and effort.

**Software 21 CFR Part 11 compliant:** All electronic documentation submitted during audits must be compliant with the 21 CFR Part 11 regulatory framework. By selecting software that automates document compliance with 21 CFR Part 11, customers also receive improved data management when using multiple incubators. We strongly recommend choosing this accessory during your purchase because it provides a more efficient and convenient data management solutions. With this software, finding old data is also much easier.

**Stand-by refrigeration and sensor with auto change over:** While many accessories can help you follow regulations and be compliant across several spectrums, some are just in place for convenience. No guidelines exist that demand incubators have a stand-by system, although there are guidelines that state incubators must function uninterruptedly during an entire test period.

Because some components can wear and tear through extensive use, auditors do have the power to demand there are failsafe mechanisms in place to prevent component decay. That possibility makes adding a proper periodic maintenance plan in place an ideal solution. Customers should include this addition if they have experience of needing stringent compliance that demands failsafe technology be implemented.

During operation, if the refrigeration system or sensor fails malfunctions, the system detects an error and triggers the stand-by systems to function. This allows incubators to continue working and maintain conditions that are not interrupted, while the faults are attended by service staff. This is not a 100% failsafe mechanism, as there are several other components that could fail, but stand-by systems take care of the critical components by providing support during failure.

FDA guidelines clearly state that there should be a completely functional incubator, which is validated for all required conditions to be maintained as a stand-by incubator. In the event of an incubator with samples failing, all samples should be transferred to the stand-by incubator immediately.

**Multi Point Data logger:** By choosing this accessory, your incubator will be able to record data at multiple points and submit documented evidence of functionality across conditions. Generally, if a temperature mapping cycle is conducted as part of PQ during installation then it is sufficient evidence of condition being uniform within the incubator. Yet, for customers dealing with larger volumes, a multi-point data logger is potentially a necessary addition.

**Magnetic door lock facility:** Standard incubator equipment features only a single lock and key. By choosing a magnetic door, the incubator is more secure through a door that can be accessed via a password or fingerprint scanning technology. This means only people authorized to use the incubator will have access to it. It is worth remembering that a magnetic door can only be added if you have also chosen the PLC control accessory.

**GSM Module:** There are no compliance requirements that demand mobile integration, so a GSM module is all about convenience.

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## Sample Incubator

Here we will create a sample incubator with accessories. If you are a drug manufacturer seeking to produce the best quality medicines, the Incubator we suggest for optimum outcomes features the following accessories:

1. **PLC Control with HMI Touch Screen**
2. **Single Point Data Logger**
3. **Software 21 CFR Part 11 complaint**
4. **Stand-by refrigeration and sensor with auto change over**

For interrupted failure free operation, add through local vendors:

5. UPS power system if there are power failures
6. Room air conditioning to keep surrounding temperature within limits

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