ClorDiSys

"The Chlorine Dioxide People"

Application Note #23

Chlorine dioxide gas and Isolators

Isolator Use:

Isolators are gas-tight enclosures typically used in either animal isolation or production applications. The isolator acts as a small clean room to protect the animal or product contained within it from any type of contaminant that exists in the normal environment. Alternatively, here are some applications where the material worked on within the isolator may be hazardous. In those setups, chambers are kept at a negative pressure realtive to its environment to keep the contaminants contained within the isolator.

Presented Need:

In any scenario of isolator use, the cleaning of the inside is periodically needed and can often present a challenge to the user and facility. In many applications, the isolator will be sprayed with a variety of cleaning compounds and then wiped down. While the spray and wipe may be better than not cleaning at all, it will rarely result in creating a sterile envornment within the isolator.

The best method for creating a sterile isolator before or after use is by exposing it to a true gas, such as a chlorine dioxide cycle. These cycles are relatively quick, repeatable, and easily validated. The setup is very versatile and capable of interfacing with almost any application.

Equipment Required:

The equipment required to decontaminate an isolator consists of:

- Minidox-M/Cloridox-GMP Portable CD Generator.
- Connection plate or proper ports on the isolator.
    - Qty.4 rectus quick connect valved fittings, Qty. 3 cord grips, and Qty.2 cam-lock fittings. (optional)
- Air supply and exhaust valves / dampers and pressure relief system.
- SCT System. (Optional)
    - Contains Mixbox, Regen blower, Hosing, and Adapter tees.
- Carbon Scrubber System (Optional)

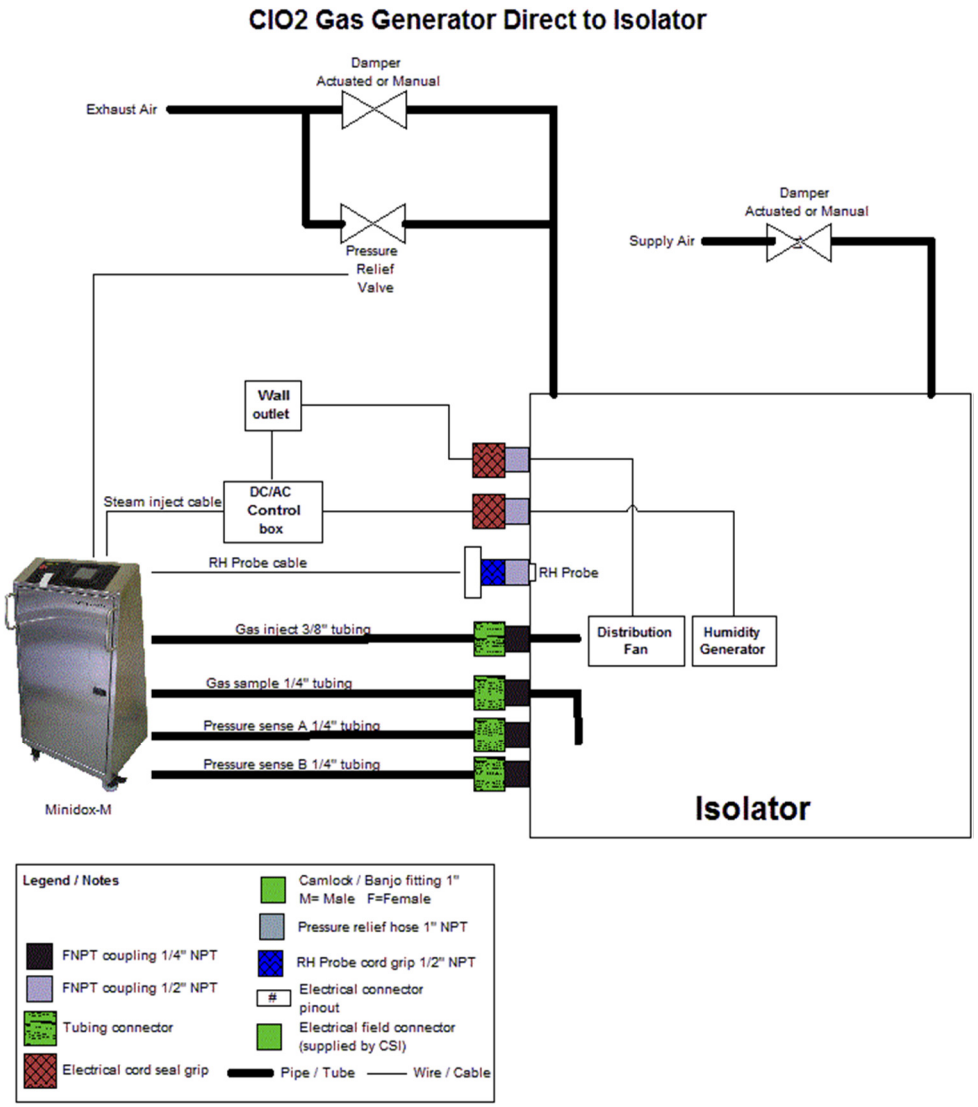
Equipment Setup and Operation 1st Approach:

The first setup discussed is the most direct. This is typical whether the user has a single isolator or multiple isolators at their facility. In this scenario the ClO_2 generator is connected directly to the isolator that is to be sterilized. Only one isolator at a time can be targeted in this setup. The quick connect fittings and electrical cables make it easy to switch from isolator to isolator. If multiple isolators are to be done at once, move onto the setup with the SCT with multiple isolators section.

Connections:

There must be four ¼" FNPT connections on the chamber for the rectus quick connect fittings to be threaded into. These can be in the form of ¼"FNPT tapped holes, tank adapters, or welded couplings.

Three ½" FNPT connections are required for the cord grips for the Temp / RH probe, steamer power, and fan power.



Aeration:

The cam-lock fittings for aeration may or may not be needed depending on the type of ducting already run to and from the isolator.

Aeration can be completed in a few different ways:

1. Facility supply and exhaust can be connected with valving on each side for isolation during the sterilization cycles.
2. Exhaust may also be in the form of a scrubber with the supply being from the facility supply or from a filtered inlet from the surrounding room.

A major consideration that dictates the air supply and exhaust setup is what pressure the user wants the isolator to be at during the aeration step. A pressure-relief valve typically is installed to bypass the exhaust damper / valve and prevent the isolator from over pressurizing. A pressure-add valve can also be added to keep the isolator positive to its containing room. This would require a filtered airline from the facility or an additional pump.

Process:

The cycle would progress through these steps:

1. Close supply and exhaust dampers.
2. Run pressure decay test on isolator (Pressure add required).
3. Monitor RH and turn on steam until RH set point is reached, then dwell.
4. Introduce gas until set point is hit and dwell until desired exposure is reached.
5. Open supply and exhaust dampers to remove gas.

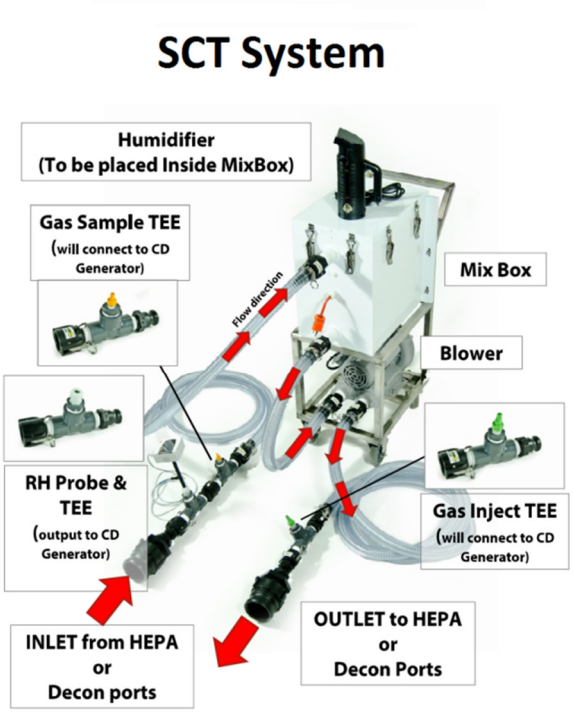
During this process a gas and humidity sample will continuously be taken and more gas or humidity will be injected if needed. The gas generators have the ability to control the supply and exhaust dampers and other valving if desired.

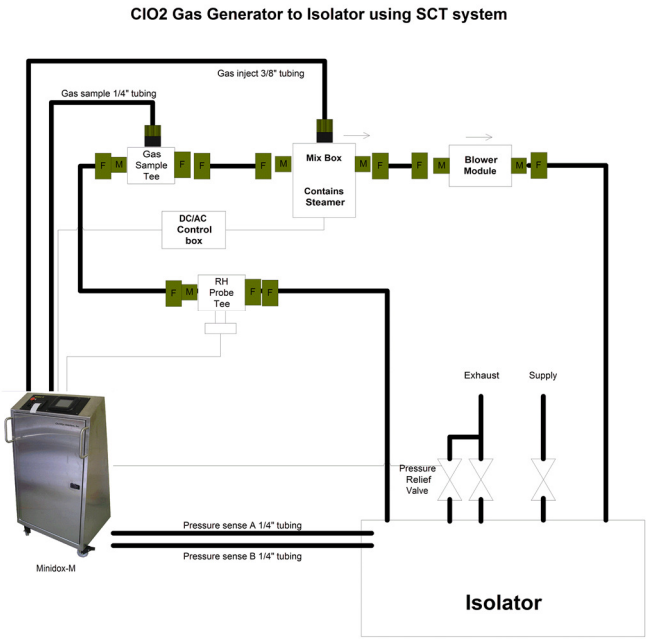
Equipment Setup and Operation 2nd Approach

This approach utilizes an enclosed recirculating system (SCT) that gets connected to the target chamber. The major difference is most of the connections from the gas generator go to the SCT system instead of directly to the isolator. This setup is used when either the target isolator is too small to place the steamer, fan , and probe within, or if the user doesn't want to have steamer, fan, and probe inside of the isolator during the cycle or after it is completed.

There are a few diagrams below that demostrate possible setups of one or more isolators. The *ClO2 Gas Generator to isolator using SCT system* diagram is a common setup if the isolator already has its own supply and exhaust that can be closed for the streilization cycle. This isloator setup would aerate by simply opening its supply and exhaust valves and running in normal operation. The SCT blower would keep running for a short period to ensure all gas leaves the SCT system.

The last two diagrams demonstrate a common setup if the target isolator or isolators do not have a supply and exhaust run to them. These are titled *ClO2 Gas Generator to (Multiple) isolator(s) using SCT System with Aeration Valves* In these cases instead of returning the isolator to its normal mode, a series of valves would be opened and closed to break the recirculating loop and force aeration. Fresh air would be pulled in through a filter or any form of supply, and that air would go through the isolator , the SCT system, and then be forced out to an exhaust or scrubber.





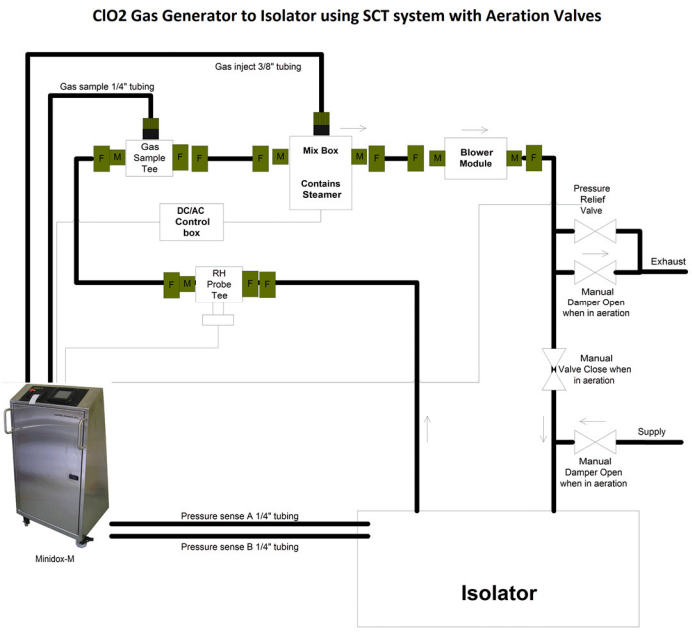
SCT Method Summary:

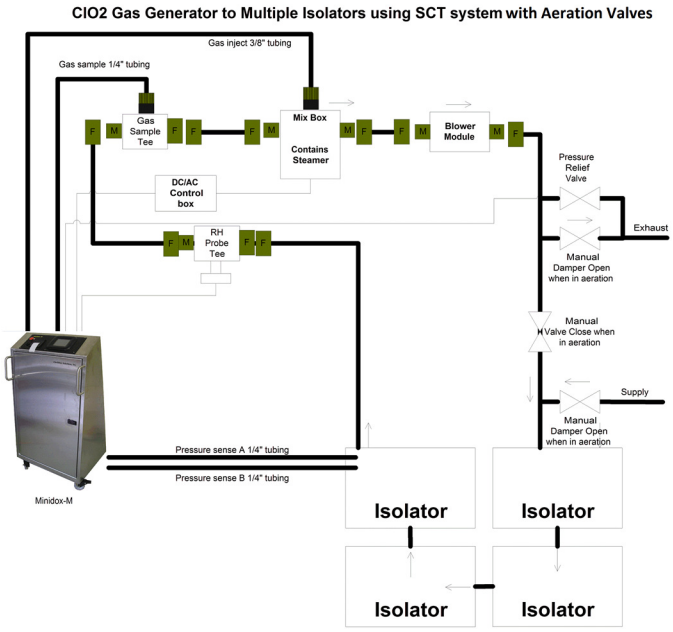
The additional equipment needed for these setups primarily consists of the SCT system. In the case of multiple isolators, additional hosing and cam lock fitting would be required.

Using the SCT system on a single isolator is typically only done when the size of the chamber is very small and does not permit some of the equipment to be placed within.

The primary advantage of this method is being able to target multiple chambers at the same time by simply connecting the chambers together in series as shown in the lower diagram.

The cycles involving the SCT system are similar to the cycle for the direct connection with the addition of turning on/off the regen blower prior to and after the cycle.





General Equipment Operation:

The operation of the equipment for a ClorDiSys CD gas generator utilized to decontaminate isolator is as follows:

Make all appropriate physical connections.

1. Isolators typically come with couplings or ports that can be utilized by the Minidox. If these ports do not exist then the couplings can be installed.
2. Insert a small steamer and Temp/RH probe into the system.
3. Plug the DC/AC control box into an outlet and the steamer into the DC/AC control box. A section of the power cord between the control box and steamer will be passed through the second cord grip
4. Connect the M-12 cables (small 4 pin connector) from the back of the Minidox to the corresponding cables on the RH / Temp probe, DC/AC control box, PR, and PA valves.
5. Use ¼" Kynar tubing to connect the Minidox sample port to the system sample point.
6. Use ¼" Kynar tubing to connect the Minidox pressure sensing ports to the system pressure sensing ports.
7. Use 3/8" tubing to connect the Minidox gas injection port to the system injection port.

8. Use 1 ¼” hosing to connect the gas outlet of the isolator to the scrubber. (This is if scrubber is used versus facility supply and exhaust.)

Sterilization Process:

The normal sterilization process is automated and consists of 5 steps:

1. Precondition: Raising of humidity to make spores susceptible to gas.

   This is achieved by using the RH probe in the system to read humidity and then injecting steam until the setpoint is reached.

2. Condition: Holding of raised humidity level for spore softening.

3. Charge: Injection of gas into system.

   This is achieved by injecting CD gas until the photometer measures that the concentration is reached.

4. Exposure: Holding of gas concentration for the set amount of time.

5. Aeration: Removal of gas and humidity. For ducted isolators, this is simply accomplished by turning on the exhaust blower and opening the infeed and exhaust dampers on the isolator. For non- ducted isolators, this is accomplished by using a carbon scrubber to break down the CD gas. This method aerates the isolator in under an hour.

Comments/Notes:

The above are the common methods of interfacing a Minidox with an isolator. There are several different layouts that can be used depending on the particular setup;for help with a specific setup please call us at 908-236-4100.