PrimaTec Management Limited

Equipment Division

Expert Providers of Low Temperature Residue Free Gaseous Bio-Decontamination Solutions

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What is Chlorine Dioxide?

Chlorine Dioxide (CD) is a greenish yellow gas and is a single-electron-transfer oxidising agent with a Chlorine like smell. CD has been recognised since the beginning of the century for its disinfecting properties; these properties have led to the widespread use of CD in the treatment of drinking water. Beyond this and numerous other aqueous applications, the sporicidal properties of *gaseous* CD were demonstrated in 1986. Subsequent to these initial studies it has been shown that gaseous CD is a rapid and effective sterilant against bacteria, yeasts, moulds and viruses. This sterilising activity is present at ambient temperature and at relatively low gas concentrations.

Although Chlorine Dioxide has 'chlorine' in its name its chemistry is radically different from that of chlorine. When reacting with other substances it is weaker and more selective. For example it does not react with ammonia or most organic compounds. Chlorine Dioxide oxygenates products rather than chlorinating them. Therefore, unlike chlorine does not produce environmentally undesirable organic compounds containing chlorine.

Process Advantages

- Biocidal at low concentration and ambient temperature
- Short Cycles
- It is a true gas that distributes rapidly
- No manual wiping required
- Process tolerates temperature fluctuations and gradients
- No Liquids
- Process effectiveness independent of dew point and condensation
- No neutralisation required
- Efficacious under vacuum or at atmospheric pressure
- Extremely low residuals
- Rapid Aeration
- True flexibility with simple cycle development able to be performed by the user

Antimicrobial properties / Mode of Action:

CD acts as an oxidising agent and reacts with several cell constituents, including the cell membrane of microbes. By 'stealing' electrons from them (oxidation), it breaks their molecular bonds, resulting in the death of the organism by the break up of the cell. Since CD alters the proteins involved in the structure of the microorganisms, the enzymatic fintion is broken causeing very rapid bacterial kills.
The oxidative attack on many proteins simultaneously is behind the potency of CD and explains why the cells of microorganisms are unable to mutate to a resistant form.

Environmental Impact

Chlorine dioxide's special properties make it an ideal choice to meet the challenges of today's environmentally concerned world. Actually, chlorine dioxide is an environmentally preferred alternative to elemental chlorine.

When chlorine reacts with organic matter, undesirable pollutants such as dioxins and bio-accumulative toxic substances are produced. Thus, the EPA supports the substitution of chlorine dioxide for chlorine because it greatly reduces the production of these pollutants. It is a perfect replacement for chlorine, providing all of chlorine's benefits without any of its weaknesses and detriments. Most importantly, chlorine dioxide does not chlorinate organic material, resulting in significant decreases in trihalomethanes (THMs), haloacetic acids (HAAs) and other chlorinated organic compounds.

This is particularly important in the primary use for chlorine dioxide, which is water disinfection. Other properties of chlorine dioxide make it more effective than chlorine, enabling a lower dose and resulting in a lower environmental impact.

Gas Generation Method

Reagent (gas) + Sodium Chlorite (solid) = Chlorine Dioxide (gas) + Salt (solid)
Only pure gas is delivered to the chamber, the salt solid remains in the CD Cartridge
Gaseous CD is not corrosive like liquid CD. The method of generation of CD has a direct impact on its corrosiveness.
Comparison of liquid vs. gas showed a 3.7 log reduction with liquid CD and a 7.4 log reduction with gaseous CD with equal concentrations and exposure times.

The Process

A Chlorine Dioxide Sterilisation consists of 5 steps. These steps are automatically controlled by the Chlorine Dioxide Generator or are undertaken by professionally trained staff in the instance of a service being provided.

The Steps:

1. Pre – Condition - The area is humidified to 70%RH, monitored continuously with calibrated equipment.

2. Condition – Once humified the area is held at the set humidity to allow

   penetration into all areas. Leak tests are also performed at this point.

3. Charge – The gas injected and concentration is raised to the set point (typically 360ppm)

4. Exposure – Once satisfied the gas is maintaining the set concentration the exposure time is started.

5. Aeration – At the end of the exposure period, the gas is aerated, either vented to atmosphere or removed by a carbon scrubber system.

Dependent on the size of area and gas concentration used, this complete process

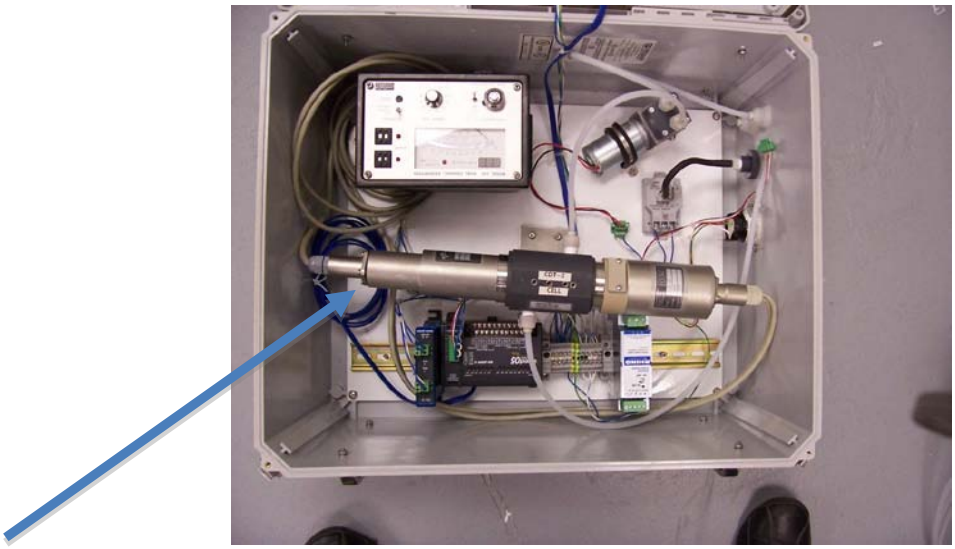
Cycle Development:

Cycle development will initially be worked out in conjunction with the user as part of the installation process and during the training period.

Thereafter should the user wish to perform a cycle on a new area the user can perform chamber or room cycle development literally in seconds. This means that there are no expensive charges for cycle development within new areas as with some other methods of de-contamination.

Concentration Monitoring

Due to the colour of the gas, highly accurate concentration monitoring is available via a UV Viz Spectro Photometer.



This piece of equipment along with its control system is used to continuously monitor the gas concentration from start to finish of a cycle. The cycle not ending until the monitor reads zero and a safety period of extraction has also then been allowed.

An alternate option for this if a generator has been purchased which does not have the inbuilt concentration monitor (i.e. Minidox B or L) is our Environmental Monitoring System (EMS). The EMS is a separate unit, which can be used to monitor gas concentrations, temperature and humidity values, and data log these onto a USB flash drive.

Aeration

Aeration of Chlorine Dioxide can be performed by simple extraction to atmosphere using the room exhaust where it is quickly dispersed and diluted, then rapidly breaks down.

Where this is deemed unsuitable (i.e. in a room where it is not possible to shut down the ventilation for the period of decontamination) another option is a Carbon Scrubber unit.

This highly effective unit can be used to break down the gas quickly. It is controlled by the generator to keep the process automatic and is designed to be either internal or external to the chamber/room. If in such areas room vents are to be temporarily sealed during the cycle this optional piece of equipment is recommended.

Externally it can be connected via piping with quick connect cam-lock fittings and will re-circulate the gas whilst breaking it down.

Connecting the Generator:

There are many different options for connecting the generator to chambers / rooms for decontamination.

The following pages outline some of the options available.

Under doorplates allow all connections to be made where there is a slight gap under the door. It provides a quick and simple connection and an easy surface to tape in place where a permanent connection is not necessary or desirable due to the sterilisation of an area being an infrequent process.

Wall plates are a more permanent solution. Providing sealed valve connections through the wall into the target area. Made to measure but typically the size of one building block these plates again provide an easy solution for connection and disconnection and are particularly useful for frequent sterilisation of a particular area, and where the area has sealable doors removes the need for taping.

Also available are door plates. These are designed to be fitted into any door, and similar to the wall plates offer a quick connect / disconnect option for fumigating rooms.

All the necessary connections are made through the plate making it easy to set up and fumigate a room or chamber.

Changing from VHP systems:

Moving from Chlorine Dioxide to replace an existing VHP system is very simple and can be done without the need to change over all your existing connections.
The VHP cam locks can be fitted to using the adaptors shown below for the minimum amount of effort or fuss.

These adaptors, which allow all Chlorine dioxide connections to be fitted to them, are also useful to turn existing autoclaves or washers into chambers for sterilisation as many of these come with cam lock fittings already installed.

Many people move to Chlorine Dioxide Gas because of its efficacy advantage over Hydrogen Peroxide Vapour. Being a true Gas Chlorine Dioxide is able to reach places that Hydrogen Peroxide is unable to and provide a more thorough sterilization.

Although Hydrogen Peroxide can work in many situations there are also many others where it is less suitable than Chlorine Dioxide.

The Safest Fumigant:

This paper highlights some of the reasons why gaseous chlorine dioxide (CD) is the safest of all the gas or vapor decontamination agents. To be clear, all decontamination agents are deadly. This is their function.

Safety Warnings (Self Alerting): The best safety feature with CD is that it is self-alerting. CD has an odor threshold at or below the 8 hour Time Weighted Average (TWA), so the user is self alerted to exposure at a low level and the reliance on external equipment is not as imperative as with VPHP. This alone makes CD safer since the user is self- alerted before unsafe levels are achieved.
With VPHP, odor does not provide a warning of exposure. The user becomes aware of a harmful exposure when choking occurs. The user cannot detect VPHP until the safe levels are exceeded and *must* rely on external equipment to alert of possible exposure. This makes it extremely important to place personal safety detection devices all around the area when using VPHP.
With CD, this reliance upon external equipment is not a necessity because of the odor. Minimal area monitors are required when using CD.

Shorter Cycle Times: Chlorine dioxide is the fastest acting decontaminating gas or vapor. For the various decontaminating agents the cycle times can range from 3-1/2 hours to over 12 hours in decontaminating a 2500 cubic foot room. With normal aeration exhaust rates, a CD cycle would be about 3-1/2 hours or less, formaldehyde would be about 12-1/2 hours, and VPHP could be 10 to 12 hours when you include the aeration times.
This means that a potentially unsafe condition exists for a far shorter time when using chlorine dioxide for room decontamination.
VPHP has long cycles because of the longer aeration times because of vapor condensation and absorption issues that
do not apply with a true gas. Formaldehyde has long cycles because of long exposure times and the neutralization time.

Lower Concentration Levels: Chlorine dioxide is typically used at lower concentrations for room decontamination. VPHP concentrations are typically 750-1500 ppm. Formaldehyde concentration is typically 10,000 ppm. CD concentration is typically only 360 ppm. If something goes wrong, the higher concentration of formaldehyde and VPHP poses a greater risk due to the higher concentrations in the room.

Non-carcinogenic: Chlorine dioxide gas is not carcinogenic unlike formaldehyde.

Safety Continued……

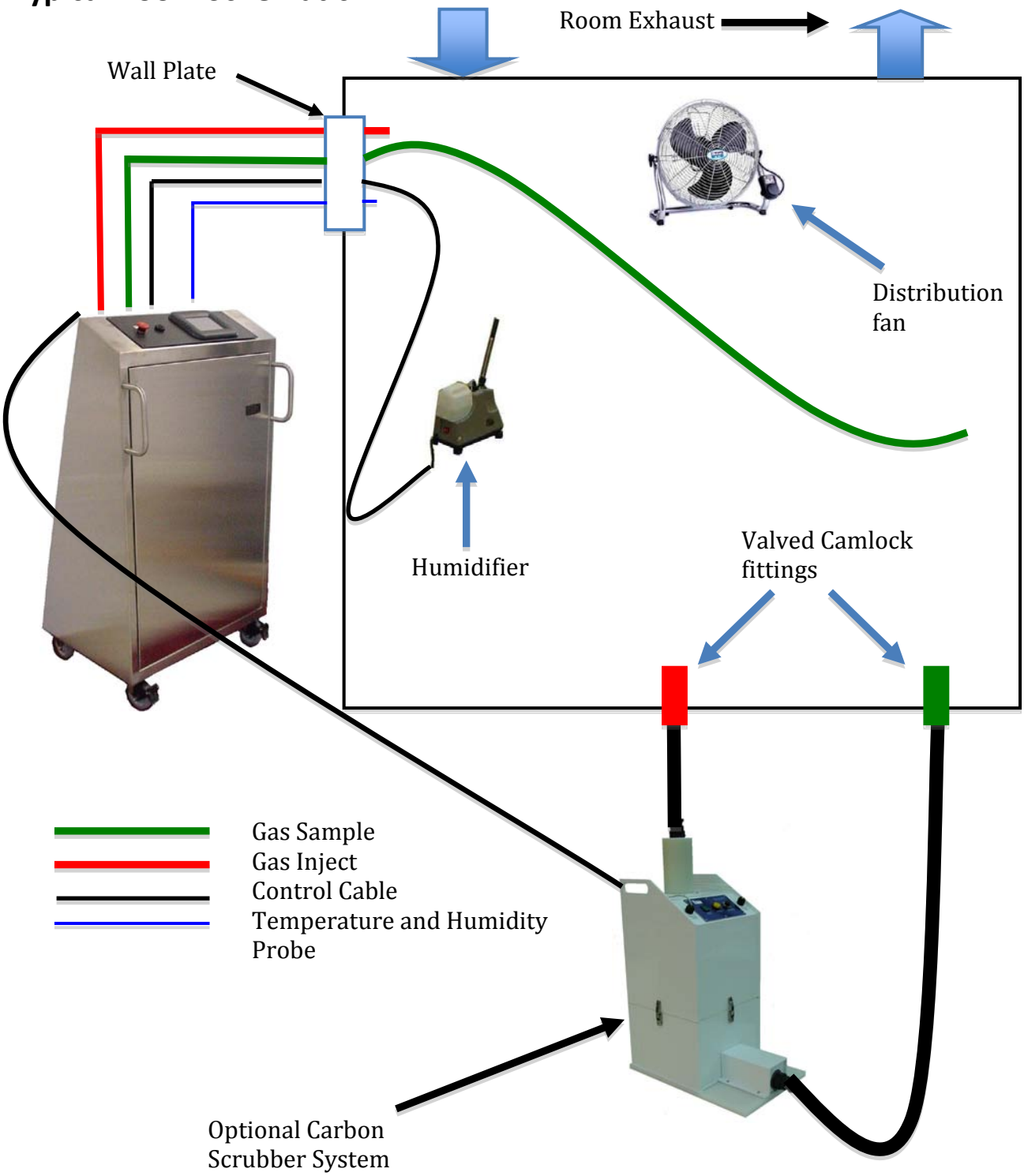
Equipment Located Outside the Target Chamber: The CD generating equipment is located outside the decontamination target chamber. If equipment is inside the chamber and some issue occurs, the user may have to enter the chamber with a decontamination agent present to shutdown the equipment. Since CD generation equipment is located outside the chamber and if some issue occurs the equipment can easily be shutdown by hitting the stop button located on the generator or even by pulling the plug.

Quicker Emergency Aeration: Chlorine dioxide is quicker to aerate down to the 8-hour TWA compared to VPHP and formaldehyde so the room returns to a safe condition quicker when CD is used. If something goes wrong during the CD cycle, aeration can be started and in 30-45 minutes there will be no CD left (below the 0.1ppm TWA). Unsafe levels of a sterilant are present for much longer with VPHP and formaldehyde than CD and provide a greater risk due to having hazardous concentrations present longer. CD can be removed from the room up to 12 times faster. Another way of describing this is that it will take hours for VPHP or formaldehyde to aerate from a room to reach safe levels. For example, it takes 4 hours for VPHP to be reduced from 300 ppm to 1.0 ppm. As a contrast it takes 45 minutes to aerate CD from 300 ppm to 0.1 ppm. So even though the TWA for CD is 0.1 vs. 1.0 for VPHP, CD gets to the safe levels much quicker and therefore is much safer.

Complete Decontamination: Chlorine dioxide and formaldehyde are gasses and gasses reach and penetrate all areas that vapors have trouble reaching. If the decontaminating agent cannot reach ALL of the dangerous organisms in a BSL-3/4 facility, at the proper concentration, for the prescribed amount of time, then a complete decontamination will not occur and worker safety is compromised.

Summary: There are many reasons chlorine dioxide provides a better safety measure when compared to VPHP and formaldehyde. The cycles are shorter limiting the “unsafe” time when the decontaminating agent is present. It is far quicker to aeration to its TWA level if an emergency does occur. The actual concentration levels are significantly lower.
And, most importantly, CD is self-alerting. CD has an odor threshold at or below the 8 hour Time Weighted Average (TWA), so the user is self alerted to exposure at a low level, which is not the case with VPHP.

Typical Room Schematic:



The above is a typical room sterilization installation and comprises of quick connect / disconnect couplings. A set up and cycle start takes only minutes with a typical sterilization being complete in approximately 3 – 4 hours and fully automated.

All doors would have to be either sealable or taped with gas proof tape. Training on how to do this correctly will be given if necessary.

Training and commissioning:

Training typically comprises of 2 to 3 days on site which. This is to train users in all aspects of using the equipment safely and effectively. After this point users would be competent to set up, decontaminate, change consumables and in some cases develop cycles for new areas as necessary.

Cycles will have also been developed for a number of specified areas if required.

Upon Completion of training a certification sheet (see below) will be completed and copies retained by both the supplier and customer.

Training Certification Sheet F

CSI ClorDiSys Solutions, Inc.

Minidox-M TRAINING CERTIFICATION SHEET

☐ Attended Minidox-M training session consisting of the familiarization with the Operations Guide, safe use of the equipment, cycle development techniques and procedures, hardware connections, and safety regarding the equipment operation and the chlorine and chlorine dioxide gases.

Training Site:	Trainers Title:
Training Date:	Trainer: (print/Signature)

Print Name	Signature	Date

Minidox-M Decontamination System Reference Guide 104

Minidox - B
Dimensions 761mm W x 1422mm H x 609.5mm D
Weight 181kg
CE Marked

The Minidox - B Decontamination System is a basic chlorine dioxide gas generation system designed for use in any animal research facility, pharmaceutical, manufacturing, laboratory, or research setting. It provides a rapid and highly effective method to decontaminate a target chamber. The target can be any chamber such as an isolator (sterility test, filling line, containment…), pass through, processing tank or vessel, clean room, Lyophilizer, etc. The Minidox Decontamination System is portable in design and easily connected to various targets. The process is easy to validate due to the repeatable cycle and tight process control.

Why use the Minidox - B gas generators?
• short cycle times
• does not condense out or breakdown during the process
• sterilization at ambient temperatures
• generates a true gas
• excellent distribution into hard to reach areas
• quick aeration (can literally be minutes)
• does not require tight control of dew point temperatures
• no down time between cycles
• portable
• rugged and reliable industrial components
• quality construction
• quick connection to chamber
• complete cycle automation
• easy to use touch screen operator interface
• no liquids in process
• quick consumable replacement
• no manual wiping or neutralization
• no concern for condensation as with hydrogen peroxide
• long life span when compared to ozone
• non-carcinogenic
• non-flammable

Utility Requirements
• 100 - 240 VAC, 5 amp, single phase

Minidox - L

Dimensions 584mm W x 1219mm H x 609.5mm D
Weight 90 kg

Description

The Minidox - L Decontamination System is a smaller, more economical chlorine dioxide gas generation system designed for use in any chamber under 300 ft3 (8.5 m3) such as an isolator, incubator, or a Biological Safety Cabinet (BSC). The Minidox – L can be used in any animal research facility, pharmaceutical, manufacturing, laboratory, or research setting. It provides a rapid and highly effective method to decontaminate a target chamber. The Minidox-L Decontamination System is portable in design and easily connected to various targets. The process is easy to validate due to the repeatable cycle and tight process control.

Why use the Minidox - L gas generators?

- Replacement for formaldehyde
- Generates a true gas
- Complete cycle automation
- Portable
- Excellent distribution into hard to reach areas
- Does not require tight control of dew point temperatures
- No manual wiping or neutralization
- Does not condense out or breakdown during the process
- Non-carcinogenic
- Non-flammable
- Short cycle times
- Quick aeration (can literally be minutes)
- No down time between cycles
- Quick connection to chamber
- Sterilization at ambient temperatures
- Easy to use touch screen operator interface
- Quick consumable replacement

Utility Requirements at Point of Use
100 - 240 VAC, 5 amp, single phase

Minidox – M

Dimensions 761mm W x 1422mm H x 609.5mm D
Weight 181kg

Description
The Minidox - M Decontamination System is a basic chlorine dioxide gas generation system designed for use in any animal research facility, pharmaceutical, manufacturing, laboratory, or research setting. It provides a rapid and highly effective method to decontaminate a target chamber. The system features a sophisticated sterilent concentration monitoring system to assure a tightly controlled decontamination process. The target can be any chamber such as an isolator (sterility test, filling line, containment…), pass through, processing tank or vessel, clean room, Lyophilizer, etc. The Minidox Decontamination System is portable in design and easily connected to various targets. The process is easy to validate due to the repeatable cycle, tight process control, and its highly accurate sterilent monitoring system.

- short cycle times
- does not condense out or breakdown during the process
- sterilization at ambient temperatures
- generates a true gas
- precise concentration monitoring
- excellent distribution into hard to reach areas
- quick aeration (can literally be minutes)
- does not require tight control of dew point temperatures
- portable
- rugged and reliable industrial components
- quick connection to chamber
- complete cycle automation
- easy to use touch screen operator interface
- no liquids in process
- quick consumable replacement
- no manual wiping or neutralization
- long life span when compared to ozone
- non-carcinogenic
- non-flammable
- no down time between cycles

Utility Requirements at Point of Use
- 100 - 240 VAC, 5 amp, single phase