

Portable Decontamination and Sterilization System

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Decon Downunder

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Organization of Presentation

- **Related work in decontamination at TDA**
- **Related work in portable devices**
- **Portable sterilization/decon system**
 - Overall design
 - Gas-generating reactions
 - Packaging of reactive ingredients
 - Indicators
 - Performance and applications

Decontamination Research at TDA

- **Protection of Building Occupants**
 - Gas-phase decontaminants, focus on bacterial spores
- **Spray-On Coating**
 - Facilitates decontamination of personal equipment
- **Catalytic Coatings**
 - Detoxification of CW agents under ambient conditions
 - HD oxidation catalysts
 - VX hydrolysis catalysts

Portable Devices at TDA

No Batteries or External Power Source Required

- **Self-heating products**

- Heater for military rations
 - Solid, activate by adding water
 - Designed to heat food pouches like US Army MRE
 - Being evaluated in US and other countries
- Self-contained package to heat liquids and oils
 - Easily activated by breaking frangible seal; product does not contact heater

- **Mosquito trap**

- Survey disease-carrying insects, monitor control programs
- Self-contained source of CO₂ attractant

- **Portable sterilizer/decon unit**

Sterilizer/Decon System

- **Sterilizer for medical/dental instruments**
 - Replaces steam autoclave, which is heavy and requires substantial electrical power
 - For military medics, humanitarian relief workers
 - Medics can take fewer units of each instrument, sterilize for re-use, so fewer medical supplies must be carried
 - Sterilant generated by chemical reaction
 - No external power required
- **Sterilant is chlorine dioxide gas, ClO₂**
- **Can also be used for biodecon of sensitive equipment and small spaces, such as crew compartments**

Chlorine Dioxide Use in Decon

- **Widely used in water purification**
- **Used to treat fruits and vegetables to increase shelf life**
- **Solutions of ClO₂ in water are effective against VX and HD on surfaces; no data for gaseous ClO₂ with CW agents**
- **ClO₂ is effective against bacterial spores**
 - Used to decontaminate anthrax spores in buildings
 - Bacterial spores are severe challenge, used in U.S. FDA certification protocol for sterilizers
 - Sterilization possible in less than 30 minutes

Sterilizer Unit and Subsystems

- **Unit is lightweight plastic bag**
 - Folding seal with adhesive closure, gas-tight
 - Transparent but colored to prevent photodecomposition of ClO_2
 - Cannot easily re-open
 - Peelable foot for easy access after sterilization cycle
 - Obvious if opened, indicates sterilizer has been used
- **Subsystems:**
 - Gas-generating reactions
 - Packaging of reactive ingredients
 - Sterilizer bag design (single use)
 - Indicators
 - Vent with ClO_2 scavenger
 - Overwrap

Generation of ClO₂

- **ClO₂ cannot be shipped, must be prepared at point of use**
- **Common ClO₂ production methods:**
 - Electrochemical processes
 - Sodium chlorate reduction with SO₂ or organics
 - Acidification of sodium chlorite
- **In TDA's system, ClO₂ is generated by chemical reaction**

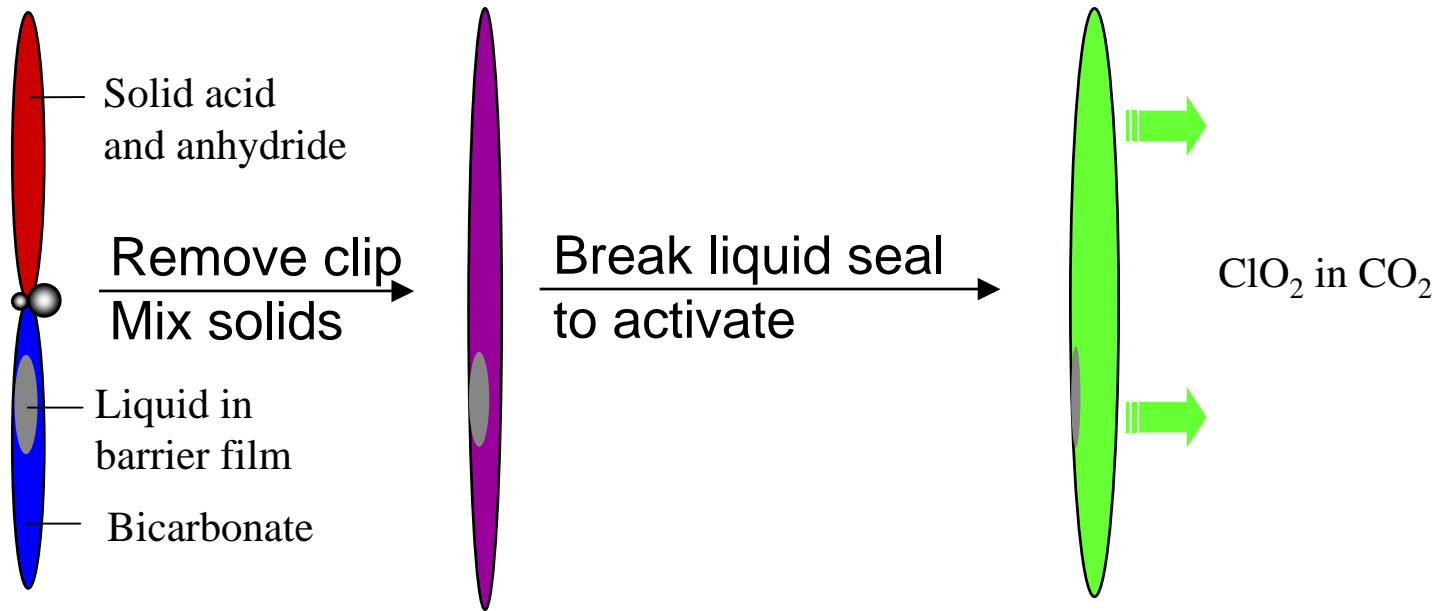
Gas-generating Reactions in Portable System

- **Generate mixture of ClO₂ and CO₂**
 - React solid acid and/or anhydride (HA) with solid NaHCO₃ and solution of NaClO₂ in water:



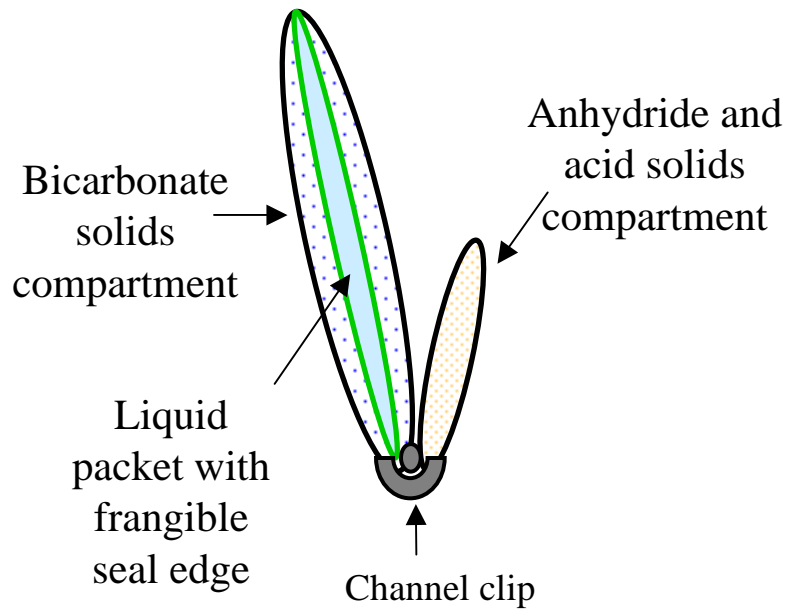
- **Use of gas mixture:**
 - Increases safety: high concentrations of ClO₂ (>10%) can explode, but our low concentration is stable
 - Improves gas distribution: larger total volume of gas produced
 - Adding salt to the aqueous solution used to produce sterilant allows humidity control, which improves kill of bacterial spores

Packaging Reactive Ingredients for Long Shelf Life

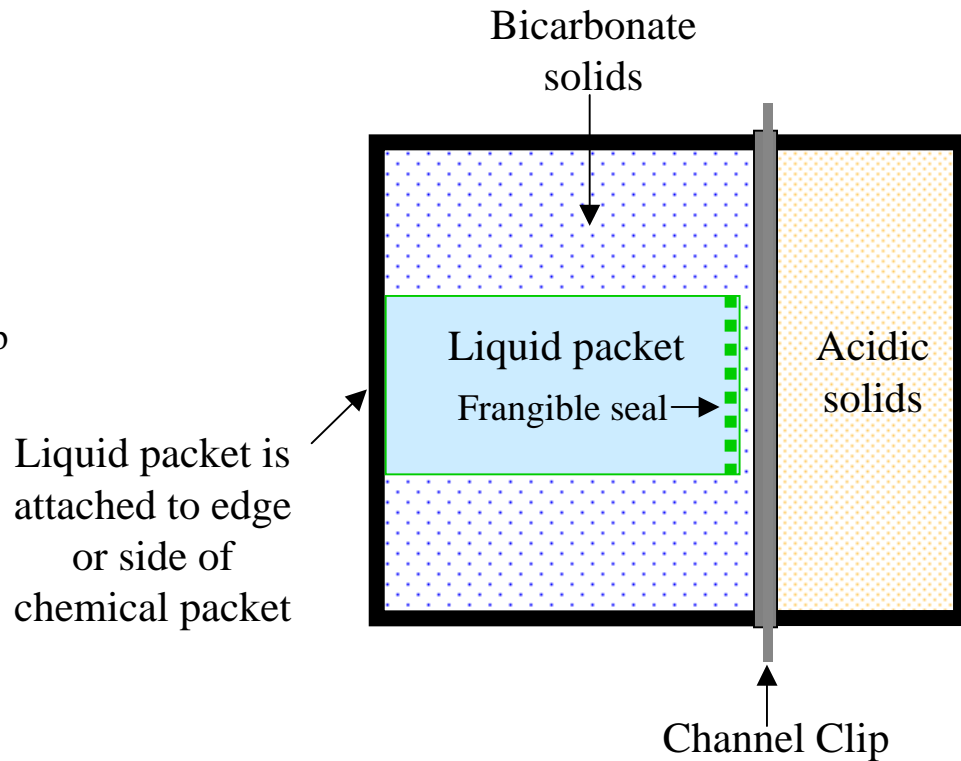


Schematic of Gas Generator

Side View

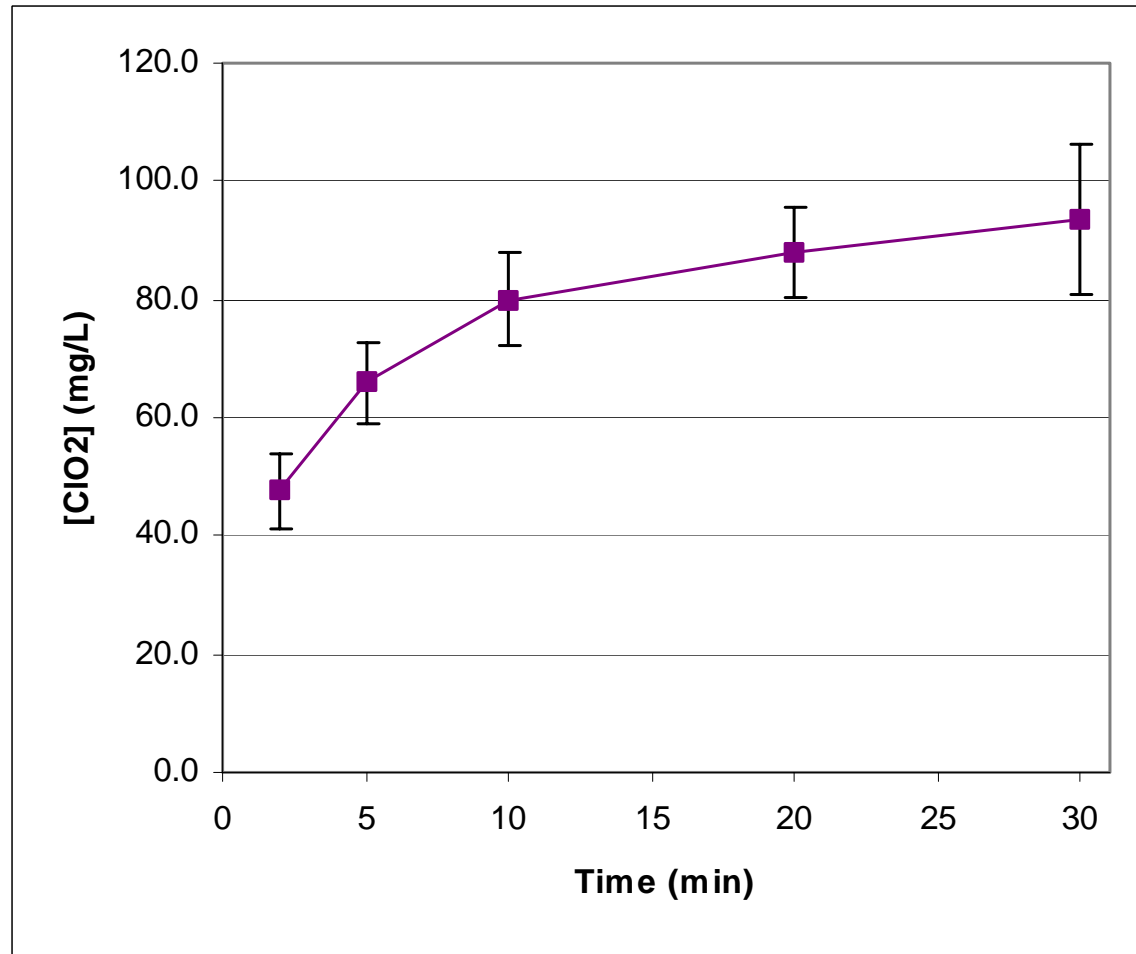


Top view (unfolded)



Gas Generator Performance

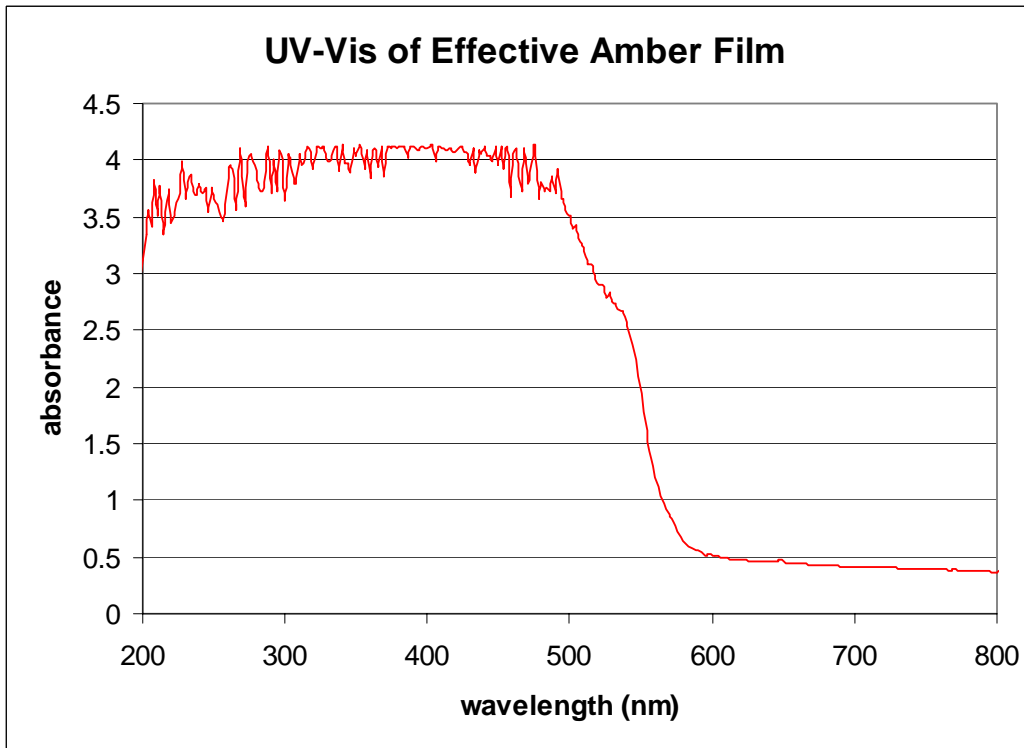
Example of Chlorine Dioxide Concentration vs. Time



Sterilizer Materials (1)

- **Outer film**

- Transparent polyolefin, polyester, nylon, or laminates to see indicators inside
- Inner heat-seal surface
- Colored to avoid photodecomposition of ClO_2
- Best: polyester (dye uptake) laminated to polyolefin (heat sealing)



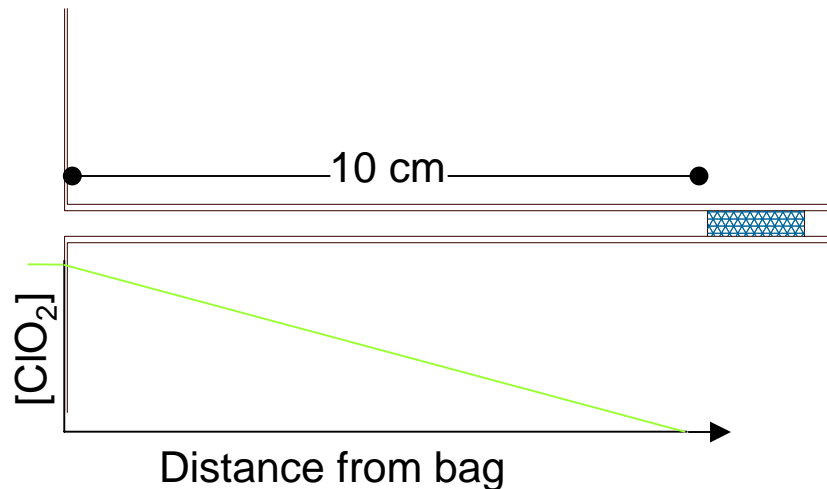
Film must block violet and UV light to prevent photodegradation of ClO_2

Indicators

- **Indicator to show ClO₂ is present**
 - Indicator is printed on or attached to inside of pouch
 - Changes color on exposure to ClO₂
 - Located at side of sterilizer; ClO₂ contacts this indicator after it has spread through the sterilizer
- **Temperature**
 - Reversible indicator on outside of sterilizer bag to show when unit is too cold and should be warmed for correct functioning

Vent with ClO_2 Sorbent

- **Use activated carbon to remove ClO_2**
 - To assure operator safety
 - Carbon filter units simple, inexpensive
- **If filter is sufficiently far from sterilizer interior, no check valve needed**
 - Calculations indicate that 10 cm is far enough
- **Requires fitting to attach tubing to sterilizer bag and manually powered pump**



Operation of Portable Sterilizer

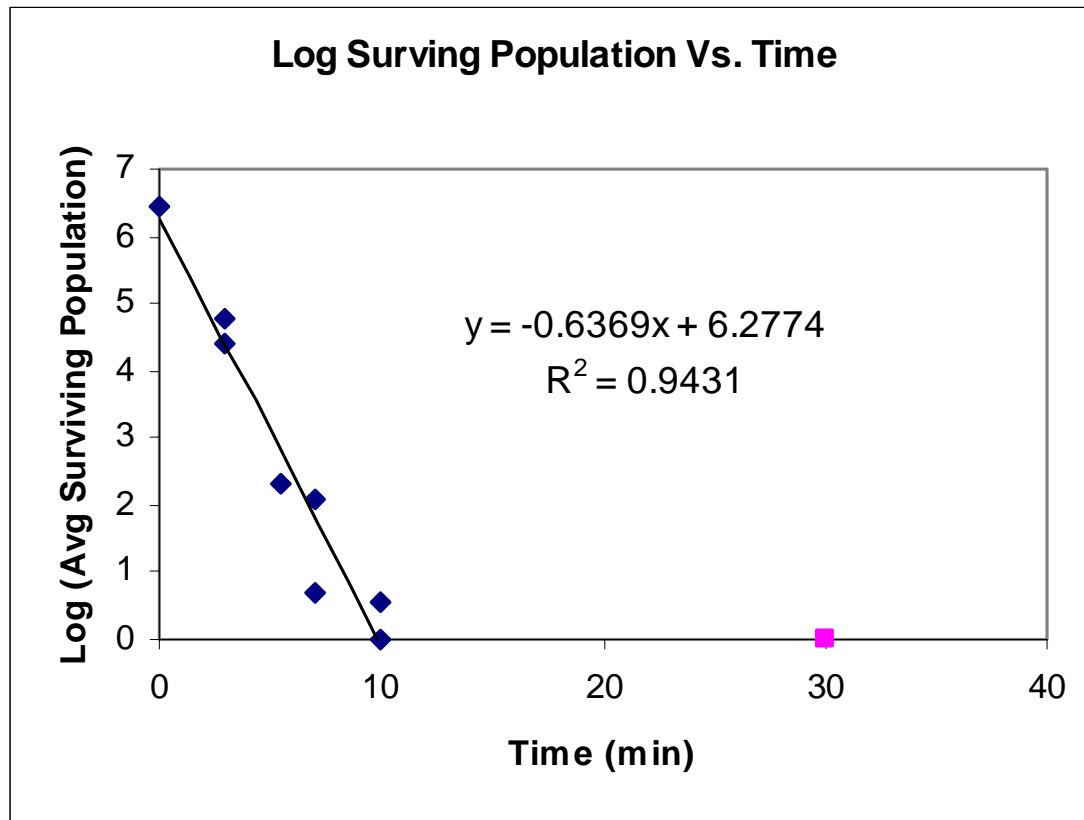
- **After use, medical instruments are cleaned and placed in sterilizer bag**
 - **Instruments may be treated in Tyvek pouches, to allow transport after treatment while maintaining sterility**
- **Remove channel clip separating powder solids; place gas generator in sterilizer bag and seal the bag**
- **Use pump (pipet bulb) to remove air**
- **Activate gas generator – pressure to break seal**
- **Gas mixture inflates sterilizer bag**
- **Indicator confirms presence of ClO_2**
- **After specified time (e.g., 30 minutes), sterilization is complete**
- **Use pump to remove gas mixture; carbon trap absorbs ClO_2**
- **Open sterilizer bag at foot to remove instruments**

Test Methods

- **Use Biological Indicators (BIs)**
 - Each BI is 1-cm diameter stainless steel disc, inoculated with *ca.* 10^6 spores of *B. atrophaeus*, in Tyvek/Mylar bag.
- **Test in plastic bag; generate ClO₂ from solid mixture**
 - During sterilization, ClO₂ penetrates Tyvek
- **Vary exposure time, ClO₂ concentration, temperature, humidity**

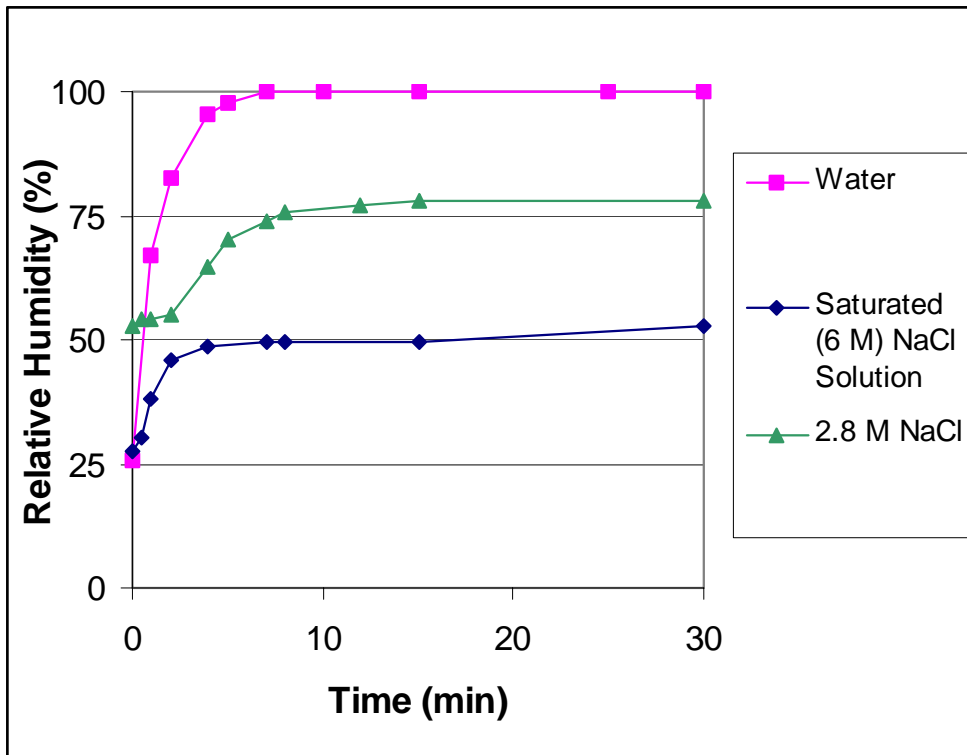
D-Value Calculation

- D-value (time for 1-log population reduction) from population data (graph below) is 1.6 minutes
- Growth/no-growth analysis by Stumbo-Murphy-Cochran equation indicates D-value of 1.1 minutes
- Also effective when instruments are in standard Tyvek resterilization pouches



Humidity Control

To eliminate bacterial spores, it is highly desirable to control the humidity during sterilization to 70 to 95%, preferably 90 to 95%. Adding NaCl to the NaClO₂ solution lowers the humidity of the gases produced from 100% to the desired range.



- In a single-use collapsible bag, most of the gas in the bag during sterilization is from the gas generator.
- By preventing condensation, we minimize the time for decontamination and help prevent corrosion

Performance and Dimensions

- **Demonstrated generation of effective ClO₂ dose and humidity control in portable device**
- **Tested with biological indicators (BIs), and with instruments inoculated with bacterial spores**
- **Sterilization in less than 30 minutes at room temperature**
 - Longer treatment times required at low temperature
 - Reduced efficacy when spores were deposited in combined serum/hard water matrix; instruments must be thoroughly cleaned before treatment to assure sterilization
- **Size (largest tested to date)**
 - 56 cm by 36 cm
 - Weight 125 g
- **Can process medical instruments weighing more than 10 times as much as the sterilizer**

Summary

- **Convenient, safe source of ClO₂ gas**
- **Readily transported**
- **Requires no batteries or external power**
- **Suitable for sterilization of medical/dental instruments, biodecontamination of small items**
- **TDA has applied for patent**
- **Development is continuing**

Disclaimer and Acknowledgements

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