Portable Decontamination and Sterilization System

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Abstract

TDA Research, Inc., (TDA) is developing a portable system to generate chlorine dioxide, which can be used for biodecontamination of small items and to sterilize medical and dental instruments in austere environments. Prototype systems can effectively sterilize both biological indicators and medical instruments inoculated with bacterial spores. At room temperature we found D-values (time for 90% kill) consistent with a sterilization cycle time of less than 30 minutes. The system has multiple features to assure simple and reliable operation. It requires no external power and includes indicators to verify correct functioning.

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 CO_2 attractant
- **Portable sterilizer/decon unit**

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Sterilizer/Decon System

- **Sterilizer for medical/dental instruments, biodecon of small items**
  - 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
- **Gas-phase sterilant generated by chemical reaction**
  - Sterilant is chlorine dioxide, ClO_2
  - Rapid, proven effective in earlier studies
  - Solutions of ClO_2 in water are effective against VX and HD on surfaces; no data for gaseous ClO_2 with CW agents
- **ClO_2 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 in less than 30 minutes

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Sterilizer Unit and Subsystems

- **Unit is lightweight plastic bag**
  - Folding seal with adhesive closure, gas-tight
  - Similar to currently used resterilization pouches
  - 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 ClO_2

- **Widely used in water purification**
- **Cannot be shipped, must be prepared at point of use**
- **Common ClO_2 production methods:**
  - Electrochemical processes
  - Sodium chlorate reduction with SO_2 or organics
  - Acidification of sodium chlorite

Gas-generating Reactions in Portable System

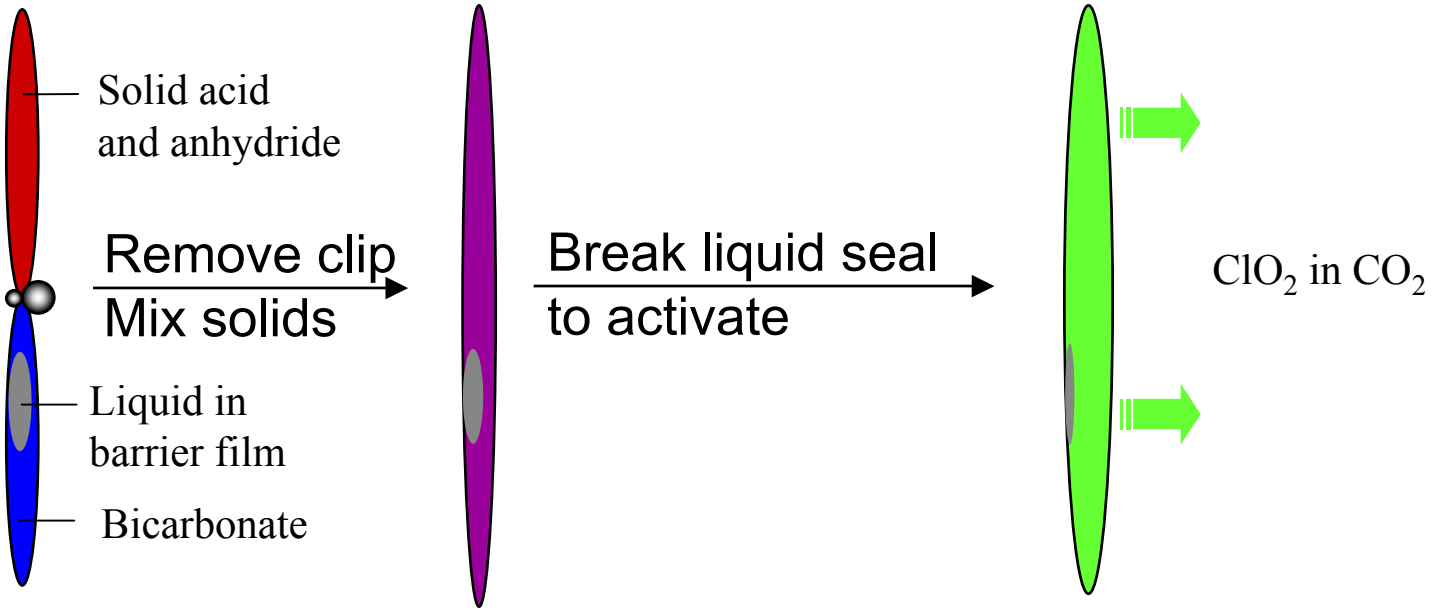
- **Generate mixture of ClO_2 and CO_2**
  - React solid acid and/or anhydride (HA) with solid $NaHCO_3$ and solution of $NaClO_2$ in water:

$$\mathbf{4\ NaClO_2 + 2\ HA \rightarrow 2\ ClO_2 + NaCl + NaClO_3 + 2\ NaA + H_2O}$$

$$\mathbf{HA + NaHCO_3 \rightarrow NaA + CO_2 + H_2O}$$

- **Use of gas mixture:**
  - Increases safety: high concentrations of ClO_2 (>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



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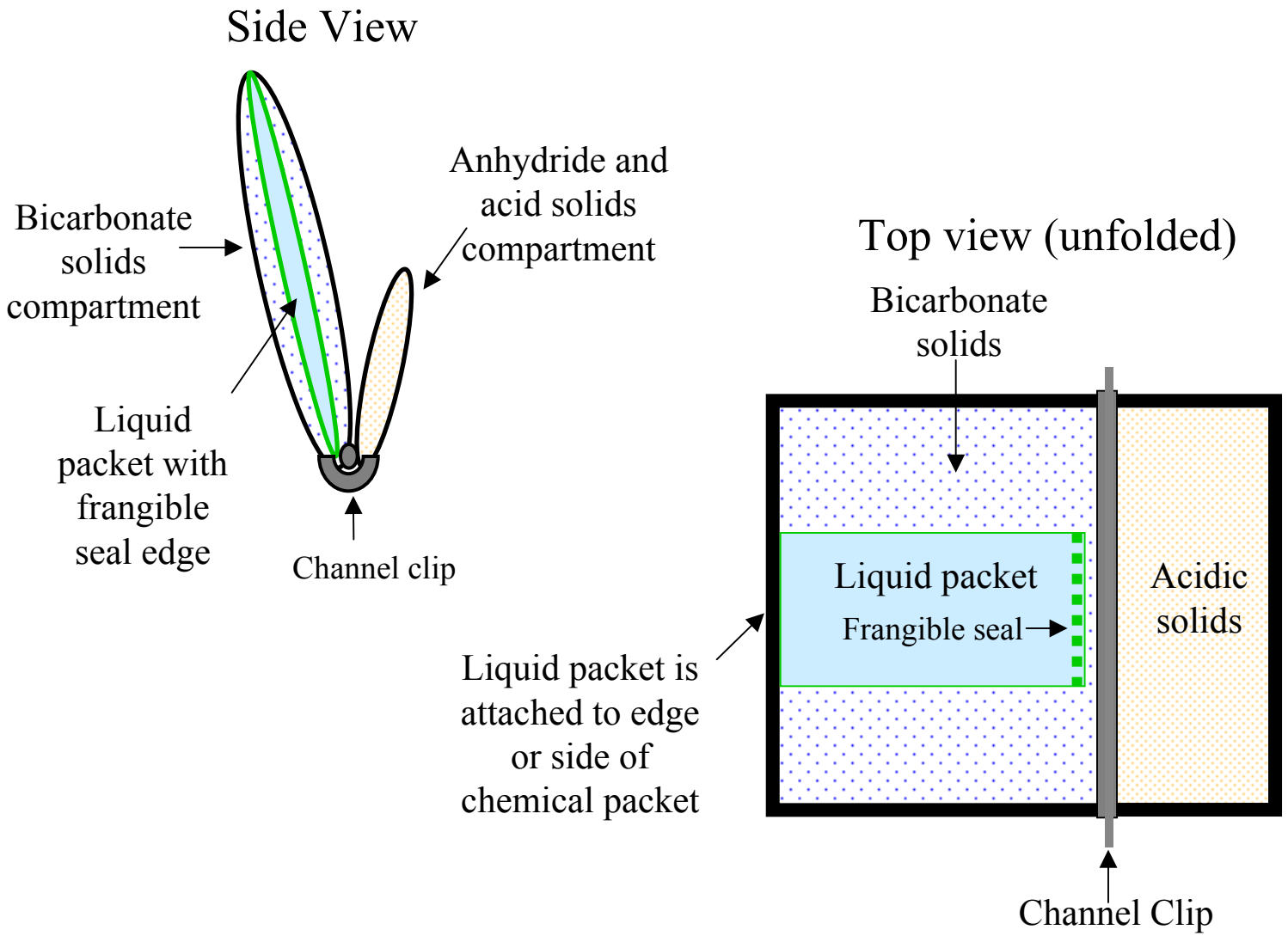
Schematic of Gas Generator



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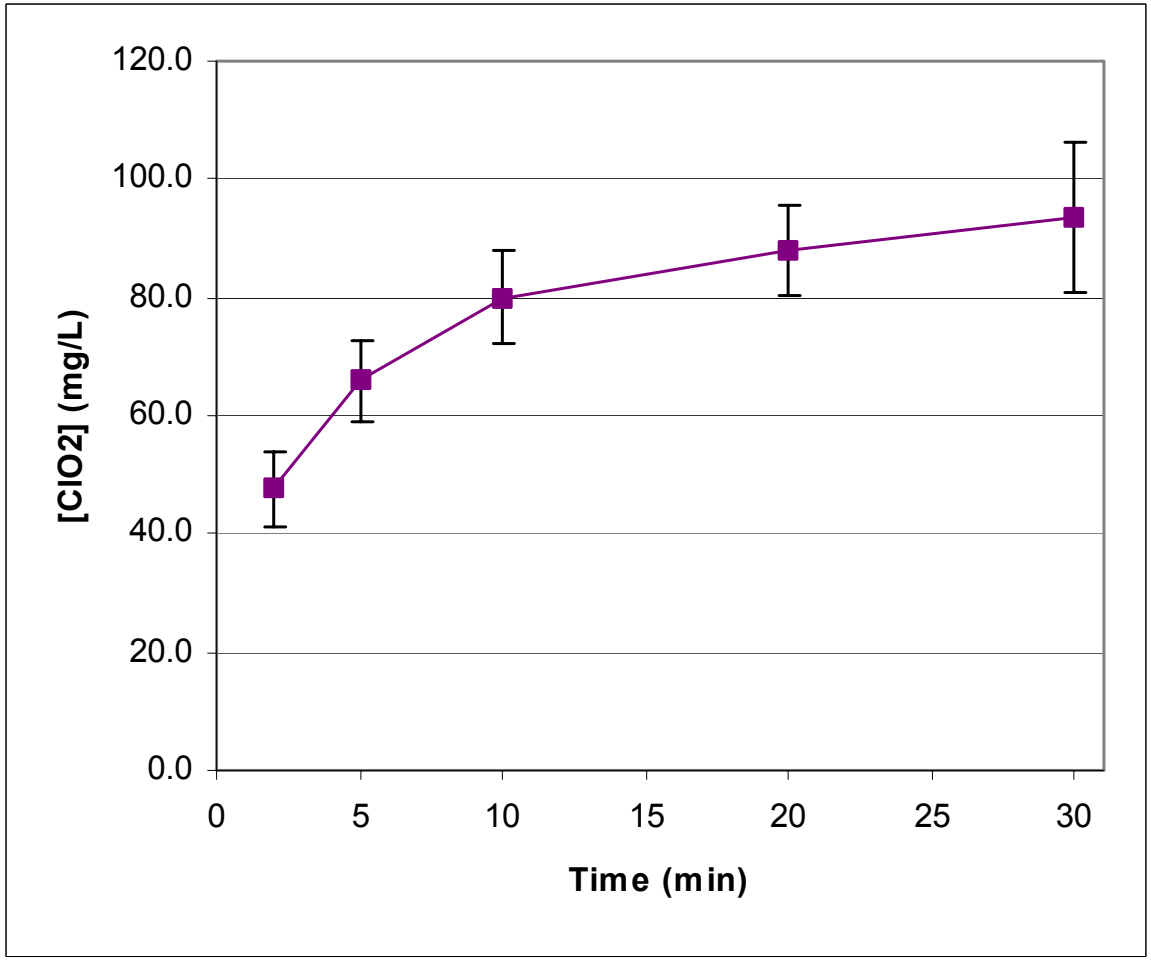
Gas Generator Performance

Chlorine Dioxide Concentration vs. Time



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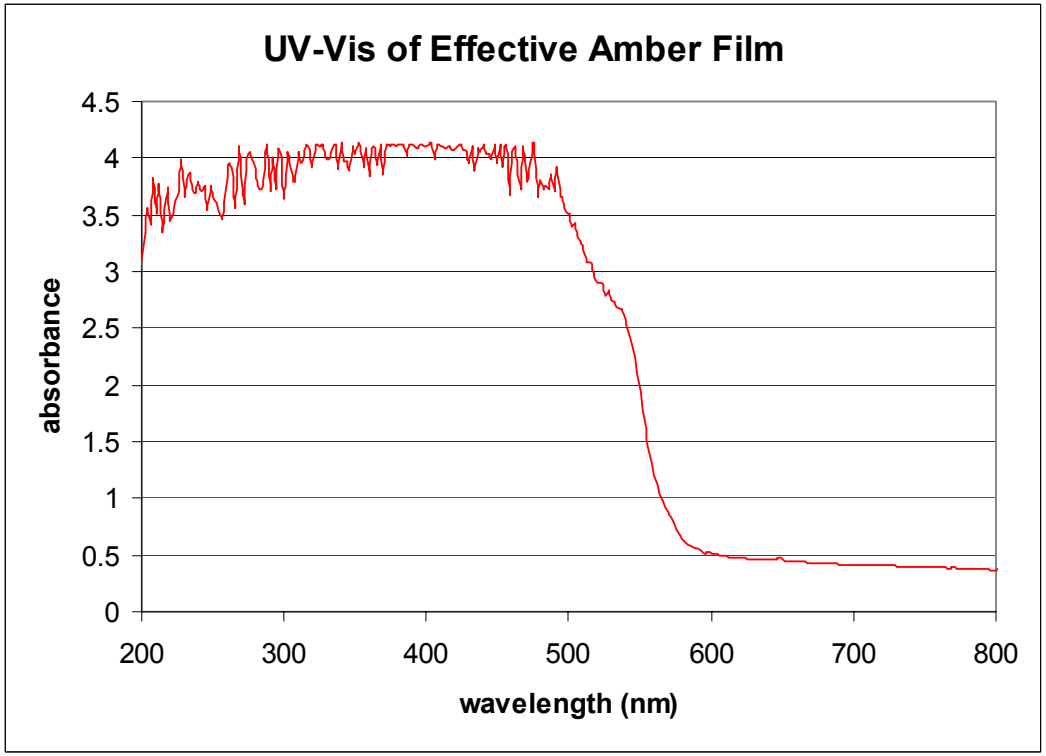
Sterilizer Materials (1)

- **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

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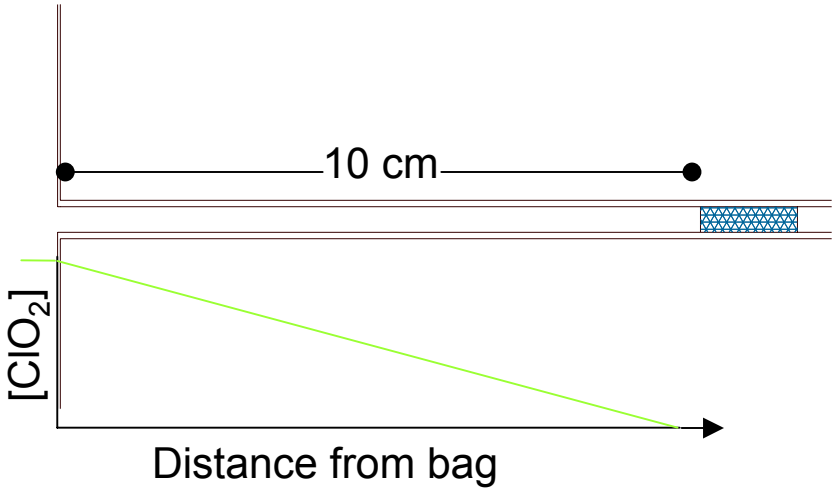
Indicators

- **Indicator to show ClO_2 is present**
  - Indicator is printed on or attached to inside of pouch
  - Changes color on exposure to ClO_2
  - Located at side of sterilizer; ClO_2 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 absorb 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**



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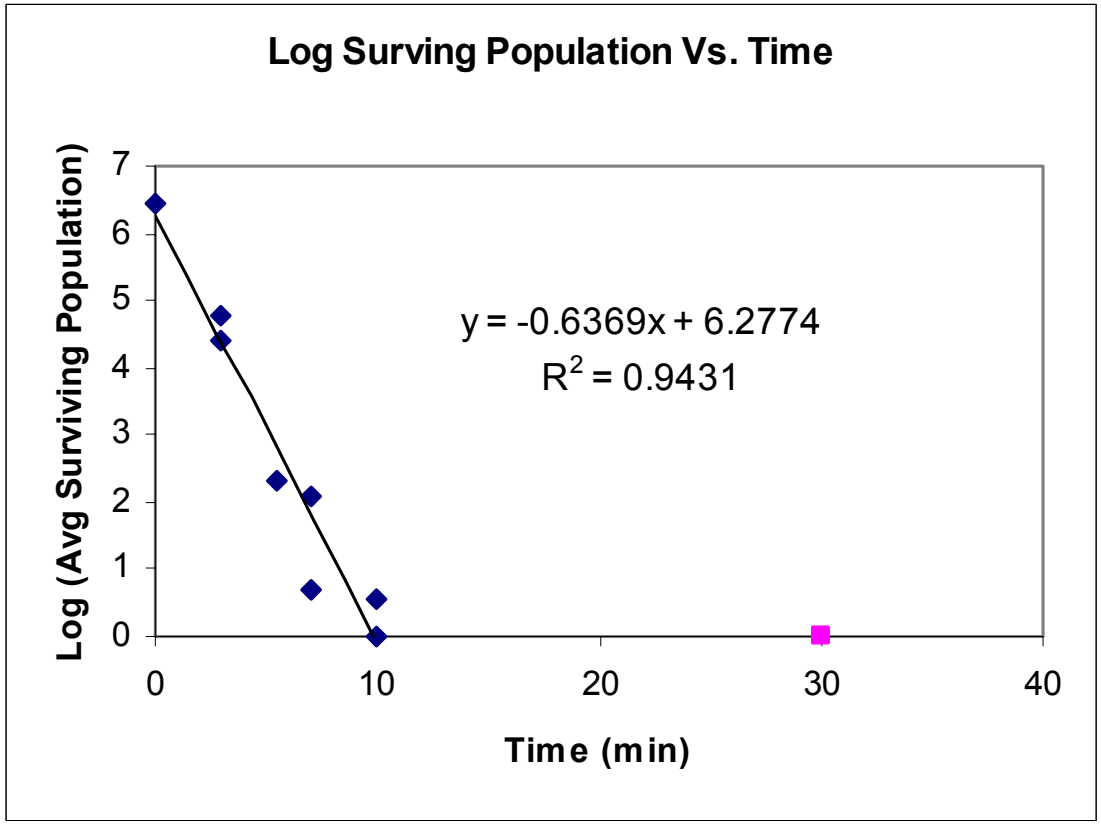
Test Methods

- **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 ClO_2 from solid mixture**
  - During sterilization, ClO_2 penetrates Tyvek
- **Vary exposure time, ClO_2 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



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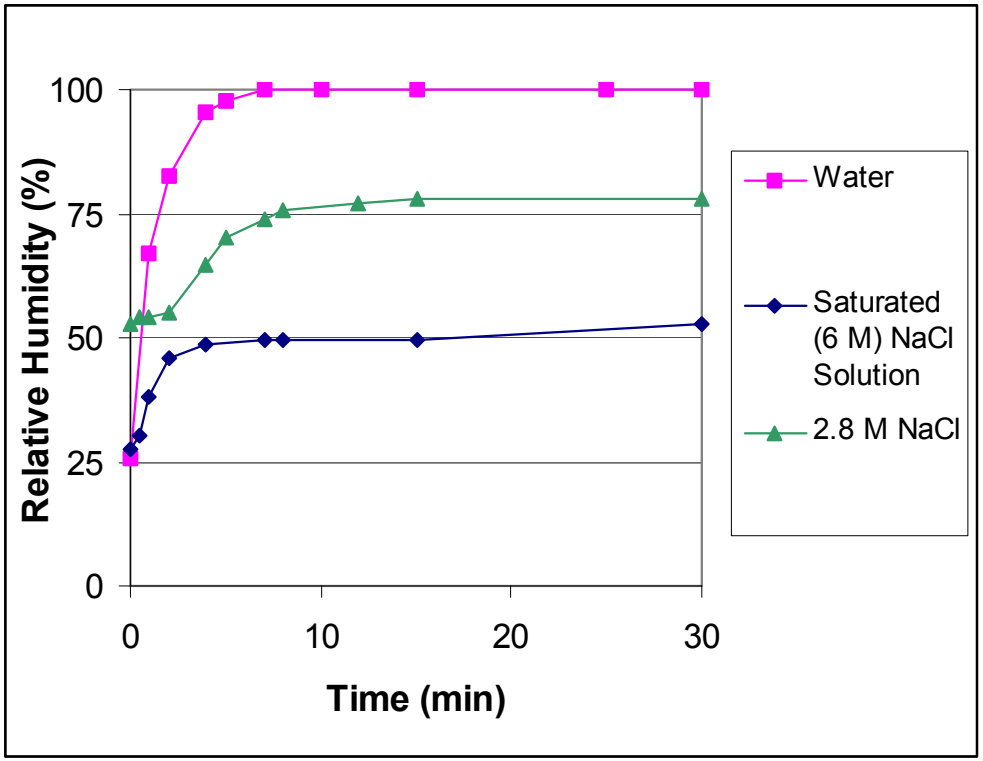
Humidity Control

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 $NaClO_2$ 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

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Performance and Dimensions

- **Demonstrated generation of effective ClO_2 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**

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Summary

- Convenient source of ClO_2 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

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- The views, opinions and/or finding contained in this report are those of the authors and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

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