PRESENTED BY:

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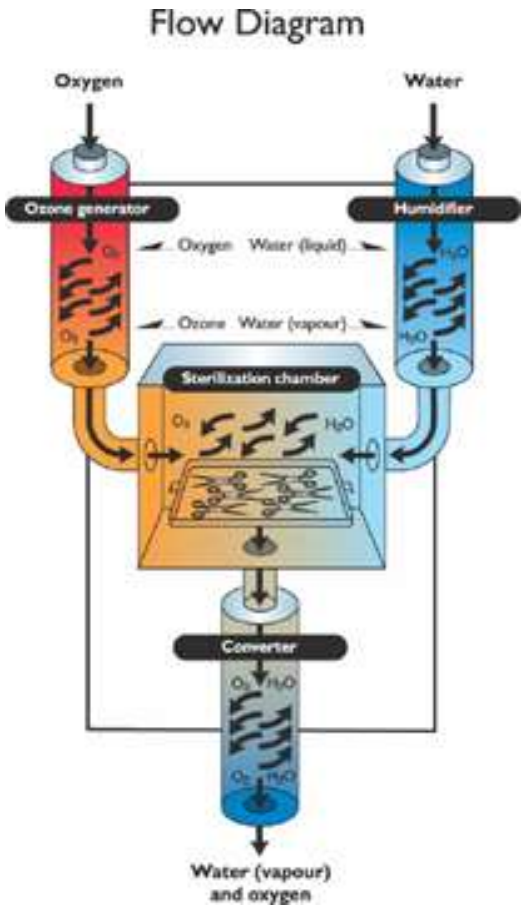
Agenda

- TSO_3*125L* Technology
- D-value Expression
- Chick and Watson Law
- Material Compatibility

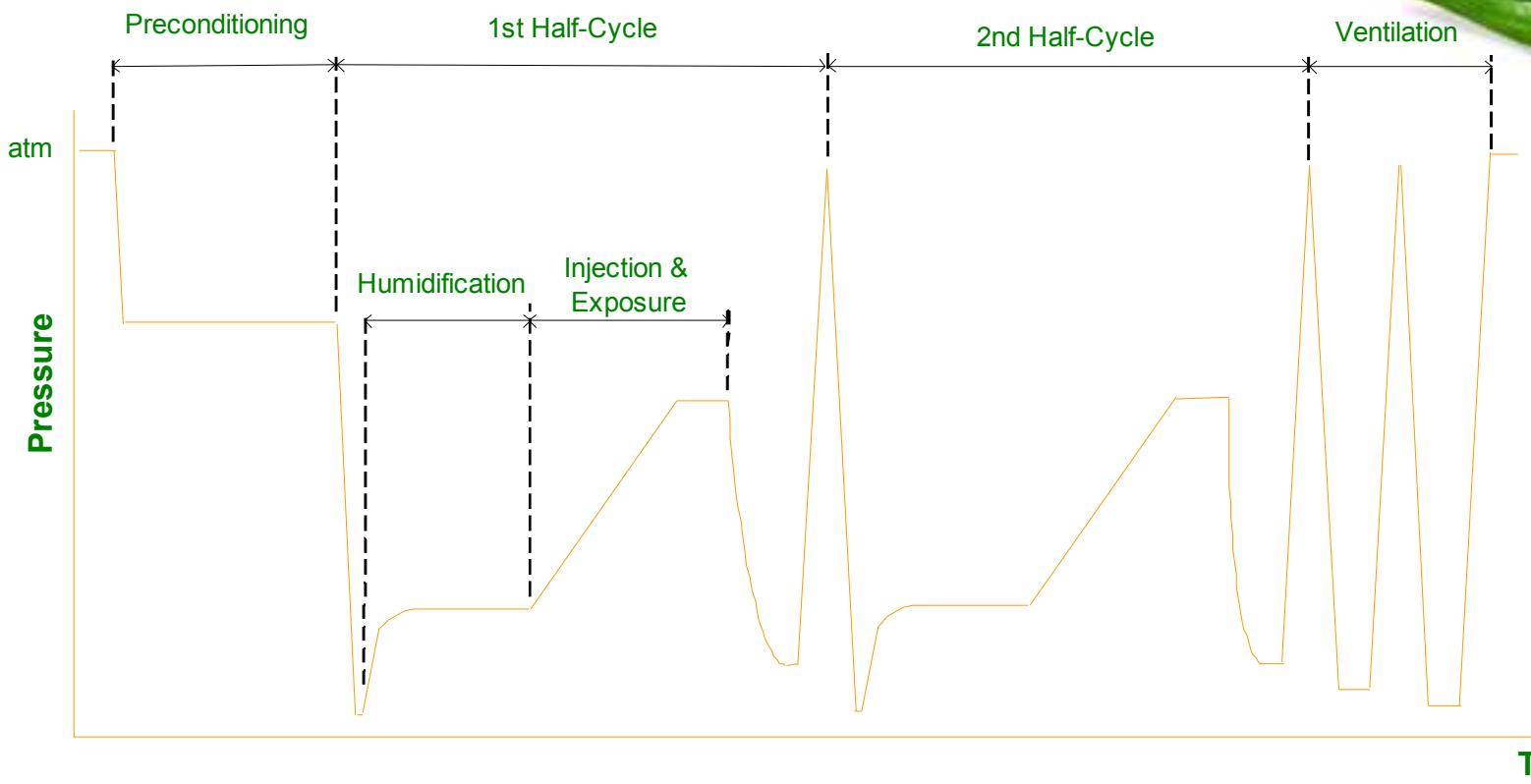
TSO_3 *125L's* Features

- ✓ Economical
- ✓ Fast
- ✓ Safe for patients and users
- ✓ Efficacious
- ✓ Green Technology

Schematic of the TSO_3 *125L*

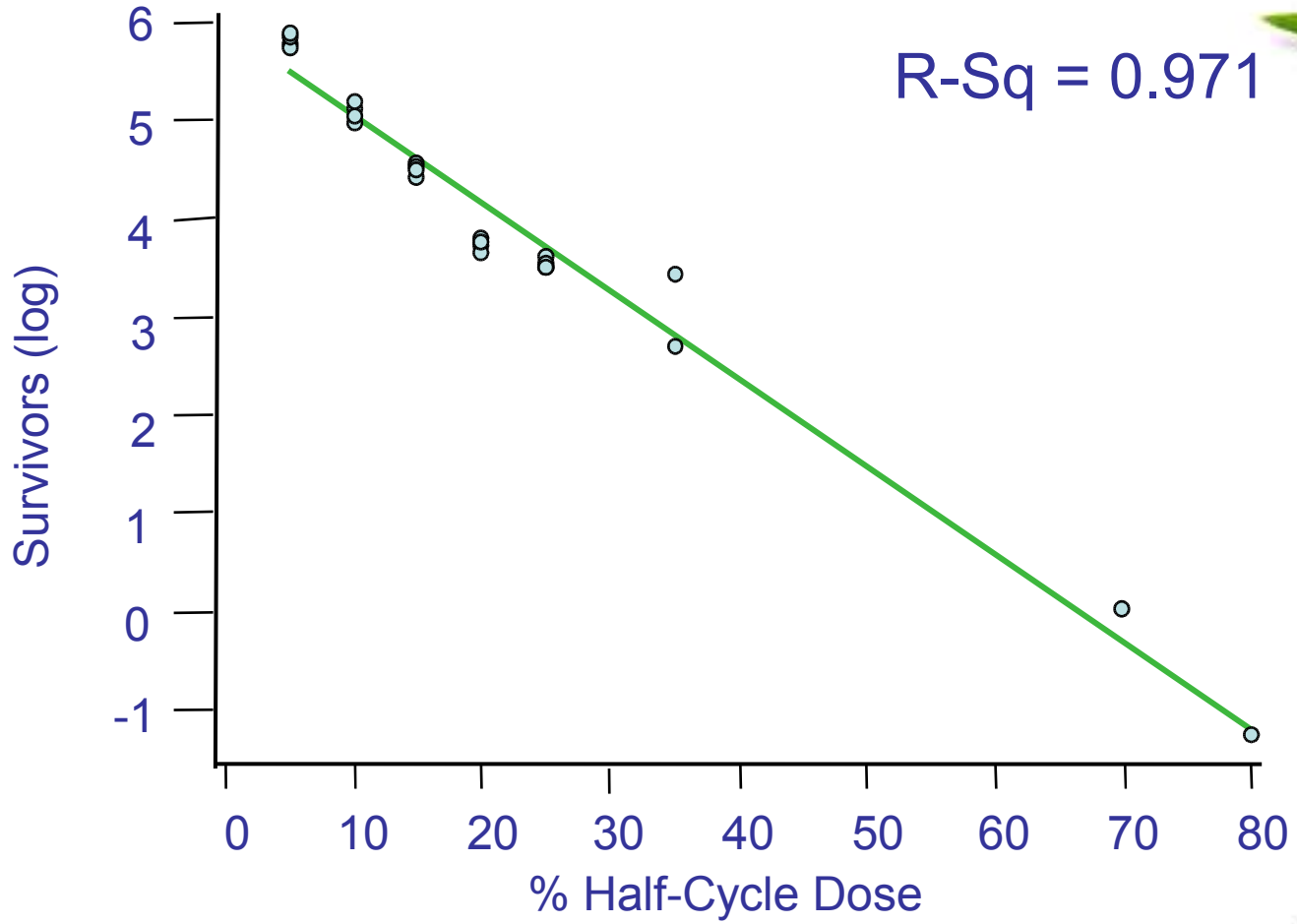


Sterilization Cycle

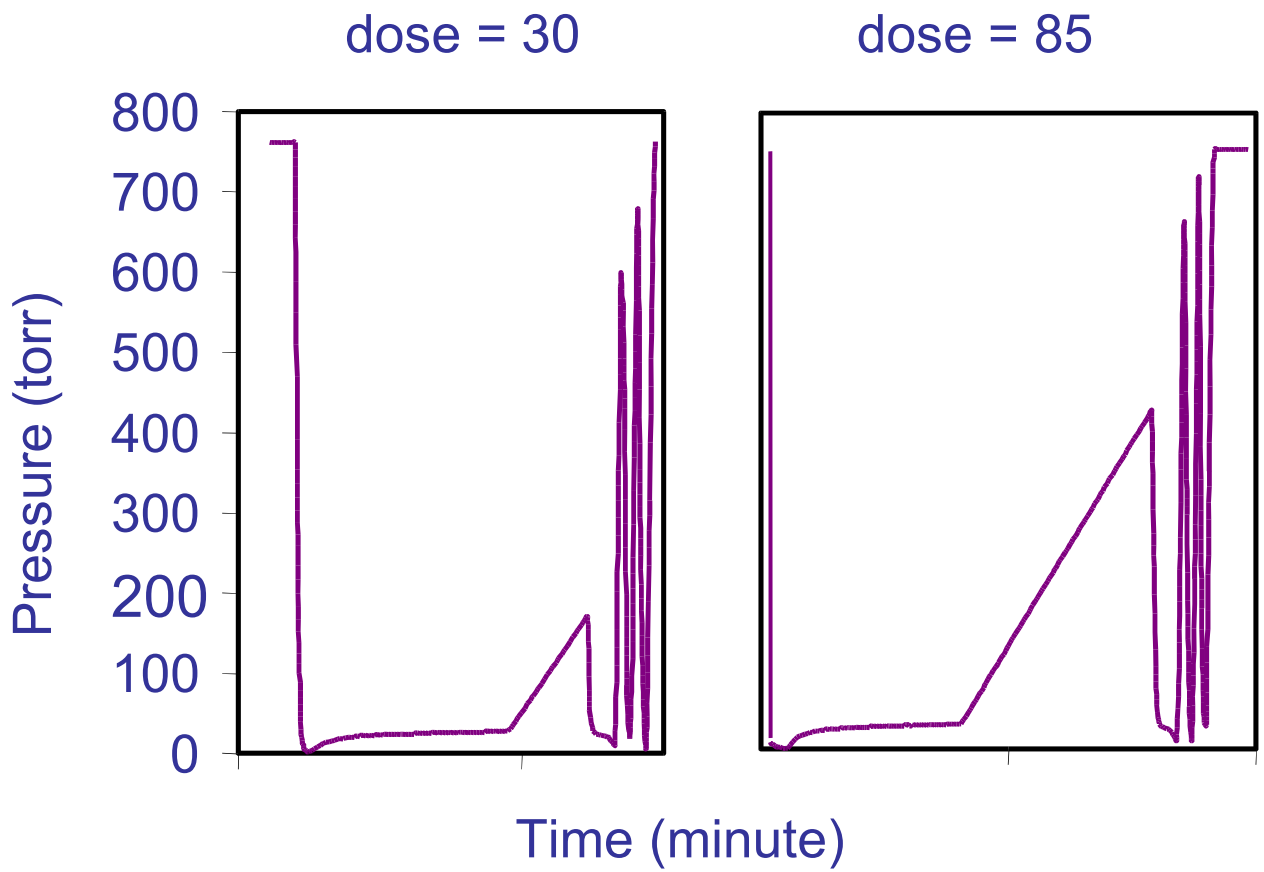


Validation Load

Kill curve by plate count and fraction negative analysis

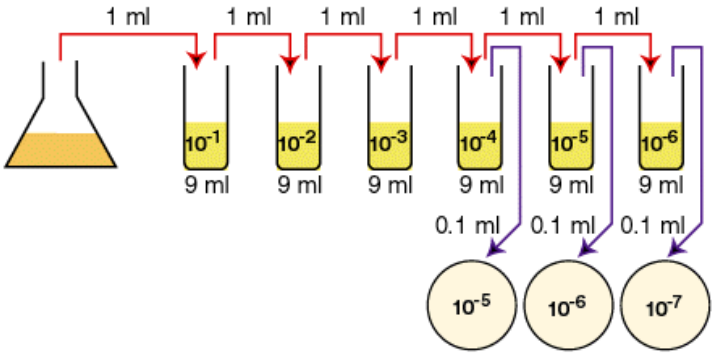


D-value: in dose (mg/L)

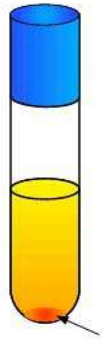


Count

- Survival curve
  - BI homogeneisation
  - Serial dilution
  - Pour plate count



- Fraction negative
  - Direct transfert of BI in broth (20 samples /load)



Microorganisms tested

Bacterial spores	*Bacillus atrophaeus* var. *niger* ATCC 9372
	Geobacillus stearothermophilus ATCC 7953
	Clostridium sporogenes ATCC 3584
Vegetative bacteria	*Staphylococcus aureus* ATCC 6538
	Salmonella choleraesuis ATCC 10708
	Pseudomonas aeruginosa ATCC 15442
Mycobacteria	*Mycobacterium terrae* ATCC 15755
Fungi	*Trycophyton mentagrophytes* (with conidia) ATCC 9533
Non-lipid virus	Poliovirus Type II VR-301
Lipid virus	herpes simplex VR-260
Additional test organisms suggested in literature	*Bacillus pumilus* ATCC 27142

AOAC Sporicidal Screening Test

Test Number	Carrier	Number of Positives / Number Tested	
		B. subtilis	***C. sporogenes***
1	Porcelain Penicylinder	0/60	0/60
	Silk Suture Loops	0/60	0/60
2	Porcelain Penicylinder	0/60	0/60
	Silk Suture Loops	0/60	0/60
3	Porcelain Penicylinder	0/60	0/60
	Silk Suture Loops	0/60	0/60

Partial list of instrument tested in in-use

Instruments	Number of contaminated sites / Number of sites tested		
	Aerobic bacteria	Anaerobic bacteria	Yeast and fungi
Sponge classic holding forceps	0/4	0/4	0/4
Peers towel clamp	0/4	0/4	0/4
Gregory classic bulldog clamp	0/4	0/4	0/4
Satinsky Forcep	0/4	0/4	0/4
Articulated Greenberg arm	0/4	0/4	0/4
Vaginal speculum	0/4	0/4	0/4
Biopsy forcep	0/4	0/4	0/4
Stopcock	0/4	0/4	0/4
Kerrisson	0/4	0/4	0/4
Rongeur	0/4	0/4	0/4
Lip retractor	0/4	0/4	0/4
Hardy nasal speculum	0/4	0/4	0/4
Raney clip applier	0/4	0/4	0/4
Anderson-Adson retractor	0/4	0/4	0/4
Detrich clamp	0/4	0/4	0/4
Needle holder	0/4	0/4	0/4

Microbial Efficacy

Microorganisms	Control CFU*	Results (#positive / #sample)		
		No load	Hard water	Serum
Vegetative bacteria *Pseudomonas aeruginosa*	1.34×10^6	0/20	0/20	0/20
Staphylococcus aureus	2.23×10^6	0/20	0/20	0/20
Samonella choleraesuis	1.07×10^6	0/20	0/20	0/20
Fungi with conidia *Trychophyton mentagrophytes*	1.11×10^6	0/20	0/20	0/20
Mycobacteria *Mycobacterium terrae*	1.12×10^6	0/20	0/20	0/20
Spore-forming bacteria *Clostridium sporogenes*	0.79×10^6	0/20	0/20	0/20
Bacillus atrophaeus	1.18×10^6	0/20	0/20	0/20
Bacillus pumilus	1.97×10^6	0/20	0/20	0/20
Geobacillus stearothermophilus	1.38×10^6	0/20	0/20	0/20

* CFU: colony forming unit

Prions and Endotoxins

- Inactivation of at least 4 logs at the quarter of cycle
- Oxidation of 0.5µg endotoxin (equivalent to 5 x 10^5 *E.coli* cells)
- Oxidation of 91,8% of a high level endotoxin vial (125 µg)

Tubing: Diameter vs Length

Internal diameter (mm)	Length (cm)	Number of Positives / Number of Samples
2	25	0/9
3	47	0/9
4	60	0/9

Chick and Watson Law

$$N/N_0 = e^{-\Lambda C^n t}$$

$$\ln\left(N/N_0\right) = -\Lambda C^n t$$

$$t = t_i + t_e$$

Chick and Watson Law

$$\ln(N) = \ln(No) - \Lambda C_c^n t_i - \Lambda C_c^n t_e$$

$$C_c = C_n \times \frac{P_c}{P_n} \times \frac{T_n}{T_c}$$

$$t_i = \frac{C_c}{C_n} \times \frac{V_c}{Q_{O_2}} \times \frac{(1000 + 0{,}2334 \cdot C_n)}{1000}$$

Chick and Watson Law

$$Ln(N) = Ln(No) - \Lambda\,(Cc)^{n+1}\,K - \Lambda\,(Cc)^{n}t_e$$

$$n = 0$$

dose

$$\ln(N) = \ln(No) - \Lambda C_c K - \Lambda t_e$$

Categories of Compatible Materials

- Inorganic (metals – stainless, aluminum)
- Silicones (o-rings, gaskets, seals)
- Halogenated polymers
- High engineered polymers (rulon, ultem)
- Olefins (HDPE, polypropylene)

TSO_3 Ozone Technology Optimized

- Humidification
- Temperature
- Contact time

Reusable Medical Device Materials

Metals, Non-Metals and Processes

Materials	Rigid Endoscopes	Flexible Endoscopes	Laryngoscope	Cameras	Light Cable	Graspers	Powered Instruments	Lenses
Metals								
Stainless Steel	X	X	X	X	X	X	X	X
Aluminum	X	X	X	X			X	X
Titanium						X	X	
Non-Metals								
Ceramic	X					X		X
Glass	X	X	X	X	X			X
Adhesive	X							
Processes								
Anodizing	X	X	X	X			X	X
Hard Coat	X	X	X	X	X		X	X
Chem Etching	X	X	X	X	X	X	X	X
Laser Etching	X	X	X	X	X	X	X	X

Reusable Medical Device Materials

Metals, Non-Metals and Processes (Continued)

Materials	Surgical Instruments	Cables	Trocar	Sheath / Bridge	Defibrillators	Dilators	Sterilization Containers	Cases and Trays	Instruments Protectors
Metals									
Stainless Steel	X	X	X	X	X		X	X	
Aluminum		X			X		X	X	X
Titanium	X								
Non-Metals									
Ceramic				X	X				
Glass									X
Adhesive		X			X	X	X	X	
Processes									
Anodizing		X			X		X	X	
Hard Coat	X	X		X	X				
Chem Etching	X	X	X	X	X	X	X	X	
Laser Etching	X	X	X	X	X	X	X	X	

Reusable Medical Device Materials

Plastics and Elastomers

Materials	Rigid Endoscopes	Flexible Endoscopes	Laryngoscope	Cameras	Light Cable	Graspers	Powered Instruments	Lenses
Plastics and Elastomers								
PTFE - Teflon		X		X		X	X	
Silicone		X		X	X	X	X	
Nylon	X	X		X	X	X	X	
ETFE								
Polyethylene HDPE / LDPE								
Polypropylene								
Polysulfone								
Urethane		X		X	X			
Polyetherimide								

Reusable Medical Device Materials

Plastics and Elastomers (Continued)

Materials	Surgical Instruments	Cables	Trocar	Sheath / Bridge	Defibrillators	Dilators	Sterilization Containers	Cases and Trays	Instruments Protectors
Plastics and Elastomers									
PTFE - Teflon	X		X	X					
Silicone	X	X	X	X	X	X			X
Nylon		X			X				
ETFE	X			X					
Polyethylene HDPE / LDPE									X
Polypropylene									X
Polysulfone								X	
Urethane		X			X				
Polyetherimide							X	X	

Materials Compatibility with Oxidizing Decontamination Processes

Material	Peracetic Acid	Hydrogen Peroxide	Hypochloric Acid	Ozone
Metals	4	3	3	3
Non-metals	3	3	2	3
Plastics and Elastomers	27	23	18	16
Processes	4	1	1	5
Lubricants	Not Listed	Not Listed	Not Listed	6

Metals and Non-Metals

- Stainless Steel
- Titanium
- Anodized Aluminium

- Ceramic
- Glass
- Silica

Plastics and Elastomers

- Ethylene ChloroTetraFluoroEthylene (ECTFE, Halar®)
- Ethylene TetraFluoroEthylene (ETFE, Tefzel®)
- Filled PolyTetraFluoroEthylene (Rulon® 123)
- Fluorinated Ethylene Propylene (FEP)
- High Density Polyethylene (HDPE)
- Low Density Polyethylene (LDPE)
- Polyamide (Nylon)
- PolyChloroTriFluoroEthylene (PCTFE, Kel-F®, Neoflon®)
- Polydimethylsiloxane (PDMS, Silicone)
- Polyetherimide (Ultem®)
- Polymethylmethacrylate (PMMA)
- Polypropylene (PP)
- PolyTetraFluoroEthylene (PTFE, Teflon®)
- PolyVinyliDeneFluoride (Kynar®, PVDF)
- Rigid Polyvinylchloride (PVC)
- Ultra High Molecular Weight Polyethylene (UHMW)

Processes

- Anodizing
- Chemical Etching
- Laser Etching
- Hard Coat Color Anodizing
- PolyPrint™

Questions?