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RECENT TRENDS IN HIGH-LEVEL DISINFECTION: ARE OXIDIZERS THE WAY OF THE FUTURE?

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BASIC OBJECTIVE

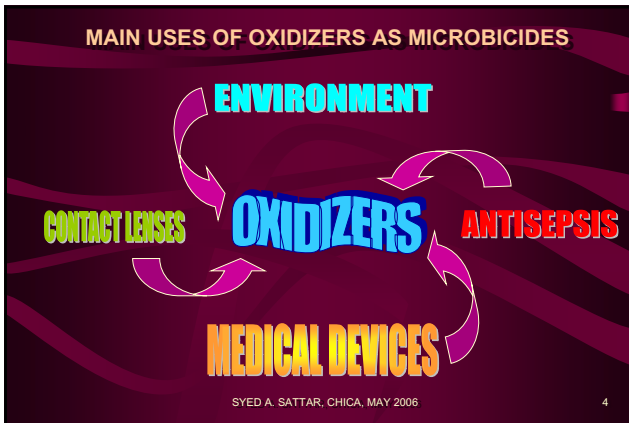
- COMMON TERMS
- COMMON TYPES OF HIGH-LEVEL DISINFECTANT (HLD)
- DESIRABLE TRAITS IN HLD
- OXIDIZER-BASED PRODUCTS USED FOR:
 - MEDICAL DEVICES; ENVIRONMENTAL SURFACES/SPACES
 - CONTACT LENSES; ANTISEPSIS
- RECENT STUDIES WITH OXIDIZER-BASED HLD
 - SUPER-OXIDIZED WATER
 - PERACETIC ACID
 - ACCELERATED HYDROGEN PEROXIDE (AHP)
- UNRESOLVED ISSUES
- CONCLUDING REMARKS

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COMMON TERMS

- **SEMI-CRITICAL MEDICAL DEVICE:** CONTACTS MUCOUS MEMBRANES; MAY ACCIDENTALLY ENTER STERILE TISSUES
- **HIGH-LEVEL DISINFECTANT (HLD):** A MYCOBACTERICIDE WHICH MAY ALSO INACTIVATE SPORES
- **OXIDIZER:** A CHEMICAL WHICH 'OXIDIZES' ANOTHER BY DONATING ELECTRONS
 - HALOGEN-BASED OXIDIZERS (E.G., CHLORINE, IODINE)
 - NON-HALOGEN-BASED OXIDIZERS (E.G., HYDROGEN PEROXIDE)
- **COLD- OR CHEMI-STERILANT:** A GAS OR LIQUID WITH ACTIVITY AGAINST ALL FORMS OF MICROBIAL LIFE; USE OF TERMS FOR LIQUIDS IS NOT RECOMMENDED

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- CHEMICALS COMMONLY USED AS HLD
- FIXATIVES**
- **GLUTARALDEHYDE:**
 - ACID OR ALKALINE FORMS WITHOUT OR WITH OTHER ACTIVES
 - GOOD MATERIALS COMPATIBILITY BUT SLOW SPORICIDAL ACTIVITY
 - SENSITIZES SKIN & MUCOUS MEMBRANES
 - **ORTHO-PHTHALALDEHYDE (OPA):**
 - GOOD MATERIALS COMPATIBILITY & MYCOBACTERICIDAL ACTIVITY, BUT WEAK SPORICIDAL ACTIVITY
 - STAINS PROTEINS
 - REPORTS OF SENSITIZATION
 - **FORMALDEHYDE/PARAFORMALDEHYDE:**
 - STRONG BUT SLOW-ACTING; GOOD MATERIALS COMPATIBILITY; USED WITH LOW-TEMPERATURE STEAM
 - PUNGENT SMELL & POTENTIAL CARCINOGEN
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- CHEMICALS COMMONLY USED AS HLD (CONT'D.)
- OXIDIZERS**
- **HYPOCHLOROUS ACID:**
 - STRONG BUT UNSTABLE OXIDANT; ON-SITE GENERATION
 - **PERACETIC ACID (PAA):**
 - STRONG OXIDANT; OFTEN USED WITH H_2O_2 ; ON-SITE GENERATION
 - **HYDROGEN PEROXIDE (H_2O_2):**
 - STRONG, UNSTABLE & SLOW-ACTING OXIDANT
 - CAN BE STABILIZED & MADE FASTER-ACTING BY 'ACCELERATION'
 - GAS PLASMA FORM IN MACHINES
 - **CHLORINE DIOXIDE:**
 - STRONG, UNSTABLE OXIDANT OFTEN NEEDS ON-SITE GENERATION
 - **OTHER OXIDIZERS:**
 - SOD. DICHLOROISOCYANURATE (NaDCC)
 - POTASSIUM PEROXYMONOSULFATE
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DESIRABLE TRAITS IN HLD'S

- MINIMALLY TOXIC TO HUMANS & ENVIRONMENT
- BROAD-SPECTRUM MICROBICIDAL ACTIVITY
- FAST-ACTING; PREFERABLY SPORICIDAL IN 5-15 MINUTES
- BROAD MATERIALS COMPATIBILITY
- NON-STAINING & NON-FIXATIVE
- LOW POTENTIAL FOR MICROBICIDE RESISTANCE
- COMPATIBLE WITH MANUAL & MACHINE USE
- SAFE TO SHIP & STORE; EASY TO USE/PREPARE

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REGISTERED OXIDIZER-BASED HLD FOR MEDICAL DEVICES

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OXIDIZER-BASED PRODUCTS LISTED WITH U.S. FDA AS OF FEB. 06, 2006
(<http://www.fda.gov/cdrh/>)

TRADE NAME (COMPANY)	ACTIVE INGREDIENT(S)	USE AS HLD
ACECIDE (MINNTECH CORP.)	8.3% H ₂ O ₂ + 7.0% PAA	5 MIN AT 25°C; 5 DAYS REUSE
STERILOX LIQUID (STERILOX TECH.)	HYPOCHLORITE & HYPOCHLOROUS ACID (650-675 PPM FREE CL ₂)	10 MIN AT 25°C; SINGLE USE
ENDOSPOR (COTTRELL LTD.)	7.35% H ₂ O ₂ + 0.23% PAA	15 MIN AT 20°C; 14 DAYS REUSE
SPOROX II (SULTAN)	7.5% H ₂ O ₂	30 MIN AT 20°C; 21 DAYS REUSE
PERACT 20 (MINNTECH CORP.)	1.0% H ₂ O ₂ + 0.08% PAA	25 MIN AT 20°C; 14 DAYS REUSE
STERIS 20 FOR USE WITH STERIS-1 (STERIS CORP.)	0.2% PAA	12 MIN AT 50-56°C.; SINGLE USE

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SELECTED OXIDIZER-BASED PRODUCTS REGISTERED WITH U.S. EPA AS OF DECEMBER 02, 2002
 (<http://www.unh.edu/ehs/BS/Resources/Complete-EPA-List-December-2002.pdf>)

PRODUCT (COMPANY)	ACTIVE INGREDIENT(S)
ACTRIL (MINNTECH)	0.8% H ₂ O ₂ + 0.06% PAA
ALCIDE EXSPOR (ALCIDE)	SODIUM CHLORITE 1.52%
KX-6049 (ECOLAB)	6.9% H ₂ O ₂ +4.4% PAA+3.3% OCTANOIC ACID
MINNCARE (MINNTECH)	22.0% H ₂ O ₂ + 4.5% PAA
OXONIA ACTIVE (ECOLAB)	27.5% H ₂ O ₂ + 5.8% PAA
H ₂ O ₂ STERILANT (STERIS)	31.0% H ₂ O ₂
VAPROX (STERIS)	35% H ₂ O ₂

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SELECTED OXIDIZER-BASED MEDICAL DEVICE DISINFECTANTS REGISTERED WITH HEALTH CANADA AS OF JAN. 31, 2006

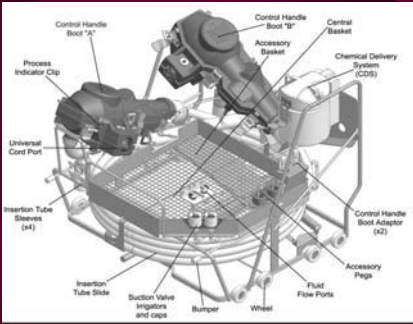
PRODUCT (COMPANY)	ACTIVE INGREDIENT(S)
STERRAD (ASP)	58% H ₂ O ₂
ACCEL (VIROX)	7% ACCELERATED H ₂ O ₂
ACCEL KDS (VIROX)	7% ACCELERATED H ₂ O ₂
OPTIM CS (VIROX)	7% ACCELERATED H ₂ O ₂
SPOROX II (SULTAN)	7.5% H ₂ O ₂
SANIT C (PACE)	26.5% SOD. DICHLOROISOCYANURATE (NaDCC)
PRECEPT TABLETS (JD)	0.5-2.5 GRAMS NaDCC
VIRKON TABLETS (ANTEC)	21.4% POTASSIUM PEROXYMONOSULFATE
ACTRIL (MINNTECH)	0.8% H ₂ O ₂ +0.06% PERACETIC ACID (PAA)
RENALIN (MINNTECH)	20% H ₂ O ₂
PERACT (UNITROL)	1.0% H ₂ O ₂ +0.08% PAA

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- SUPEROXIDIZED WATER**
- TESTING OF A 'STERILOX UNIT AT CREM IN 2003
 - 0.9% NaCl SOLUTION TO GENERATE HYPOCHLOROUS ACID ON-SITE BY ELECTROLYSIS
 - ABOUT 650 PARTS OF AVAILABLE FREE CHLORINE
 - MICROBICIDAL ACTIVITY AT ROOM TEMPERATURE:
 - MYCOBACTERICIDAL IN 10 MINUTES
 - SPORICIDAL IN 10 HOURS
 - FURTHER CHANGES/IMPROVEMENTS MAY HAVE OCCURRED IN THE PAST THREE YEARS
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IN SITU GENERATION OF PERACETIC ACID

- STERIS CORPORATION'S RELIANCE™ ENDOSCOPE REPROCESSING SYSTEM
- GENERATES PERACETIC ACID WITH IN-MACHINE MIXING OF ASA & SOD. PERBORATE



Labels in diagram: Control Handle 'Boot' 'B', Control Handle 'Boot' 'B', Accessory Basket, Central Basket, Chemical Delivery System (CDS), Control Handle 'Boot' Adapter (QA), Fluid Flow Ports, Accessory Page, Wheel, Bumper, Suction Valve Inlets and caps, Insertion Tube Slide, Insertion Tube Sleeves (M), Universal Cord Port, Process Indicator Dip.

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TESTING OF STERIS RELIANCE SYSTEM


- TESTING RECENTLY COMPLETED (SATTAR ET AL. 2006)
- A BRONCHOSCOPE, TRANSNASAL ESOPHAGOVIDEOSCOPE, COLONOSCOPE, DUODENOSCOPE TESTED
- OUTER SURFACES & CHANNELS SEPARATELY CONTAMINATED WITH:
 - PSEUDOMONAS AERUGINOSA, CLOSTRIDIUM DIFFICILE SPORES, GLUT-RESISTANT MYCOBACTERIUM CHELONAE, VRE & MRSA
- INOCULUM DRIED, DEVICES PROCESSED & SAMPLED FOR BACTERIA
- INACTIVATION OF 5-7 LOG₁₀ CFU ON ALL SCOPES IN 10 MINUTES
- SOLD IN CANADA, EUROPE & AUSTRALIA; OTHER MARKETS?

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REUSE TESTING OF PAA-BASED 'SEKUSEPT EASY'

- ECOLAB'S TWO-COMPONENT SYSTEM TO GENERATE ABOUT 975 PPM PERACETIC ACID IN ACTIVATED SOLUTION
- DESIGNED FOR MANUAL DISINFECTION OF ENDOSCOPES OVER A 12-HOUR REUSE PERIOD
- CONTACT TIME 10 MINUTES AT ROOM TEMP.

SOLUTION BEING STRESSED WITH RESPIRATORY THERAPY EQUIPMENT



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TESTING OF ECOLAB'S SEKUSEPT EASY

- TESTING FOR MICROBICIDAL ACTIVITY:
 - *P. AERUGINOSA*, *S. AUREUS* & *S. CHOLERAESUIS*, *B. SUBTILIS*, *C. SPOROGENES*, *MYCOBACTERIUM TERRAE*, *TRICHOPHYTON MENTAGROPHYTES*, POLIOVIRUS TYPE 1 (SABIN)
 - SECOND TIER OF QUANT. CARRIER TEST (QCT-2) USED
 - INACTIVATION OF ALL ORGANISMS IN 10 MINUTES AT ROOM TEMP.
- 12-HOUR STRESSING USING EPA-FDA ACCEPTED METHOD
 - BACTERIA-LADEN CARRIERS & RESPIRATORY THERAPY EQUIPMENT
 - PRODUCT RETAINED BROAD-SPECTRUM MICROBICIDAL ACTIVITY
- ECOLAB ALSO SELLS SINGLE-USE OXIDIZER HLD IN EUROPE & ELSEWHERE THROUGH OLYMPUS

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VIROX AHP-BASED FORMULATIONS

- TESTING OF SEVERAL SUCH FORMULATIONS AT CREM USING HEALTH CANADA-APPROVED PROTOCOLS
- 14-DAY STRESSING OF THREE HLD SINCE JUNE 2004
 - 2% AHP-BASED 'PREVENTION'/'ACCEL HLD 5'; MICROBICIDAL IN 5 MIN & SPORICIDAL IN 6 HOURS AT ROOM TEMP.
 - 7% AHP-BASED 'ACCEL CS20'; KILLED SPORES & MYCOBACTERIA IN 20 MIN AT ROOM TEMP.
 - 2% AHP-BASED 'PREVAIL'/'ACCEL HLD 10'; KILLED MYCOBACTERIA IN 15 MIN SPORES IN 6 HOURS
- ALL REGISTERED IN CANADA OR EXPECTED TO BE SOON

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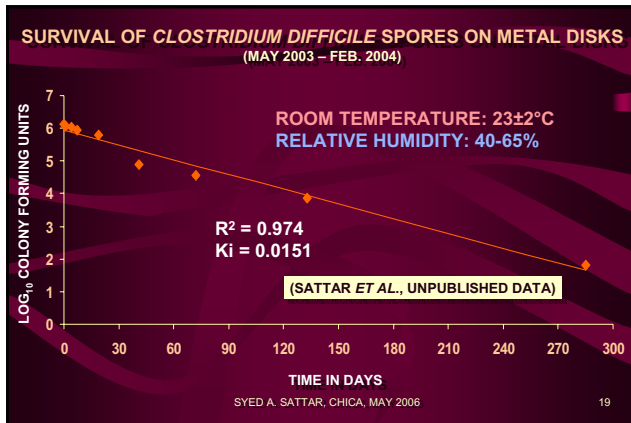
A WORD ABOUT *CLOSTRIDIUM DIFFICILE*

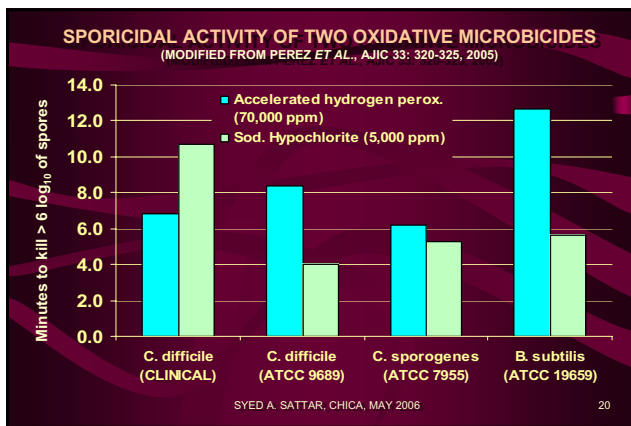
- INCREASING IMPACT OF *C. DIFFICILE*
- SPORES SURVIVE FOR MONTHS INDOORS
- DIFFICULTIES IN ENVIRONMENTAL DECONTAMINATION
 - CONTACT TIME
 - WORKPLACE SAFETY
 - MATERIALS COMPATIBILITY
- RECENT STUDIES WITH OXIDIZER-BASED DISINFECTANTS FOR ENVIRONMENTAL SURFACE DECONTAMINATION

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- ### UNRESOLVED ISSUES
- DEVICE-RELATED INFECTIONS CONTINUE TO OCCUR
 - PROTOCOL FOR STRESS TESTING
 - NO INTERNATIONALLY-RECOGNIZED METHOD AVAILABLE
 - CORROSION & MATERIALS COMPATIBILITY STILL ISSUES
 - COMMUNICATION BETWEEN DEVICE & HLD MAKERS
 - NOW GREATER DESIRE FOR COLLABORATION
 - AUTOMATED ENDOSCOPE REPROCESSORS
 - QUALITY CONTROL IN ENDOSCOPY UNITS
 - BREACHES IN REPROCESSING PROCEDURES STILL OCCUR
 - NEED FOR RESEARCH & THIRD-PARTY TESTING
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CONCLUDING REMARKS

- THE LONG-TERM SUCCESS OF CERTAIN PRODUCTS DESCRIBED REMAINS TO BE DETERMINED
- ALKALINE & ACID GLUTARALDEHYDES ARE STILL IN COMMON USE AS LIQUID HLD
- ETHYLENE OXIDE REMAINS A COMMON GASEOUS FORM
- OXIDIZER-BASED ENVIRONMENTAL SURFACE DISINFECTANTS COMMERCIALY AVAILABLE
- MANY OXIDIZER-BASED CHEMICALS NOW BEING USED FOR SPACE DECONTAMINATION

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PLEASE VISIT THE CREM WEBSITE AT

WWW.ENVIRONMENTAL-MICROBIOLOGY.CA

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