## DEVELOPMENTS IN STERILIZATION

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## Overview

- Evolution in steam sterilizers
- Developments in low temperature sterilization
- Robots in sterilization
- RFID in sterilization
- What is new in routine control and validation of sterilization process
- What is new in packaging?
- Current issues in reprocessing endoscopes
- Centralization of endoscope reprocessing units
- New logistical approach



## Sustainable sterilization

- Typical sterilizers continuously use between 1 gallon (3.78 L) and 5 gallons per minute to reduce the temperature of the hot condensate used in the sterilization process before it is sent down the drain
- To eliminate the need for a continuous flow of water, a jacket and chamber condensate kit can be installed on the sterilizer
- This retrofit kit captures the condensate during ready/standby mode and dissipates heat to the room before discharging the cooled condensate
- It reduces the amount of water needed to cool the condensed steam during the ready/standby operation, significantly reducing in overall water use



## Green sterilizers (WaterEco®)



## Water saving sterilizers

- The ability to reclaim water from steam condensation, steam creation and vacuum.
- The internal water reservoir maintains consistent water supply despite possible pressure fluctuations that can result in wet packs or cycle failures.
- Water temperature in the reservoir is maintained, thereby eliminating the need for additional cold water to meet drain temperature requirements.



Water Recirculation System

reducing water consumption up to 35% to 65%



J Health Serv Res Policy OnlineFirst, published on January 13, 2016 as doi:10.1177/1355819615625698

**Original Research** 

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Forbes McGain<sup>1</sup>, Graham Moore<sup>2</sup> and Jim Black<sup>3</sup>

Hospital steam sterilizer usage: could we

switch off to save electricity and water?

#### Abstract

**Objectives:** Steam sterilization in hospitals is an energy and water intensive process. Our aim was to identify opportunities to improve electricity and water use. The objectives were to find: the time sterilizers spent active, idle and off; the variability in sterilizer use with the time of day and day of the week; and opportunities to switch off sterilizers instead of idling when no loads were waiting, and the resultant electricity and water savings.

**Methods:** Analyses of routine data for one year of the activity of the four steam sterilizers in one hospital in Melbourne, Australia. We examined active sterilizer cycles, routine sterilizer switch-offs, and when sterilizers were active, idle and off. Several switch-off strategies were examined to identify electricity and water savings: switch off idle sterilizers when no loads are waiting and switch off one sterilizer after 10:00 h and a second sterilizer after midnight on all days.

**Results:** Sterilizers were active for 13,430 (38%) sterilizer-hours, off for 4822 (14%) sterilizer-hours, and idle for 16,788 (48%) sterilizer-hours. All four sterilizers were simultaneously active 9% of the time, and two or more sterilizers were idle for 69% of the time. A sterilizer was idle for two hours or less 13% of the time and idle for more than 2 h 87% of the time. A strategy to switch off idle sterilizers would reduce electricity use by 66 MWh and water use by 1004 kl per year, saving 26% electricity use and 13% of water use, resulting in financial savings of AUD\$13,867 (UK£6,517) and a reduction in 79 tonnes of CO<sub>2</sub> emissions per year. An alternative switch-off strategy of one sterilizer from 10:00 h onwards and a second from midnight would have saved 30 MWh and 456 kl of water.

**Conclusions:** The methodology used of how hospital sterilizer use could be improved could be applied to all hospitals and more broadly to other equipment used in hospitals.

#### Keywords

energy, sterilization, sustainability, water

## Energy efficient designs







Reducing energy consumption by ~32%



## Hybrid systems



The hybrid system comprised of a "Steam Cell®" heat regenerative steam generator, **RO** water generator and steam sterilizer all unitized



# Turning water to steam, no boiling required

Nanoparticles make extremely black material that enables "plasmonic" heating BY EMILY CONOVER 2:10PM, APRIL 8, 2016



HOT STUFF Gold nanoparticles line the pores of a new material that can absorb a range of visible and infrared wavelengths of light, creating heat. Inset (right) shows the material's tiny nanopores.

### Plasmonic heat with nanoparticles

- A new, extremely black material can turn water into steam using only sunlight, without the need to bring the water to a boil.
- Made of gold nanoparticles tens of billionths of a meter wide affixed to a scaffold pocked with "nanopores," the material is a deep black color because it reflects very little visible light.
- It is <u>99 percent efficient</u> at absorbing light in the visible spectrum and parts of the infrared spectrum

Available low temperature sterilization methods

- Ethylene oxide
- Formaldehyde
- Hydrogen peroxide gas (plasma)
- Ozone
- Chlorine dioxide
- Sterilization with liquid sterilants ????

## New methods for LTS

Device name	Method	Company, Country
Sterizone VP4	Ozone & H <sub>2</sub> O <sub>2</sub>	TSO3 Inc, Canada
Revox	Vaporized peracetic acid	Revox Sterilization Solutions, US
Noxilizer	Nitrogen dioxide	Noxilizer Inc. US

## **Sterizone VP4**



- A dual sterilant, low-temperature sterilization system that utilizes vaporized H<sub>2</sub>O<sub>2</sub> and ozone
- More devices and greater flexibility of load configurations
- Unique Dynamic Sterilant Delivery System<sup>™</sup> automatically adjusts the quantity of injected sterilant based on the load composition, weight and temperature
- 46 min cycle at room temperature

## Revox VPA



- Gentle room temperature process
- No harmful residuals
- PAA chemistry breaks down to CO<sub>2</sub>, H<sub>2</sub>0, and O<sub>2</sub>
- No lengthy pre-conditioning or postprocessing aeration required
- Multiple chamber configuration options for safe, efficient, on-site sterile processing
- The most gentle sterilization method available for fragile biologicals
- Onsite donor tissue sterile processing capabilities

### Noxilizer RTS 360 NO<sub>2</sub> Sterilization System Summary Advantages vs EO

- Simple, effective and economical in-house sterilization
  - Operates at Room Temperature
  - Maintains Material Properties
  - Shorter Cycle Time
  - No Pre-Conditioning
  - No Lengthy Aeration Required
  - No Residuals
  - Free Standing/Non-Hazardous Bi-Product
  - · Safer than Ethylene Oxide
  - Fully Scalable

	Nox. RTS-360	Typical EO System
Chamber Capacity	360 Liters	2200 Liters
Standard Cycle Time	80 Minutes	12-18 Hours *
Manufacturing to Release Time	On-Site, Immediate Use	Off-Site, 7-25 Day Turnaround



Patented Noxilizer Sterilization System





### **Robots in sterilization**





- French Centre Hospitalier Universitaire (CHU) de Nantes are using two robots, "Betty" and "Daisy", to improve efficiency in delivering sterile endoscopes to the ICU.
- The pilot for this on-demand logistics solution was deemed "very satisfactory", providing great flexibility to the ICU's logistics

## **Robots in sterilization**

- The surgical operation and recovery setting is considered
  - the fastest growing and most resource intensive section of the hospital
  - accounting for approximately 30 50% of a hospital's budget
- Automating the device recognition, delivery, and accounting processes is expected to significantly reduce hospital costs

## **Robots in sterilization**



An intelligent system managing the surgical tool sterilization process in a hospital

- ensuring safe delivery of care
- enabling new levels of hospital efficiency,
- delivering with surgical accuracy all of the medical devices doctors need to perform life-saving procedures



## Expected benefits include

- Increased patient safety, hospital quality and cost performance through reduction in surgical infections
- Increased efficiency in OR scheduling due to increased kit accuracy and reduction in instrument count time
- Freeing-up hospital personnel





#### MARKETS | DEALS | DEALS & DEAL MAKERS

### China's Midea Offers \$5 Billion for German Robot Maker Kuka

Bid aims to help satisfy Beijing's ambitions to become high-end manufacturing power

By KANE WU in Hong Kong, EYK HENNING and CHRISTOPHER ALESSI in Frankfurt Updated May 18, 2016 12:23 p.m. ET



# Data matrix coding and traceability





## **RFID Tray tags**



## Super-Rugged RFID

 The ultra high frequency (UHF) radio frequency TegoChip can easily stand up to gamma, eBeam, autoclave, and ethylene oxide sterilization without performance degradation



http://www.qmed.com/mpmn/medtechpulse

## Advantages of RFID reading

- simultaneous reading of several instruments
- counting control during and after surgery
- readability of blood-smeared or packed instruments
- unique number for identification
- continuous life cycle of each instrument
- tracking of goods through automated reading







### RFID for Surgical Instrument Tracking Saves Estimated 31,000 Hours for Rigshospitalet During Trial

#### Posted on April 2, 2015

Innovative Solution from Caretag Surgical and Xerafy Shows RFID is Highly Effective for Managing Sterilization and other Track-and-Trace Processes

HONG KONG, April 02, 2015 – Read-on-metal UHF RFID tags from Xerafy proved their suitability and value for surgical instrument tracking during an 18-month trial at New Rigshospitalet hospital in Copenhagen, Denmark. Tracking surgical instruments with RFID could save the hospital 31,000 hours a year in operating room procedures alone while also improving patient safety and providing additional time saving and infection control benefits during sterilization and other processes. Dr. Henrik Eriksen, project director for the RFID trial, announced the results last month during a press conference in Copenhagen.

When surgical trays were prepared for use in the operating room (OR), an RFID reader was used to automatically identify and record all the items that were contained in the tray. The trays were read at several more process points before entering the OR to make sure counts were accurate. Trays were read again before they left the OR after surgery to make sure no surgical instruments were missing, and were read at the hospital's



central sterile processing department to document the sterilization process for each item.

### **Electronic indicator**



![](_page_29_Picture_2.jpeg)

## New biological indicators

4 Hour E0 1294 Green Cap

3 Hour Steam 1292 Brown Cap

1 Hour Steam 1291 Blue Cap

![](_page_30_Picture_4.jpeg)

- 3M Attest Rapid Readout BI 1295 & Autoreader 490H
- Routine monitoring of vaporized hydrogen peroxide sterilization processes in STERRAD® NX and 100NX systems

![](_page_30_Picture_7.jpeg)

# Change in container design to prevent wet packs

![](_page_31_Picture_1.jpeg)

![](_page_31_Picture_2.jpeg)

![](_page_31_Figure_3.jpeg)

![](_page_32_Picture_0.jpeg)

wrapped trays, 0 (0%) demonstrated bacterial ingress into the tray. Contamination rates of rigid containers increased significantly with increasing duration of use.

> particle size of 1 juin, while simultaneously expendicing an wordine exchanges the to vacuum cycles two 1-psicycles, three 0.7-psi cycles, and three 0.4-psi cycles—to simulate air exchange events occurring during the sterilization, transportation, and storage of sterilized instrument trays in health care facilities. **Results:** Of 111 rigid containers tested, 97 (87%) demonstrated bacterial ingress into the container. Of 161 wrapped trays, 0 (0%) demonstrated bacterial ingress into the tray. Contamination rates of rigid containers increased significantly with increasing duration of use.

> **Conclusions:** In this study using a dynamic bacterial aerosol challenge, sterilized wrapped trays demonstrated significantly greater protection than sterilized rigid containers against the ingress of airborne bacteria.

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![](_page_33_Picture_0.jpeg)

#### **Dunkelberg H., Germany**

## New packaging materials: Dry, Drier, Driest

- A patented tray wrap to assist with achieving dry packs
- An inner surface with a degree of absorbency, whilst the outer surface repels both water and alcohol
- The absorbent surface allows the condensate to be dispersed, assisting evaporation during the vacuum cycle

![](_page_34_Picture_4.jpeg)

![](_page_34_Picture_5.jpeg)

### **Protective packaging**

![](_page_35_Picture_1.jpeg)

![](_page_35_Picture_2.jpeg)

![](_page_35_Picture_3.jpeg)

![](_page_35_Picture_4.jpeg)

![](_page_35_Picture_5.jpeg)

## Dye migration test

![](_page_36_Picture_1.jpeg)

![](_page_36_Picture_2.jpeg)

#### **Push Indicator Dye Test**

1. Step one

![](_page_36_Picture_5.jpeg)

Put the test in The pouch or sleeve

3. Step three

![](_page_36_Picture_8.jpeg)

Press the test in the direction of arrow

#### 2. Step two

![](_page_36_Picture_11.jpeg)

Seal the pouch or sleeve

#### 4. Step four

![](_page_36_Picture_14.jpeg)

4. Observe 5 sec per seal

#### ARROWPACK >>>

# Current issues in reprocessing of semi-critical instruments

- Infectious outbreaks associated with improper cleaning of endoscopes
  - MDROs on flexible duedonoscopes,
  - HPV on intracavitary ultrasound probes
- Lack of validation requirements for cleaning of endoscopes
- Lack of manufacturer's instructions for cleaning
- Lack of cleaning control
- Survival of microbes even after HLD and sterilization if there are organic residuals

#### Infection Control & Hospital Epidemiology

Infection Control & Hospital Epidemiology / First View Article © 2015 by The Society for Healthcare Epidemiology of America. All rights reserved DOI: http://dx.doi.org/10.1017/ice.2015.123 (About DOI), 7 pages. Published online: 29 May 2015

#### Evaluation of the Quality of Reprocessing of Gastrointestinal Endoscopes

Philippe Saviuc<sup>a1</sup>, Romain Picot-Guéraud<sup>a1 c1</sup>, Jacqueline Shum Cheong Sing<sup>a1</sup>, Pierre Batailler<sup>a1</sup>, Isabelle Pelloux<sup>a2</sup>, Marie-Pierre Brenier-Pinchart<sup>a2a3</sup>, Valérie Dobremez<sup>a1</sup> and Marie-Reine Mallaret<sup>a1a4</sup>

#### Abstract

OBJECTIVES To evaluate the quality of gastrointestinal endoscope reprocessing and discuss the advantages of microbiological surveillance testing of these endoscopes.

METHODS Retrospective analysis of the results of endoscope sampling performed from October 1, 2006, through December 31, 2014, in a gastrointestinal endoscopy unit of a teaching hospital equipped with 89 endoscopes and 3 automated endoscope reprocessors, with an endoscopy quality assurance program in place. The compliance rate was defined as the proportion of the results classified at target or alert levels according to the French guidelines. A multivariate analysis (logistic regression) was used to identify the parameters influencing compliance.

RESULTS A total of 846 samples were taken. The overall compliance rate was 86% and differed significantly depending on the sampling context (scheduled or not scheduled), the type of endoscope, and the season. No other parameter was associated with compliance. A total of 118 samples carried indicator microorganisms such as *Pseudomonas aeruginosa, Stenotrophomonas maltophilia*, Enterobacteriaceae, and *Candida* sp.

CONCLUSION The systematic use of an automated endoscope reprocessor does not provide totally satisfactory compliance. Microbiological surveillance is indispensable to monitor reprocessing, reinforce good practices (endoscopes, reprocessing units), and detect endoscopes requiring early technical maintenance.

fppt.com

![](_page_39_Picture_0.jpeg)

Contents lists available at ScienceDirect

#### American Journal of Infection Control

journal homepage: www.ajicjournal.org

Major article

Persistent contamination on colonoscopes and gastroscopes detected by biologic cultures and rapid indicators despite reprocessing performed in accordance with guidelines

![](_page_39_Picture_6.jpeg)

Infection Control

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Key Words:

Endoscope reprocessing Reprocessing medical devices High-level disinfection Epidemiology Gastrointestinal endoscopy Colonoscope **Background:** Pathogens have been transmitted via flexible endoscopes that were reportedly reprocessed in accordance with guidelines.

**Methods:** Researchers observed reprocessing activities to ensure guideline compliance in a large gastrointestinal endoscopy unit. Contamination was assessed immediately after bedside cleaning, manual cleaning, high-level disinfection, and overnight storage via visual inspection, aerobic cultures, and tests for adenosine triphosphate (ATP), protein, carbohydrate, and hemoglobin.

**Results:** All colonoscopes and gastroscopes were reprocessed in accordance with guidelines during the study. Researchers collected and tested samples during 60 encounters with 15 endoscopes. Viable microbes were recovered from bedside-cleaned (92%), manually cleaned (46%), high-level disinfected (64%), and stored (9%) endoscopes. Rapid indicator tests detected contamination (protein, carbohydrate, hemoglobin, or ATP) above benchmarks on bedside-cleaned (100%), manually cleaned (92%), high-level disinfected (73%), and stored (82%) endoscopes. Visible residue was never observed on endoscopes, but it was often seen on materials used to sample endoscopes. Seven endoscopes underwent additional reprocessing in response to positive rapid indicators. Control endoscope channels were free of biologic residue and viable microbes.

**Conclusion:** Despite reprocessing in accordance with US guidelines, viable microbes and biologic debris persisted on clinically used gastrointestinal endoscopes, suggesting current reprocessing guidelines are not sufficient to ensure successful decontamination.

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### **Conclusions from both researches**

- GI endoscopes are highly contaminated during clinical use, and residual organic materials including viable organisms, persist despite reprocessing in accordance with guidelines
- Technicians may believe that each step in reprocessing is important, but they may not always perform each step correctly and completely
- The use of automated reprocessor does not provide completely satisfactory compliance
- Microbiological surveillance is indispensable to reinforce good practices
- Highly trained staff and more standardized techniques are needed for good practice

### Confusion between....

![](_page_41_Picture_1.jpeg)

![](_page_41_Picture_2.jpeg)

#### ORIGINAL ARTICLE

#### Impact of ethylene oxide gas sterilization of duodenoscopes after a carbapenem-resistant Enterobacteriaceae outbreak

Igor Naryzhny, DO,<sup>1</sup> Dean Silas, MD,<sup>1</sup> Kenneth Chi, MD<sup>1</sup>

Park Ridge, Illinois, USA

**Background and Aims:** Carbapenem-resistant Enterobacteriaceae (CRE) outbreaks have been implicated at several medical institutions involving gastroenterology laboratories and, specifically, duodenoscopes. Currently, there are no specific guidelines to eradicate or prevent the outbreak of this bacteria. We describe ethylene oxide (ETO) gas sterilizations of duodenoscopes to address this issue.

**Methods:** A complete investigation of the gastroenterology laboratory and an evaluation by the Centers for Disease Control and Prevention concluded that no lapses were found in the reprocessing of the equipment. With no deficiencies to address, we began a novel cleaning process using surgical ETO gas sterilizers in addition to standard endoscope reprocessing recommendations and guidelines, all while trying to eradicate the CRE contamination and prevent future recurrences. We also instituted a surveillance system for recurrence of CRE contamination via monthly cultures of the duodenoscopes.

**Results:** Between October 2013 and April 2014, 589 ERCPs were performed with 645 ETO gas sterilizations of 6 duodenoscopes. Given the extra 16 hours needed to sterilize the duodenoscopes, our institution incurred costs resulting from purchasing additional equipment and surveillance cultures. Four duodenoscopes sustained damage during this period; however, this could not be directly attributed to the sterilization process.

Conclusions: Proper use of high-level disinfection alone may not eliminate multidrug-resistant organisms from duodenoscopes. In this single-center study, the addition of ETO sterilization and frequent monitoring with cultures reduced duodenoscope contamination and eliminated clinical infections. As such, ETO gas sterili-

from duodenoscopes. In this single-center study, the addition of ETO sterilization and frequent monitoring with cultures reduced duodenoscope contamination and eliminated clinical infections. As such, ETO gas sterilization may provide benefit in further decontamination of duodenoscopes, but further investigation is necessary. (Gastrointest Endosc 2016;  $\blacksquare$ :1-4.)

A New Trend in Europe: Centralized Endoscope Decontamination Units (CEDU)

# Centralization of endoscope reprocessing units

#### In decentralized units

- Too many machines located in areas not designed for endoscope decontamination
- Too many operators
  - Training problems
- Lack of standardization in practices
- Lack of quality control

### In centralized units

- One production site / standardized logistics
- Clear responsibilities
- Quality assurance
- Efficiency
- Process knowledge
- Education

### How does a CEDU work?

- Endoscope reprocessing units should have in place the medical devices quality management system ISO 13485 and operate in a manner consistent with the Medical Devices Regulations
- Patient throughput now and for the future must be calculated
- If the workload is more than 2000 per year and if there are plans for a new endoscopy unit structure, it is more logical to have a CEDU

### How to design a CEDU?

- If possible, use at least two rooms:
  - 1. Endoscope cleaning areas
  - 2. Decontaminated equipment area (optional for best practice)

3. Drying or storage and dispatch area

- If only a single room is available, design the elements so that a flow from dirty to clean is clearly defined.
- Double-ended EWD(s) and double-ended drying and/or storage cabinets are preferred
- Allow for the storage of decontaminated endoscopes in a clean environment, preferably a drying cabinet.
- If RO-treated water is required, the unit may need to be installed in the decontamination room.

### Two-room decontamination unit using double-ended EWDs

![](_page_47_Figure_1.jpeg)

**CFPP 01-06 Decontamination of flexible endoscopes: Design and installation** 

### Centalized EDU design (Best practice-3 rooms)

![](_page_48_Figure_1.jpeg)

**CFPP 01-06 Decontamination of flexible endoscopes: Design and installation** 

![](_page_49_Picture_0.jpeg)

![](_page_49_Picture_1.jpeg)

![](_page_49_Picture_2.jpeg)

#### **Central Endoscope Reprocessing Unit**

![](_page_49_Picture_4.jpeg)

![](_page_49_Picture_5.jpeg)

![](_page_49_Picture_6.jpeg)

![](_page_49_Picture_7.jpeg)

![](_page_49_Picture_8.jpeg)

## Endoscopy room

![](_page_50_Picture_1.jpeg)

## Precleaning at bedside

![](_page_51_Picture_1.jpeg)

### Suctioning at bedside

![](_page_52_Picture_1.jpeg)

10-15 sc pressurised water to remove blood ad tissue debris

### Transfer of used endoscopes to CEDU

![](_page_53_Picture_1.jpeg)

## Leakage test in CEDU

![](_page_54_Picture_1.jpeg)

![](_page_54_Picture_2.jpeg)

## Manual precleaning

![](_page_55_Picture_1.jpeg)

### Endoscope washer disinfectors

![](_page_56_Picture_1.jpeg)

### Connection of endoscope channels to the EWD

![](_page_57_Picture_1.jpeg)

## Disconnection of endoscope from clean side of EWD

![](_page_58_Picture_1.jpeg)

## Drying cabinets and storage

![](_page_59_Picture_1.jpeg)

![](_page_59_Picture_2.jpeg)

### Transport of clean endoscope

![](_page_60_Picture_1.jpeg)

### In conclusion this new trend

- Increases the quality of reprocessing
- Increases the number of interventions with 10%
- Gives the advantage of working with highly trained and dedicated staff
- Allows quality control
- Decreases the cost for decontamination
  - Less staff
  - Less EWDs
  - Less space

### "It is not the strongest or the most intelligent who will survive but those who can best manage change."

Leon C. Megginson

![](_page_63_Picture_0.jpeg)

International Sterilization and Disinfection Congress 29 November - 3 December 2017 Belek, Antalya- Turkey www.das.org.tr