



# Using the Low temperature Sterilization (Ethylene oxide and Plasma sterilization) in reuse of a single-Use Cardio Catheters Devices: A study Case at RMS

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## Abstract

In hospitals, there is always the need to enforce stringent infection control criteria for sterilization. Steam sterilization has long been the primary method used by most health care facilities to eliminate microbiological contaminants from various types of devices and instruments. However, In the case of catheterization devices, which are usually made from heat-susceptible rubber or polyethylene, we are faced with a challenge; since steam sterilization would, in most cases, cause permanent deformation to such devices, or at least affect their functionality.

Cardio Catheters and balloons are expensive, the purpose of this study is establish whether or not such devices, though intended for single use, could be sterilized and used multiple times to lower cost, without constituting any risk to patients, or compromising functionality, this study is done in RMS hospitals .

**Key words:** Low temperature Sterilization (LTS), Single-Use Cardio Catheterization (SUCC). Ethylene Oxide (ETO) , Royal Medical Services (RMS).

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## Introduction

It's important in our study to distinguish between the two terms, disinfection and sterilization. Sterilization is techniques used to kill all microorganisms including high resistance bacterial forms. Disinfection is a thermal or chemical process used to remove or destruction a many types of microorganisms, usually not including bacterial spores, and the Sterilization is a chemical or physical procedure used to destroy and kill all living microorganisms types, include high resistant bacterial spores.

Disinfection is less effective than sterilization because it doesn't destroy all recognized microorganisms while sterilization does .

## Methods of low temperature sterilization

A sterilization process kills and destroy the most resistance microbial spores, in the same time we must balance between this and limitation of damage of a materials being damaged.

## Ethylene Oxide sterilization

Ethylene Oxide gas is a type of LTS, used to sterilize a heat sensitive devices and medical devices made of plastic and rubber materials that may damages using high temperature sterilization, it has excellent powers of penetration lumen devices , and it has an ability to kills all types of micro-organisms such as viruses and bacterial high resistant spores. However the ETO gas is a toxic , flammable gas , has a boiling temperature about 13.5 °C, and the best sterilization using this gas must be in proper consideration of four conditions to



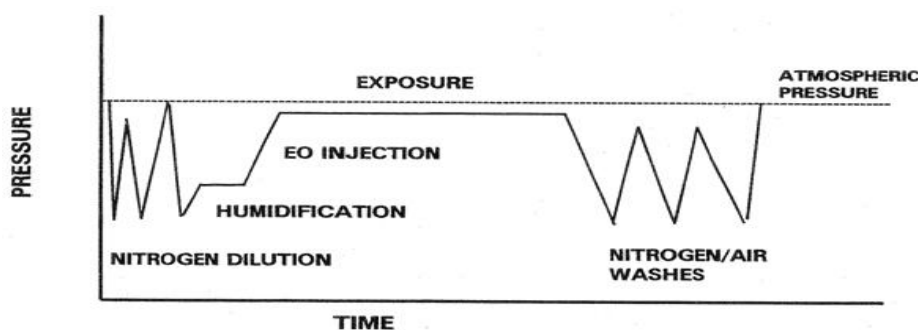
get an effective LTS using the ETO gas : Temperature, concentration , and humidity of this gas , and the exposure time .

Table 1: ranges of four variables used in sterilization using ETO

Exposure time	Temperature	ETO concentration	Humidity
1-3 hours	50-60 °C	500-1500 mg/l	45-90%

The SUCC must be clean , dray, then wrapping in paper/ polypropylene bags using a gas-sensitive indicator tape before entering the ETO sterilization cycle shown in figure 1.

Figure 1: ETO sterilization cycle



Plasma is a collection of ionized gases generated in vacuum at low-pressure conditions have a collective behavior, it has an ability to vaporize microorganisms causing a high sensitive bacteria spores to destroy .it doesn't contains any chemicals, toxic materials.

Its used mainly in sterilizes high sensitive materials that damage its materials under a high temperature.

The comparison between these LTS types will be described in table (1)

Table 2: low temperature sterilization comparison

Type of LTS	Temperature	Cycle time	Gas mixture
ETO sterilization	50-60 °C	3 hr + ( 9-12 hr ventilation)	Chlorofluorocarbon ETO + CO <sub>2</sub>
Plasma sterilization	40°-60° C	from 30-40 minutes, depending on size of system	hydrogen peroxide (H <sub>2</sub> O <sub>2</sub> )

**Single use cardiac catheters**

Catheters are plastic narrow tubes with different diameter sizes used for heart operation and diagnostic ex. a cathlab

Cath lab is a diagnostic/ therapeutic procedure to open a blockage arteries using a hollow lumen tube called catheters, the type of catheter used is depends on the type of procedure used. This cardiac catheters is a single used , in the same time it have a high cost .In our study we will use two types of low temperature sterilization; The Ethylene Oxide gas sterilization and the plasma sterilization in sterilize the SUCC without damaging or destroy its structure.Comparing of the two types of LTS in reuse of SUCC will be also described , A 6 frnch ( 2mm in diameter) SUCC is used in our study .

## Methodology

In our experiment we will use a Two groups of SUCC size 6 Frnch ( 2mm in diameter) contains A, B , CR, CL, D , which assumes used in one operational Cath lab ( guide and diagnostic SUCC) .

These catheters contaminated with blood plasma and left in open air for 24hrs

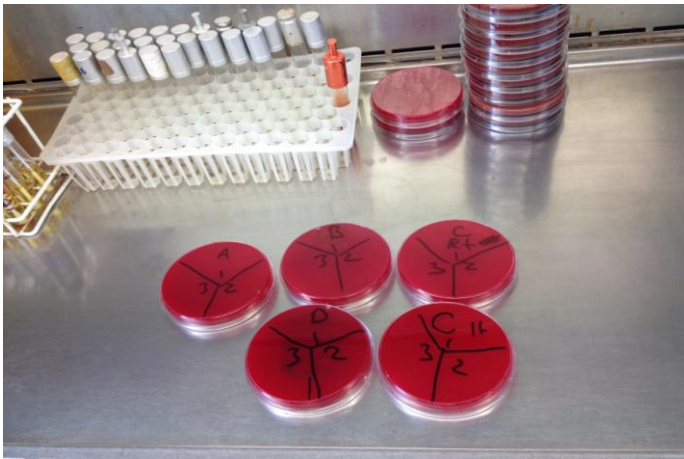
then the SUCC disassembled and sterilized using low-temperature sterilizer types available at RMS facilities, (1) with ETO sterilizer machine (3M™ Steri-Vac™ Sterilizer/Aerator 8XL) installed at Queen Alia Heart Institute,.

After that, sterile normal saline was injected into all catheters for a three sequent times to get a three Samples as shown in the figure 1 , then harvested and sent to Princess Iman Center for Studies and Laboratory sciences/Microbiology Lab in RMS to check for growth.

Then the experiment is repeated using a plasma sterilizer machine type (the Sterrad 100S PLASMA model by gohnson & gohnson) installed at Prince Hashim hospital in Aqaba to send it also to Princess Iman Center for Studies and Laboratory sciences/Microbiology Lab to check for growth.

In Microbiology Lab (Princess Iman Center for Studies and Laboratory sciences) we will inject a normal saline into the catheter for a three sequent times and take three samples to check for growth.

**Figure (1) SUCC samples for growth**



## Results

After a week of incubation at the microbiology laboratory, no growth was detected in any of the samples as shown in the figure 2 and figure 3.

Figure 2: The results of microbiology lab using ETO sterilization

**KING HUSSEIN MEDICAL CENTER****PRINCESS IMAN RESEARCH AND LAB SCIENCES CENTER****MICROBIOLOGY DEPARTMENT****MICROBIOLOGY LAB CULTURE TEST RESULTS 20/3/2014**

#	CATHETER	RESULT
.1	CATH A1	NO GROWTH
.2	CATH A2	NO GROWTH
.3	CATH A3	NO GROWTH
.4	CATH B1	NO GROWTH
.5	CATH B2	NO GROWTH
.6	CATH B3	NO GROWTH
.7	CATH C Lt1	NO GROWTH
.8	CATH C Lt2	NO GROWTH
.9	CATH C Lt3	NO GROWTH
.10	CATH C Rt1	NO GROWTH
.11	CATH C Rt2	NO GROWTH
.12	CATH C Rt3	NO GROWTH
.13	CATH D1	NO GROWTH
.14	CATH D2	NO GROWTH
.15	CATH D3	NO GROWTH

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Lab Tech  
Lieutenant  
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**KING HUSSEIN MEDICAL CENTER****PRINCESS IMAN RESEARCH AND LAB SCIENCES CENTER****MICROBIOLOGY DEPARTMENT****MICROBIOLOGY LAB CULTURE TEST RESULTS 14/5/2014**

#	CATHETER	RESULT
.1	CATH A1	NO GROWTH
.2	CATH A2	NO GROWTH
.3	CATH A3	NO GROWTH
.4	CATH B1	NO GROWTH
.5	CATH B2	NO GROWTH
.6	CATH B3	NO GROWTH
.7	CATH C Lt1	NO GROWTH
.8	CATH C Lt2	NO GROWTH
.9	CATH C Lt3	NO GROWTH
.10	CATH C Rt1	NO GROWTH
.11	CATH C Rt2	NO GROWTH
.12	CATH C Rt3	NO GROWTH
.13	CATH D1	NO GROWTH
.14	CATH D2	NO GROWTH
.15	CATH D3	NO GROWTH

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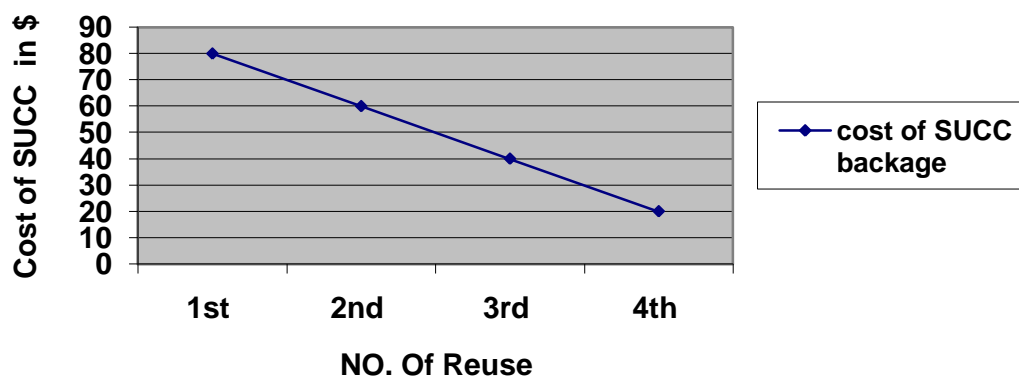
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### Cost saving in reuse of SUCC

The cost of SUCC package used in one operational cath lab (supposed to be five SUCC) is approximately 100\$, and an ETO sterilization and plasma sterilization cycle cost approximately 20\$. If the SUCC is used up to 4 times the cost saving results in 100 \$, for one operational cath lab. Seems that the catheter price become free in the fourth use of the catheter, also The capacity of each sterilizer should be concerned to get more cost saving . As shown in the figure 3.

Figure 4: Plasma and ETO sterilization Cost Saving

#### Cost Of SUCC is decrease with every reuse



### Conclusion

SUCC devices can be safely sterilized using ETO and PLASMA sterilizers and reused up to four times without constituting any risk to patients, or compromising functionality

The a cost saving about (80 \$ ) in each reuse of SUCC used in one operational Cath lab .

The use of PLASMA sterilizers may be preferred in this case since the cycle time is generally shorter than that of ETO machines, as shown in table(2), also the plasma sterilization process doesn't contains any toxic like ETO sterilization.

Ethylene oxide has a disadvantage that it's very toxic, aeration of the sterilized materials is need to remove residual ethylene oxide gas which is toxic.

Further testing may be conducted on specific types from specific manufacturers commonly used at RMS facilities to determine the number of times they can be safely reused.

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