



**PIT & MUKERNAS  
HISFARSI 2026  
PEKANBARU-RIAU**



## **Mengenal Klasifikasi Alat Kesehatan dan Metode Sterilisasi di Central Sterile Supply Department (CSSD) Teori dan Praktik**

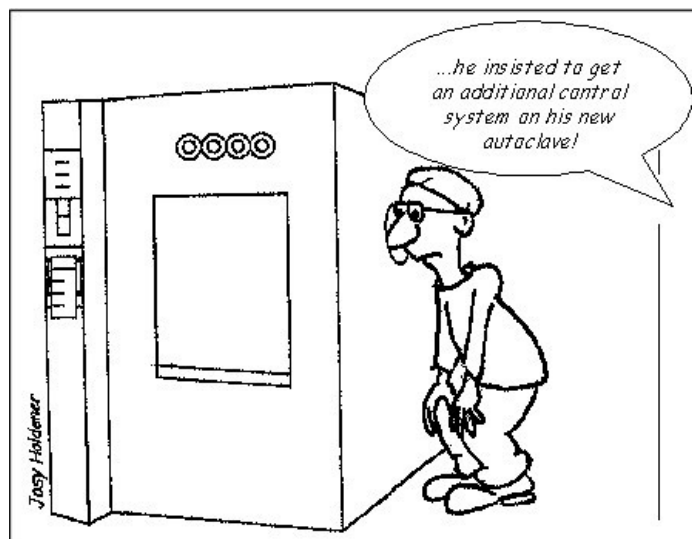
apt. Ammar Widitaputra, S.Farm

**Setelah mengikuti seminar, Peserta diharapkan mampu:**

Mengklasifikasikan alat kesehatan berdasarkan risiko infeksi dan jenis material

Menganalisa kelebihan dan kekurangan metode Steam Autoclave, Ethylene Oxide (EO), dan Plasma Sterilization

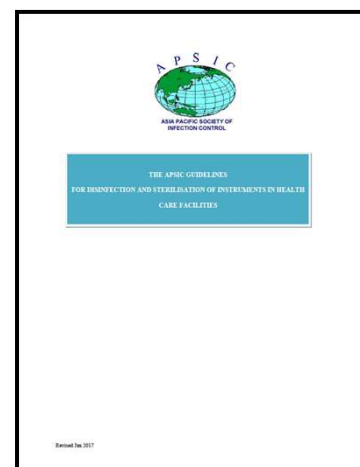
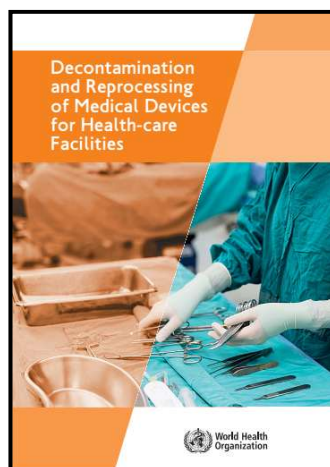
Melakukan pengemasan (packaging) dan pelabelan indikator sesuai standar prosedur operasional



## Pokok Bahasan:

- **Klasifikasi Spaulding & Pemilihan Material:**
  - Mengenal instrumen bedah, endoskopi, dan alat penunjang lainnya
- **Teknik Dekontaminasi & Pencucian:**
  - Penggunaan mesin washer disinfector dan ultrasonik
- **Packaging:**
  - Penggunaan pouch, wrapping paper,
- **Metode Sterilisasi Modern:**
  - Perbandingan efektivitas suhu tinggi vs suhu rendah
- **Monitoring**
  - Pembacaan indikator biologi

## Pustaka



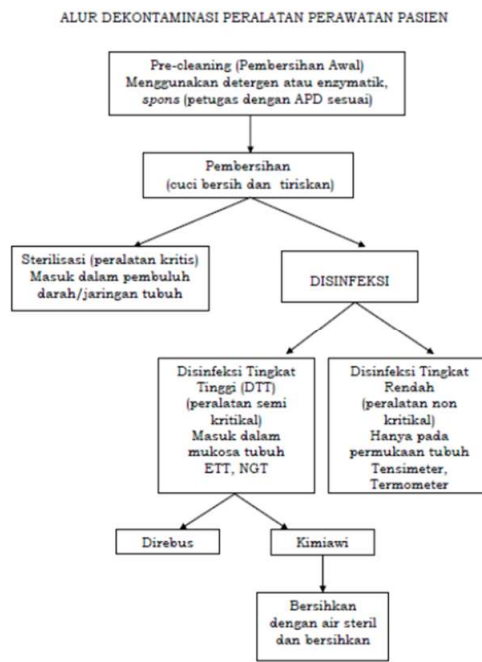
## Dekontaminasi

According to OSHA,

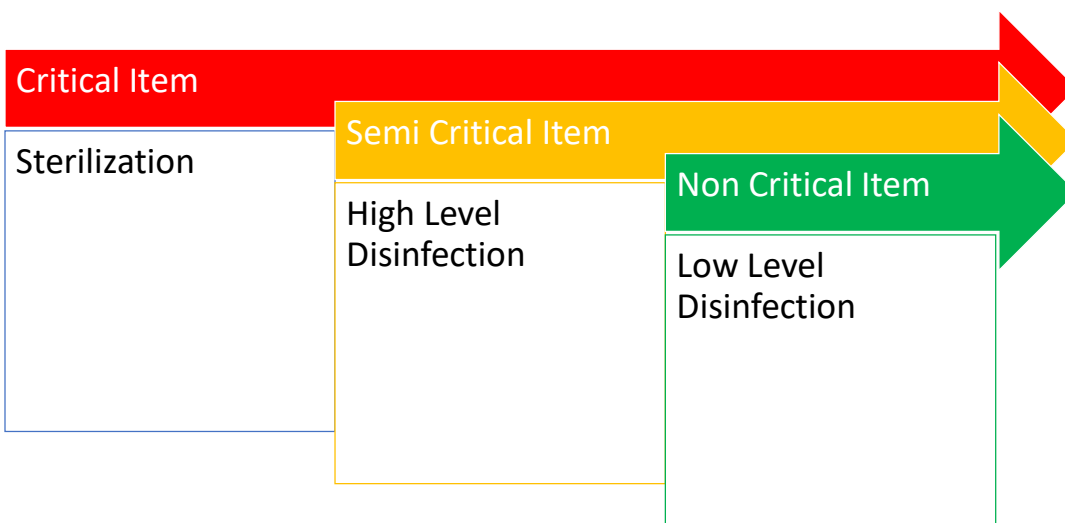
"the use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal"

[29 CFR 1910.1030].

In health-care facilities, the term generally refers to all pathogenic organisms.



## Klasifikasi Spaulding

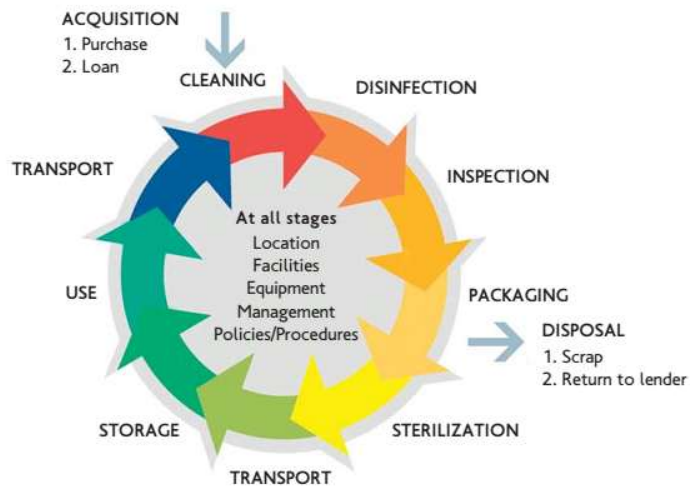


Resiko	Definisi	Contoh	Metode yang Sesuai
<b>High Risk</b>	Instrumen yang menembus kulit atau membran mukosa. Atau mengenai bagian tubuh yang steril	Instrumen bedah, spuit injeksi dan jarum, IUD, linen bedah, kateter	Sterilisasi PERALATAN KRITIKAL
<b>Intermediate Risk</b>	Instrumen yang melakukan kontak dengan membran mukosa atau kulit tidak utuh	Peralatan respirasi, gastroscope	Disinfeksi Tingkat Tinggi PERALATAN SEMI KRITIKAL
<b>Low Risk</b>	Instrumen yang melakukan kontak dengan kulit utuh	Stetoskope, Termometer	Pencucian dan pengeringan Disinfeksi Tingkat Rendah
<b>Minimal Risk</b>	Barang yang tidak melakukan kontak langsung dengan pasien, lingkungan	Lantai, dinding, Tirai	PERALATAN NON KRITIKAL

**Table 1. Level of decontamination**

<b>Cleaning</b>	The physical removal of body materials, dust or foreign material. Cleaning will reduce the number of microorganisms as well as the soil, therefore allowing better contact with the surface being disinfected or sterilized and reducing the risk of soil being fixed to the surface. Removal of soil will reduce also the risk of inactivation of a chemical disinfectant and the multiplication of microorganisms. The removal of contamination from an item to the extent necessary for further processing or for intended use. [ISO/TS 11139]
<b>Disinfection</b>	The destruction or removal of microorganisms at a level that is not harmful to health and safe to handle. This process does not necessarily include the destruction of bacterial spores.
<b>Sterilization</b>	The complete destruction or removal of microorganisms, including bacterial spores. <b>Sterility</b> State of being free from viable microorganisms. <b>Sterilization</b> Validated process used to render a product free from viable microorganisms.

## Kegiatan Utama Dekontaminasi - CDS Cleaning, Disinfection, Sterilization



## Cleaning

Cleaning is the first and most essential step before any process of disinfection or sterilization can be carried out.

One can clean without sterilizing, but one cannot sterilize without cleaning!

## Pembersihan

Cleaning is the **removal of visible soil** (e.g., organic and inorganic material) from objects and surfaces and normally is accomplished manually or mechanically using water with detergents or enzymatic products.

Cleaning is accomplished by manual cleaning with **cleaning chemicals (detergent)** and water, **brushing or flushing**, or by using **ultrasonic and or washer disinfectors** to remove foreign material

- Penyediaan bahan kimia deterjen yang tepat
- Penggunaan deterjen yang tepat
  - Konsentrasi
  - Suhu
  - Waktu

## Bahan Kimia - Deterjen



- Deterjen adalah surfaktan atau campuran surfaktan dengan bahan pembersih dalam sebuah larutan
- A *detergent* is a surfactant or a mixture of surfactants with cleaning properties in dilute solutions

Water	Universal solvent
Bases, Acids, Enzymes	Hydrolysis- in the presence of water
Surfactants	Wet, emulsify, disperse & suspend solids
Chelants, Sequestering Agents	Tie up hard water & metal ions
Builders	Assist in detergency
Corrosion Inhibitors	Protect surfaces against corrosion
Biocides	Preservative, antimicrobial agents
Solvents	Solubilise

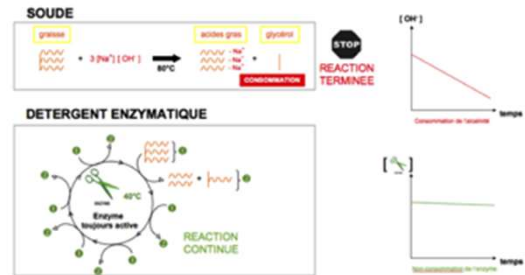
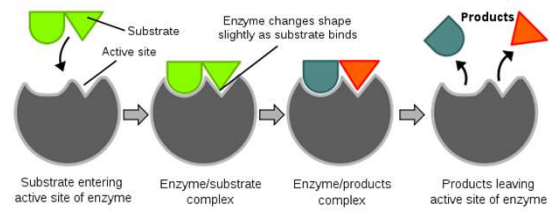
### REMEMBER

Only use appropriate detergents for instrument cleaning in the SSD. Detergents used for home cleaning or laundry use are not suitable for the cleaning of medical devices or instruments.

## Enzim

- Protease → Darah; Lipase → Lemak; Amilase → Polisakarida

- Break down larger molecules into smaller molecules (Hydrolysis)



## Manual Cleaning

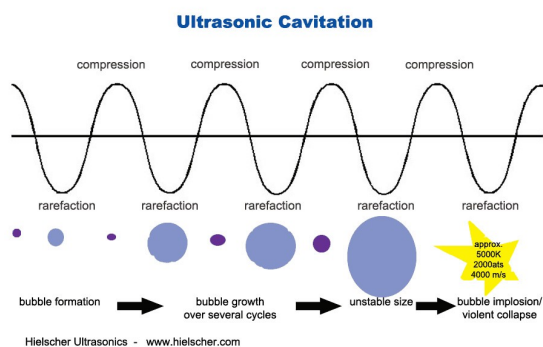


## Pembersihan Mekanis

**Konsistensi, standar yang lebih tinggi, tervalidasi, perlindungan petugas**

- Ultrasonik washer direkomendasikan untuk instrumen yang memiliki rongga, celah, lumen dan area yang sulit untuk dibersihkan
- Washer disinfector direkomendasikan untuk semua instrumen yang tahan terhadap pembersihan mekanis untuk mendapatkan paparan pembersihan yang baik dan mengurangi resiko paparan pada petugas CSSD

## Ultrasonic Cleaner



Ultrasound cleaner

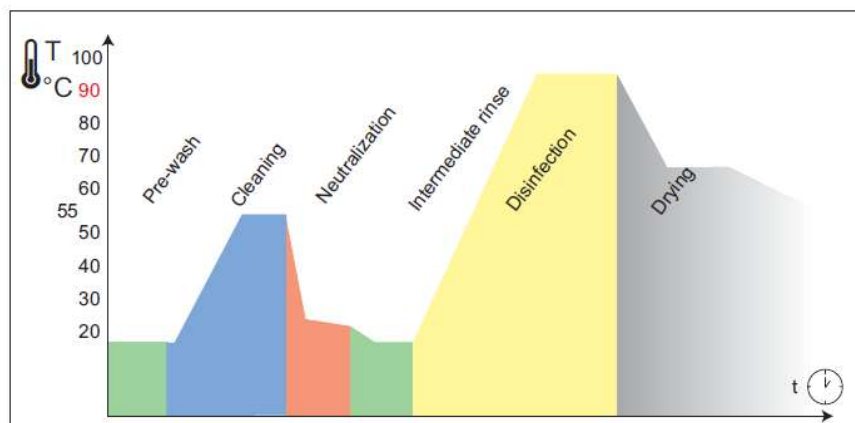


## Washer Disinfector

Mesin otomatis yang digunakan dalam pelayanan sterilisasi untuk mencuci, membilas, melakukan disinfeksi termal, dan mengeringkan instrumen medis dalam satu siklus yang terstandar dan tervalidasi



## Washer Disinfector Thermal Disinfection



Cleaning programme with thermal disinfection

## A<sub>0</sub>-Concept

Thermal disinfection with moist heat, based on the A<sub>0</sub> concept (EN ISO 15883-1), is the most common method for disinfection of medical devices in the hospital setting. A<sub>0</sub> is a physical parameter denoting the inactivation of microorganisms. The concept of A<sub>0</sub> is intended to allow equivalent disinfection efficiencies to a reference time/temperature to occur at other disinfection temperatures.

$$A_0 = \sum 10^{(T-80)/z} \Delta t$$

t = preset time interval, expressed in °C

T = Temperature in the load, in °C

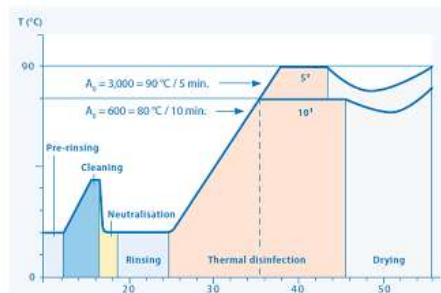
z = germ-specific temperature value

A<sub>0</sub>-Value = A-Value, if z = 10°C

## A<sub>0</sub>-Concept

Process temp. (°C)	Holding time for A <sub>n</sub> = 6000		Holding time for A <sub>n</sub> = 3000		Holding time for A <sub>n</sub> = 600		Holding time for A <sub>n</sub> = 60	
	sec	min	sec	min	sec	min	sec	min
70	60 000	1 000	30000	500,0	6000	100,0	600	10,0
80	6 000	100	3000	50,0	600	10,0	60	1,0
90	600	10	300	5,0	60	1,0	6	0,1
93	300	5	150	2,5	30	0,5	3	0,1

### Thermal disinfection in WD



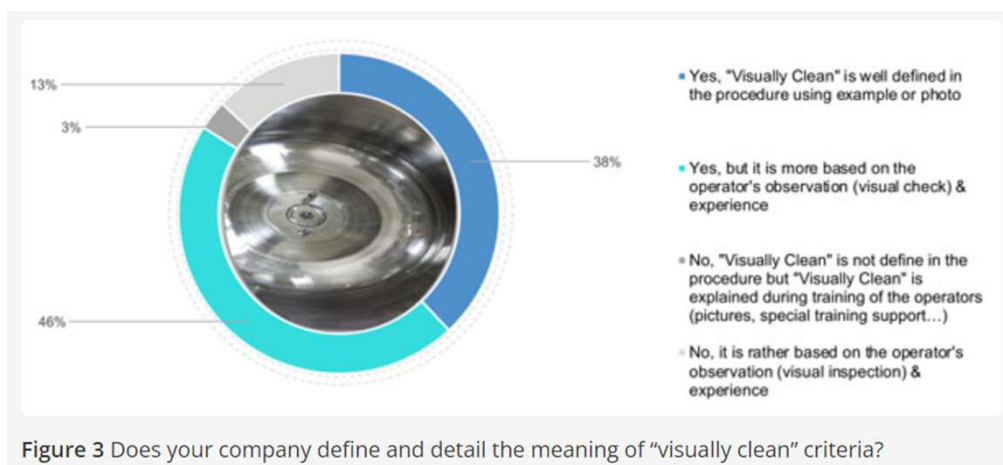
# Validasi Proses Pencucian - Visual Control

**Table 4. A summary of decontamination processes and measurements for validation and their application**

PROCESS	WHAT IS MEASURED AND WHEN?	
Cleaning	Daily Use of detergent and disinfectant	Per item Cleaning results by visual control or by using a cleaning test



## Visually Clean



## Pengecekan Hasil



## Pengecekan Proses



## Packaging Pengemasan



Memastikan sterilant (contoh: uap air) dapat melakukan penetrasi

Kompatibel dengan fase sterilisasi lainnya (contoh: fase pengeringan)

Memastikan sterilitas isi kemasan tetap terjaga hingga digunakan

Isi kemasan tetap steril

Memastikan kemasan dapat dibuka secara aseptis

Tidak mengkontaminasi isi kemasan

Memberikan bukti kemasan belum terbuka dan atau belum dimodifikasi (re-sealed)

## New packaging (1)

Not complying with EN or ISO standards

These boxes  
are no longer  
used, and it is  
easy to  
understand  
why...



## New packaging (2) Complying with EN or ISO standards



Containers  
with  
permanent  
filters



Plastic and paper  
pouches



Unwoven  
materials

## Pelabelan

Label yang aman, tidak merusak kemasan. Pemasangan yang tepat

- Isi Kemasan
- Inisial pengemas
- Nomor Lot
- Identifikasi Sterilisasi dan Siklus
- Tanggal sterilisasi – atau tercatat pada nomor lot
- Tanggal kadaluwarsa

Traceability



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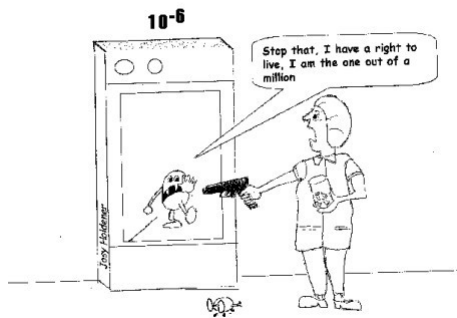
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# Sterilisasi

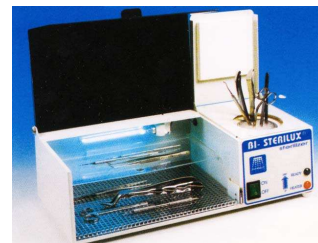
Penghancuran semua jenis mikroorganisme sampai dengan spora



- Konsep F0 adalah menu wajib dalam mata kuliah Teknologi Sediaan Steril, Mikrobiologi Analisis/Farmasi, dan Validasi Proses di seluruh Fakultas Farmasi di Indonesia.
- Farmasi sangat erat kaitannya dengan pembuatan sediaan injeksi, infus, dan mata (khususnya sterilisasi akhir atau terminal sterilization menggunakan autoklaf).
- Mahasiswa farmasi diajarkan secara matematis bagaimana menghitung nilai F0
- Wajib memahami bagaimana menghitung kecukupan panas uap jenuh untuk membunuh spora *Geobacillus stearothermophilus*. Suhu 121,  $Z_{\text{value}} 10^{\circ}\text{C}$ , mencapai **SAL  $10^{-6}$**

Ada yang tahu alat apa ini?

ecatalogue



## Metode Sterilisasi Terlarang

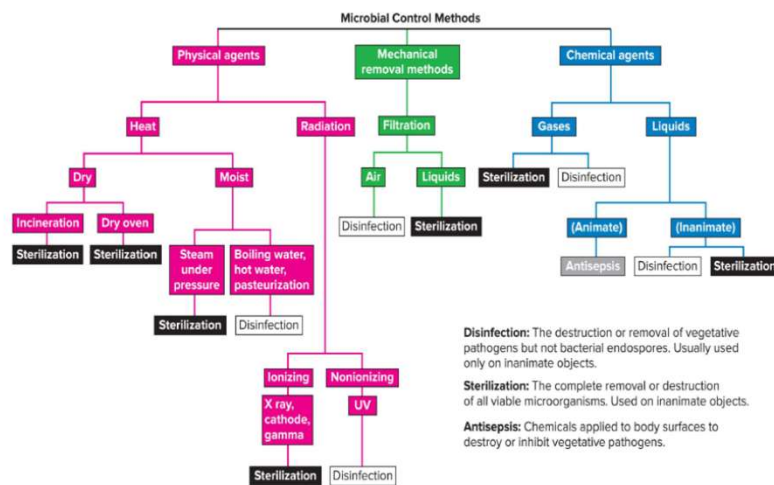


- Merebus/ Godokan
- Ultraviolet irradiation
- Chemiclave
- Microwave oven
- Glass Bead Sterilizer (dental)



APUSIC, Asia Pacific Guidelines for Disinfection & Sterilization

## An overview of microbial control methods



Talaro and Chess, 2018

## Penentuan Metode Sterilisasi

- Penentuan metode sterilisasi sangat penting
  - Tidak merusak instrumen; tetap fungsional, aman kepada pasien
  - Tetap mencapai kondisi steril
- Jenis bahan dan desain instrumen/ alkes
- Tingkatan bioburden (kebersihan) sebelum proses sterilisasi



### Efektivitas Proses Eliminasi Mikroorganisme (Disinfeksi / Sterilisasi)

- Kebersihan peralatan dan instrument (type bioburden)
- Keberadaan material organik ataupun anorganik.
- Tipe dan level kontaminasi mikroorganisme.
- Konsentrasi dan waktu paparan disinfektan atau sterilant
- Sifat dari material peralatan atau instrument (lumen, non lumen)
- Kelembaban dan suhu

## Steam Sterilisation

- **Kontak langsung** instrumen dengan **uap** pada **suhu dan tekanan** tertentu selama **waktu tertentu**.
- Paling dapat diandalkan
- Tidak beracun
- Memiliki aktivitas mikrobiosidal - Spektrum luas
- Penetrasi tinggi
- Murah dan mudah untuk memantau efektivitas
- 2 jenis utama: gravitasi dan pre-vakum



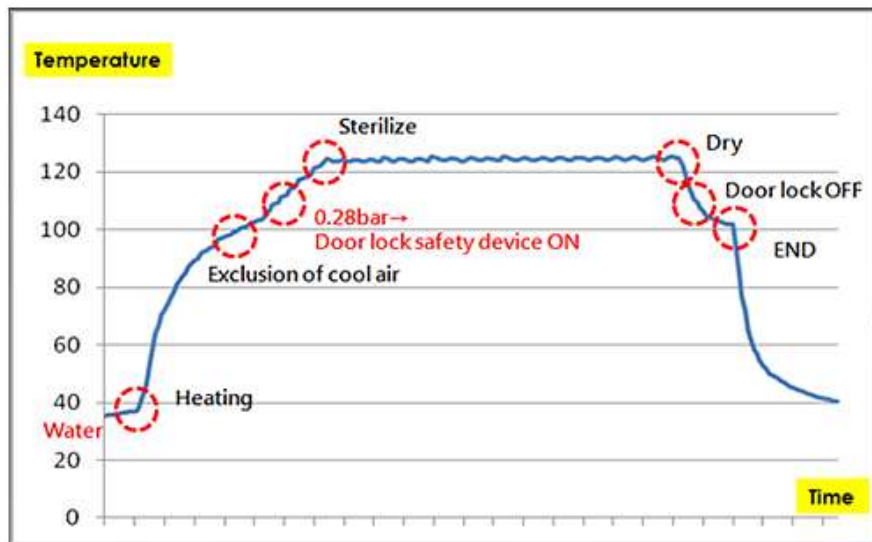


**Chamberland Autoclave (1884)**

## Gravity Displacement Autoclaves

- Uap air dimasukkan untuk mendorong udara keluar dan tekanan – suhu dinaikkan.
- Suhu dinaikkan hingga 121°C pada tekanan 15 psi dan dijaga selama 15-45 menit
- Untuk sterilisasi cairan dan instrumen dalam kemasan yang dapat ditembus oleh uap.



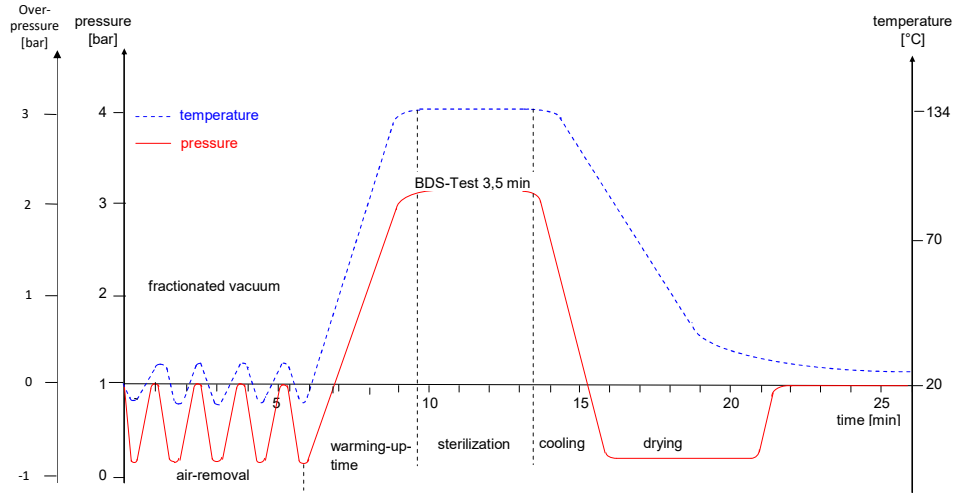


## High-Vacuum/ Pre Vacuum Autoclaves

- Pertama udara dikeluarkan dengan proses vakum dan uap dimasukkan.
- Proses lebih cepat dan penetrasi lebih baik.
- Suhu dan tekanan lebih tinggi; 134°C pada 30 psi
- Waktu sterilisasi 3-4 menit
- Tidak cocok untuk sterilisasi cairan. Kemasan dapat pecah karena proses vakum.
- Pilihan utama sterilisasi instrumen, BMHP steril dan linen.



### Sub-atmospheric Fractionated Vacuum Sterilization Process

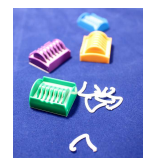


## Sterilisasi Suhu Rendah

- Digunakan untuk melakukan sterilisasi peralatan unik dengan desain kompleks yang terbuat dari bahan yang tidak tahan panas atau tidak tahan kelembaban.
  - Fiber optic
  - Polimer
  - Kamera

Table 12. Types of endoscopic procedures

Types of endoscopes	Rigid endoscope example	Flexible endoscope example	Level of decontamination
<b>Invasive</b> – passed into normally sterile body cavities or introduced into the body through a break in the skin or mucous membrane	Arthroscope Laparoscope Cystoscope	Nephroscope Angioscope Choledochoscope	Sterilization by steam or a low temperature method e.g. gas plasma
<b>Non-invasive</b> in contact with intact mucous membrane, but does not enter sterile cavities	Bronchoscope	Gastroscope Colonoscope Bronchoscope	High-level disinfection, e.g. immersion in glutaraldehyde, peracetic acid, chlorine dioxide



## Metode Sterilisasi Suhu Rendah

### Etilen Oksida(EtO)

- Waktu paparan lama
- Membutuhkan aerasi
- Daya **penetrasi yang sangat tinggi. Fase aerasi penting**
- Agen alkilasi
- >> Waktu, suhu, konsentrasi, kelembaban
- Resiko Karsinogenik dan keamanan lainnya

### Low Temperature Steam Formaldehyde (LTSF)

- Waktu paparan lebih singkat dari EtO
- Membutuhkan pembilasan dengan uap panas
- Daya penetrasi terbatas
- **Lebih murah**
- Agen alkilasi
- >> Waktu, suhu, konsentrasi, kelembaban, tekanan vakum

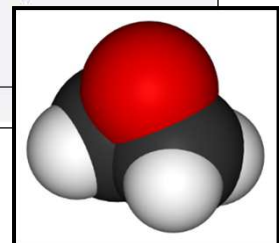
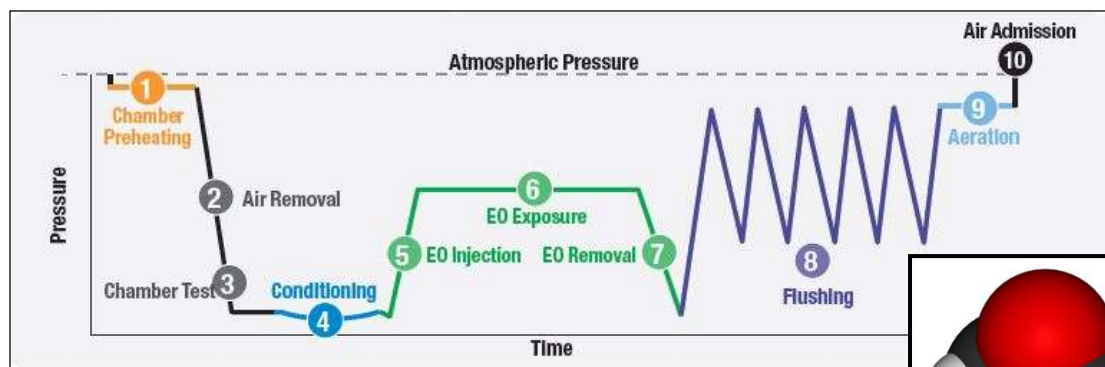
### Hydorgen Peroxide Gas Plasma

- Reaktif dan tidak stabil dalam bentuk cairan
- **Pengoksidasi kuat**
- Aman, berubah ke H<sub>2</sub>O dan O<sub>2</sub>
- Keterbatasan jenis bahan dan ukuran lumen
- >> Waktu, suhu, konsentrasi, plasma, vakum

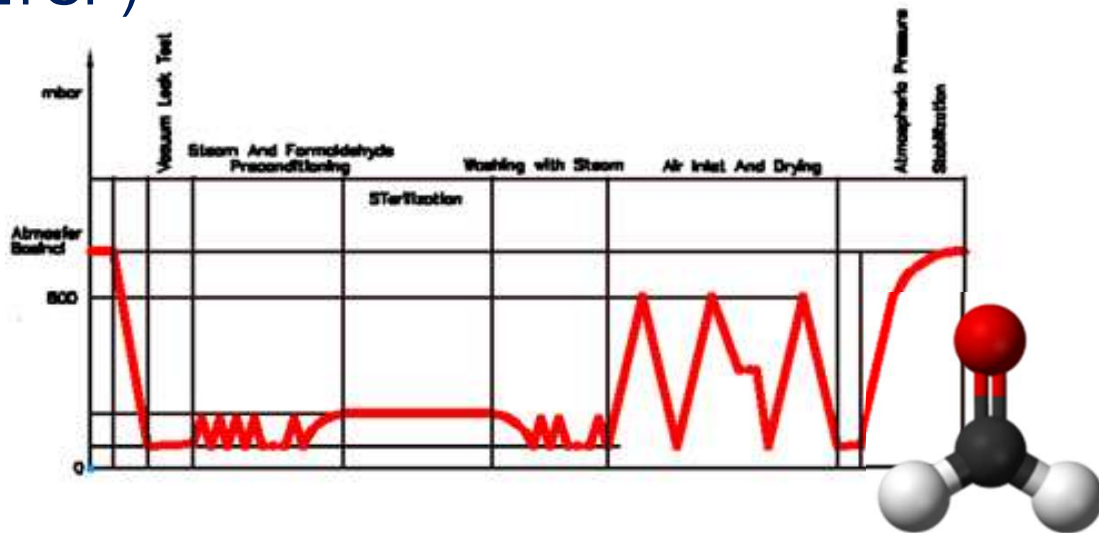
### Vapour Hydrogen Peroxide

- Reaktif dan tidak stabil dalam bentuk cairan
- **Pengoksidasi kuat**
- Aman, berubah ke H<sub>2</sub>O dan O<sub>2</sub>
- Keterbatasan jenis bahan dan ukuran lumen
- >> Waktu, suhu, konsentrasi, kelembaban

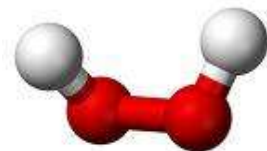
## Etilen Oksida (ETO)



# Low Temperature Steam Formaldehyde (LTSF)

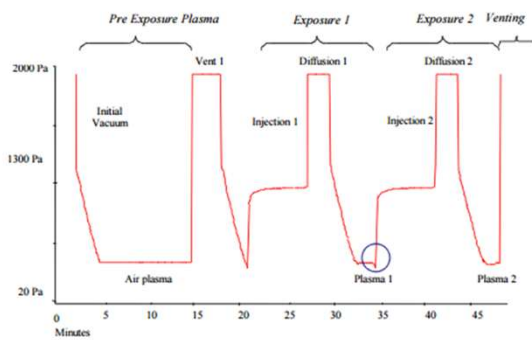
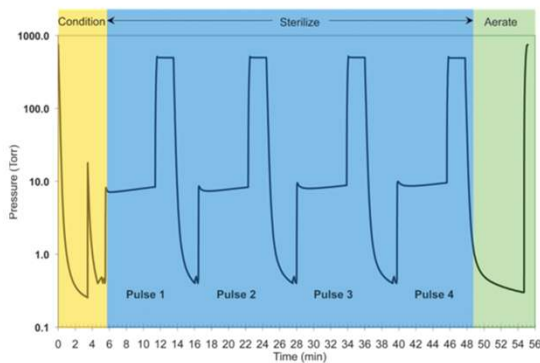


# Hidrogen Peroksida (Plasma)



**H2O2 Vapour**

**H2O2 Plasma**



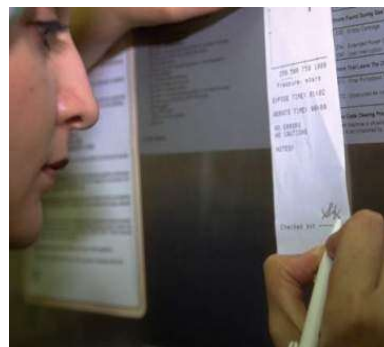
## Sterilisation Process Monitoring

- Berbagai macam pemantauan dalam proses sterilisasi.
- Berbagai macam pemantauan:
  - Physical monitoring
  - Chemical monitoring
  - Biological monitoring


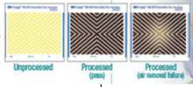





## Monitoring Fisik

- Gunakanlah monitoring fisik untuk semua load
- Verifikasi dimana setiap parameter dalam siklus sterilisasi telah tercapai.
  - Grafik
  - Gauges
  - Printouts
  - Digital displays



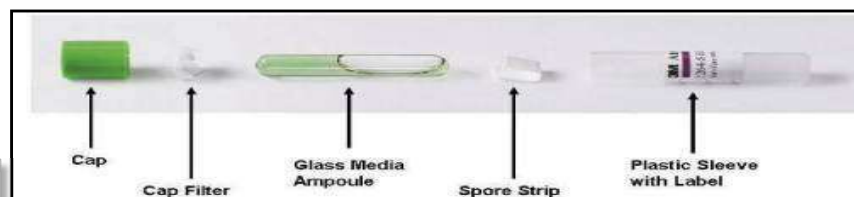
## Indikator Kimia

Tipe	Kode	Fungsi	Contoh
1.	e1	Exposure	Indikator tape Strips 
2.	s2	Special test	Bowie Dick test 
3.	i3	Internal Satu variabel	Temperature tubes
4.	i4	Internal Multi variabel	Strips 
5.	i5	Semua variabel, korelasi dengan Indikator Biologis	Strips 
6.	i6	Semua variabel	Strips 

## Indikator Biologi

- Spora yang terpapar proses sterilisasi  
Setelah proses, spora yang dicampur dalam media dan diinkubasi pada suhu yang optimal.
- Pembacaan visual atau dengan mesin

*If spores viable – process failure*



## Perkembangan BI

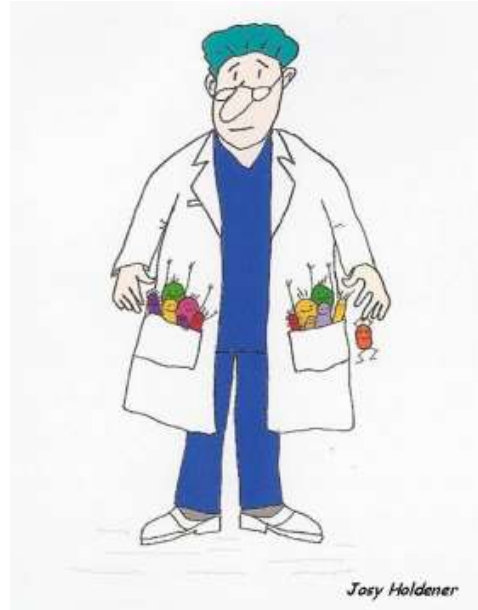


**Table 4. A summary of decontamination processes and measurements for validation and their application**

PROCESS	WHAT IS MEASURED AND WHEN?	
Cleaning	Daily Use of detergent and disinfectant	Per item Cleaning results by visual control or by using a cleaning test
Disinfection	Daily Use of disinfectant by concentration, temperature and pH of disinfectant	Per load Time of exposure
Chemical sterilizers		Per process Biological indicator Chemical indicators Physical indicator Per item External indicators
Moist heat (steam sterilizers)	Daily Bowie-Dick test for steam penetration in porous loads (pre- vacuum autoclave) (Helix test for hollow lumen instruments, if available.) Clean the chamber every week	Per process Biological indicator Chemical indicators Physical parameters met as per PQ Per item External indicators

## Apoteker Punya Peran

- Pembelajaran proses sterilisasi di jenjang Pendidikan
- Pemahaman proses pembunuhan mikroorganisme; konsep F0 untuk sterilisasi dan A0 untuk disinfeksi thermal
- Pemahaman logistik dan supply chain
- Pola pikir quality assurance dan validasi



## WFHSS Honorary President - Wim Renders



### Curriculum vitae Wim Renders

Obtained the degree of pharmacist in 1973 at the Rijksuniversiteit Ghent, Belgium.

From 1973 to 1977 pharmacist in a private pharmacy.

From May 1977 to 2011 pharmacist in the AZ St Jan hospital, Bruges, Belgium.

- Responsible for the Central Sterilization Department from 29/05/1991
- Adjunct-head pharmacist from 01/05/1993
- Head pharmacist a.i. from 09/02/2009 to 2011

From 1996 to 2010 president of the Flemish Society for Sterilization.



From 1999 to 2014 president of the World Forum for Hospital Sterile Supply (WFHSS, [www.wfhss.com](http://www.wfhss.com)).

Editor of "Zentral Sterilisation" from 1999 to 2015.

Currently the Honorary-President of WFHSS.

# WFHSS Education Officer – Carolina Chiodini



**Pharmacist Specializing in Sterilization:  
CAROLINA CHIODINI**

**EDUCATION**


Licenciatura in Pharmacy – School of Chemistry National University of Cordoba – ( 1998)	Argentina (1998-2005)
Specializing in Sterilization and biomedical devices - Juan Agustín Maza University – Mendoza – September (2008)	Argentina (2005-2018)
Certification of the Certification Board for Sterile Processing and Distribution of the United States of America (CBSPD), (2010)	France (2006-2015).
Interuniversity Certificate of Advanced Studies in Hospital Sterilization. Joseph Fourier University – Grenoble, Claude Bernard University – Lyon. ( 2012 )	Argentina (2006-2012)
Implementation of Quality Processes with guidelines towards the National Quality Award in the Sterilization Center at the Dr. Natalio Burd Hospital – Centenario, Argentina (2007).	Argentina (2008-2018)
Representative of the Undersecretary of Health in the first Quality Forum in the Province of Neuquén about Application of Criteria of the National Quality Award for the Public Sector (2009).	
Internships at 19 Sterilization Centers in French, Swiss and Spanish Public Hospitals (2011 - 2012).	
Lecturer at the 16 <sup>th</sup> World Sterilization Congress of the WFHSS in Lille, France on October 9 <sup>th</sup> , ( 2015 ) “Training of Pharmaceutical professionals specialists and technicians in sterilization in Argentina”	

*CC*

# WFHSS last President – Christine Denis



**CURRICULUM VITAE**



**Christine Denis Delebecque**  
Pharmacienne

- Responsable CSSD, CHRU Lille, France
- Chargée de mission AFS
- Membre du Comité Exécutif du WFHSS

Terima kasih