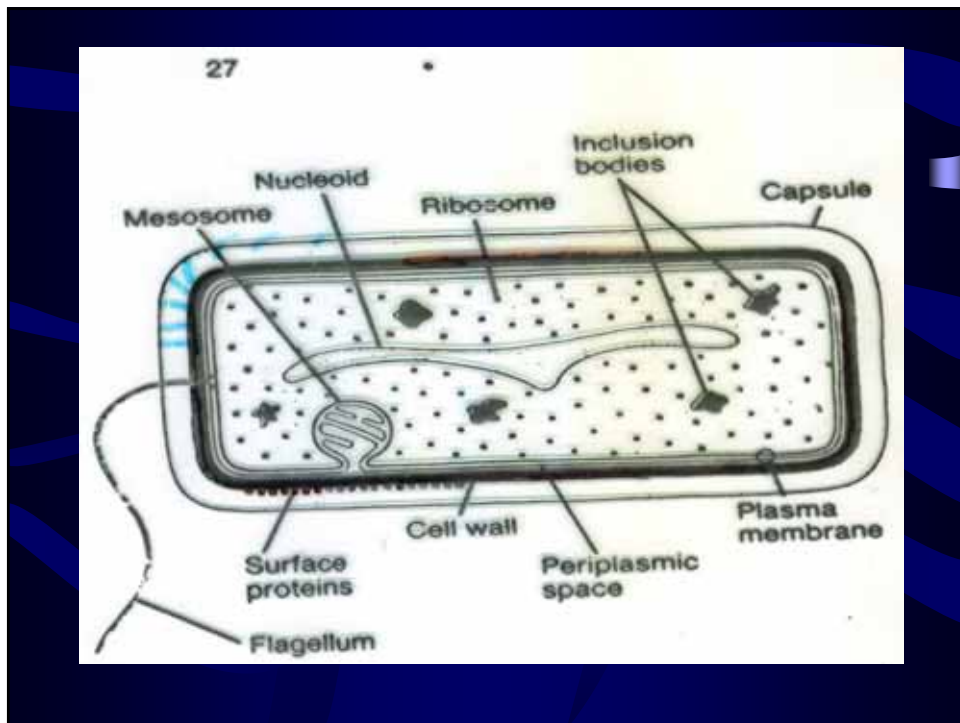
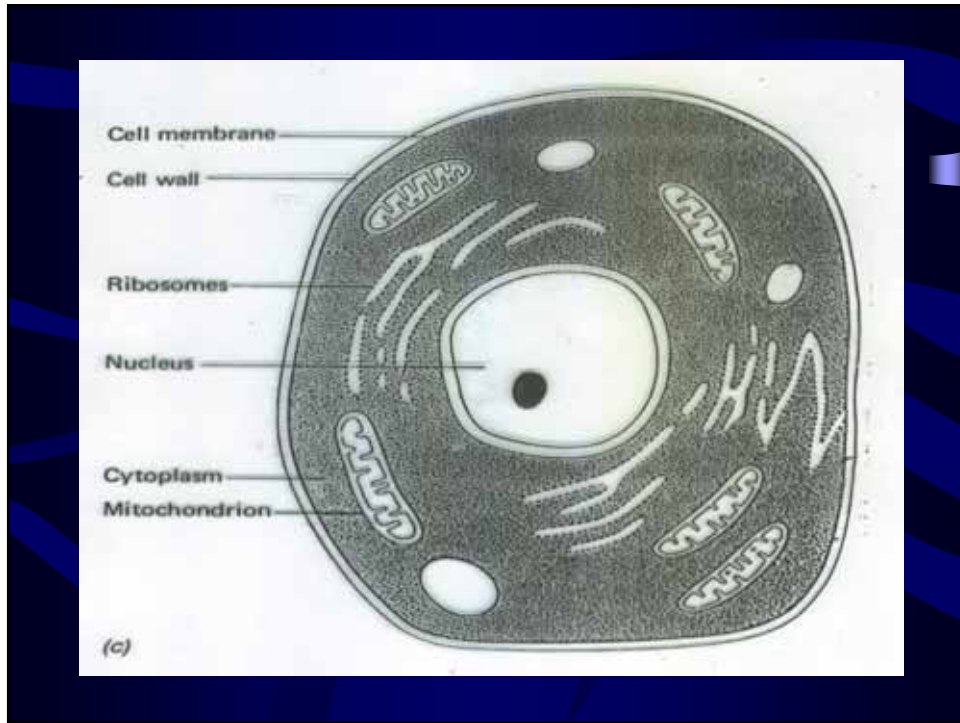


Validation Process

A presentation by
Lin Lohead B.App.Sc., CST

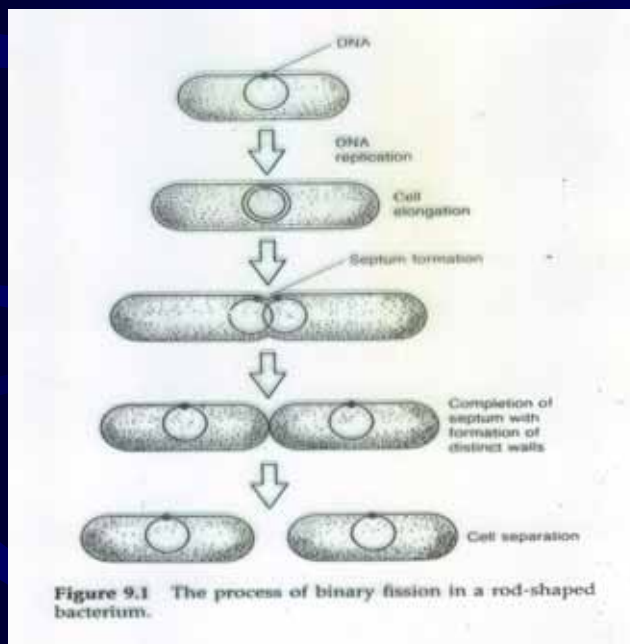
Microbes

- **Eucaryotic cells – people, plants, animals, algae, fungi**
- **Procaryotes – bacteria**



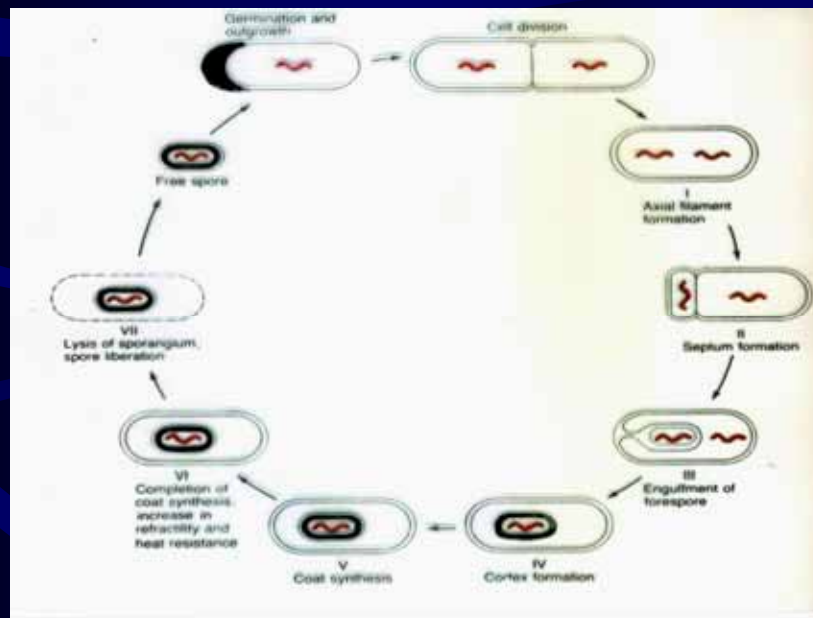
Bacterial Reproduction

- **Divide every 20 minutes if conditions are favourable ie temperature, moisture, nutrients.**
- **1 organism = more than 1,000,000 organisms in seven hours = serious infection**



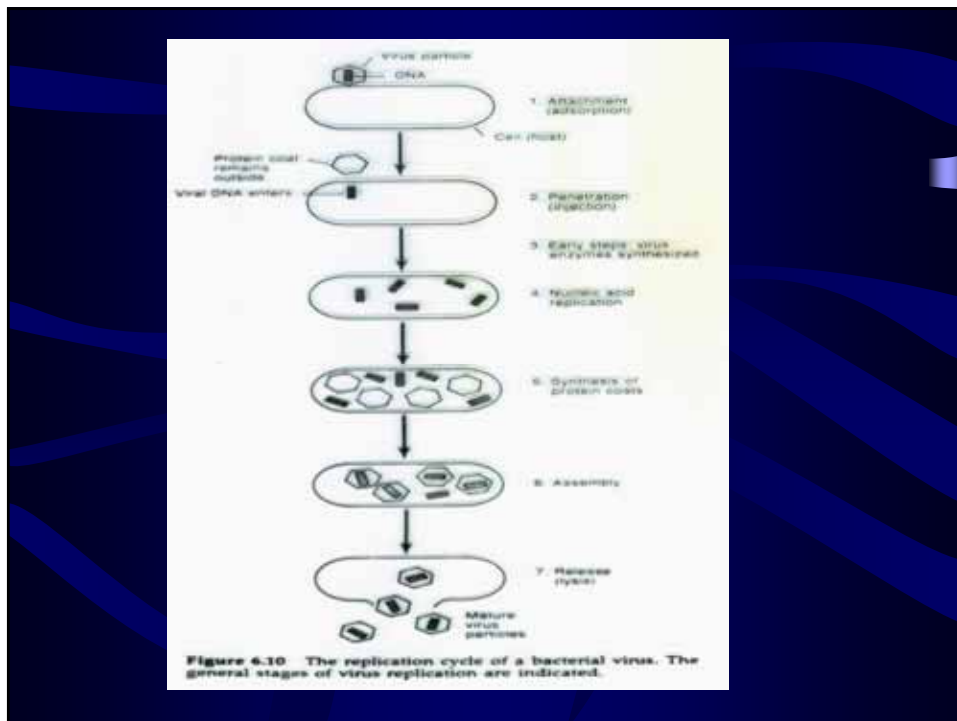
Spores

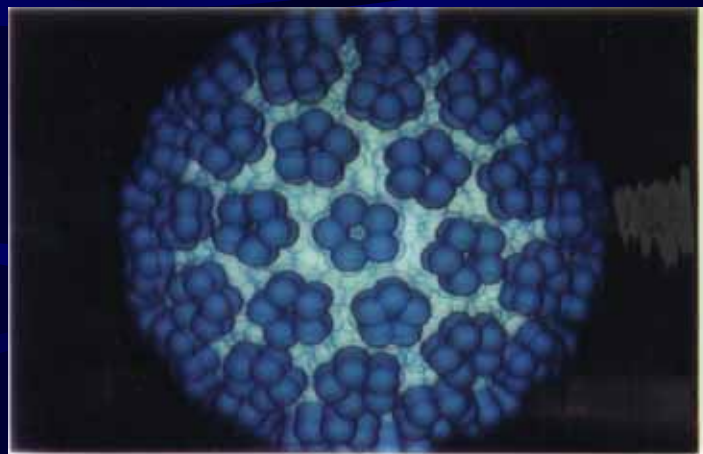
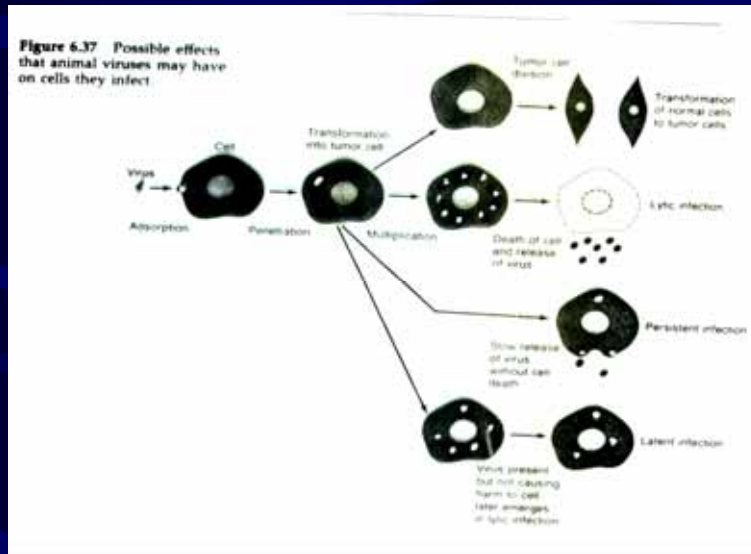
- **SOME bacteria can form spores**
- **Protects the organism in adverse conditions**
- **Able to survive for many years**
- **Revert to vegetative organisms when more favourable conditions return**
- **Very resistant**



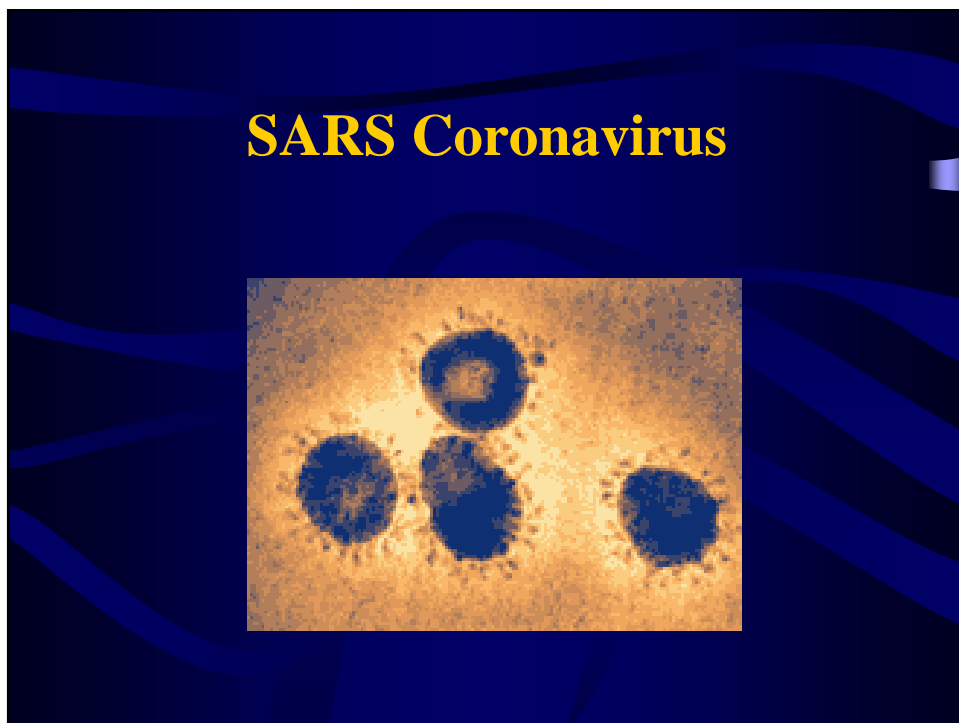
Viruses

- Not cells
- Can only replicate when associated with a cell
- Trick cells into replicating the virus instead of itself
- Very Small

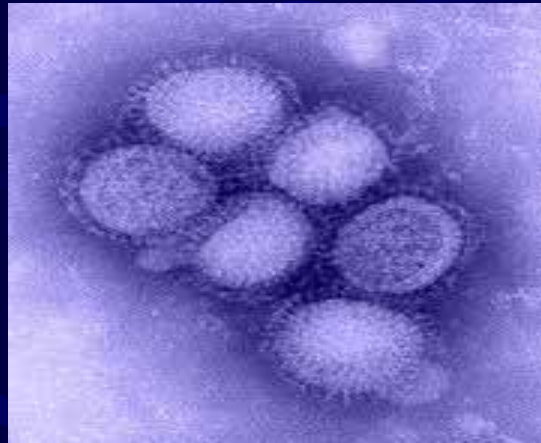




(c) Computer-enhanced image of the polyomavirus that causes a rare demyelinating disease of the central nervous system.



H1N1 Influenza Virus



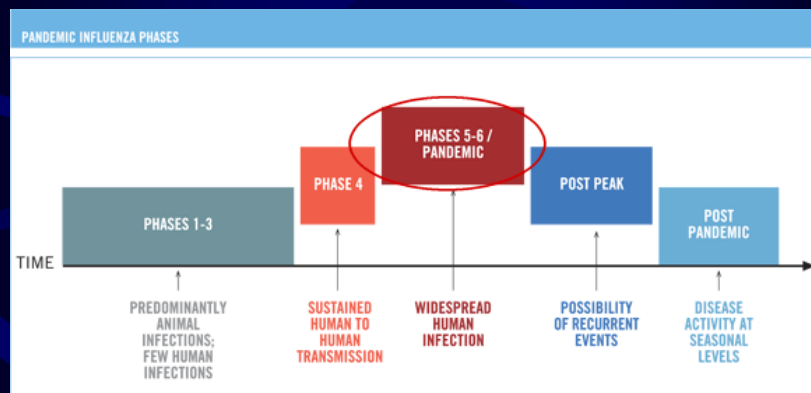
Epidemic

- A short outbreak of disease
- Spreads through single population or region
- Short period of time

Pandemic

- *Pan* meaning all *demos* meaning people
- Rapid spread
- Affects most countries and regions of the world
- Virus very different – no immunity

Pandemic Influenza Phases



Phase 1-2

- **Phase 1 - No animal viruses reported to be causing infections in humans**
- **Phase 2 – an animal influenza virus circulating among domesticated or wild animals known to have caused infection in humans, and is therefore considered a potential pandemic threat**

Phase 3

- **An animal or human-animal influenza mutant virus has caused sporadic cases or small clusters of disease in people, but has not resulted in human-to-human transmission sufficient to sustain community-level outbreaks.**
- **People living or working with these animals**

Phase 4

- **verified human-to-human transmission of an animal or human-animal influenza mutant virus able to cause “community-level outbreaks.”**

Phase 5

- **human-to-human spread of the virus into at least two countries in one WHO region.**
- **most countries not yet affected at this stage,**
- **strong signal that a pandemic is imminent**
- **time to finalize the organization, communication, and implementation of the planned mitigation measures is short.**

Phase 6

- Designation of this phase will indicate that a global pandemic is under way
- Subdivided into other phases -

Phase 6

- 6a CONTAIN -Novel virus has arrived in Australia causing a small number of cases and/or small number of clusters.
- 6b SUSTAIN -Novel virus established in Australia and spreading in the community.

Phase 6

- **PROTECT**

New phase added in

The growth in confirmed cases across the country (and across the world) is evidence that it's no longer possible to contain the virus in any particular geographic area

Phase 6

- **6c CONTROL –**

- Pandemic vaccine widely available and bringing pandemic under control.

- **6d RECOVER –**

– Pandemic controlled in Australia but further waves may occur

20th Century Pandemics

- **1918-1919 – Spanish Flu (H1N1)**
- **3 waves**
- **Affected mostly healthy, young 15-35yrs and pregnant women**
- **approx 50 million deaths (10,000 Aus)**

20th Century Pandemics

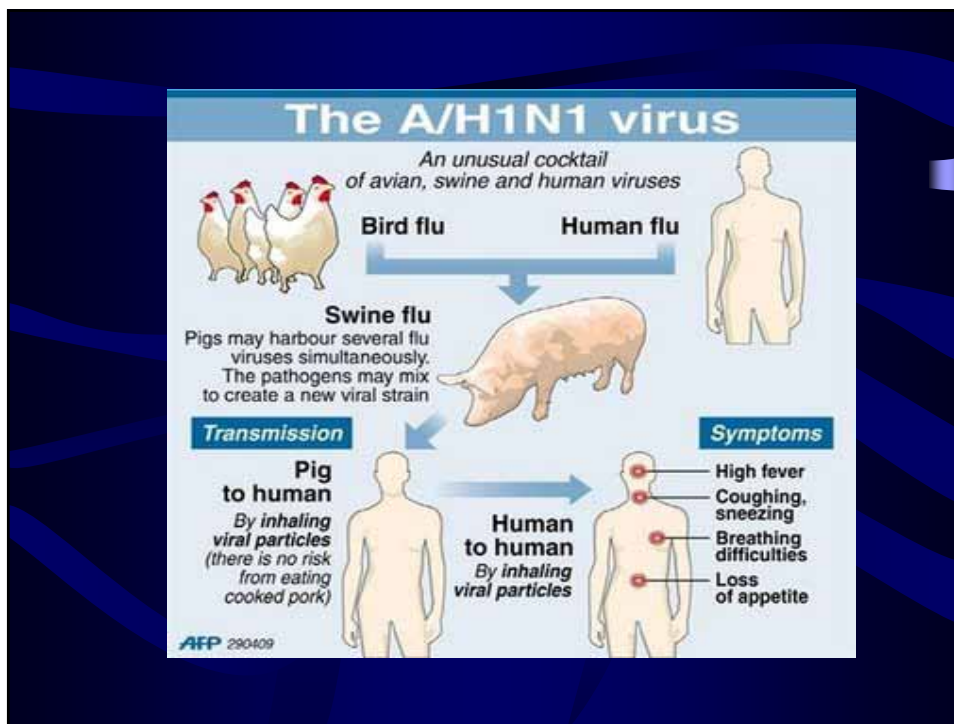
- **1957 – Asian Flu (H2N2)**
- **2 waves**
- **1st wave affected school children, young adults and pregnant women**
- **2nd wave mainly affected elderly**
- **2million deaths worldwide**

20th Century Pandemics

- **1968 – Hong Kong Flu (H3N2)**
- **Mainly affected elderly**
- **Caused over 1 million deaths worldwide**

Current Pandemic

- **2009 – Swine Flu (H1N1)**
- **Thought to be a mutation of 4 known strains**



Infection Control

- Several methods of controlling infection within a home or work environment including-
 - Isolation
 - effective hand washing practices
 - Good personal hygiene
 - Cough etiquette

Cough Etiquette

- **Cover mouth.nose when coughing or sneezing**
- **Use disposable tissues to contain**
- **Dispose of tissues in general waste**

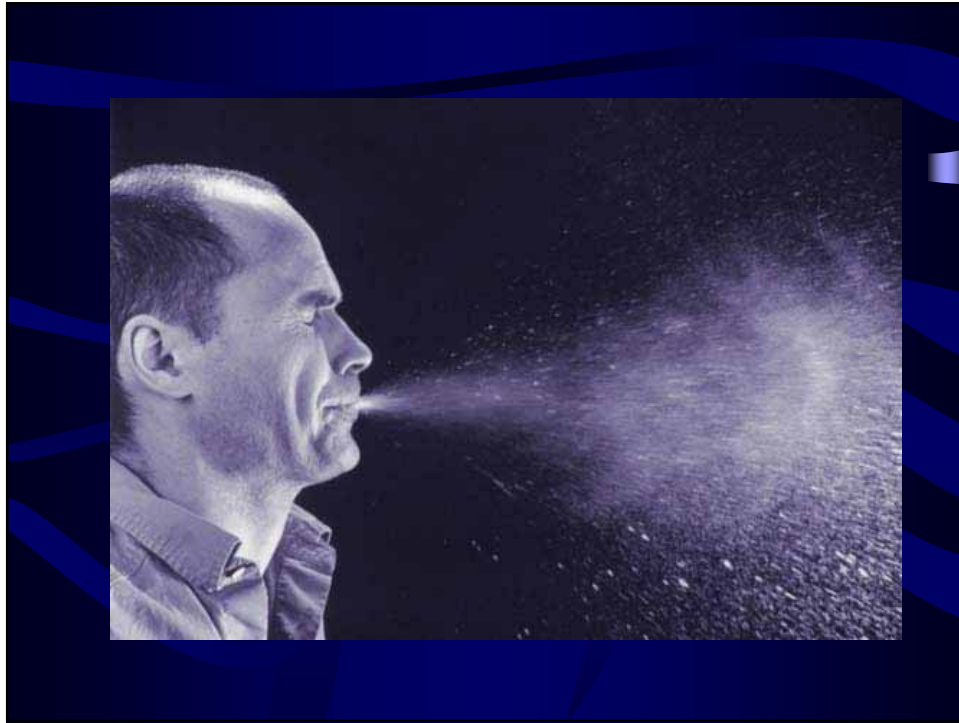
Transmission

- **Airborne – sprayed into the air**
- **Contact – direct or indirect**
- **Vehicle – Inanimate objects**
- **Vector – eg mosquitoes**

Transmission

- **Airborne – sprayed into the air (flu) – coughing, sneezing, talking**
- **Droplets – travel over a metre or more from the source**
- **Droplet nuclei (small) can remain airborne for hours or days**
- **Travels 100m/sec**

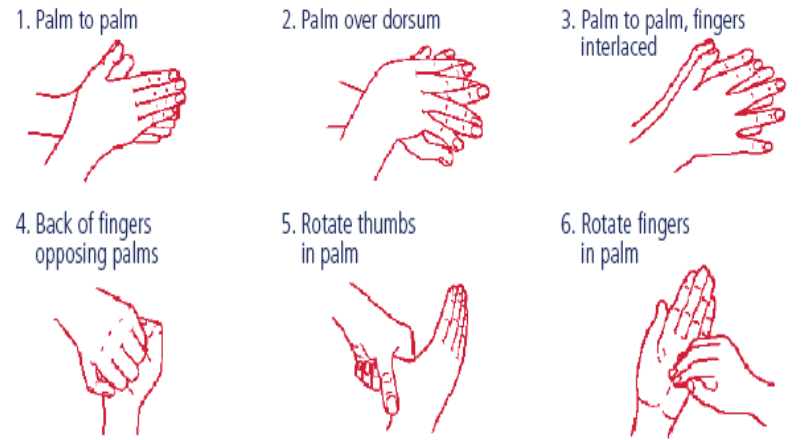




Handwashing

- **Wash hand or use hand disinfectants after coughing or sneezing**
- **Liquid soap**
- **Disposable towels where possible**
- **Method of washing – all surfaces**
- **Length of time**
- **Hand disinfectants**

Figure 2. Recommended technique for all hand hygiene agents



Gloves

- **Worn badly - worse than no gloves at all**
- **Supplement to handwashing**
- **Aseptic zone – not continued use**
- **Changed frequently**
- **Used correctly**

Masks

- **Change frequently - each patient or when damp**
- **Never touch the front of the mask – only strings or loops**
- **Never wear under the chin – on or off**

Validation

- **“A Documented Procedure for obtaining, recording and interpreting the results required to establish that a process will consistently yield a product complying with predetermined specifications”**
- **The recipe used to produce the same result every time**

Validation

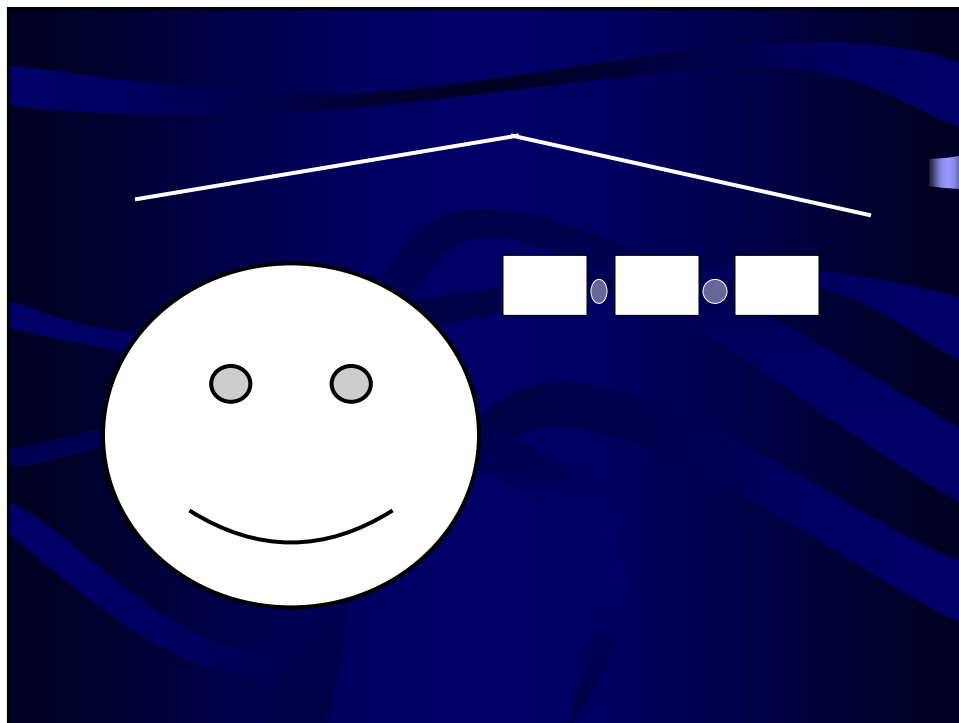
- **Step 1 - Establish Protocols, procedures**
- **Step 2 - Empty chamber study, heat distribution patterns – Determine ‘Cold Spot’ in the sterilising chamber**
- **Step 3 – Validate the sterilising process**
- **Step 4 - Implement a QA program**

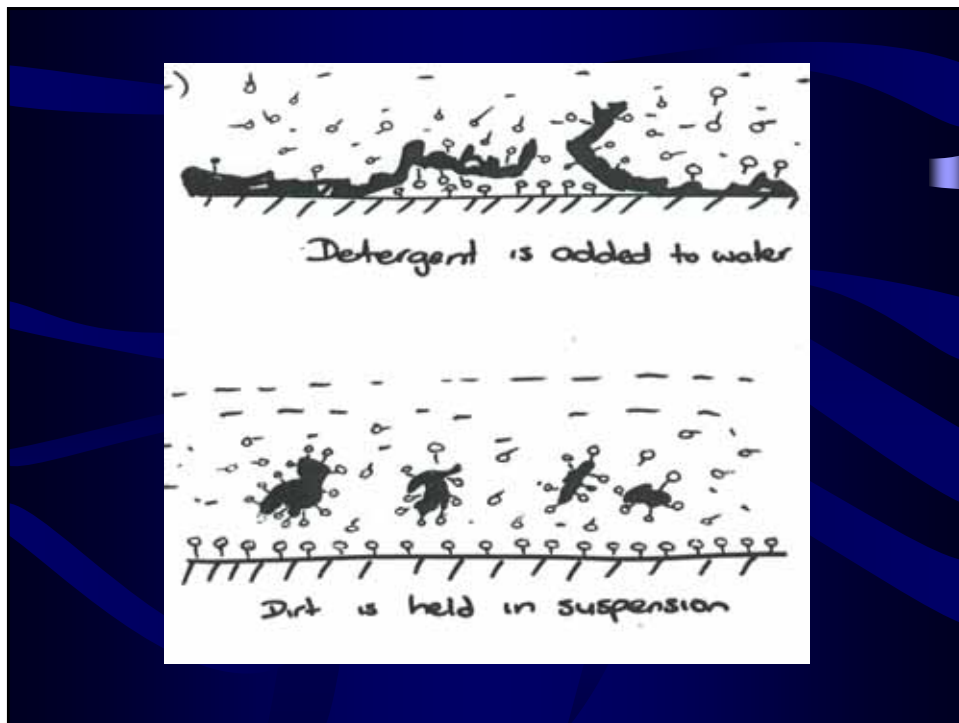
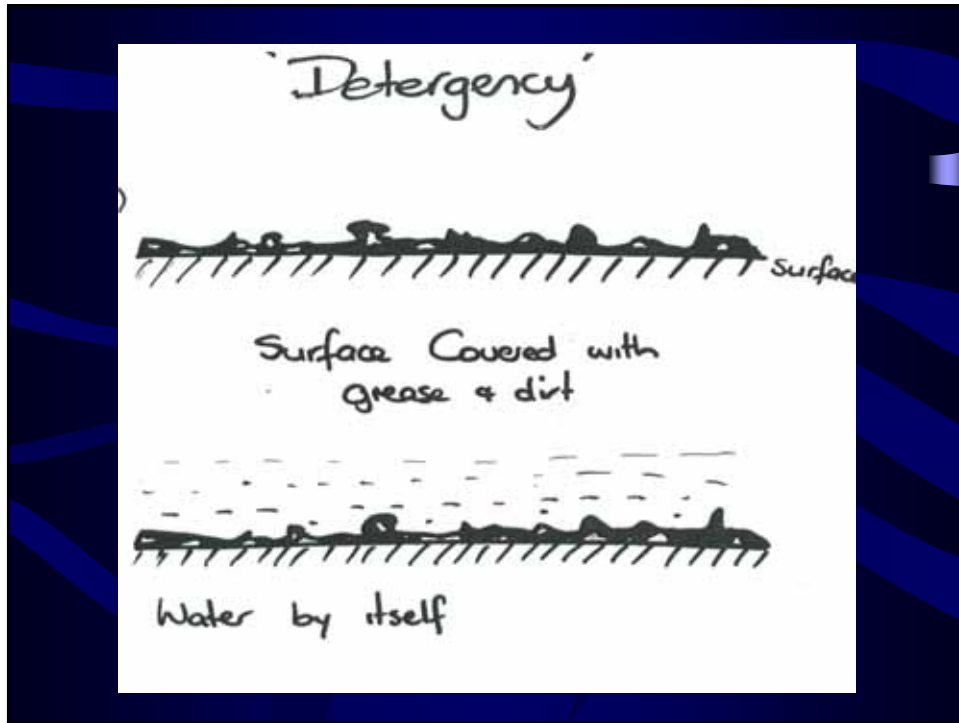
Step 1 -Policy and Procedure Manuals

- **Need to be specific to the practice**
- **Need to be read by all staff involved in the sterilising process**
- **Need to be signed by all staff to show they have read, understood and will follow the practice protocols**

Cleaning

- **Cleaning is the most important part of reprocessing any item. If an item is not cleaned properly, it cannot be disinfected or sterilised**





Cleaning cont'd

- A good cleaning agent is the key to proper cleaning. According to the Australian standards, the detergent should be;

Cleaning agents;

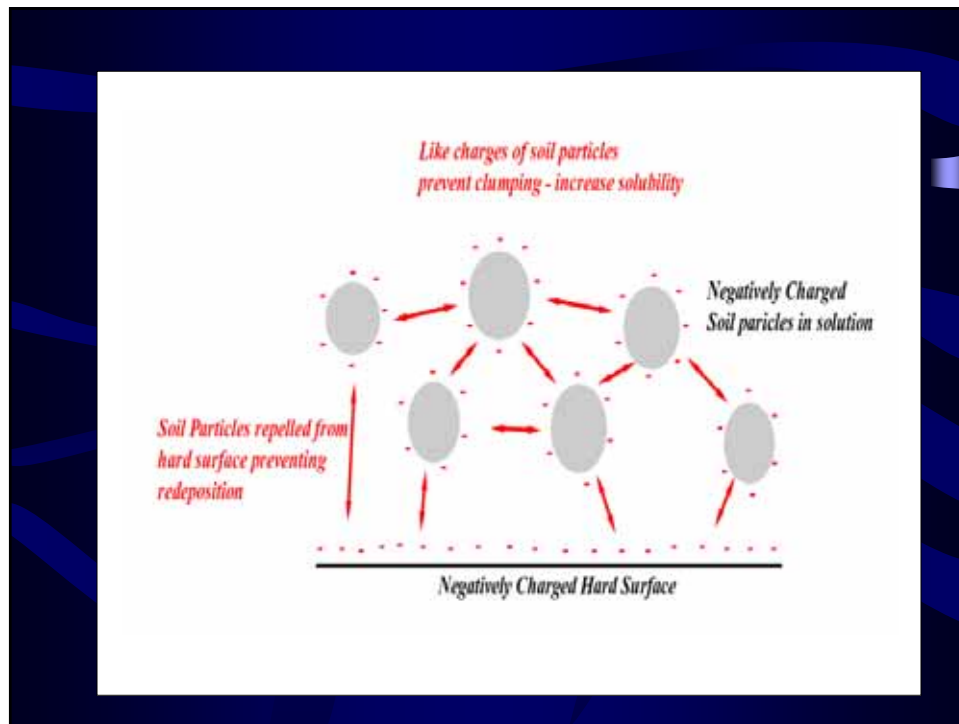
- Biodegradable
- Non-corrosive
- Non-toxic
- Non-abrasive
- Low Foaming
- Free Rinsing
- Preferably liquid
- Mild alkali formula
(p38 Sec 3)
- Contain NO -
- perfumes,
- Chlorine (>200 ug/g
- fatty soaps
- glycerine
- lanoline
- optical brighteners

Detergents cont'd

- **Mild alkaline detergents in the pH range 8.0 to 10.8 are preferred over neutral pH detergents in most applications.**
- **Aust Standards recommends the use of mild alkaline detergents (pH 8.0-10.8) for cleaning recommended because they clean better than neutral or acidic detergent**

Why alkaline detergents?

Alkalinity helps keep soil particles suspended in the cleaning solution, this prevents “clumping” and re-deposition of soil onto the cleaned surface.



Detergents cont'd

- **One good detergent can be used for;**
- **cleaning instruments**
- **wiping benches**
- **washing trolleys**
- **cleaning tables**
- **washing floors**
- **in fact all surfaces - even dishes**

Detergents cont'd

- **One product is cost efficient**
- **Enzyme products - Not recommended in Office-based practice**
- **Ask supplier or read the label -
Manufacturers must, by law, provide data to support any claims e.g...Product Data Bulletins; Material Safety Data Sheet; Validation of compliance to claims**

Manual Cleaning

- **Preferably 2 sinks or bowls - separate from hand washing and dishes**
- **Cool/tepid Water (not hot)**
- **Detergent - no foam or froth**
- **Brushes with firm bristles that can be processed**
- **Hot rinse**

Ultrasonic Cleaners

- **Many advantages – (Sec4, p57)**
 - **Clean without scratching**
 - **Time effective**
 - **Minimize OH&S risk**
 - **Simple and easy to use**
 - **Cost effective**



Ultrasonic Cleaning cont'd

- **Fill with cool/cold water**
- **degas for recommended time (5 minutes)**
- **Rinse instruments, open fully.**
- **Do Not overload**
- **Change water whenever it looks dirty**

Ultrasonic cleaning cont'd

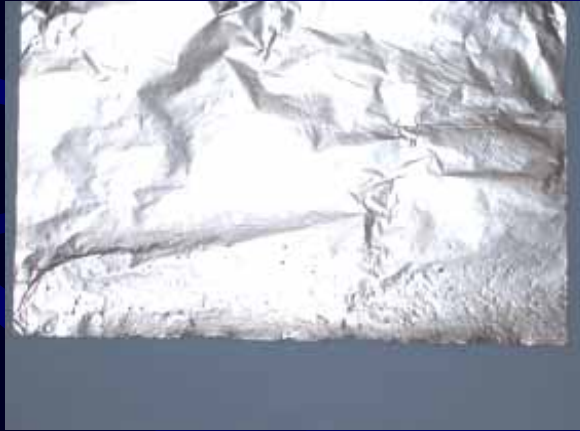
- **Alfoil test monthly (sec4, p57)**
- **Safety precautions - lid, do not submerge hands (p65)**
- **More suitable when high volume of jointed instruments**
- **Not suitable for plastic, glass, cemented or lensed instruments**

ULTRASONIC CLEANERS PERFORMANCE TEST



Aluminum foil should extend well clear of the ultrasonic tank

ULTRASONIC CLEANERS PERFORMANCE TEST



Evenly distributed perforations in the aluminum sheet indicate a positive test result. Document the result – pass/fail

Ultrasonic cleaning cont'd

- **Alfoil test monthly (Sec4, p57)**
- **Safety precautions - lid, do not submerge hands (p65)**
- **More suitable when high volume of jointed instruments**
- **Not suitable for plastic, glass, cemented or lensed instruments**

Environment Cleaning

- **Clean and dry**
- **Detergent rather than disinfectant**
- **Clean from outer perimeter to inside – prevents spread**
- **Detergent and water Not wipes**
- **Remove and replace plastic barriers but
CLEAN IN BETWEEN**

Chemical Disinfection

- **Limited in their usefulness**
- **Should never be left in containers around the surgery -contribute to rust and increase the risk of cross-infection - not cost effective.**
- **Become ineffective after very short time**
- **Do not use alcohol - it is flammable and has strict Worksafe Australia guidelines**

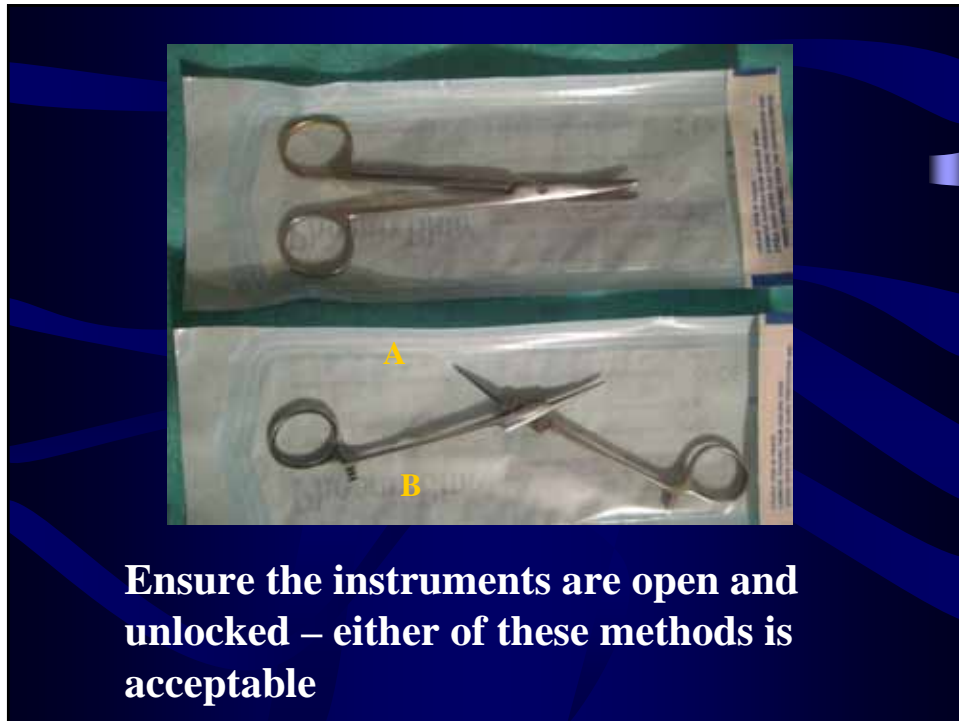
Wrapping/Packaging materials

- Used to protect contents against recontamination and damage
- Allows storage in readiness until needed - more time efficient
- Use mainly bags - double fold and tape ends if no heat sealer
or pouches – ensure sealed along dotted lines
- Label using felt-tipped pen



Fold the pouch along the dotted line at the top as per instructions

Place cleaned, dried instrument into the pouch handle first to prevent contamination and damage of the working end when the instrument is retrieved.



Packaging cont'd

- **When using paper/plastic rolls or paper sterilising bags, seal with a heat sealer. Where no heat sealer is used, double fold and tape ends**
- **Label using felt-tipped pen - write contents and date of sterilisation**

Tracking/Batch Codes

- **It is considered Best Practice to track critical items (sterile at the point of use)**
- **RACGP states the need to track instruments should not be necessary if the validated process is strictly adhered to and monitored.**
- **Where tracking system is implemented each item has 'piggy back' label or batch code written on the packaging which is transferred to the patients' notes when used.**

Validation

- **Complete system to replace routine monitoring**
- **Establish Protocols, procedures**
- **Document all phases of the process**
- **Empty chamber study, heat distribution patterns – Determine 'Cold Spot' (Step 2)**



Installation Qualification

- **“Obtaining and documenting evidence that equipment has been provided and installed in accordance with its specifications”**
- **Commissioning of a new steriliser**

Operational Qualification

- **“Obtaining and documenting evidence that installed equipment operates within pre-determined limits when used in accordance with its operational procedures “**
- **Calibration**

Calibration

- **“ The comparison of a measurement system or device of unknown accuracy to a measurement system or device of a known accuracy to detect, correlate, report or eliminate by adjustment, any variation from the required performance limits of the unverified measurement system or device**
- **3-6-12 monthly depending on age and usage**
- **Using Trained personnel**
- **Results documented and retained**



Performance Qualification

- **“Obtaining and documenting evidence that the equipment, as installed and operated in accordance with operational procedures, consistently performs in accordance with pre-determined criteria, and thereby yields a product meeting its specification.”**

Step 3 - Validation Process

1. Check that all processes achieve the desired result
2. Check that all the policies within practice are implemented and carried out correctly (QA)
3. Obtain empty chamber heat distribution studies (from the service company) and determine the "Cold Spot" – just ONCE unless major repairs or relocation (p74)

BACK

1. (Bottom Shelf)

2. (Centre)

3. (Top Shelf)

FRONT

TEMPERATURE READINGS

Pos one: av temperature = 134.1°

Pos two: av temperature = 134.5°

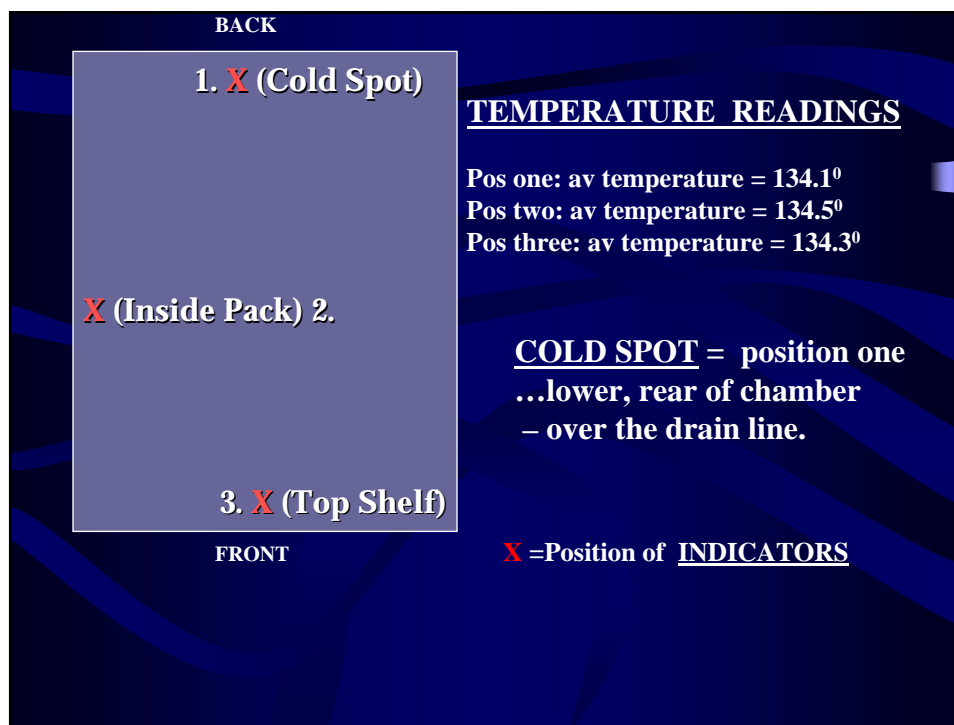
Pos three: av temperature = 134.3°

COLD SPOT = position one
...lower, rear of chamber
– over the drain line.

Penetration Time established initially. Rechecked if packaging changes (p73)

Validating of the Sterilising Process

4. Determine the Challenge Pack – ie the worst case scenario within YOUR surgery. The hardest to sterilise set/pack in terms of density and size
5. List the contents of the challenge pack
6. List the contents of the challenge load – full normal load including the challenge pack



Validation Process

7. Run the load through a full cycle – Practice staff NOT service technician (p126)
8. On completion of the cycle, check the load for moisture and changed CI's
9. Allow the load to cool then remove packaging and spores, re- package same load replacing spore tests
10. Repeat same process again - 3 times consecutive cycles - Same day

Validation Process cont'd

- Record all the spore/enzyme test results –
100% =Pass

	Pos 1	Pos 2	Pos 3	Control
Load 1	Pass	Pass	Pass	Fail
Load 2	Pass	Pass	Pass	
Load 3	Pass	Pass	Pass	

Monitoring of the process

- **Every cycle must be monitored either by a printer and by multi-parameter chemical indicators**
- **Air removal must be monitored daily when a pre-vacuum cycle is used**

Classification of Sterilisers

- **Classified by Air Removal –**
 - 1) Downward/Gravity Displacement**
 - 2) Vacuum extraction (trans-atmospheric or sub-atmospheric)**

Need a New Steriliser?

- **Determine type of instruments to be processed**
 - a) **Hollow → Class B Cycles → Pre-Vacuum machine**
 - b) **Solid → Class S Cycles → Vacuum Assisted machine**

Monitoring of the process

Every cycle must be monitored either by a printer or by multi-parameter chemical indicators with additional daily testing when a pre-vacuum cycle is used

Sterilisers with a Printer



- The person who turns the machine off, must check the printout, circle the parameters and sign the printer strip

- Circle Date
- Circle Load Number
- Circle 3 consecutive minutes at 134°
- Sign and release load

printout

```
AUTOCLAVE NO:2  
LOAD NO:082  
OPERATOR:  
O - K -  
D43 085°C 0.00  
D40 086°C 0.00  
D37 088°C 0.00  
D34 091°C 0.00  
D31 094°C 0.00  
D28 101°C 0.00  
E25 121°C 0.20  
E25 122°C 0.20  
S24 134°C 2.10  
S23 134°C 2.10  
S22 134°C 2.10  
S21 134°C 2.10  
S20 134°C 2.20  
S19 134°C 2.20  
S18 134°C 2.20  
S17 134°C 2.10  
H16 130°C 1.00  
H12 116°C 0.00  
H08 087°C 0.00  
H04 029°C 0.00  
H00 021°C 0.00  
HN TEMP PRES  
DRY :20min  
TIME:07min  
TEMP:134°C  
PROG:INS  
TIME:11:42:30  
DATE:24:05:06
```

inn process.

Sterilisers with a Printer cont'd

- **This person releases the load (Parametric release- Declaring a product as sterile, based on the records demonstrating that the process parameters were delivered within specified tolerances)**
- **If commercial Tracking system in place, there is no need for other monitors such as chemical indicators**
- **Further spore tests - optional**

Sterilisers with LCD readout

- **The person who turns the machine off, must check the screen, and sign the record book**
- **This person releases the load (parametric release) deemed sterile based on the parameters set during validation**
- **Download the computer memory card as per manufacturer's instructions**

Sterilisers without a printer

- These machines should be replaced
- Every load must contain a class 4, 5, or 6 indicator after validation
- Manual records of each load must be generated (p77)



Added test for Class B Cycles

- Leak Rate and Vacuum test – performed in a cold chamber on the warm-up cycle
- Air Removal test - first load each day in warm chamber using an air removal test device that conforms to EN 867-5. eg Helix tester, green card, Bowie-Dick test pack



Documentation for each cycle (p82)

- **Date**
- **Load number**
- **Steriliser ID where more than one**
- **Contents of the load**
- **Operator**
- **Results of the cycle monitoring eg printer readout**

Cycle documentation cont'd

- **Chemical indicator change - record and discard (p77)**
- **Pack condition – dry, sealed, clear, intact**
- **Signature of person releasing/rejecting the load**
- **Comments re faults and action taken**

Date	Load #	Contents	Packaging			Al foil		Signature
			Dry	Intact	CI	BD/helix		
16/5	01					Pass	Pass	_____
16/5	02	5 exam sets, 2 bowls	✓	✓	✓			_____

Off Site Records

Date Sent	Item sent	Date received	Batch code #	Packaging			Signature
				Dry	Intact	CI	

Legal requirements

- **Policy and Procedure Manual**
- **Records of the calibration of the steriliser**
- **Validation result records**
- **Monitoring records – print outs or manual records**
- **Tracking system**

Step 4 -Quality Assurance Program

- **Select the Infection Control Officer**
- **Draw up a QA checklist**
- **Complete the checklist 1-3 monthly**
- **Address any areas that produce a negative outcome**

Cleaning - QA

- **PPE's worn**
- **Tepid water not hot**
- **Dedicated sink/bowl**
- **Correct detergent used**
- **Correct dilution**
- **Solution changed regularly/as required**
- **Suitable brushes**
- **Rinsed in warm/hot flowing water**

Ultrasonic QA

- **Water degassed after each fill**
- **OH&S requirements understood and followed – Lid on, hands out, PPE's worn**
- **Instruments rinsed, open and submerged**
- **Ultrasonic Cleaner tested daily**

Summary/List of policies

- **General Principles**
- **Standard Precautions**
- **Handwashing**
- **Handling Used Items**
- **Cleaning - instruments -mechanically or manually**
- environment

List of Policies cont'd

- **Drying – lint free cloth**
- **Wrap - bags or pouches**
- **Tracking system - batch number**
- **Loading the steriliser**
- **Operating the steriliser**
- **Unloading the steriliser**

List of Policies cont'd

- **Store - when cool, in closed cupboard**
- **Shelf life - event related not time related**
- **Calibrate the machine 6-12 monthly**
- **Validate the sterilising process annually**
- **Monitor the process every load – printer or multi-parameter indicators**

List of policies cont'd

- **Blood Spills – Spill Kit - detergent and water, disposable cloths, absorbant materials**
- **Needlestick/Sharps Injuries – prevention is better than cure – approved containers**
- **Waste Disposal – check with local councils**
- **Staff Immunisation – record details.**

Validation

- **Step 1 - Establish Protocols, procedures**
- **Step 2 - Empty chamber study, heat distribution patterns – Determine ‘Cold Spot’ in the sterilising chamber**
- **Step 3 – Validate the sterilising process**
- **Step 4 - Implement a QA program**

Contact details

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