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your complete sterilization partner
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SafMed Steri-View

A SPECIALIST NEWSLETTER IN STERILIZATION & INFECTION PREVENTION TOPICS FOR HEALTHCARE PROFESSIONALS

# Sterilization Cycles and How to Monitor Them

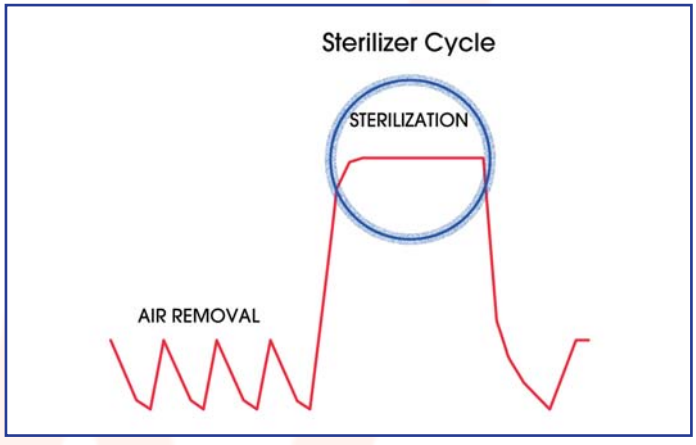
## Standard Steam Sterilization Cycles

The standard EN 556-1:2001[1] requires that for a terminally-sterilized medical device to be designated "STERILE", the theoretical probability of there being a viable micro-organism present on/in the device shall be equal to or less than $1 \times 10^{-6}$. Standard steam sterilization cycles have been adopted throughout the world in order to process terminally-sterilized devices and these vary from 134°C for three minutes to as long as 18 minutes, in the case of prion cycles.

## Extended Steam Sterilization Cycles

Extended steam sterilization cycles are cycles with longer exposure and/or drying times than those commonly used. A standard cycle might be 134°C for four minutes for example, while an extended cycle could be 134°C for seven minutes. The need to use longer sterilization cycles is because medical instruments have become more complex in design and have areas that create challenges for air removal and steam penetration, such as lumens, crevices and other small interior features.

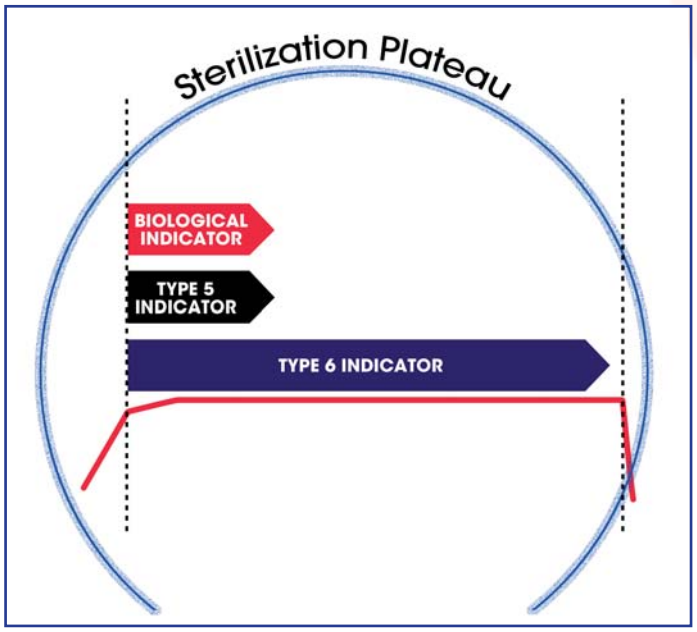
In many countries, medical device manufacturers are required to provide written recommendations to hospitals on how to reprocess their medical devices and what sterilization cycles to use. Where these differ from standard cycles being used, hospitals need to consult their sterilizer manufacturers in order to have additional cycles programmed into their sterilizers.




## Monitoring of Sterilization Cycles

Sterilization cycles can be monitored by using either biological or chemical indicators. It should be appreciated that these indicators work in different ways and monitor different parts of the sterilization cycle, as can be seen from the diagram below. Chemical indicators are divided into six types dependent on their usage or performance. More information on this can be obtained by referring to the standard for Chemical indicators ISO 11140-1: 2014.

- Biological indicators can only operate during the first part of the cycle when used for routine monitoring
- Type 5 chemical indicators perform similarly to biological indicators and do not measure the entire cycle at 134°C
- Type 6 chemical indicators measure the entire cycle at 134°C, no matter what length, as long as the correct indicator is chosen




## Performance of Chemical Indicators

It should be noted that the different types of in-pack indicators defined in the standard ISO 11140-1: 2014 have differing requirements as far as accuracy is concerned.

- Type 6 is the most accurate and comprehensive technology
- Tolerances of 15%* are allowed for Type 5 indicators versus 6% for Type 6 indicators

** 15% is the tolerence between the pass and fail condition; ISO 11140-1: 2014 cites the value of the fail condition as 85% of the pass condition.*

***References:***

(1) EN 556-1: 2001 Sterilization of Medical Devices - Requirement of medical devices to be designated 'STERILE'. Part 1 Requirements for terminally sterilized medical devices.

(2) ISO 11140-1: 2014 Sterilization of Health Care Products - Chemical Indicators Part 1: General Requirements

# Browne TST Controls™ Monitor the Complete Sterilization Cycle, No Matter What Length

Sterilization cycles have been scientifically calculated to provide the best chance of acheivement 'sterility'. The most common cycles by far are 134°C for 3.5 minutes and 121°C for 15 minutes and TST Control™ Cycle Verification indicators are available to match these cycles. However, to make sure you get the accuracy you need, Browne has a range of Type 6 Indicators to suit any cycle profile. Type 6 Cycle Verification (Emulating) Indicators are the only type of indicator that has this capability.


## Browne TST Controls™ are the most accurate type of chemical Indicators available

ISO 11140-1: 2014 requires that Type 6 indicators have a very small tolerance of 6% at each stated value, whereas Type 5 indicators are allowed a much larger tolerance of 15% at each of their stated values.

## Browne TST Controls™ are easy to interpret

By placing a TST Control™ Cycle Verification Indicator on every tray or inside each pack or pouch prior to sterilization, you can easily see whether or not it has been exposed to adequate sterilizing conditions. Using Browne's unique thermo-chromic ink technology, the TST Control Cycle Verification Indicator will change from yellow to a uniform blue/purple on exposure to an effective sterilization cycle. The colour change is abrupt when it reaches the endpoint, making interpretation very easy.


## Browne TST Controls™ are independently certified to conform to ISO 11140-1: 2014

Most companies self-certify the performance of their chemical indicators, which is not an ideal situation. Albert Browne Ltd was the first company in the world to be able to display the BSI Kitemark on the Type 6 emulating indicators for cycle verification. British Standards Institution (BSI) not only undertook the independent testing, but also examined all the necessary production control systems in place, to ensure consistency of manufacture. This arguably makes Browne TST Control™ Cycle Verification (Emulating) Indicator the most stringently tested indicators available worldwide.

ISO 11140-1: 2014
KM 60358

## Browne TST Controls™ are non-toxic and lead free

Browne TST Control™ Cycle Verification (Emulating) Indicators incorporate the unique TST ink technology, which is Lead Free and Non-Toxic. This patented ink technology is both safe to use and environmentally friendly.

### TST Control™ Cycle Verification (Emulating) Indicator

### Order Code

To make sure you get the accuracy need, Browne have a range of Type 6 indicators to suit any cycle profile.

Please contact your SAFMED representative who can advise on the correct product for your sterilization cycle.

**Order Code 2317**
134°C / 3.5 minutes 'Flash'
200 indicators/box

**Order Code 2340**
134°C / 3.5 minutes
100 indicators/box

**Order Code 2341**
134°C / 4 minutes and
121°C / 12 minutes
100 indicators/box

**Order Code 2342**
134°C / 5.3 minutes and
121°C / 15 minutes
100 indicators/box

**Order Code 3760**
134°C / 7 minutes and
121°C / 20 minutes
200 indicators/box

**Order Code 3702**
134°C / 9 minutes
200 indicators/box

**Order 3706**
134°C / 18 minutes
200 indicators/box

**Conforms to**
**ISO 11140-1 Type 6**

SafMed
SAFMED (Pty) Ltd
Johannesburg Office:
PO Box 1654,
Edenvale 1610
Tel: 011 201 4300
Fax: 011 507 5550
E-mail: info@safmed.co.za

Durban Office:
PO Box 846,
Umhlanga Rocks 4320
Tel: 082 464 3832
Fax: 031 561 5138
Website: www.safmed.co.za

Cape Town Office:
PO Box 46939,
Glosderry 7702
Tel: 021 763 3280
Fax: 021 762 2760

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# How Do I Know If I Am Using An Effective Liquid Chemical Disinfectant?

Current guidelines recommend that heat-sensitive, semi-critical medical devices used on patients undergo chemical disinfection. But how do I know if the disinfectant I am using is good enough?

An effective, ideal, high-level disinfectant is one that:

- Has high germicidal activity
- Rapidly kills a wide range of micro-organisms including spores
- Is chemically stable
- Is effective even in the presence of organic compounds
- Is compatible with the material substrates of the devices to be disinfected
- Is inexpensive and aesthetically acceptable

Many factors will affect the efficacy of a disinfectant or the disinfection process including:

**Quantity of microorganisms and organic matter**
It is critical to thoroughly clean medical devices before they are placed in a chemical disinfectant. The more micro-organisms on a device the greater the time a disinfectant needs to act. If soils are not removed they can impair successful disinfection or sterilization of that device. Organic matter like blood, urine, faeces and sputum can inactivate a chemical disinfectant, and they prevent the chemistry from making contact with the device itself.

Complex devices with multiple components must be disassembled, cleaned and disinfected piece by piece as the disinfectant must make contact with all the surfaces. The devices must therefore also be fully submerged in the liquid chemical disinfectant.

**Resistance of micro-organisms to chemical agents**
Some microorganisms have become resistant to disinfectants. An outbreak of infection post laparoscopic surgery was reported in Brazil in 2009 from an atypical mycobacterium. A glutaraldehyde based disinfectant was used in this instance.

**Concentration of agents**
It is important to use chemical disinfectants as per the manufacturers instruction. Devices must be cleaned, rinsed and dried before placing them in the disinfectant. Care must be taken not to dilute the disinfectant with remnants of the rinse water. The minimum concentration of disinfectant should be tested before the chemistry is used. This is done using a test strip.

**Physical and chemical factors**
The disinfectant manufacturer may specify the temperature at which the disinfectant performs optimally.

**Duration of exposure**
The manufacturer will specify how long medical devices need to soak in the disinfectant. It is critical that this is adhered to in the clinical setting.

## Disinfectants commonly used to disinfect medical devices in the operating room in SA

**Ortho-phthaladehyde (OPA)**
Kills micro-organisms by 'acting directly on the nucleic acids' found in the cells of micro-organisms (WHO:2016). Depending on the manufacturer, once opened this disinfectant can be used for two weeks and the contact time in SA is five minutes. The effective minimum concentration must be tested before use. This chemistry is not carcinogenic 'but it is recommended that it be used in ventilated areas'. (WHO:2016).

**Peracetic acid**
'Peracetic acid is an oxidising agent' (WHO:2016). It kills by denaturing (breaking down) proteins and altering the permeability of the cell walls of microorganisms. It is available in powder form in SA, and the contact time required is 10 minutes. The manufacturer stipulates that the product is to be used in a 24-hour period, meaning a fresh batch is prepared each day for surgery. Test strips are used to check the effective concentration of the product. This chemistry 'remains effective in the presence of organic matter' (WHO:2016). It can be corrosive to brass and copper.

***References:***
Duarte RS, *et al*. 2009. *Epidemic of Postsurgical Infections Caused by Mycobacterium massiliense.* JOURNAL OF CLINICAL MICROBIOLOGY, 47, p. 2149–2155.

WHO. 2016. Decontamination and Reprocessing of Medical Devices for Health-care Facilities http://apps.who.int/iris/bitstream/10665/250232/1/9789241549851-eng.pdf


# PERA safe

- Wide range of material compatibility (Flexible scopes, etc)
- 10 minutes sterilization / high-level disinfection
- Only 1 thorough rinse needed after high-level disinfection / sterilization
- NOT a fixative, dissolves proteins
- Safe to discard in normal disposal channels

DUPONT®

SafMed

Johannesburg Office:
Tel: 011 201 4300
Fax: 011 507 5550

Durban Office:
Tel: 082 464 3832
Fax: 031 561 5138

Cape Town Office:
Tel: 021 763 3280
Fax: 021 762 2760

E-mail: info@safmed.co.za
Website: www.safmed.co.za
www.facebook.com/Safmed.SA/
Twitter: @SafMedSA