BROWNE Assurance through Technology

Chemical Indicators & Accessories from Albert Browne International Ltd

What are Chemical Indicators?

The Browne range of chemical indicators has been categorised into six areas, broadly defined by intended use.

They are also colour-coded for easy identification;

- Process Indicators
- Specific-Use Indicators
- Multi-Parameter Indicators
- Integrating Indicators
- Cycle Verification (Emulating) Indicators
- Biological Indicators

Perhaps the simplest analogy for a chemical indicator is one found in nature; if planted in alkaline soil, the blooms of a hydrangea will be pink; conversely, if planted in acid soil, the blooms will be blue. So by way of a simple display of colour, the hydrangea is providing information about its' immediate environment; it is indicating the pH of its' surrounding soil.

This is a very simplistic analogy and of course the Browne range of chemical indicators provides much more information than an indication of the surrounding pH.

There are similarities however, as they do provide information about their immediate surroundings by way of an easily interpreted colour change.

BROWNE Assurance through Technology

Browne Chemical Indicators

Most of the products are designed for use during the different stages of a decontamination process (cleaning, disinfection and sterilization) and are available for most types of process.

Contents

The Six Indicator types

It is important to bear in mind that each of the six categories has specific characteristics that determine where and how the indicators should be used. This also determines the level, depth and kind of information provided, so do be sure that you choose the right type of indicator for what you want to achieve.

The explanation below will help but if you have any questions, please do not hesitate to contact us or your local Browne representative.

Process Indicators

Browne Process Indicators are usually placed on the outside of the tray, pack or pouch so that processed and unprocessed items can be identified at a glance. They give users assurance that the tray, pack or pouch has been exposed to a particular process, e.g. steam, ethylene oxide etc. but cannot provide quantitative information about the process or determine how effective it has been.

They are sometimes referred to as 'exposure control' or 'through-put' indicators.

Specific-Use Indicators

Browne specific-use indicators are designed for use in two fundamental areas; in specific test procedures defined in relevant standards and guidance documents and in monitoring defined stages of a process that would otherwise be difficult to routinely assess.

Mechanical equipment used throughout the decontamination process will have undergone validation before being sanctioned for daily use. Most machines equipped with electronic or mechanical sensors to record specific aspects of the machines activity.

These sensors are connected to monitoring and recording gauges, graphical charts and digital displays that provide fundamental information on the machine's performance. Although providing vital information on the machine's mechanical activity, they cannot provide monitoring of the physical conditions occurring inside the chamber of the machine. Furthermore, between scheduled maintenance visits, these sensors, monitors and recorders can lose calibration.

Browne specific-use indicators can help resolve these two issues by providing supplementary data on critical aspects / stages of a process.

Multi-Parameter Indicators

Browne Multi-Parameter Indicators are the first of three types of indicator available for 'in-pack' monitoring and like the others are placed inside each tray, pack or pouch before processing.

These indicators will change colour when exposed to the sterilant / disinfectant providing users with clear visual reassurance that the agent has penetrated to the point of placement in each tray, pack or pouch.

Integrating Indicators

Browne Integrating Indicators are the second of three types of indicator available for 'in-pack' monitoring and like the others are placed inside each tray, pack or pouch before processing.

The indicators will change colour when exposed to a sterilant / disinfectant in sufficient quantity or duration to inactivate the equivalent challenge presented by a defined and stated test organism. This provides users with clear visual reassurance that the agent has penetrated to the point of placement in each tray, pack or pouch.

Cycle Verification Indicators

Browne Cycle Verification (Emulating) Indicators are the third of three types of indicator available for 'in-pack' monitoring.

Cycle Verification Indicators provide the most specific information of any chemical indicator available and like the others are placed inside each tray, pack or pouch before processing.

The primary difference between these and other chemical indicators is their cycle specificity. All conform to the ISO 11140-1 classification as Class 6 indicators, which means that each product will have been calibrated to perform to the predefined parameters of a particular process. The use of a Cycle Verification Indicator will help end-users detect process failure by confirming that all of the predetermined cycle parameters have occurred at point of placement in each tray, pack or pouch. This is demonstrated through an easy to interpret colour change.

Biological Indicators

Browne Biological Indicators have two main areas of use; firstly, where regulatory authorities and guidance documents require the use of a biological indicator in a specified decontamination process. These usually include Ethylene Oxide, Plasma and Low Temperature Steam with Formaldehyde. And secondly, during a machine validation process where cycle variables need to be defined and established.

All conform to ISO 11138 and are supplied with a certificate containing the culture collection number, lot number, expiry date, spore population, resistance data and Biological Indicator Evaluation Resistometer (BIER) exposure.

Process Indicators

Process Detector Spots

Formaldehyde
Order code **2402**
250 spots/box

Ethylene oxide
Order code **2421**
1000 spots/box

Gamma/Electron beam
Order code **3301**
1000 spots/box

Conform to
EN 867-1 Class $A_{(1)}$
ISO 11140-1 Class $1_{(2)}$

The self-adhesive spots should be placed on the outside of every pack being sterilized. The spots change colour after passing through the process allowing differentiation between processed and unprocessed loads.

Colour change;

Formaldehyde
blue to yellow

Ethylene oxide
brown to green

Gamma/electron beam
gold to dark red

Note;

The spots do not act as a control and are not intended as a guide to the efficacy of the process.

Process Indicators

Process Indicator Labels

Order code
Browne has a range of Process Indicator Labels.

Please refer to your Browne representative who can advise on the product range.

Conform to
EN 867-1 Class $A_{(1)}$
ISO 11140-1 Class $1_{(2)}$

The process indicator labels can be used with all types of commonly used printer and are available in a range of sizes and designs compatible with most computerised traceability systems. The labels can also be handwritten.

Patented indicator technology

US Patent no. 6149863 - European Patent No. EP0963418 & others

Browne produces a range of labels in various sizes, substrates and designs but can produce custom labels to your own specification.

Custom options for labels include;

- Simplex or duplex backing – single or double backing layers for repositioning
- Personalisation– hospital or company logo etc.
- Multiple indicators- e.g. steam and ethylene oxide
- Multi-part labels– detachable sections for documenting different stages
- EN 867-1 Class A/ISO 11140-1 Class 1 indicators for steam, ethylene oxide, formaldehyde or gamma/electron beam
- Choice of colour change for steam indicators–pink to dark brown or colourless to black

Please contact us to discuss your requirements.

Process Indicators

Process Indicator Autoclave Tape

Dry heat
Order code **0140**
19mm (3/4") x 50m
48 rolls per carton

Steam
Order code **0142**
18mm (3/4") x 50m
48 rolls per carton

Steam
Order code **0143**
24mm (1") x 50m
36 rolls per carton

Steam Hi Tack
Order code **0147**
18mm (3/4") x 50m
48 rolls per carton

Ethylene Oxide
Order code **0151**
18mm (3/4") x 50m
48 rolls per carton

Plain
Order code **0160**
18mm (3/4") x 50m
48 rolls per carton

Plain
Order code **0161**
24mm (1") x 50m
36 rolls per carton

Conform to
EN 867-1 Class $A_{(1)}$
ISO 11140-1 Class $1_{(2)}$

Traditional process indicator tape allows identification of processed from unprocessed items at a glance. The easily recognisable stripes change colour when exposed to the specific sterilant, verifying exposure to the process without the need to open packs or check records.

Dry Heat Process Indicator tape is specially formulated to withstand the high temperatures experienced during dry heat sterilization while still maintaining excellent adhesive qualities. The green indicator ink changes colour to brown when exposed to the dry heat process.

Steam Process Indicator Tape is a packaging tape with steam-sensitive indicator ink.

The high contrast colour change is designed to show at a glance that the pack has been exposed to a steam sterilization process. Manufactured from treated crepe paper and coated with high performance cross linked pressure sensitive adhesive, the tape securely bonds to paper, plastics, non-wovens, board, metal, glass and linen.
The 'hi tack' version is as above but incorporating a stronger adhesive to adhere to 'treated' paper wrap. This is not recommended for use with textiles as it can leave a residue. The tape is blue in colour.

Plain tape is similar to steam indicator tape but without the stripes. Designed as a packaging tape but with special adhesive qualities to withstand steam sterilization.

IMPORTANT: Please remember to confirm the tape dimensions when ordering.

Specific Use Indicators

TST Bowie Dick
Single use test pack

Daily steam penetration tests for large porous load sterilizers

Order code **2352**
134°C-137°C for up to 3.5min
20 test packs/box

Order code **2310**
121°C-124°C for 8–8.3 min
20 test packs/box
(see additional information across)

Conform to EN 867 – 4(3)

National and International Standards advise that vacuum assisted steam sterilizers must be tested at the beginning of each working day.

EN 554:1994(5)

'Sterilization of medical devices – Validation and routine control of sterilization by moist heat'
Porous load autoclaves must be tested periodically to check that the amount of non-condensable gas remaining in the sterilization chamber after the air removal phase will not impair the effectiveness of steam penetration into the load to be sterilized.

A Bowie Dick type test is an accepted method of testing the steam penetration and air removal capability of a vacuum sterilizer.

Specific Use Indicators

Daily steam penetration tests for small bench top Type B porous load sterilizers

Eschmann Little Sister 3 Vacuum & SES 2000 Vacuum
Order code **2358**
10 test packs/box

Prestige Century (22,16&11 Litre)
Order code **2365**
10 test packs/box

Getinge GE 224 C Vac & Citomat 164 V
Order code **6536**
20 test packs/box

W&H Lisa MB17/22
Order code **2356**
10 test packs / box

Matachana M20 – B
Order code **2352**
20 test packs / box

Conform to EN 867 – 5(4)

A successful test confirms that steam penetration into a test pack is rapid and even and, by implication, that air and other non-condensable gases have been effectively removed. The chemical indicator sheet at the centre of the pack shows a defined colour change from yellow to dark blue / purple when exposed to a specific combination of time, temperature and steam. When there is no air or other non-condensable gases in the chamber, steam will penetrate the pack rapidly and completely and the indicator will show a uniform colour change. When air or other non-condensable gases are present they will collect towards the centre of the pack as an air / gas pocket which will impair contact between the steam and the indicator sheet. The temperature or moisture level (or both) will be lower in the region of the air / gas pocket and will result in a non-uniform colour change of the indicator; distinct yellow markings will be evident on the sheet.

The unique combination of advanced thermo-chromic technology and the original Bowie Dick concept, checks not only the mechanical function of the sterilizer, but also the quality of the steam supply. So when the Browne TST Bowie Dick Type Test Pack does detect a fail, the distinctive results generated by the TST indicator sheet can help diagnose the problem more quickly, saving both time and money.

Strong colours – High definition – Easy to read

Unused

Fail - air

Fail - NCGs

Fail - wet steam

Fail - super heat

Pass

Albert Browne Ltd was the first company in the world to attain the BSi Kitemark for Bowie Dick test packs. British Standards Institution 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 Bowie Dick type test pack the most stringently tested and monitored test pack available worldwide.
There can be no greater assurance of conformance to safety and quality than the BSi Kitemark displayed on the Browne TST Bowie Dick type test pack.

The Bowie Dick Test at 121˚C

The Bowie Dick test was originally devised* to assess steam penetration in steam sterilizers working at 134˚C for 3.5 minutes. However, a steam penetration test is equally valid for assessing steam penetration in sterilizers working at lower temperatures such as 121˚C. Unfortunately there is however, little historical data relating to Bowie Dick tests run at 121˚C; research work conducted by Browne however, has shown that there are potential problems in running this test at 121˚C with a standard plateau period in excess of 15 minutes.

Air and other non-condensable gases prevent steam from penetrating into packaging, lumens and other porous loads. When air is trapped within a load, the air generally forms a bubble or pocket. The temperature in this region is generally lower than that of surrounding (steam) environment.

The Bowie Dick test is historically calibrated such that when sufficient air is introduced into a sterilizer to produce a cooling effect of 2-3°C (temperature depression) in the centre of a standard test pack, the Bowie Dick test must show a failure. The 'Laws of Physics' dictate that a temperature depression caused by air will disappear gradually as the air pocket heats up and is downwardly displaced, until it is no longer detectable. This normally takes 2 to 4 minutes. When performing the test at 134°C, the sterilization plateau is no longer than 3.5 minutes, and the disappearance of the temperature depression has little effect on the sensitivity of the Bowie Dick test. When performing the test at 121°C, the sterilization plateau can range from 15 minutes to in excess of 30 minutes. The rate of disappearance of the temperature depression still however, takes 2 to 4 minutes, thus increasing the risk of a false positive result. The sensitivity of the Bowie Dick test at 121ºC will be potentially reduced as a consequence of this and the final result of the test bought into question.
The original Bowie Dick test principle therefore, cannot equally apply to short (3.5 mins) and long (15+ mins) sterilization plateau times.

Browne has developed the 121 TST Test Pack to counteract this problem by producing a Bowie Dick test that has a maximum plateau of 8.3 minutes. This enables the sensitivity of a 121°C Bowie Dick test to be comparable to that of a 134°C Bowie Dick test.

It is important that the product is used with a sterilization plateau that does not exceed 8.3 minutes. This will necessitate a separate cycle, which should be identical to the cycle used for sterile product production in all but the sterilization plateau time.

* Bowie J.H., Kelsey J.C., Thompson G.R. 1963 The Lancet. I pp 586 – 1215

Specific Use Indicators

TST Helix

Order code **3780**
TST Helix and 250 Indicators

Conforms to EN867-5(4)

National and International Standards advise that vacuum assisted steam sterilizers must be tested at the beginning of each working day.

EN 554: 1994(5)
'Sterilization of medical devices – Validation and routine control of sterilization by moist heat'
Porous load autoclaves must be tested periodically to check that the amount of non-condensable gas remaining in the sterilization chamber after the air removal phase will not impair the effectiveness of steam penetration into the load to be sterilized.

The Browne TST Helix is a Hollow Load Process Challenge Device (PCD) as defined in EN 867-5 and has been developed and validated for testing the air removal (steam penetration) capability of small Type B steam sterilizers **only**.

Use in any other sterilizer or with any other type of indicator, may give dangerously misleading results.

A successful test confirms steam penetration through the helix and confirms by implication that air and other non-condensable gases have been removed.

The chemical indicator located in the capsule will show a defined colour change from yellow to dark blue / purple when exposed to a specific combination of time, temperature and steam. When all air has been removed from the sterilizer chamber, steam will penetrate through the helix and the indicator will show a uniform colour change. If air or non-condensable gases are present they will impair contact between the steam and the indicator resulting in a non-uniform colour change; distinct yellow markings will be evident on the indicator.

The TST Helix has a limited life, so after 250 indicators have been used, the device must be replaced. Failure to do so could result in failure of the device and dangerously misleading results.

Strong colours – High definition – Easy to read

Unused

Pass

Fail

Specific Use Indicators

Sensor sheet

Order code **2385**
50 sheets / folder

Conforms to
EN867 – 3 Class B(6)
ISO 11140-1 Class 2(2)

The Sensor sheet has been calibrated for use in the standard towel pack as specified in EN285:1997(7) and in UK Guidance Document HTM 2010(8). It is designed to detect failures where the temperature in the centre of a standard towel pack is 2°C cooler than the chamber drain at the start of the sterilization plateau.

If the sterilizer achieves complete air removal and rapid steam penetration into the centre of the towel pack, the **Sensor** sheet will indicate a pass i.e. the pale yellow sheets will change colour to a blue/green colour.

In the event of failure, the presence of air or other non-condensable gas is sensed by a chemical reaction. The **Sensor** sheet will demonstrate a fail pattern i.e. a yellow or brown will be clearly visible.

The Browne Sensor sheet incorporates Sensor Technology. Free from the lead and heavy metal salts traditionally associated with Bowie Dick test sheets, the Browne Sensor test sheet is safe to handle and easy to dispose of.

Detailed instructions for running a standard cotton sheet Bowie Dick test are included with the Sensor sheets.
Browne Plain Cotton sheets for use with the Sensor sheet are available on order code 9053. Please refer to the relevant page of this catalogue for further details.

Specific Use Indicators

Bowie Dick
Lead Free Test Sheet

Order Code **2561**
50 sheets / folder

Conforms to
EN867 – 3 Class B(6)
ISO 11140-1 Class 2(2)

The Browne Bowie Dick test sheet incorporates patented* MVI technology. Free from the lead and heavy metal salts that have traditionally been associated with Bowie Dick test sheets, the Browne Bowie Dick test sheet is safe to handle and easy to dispose of.

The colourless indicator sheet turns to a uniform deep purple when exposed to rapid and even steam penetration. However, should the sheet be exposed to an inadequate Bowie Dick cycle, inefficient air removal, the presence of an air leak or other non-condensable gas, a clearly visible fail will be evident on the sheet.

* US Patent no. 6149863 - European Patent No. EP0963418 & others

Browne Plain Cotton sheets for use with this test sheet are available on order code 9053. Please refer to the relevant page of this catalogue for further details.

Specific Use Indicators

Plain Cotton Sheets

Order Code **9053**

36 sheets / box
(also available separately)

For use in small load thermometric test and traditional Bowie Dick test.

Bleached white cotton sheets
- Size:900 mm x 1200 mm
- Warp:30 +- 6 threads per cm
- Weft:27 +- 5 threads per cm
- Conform to specifications given in UK Guidance document HTM 2010(8) and EN 285:1997(7)

Approximately 32 – 36 sheets folded to 220 mm x 300 mm would be required to produce a pack approx. 250 mm in height and 7kg +- 10% in weight.

Note: must be laundered before use without the use of fabric conditioning agent.

The Browne Sensor sheet shown is available on order code 2385. Please refer to the relevant page of this catalogue for further details.

Specific Use Indicators

Washer Disinfector
Soil Test

Order code **2304**

10 ready to use tests / box

Inefficient cleaning can put disinfection and sterilization procedures at risk. A poorly functioning washer-disinfector can leave behind microscopic debris that can severely compromise both the disinfection and sterilization process. One of the best and easiest ways to check whether instruments are being cleaned effectively is to present the cleaning equipment with a physical challenge such as the cleaning efficacy tests described in BS2745(9), prEN15883(10) and UK Guidance Document HTM2030(11).

The Browne Washer-Disinfector Test Soil is designed to simulate the soiling that naturally occurs during theatre use and performs in an equivalent manner to the Edinburgh soil*.

The Browne Soil Test is supplied in powder form as individual test pots. One pot, One test.

Simply add water to the fill line, replace the cap, shake vigorously and apply to the test load with the brush provided. Following a 30-minute** drying period at room temperature, the test load should be cleaned using normal procedures and then inspected for residual soil. Detailed instructions for use included in each box.
***Drying time should not exceed 2 hours.*

The bright red colour of the Browne Test Soil allows easy identification of areas that have not been properly cleaned, providing a visual analysis of equipment efficiency.

Non-toxic; contains no blood products.

* Data on file. A. Browne Ltd 1998 - supplied with every box

Specific Use Indicators

STF Load Check

Order Code **2315**

Load Check Indicator
100/box

Order Code **2316**
Load Check Holder

The STF Load Check indicator and holder are intended for use inside each basket or tray to verify the cleaning efficacy of a surgical instrument washer-disinfector machine.

The dried test soil formula, printed on both sides of the indicator, contains two sources of protein, lipids and polysaccharides and is formulated to mimic the cleaning efficacy soil tests for surgical instruments described in BS2745$_{(9)}$, prEN15883$_{(10)}$ and UK Guidance Document HTM2030$_{(11)}$.

Simply place an STF Load Check indicator in the holder, and place the device (indicator and holder) in the tray or basket. After running one complete cycle, remove the STF Load Check indicator from the holder and examine for evidence of residual soil.

Complete removal of the dried 'test soil' pattern from the plastic substrate provides a qualitative assessment of the washer-disinfector cleaning performance.

Specific Use Indicators

Ninhydrin Protein Detection Kit

Order code **2370**
4 tests/box

To be used with Browne Incubator – please specify voltage required when ordering.

The Ninhydrin Protein Detection kit is intended as a method of detecting protein residues that may have remained on surgical instruments after going through a washer-disinfector process.

Each test of the four tests contains;
1 x test vial*
1 x positive control vial*
1 x negative control vial*
1 x Arginine vial for use in positive control test
3 x sterile swabs

**contains ninhydrin reagent*

Clean instruments are swabbed to pick up any non-visual proteins that may be present. The swab is then placed in the vial of ninhydrin reagent and incubated at 57°C.
The reagent will react with amino acid, peptides and protein residues present and show a purple discolouration should the swab be contaminated.
The test kit also contains vials of ninhydrin reagent to perform positive and negative controls during each test.

Detailed instructions for use are supplied with every box and further guidance can be obtained from;
- UK guidance document HTM 2030 Washer-disinfectors; Validation and verification.
- prEN 15883 –1: 2002 Washer-disinfector - Annex E

Multi-Parameter Indicators

Sterilization Control Tubes

Type 1 Black spot
Product Code **7301**
Fluid Sterilization
121ºC/15 mins

Type 2 Yellow spot
Product Code **7302**
Steam Sterilization*
134ºC/3 mins

Type 3 Green spot
Product Code **7303**
Dry Heat Sterilization
160ºC/60 mins

Type 4 Blue spot
Product Code **7304**
Dry Heat Sterilization
180ºC/12 mins

Type 5 White spot
Product Code **7305**
Dry Heat Sterilization
160ºC/120 mins
180ºC/35 mins

* Browne recommends the use of TST Control™ Cycle Verification (Emulating) Indicators for monitoring porous load steam sterilization processes.

Conform to
EN867-1 Class D$_{(1)}$
ISO 11140-1 Class 4$_{(2)}$

Effective and immediate visual check on sterilization conditions
- Integrated 2 criteria control of temperature and time.
- Ideal for fluid and dry heat sterilizers.

Select the Control Tube to match your sterilization parameters (time/temperature) and distribute them throughout the load prior to sterilization.

Dry Heat
place the tubes closely beside or inside the most inaccessible articles to be sterilized.

Fluids
place a control tube in a test bottle of the solution to be sterilized and place in the centre of the sterilization chamber.

Instructions for use and colour guides are included with each box.

Custom Control Tubes
Fluid or Dry Heat Sterilization.
For cycles different to those specified above, Browne can manufacture Control Tubes to meet your specific time / temperature parameters.
Using the same clear red to clear green colour scale verification as the standard tubes, they will provide an immediate visual check for your specific sterilization cycle.

1 litre of the solution can be manufactured and stored on our premises for up to 12 months. This is sufficient quantity for approximately 50 boxes of tubes and can be called off when required. Please contact us to discuss your individual requirements.

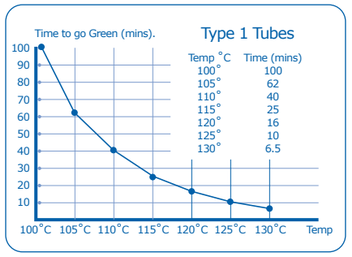
Colour Scale:

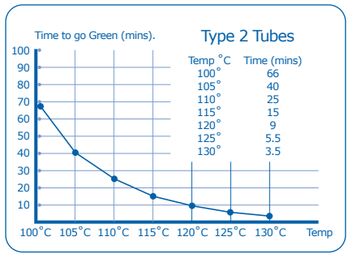
Unused

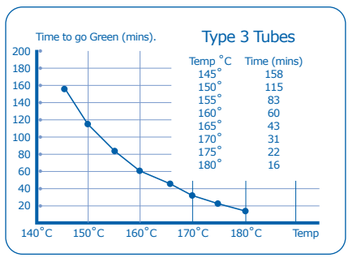
Unsafe

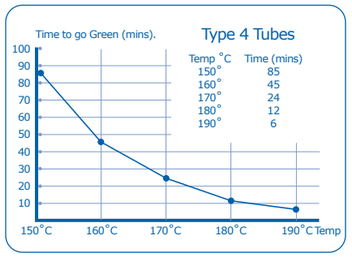
Effective Cycle

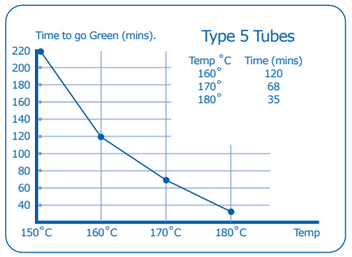
Time / Temperature Graphs











Multi-Parameter Indicators

Formaldehyde Control Indicators

Order Code **2401**

100 indicators/box

Conform to
EN867-1 Class $D_{(1)}$
ISO 11140-1 Class $4_{(2)}$

Formaldehyde Control Indicators should be used inside each pack to show that Low Temperature Steam and Formaldehyde gas (LTSF) has penetrated the pack in a sufficient quantity and for the correct length of time for sterilization to occur.

The control indicator turns from blue to a complete green when adequate sterilizing conditions have been reached.

It is recommended that Browne Formaldehyde Process Detector (Order Code 2402) Spots are placed on the outside of each pack to allow processed and unprocessed items to be identified at a glance. Note that the spots are not calibrated to be used as an 'in-pack' control indicator.

Multi-Parameter Indicators

MVI Ethylene Oxide Indicator

Order code **2563**

250 indicators/box

Conform to
EN867-1 Class $D_{(1)}$
ISO 11140-1 Class $4_{(2)}$

When placed inside trays, packs or pouches, MVI Ethylene Oxide Indicators will confirm that the gas has penetrated to the point of placement. Changing from bright orange to vivid red, end users have clear visual reassurance of exposure to an ethylene oxide sterilization process.

MVI Ethylene Oxide Indicators can be used in all current ethylene oxide sterilization processes.

Lead free and non-toxic, this advanced ink technology is both safe to use and environmentally friendly.

Multi-Parameter Indicators

MVI Steam Indicator

Order code **2560**

White to purple colour change
250 indicators/box

Order code **2551**

White to black colour change
250 indicators/box

Conform to
EN867-1 Class $D_{(1)}$
ISO 11140-1 Class $4_{(2)}$

When placed inside trays, packs or pouches, MVI Steam Indicators will confirm that steam has penetrated to the point of placement. With a choice of colour change from white to purple or white to black, end users have a clear visual assurance of exposure to a steam sterilization process.

Browne MVI Steam Indicators can be used in all cycles ranging from 120ºC - 140ºC.

Lead free and non-toxic, this patented* ink technology is both safe to use and environmentally friendly.

* US patent no. 6149863 European patent No. EP0963418 & others

Multi-Parameter Indicators

Vapour Strip

Order Code **2500**

200 indicators/box

Conform to
EN867-1 Class $D_{(1)}$
ISO 11140-1 Class $4_{(2)}$

The Vapour Strip is intended for use by healthcare providers for the monitoring of the STERRAD® Sterilization System. The Vapour Strip is validated for use in STERRAD® 50 and STERRAD® 100S sterilizers.

When placed inside trays, packs or pouches, the Vapour Strip will confirm that sterilant has penetrated to the point of placement. The indicators change from green to pink, giving end users clear visual assurance of exposure to an effective STERRAD® process.

Browne Vapour Strip indicators incorporate advanced ink technology that is both safe and environmentally friendly.

STERRAD is a registered trademark of Advanced Sterilization Products.

Integrating Indicators

Ethylene Oxide Integrators

Order code **2420**

100 indicators/box

Conform to
EN867-1 Class $D_{(1)}$
ISO 11140-1 Class $5_{(2)}$

Ethylene Oxide Integrators should be placed inside each pack.
The control indicator turns from red to green when adequate sterilizing conditions have been reached, giving the end-user assurance that adequate sterilizing conditions occurred at point of placement.

Ethylene Oxide Integrators will show a fail if the relative humidity level, gas concentration, temperature or duration of exposure fall outside of the specified limits.

900mg Concentration (mg per litre)
Temperature: 55ºC - 37ºC
Time: 20 - 55 minutes
Humidity: 40–60%

600mg Concentration (mg per litre)
Temperature: 55ºC - 37ºC
Time: 35 - 70 minutes
Humidity: 40–60%

It is recommended that Browne Ethylene Oxide Process Detector (Order Code 2421) Spots are placed on the outside of each pack to allow processed and unprocessed items to be identified at a glance. Note however, that the spots are not calibrated for use as an 'in-pack' control indicator.

Cycle Verification (Emulating) Indicators

Des Check

Order Code **2460**
73˚C/12 minutes
100 indicators/box

Order Code **2470**
93˚C/10 minutes
100 indicators/box

Conform to
EN867-1 Class $D_{(1)}$
ISO 11140-1 Class $6_{(2)}$

Cycle verification indicators for use in moist heat processes.

The Des Check range provides an accurate, convenient method of routine control for moist heat processes. When distributed through out the load, the indicators provide visual confirmation of conditions achieved at point of placement. The vivid colour change from yellow to blue gives clear evidence of the conditions attained, thus allowing a quick and easy assessment of the success of the process.

Designed using advanced polymer technology to withstand conditions present during moist heat processes.

Des Check technology can be applied to different time and temperature combinations. Please contact us to discuss your individual cycle requirements.

Store at or below 0˚C

Cycle Verification (Emulating) Indicators

TST Control™
Cycle Verification (Emulating) Indicator

Order code
To make sure you get the accuracy you need, Browne have a range of Class 6 Integrators to suit any cycle profile.

Please refer to your Browne representative who can advise on the correct product for your sterilization cycle.

Conforms to
EN867-1 Class $D_{(1)}$
ISO 11140-1 Class $6_{(2)}$

When placed inside trays, packs or pouches, a TST Control™ Cycle Verification (Emulating) Indicator will confirm that good quality steam has penetrated to the point of placement. Changing from yellow to dark blue / purple, end users have clear visual reassurance of exposure to the specific cycle parameters proven to render items 'sterile'*.

The TST Control™ Cycle Verification (Emulating) Indicator allows the end user to single out individual trays, packs or pouches that were not exposed to sufficient sterilization conditions.

Strong colours – High definition – Easy to read
A pass from the TST Control™ Cycle Verification (Emulating) Indicator proves exposure to conditions essential for sterilization to occur.

Unused

Fail

Fail

Pass

*EN 556: 2001 Sterilization of Medical Devices Requirements for medical devices to be designated 'sterile'
'A sterile product is one which is free of viable micro-organisms'
' The European Pharmacopoeia Commission considers that a product may be regarded as 'sterile' when the theoretical level of not more than one living micro-organisms is present in $1x10^6$ sterilized units of final products'

TST Control™ Cycle Verification (Emulating) Indicator incorporates the unique TST ink technology. Lead free and non-toxic, this patented ink technology is both safe to use and environmentally friendly.

Albert Browne Ltd was the first company in the world to be able to display the BSi Kitemark on Class 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™ Integrators the most stringently tested and monitored indicators available worldwide.

There can be no greater assurance of conformance to safety and quality than the BSi Kitemark displayed on the TST Control™ Cycle Verification (Emulating) Indicator.

ISO 11140-1: 1995
KM 60358

Cycle Verification (Emulating) Indicators

TST Control™ Duplex Label

Order code **5017**
134˚C/3.5 minutes
200 indicators/box

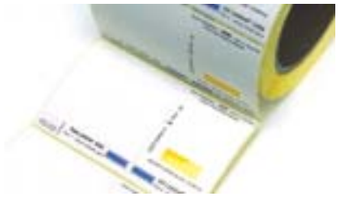
Conforms to
EN867-1 Class $D_{(1)}$
ISO 11140-1 Class $6_{(2)}$

Using the same technology as the TST Control™ Cycle Verification Indicators, this duplex label can create a direct link between the patient, the instruments and in-pack evidence of an effective sterilization cycle.

Compatible with all manual traceability systems the TST Control™ Duplex label is ideal for use in departments, clinics or surgeries that use small steam bench top sterilizers.

During preparation and packing, information about the tray, pack or pouch can be written on the label. At point of use, the label is retrieved and reapplied into the record card as evidence of an effective sterilization cycle.

Cycle Verification (Emulating) Indicators



TST Control™ Multi-part Label

Order code **5006**
134˚C/3.5 minutes
1500 labels/reel

Conforms to
EN867-1 Class A & $D_{(1)}$
ISO 11140-1 Class 1 & $6_{(2)}$

Using the same technology as the TST Control™ Cycle Verification Indicators, this multi-part label creates a direct link between the patient, the instruments and in-pack evidence of an effective sterilization cycle.

Compatible with most computerised traceability systems, the left hand section is pre-printed with a Class A process indicator while the right hand section incorporates a Class 6 cycle verification indicator using Browne's unique TST Control™ technology.

During packing, both sections are printed with bar coded pack data using the existing computerised traceability system. The right hand section is then placed inside the pack, affixed to the tray list if appropriate, while the left hand section is attached to the outside of the tray, pack or pouch in the usual way.

At point of use, the right hand section is retrieved from the tray, pack or pouch and reapplied into the patient's notes as evidence of an effective sterilization cycle.

Biological Indicators

Bio Monitors

Steam Processes 10^5
Order Code **2232**
100 units per box

Steam Processes 10^6
Order Code **2236**
100 units per box

Ethylene Oxide Processes
Order Code **2233**
100 units per box

Biological Indicators

Low Temp Steam & Formaldehyde Process
Order Code **2230**
100 units per box

Accessories

Recovery Medium for LTSF Biological Indicators
Order code **2231**
12 units per box

Dual Temperature Incubator 37º/57ºC
Order code **2244**
single unit

Browne Bio Monitors - conform to the US Pharmacopeia XXIII and AAMI / ANSI standards, EN866(12) and ISO11138(13). Browne Bio Monitors contain a stated population of bacterial spores inoculated onto filter paper and placed inside a plastic culture tube. A crushable glass ampoule contains the culture medium for release after exposure to the sterilization process.
Each box contains a certificate including; Culture collection number – Lot number – Expiry Date - Spore Population – Resistance data – Exposure in Biological Indicator Evaluation Resistometer (BIER).

Browne Bio Monitors for a steam process contain the spores of Geobacillus stearothermophilus and have an external chemical indicator on the label. This changes from green to blue/grey when sterilization exposure has occurred. The Bio Monitor should be incubated at 57ºC for no longer than 48 hours following exposure and the results read approximately every 12 hours.
If spores survive the sterilization cycle, the culture medium will turn to yellow (positive). If the spores have been killed, the culture medium will retain the original purple colour.

Browne Bio Monitors for an ethylene oxide process contain the spores of Bacillus atrophaeus and have an external chemical indicator on the label. This changes from light blue to tan when sterilization exposure has occurred. The Bio Monitor should be incubated at 37ºC for no longer than 48 hours following exposure and the results read approximately every 12 hours.
If spores survive the sterilization cycle, the culture medium will turn to yellow (positive). If the spores have been killed, the culture medium will retain the original red colour.

Note: Positive (yellow) results should be recorded and the culture tube autoclaved again prior to disposal.

Browne Biological Indicators for LTSF processes – conform to EN866 part 5(12) Self-contained biological indicators are unsuitable for use in formaldehyde sterilization processes due to the risk of sterilant residues remaining in the culture tube after sterilization. These residues can release formaldehyde gas during the incubation period causing spores that survived the sterilization process to be destroyed. This gives the end user a false negative growth result. The use of spore strips eliminates this problem.
Browne LTSF Biological Indicators are inoculated with between 1x10^6 and 5 x 10^6 spores of Geobacillus stearothermophilus on a 6mm diameter paper disc. These are individually packed in a sterilization pouch ready for use or can be aseptically removed and used in a Line & Pickerill helix.
After exposure to the sterilization process should be placed in a recovery medium and incubated at 56ºC for 48 hours for routine testing and 7 days for validation. A minimum of 15ml of Tryptone Soya Broth should be used as the recovery medium.
Browne LTSF Biological Indicators are derived from the ATCC strain. The resistance, determined in relation to 10mgl-1 formaldehyde at 73ºC, is printed on each box of 100 indicators.

Accessories

Browne Recovery Medium for LTSF Biological Indicators is contained in a 28ml glass bottle with polypropylene screw top lid and not less than 15ml modified Tryptone Soya Broth.
Please contact your Browne representative for order information.

Browne Dual Temperature Incubator 37º / 57ºC features 14 incubating cavities, optional thermometer cavity, power-on light and temperature selector switch.
Please contact your Browne representative for order information.

10. prEN / ISO 15883 –1: 2002
Washer-disinfectors. Part 1 General requirements and tests -
Annex E

11. Health Technical Memorandum
HTM 2030 Washer-Disinfectors –Validation and verification - 'Guidance Document' issued by NHS Estates, An Executive Agency of the Department of Health, UK.

12. EN 866: 1997
Biological systems for testing sterilizers and sterilization processes.
Part1: General requirements
Part 7: Particular requirements for self-contained biological indicator systems for use in moist heat sterilizers
Part 8: Particular requirements for self-contained biological indicator systems for use in ethylene oxide sterilizers

13. ISO 11138: 1994
Sterilization of health care products – Biological indicators.

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

References

1. EN 867-1: 1997
Non-biological systems for use in sterilizers.
Part 1: General requirements

2. ISO 11140-1: 1995
Sterilization of health care products – Chemical indicators.
Part 1: General requirements.

3. EN 867-4: 1997
Non-biological systems for use in sterilizers.
Part 4: Specification for indicators as an alternative to the Bowie and Dick test for the detection of steam penetration.

4. EN 867-5: 2001
Non-biological systems for use in sterilizers –
Part 5: Specification for indicator systems and process challenge devices for use in performance testing for small sterilizers Type B and Type S

5. EN554: 1994
Sterilization of Medical Devices – Validation and Routine Control of Sterilization by Moist Heat

6. EN 867-3: 1997
Non-biological systems for use in sterilizers.
Part 3: Specification for Class B indicators for use in the Bowie and Dick test.

7. EN 285: 1997
Sterilization – Steam sterilizers – Large sterilizers.

8. Health Technical Memorandum
HTM 2010 Sterilization - 'Guidance Document' issued by NHS Estates, an Executive Agency of the Department of Health, UK.

9. BS 2745: 1993
Specifications for Washer-disinfectors for Medical purposes.

Integrating Indicators & Accessories

Box Quantity	Description	Order code
100 indicators per box	Ethylene Oxide Integrators	**2420**

Cycle Verification (Emulating Indicators) & Accessories

Box Quantity	Description	Order code
200 indicators per box	Des Check 73°C / 12 mins (previously known as LTSD Indicators)	**2460**
200 indicators per box	Des Check 93°C / 10 mins	**2470**
200 indicators per box	TST Control™ Indicators 134ºC / 3.5 mins 'Flash'	**2317**
100 indicators per box	TST Control™ Indicators 134ºC / 3.5 mins	**2340**
100 indicators per box	TST Control™ Indicators 134ºC / 3.5 mins Self Adhesive	**3727**
100 indicators per box	TST Control™ Indicators 134ºC / 4 mins & 121ºC / 12 mins	**2341**
200 indicators per box	TST Control™ Indicators 134ºC / 5.3 mins & 121ºC / 15 mins	**2302**
100 indicators per box	TST Control™ Indicators 134ºC / 5.3 mins & 121ºC / 15 mins	**2342**
100 indicators per box	TST Control™ Indicators 121ºC / 15 mins	**2347**
100 indicators per box	TST Control™ Indicators 134ºC / 5.3 mins & 121ºC / 15 mins Self Adhesive	**3726**
200 indicators per box	TST Control™ Indicators 134ºC / 7 mins & 121ºC / 20 mins Self Adhesive	**3725**
200 indicators per box	TST Control™ Indicators 134ºC / 7 mins & 121ºC / 20 mins	**3760**
200 indicators per box	TST Control™ Indicators 134ºC / 9 mins	**3702**
200 indicators per box	TST Control™ Indicators 134ºC / 18 mins	**3706**
1500 per reel	TST Control™ Multi part Label 134ºC / 3.5 mins	**5006**
200 indicators per box	TST Control™ Duplex Label 134ºC / 3.5 mins	**5017**

Browne Biological Indicators & Accessories

Box Quantity	Description	Order code
Single item	Dual Temperature Incubator 37ºC / 57ºC	**2244**
100 units per box	Bio Monitor – Ethylene Oxide	**2233**
100 units per box	Bio Monitor – Steam 10^6	**2236**
100 units per box	Bio Monitor – Steam 10^5	**2232**
12 units per box	Recovery Medium for LTSF Biological Indicators	**2231**
100 units per box	Biological Indicator for LTSF	**2230**

Product Index

Process indicators & Accessories

Box Quantity	Description	Order code
250 spots per box	Formaldehyde Process Detector Spots	**2402**
1000 spots per box	Ethylene Oxide Process Detector Spots	**2421**
1000 spots per box	Gamma Check Irradiation Detector Spots	**3301**
1000 labels per reel	Gamma Check Irradiation Detector Labels	**3303**
48 rolls per carton	Dry Heat Indicator Tape 19mm (3/4") x 50m	**0140**
48 rolls per carton	Steam Indicator Tape 18mm (3/4") x 50m	**0142**
36 rolls per carton	Steam Indicator Tape 24mm (1") x 50m	**0143**
48 rolls per carton	Steam Indicator Tape Hi Tack (blue) 18mm x 50m	**0147**
48 rolls per carton	Plain Masking Tape 18mm (3/4") x 50m	**0160**
36 rolls per carton	Plain Masking Tape 24mm (1") x 50m	**0161**
Please call	Process Indicator Labels - various	**Please call**

Specific Test Indicators & Accessories

Box Quantity	Description	Order code
20 packs per box	TST Bowie Dick test pack for sterilizers working at 134ºC - 137ºC / up to 3.5 mins	**2352**
20 packs per box	TST 121 Bowie Dick test pack for sterilizers working at 121ºC - 124ºC / 8 – 8.3 mins	**2310**
10 packs per box	TST Bowie Dick Dick test pack for Eschmann Little Sister 3 Vacuum & SES 2000 Vacuum	**2358**
10 packs per box	TST Bowie Dick test pack for Prestige Century (22, 16 & 11 litre)	**2365**
20 packs per box	TST Bowie Dick test pack Getinge GE 224 C Vac & Citomat 164 V	**6536**
10 packs per box	TST Bowie Dick test pack for W & H Lisa MB 17/22	**2356**
20 packs per box	TST Bowie Dick test pack for Matachana M20 – B	**2352**
1 helix / 250 indicators	TST Helix for daily steam penetration test in Type B small steam sterilizers	**3780**
50 sheets per folder	Sensor Sheet for use in standard towel pack	**2385**
36 sheets per box	Plain cotton sheets for use in standard towel pack	**9053**
50 sheets per folder	Lead Free Bowie Dick Test sheet	**2561**
10 pots per box	Washer disinfector test soil	**2304**
100 per box	STF Load Check Indicators	**2315**
Single item	STF Load Check holder	**2316**
4 tests per box	Ninhydrin Protein Detection Test	**2370**
Single item	Dual Temperature Incubator 37ºC / 57ºC	**2244**

Multi-parameter Indicators & Accessories

Box Quantity	Description	Order code
100 indicators per box	Formaldehyde Control Indicators	**2401**
200 indicators per box	Vapour Strip	**2500**
250 / 500 indicators per box	MVI Steam Indicator -White to Purple	**2560**
250 / 500 indicators per box	MVI Ultra Steam Indicator -White to Black	**2551**
250 / 500 indicators per box	MVI Ethylene Oxide Indicator	**2563**
100 tubes per box	Browne Control Tubes Type 1 Black Spot Fluid Sterilization 121º/15 mins	**7301**
100 tubes per box	Browne Control Tubes Type 2 Yellow Spot 134º/3 mins	**7302**
100 tubes per box	Browne Control Tubes Type 3 Green Spot Dry Heat Sterilization 160º/60 mins	**7303**
100 tubes per box	Browne Control Tubes Type 4 Blue Spot Dry Heat Sterilization 180º/12 mins	**7304**
100 tubes per box	Browne Control Tubes Type 5 White Spot Dry Heat Sterilization 160º/120 mins & 180º/35 mins	**7305**

BROWNE Assurance through Technology

Albert Browne
International Ltd.

Chancery House,
190 Waterside Road,
Hamilton Industrial Park,
Leicester, LE5 1QZ, UK.

Tel: +44 (0)116 276 8636
Fax: +44 (0)116 276 8639

E-mail:
info@thebrownegroup.co.uk
www.thebrownegroup.co.uk

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