Assured Sterilisation

In the past it was generally assumed that a load that went through a sterilisation cycle would come out completely sterile. However, advances in validation processes and ever more demanding loads have proved that validation is now an essential part of Microbiology Lab practice.

Just because the steriliser has finished its cycle, it cannot be assumed that sterilisation has been achieved in every part of the load. With laboratories sterilising what could potentially be harmful loads, prior to disposal, it is imperative that they can be sure that when the cycle has finished, absolutely no part of the sterilised materials remain contaminated.

More often than not, a laboratory will work to a set of procedures as laid down by their governing bodies or standards agency, with the onus being on them to conduct a thorough independent validation, to enable them to provide evidence that what they are disposing of is indeed safe.

Environmental concerns are now at the forefront of good laboratory practice, and as such there is now even more pressure for labs to ensure that they comply fully with all relevant legislation regarding waste disposal. A great deal of organisations are moving away from disposal through incineration, so now more than ever, proof that loads are sterile is of utmost importance.

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VALIDATION – PAST AND PRESENT

Initially, when sterilisation was first conceived as a method of 'making safe', simply processing the load in an autoclave or steriliser would have been seen as sufficient.

New methods became available and involved using materials such as indicator tape or spore strips in and around the load. At the end of the cycle these would be examined for evidence that the set temperature had been reached. If it had not, then the load would be repeated until the tape or spore strips showed a satisfactory result.

This method works well as a guide, but gives no indication that the entire load has reached sterilisation temperature for the selected time. Although a good instant guide, this method could not be said to represent the result throughout the entire load.

The spore strip or indicator tape method also lacks information regarding timings. Some of the more resilient viruses or spores require sterilisation for a preset time to ensure that they are fully destroyed.

In short, more labs have to provide independent proof that the sterilisation temperature is achieved throughout the load, but more importantly that it was for the selected length of time.

Validation Technician placing probes throughout the load

HOW CAN IT BE PROVED THAT A LOAD IS STERILE?

Whilst sterility is a general term, certain loads need to be sterilised at a certain temperature for a pre-set period, for example 121°C for 15 minutes. Only then can there be any certainty that the load is sterile.

The most common form of load validation typically uses a Data Logger with 12 thermocouple probes. The thermocouples are placed inside the chamber and example load at various points. Each individual probe is connected to the Data Logger via a thin wire, passed through the entry port in the chamber wall.

Through having the probes placed in all areas, a detailed record can be made indicating which probed areas reached sterilisation temperature, along with the time period.

BUT WHAT IF THIS VALIDATION SHOWS STERILISATION IS NOT ACHIEVED?

Once the test load has processed and all the temperature and time data examined, it could be found for example that certain areas of the load have not reached temperature for the specified time.

This could be for one of many reasons: the load is dense / compact – all parts of the load need to reach temperature; air is remaining in the load – all air must be removed; insufficient Vacuum Pulses; or the load is either placed badly or the chamber is overloaded.

A typical autoclave load

If the load is found to have a high mass, the cycle programme can be altered to allow for a longer sterilisation time to ensure all areas achieve the correct temperature for the set time. For example, after validation, a sterilisation period of 15 minutes could be necessary to ensure 10 minutes of sterilisation throughout the load.

Secondly, the free-steam period of the cycle could be increased. This occurs before actual sterilisation and allows steam to circulate around the load freely displacing any remaining air.

If the unit is equipped with a vacuum system there could be insufficient positive and negative pulses prior to the cycle beginning, resulting in air remaining in the load. The number of pulses could be increased in order to ensure that all air is removed.

Importantly, the autoclave chamber needs to be loaded in such a way that steam penetration is possible throughout the load. Before validation begins the Astell engineer can advise upon the best loading method.

A Load Sensed Process Timing probe may also be suggested. This wandering probe would be inserted into the load and would allow the sterilisation period to begin only when the probe has reached the required temperature.

USER TRAINING

After validation has been performed and the optimum loading method discussed, it is always important for all autoclave users to be informed of the procedure to be used when loading the autoclave to ensure that sterilisation is always achieved.

RE-VALIDATION

The load is then re-validated with the 12 probes to ensure that all changes made to the cycle parameters have been effective.

The autoclave then receives a certificate to show that a typical load has been validated. In addition, the paper chart records are archived should the load validation be questioned.

FREQUENCY OF VALIDATION

This would usually be determined by in house protocols, but frequency may also be stipulated by external assessment bodies. Typically, revalidation would be performed annually. Validation should also be repeated if there are any major changes in the load type, i.e., an increase in container or bottle size, or the replacement of any major temperature / pressure components within the steriliser.

Advanced Thermal Calibrator Tests to 700°c

A new dry-block thermal calibrator with several advanced features for testing a wide variety of thermocouples, probes and switches between 25°C above ambient and 700°C has been introduced by **Techne**. The Tecal 700X incorporates a special design of heater block that combines rapid heating rates, particularly good temperature uniformity and the ability to accommodate a wide variety of probe sizes. It also allows thermostat switches to be calibrated very accurately.

The design of the isothermal block and the use of gradated heating elements combine to produce exceptionally good temperature uniformity and stability. A combination of fixed holes and removable inserts allow a virtually infinite variety of probes to be accommodated with minimal changing of inserts.

The equipment reaches maximum temperature from 50°C in 25 minutes and cools to 50°C in 30 minutes – a significant improvement on existing models. A USB port connects conveniently to the TechneWorks software package provided with the equipment. Weighing only 10kg, the new model is easily portable. With the addition of the Tecal 700X, Techne's range of portable calibrators now includes five models covering temperatures from 45°C below ambient to 1200°C.

Circle no. 597

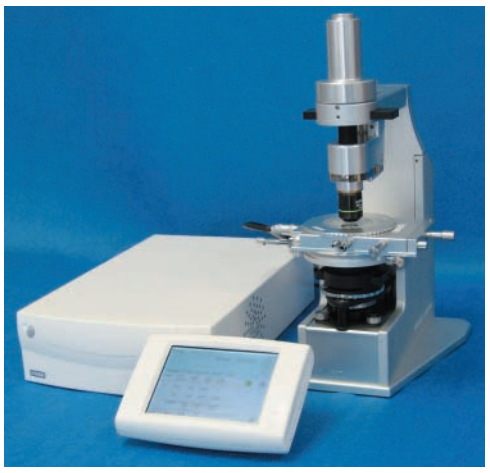
Heat Strategy Fails to Lift Jobs Threat to Industry

The Government's Heat Strategy offers massive help for homeowners, but does little for industries struggling to manage energy costs and rising carbon emissions. Jobs in manufacturing will be under threat without Treasury incentives to cut energy costs and deliver carbon savings in our energy-intensive industries, claims the **Combined Heat and Power Association** (CHPA). The Government recently launched a consultation on its Heat and Energy Savings Strategy, a key part of national efforts to reduce greenhouse gas emissions and cut energy costs. Commenting on the Launch, Graham Meeks, Director of the CHPA said: "Unless the Government acts now and commits to an effective and ongoing package of fiscal stimulus for combined heat and power (CHP) then there is a real risk that manufacturing industries will simply be frozen out of this important new initiative to decarbonise heat."

"Combined heat and power (CHP) could deliver the efficient, low-cost heat supplies that are urgently needed to cut costs, boost profitability and safeguard thousands of jobs in UK manufacturing. But in difficult times the industry needs the certainty of clear, long-term and stable incentives before it can invest, and right now we simply haven't got that," he added. Heat use accounts for 47% of UK's total CO2 emissions. The Government's own analysis suggests that as much as 43% of these emissions are from the industrial sector, roughly the same amount caused by domestic heat use. The CHPA is calling for the Treasury to provide a continuation of the outputs exemption from the Climate Change Levy (CCL), as extended to all supplies of GQCHP electricity, until at least 2037 and ensure the universal applicability of Enhanced Capital Allowances, to all CHP plant.

Circle no. 598

High Precision Temperature Controllers for Heating Stages



Linkam has been manufacturing world-leading temperature controlled microscopy products for over 25 years. At the 2009 Pittsburgh Conference in Chicago, the company will announce an exciting new temperature programmer and its new approach for users to upgrade their existing systems. The new T95 range of temperature programmers have been designed to provide more capabilities, connectivity and resolution than previous generation controllers. The performance of existing Linkam products such as the definitive LTS350 and THMS600 hot stages is extended with broader heating/cooling rate ranges and higher heating temperature limits.

Improved sensor precision and resolution benefits the measurement and control of Linkam's advanced thermal techniques such as the TST350 tensile stage and optical DSC instruments.

The T95 programmer leads Linkam's new campaign of 'trade-in to trade-up'. All heating stage users, whether users of Linkam systems or not, have the opportunity to upgrade to a new Linkam system incorporating either of the new T95-linksys or T95-linkpad controllers. Linkam also commits to take away any old electronic components and either use them as spare parts or recycle them as part of the WEEE Directive.

Commenting on this announcement, Linkam's Director of Operations, Vince Kamp, said: "Linkam is committed to make all new developments as environmentally compatible as possible, whether this be to use low energy components or to play an active role in recycling, such as following the WEEE Directive which aims to both reduce the amount of electrical and electronic equipment being produced and to encourage everyone to reuse, recycle and recover it."

Circle no. 599

Pipet Offers Improved Accuracy & Sterility

Excel Scientific's redesigned 50 mL Serological Pipets are constructed from high clarity virgin polystyrene. They are certified RNase-, DNase-, pyrogen-free, and non-cytotoxic. The smooth non-welded tip eliminates sample hang-up, leakage, and breakage. A 3 mm I.D. opening minimises shear. Sterile, individual one-side-paper, one-side-plastic packaging is easily opened by peeling or pushing through the paper.

A colored woven polypropylene plug provides easy size identification. There are forward and reverse 0.5 mL graduations with printed volumes at 1 mL intervals and negative graduations to -5.5 mL. Accuracy is ± 1.5 % and sterility better than 10-6.

Circle no. 600

Lab Autoclaves that Save Money

Unreliable sterilisation of lab glassware can be expensive. Discover the benefits and cost-effectiveness of the superb range of Getinge autoclaves launched in UK by **Lancer**.

Medical and research laboratories know the importance of avoiding cross-contamination and ensuring that the integrity of procedures is not prejudiced by dirty lab glassware or micro-organisms. Long term it costs less to know that glassware is cleaned and sterilised properly first time.

Lancer offers the Getinge branded range of small to medium sized autoclaves that provide all the benefits and efficiency you would look for and expect from the world's leading infection control company.

From the small freestanding HS33 to the high capacity HS66 model you will enjoy outstanding versatility and reliability. These fully automatic, high-pressure steam autoclaves have vertical sliding doors to save space and can use a central steam supply or built-in steam generator. Capacities from 60 litres to 298 litres and more. Quick processing, safe and easy to use.

Circle no. 601