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# Hydrogen peroxide gas plasma sterilisation

By Professor Laurence J. Walsh AO

Low-temperature plasmas have been used industrially for a range of processes including surface modification (etching), cleaning and decontamination, as well as for sterilisation of medical devices. The technology has been on the global market since the late 1980s. An example of a TGA-approved hydrogen peroxide gas plasma sterilization (HPGPS) system is shown in Figure 1 and the associated materials for monitoring performance in Figure 2.

HPGPS can achieve greater than a 6 log reduction in viable bacteria or endospores. The hydrogen peroxide is a source for oxygen which in turn generates O, OH, OOH and other radicals, all of which contribute to the sterilising actions. The OH radical is particularly reactive and is especially potent for achieving inactivation of microorganisms.

HPGPS units and their cassette packaging systems require approval by the TGA as medical devices. In Australia, there is not an equipment standard for HPGPS, so the most recent instrument reprocessing standard (AS/NZS 4187:2014) points

to the most recent edition of ISO 14937 (2009) for guidance. This ISO standard, *"Sterilization of health care products - General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices"* covers quality assurance processes. Throughout (AS/NZS 4187:2014, additional reference is made to the recommendations of the manufacturer of the HPGPS system.

## Composition of plasma

Plasma is the fourth state of matter (after sold, liquid and gas) and is best thought of as a highly energised gas-like mixture of charged particles such as positive ions and electrons. Concentrated hydrogen peroxide (e.g. 60-65% w/v) in a special sealed cartridge or the end reservoir of a specially designed pouch is the starting material and it is first vaporized into a gaseous state by heating it up in a vapouriser.

HPGPS technology employs gases generated under deep vacuum (low-pressure) conditions (typically < 0.1 Torr). Hence, the sterilising cycle includes air removal at the beginning and the method is suitable for sterilising hollow cannulated items as well as wrapped instruments. The effectiveness can be altered by lumen length and lumen diameter and specially designed PCDs are used to assess air removal from hollow items in HPGPS.

The low pressure in the chamber plays another important role, in that it allows for a relatively long free path of accelerated electrons and ions within the chamber, with relatively few collisions with molecules, ensuring that the whole system remains at a low temperature when plasma is generated - less than 50 degrees Celsius and typically 37-44 degrees.

## Antimicrobial actions during the sterilising cycle

Gaseous hydrogen peroxide is highly toxic to microorganisms and exerts lethal effects on any bioburden left on instruments or devices in the chamber. Its second and more important role is to serve as the precursor material from which the plasma is generated, by applying a high electrical field or bursts of microwave or radio frequency (RF) energy. These ionise the peroxide vapour and turn the vapour into plasma. The plasma contains charged ions and electrons, as well as various oxygen free radicals. The radicals collide and react with and kill microorganisms, creating a type of etching action that degrades the organic material one atom layer at a time, as electrons are stripped away. This damages all the key cell components (e.g., enzymes, nucleic acids). HPGPS has the ability to inactivate a broad range of microorganisms, including vegetative bacteria, bacterial spores, fungi and viruses.


*Figure 1. An example of a TGA-approved ARTG hydrogen peroxide gas plasma steriliser system (Plasmapp™ , ARTG 31804): A. Compact version; B. A larger capacity unit with the pump housed in the twin side unit; C. Heat sealer designed for use with Tyvek™ laminate pouches; D. Process challenge devices of the helix configuration designed for use with the HPGPS sterilization method; E. Different sizes of Tyvek laminate pouches with built in external Class 1 chemical indicators; and F. Different types of porous cassettes and holders.*

The plasma generation phase also helps break down residual hydrogen peroxide in the chamber at the end of the cycle. To achieve this, late in the overall process, plasma generated from the peroxide gas is removed by the vacuum pump.. In some modern units, there are two equal and consecutive half cycles, each with a separate injection of hydrogen peroxide followed by plasma generation.

Ensuring complete removal of hydrogen peroxide in both gas and liquid forms from the items in the chamber is essential for making the contents completely safe for staff to handle when

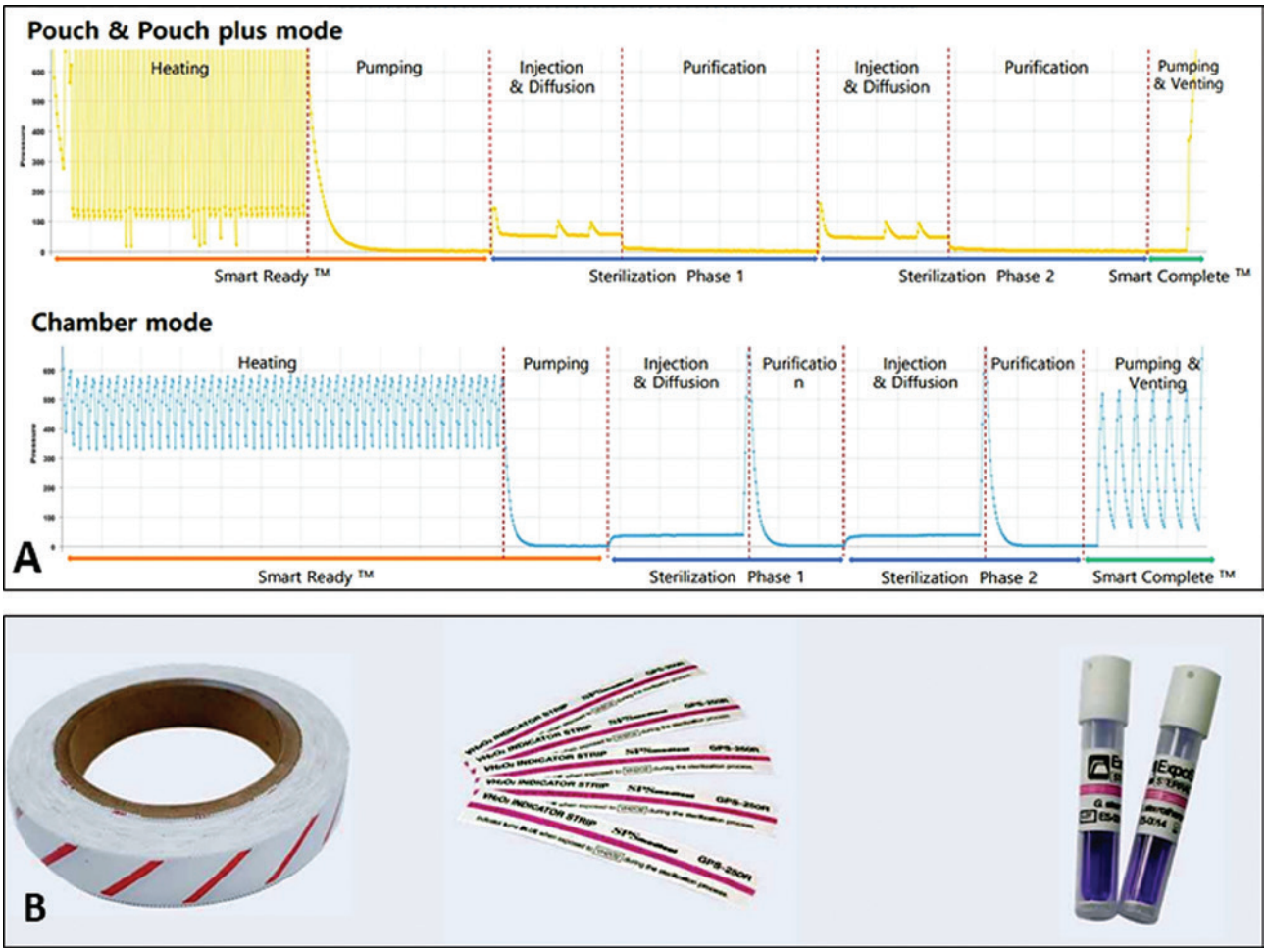


*Figure 2. Sterilisation quality assurance processes: A. Examples of hydrogen peroxide gas plasma steriliser cycles for special all-in-one pouches or using the whole chamber. The heating phase refers to heating the concentrated hydrogen peroxide liquid in a special vapouriser to generate the vapour. Each cycle starts with air evacuation ("pumping"), followed by two separate cycles of injection and activation of the gas. The cycle concludes with venting the chamber of all the gases and restoring the chamber to normal atmospheric pressure; B shows Class 1 chemical indicator tape for use on the outside of wrapped items (left), Class 4 chemical indicators designed for use inside wrapped items (centre) and biological indicators (spore tests). Each of these is specific to HPGPS and not suitable for use with steam sterilisation.*

removing them from the chamber. After the excess hydrogen peroxide vapour is removed and the chamber is vented, the chamber is returned to normal atmospheric pressure by the introduction of HEPA-filtered air. All the by-products of the cycle (e.g. oxygen) are not toxic. The sterilised materials can be handled safely, either for immediate use, or storage. It is not necessary to undertake environmental atmospheric monitoring for hydrogen peroxide, although such monitors can be found, but tend to only be used in hospital sterilisation departments where many large HPGPS units are in simultaneous operation and the likelihood of a failed or expired catalytic converter is greater than would be the case in dental practice.

## Advantages of HPGPS

The low chamber temperature of HPGPS sterilisers makes the HPGPS process suitable for sterilising polymer-based instruments, which cannot be subjected to autoclaving because they would melt, or other items that cannot withstand steam sterilisation, including electrical items and batteries. This has led to the increasing use of HPGPS in hospitals, especially for expensive, intricate instruments and for laser handpieces, replacing the much slower approach using ethylene oxide (EO) gas. It can be used with unwrapped items as well as with wrapped items.

Various other advantages of HPGPS have been cited, including faster turnaround because of a short cycle time, gaining more use from a given steriliser and resulting in cost savings.

Cycle times for single items can be as short as 4 mins of HPGS with a total cycle duration of only 7 minutes. If multiple packaged items are used in a full chamber (e.g. 7 litres), the total cycle time can be as short as 36 minutes - taking on board that no cooling is needed and the items can be used immediately.

Additional cited benefits include a lack of chemical residues and simplified handling of items after removal from the steriliser chamber, as well as reduced energy usage compared to steam sterilisation.

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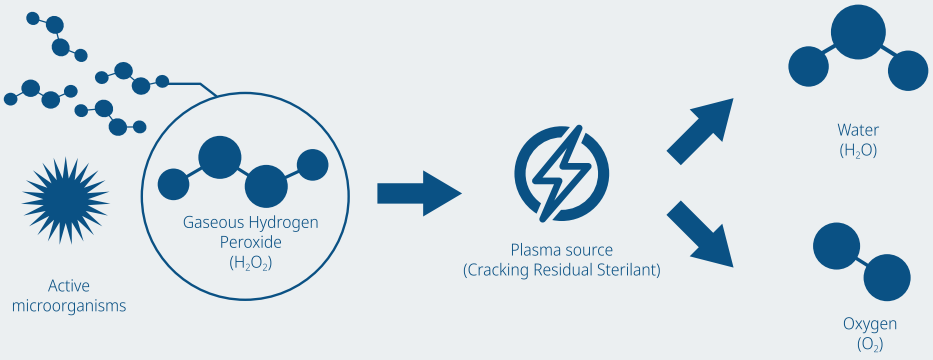


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Compact HPGPS units are available, with the small size being well-suited to mobile dental service delivery. Such units have low servicing requirements, including periodic replacement of catalytic converters that inactivate ozone and oxygen radicals in the chamber exhaust line.

## Limitations of HPGPS

HPGS is not suitable for cellulose (and thus paper), cotton (e.g. cotton rolls), or copper/brass. Cellulose and cotton-based material will also absorb and convert the gas back into a liquid state. This impairs the sterilisation process and also increases the possibility that a staff member could experience minor chemical burns from residual peroxide liquid trapped on these items.

## Packaging

HPGPS requires specific synthetic packaging materials to be used. Since paper products (including autoclave pouches) are contraindicated when HPGPS is used, the pouches for HPGS are typically made of a special compatible plastic (Tyvek™ ), rather than of paper and plastic. This makes them somewhat more expensive per pouch. Plastic peel pouches have Tyvek on one side, and a polyethylene/polyester lamination on the other side. Such pouches are not suitable for use with steam sterilisation because of their low melting point. The pouches are sealed using a thermal-impulse, narrow jaw-type heat sealer designed for these materials. There are also various small rigid containers made of aluminium, plastic or stainless steel, with pores designed for use in HPGPS. These are then placed into a Tyvek laminated bag. An alternative is to wrap the cassette in a synthetic non-woven fabric that is compatible with HPGPS. Kimberley-Clark KIMGUARD ONE-STEP Steriliszation Wrap™ is one of the few materials that is approved for such use.

## Requirements for quality assurance

Chemical indicators (CI), biological indicators (BI) and PCDs specifically designed for HPGPS are readily available. Those indicators stipulated by the manufacturer must be used, not ordinary CI and BI designed for steam sterilisation. The manufacturer will already have taken the requirements of validation from ISO 14937 into account and ensured that the indicators are resistant to HPGPS and are more resistant than any bioburden that could remain on instruments after cleaning. When using CI and BI for HPGPS, place these within cassettes or pouches at positions where sterilising conditions are most likely to be difficult to achieve.

As with autoclaves, it is necessary to record key data for each cycle and for staff to check the data for each cycle at the completion of each sterilisation cycle (e.g. Time, temperature pressure data for every cycle). As well, chemical concentration data must also be recorded for every cycle.

This is important for verifying from the parameters that the HPGPS process was actually delivered in accordance with the validated specifications. Recording of humidity data is optional.

Table 8.2 of AS/NZS 4187:2014 stipulates the routine monitoring processes. External CI are to be used on each wrapped item (e.g. pouch or wrapped cassette). Because a full validation process should have been done, use of internal CI in each pouch or package is optional. Inclusion of a PCD for HPGPS (e.g. a helix PCD designed specifically for HPGPS) is optional and should be as recommended by the manufacturer. A Bowie and Dick type test is not required with HPGPS, nor is an air detector function test, however a leak rate test is optional and is to be done at the interval recommended by the system manufacturer. In line with ISO 14937, annual maintenance and recalibration is necessary. On more frequent intervals, as specified by the manufacturer, various other user checks may be needed, e.g. checking and replacing the cartridges that scavenge ozone and other oxygen compounds, or replacing the oil in the vacuum pump.

At the end of a cycle, product release must only occur after checking the cycle data, the external CI and any internal CI and after carefully inspecting each wrapped item for package integrity. Each packaged item must be completely intact and there must not be any visible moisture or fluid present - this could represent residues of hydrogen peroxide which could cause chemical irritation if the item comes into contact with skin or mucosa.

## About the author

*Emeritus Professor Laurence J. Walsh AO is a specialist in special needs dentistry who is based in Brisbane, where he served for 36 years on the academic staff of the University of Queensland School of Dentistry, including 21 years as Professor of Dental Science and 10 years as the Head of School. Since retiring in December 2020, Laurie has remained active in hands-on bench research work, as well as in supervising over 15 research students at UQ who work in advanced technologies and biomaterials and in clinical microbiology. Laurie has served as Chief Examiner in Microbiology for the RACDS for 21 years and as the Editor of the ADA Infection Control Guidelines for 12 years. His published research work includes over 330 journal papers, with a citation count of over 15,400 citations in the literature. Laurie holds patents in 7 families of dental technologies. He is currently ranked in the top 0.25% of world scientists. Laurie was made an Officer of the Order of Australia in January 2018 and a life member of ADAQ in 2020 in recognition of his contributions to dentistry.*

## Recommended reading

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