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THE QUEEN'S AWARDS FOR ENTERPRISE: INTERNATIONAL TRADE 2022

A Specialist Overview on Autoclaves

By Richard Clarke

- Types of Sterilization
- 50 Years of Evolution
- Modern Autoclave Advancements
- Steelco Barrier Solutions
- Problems & Solutions
- Regulatory Requirements
- Information, Training
- Order Process
- Best Practice
- A Manufacturers Guidelines
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- Reputable Servicing Support

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Types of Sterilization

Sterilization is the process of complete elimination or destruction of all forms of microbial life.

The main types of sterilizer are:

- Steam sterilizers
- Low-temperature sterilizers (VHP/EtO/Ozone)
- Dry heat sterilizers

All configurations to suit many applications

- Benchtop 15ltr – 85ltr
- Free standing 250ltr – 900ltr
- Bulk 1000ltr – 6000ltr

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50 Years of Autoclave Evolution

1980s

- Predominantly bulky and often operated manually.
- Typically used traditional heating elements and pressure gauges for temperature and pressure control.
- Sterilization cycles were relatively long, and the process required significant manual intervention.
- Utility hungry, large quantities of water used in cooling

1990s

- More advanced control systems, including digital temperature and pressure monitoring.
- Automation became more prevalent, reducing the need for manual intervention during sterilization cycles.
- Move towards more compact designs and improved energy efficiency.

2000s

- Advancements in materials and manufacturing, leading to more durable and corrosion-resistant designs.
- Integration of PLCs and touchscreen interfaces.
- Rapid cycles and improved cycle validation became standard features, for enhanced productivity and compliance with regulatory requirements.

2010s

- Further integration of automation and connectivity.
- Energy-saving features such as intergration to chilled water circuits for reductions in water usage and advanced insultation materials became increasingly more common.
- More user-friendly interfaces and intuitive software for easier operation and maintenance.

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Modern Autoclave Advancements

- **Advanced Eco Options:** State-of-the-art ECO technology provides unrivalled efficiency levels, reducing energy and water consumption to provide the lowest operating costs per load (reliant on Chilled water circuits)
- **User-Friendly HMI:** Touchscreen control panels support operators in every step of their interaction with devices giving clear and easy-to-understand operation tasks.
- **Management & Traceability System:** Integrated software suite that is web-based, cloud-ready, and fully modular to adapt to your specific needs.
- **Fully Customisable Solutions:** Our autoclaves as an example offer flexible configuration and can be fully customized to meet the needs of any facility.
- **Temperature Mapping:** Integration of advanced sensors and monitoring systems for precise temperature control and monitoring throughout the autoclave chamber.

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Barrier Solutions

Double door sterilizers function as a pass-through between hot and cold zones. They must be sealed to the wall forming a cross-contamination barrier.

Our partner, Steelco (as do others), offers three biocontainment barrier solutions, suitable for all biosafety levels:

- **Air differential seal** provides a solid AISI 304 stainless-steel flange which is bolted to the sterilizer body, and stainless-steel panels are inserted between the flange and the building structure.
- **Single Bioseal** includes two stainless-steel 304 flanges. One is fixed or welded to the chamber and the second one is attached to the building structure. The flanges are connected by a long-life flexible gasket to ensure complete airtightness.
- **Double Bioseal** is a similar design of the Single Bioseal, the difference being that the flanges are welded (no dismountable solution) and the separation flexible gasket is double.

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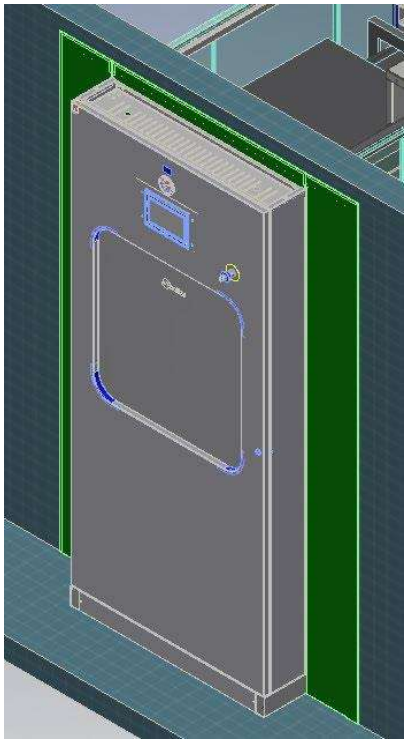
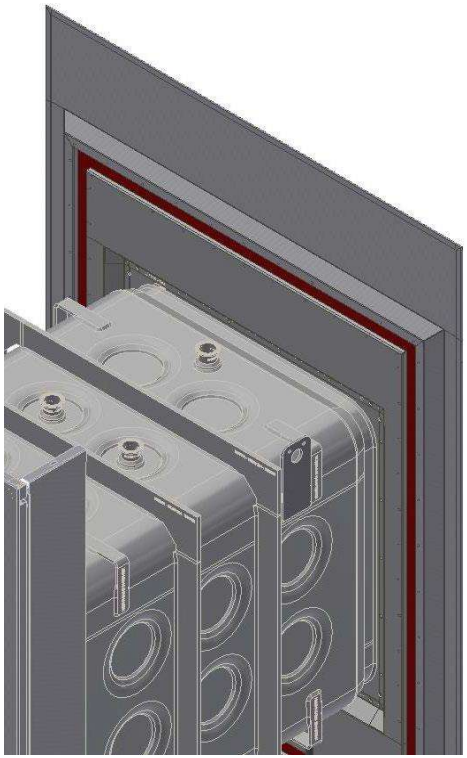
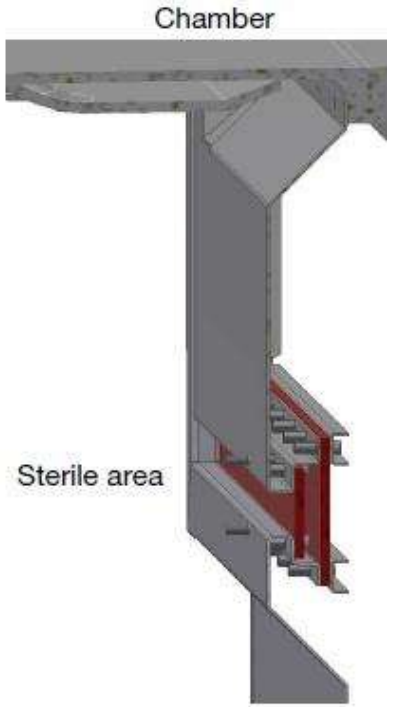
Barrier Solutions



Air Differential



Single Gasket Bioseal



Double Gasket Bioseal

Further Safety Control Measures

Further contamination and safety systems include:

- **Air & Steam Inflatable Door Gasket**
- **Effluent decontamination feature**

This feature is used for processing contaminated items like biohazardous laboratory waste (BL-3 and BL-4). To prevent harmful pathogens and viruses from exiting the sterilization chamber during the exhaust and vacuum phases, the condensate produced during the processing cycle is decontaminated before discharge to the drain. The drain is controlled by an hydrophobic 0.2 µm (8µ inch) filter and both filter and condensate are sterilized during the cycle.

- **Additional filter for effluent decontamination feature**

To increase the safety of the decontamination cycle and avoid the risk of release of non-sterile and unfiltered fluids in the event of failure of the Drain/Vacuum Pump filtration system, a second hydrophobic 0.2 µm (8µ inch) filter is positioned on the drain line. In this way, in the event of breakage or malfunction of the first filter, the second filter still guarantees the sterility of the fluids discharged. The filtration system can be tested installing an automatic Water Intrusion Test (WIT).

- **Isolation valves and injection ports**

Isolation valves and injection ports to enable the decontamination of process piping prior to maintenance.

- **Sealing of Electrical and pneumatic signals**

Additional features include the sealing of conduits containing electrical cabling and the filtration of any pneumatic lines passing across the Bioseal.

- **Incineration systems**

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Common Problems & Solutions

Problem The load is wet even after the end of the sterilisation cycle

Possible Solution Adopt a loading style that spaces out the goods, with lighter sets on top and heavier on the bottom.

Possible Solution Consider how the load is wrapped and prepared for sterilization.

Possible Solution Consider the material of the product being sterilized (plastic and Stainless Steel require different sterilization profiles

Problem The load is damaged by the steriliser

Possible Solution Ensure that any items loaded in the steriliser are autoclave-safe.

Investing in Planned Preventative Maintenance can reduce machine downtime and extend the life of your autoclave. Sychem provide individual PPM packages tailored to your needs.

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Solutions towards extending the Life of Your Autoclave

Regular Service Intervention

Typically a Quarterly or Half Yearly check in addition to an Annual service

- Visual inspection of all critical components
- Periodic replacement of seals and gaskets based on actual wear/condition
- Recalibration of measurement systems (temp/pressure)

On Site Critical Spare Part Warehouse

- Common failure parts (seals, gaskets, pneumatic valves, door seals)

Partnership with a qualified service provider to help with day to day failures

Full system Overhaul (typical 10 year+ action)

- Replacement of all critical control vales and associated pipework
- Vacuum Pump replacement (overall efficiency of the autoclave is directly linked to the performance of this component)

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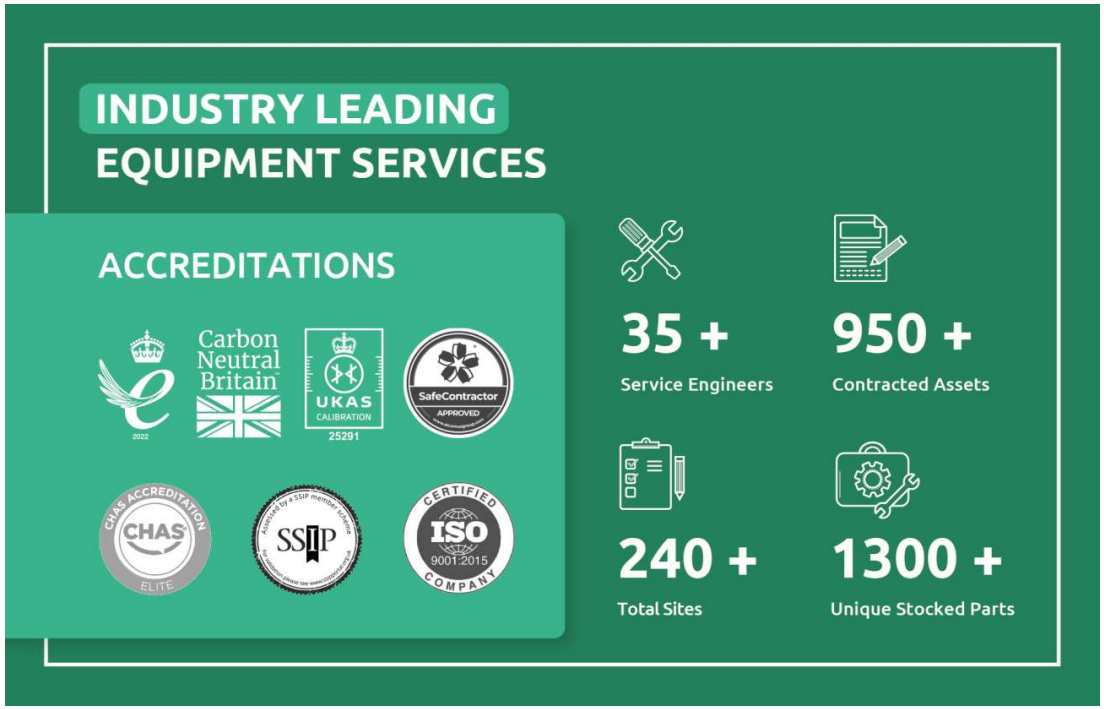
Reputable Servicing Support

- **Experienced Team:** Engineers stationed nationwide, dedicated office-based Resource Coordinators & specialist Technical Support Desk.
- **Communication:** Transparent in communication, providing clear explanations of work, associated costs, and any potential limitations.
- **Comprehensive Solutions**: Fully comprehensive solutions covering a complete range of autoclave services.
- **Quality Service:** Consistently delivering high-quality services to ensure equipment remains operating at its maximum capabilities.
- **Regulations and Standards:** Adherence to industry regulations and standards, ensuring that work is always performed safely and within compliance.
- **Continuous Improvement:** Continuously seeking to improve services, invest in training, technology, and processes to stay ahead of industry advancements and better serve clients.



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Regulatory Requirements

For autoclaves within the Laboratory and Life Science sectors, Sychem works to the BSI's (British Standards Institution) **BS2646 standard**.

This covers all aspects of the service and validation process.

And

HTM 01-01, help health organisations to develop policies regarding the management, use and decontamination of reusable medical devices at controlled costs using risk control, which will enable them to comply with Regulations 12(2)(h) and 15 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 .

bsi.

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Information, Instructions & Training Provided ?

When purchasing an Autoclave from a reputable manufacturer, you will and should receive:

- CL Drawing – layout drawing of the machine
- P&I – piping diagram
- Wiring Diagram
- Instruction / Operation manual
- Training certificates (if training has been purchased)
- Project programme
- Declaration of conformity (on request)

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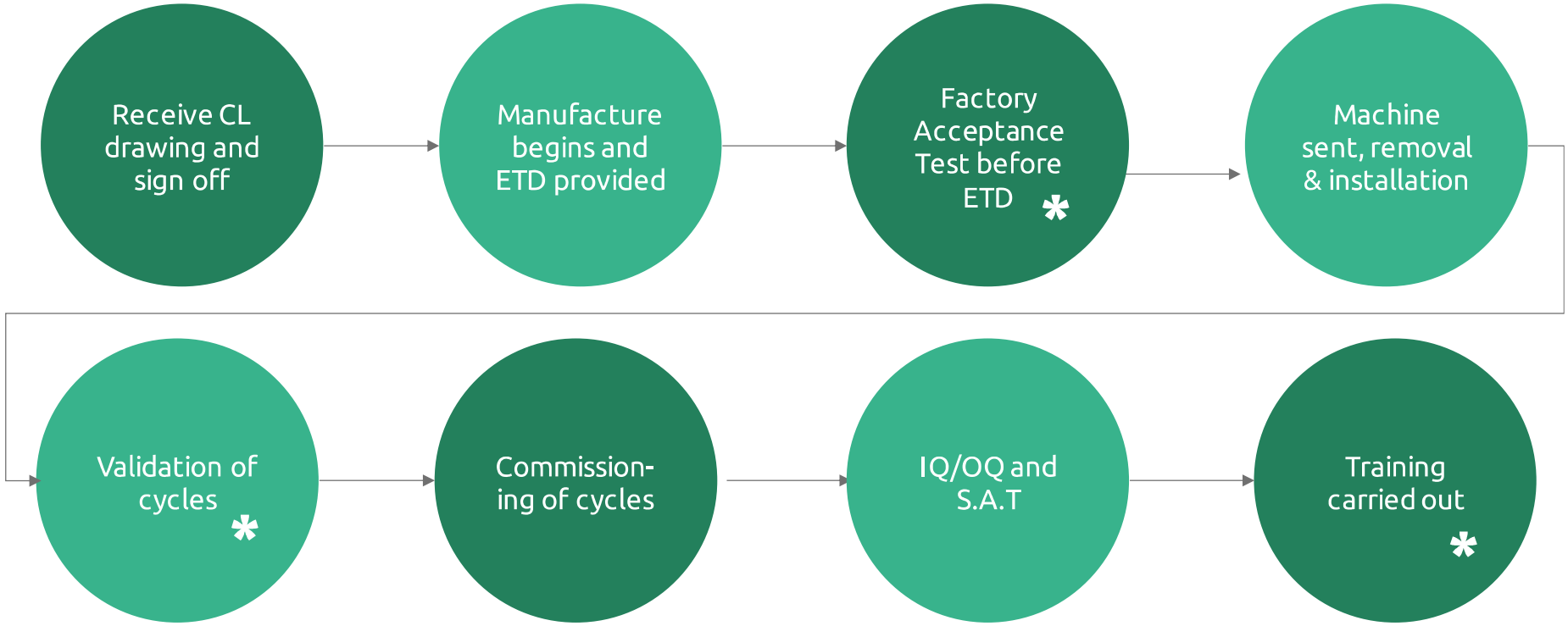
Order Process



* Optional add-on

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What Does "Best Practices" Look Like?
The Sales Bit

- With over 40 years of experience, Sychem is a leading, expert provider of disinfection, sterilization and decontamination solutions.
- Sychem is a customer-driven business, and our client's needs are at the heart of what we do. We strive to deliver complete customer satisfaction on every project we undertake by taking the time to carefully listen to your requirements to advise the most appropriate solutions for your application.
- In 2022, we won the Queen's Award for Enterprise for our work in the International Trade category.
- Sychem are UKAS accredited for the thermocouple validation of Laboratory autoclaves. UKAS validation adds another level of protection to ensure the correct temperatures are achieved within the processed loads.
- With a strong commitment to excellence, we adhere to the rigorous UKAS standards, ensuring that your machines meet the necessary requirements and regulations.

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Manufacturer Guidelines

Sychem and Steelco have worked together since 2008 to support facilities across the UK with their washing, disinfection, sterilization, and decontamination needs.

When purchasing a sterilizer, they will supply a list of spare parts, alongside a timetable of frequency of replacement. *This covers year 1 – year 5.*

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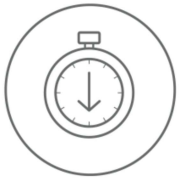
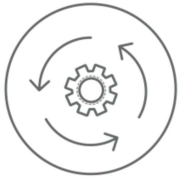
Servicing: Key Benefits

Benefits of a Planned Preventative Maintenance Packages



Reduced Downtime

Our team of specialist service and test personnel provide regular health checks to significantly reduce downtime for your autoclave.



Equipment Longevity

Our fully customizable servicing and PPM packages ensure the long-term reliability and performance of your autoclave.

Equipment Efficiency

With support from our team of experts, we help to maximize the efficiency of your autoclave ensuring its peak operational performance.

Maintenance & Spare Part Kits

Our maintenance kits include manufacturer-guaranteed replacement parts, with critical spares available on-site for immediate emergency use.

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Thank you

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