STERSTAR 2
STATE OF THE ART ON-LINE E-BEAM CONTINUOUS TUB STERILIZATION TUNNEL
GETINGE'S E-BEAM SYSTEMS

According to the IAEA (1), over the past decade, the fastest growing market for industrial electron beam accelerators has been in the low-energy area. GETINGE developed the STERSTAR system in the early 2000’s in response to an emerging demand from the pharmaceutical industry and in conformity with GMP pharmaceutical regulations.

The first installations, which began production in 2002, provide surface sterilization and aseptic transfer without any contamination to tubs of syringes entering an filling line under isolator.

Since then a considerable number of other STERSTAR units (over 20) have been supplied to pharmaceutical companies.

Some units have been designed specifically to comply with the particular requirements of our clients.

The success of this in-line unit together with the experience accumulated for over 13 years on all the systems installed, led GETINGE to develop the STERSTAR 2™, a result of new requirements issued by our clients and the competent authorities, plus the company’s own improvements to the existing system.

1 “Industrial Radiation Processing With Electron Beams and X-rays”, IAEA 2011, Page 25: 2.5. Low-energy Accelerators
ELECTRON BEAM TECHNOLOGY
STERILITY ASSURANCE GUARANTEED

Getinge’s low energy electron beam systems are specially designed for surface sterilization.

Various decontamination techniques have been used to ensure that microorganisms are inactivated.

Most of these systems have disadvantages such as side effects, long cycle time, low Sterility Assurance Level (SAL) or insufficient log reduction. For sterility assurance, the default dose is 25 kGy.

Thanks to low energy electron accelerators specially designed for surface sterilisation, electrons sufficiently but barely penetrate the material, thus preserving the mechanical features of the packaging as well as the contents.

Because sterility is imperative to ensure the safety of parenterals or injectable drugs, nearly all high-speed nested syringe filling lines are equipped with e-beam decontamination systems and isolator.

This trend continues today for medium-speed nested syringes filling lines.

With the development of low energy accelerators small enough to fit into self-shielded units, in-line sterilization tunnels using electron beams can be integrated into the overall production lines.

In-line systems drive to major operational economies in terms of operating costs, logistics, time, labor, maintenance, etc.

Electron beam technology is clean, powered by electricity, simple to validate, and traceable. It provides fast continuous sterility assurance at room temperature.

Environmental impact is usually low.

APPLICATION
CONTINUOUS IN-LINE TREATMENT
IN SAFE CONDITIONS

The STERSTAR 2™ is a stand-alone syringes tub sterilization equipment aligning to constraining safety standards and security regulations.

The STERSTAR 2™ is designed for the in-line treatment of 3” and 4” tubs containing pre-sterilised syringes with a throughput up to 6 tubs/minute.

Thanks to low energy electron beam providing the highest SAL, the tubs are transferred sterile from a Class D/C area into a Class A area.

STANDARDS AND CODES

The STERSTAR 2™ system complies with appropriate standards, codes and directives relevant to the EC (CE mark).

The equipment is manufactured according to industry requirements and standards. A sample Declaration stating the relevant standards, codes and machine directives with which the equipment complies is available on request.

Additionally, GMP procedures and guidelines are followed throughout the project lifecycle and all documentation and validation support materials are issued accordingly.
STERSTAR 2 LOW ENERGY ELECTRON BEAM TUNNEL FOR SURFACE STERILIZATION

KEY FEATURES
- Highest Sterility Assurance Level
- 6 log reduction
- KEVAC electron accelerators with beam scanning
- Sterilization at room temperature
- Isolator integration
- Integrated self bio-decontamination reduces down time
- The conveyor uses a "hop-over" concept, GETINGE’s own design
- Stainless steel outer structure complies with GMP guidelines
- Laminar flow for reduced particle generation (Class A compliant)

3 emitters provide sufficient dose on all parts of the tub surface. The STERSTAR 2 uses the latest version of GETINGE-LA CALHENE’s KEVAC accelerators, with thousands of hours of reliable service.

KEYVAC ACCELERATOR CHARACTERISTICS
- BEAM ENERGY: Variable - from 10 to 200 KV
- BEAM POWER: 800 W
- BEAM CURRENT: From 0 to 4 mA
- SCANNING WIDTH: From 7 to 20 cm
- CONVEYOR SPEED: According to necessary throughput
- HV GENERATOR: Continuous voltage

200 KeV EMITTERS — A Crucial Success Factor
GETINGE’s KEVAC emitters ensure that the sterilization dose of 25 kGy is deposited at all points on the surface of the tubs; each accelerator emits an electron beam with 200 keV energy and about 1 kW power.

Simulation tests done by GETINGE showed that, without appropriate treatment, a contaminated particle located underneath the Tyvek® lid is very likely to enter the syringes when the Tyvek® lid is peeled off in the filling isolator. So it is vital that the sterilization dose reaches any particles that may be hidden underneath the lid. The easiest way is to provide the dose THROUGH the Tyvek® lid.

GETINGE performed dosimetry tests at two energies (150 keV and 200 keV) which concluded that the 200 keV energy is most efficient, with less impact on the Tyvek® and fewer particles generated.

GETINGE commits to minimum 25 kGy all over the outside surfaces of the tub and underneath the Tyvek® lid, with maximum 90 kGy on the Tyvek® lid.

Refer to the "Justification of the GMP parameters" White Paper issued in May 2012 www.getinge.com

COMPLETE OPERATOR PROTECTION
- A lead shield surrounds the STERSTAR 2 to protect operators working in the environs. This biological protection is designed and constructed according to European regulation Euratom which is the most stringent standard in the world.
- Shielded doors are located on the upstream and downstream tunnels for easy access to the tunnel interior. The door locks are controlled by safety contacts linked to a safety PLC.
- The shield contains no moving parts for optimal security.
- The S-shape of the inlet and outlet of the shielding is designed to protect the workers from any emission of X-rays to the production room.

Radioprotection calculations are optimized by MCNP modelizations showing mSv/h cartography.

An ergonomic lifting tool (option) has been designed for quick emitter change-over in optimal working conditions.
WE PROVIDE LIFE SAVING KNOWLEDGE

“An investment in knowledge always pays the best interest”. Benjamin Franklin (1706-1790).

The world’s increasing requirement of quality assurance is of the utmost importance and includes the competence and skills of staff in the organization. Concurrently with the implementation of new norms and standards, there is an increasing need for quality assurance of you and your staff.

BUILT-IN ACCESS FOR FAST SERVICE

GETINGE designed the STERSTAR 2 system with hinged shield doors for easy access and fast service.

Integrated DPTE ® glove ports (option) can be installed for manual dejamming without breaking containment, using cameras placed inside the sterilization tunnel (option).

TRAINING

Your staff start to gain hands-on experience during system qualification in our workshop. Training for your operators and technicians consists of theoretical and hands-on training on all aspects of the use of your e-beam system. We aim to build a two-way relationship with your staff who gain expertise in trouble-shooting and basic maintenance tasks.

Boosting their knowledge improves plant safety and extends equipment lifetime.

GETINGE’s training courses are tailored to the professional needs of the participants. They include:

- **Introduction to e-beam systems**
  - Working with electron beam irradiation
  - Presentation of the system
  - Description of the principles of e-beam treatment

- **Functional aspects**
  - Treatment characteristics, relationship between sterility and machine parameters
  - Discussion of specific product treatment
  - Basic principles of the sub-assemblies including product transfer and management

- **Operational aspects**
  - Operating modes
    - Production
    - Maintenance
    - Decontamination (if relevant)
  - Access levels
    - Process description
    - Interaction with upstream and downstream equipment
    - Dosimetry

- **Maintenance**
  - Preventive maintenance / repair
  - Trouble-shooting (Breakdown diagnosis)

New training courses are carried out periodically to keep your staff updated, ensure compliance and improve process efficiency.
CUSTOMER SUPPORT AND OPTIMIZATION
HELPING YOU GET THE MOST OUT OF YOUR EQUIPMENT INVESTMENT

Getinge offers you a wide variety of customer support and optimization services to help ensure your equipment performs at peak levels from the day it's installed. These include: Service Plans, Parts Packages, Calibration Services and Optimization Programmes.

Flexible service plans
From routine preventive maintenance to customer support help line assistance, Getinge provides fast, effective service. To make it even easier, we offer a range of service plans tailored to your budget, production levels and facility requirements. Whether your operation is small or large, we’ll provide a plan that fits your workflows, controls your costs, and keeps your equipment operating in peak condition. A service plan forecast can be provided for a period of up to 6 years with Key Production Indicator follow-up. Our technicians are available for site visits within guaranteed time limits.

Parts packages
Getinge provides original parts and parts-rebuild packages to help minimize downtime:

- We tailor our Recommended Spare Parts (RSP) packages so you’ll always have on hand what’s necessary for routine repairs.
- You’ll get genuine parts, tested for performance, operation life, and cost-effectiveness.
- By ordering your parts by the "package" you’ll enjoy cost-savings over purchasing the parts individually and ensure availability.

Optimization programmes
Getinge’s optimization programs allow you to enhance the capabilities and features of your existing equipment, without incurring a major capital expense.
- Improve equipment performance
- Extend equipment life
- Provide greater consistency of controls for ease-of-use
- Comply with new regulations

We work with you to optimize your equipment at all stages throughout its lifetime. These integrated systems may need refurbishment in the field; our engineers aim to find solutions which minimize downtime.

<table>
<thead>
<tr>
<th>Getinge Service Plans</th>
<th>Preventive Maintenance</th>
<th>Corrective Maintenance</th>
<th>Consumables</th>
</tr>
</thead>
<tbody>
<tr>
<td>Warranty</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Preventive Maintenance</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Corrective Maintenance</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Help line</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Parts packages</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

- Warranty: All equipment comes with warranty coverage, which includes corrective maintenance labor, parts, and callbacks. Extended warranties are available, and are often packaged with Preventive Maintenance plans to provide full coverage.
- PM Plan: The Preventive Maintenance plan is a package of services performed at scheduled intervals. This assures uninterrupted operation, and extended equipment life, as well as maintaining the integrity of your equipment warranty.
- Total Care Plan: This full-service agreement includes inspections, call-backs, parts, and preventive maintenance visits. The Total Care plan provides the most complete coverage available, and is the service plan of choice after warranty expiration.
- Custom Plan: Getinge allows you to create a custom plan that meets your needs. These may include adjusting the number of preventive maintenance visits, different call-back options, parts and labor options, and other site-specific requirements.

Program optimized to specific customer needs
COMPLETE SOLUTIONS FOR CONTAMINATION PREVENTION
Getinge is the world’s leading provider of solutions for effective cleaning, disinfection and sterilization in the healthcare and life science sectors. We are dedicated to helping our customers provide maximum productivity in the most cost-efficient way. We do this by offering well-thought-through and customized solutions. This means that we are with our customers all the way from architectural planning and education to traceability and support – with complete solutions, long-term commitment and global presence. Getinge – Always with you.