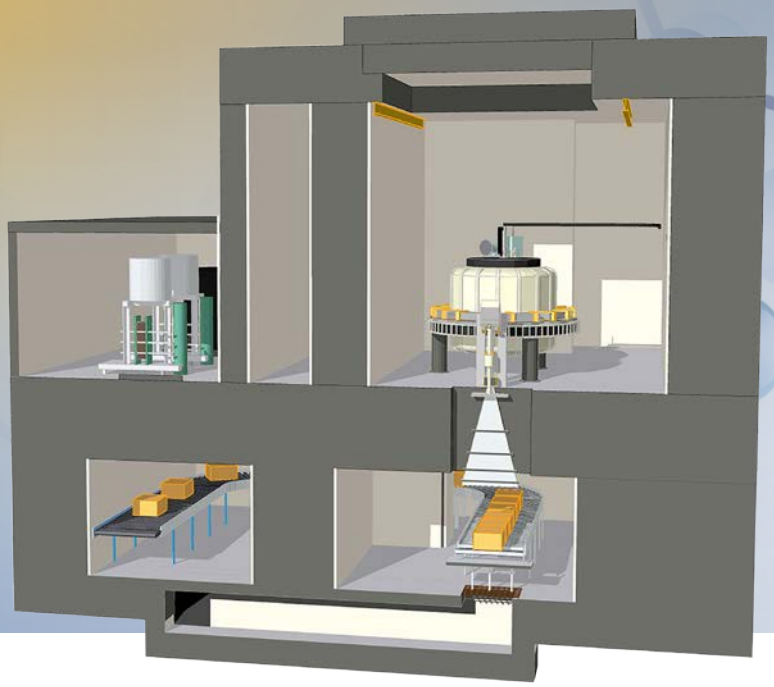
LEONI *technical**report***

Irradiation Services



Web links to the topic

→ Information on sterilisation

→ LEONI Studer AG

Sterilisation

with 10 MeV electron beams

Sterilisation with accelerated electrons has been a widespread process for decontamination of medical products, laboratory articles, packaging materials for the pharmaceutical and food industry and other applications for more than 30 years.

The process takes place as terminal sterilisation on the finished product, which is normally hermetically packaged in boxes on a conveyor system passing under the beam. The treatment takes place on one or two sides depending on the density and size of the package units with automatic turning of the units.

External product conveyor system with turning station

Business Activity
Irradiation Services

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Benefits of the process

Electron beam sterilisation is a practically cold process especially well-suited for products which do not permit sterilisation with heat or steam. For many products the process is the quickest and most cost-effective sterilisation process, especially for large volumes. With the service concept of LEONI Studer AG, the manufacturer does not have to make any investments in equipment and no personnel are required for the treatment and testing. Unlike any alternative is the sterilisation process with gas, no toxic and environmentally harmful ethylene oxide is required for the treatment. The products are released parametrically and are available immediately after the treatment without quarantine or degassing times. Unlike sterilisation with gamma rays of cobalt 60, only current is used for the treatment, making the process energy-efficient and environmentally friendly. The energy requirement is significantly lower than for heat or x-ray sterilisation processes.

The process is described in the standard ISO 11137 and is well accepted in the market. It guarantees a high level of safety and reproducibility and achieves the required Sterility Assurance Level of 10^{-6} for sterile medical products.

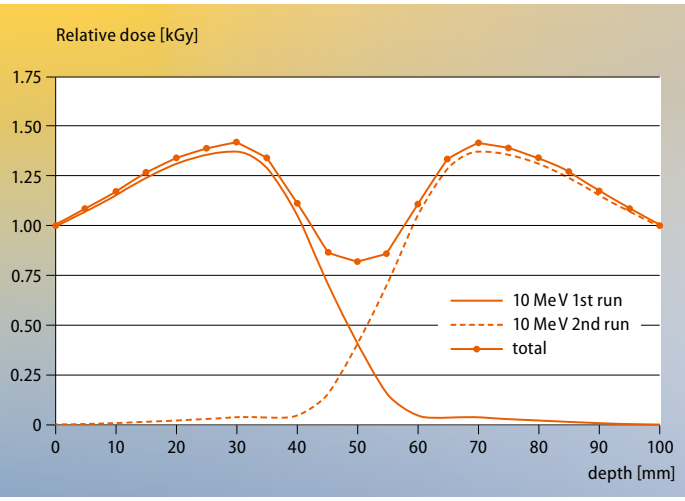
Limitations of the process

Electron beam sterilisation is not suitable for materials that can decompose under the treatment. PTFE, unstabilized PP, or PVC can become brittle or discoloured. However, there are compatible alternatives for many materials. The process is less suitable for solid parts, particularly metallic components, because the usable penetration depth is reached at about 8 cm with double-sided treatment and a density of 1. The process is less suitable for very heterogeneous loads and is not suitable for re-sterilisation of used medical products.

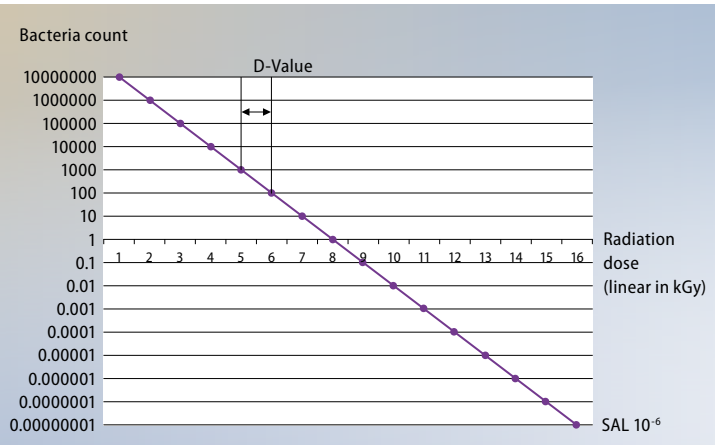
Process validation

The procedure for process validation and approval is clearly defined and easy to perform. LEONI Studer AG will be happy to assist you in the development of new products that can be sterilised with electron beams. The services of the Business Activity Irradiation Services include:

- Determining the optimal box size and configuration
- Inspection of materials for compatibility with the process
- Review of effectiveness by means of biological testing methods (dose audits)
- Grouping of products with the same treatment parameters
- Dosimetric process validation
- Approval and industrial implementation



Dose distribution with double-sided electron beam radiation



Principle of logarithmic elimination rate

Quality certifications

LEONI Studer AG is certified for process validation in accordance with the standard ISO 11137. The company also has certification in accordance with ISO 13485 and 14001. The plant is qualified by means of IQ/OQ/PQ and approved for the treatment of medical devices.

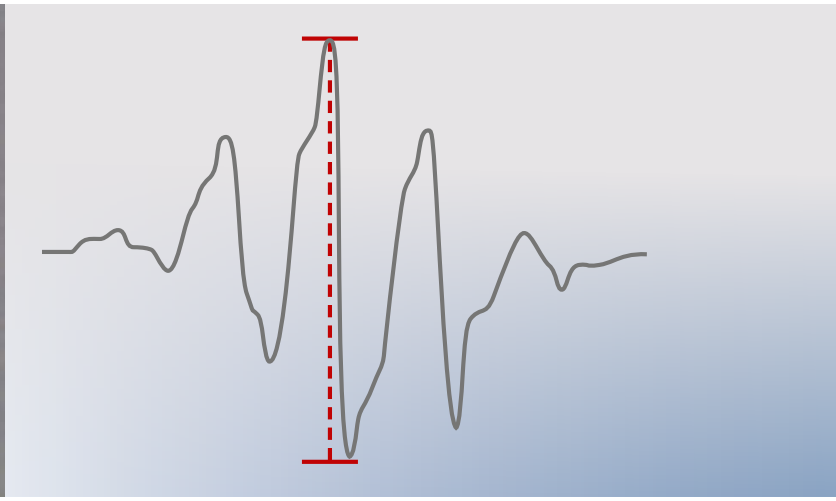
Work takes place in accordance with the European GMP Directives (Swissmedic Certificate available) for pharmaceutical applications and in accordance with FDA 21 CFR part 820 for medical devices.

Validation report

A validation protocol is created and approved with the client, providing a definition of the precise boundary conditions and criteria, as well as the procedure for the process validation. After the validation runs are completed (dose mapping), a detailed report of the results and calculations is created, which defines the criteria and parameters of the routine treatment and is approved together with the client.

Dosimetry

The plant qualification, process validations, and routine monitoring are performed with calibrated dosimetry systems. The alanine dosimetry system in use can be traced back to the British Standard NPL and enables precise measurements of the dose distribution and consistency in the routine process. For validated sterilisation processes the client receives a radiation certificate which documents compliance with the defined treatment parameters and provides evidence on the measured values.



Alanine dosimeter with ESR measuring signal

Find out more:

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