

LEONI Studer Hard, Pioneering X-ray Sterilization

Customer Success Story

LEONI Studer Hard AG is located in Däniken (Switzerland) and offers services sterilization, decontamination and crosslinking services to third parties. LEONI Studer Hard AG is a well known established European player, experienced in **E-beam, gamma and X-ray Irradiation technologies**.



LEONI Facility including the storage area.

WHY X-RAY STERILIZATION?

Up till 2011, LEONI Studer Hard proposed two sterilization services based on two technologies: gamma pallet sterilization and E-beam (box) sterilization.

The decision to use gamma or E-beam sterilization is mainly based on the treatment Dose Uniformity Ratio (DUR) requirement. For small packages of products with limited density, E-beam is the preferred technology since faster processing and more efficient. But for other products packaged on pallets, too dense or with non-homogenous density, E-beam could not make it and gamma was required to achieve target DUR.

Managing a gamma facility is increasingly complex. Regulations are stricter in terms of workers safety and Co-60 transportation, the price of Co-60 is steadily increasing year by year and the local authorities are very uncomfortable with radioisotope based facilities.

On the other hand, customers are requesting more and more pallet sterilization services, with a very uniform distribution of the sterilization dose... which cannot always be done with E-beam.

All these reasons initiated LEONI Studer Hard's reflection of potentially using X-ray as an alternative to gamma sterilization.

The expectations towards X-ray were:

- Become much less dependent on cobalt-60, because of X-rays' ability to adjust power immediately, depending on workload.
- Limiting or even avoiding some years to refill the gamma facility with additional cobalt.
- Having a back-up solution in case of an unexpected issue with one of the sterilization solutions.



X-ray systems have the key advantage of adapting the required power to the facility workload.

WHY IBA?

LEONI Studer Hard's collaboration with IBA is not new. They acquired and are still operating the first Rhodotron® E-beam accelerator from IBA. At that time, the Rhodotron® was new and brought to the market an innovative solution for E-beam sterilization. Over the past decades, the Rhodotron® proved to be a robust machine for the sterilization industry. Even though X-ray sterilization is a new technology, from a technical point of view it is based on IBA's well known Rhodotron®.

But having an X-ray generator is not enough. On top of the accelerator, an equally important topic is the product processing: how will products be presented to the X-ray field. The product conveying system configuration and planning was the result of LEONI Studer Hard AG's many years of experience as well as an in-depth and fruitful partnership with IBA. LEONI Studer brought the industrial experience of large processing facilities. IBA included in the partnership the system optimization experience based on simulations allowing to predict irradiation effects.



eXelis®: IBA's high power X-ray accelerator able to sterilize from 40.000 m³ to more than 150.000 m³ of medical devices per year.

THE SELECTED X-RAY CONFIGURATION

The conclusion of the feasibility study was that the most appropriate solution allowing LEONI Studer Hard to best serve its customers was:

- IBA's eXelis® 1000: the X-ray generator based on the Rhodotron® TT1000 with an X-ray target.
- A 2-level pallet solution using a rolling conveying system designed by LEONI Studer Hard.



The final configuration is an excellent compromise between optimal use of generated X-rays and efficient labor requirements for large facility processing”.

Hans Joerg Hartmann, Managing Director of LEONI Studer Hard AG.

The main characteristics of the designed facility are:

■ Quality

X-ray sterilization simulated Dose Uniformity Ratio (DUR) was much better than typical DUR of 1.45 for Gamma pallet processing.

■ Efficiency

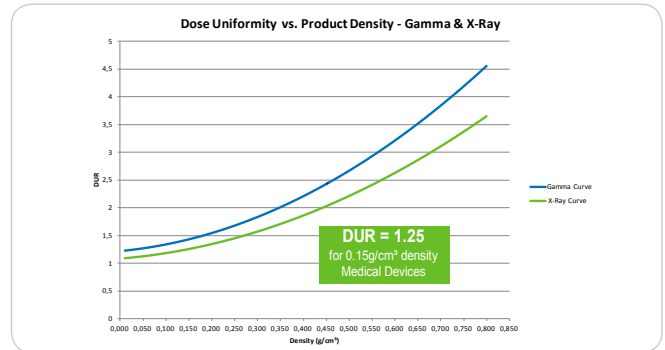
By designing a 2-level conveying system, most of the X-rays are captured by the products. Losses of X-rays are minimized compared with a 1-level conveying system where the products must be over-scanned in order to achieve good Dose Uniformity. Overscanning means “losing” X-rays above and below the products.

■ Flexibility

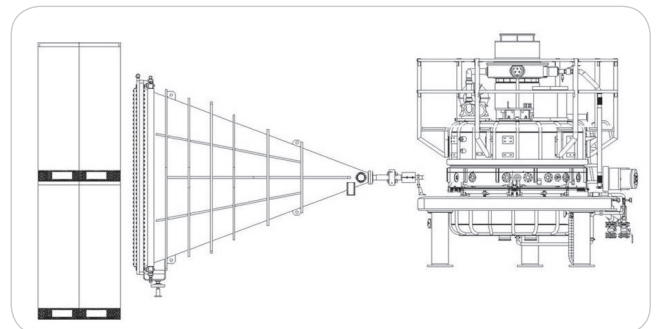
Ability to mix different products with different dose requirements in the same irradiation cycle is possible since the solution is based on an incremental dose concept. One increment consists of four passes of the pallet in front of the X-ray target (pallet irradiated from the top and bottom, front and rear side). The increment dose is the minimum dose the product can receive. Any multiple of the increment dose can be given to the product by adding increments (ie: if increments have a value of 2.5 kGy, 25 kGy can be given to the product with 10 increments).

■ Capacity

Possibility to process very large volumes of medical devices on pallets with minimum labor required.



X-rays' quality of treatment, measured by the Dose Uniformity (DUR), is in average 20% better than gamma sterilization



Two level pallets in front of the beam combine efficient use of X-rays and excellent quality of treatment (Dose Uniformity)



A single row configuration (versus multiple pallet rows in front of the X-ray target) allows mixing multiple product batches with different density and dose requirements.



X-ray sterilization's Dose Uniformity when treating pallets can only be reached with gamma by depalletizing and reloading on totes.

START OF OPERATIONS

DUR as low as 1.25 was measured for products with densities of 0.15 gr/cc sterilized on pallets. This is an improvement of 20% compared with gamma pallet irradiation



IBA's X-ray generator has proven to be very stable. It proved to start up almost instantaneously every morning without any trouble to full power after a full night stop. IBA's experience, the stability and the power of the TT1000 were decisive criteria's which have oriented LEONI Studer Hard's choice towards IBA's X-ray solution".

Hans Joerg Hartmann, Managing Director of LEONI Studer Hard AG.

As part of the system qualification, material tests were performed in order to assess potential product activation. With the collaboration of an official Swiss lab, it was demonstrated that activation was under control and not an issue.

Today LEONI Studer Hard validated the X-ray sterilization technology for several products in commercial use in different fields of sterilization.

OPERATING COSTS

eXelis®, the X-ray generator, is a 700kW peak accelerator powered by electricity. Operational costs depend mainly on the cost of electricity and the yearly production load. Some key advantages of using an electrically powered X-ray machine are:

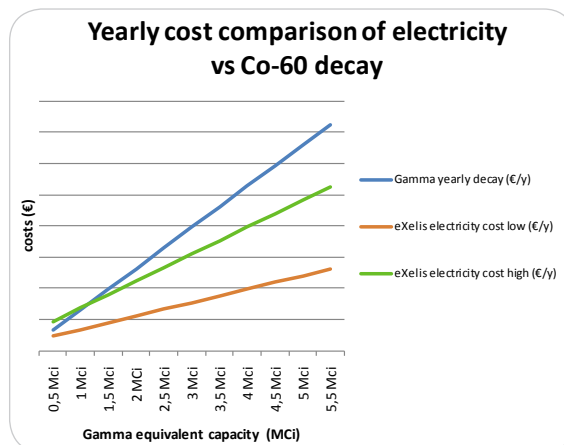
■ Stop electricity consumption when needed

Contrarily to the cobalt natural (unstoppable) decay, you can stop the accelerator and thus its electrical consumption when production stops. With X-rays, electricity is consumed only when required.

■ Electricity at night rate

Plant managers can adapt production planning in order to fit with the most interesting electricity rate offered by the power provider. Many accelerator operators choose to favor night shifts for the main part of their production, due to reduced electricity costs.

Additional operational cost savings can be achieved by capturing the power dissipated by X-ray conversion and re-use this power to heat the building or offices.



By switching off X-rays during non production hours, yearly electricity costs can be reduced unlike Co-60's continuous decay.

ABOUT LEONI STUDER HARD AG

LEONI Studer Hard provides E-beam, gamma and X-ray Irradiation services for partners all over Europe.

www.leoni-studerhard.com

ABOUT IBA

IBA is a leader in electron and proton accelerators for industrial applications. Its unique E-Beam, X-ray and Proton solutions are used across the world in medical device sterilization, food pasteurization, property enhancement, safety and detection, crystal modification.

More than 250 IBA Industrial accelerators are used in the world today, some for more than 50 years.

www.iba-sterilization.com