Electron Energy Brought to Perfection

E-Beam: Continuous tub decontamination with long life and high efficiency electron-beam emitters

Together always one step ahead

SKAN

SKAN, founded in 1968, is one of the pioneer companies in the field of cleanroom equipment and design of isolators for the pharmaceutical industry.

Innovative products, client specific solutions as well as an efficient service organization have made SKAN a market leader and important partner of industry and research laboratories worldwide.

Your needs

- Decontamination on all exterior surfaces of pre-sterilized tubs with nested syringes
- Fast, safe and easy continuous aseptic transfer of pre-sterilized tubs into high speed filling lines
- A system with high stability and low maintenance requirements
- Easy qualification and validation of the whole system
- Highly accepted by the FDA and other inspecting authorities

Our solution

The SKAN electron beam (E-Beam) tunnel guarantees, with more than 25 kGy radiation energy on all surfaces, the sterile transfer of syringe or vial tubs into an aseptic filling line isolator. The tunnel is especially constructed for a continuous process with high throughput of objects. The proven long life emitter technology is the core technology of the SKAN tunnel.

SKAN E-Beam

What is an E-Beam?

When a metal is heated, electrons will be emitted from it`s surface. These electrons form a negative charged cloud around the metal. To accelerate the electrons in a certain direction, an anode formed like a ring is assembled with distance. Then the voltage accelerates the electrons from the cathode in the direction to the anode proportional to the voltage. If this acceleration is strong enough, the electrons fly through the ring anode and hit the target. The electron beam radiation has a mass and a load, which could be either positive or negative.

The whole process takes place in a tube with ultra-high vacuum. With their energy the electrons pass through a window of ultra-thin titanium.

Electron Beam Properties

The DNA (deoxyribonucleic acid) in living cells (micro-organisms) is the main target of the radiation with accelerated electrons (Beta radiation). The major reaction of the DNA on Beta radiation is single- or double strand breaks. This leads to the sudden death of all microorganisms like bacteria, fungi yeast their spores and even viruses.

The penetration of the electron beams in solid material is very little, so there will be no adverse effect on the plastic material of the tub and the syringes.

Features and Benefits

Mechanics

- Easy access to the E-Beam for cleaning, maintenance and fast exchange of the emitters
- Small footprint for space saving (2.4 x 1.2 m)
- Lead shielding in sandwich technology: stainless steel – lead – stainless steel (GMP-compliant, AISI 316L/304, polished to R_a 0.8/1.2 µm)

Functionality

- Smooth and straight tub transport on the same level like filling line with very low particle emission
- Integrated H_2O_2 decontamination system (independent from the isolator)
- Controlled tub transport with
  – position monitoring
  – speed measurement
  – arc handling feature (reprocessing possible)
  – jog-feature (manual transport forward and backward)
- In- and outlet air is HEPA filtered

Processing

- Performance of more than 6 tubs per minute
- Reliable emitter systems with high lifetime (> 8000 hours)
- 25 kGy dose on all outside surfaces for the kill of 10^7 of spores *Bacillus pumilus*
- Unidirectional vertical airflow in the entry section (ISO 7 / class C) and behind the emitter in the transfer area to the isolator (ISO 5 / class A)
- Defined pressure cascade from the isolator in direction to the emitter and the exhaust system

Safety Features

- No detectable radiation after turn off
- 6 mm lead shielding against X-rays
- Sandwich construction of lead, covered with stainless steel, against direct contact with lead
- Parallel shutter system at the entry and exit for perfect radiation shielding
- Byproducts Ozone and NO_X are exhausted securely (TLV-sensors optional)
- X-Ray detection probes optional

Best workmanship with GMP-compliant design

Door sandwich construction for shielding is made of lead covered with stainless steel

Solid construction for maximum safety

Process of the E-Beam

Operation of the E-Beam tunnel

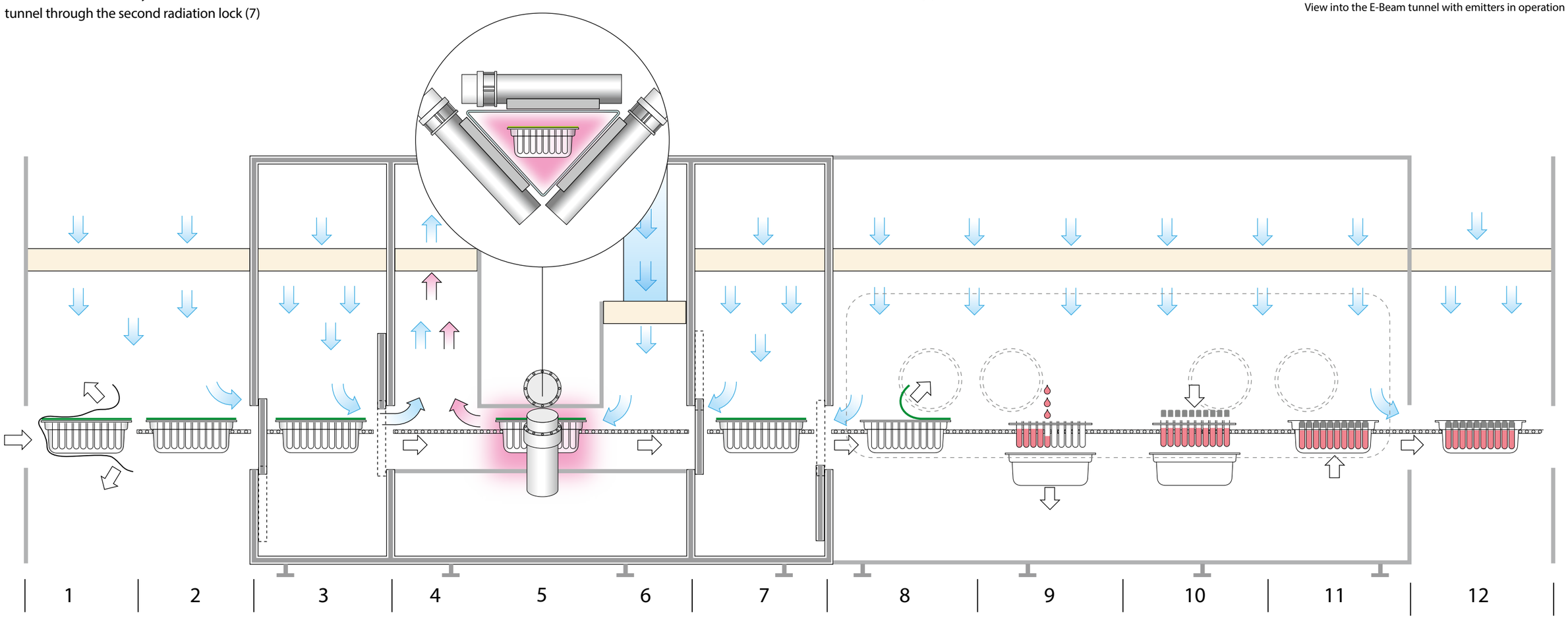
The tubs with the nested and sterilized syringes are double wrapped in PE pouches. They are ETO (Ethylene dioxide) sterilized, so the bioburden on the tub is very low. After the two outer pouches are removed in front of the tunnel entry (1) the tub is still closed by a Tyvek® lid (2). The tub is moved by a conveyor system into the entry section (radiation lock) of the E-Beam (3). When it is completely transferred in the first chamber of the tunnel, the outer door closes automatically and the inner door opens (safe parallel shutter system). Then the tub moves to the emitter zone, where it gets the necessary radiation dosage of more than 25 kGy from three sides (5). Three electron beam emitters are placed in a triangle, so that all surfaces of the tub can be sterilized by the radiation. The tub leaves the tunnel through the second radiation lock (7)

Airflow in the E-beam tunnel

The inlet and outlet air of the SKAN tunnel is completely covered by HEPA H14 filters.

The inlet air is blown into the SKAN tunnel through the entry (3) and exit chamber (7) (radiation locks) and directly into the E-Beam tunnel after the electron beam process (6). At all three air inlet positions, there is a unidirectional airflow.

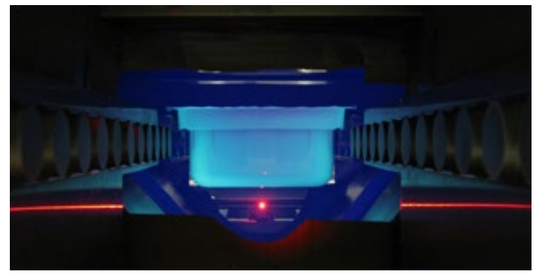
During the E-Beam process byproducts can be generated. The contaminated air has to be kept away from the isolator, where the open product is handled. A pressure cascade within the SKAN tunnel, between environmental room and attached isolator, guarantees, that no particles enter the isolator and no contaminated air enters the surrounding environment. The outlet air with Ozone and NO_X is sucked into the exhaust air system between entry chamber and emitter installation (4).



H_2O_2 Decontamination of an E-Beam tunnel

The E-Beam tunnel (4–7) is decontaminated by vaporized H_2O_2. During the decontamination process the outer doors and the ventilation flaps of the tunnel are automatically closed and hermetically sealed. There is a recirculating air flow in the decontamination chamber and the tub exit to ensure that all surfaces are reached. The hydrogen peroxide vapour is created directly inside the air handling system of the E-Beam tunnel. The H_2O_2 vapour is recirculated by the air blowers (4) into all E-Beam tunnel chambers.

For aeration, the ventilation flaps are opened and the H_2O_2 is exhausted until a safe concentration is reached. The decontamination of the tunnel is possible either independently or together with the isolator for the filling line (8–11).



View into the E-Beam tunnel with emitters in operation

Emitter Technology by Comet

COMET, founded 1948, has developed a new generation of small, highly compact e-beam emitters with an accelerating voltage range of 80 to 180 kV and treatment widths of up to 600 mm. The EBA series of e-beam emitters is based on the proven high voltage design of COMET's metal ceramic X-ray tubes and is highly reliable with proven lifetimes.

- Easy to handle non-scanning emitters
- Easy access for the exchange of the emitters
  - Only 20 minutes for each emitter
  - Possible by own personal
  - Very low downtime due to high lifetime and quick exchange
- Online dose monitoring optional

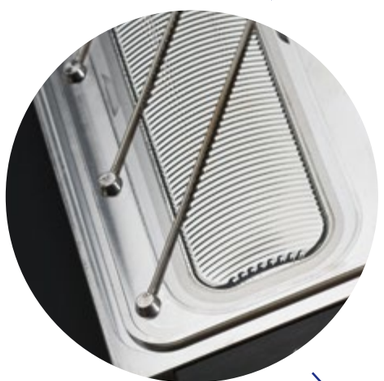
COMET Emitter

High reliability, long life

> 8000 hours achieved in lifetime test with 10 emitters

High performance, high efficiency

- Optimized electron optics
- High optical transparency of exit window



Low arcing rate

Time between arcs
> 10000 hours at 80 kV
> 100 hours at 160 kV

Corrosion protection

Special corrosion protection (also for vaporized H_2O_2)

Dose stability

Beam intensity variation is less than +/- 10 % over length of exit window and over time

Sensor for on-line dose rate measurement

- Several sensors over length of window
- Simplifies FDA approval

E-Beam qualification

SKAN´s qualification department is the knowledge centre for a successful qualification. All steps are according to state of the art standards like EN/ISO 11137 part 1-3, regulations USP <1211> and Ph. Eur. Chapter 5.1.2.

Dosimetry

On the tub surface the radiation measurement is performed with film dosimeter Riso B3. The applied dose is proportional to the colour change and is analysed by spectrometry. If requested, the radiation dose below the Tyvek® cover can also be analysed.

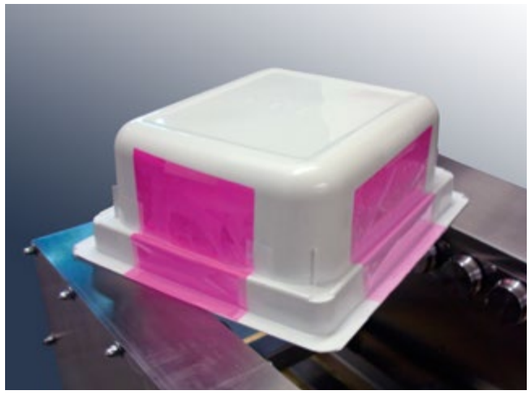
Kill kinetic

SKAN experts use bioindicators with spores of *Bacillus pumilus* 10^7 spores per carrier in consecutive trials to determine the correct radiation dose.

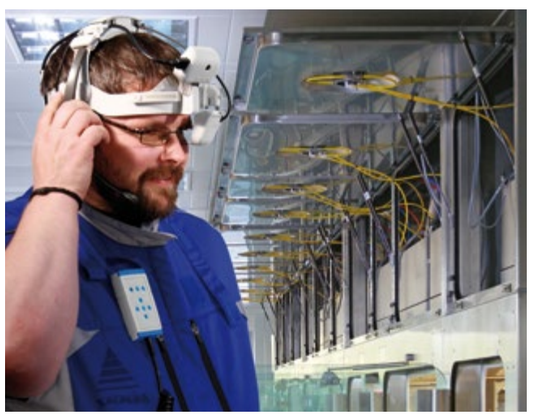
Residuals in tub and syringes

During the e-beam process, byproducts can be generated inside the tub and the syringes. SKAN in house experts can support with equipment and chemical analyses (check of concentration) and can give recommendations to the customer.

Electron emitter in operation



Colour change after dosimetry



Service

SKAN´s responsibility does not stop with delivery. There are several services offered to keep the equipment reliable and the use comfortable:

- Training of operators and service personnel by SKAN Academy
- Scheduled preventative maintenance
- Central spare parts contact
- Technical services utilizing a variety of support tools
- Life cycle partnership

Isolator Technology

The experts in our Industrial Division manage the engineering, design, fabrication and validation of your pharmaceutical isolator process solution.

Lab Equipment

Our Lab Division is specialised in ensuring the safety of the user, the product and the surrounding environment in your laboratory and cleanroom.

Together always one step ahead

Together with our team of employees, our partners, our suppliers, and together with you.

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