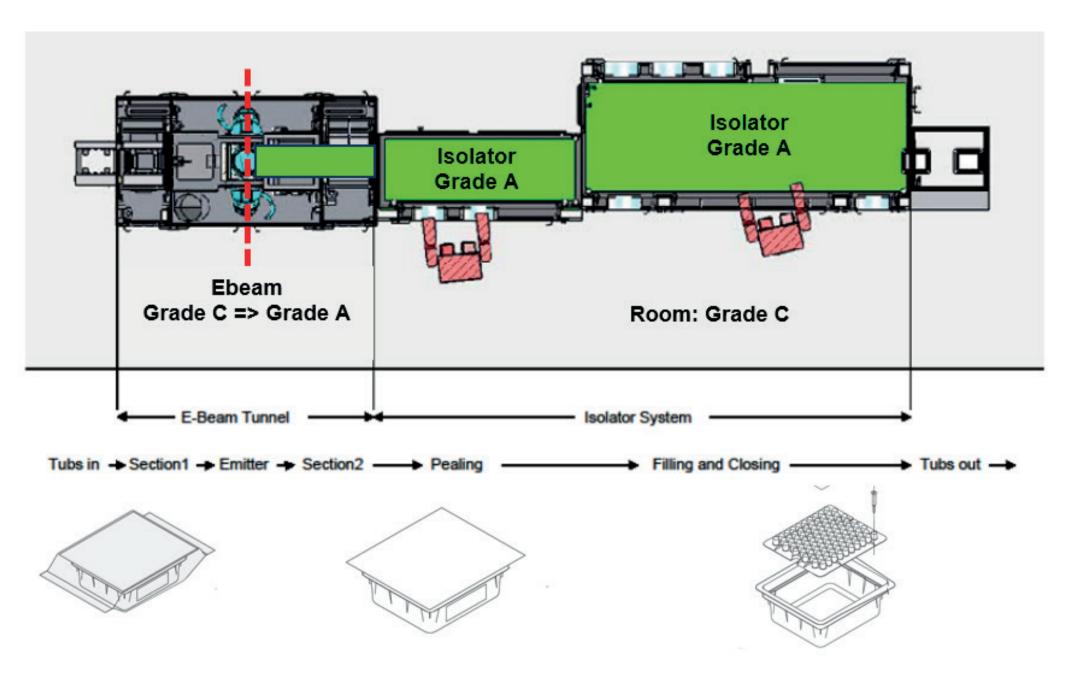
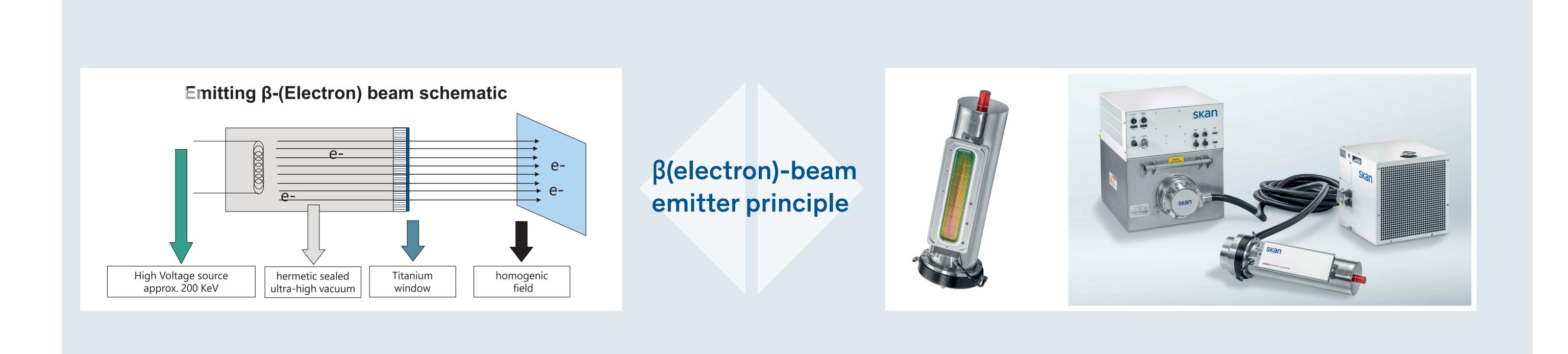
## ebeam – a transfer process



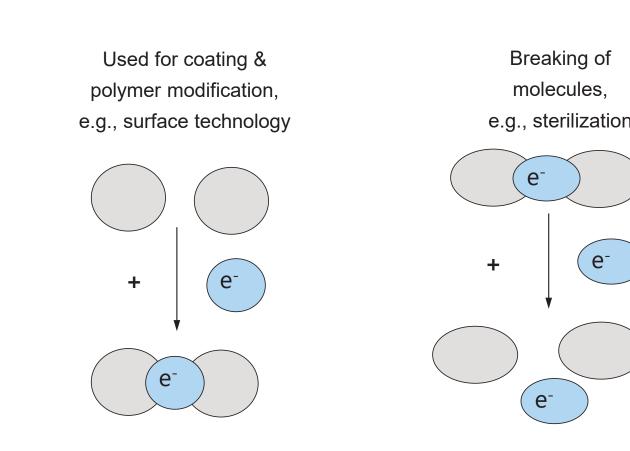
With increased demand on sealed packed, pre-sterilized ready-to-use (RTU) components like Syringes & Vials, the ebeam technology is used as transfer technology with surface decontamination for transfer of the RTU in a Grade A environment like an Isolator.

# Annex 1 – transfer of equipment & materials

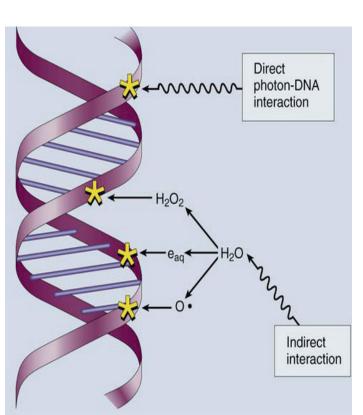
4.10 The transfer of equipment and material to and out of the cleanrooms and critical zones is one of the greatest potential sources contamination



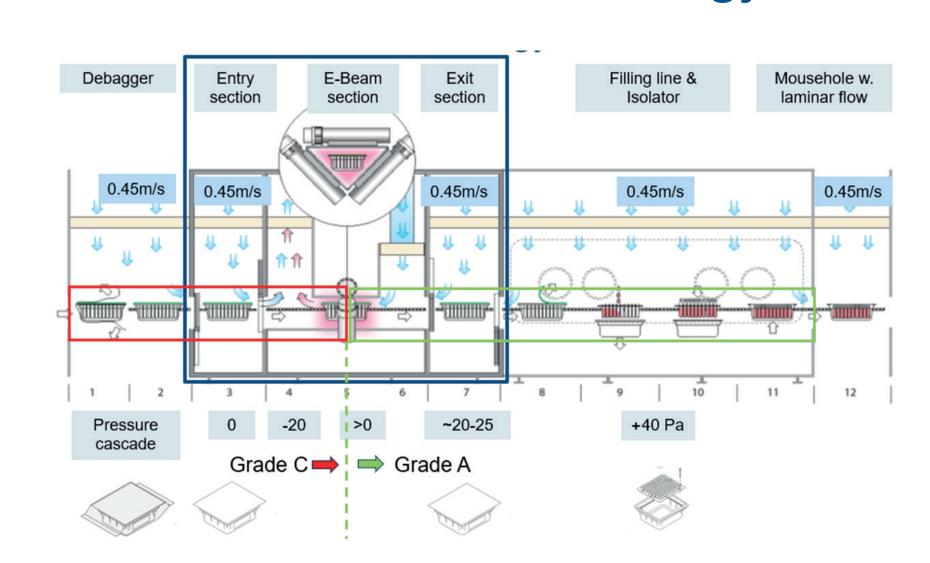
# **Properties of \beta(electron)-beam systems**



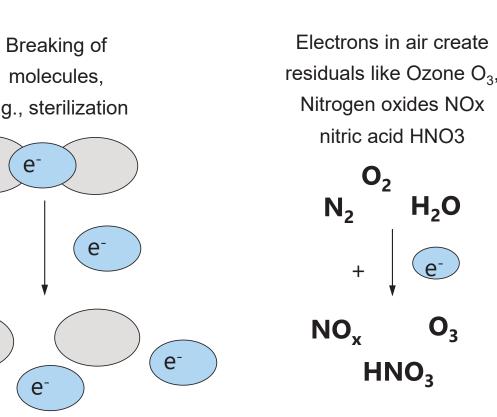
- ionized radiation damages the DNA and leads to cell death Energetic electrons destroy all types of pathogens like Viruses, fungi, bacteria, parasites, spores  $\rightarrow$  the damage is proportional to the dose  $\rightarrow$  Unit of the dose is
- Gray [Gy] = [J/kg]
- → Kilo Gray [kGy]



Any activities with the potential to compromise the cleanliness of cleanrooms or the critical zone should be assessed and if they cannot be eliminated, appropriate controls should be implemented.



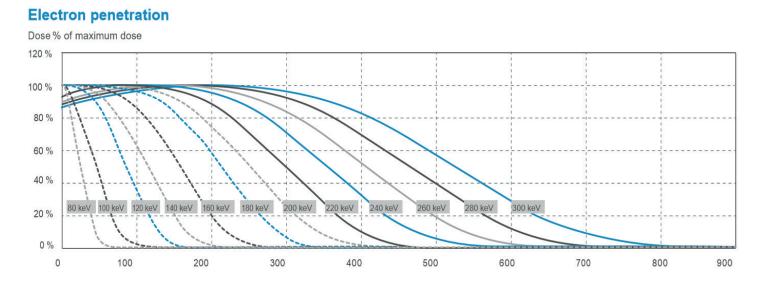
ebeam – a transfer technology



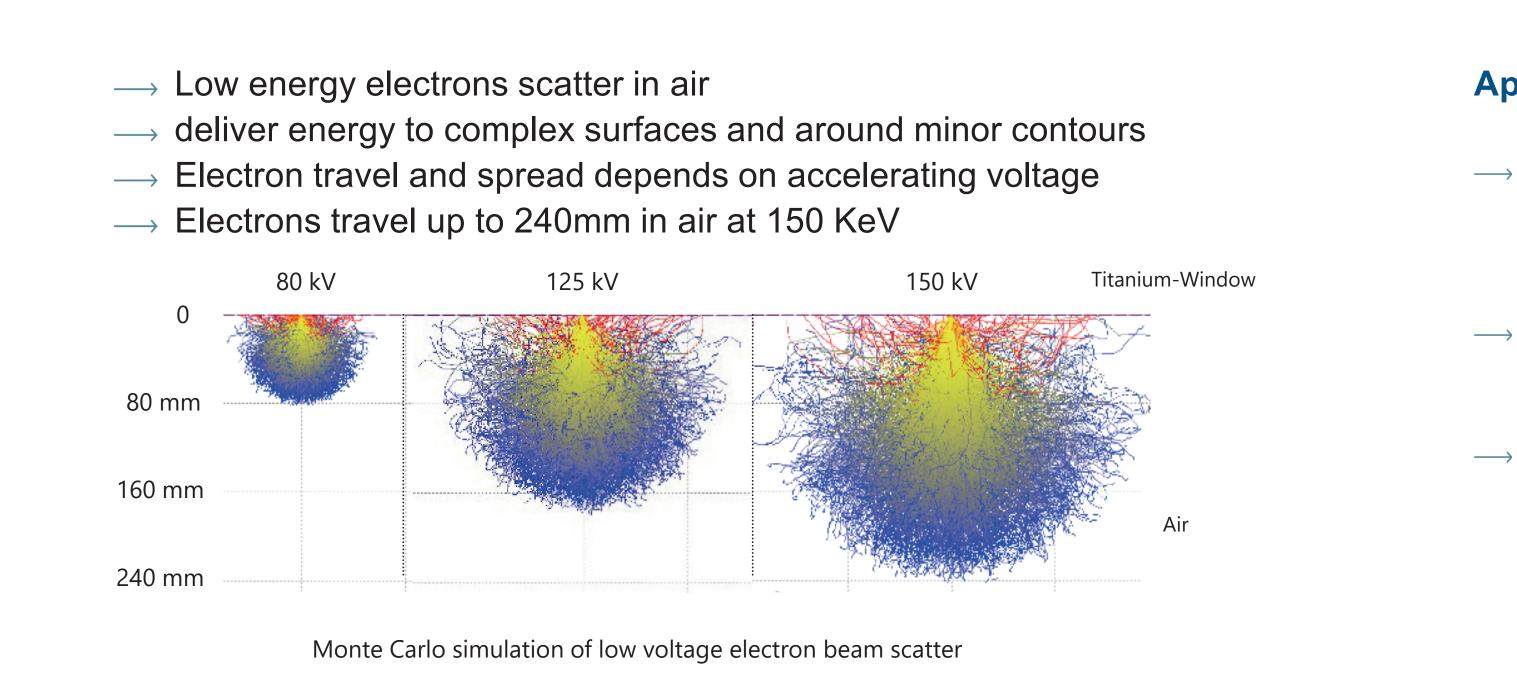
Ionized electron beams have

 $\rightarrow$  a strong biological kill effect

 $\rightarrow$  no deep penetration (low energy ebeam systems e.g., <300 kV)  $\rightarrow$  loose most of their energy on the surface and in a thin layer under the surface E.g., with 300KV electron penetrates 0.5mm deep in water



# ebeam technology – transfer technology for pre-sterilized RTU components



#### **Regulations & Guidance**

- → EN/ISO 11137 "Sterilization of health care products Radiation" - method 1: Dose will be based on the amount & resistance of the bioburden method 2: a sterilization dose of 25 kGy (15kGy) will be applied and verified
- → USP <1211> "Sterilization and Sterility assurance of compendial Articles"  $\rightarrow$  Ph. Eur. Chapter 5.1.2 "Ionising Radiation Sterilisation"

### Industry standard

→ Industry Standard Acceptance Criteria: ≥25 kGy

#### Dosimetry target

 $\rightarrow$  25 kGy at each position outside on the surface of the RTU object

# Validation of the dose of β(electron)-beam systems

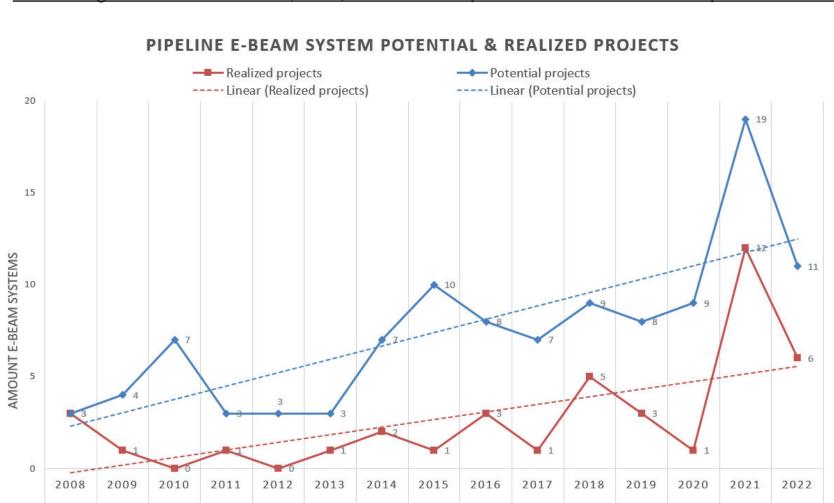
# History & Trend of RTU ebeam systems

#### **History:**

- > First ebeam system installed in 2000, FDA/EMA inspected, still in production (vaccines)
- > 80 ebeam systems are worldwide installed for RTU pre-sterilized syringes & vials
- > 80% of the ebeam systems are for filling line's with a speed of > 200units/min (estimate)

#### **Outlook:**

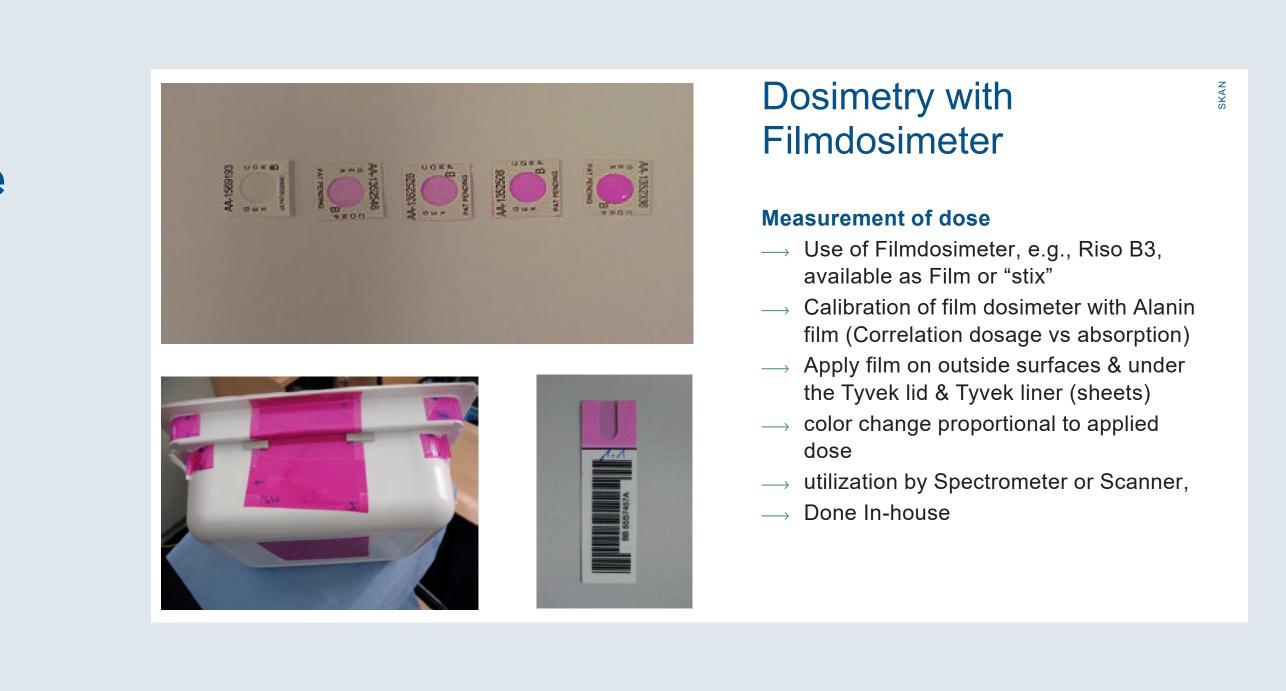
> Increasing demand for syringe filling lines for RTU pre-sterilized syringes > Increasing demand for flexible filling lines with capability to fill RTU pres. syringes or vials Increasing demand for reliable, safe, Annex 1 compliant transfer of RTU components in Grade A





#### Applied Dose depends on: Voltage (keV) - Current (mA) – Exposition time (s)

- The Voltage (keV) is responsible for -the penetration depth of the dose —how far the electrons travel
- → The Current (mA) is responsible -for the level of the dose
- $\rightarrow$  The **Dose (kGy)** on tub surface is a function of:
- -applied Voltage (keV)  $\rightarrow$  electron to reach furthest point on tub
- -current (mA)  $\rightarrow$  responsible for the level of the dose
- -Exposition time (s)  $\rightarrow$  proportional to the speed of the Tub



# Annex 1 - Sterilisation

8.47 Where materials, equipment, components and ancillary items are sterilised in sealed packaging and then transferred into grade A, this should be done using appropriate validated methods (for example, airlocks or pass-through hatches) with accompanying disinfection of the exterior of the sealed packaging.

## ebeam - Conclusion

ebeam is the only continuous transfer technology for RTU components into Grade A with a > 6 log bioburden-reduction (decontamination).

ebeam is today a reliable, reproducible & validatable transfer method.

ebeam – fulfils the required «No Risk Transfer»

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