E-beam and X-ray: Why? What? How?
Introduction & Agenda

- **Agenda:**
  - We are investing to supply and service a growing market
  - E-Beam and X-ray are complementary solution that are financially viable
  - Mevex and IBA are there to help you to move from an idea to a real project
  - Still some challenges to adoption of E-beam and X-ray
WHY? Market Situation & Complication

Complication:

- Increasing pressure on Co60 (Price, Supply, Security, …)
- Increasing pressure on EtO (Environmental, residual, …)
- Other (more specific): Product complexity, logistics, business model, …
Market Situation in 10 years…?

Today

In-House (~40%)
Service (~60%)

ETO (~60%)
Gamma (~35%)
EB & XR (~5%)

~ 1,500 MCi

In 10 years

- Volume of EO and Gamma versus E-beam and X-ray?
- Split between in-house and Service contractors?
- Medical devices market growth?
- Split between E-beam and X-ray?
Market Situation in 10 years… What if…

**What if, Only 40% in ETO, 25% in Gamma and 5% market growth?**

\[ 35\% \text{ of } 2,400\text{MCi} = 840\text{MCi} \ldots \]

\[ \sim 280 \text{ systems of } 3 \text{ MCi} \]

**What if, Only 35% in ETO, 20% in Gamma and 7% market growth?**

\[ 45\% \text{ of } 3,000\text{MCi} = 1,350\text{MCi} \ldots \]

\[ \sim 450 \text{ systems of } 3 \text{ MCi} \]

**What if, Only 30% in ETO, 30% in Gamma, 10% other modality and 5% market growth?**

\[ 25\% \text{ of } 2,400\text{MCi} = 600 \text{MCi} \ldots \]

\[ \sim 200 \text{ systems of } 3 \text{ MCi} \]

200 to 400 systems over the next 10 years
EB and XR adoption is accelerating over the last 4Y

Mevex and IBA Order Intake 5MeV+ for period of 2005-2015 and period of 2016-2019

- 6.5 MW over the last 15 years
- 4 MW over the last 4 years
- 2005-2015: Average of 4 Systems / year
- 2016-2019: Average of 12+ Systems / year

Build up the capacity – Resources & Technology
X-ray and E-beam are complementary technologies

Different customer profile, with different products…

Each case has a preferred configuration
Is X-ray viable? Many parameters to consider…

- Some info:
  - For Medical devices:
    - Min dose: 25 kGy
    - Average product density: 0.15 g/cm³

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<th>Electricity costs [$/h]</th>
<th>210 kW</th>
<th>540 kW</th>
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<td>[40 – 60]</td>
<td>[90 - 110]</td>
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*8000h; 0.1$/kW

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<th>Throughput [m³/h]</th>
<th>210 kW</th>
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<td>[2 – 4]</td>
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- At 100kW Opex are spread as follow:
  - 25% Elec, 55% Labor, 20% Others

- At 500kW Opex are spread as follow:
  - 60% Elec, 25% Labor, 15% Others

- Some question:
  For a 200 kW to 500 kW X-ray facility, Over a period of 10 years, what’s the impact on the cost per m³ of:
  - A CAPEX increase of $ 5M ?
    → $2 to 3
  - A extension of the ramp-up period from 3 to 7 years?
    → $5 to 15
  - An increase of the kW/h from 0.1 to 0.2?
    → $10 to 15
  - Running the plant in 2 shifts instead of 3 shifts?
    → $15 to 35
X-ray versus Gamma – Is the Capex higher?

- For a 5MCi equivalent
Hurdles to adoption

- **Real hurdles**
  - Existing gamma infrastructure
  - Lack of x-ray infrastructure
  - Lack of experience within medical device companies

- **Perceived hurdles**
  - Regulatory hurdles – standards already exist, FDA has pathways for transition
  - Experience with equipment - Daniken has been running 10 years, x-ray uses e-beam which has been in use decades more
Keys to success

- Leverage existing infrastructure where possible
  - Ramp up machine source with decay
- Leverage multiple modalities when possible
  - Use e-beam for efficiency
  - Use x-ray for products that can’t be treated in e-beam due to penetration
- Compatibility needs to be established
  - X-ray will be gamma compatible 99.99% of the time
  - E-beam may have differences in material properties and heating
What is happening today

- X-ray capacity is being built in Europe and North America
  - Multiple sites will allow for more adoption vs single source
  - More opportunities for product testing
- Mevex and IBA are investing in new technologies and capacity in order to meet current and future demand for equipment
  - Risk is mitigated because high power solutions already exist or are built on existing platforms
  - Industry “ramp-up” requirement due to lack of cobalt availability is matched by Mevex and IBA capabilities
What are we doing as an industry?

- Support collaborations like Team Nablo (IBA and Mevex both members)
- Partnering with service providers to make more testing facilities/resources available
- New guidance being written on transitions between radiation modalities through AAMI WG2
- Follow up from Kilmer collaboration on Modality Changes and Process Optimization
  - Support for publications
  - Identify training gaps and opportunities
  - Provide support for FDA tools
- FDA challenge to spur alternatives to EO
Conclusions

- The market has spoken – e-beam and x-ray capacity is growing
- There is a value proposition for each sterilization technology, but availability trumps economics in a supply constrained market
- The transition is happening now – and we can all help to make it easier

THANK YOU
Where can I learn more about e-beam and x-ray?

- Texas A&M eBeam Workshop, College Station, TX [ebeam-tamu.org/ebeam-workshop](http://ebeam-tamu.org/ebeam-workshop)
- GEX training workshops – [www.gexcorp.com](http://www.gexcorp.com)
- Sterigenics and Nelson Labs training [sterigenics.com/events/](http://sterigenics.com/events/)
- IMRP (International Meeting on Radiation Processing), 2021 Bangkok, Thailand [imrp-iiia.com](http://imrp-iiia.com)
- iia Membership/ website [www.iiaglobal.com](http://www.iiaglobal.com)