Getting from *Basic Safety and Essential Performance* to *Safety and Effectiveness: IEC 60601 series*

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ANSI

Background to the IEC 60601 series - *Basic Safety and Essential Performance* to *Safety and Effectiveness*

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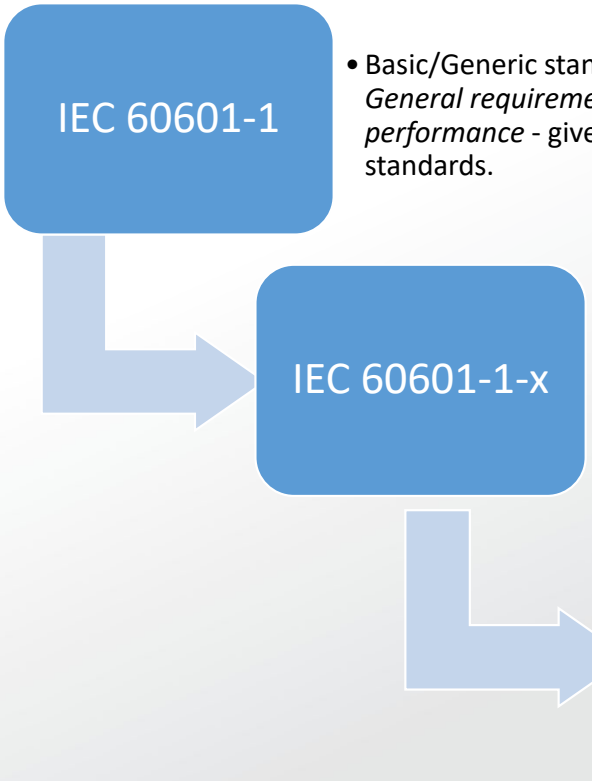
Background and Intent

- What is the IEC 60601 series?
- Where and how was it developed and supported?
- Why is the IEC 60601 series important to the medical electrical equipment industry and regulatory?

IEC 60601 series standards - General and Particular requirements for basic safety and essential performance for MEE



- Basic/Generic standard. *Medical electrical equipment - Part 1: General requirements for basic safety and essential performance* - gives general requirements of the series of standards.
- Collateral Standards. Define the requirements for certain aspects of safety and performance, e.g. Electromagnetic Compatibility (IEC 60601-1-2) or Protection for diagnostic use of X-rays (IEC 60601-1-3)
- Particular standards. Define the requirements for specific products or specific measurements built into products.

Standards and the FDA: Getting from *Basic Safety and Essential Performance* to *Safety and Effectiveness*

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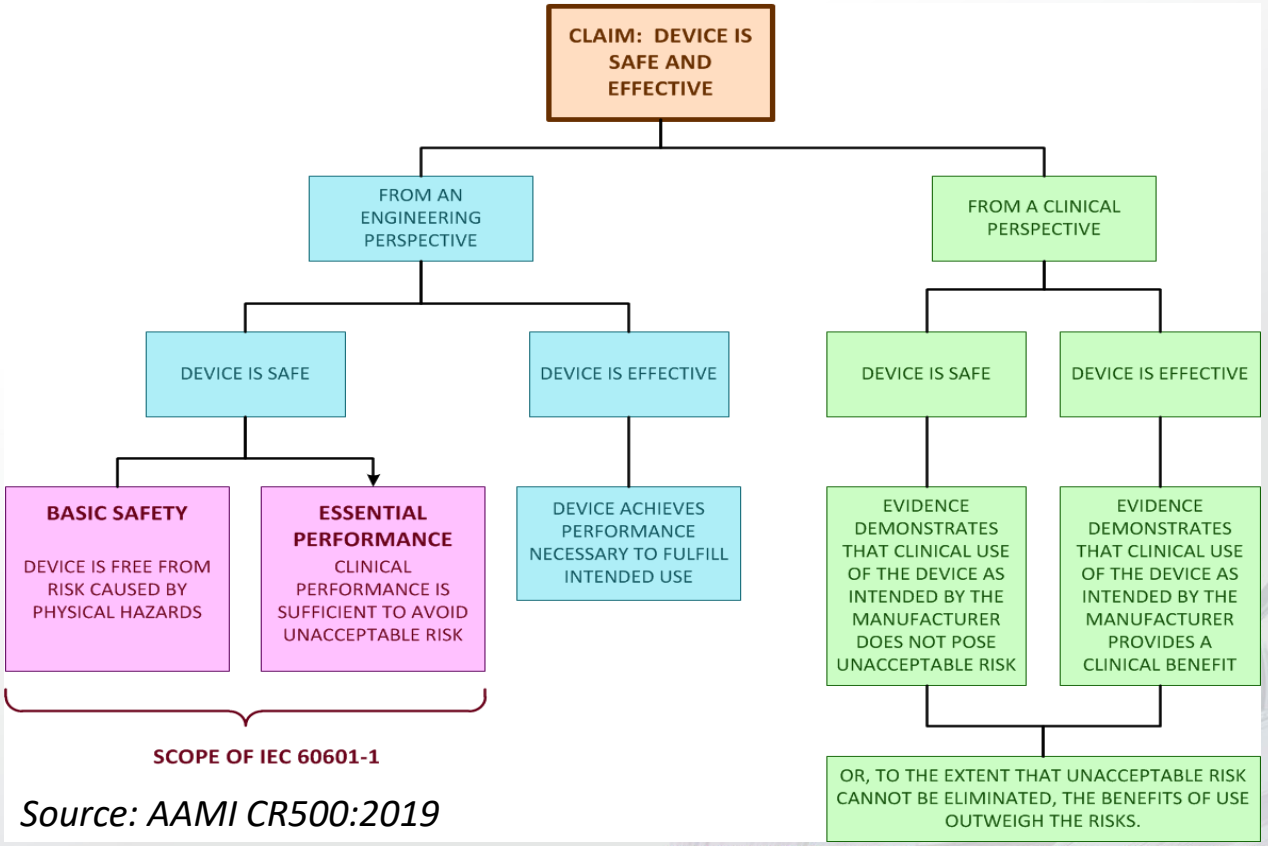
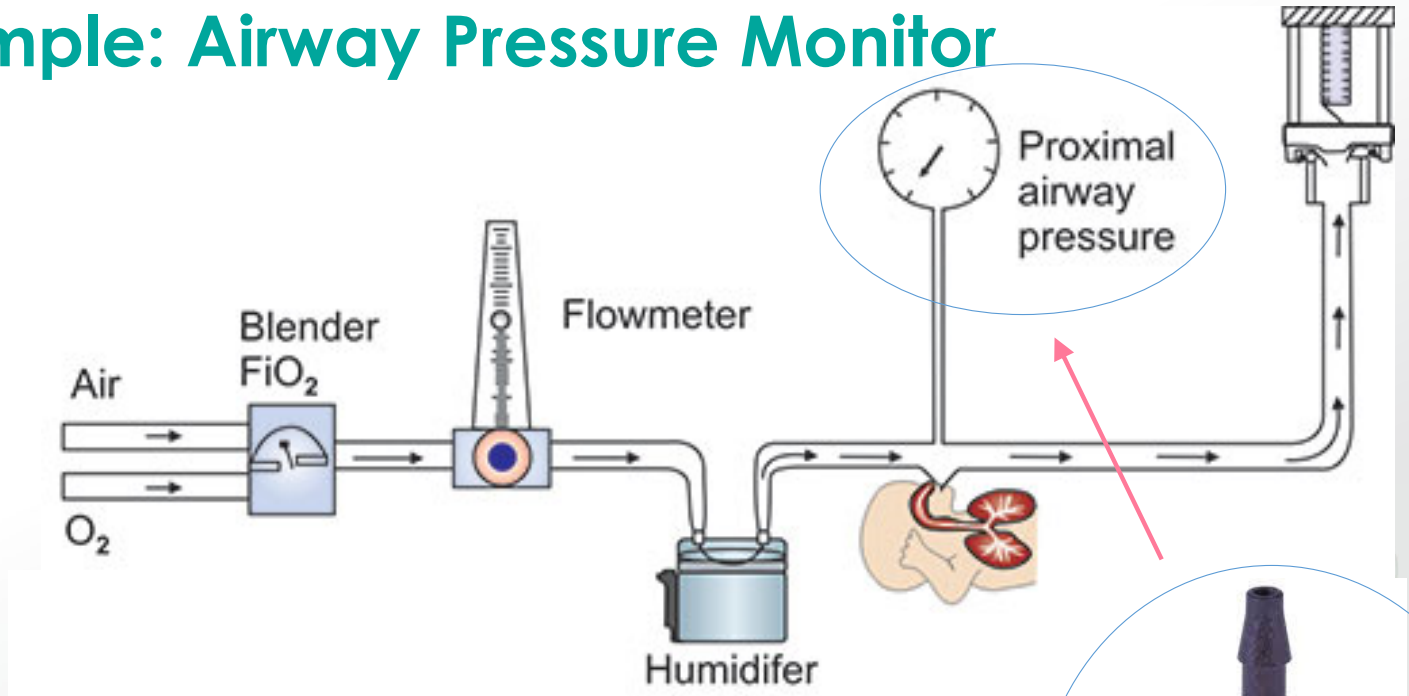
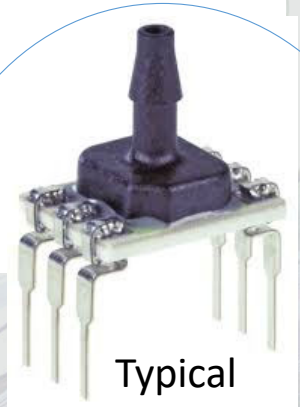
Device Safety and Effectiveness



Source: AAMI CR500:2019

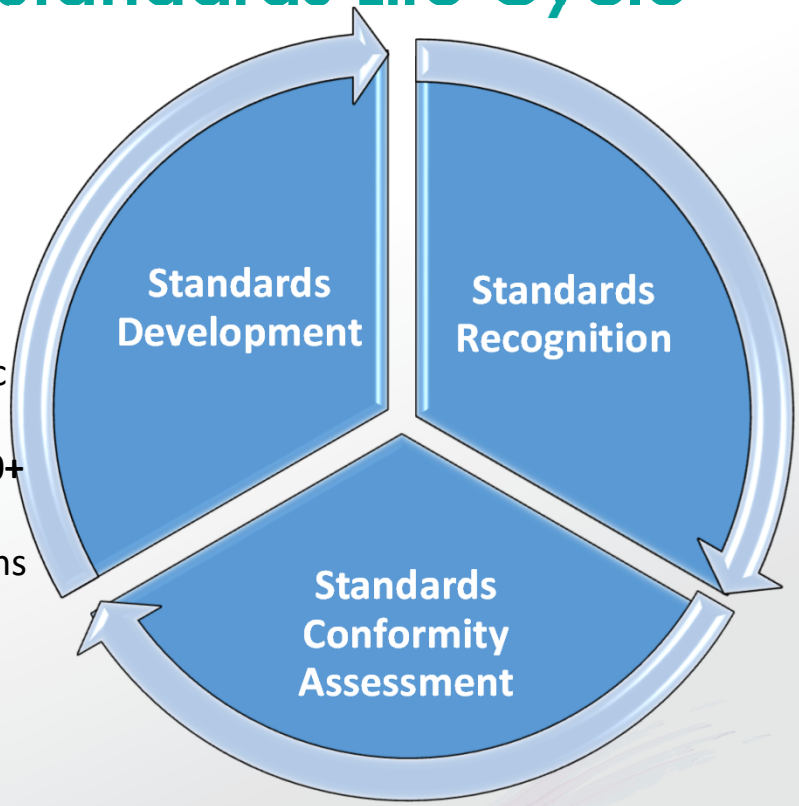
Example: Airway Pressure Monitor





Typical
pressure sensor

Managing Total Standards Life Cycle



Standards Development

- **17** internal advisory Specialty Task Groups (STGs) in **23** device/scientific areas
- **400+** CDRH staff participating in **600+** standards committees across **29** standards development organizations

Recognition Program

- **~1400** recognized standards
- 5-10% annual increase in new standards development activities
- Average of **7 (range of 1-35)** standards cited in each 510(k)

Standards Conformity Assessment

- Enhance the use of declarations of conformity in device submissions
- ASCA Pilot program

Use of Consensus Standards in CDRH

- Premarket
  - Voluntary *
  - In **any type** of submission
  - With a declaration of conformity (recognized standards only), General Use (any standards, recognized or not) or both.
- Postmarket
  - Root cause analysis for MDRs.
    - Example: Test method & acceptance criteria
  - Works to mitigate a post market risk, AAMI ES60601-1
    - Example: Prevents lead wear connection to an AC mains supply

*Only mandatory if Incorporated by Reference, e.g., 21 CFR 801 incorporates ASTM D3492

Key Takeaways

- Engineering safety standards (IEC 60601 series) provide a good evaluation protocol for medical electric devices' basic safety and essential performance.
- Regulators benefit from the use of standards to review devices' safety and effectiveness.
- FDA/CDRH's total standards lifecycle management promotes the use of voluntary consensus standards in regulatory process.