Development of a Pacemaker Re-use Programme: Evaluation

Thomas C. Crawford, MD, FACC, FHRS

The University of Michigan
Ann Arbor, MI, USA
Pacemaker Reprocessing Workflow

• PPM Receipt, Initial Battery Estimate
• Decontamination with Enzol solution
• Further Electrical Screening with Test Load
• Seal Plug and Set Screw Removal
• Second Decontamination with Enzol solution
Pacemaker Reprocessing Workflow

• Re-insertion of Set Screws
• Detailed Functionality Testing
• Seal Plug Replacement and Dipping in Silicone
• PPM Interrogation
• Packaging
• Sterilization
• Storage
Industry Standards:

- AAMI TIR30: 2011 A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices
- US Pharmacopeia and National Formulary <643> Total organic carbon
Process Validation

• Destructive Tests

• Non-destructive Tests
Destructive Testing: Cleaning and Sterilization
Process Validation: Cleaning and Sterilization

• Bio-burden Testing
• Protein and Hemoglobin Residuals
• Total Organic Carbon Residual
• Cytotoxicity
• Intracutaneous reactivity
• Pyrogenicity
• Ethylene Oxide and Ethylene Chlorohydrin Residues
Destructive Testing: Cap Integrity and Electronics
Screw Cap Pull Test

• PASS/FAIL 227 grams-force (gf) or 0.5 pound-force (lbf)
• 29 devices (MDT, SJM, BoSci) reprocessed and unprocessed – no difference

Custom pull test fixture
Extech Model 475040 Force Gauge
Destructive Testing: Hi Pot Test
Hi Pot Test

54 screw ports from 28 pacemaker headers were tested. All resistance measurements met the standard < 50kΩ.

ISO ISO5841-3:2013(E) Implants for surgery -- Cardiac pacemakers -- Part 3: Low-profile connectors (IS-1) for implantable pacemakers
Non-destructive Testing: Electronics and Functionality Testing
Functionality Testing: Key Equipment

- Programmer
- Oscilloscope
- Heart Simulator
Heart Simulator Synthesized Waveform
Functionality Testing

- Battery Voltage
- Battery Impedance
- Magnet response
- A/V lead impedance
- Base A/V pacing rate
- A/V pulse amplitude
- A/V pulse width
- A/V sense test
- AV/PV delay
- A/V refractory period
- PVARP
- Max sensor rate
- Max tracking rate
Packaging

Double Tyvex Pouches, one inside the other

Hard boxes with foam to absorb shock during shipment
Packaging Validation

• Bubble Leak, Burst, Dye Penetration Tests
• Peel Strength Test
• ISTA 2A Type Shipping Simulation
• Climatic Stressing Test (ASTM F2825-10)
Everything Happens Per Protocol
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Cleaning

• Soaking in a solution of 8 oz. of Enzol enzymatic detergent in 8 gallons of 85°F±10°F house water.
• Wiping and brushing, including use of pipe cleaner, 5x magnified glass
• Pressure rinse
• Emersion soak rinse
• pacemaker, set screws, and seal plugs were placed in the Vacuum Drying Chamber and dried in a vacuum at 35°-50°C for seven hours.
Sterilization

• Steri-Vac™ 8XL Sterilizer chamber (3M™, St Paul, MN)
• Chamber Temperature 55°C+/- 3°C
• Relative Humidity: 70% minimum
• Pressure: Gas canister puncture below 160 mBar
• Negative Pressure held between 450 and 650 mBars after gas canister puncture
• Time 1 hour on 100% EtO
• Aerated for 12 hours
• Biological Indicators as controls