



NEUROPACE RNS NEUROSTIMULATOR SYSTEM

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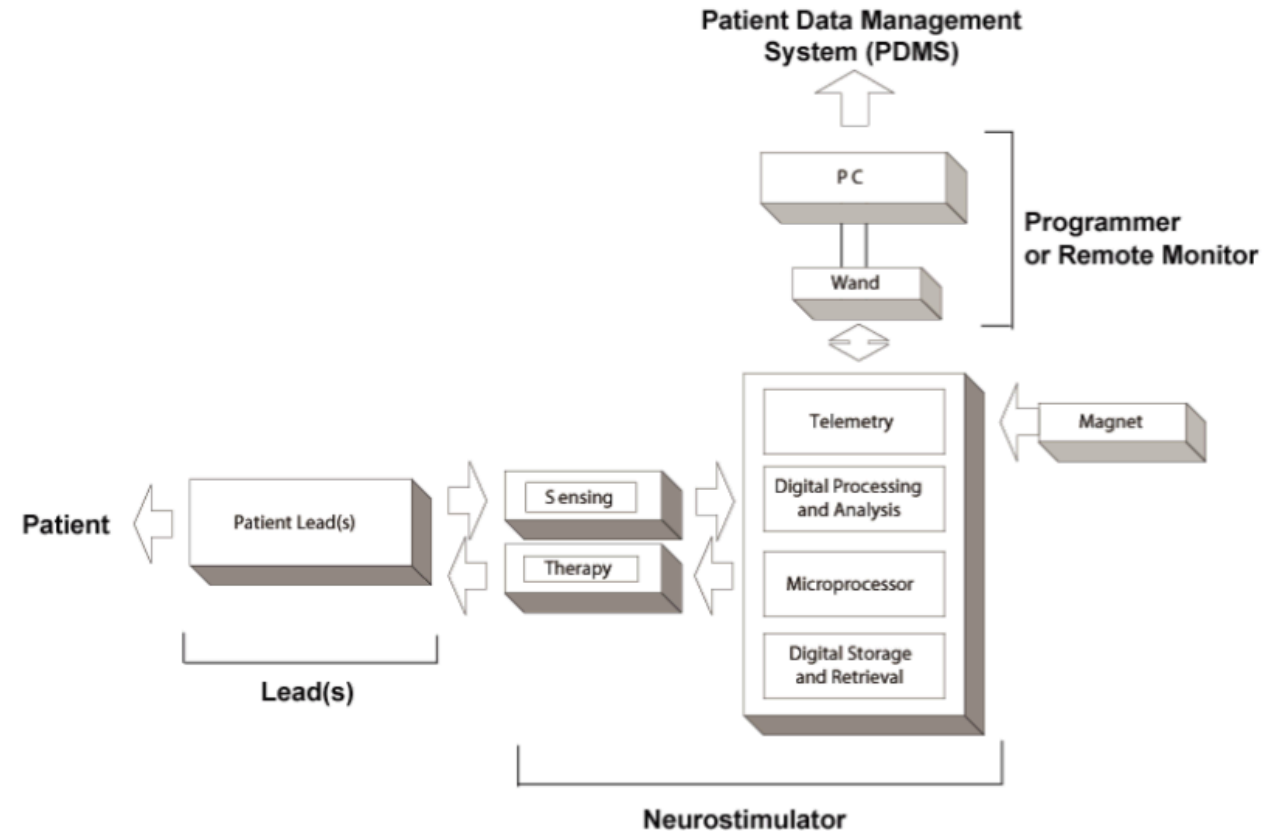
Outline

- Analog, mixed and digital system design
- Microfabrication, system integration, packaging, implantation and biocompatibility
- Reliability, safety and security
- Clinical and regulatory considerations
- Conclusion



System-level design

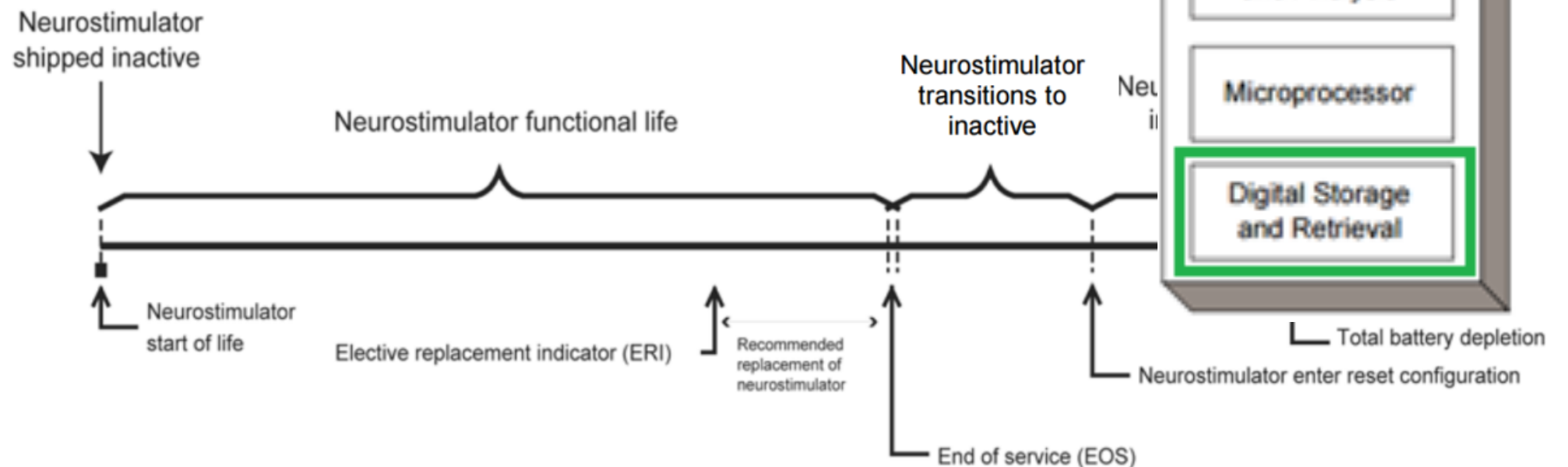
- Control
 - Telemetry
- Memory
 - Digital storage
- Functional
 - Processing
 - Microprocessor
- Trade-offs





Memory and processor

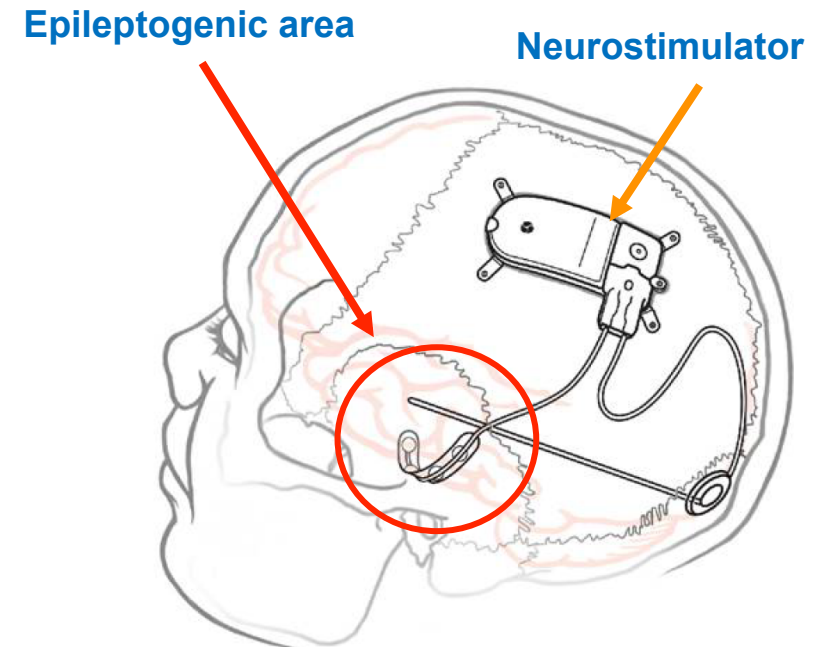
- RNS: **responsive**. No high, medium, low operating settings
- RNS can be in **Active, Reset or Inactive** mode
- Memory: up to 28 kb





Implantation

Part of Device	Area	Implantation Technique
Neurostimulator	Cranium	ferrule mechanically support
Depth Lead	Cortical (depth)	Burr hole
Cortical Strip Lead	Cortical (surface)	Secured using suture sleeves



Source: RNS® System User Manual, NeuroPace

Explantation and Replacement

1. Necessary, when battery is low (after 2 to 3.5 years with typical use)
2. Less risk than initial surgery → Change the neurostimulator



Packaging

Package and Material

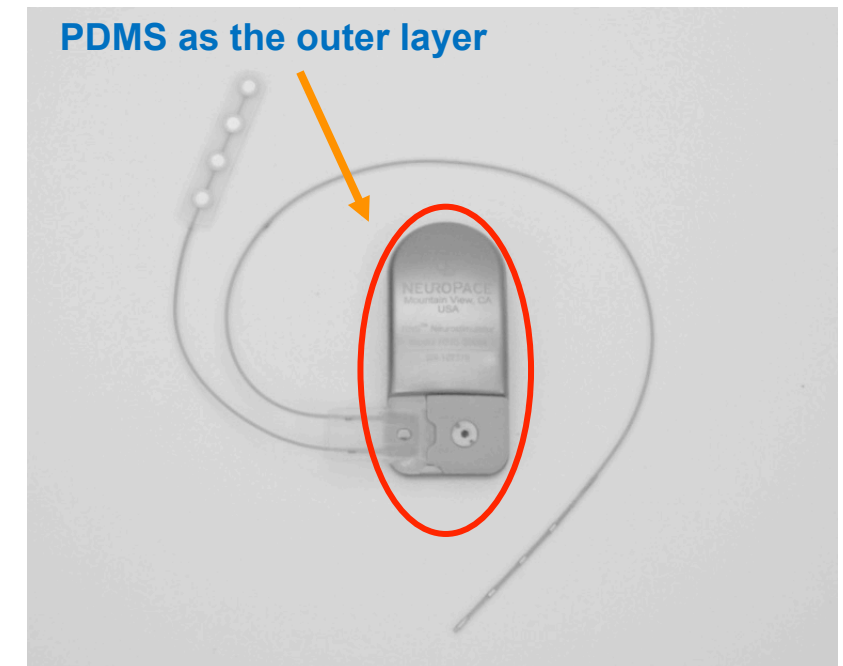
Hermetically sealed within a flat curved titanium enclosure

Benefits and Drawbacks of the Material

- Stability in vivo and impermeability (+)
- High mechanical strength (+)
- Low risk of brittle fracture (+)
- Used as reference electrode (+)
- Protection against EMI (+)
- Exact size of the hole for placement (-)
- Cause friction between scalp and device due to movement (-)

Alternative

- Avoid deformation of the component inside
- Prevent friction with the scalp



Source: RNS® System User Manual, NeuroPace



Leads

NeuroPace Cortical Strip Lead

- For seizure onsets on the surface of cortex

NeuroPace Depth Lead

- For seizure onsets beneath the cortical surface

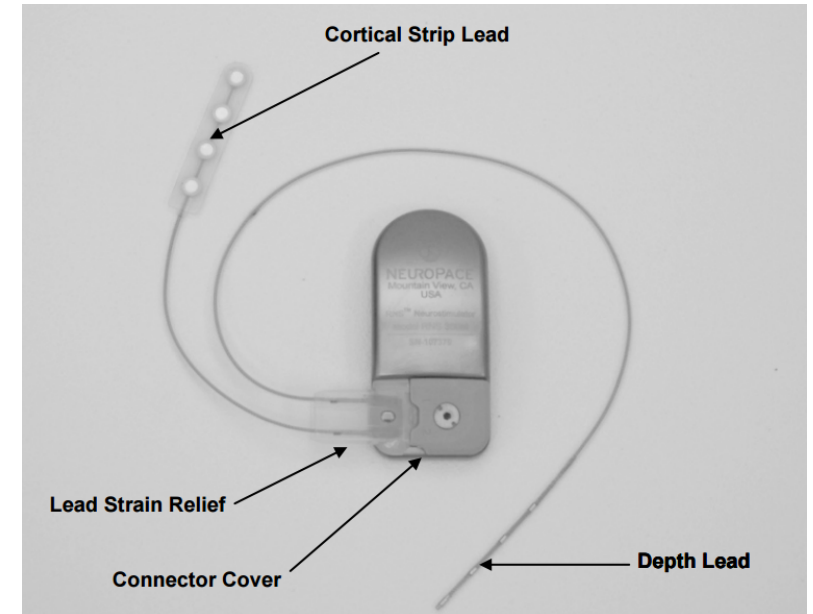
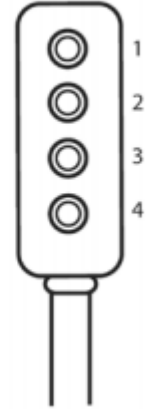
NeuroPace Lead materials:

- Lead body: Silicone
- Electrodes: Platinum/Iridium
- Stylet: Tungsten, Parylene coated
- Stylet retainer: Nylon

Distal End of Depth Lead



Distal End of Cortical Strip Lead





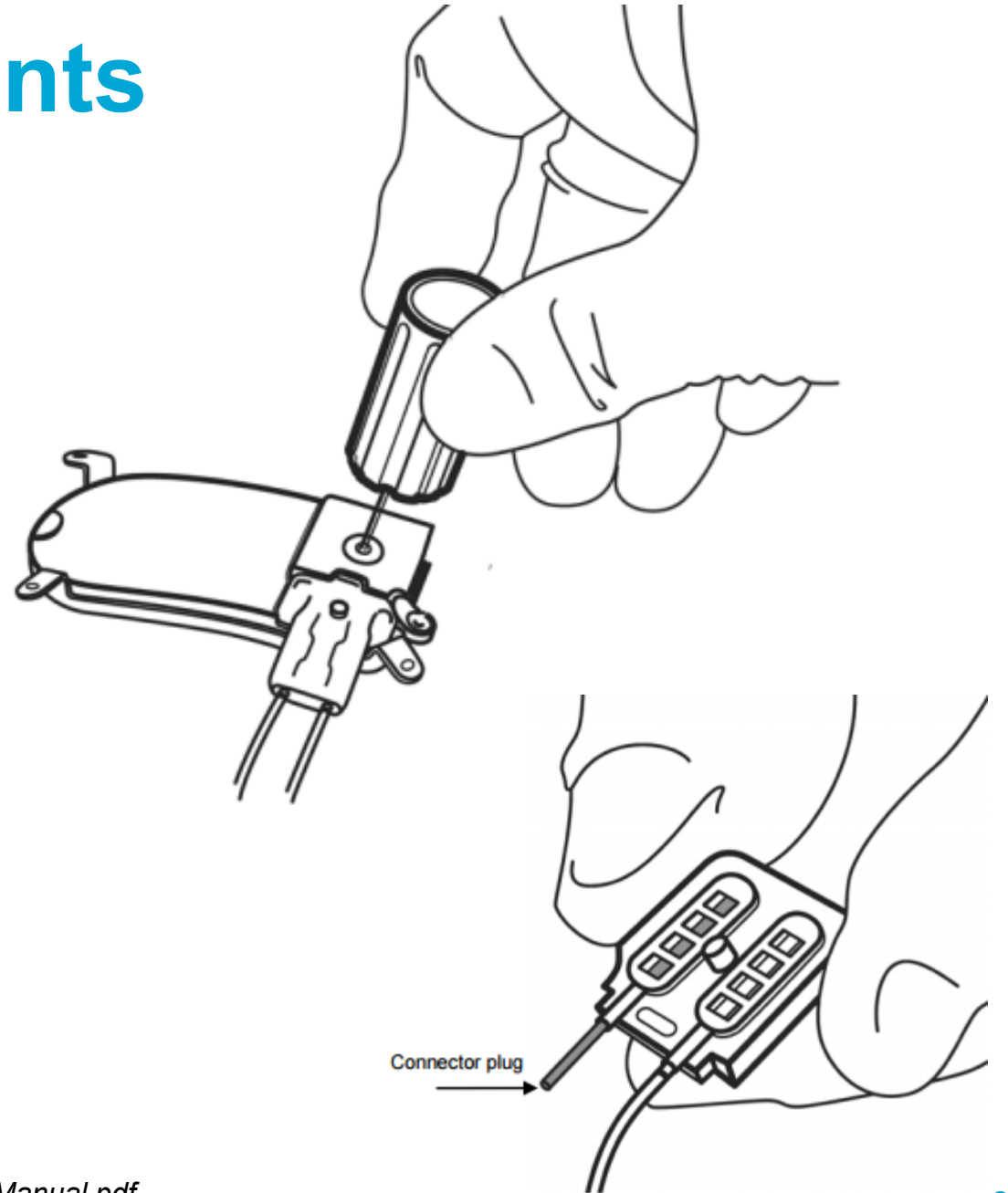
Physical components

Implant:

- Neurostimulator
- Leads
- Connector cover
- Connector plug
- Ferrule
- Suture sleeve
- Lead Strain Relief

Wireless connection:

- Magnet
- Programmer wand



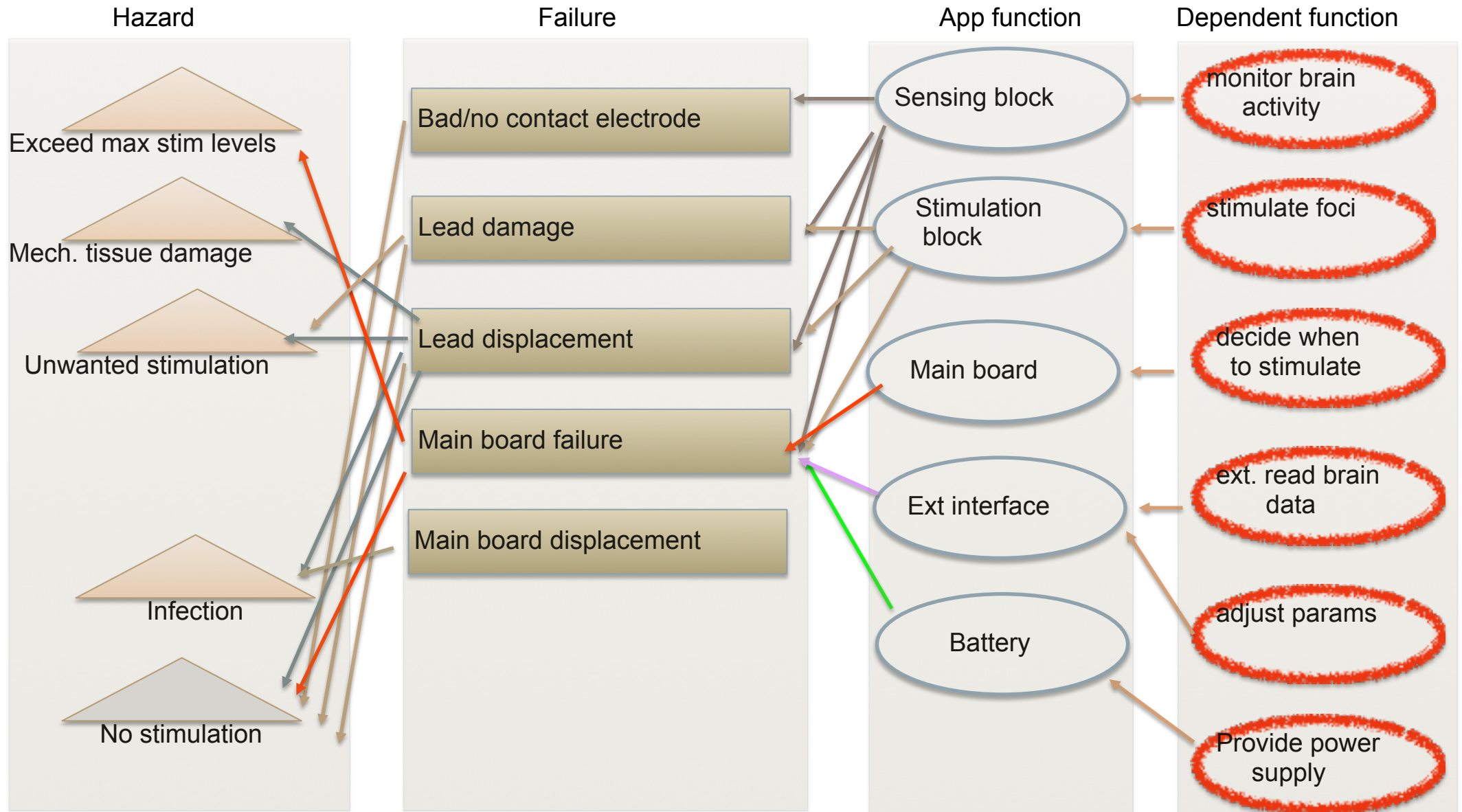


Sources of failure

- Low battery
- Lead migration/fracture/insulation damage
- Entrance of biologic fluids into device
- Bad contact leads by growth tissue layer around electrodes
- Short waves: microwave, ultrasound
- Accident, mechanical shock
- High/low pressure: diving



Hazards map





Data

Data that is stored:

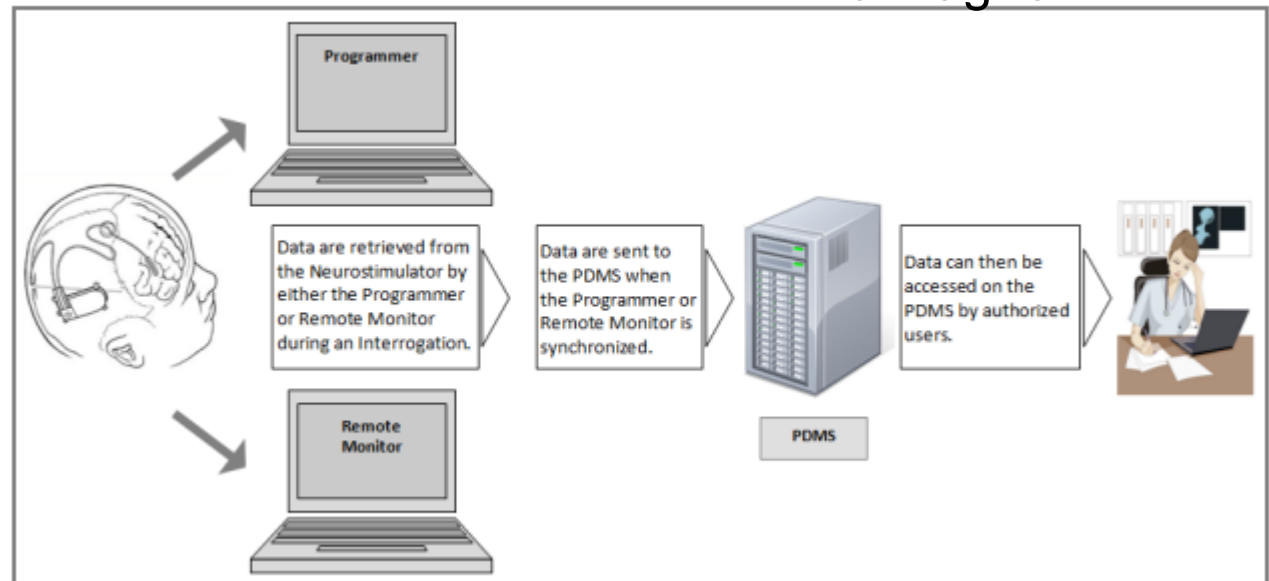
- Montage
- Detection settings
- Therapy settings
- Neurostimulator activity
- Recent ECoGs
- Lead impedance measurements
- Battery measurements

Dangers:

- Reprogramming
- Confidential information

Paramedics:

- Use the remote monitor
- Or turn stop therapy with the magnet





Regulatory process

FDA approval:

- Level 3 device
- 3 Month trial with 191 patients
- Device off 19% reduction of seizures
- Device on 34% reduction of seizures



What needs to be proven:

- The reduction of seizures needs to be persistent
- The side effects need to be treatable
- The implant needs to have high reliability
- The implant needs to be safe



Conclusion

- Regular checks to ensure safety is crucial
- Neurostimulator as alternative vs surgical resection
- Health risks vs benefits of implant
- Benefits have still to be broadly validated
- Marginal improvement live of patient?