Protection of electronics for reprocessable surgical devices

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A complete stand alone solution with connections like PTFE wires or gold connector up to over 1000 cleaning and steam sterilization cycles for your surgical devices

Background & Goals

- Miniaturized electronics like sensors is increasingly used in surgical devices
- Reprocessing (cleaning + steam sterilization) of surgical device is harsh for electronics and can cause early failure
- Building a housing around the electronics and providing an efficient barrier effect against reprocessing is necessary if the device has to be reprocessed several times
- An electrical interface (i.e. PTFE wires or gold pins) through the housing is a potential “weakest link” in the barrier effect
- Understanding and managing the failure mechanism of these interface is critical to improve the resistance of electronics against reprocessing
  - → Use of accelerated ageing to simulate reprocessing cycles
  - → IP testing to detect any failure of the interface

Experimental

Figure 1: View of the Device Under test (DUT) used in this study

- Device Under Test (DUT)’s construction
  - A test PCB is equipped with a golden pin perpendicularly soldered on top of it
  - Through adequate pre-treatment, gold’s surface is prepared for enhanced bonding properties when overmolded
  - The assembly is overmolded with our specific compound for reprocessable devices

- The DUT is going through accelerated ageing in a two chamber oven from 0 to 150° C. The extended temperature range compensate the lower heat transfer rate compared to sterilization.
- Interfaces between different material used in the device construction will be periodically loaded and induce mechanical fatigue of the bond between them.
- The DUT is then immerged under 1 meter of water for 30 minutes
- A dielectric test in water under 1500 V is performed to measure if any water ingress happened during the immersion

Figure 2: View of the two chamber oven were the DUT are going through accelerated ageing 0 – 150°C

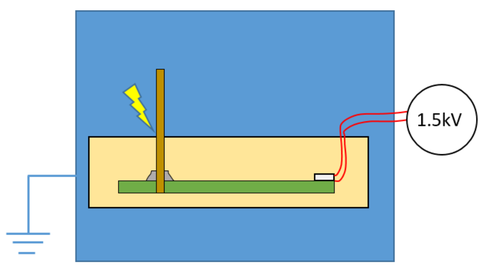

Figure 3: Scheme of the dielectric test and potential ingress point inducing current leakage

Results

- *Theoretical work results*
  - Potting or overmolding **removes microclimate** but **adds mechanical stress** on the PCB and the electronic components
  - To avoid mechanical failure of the solder joints or PCB, the **balance between mechanical properties of the polymer and max shear strain of the soldering joints** of each components has to be found
  - During **steam sterilization**, steam condensates onto the device’s surface. Water has a **heat transfer rate 30 times higher** than steam.
  - Temperature gradient throughout the sterilized device are important causing **efforts and mechanical fatigue**, especially at the **interfaces between two material**
- *Practical results*
  - The initial current leakage of the DUT during dielectric test after an IP67 immersion is around 0.010 mA
  - After pre-ageing the DUT up to 300 shock cycles or sterilization, **dielectric test results stay low and steady around 0.010 mA**

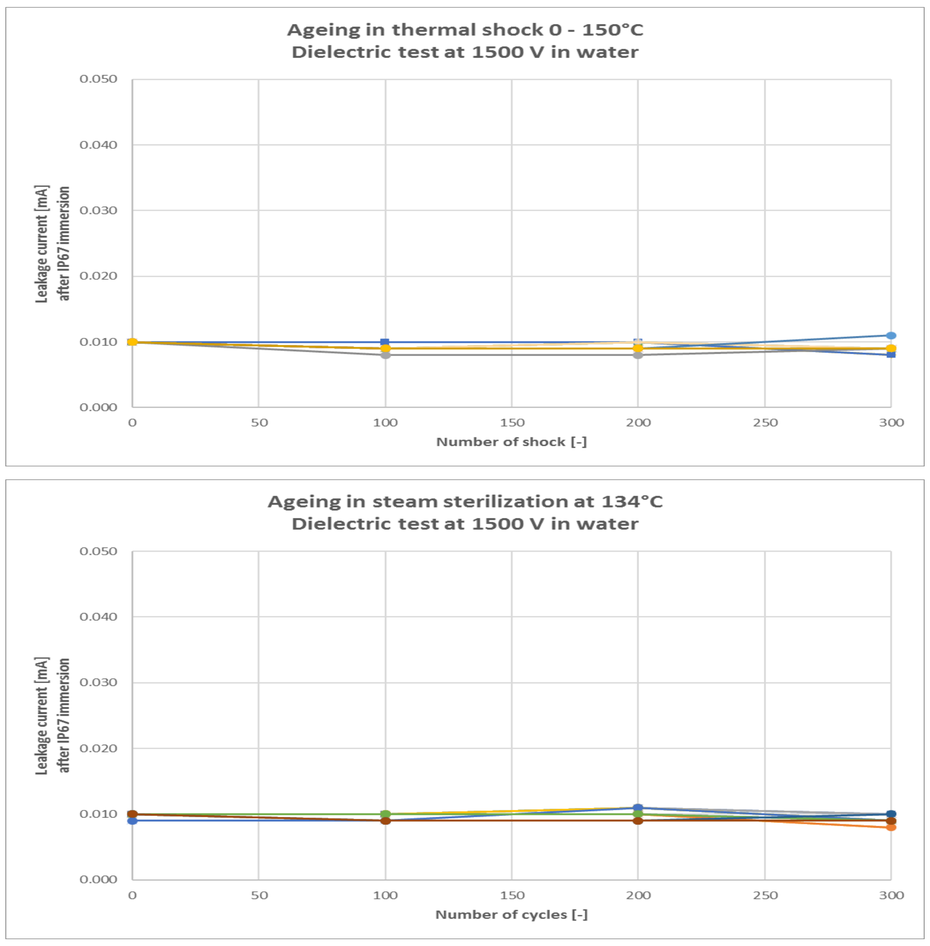

Figure 4: Leakage current measurement after different ageing processes

No significant rise of leakage current indicates a stable interface quality

Conclusions

- Electronic can be **reliably protected** from reprocessing
- Depending on the electrical interfaces needed, the performance can go up to **over 1000 reprocessing cycles**
- Metallic pins can be used as connection elements while keeping the **necessary barrier effect** against reprocessing
- The Stand-alone protection for electronic concept allows more **design freedom for the designer of the complete surgical device**