

June 21, 2021

Document ID: Disposable ECG Electrodes  
To: General Customer Statement / Electrode File  
From: Nissha Medical Technologies  
RE: Out of Pouch Shelf Life

References:

- [1.0] Accelerated Aging of Medical Devices, ASTM F1980
- [2.0] ECG Electrodes Special Guidance
- [3.0] ANSI/AAMI EC12:2000 ( R ) 2015, Electrical Testing of Disposable ECG Electrodes
- [4.0] Accelerated Aging and Real Time Shelf-Life Requirements, Work Instruction 3-19-08

The purpose of this memo is to provide a summary of results from “out of pouch” storage conditions.

Results from “out of pouch” storage conditions are only verifiable at 70°F and 20%RH. Note that disposable ECG electrodes are meant to be used per IFU at the time the pouch is opened and that expiration dates on label claims are derived from extensive shelf-life testing in sealed pouches.

Products sealed in zipper pouches have been verified to support the full life cycle until expiration on label claim if those pouches have been opened then zipped shut.

| Electrode Type | Out of Pouch Life Expectancy                    |
|----------------|---|
| Wet Gel        | < 2 days, optimal within 24 hours after opening |
| Solid Gel      | < 2 months                                      |
| Tab            | < 6 months                                      |
| Laminated      | < 2 months                                      |

Approved By:



Michael Manzella, COE – Quality Engineer