

F1980-16 Revision

ASTM Subcommittee F02.50
Meeting

04/14/2021

Jordan Montgomery

Medtronic
Further, Together

BACKGROUND

- ASTM F1980 is a widely used guide for accelerated aging sterile barrier systems for medical devices
 - It is also a widely used guide for accelerated aging medical devices and materials used in medical devices
 - Medtronic has studied the behavior of polymer materials during aging and shown moisture uptake in polymers is governed by RH not absolute humidity – failures can be masked.
- Current humidity guidance is not optimized for all materials
 - Body of the document – states humidity not a factor in aging calculation without context for inclusion/exclusion
 - Appendix – absolute humidity chart/examples
- Standard used not just for packaging, but for device aging too
 - Goal is to improve the guidance on the use of RH during aging
 - Improve guidance in the body of the document
 - Improve the appendix

UPDATE – APRIL 2021 STATUS

- Subcommittee Ballot 2020
 - Received 35 comments
 - Held a number of meetings over the course of summer 2020 to address comments
 - Redline has evolved
- Publication of Medtronic Data
 - [MDDI Online – February 2021](#)
- Latest redline includes the reference.
- Ready to ballot!
 - Subcommittee
 - Or
 - Sub / Main concurrent??
- Please advise!

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Humidity as a Use Condition for Accelerated Aging of Polymers

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It is important to understand the impact of absorbed moisture content in polymers, as high or low levels could accelerate aging damage in many materials.

Base Ther. Use In Itj. Inlet Components, Sun Chlone, Sydney Helman, Tinson Golek, Ted Tarter, and Kelly Magness, Medtronic 1st 11, 2021