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Name: Real Time Aging Work Instruction

Windchill Signature History Report			
Signature	**Role**	**Event Date**	**Vote**
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1. REFERENCES

ENG-SOP-005	Design Control
OPER-FRM-005	Material Movement Ticket
PR-0000256	Franchise Procedure for Control of Nonconforming Product and Nonconforming Processing
PR551-002	Franchise Procedure for Handling of Product Issue Assessment and Quality Review Board
ISO 11607:2006	Packaging for terminally sterilized medical devices
ASTM D4169	Standard Practice for Performance Testing of Shipping Containers and Systems
QA-SOP-010	Environmental Monitoring of Controlled Manufacturing Environment (CME)

2. SCOPE

This document applies to real time aging and verification of shelf life of Megadyne products both disposable and reusable.

3. PURPOSE

The purpose of this document is to provide instructions for initiation, monitoring and testing of real time aged product. The intention of this testing is to ensure that product safety is maintained throughout the lifespan of the product.

4. DEFINITIONS AND ACRONYMS

DHF	Design History File

5. REQUIRED TOOLS & EQUIPMENT

Tools and equipment required for individual tests are defined in protocols referenced in the product validation plan of each product. In cases where a specific product validation plan is not present, refer to the project test matrix for guidance on appropriate tests.

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6. BACKGROUND

Shelf life of new products is typically determined using accelerated aging techniques. In order to verify that these techniques are valid, real time aging studies are performed. Testing is performed to ensure product still meets specifications after real time aging to end of shelf life. The testing requirements for real time aged product should be identical to those for accelerated age testing that demonstrates conformance to required standards and DMR specifications that relate to safety and efficacy.

The guidance for using ENG-WI-009 Revision A or Revision B/subsequent revisions is given below:

- Any real time aging test protocol that has been approved at the time of released of ENG-WI-009 Revision B can continue to use ENG-WI-009- Revision A.

7. PROCEDURE

7.1. Samples for real time aging are required for the following:

7.1.1. New products stemming from design control ENG-SOP-005

7.1.2. Products with significant changes if changes require accelerated aging

7.1.3. To show compliance of product to updated standards

7.2. Products for real time aging include:

7.2.1. Disposable products that have expiration dates

7.2.2. Reusable products:

7.2.2.1. Products that have expiration dates

7.2.2.2. Products that have specific number of uses

7.2.2.3. Products with wear indicators

7.2.3. OEM products distributed by Megadyne (where the DMR resides with the OEM) and electronic hardware products do not require real time aging by Megadyne.

7.3. Process for initiating real time age study

7.3.1. Products for real time aging studies are required to be production lot builds that have been through all required manufacturing processes,

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including sterilization. Do not use prototype products or engineering samples.

7.3.2. Obtain product for aging from production. Document product movement on form OPER-FRM-005.

7.3.3. Prior to or after product aging (Accelerated or Real Time), the product will be subjected to a shipping and storage cycle as defined by an approved study. This cycle includes temperature and humidity ranges defined by an approved study, for example from -40°C to 70°C, and from 15% to 95% RH. This is followed by a transportation cycle using ASTM D4169. The transportation cycle parameters from ASTM D4169 will be defined by an approved study.

7.3.4. Testing will need to be completed for a minimum of the baseline interval (i.e. T=0 month) and the labeled shelf life.

7.3.5. Place products into real time aging at the same time the accelerated aging study begins or as soon as possible after accelerated aging begins.

7.3.6. Place enough product into real time aging to complete all the tests required.

7.3.7. Use form ENG-FRM-005 to list protocols and testing sample size rationale with the product being put into aging.

7.3.8. Information located on the filled-out form ENG-FRM-005 pertaining to the product number and lot number quarantined for real time aging is maintained by quality assurance. Quality Assurance will maintain control of the real time aging product.

7.3.9. Place product in a designated storage area for real time aging.

7.3.9.1. The storage conditions shall be controlled and monitored. A record of these conditions shall be documented and/or referenced in the stability study testing documents.

NOTE: Unless otherwise specified and justified, the controlled storage period shall only include the time when the test samples are in the controlled storage environment.

7.3.9.2. If the storage conditions deviate from the specified range, the Stability Studies SME (and other

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stakeholders, as needed) shall assess the impact of the deviation on the affected test samples. As needed, the scheduled aging period end date shall be extended.

7.3.9.3. The test samples shall be pulled from controlled storage on time. To accommodate for holidays, weekends, plant shutdowns, etc., "on time" shall be defined per the following:

- The actual pull date is within 3 calendar days after the scheduled aging period end date. (Accelerated stability method only)
- The actual pull date is within 14 calendar days after the scheduled aging period end date. (Real-time stability method only)

NOTE: The actual pull date shall not occur before the scheduled aging period end date. If the devices are not pulled in time, then the test report will address why and any potential risk associated with aging product more than originally anticipated.

7.3.10. The storage temperature range shall be 30°C ± 2°C.

NOTE: This updated temperature range is applicable to real-time stability studies approved after implementation of Revision B of this procedure. The nominal temperature for previously approved studies may be lower, e.g. 20°C or 25°C. Those previously approved studies shall be deemed as valid and shall continue at the temperature set point defined in their respective protocols.

The storage humidity range shall be 65% RH ± 5%.

NOTE: A testing interval at "Labeled Shelf Life + 12 months" shall be included with the study. This additional testing interval shall account for potential manufacturing WIP (work in progress) delays.

If the labeled shelf life is calculated based on the device assembly date, then this "+ 12 months" testing interval may be omitted. (Example: If the device is assembled and packaged on the same manufacturing line, then

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manufacturing WIP delays would not be possible, as the product shelf life is labeled immediately after device assembly.)

7.3.11. For product being tested under protocols for aging approved before Revision B of this Work Instruction, temperature and humidity in the real time aging storage area will be monitored and the readings will be stored electronically. The advisory and action levels are shown below and match what is listed in QA-SOP-010.

Monitored Parameter	Advisory Levels	Action Levels
Temperature	< 8°C (46°F) for > 24 hours > 33°C (91°F) for > 24 hours	< 5°C (41°F) for > 72 hours > 36°C (97°F) for > 72 hours
Humidity	< 17% RH for > 24 hours > 93% RH for > 24 hours	< 15% RH for > 72 hours > 95% RH for > 72 hours

For product being tested under protocols for aging approved before Revision B of this Work Instruction, if any of the temperature or humidity numbers listed in the Advisory Level are exceeded for >1 hour for temperature or humidity monitoring in the real time aging product area, notification will be automatically sent (via e-mail) to the key personnel of the Manufacturing Engineering and Facilities Maintenance departments. Those notified will monitor if a recovery to normal range E-Mail is received within 24 hours. If not received, notification will be send to Facilities, Production Manager, Manufacturing Engineering and Quality Operations. They will take appropriate action as soon as possible to avoid reaching the Action Level. Actions taken will be documented in Facilities Maintenance Departments engineering notebook.

For product being tested under protocols for aging approved before Revision B of this Work Instruction, if the real time aging product area exceeds Action Levels for temperature or humidity, Facilities shall notify R&D Engineering.

7.4. Testing of Aged Product

7.4.1. When Quality Assurance identifies that the product has reached its end of expiration life they will notify appropriate engineering personnel.

7.4.1.1. If the aged product cannot be located (e.g. lost or misplaced), then submit new product for aging as outlined above as soon as possible. Include in the test report a rationale and justification

addressing any potential risk associated with delaying the results of the real time aging testing.

7.4.2. Designated engineering personnel will perform testing outlined per the validation plan. Information may be located on an attached memo or may be determined from the validation plan or test matrix.

7.4.3. Product should be tested within six months of its expiration date. If not, then the test report will address why and any potential risk associated with testing product more than six months past its expiration date.

7.4.4. Upon completion of testing, designated engineering personnel will write a test report and process on for approval.

7.4.4.1. Upon successful completion of testing, the assigned engineer will write a summary memo and include it in the product DHF.

7.4.4.2. In the event of a product test failure, initiate product non-conforming report per PR-0000256 and Escalate issue per PR551-002 Franchise Procedure for Handling of Product Issue Assessment and Quality Review Board.