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ND Yellow Label Qualification

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Megadyne Medical Products, Inc.	TEST PROTOCOL	***Document Number*** ENG-PRT-465
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1. SCOPE

This protocol applies to the New Deantronics "Plain Label, Yellow 254X76MM" (ND Catalog Item L100700), printed with black ink.

2. PURPOSE

Successful execution of this protocol will demonstrate, through objective evidence, that New Deantronics "Plain Label, Yellow 254X76MM" (ND Catalog Item L100700) printed with black ink can withstand the anticipated distribution environment post EO sterilization.

3. REFERENCES

ASTM D4169	Performance Testing of Shipping Containers and Systems
ENG-RMF-045	Risk Analysis, Smoke Evacuation Accessories
QA-SOP-015	Risk Management of Medical Devices
ENG-PRT-049	Accelerated Aging of Packaged Product
ENG-WI-007	Operation of Vibration Table and Drop Test Equipment
2010421-01	ASTM D6344 Guided Free Fall Concentrated Impact Test Equipment
ME725M1C	ACE Blade 700, 2.5", Modified, Zip Pen, "C" Connector, 10 ft. Tubing
3151074-01	Shipping Label, MEGADYNE 700, Modified, 10 foot, Standard Connector
ME725M1E	ACE Blade 700, 2.5", Modified Zip Pen, EC Connector, 10 ft. Tubing
3151076-01	Shipping Label, MEGADYNE 700, Modified, 10 foot, EC Connector

4. BACKGROUND

Traditionally, Megadyne has labeled EO sterilized devices with a yellow label stock. With the release of the Modified ACE Blade 700 product family (Catalog Numbers: ME725M1C with 3151074-01 and ME725M1E with 3151076-01), New Deantronics will begin manufacturing devices requiring EO sterilization. As such, the ability to externally print on a yellow label stock is desired in order to complement Megadyne's current

sterilization practices. This protocol investigates the ability of the New Deantronics "Plain Label, Yellow 254X76MM" (ND Catalog Item L100700) printed with black ink to withstand the anticipated distribution environment.

5. APPARATUS

- Environmental Chamber
- LAB AccuDrop 160
- Martin Vibration Systems Vibration Table
- Metal shim 0.06 in thick, approximately 2 in wide
- Guided Free Fall Concentrated Impact Test Equipment (PN: 2010421-01)

6. RISK ASSESSMENT

The FMEA for Smoke Accessories (ENG-RMF-045) was reviewed by Quality, Engineering, and Regulatory while considering the release of a new yellow label stock. It was determined that a new line item needed to be created:

Line Item	Failure Mode	Severity	Probability of Occurrence
46.2-D	Product label information is incomplete or illegible	1	1

As shipper label legibility and damage were found to be low severity of harm and low probability of occurrence, no testing is required as outlined in QA-SOP-015. However, an illegible label could be a compliance risk therefore the following will be performed.

- Shipping Test
- Label Inspection

7. EXPERIMENT DESIGN / SAMPLE SIZE JUSTIFICATION

7.1. Experimental Design

7.1.1. 2X EO Sterilization

Prior to accelerated aging, all test products will be subject to two EO cycles.

7.1.2. Pre-Conditioning

After accelerated aging, the samples will be subjected to pre-conditioning. This cycle includes temperatures from -40^{o}C to 55^{o}C and humilities from 15% to 95%. This temperature and humidity cycling is designed to run consecutively with the ASTM D4169 pre-conditioning.

7.1.3. Shipping Test

Ship Testing shall be performed under typical warehouse conditions, which are:

Temperature: 23°C ±5°C
Relative Humidity: 50% ±35%

These conditions are a wider range than stated in ASTM D4169. This deviation from the standard is considered acceptable because actual warehouse, transport, and storage conditions will vary greatly from the range listed in the standard.

The ASTM D4169 standard requires the choice of an assurance level. For this test, assurance level II will be used. This level was chosen because it is the recommended starting level in the standard.

The test schedule for this test will follow Distribution Cycle 3: Pre-conditioning, Handling, Vehicle Stacking, Loose load Vibration, Vehicle Vibration, Concentrated Impact, and Handling. This distribution cycle has been chosen because the product may be shipped as a single package without a pallet or skid.

NOTE: This product will normally be shipped on a pallet. However, the chosen cycle (without a pallet) is considered to be a worst-case scenario and therefore should be sufficient to test all foreseeable shipping conditions.

7.1.4. Label Inspection

The label inspection shall be performed visually. All visual inspections are to be performed using no magnification, under normal, diffused (indirect) fluorescent lighting, at a distance of 16 – 18 inches, with a maximum of 5-second time limit for visual inspection.

7.2. Sample Size Justification

A samples size of eighteen (18) labels will be used for the required EO Sterilization, Pre-Conditioning, Shipping Test, and Label Inspection in a C=0 sampling plan. This is based on a lot size of up to 3200 and an AQL of 4.0. An AQL of 4.0 is acceptable as the severity of harm is negligible and the probability of occurrence is rare, as outlined in ENG-RMF-045. Additionally, because all samples to be inspected will be exposed to conditions representative of worst case shipping and sterilization a larger sample size should not be needed to identify failures if they exist.

For convenience, three (3) label will be placed on each box of product. This will result in a total of six (6) boxes being sterilized, aged, conditioned, and ship tested

in placed of eighteen (18) (see Figure 1). Placing multiple label on a box is acceptable as the label/box interaction is identical along each vertical edge and face of the box. It should be noted that four labels cannot be used on each box as an old label can be found along one vertical edge of the boxes (see Figure 1).

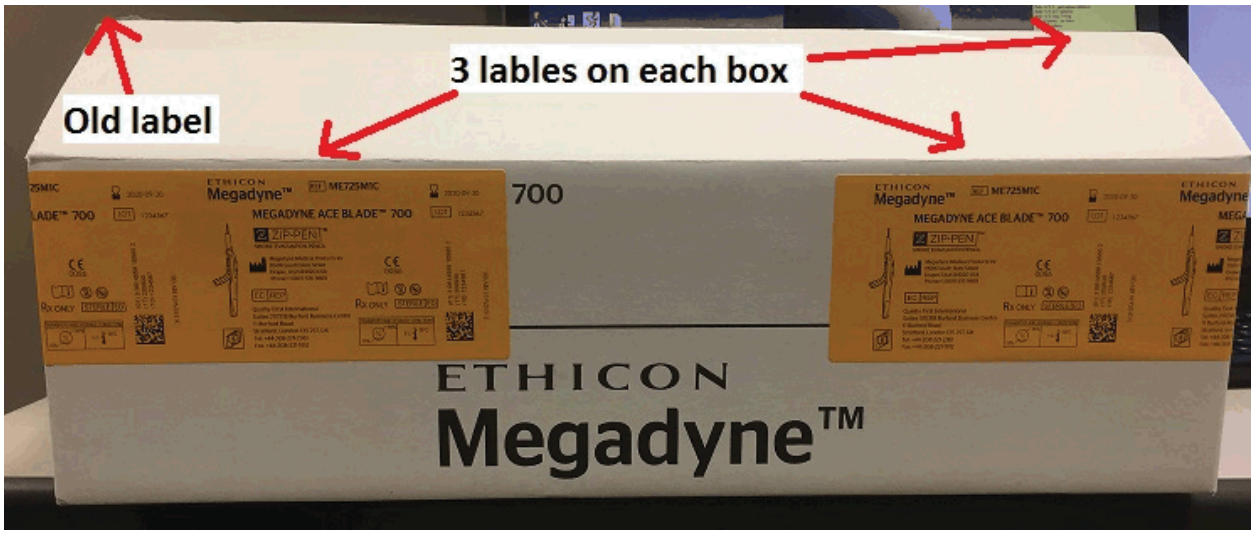


Figure 1: Label configuration to optimize testing.

8. EO STERILIZATION

8.1. All samples must be EO sterilized twice. EO sterilization will be performed per the following parameters:

Preconditioning Set Points:	
Temperature:	43.3°C
Relative Humidity:	60%
Time (Minimum):	24 hours
Time (Maximum)	n/a
Sterilization Set Points:	
EO Gas Concentration:	804 mg/L (100% EO)
Temperature:	48.9°C
Relative Humidity:	50%
Initial Vacuum:	1.0psia
EO Gas Dwell Time:	240 minutes
Steam Dwell Time:	60 minutes
Aeration Set Points:	
Temperature:	43.3 ± 5°C
Time (Minimum):	24 hours

9. PRECONDITIONING

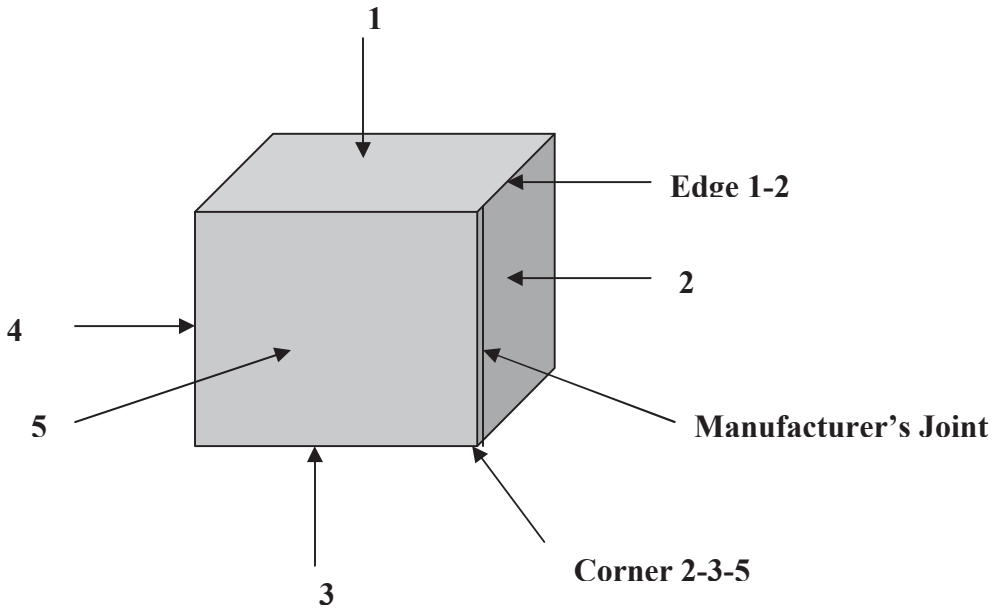
9.1. Pre-Conditioning will follow the temperature and humidity schedule listed below.

CONDITIONS	DURATION
Transition from ambient to -40°C	Based on Chamber Capability
Hold -40°C no humidity control	4 hours
Transition from -40°C to 55°C	Set time to 0:00 and set the standard deviation to 1°C
Transition from 55°C to 55°C and 95%RH	Set time to 0:00 and set the standard deviation to 1°C and 2% RH
Hold 55°C and 95%RH	4 hours
Transition from 55°C and 95% RH to 55°C and 15% RH	Set time to 0:00 and set the standard deviation to 1°C and 2% RH
Hold 55°C and 15%RH	4 hours
Transition to 23°C and 50%RH	Set time to 0:00 and set the standard deviation to 1°C and 2% RH
Hold 23°C and 50%RH	72 hours

10. SHIPPING TEST

10.1. Handling – Manual

10.1.1. Use a permanent marker to identify the faces of the shipping boxes according to the following diagram.



10.1.2. Record the gross weight (M) of the shipper box containing product in pounds.

10.1.3. Record the Catalog Number of the product.

10.1.4. Record the Lot Number of the product.

10.1.5. Perform the Handling test (drop test) as follows.

10.1.6. The required drop height from ASTM D4169 paragraph 10.2.3, using assurance level II, is 15 inches for packages from 0 to 20 pounds. Package weight is approximately 3.5 pounds.

10.1.7. Set the height on the LAB AccuDrop 160 to 15 inches. Drop the test package in the following sequence.

Drop Sequence	Orientation	Specific face, edge or corner
1	Top	Face 1
2	Edge	Edge 5-3
3	Edge	Edge 6-3
4	Corner	Corner 2-3-5
5	Corner	Corner 4-3-6
6	Bottom	Face 3

10.1.8. Record package drops on the data sheet in Appendix I.

10.2. Vehicle Stacking

10.2.1. Perform the Vehicle Stacking test (compression test). For the compression test, use ASTM D4169 section 11.3 for warehouse stacking made up of identical shipping units. For this test, the parameters for assurance level II will be applied. The formula for the weight of the compression is as follows:

$L = M \times J \times ((H-h)/h) \times F$

Where:

L is the computed load (lbf)
M is the mass (lb)
J = 1 lbf/lb
H= 108 in
h = height of package (in)
F = 3.0 (see section 11.2 of ASTM D4169)

10.2.2. Place Face 3 of the shipper box on the ground.

10.2.3. Place a wood board on top of the shipper box, such that the shipper box is centered underneath the board. The wood board must extend a minimum of two inches on all sides of the box.

10.2.4. Place the test load (determined above) on the center of the wood board.

10.2.5. Allow the weight to remain on the wood board for a minimum of 3 seconds.

10.2.6. Inspect the package for damage. Record observed shipper box damage, if applicable.

10.3. Loose Load Vibration and Vehicle Vibration

10.3.1. Following the Vehicle Stacking test, perform the Loose Load Vibration test per ENG-WI-007. Record the information in Appendix I.

10.3.2. Place the shipper box containing packaged product on the vibration table so that Face 3 rests on the platform.

10.3.3. Start the vibration system beginning at the lowest frequency.

10.3.4. Slowly increase the frequency of the vibration until the shipper box begins to momentarily leave the surface of the platform.

10.3.5. Check the frequency using the shim.

10.3.5.1. Swipe the shim under the shipping box along the longest side from one of the end to the other. The shim should be able to travel on the long side of the box from one end of the box to the other. At this low frequency, the movement of the shim will be interrupted movement.

10.3.6. Leave the box on the vibration table for a period of 40 minutes.

10.3.7. After 40 minutes of Loose Load Vibration, increase the frequency for the Vehicle Vibration Test.

10.3.8. Check the frequency using the shim.

10.3.8.1. Swipe the shim under the shipping box along the longest side from one of the end to the other. The shim should be able to travel uninterrupted on the long side of the box from one end of the box to the other.

10.3.9. If the shim does not travel uninterrupted, increase the frequency of the vibration table.

10.3.10. Leave the box on the vibration table for a period of 10 minutes.

10.4. Concentrated Impact

10.4.1. Following the Vibration tests, perform a Concentrated Impact test.

10.4.2. The Impact test will be done on the following faces using the Impact test equipment identified in ENG-DWG-768.

10.4.3. The impact energy applied to each surface will be 4.0 ft-lbf (5.4 J). This energy will be achieved by dropping the cylinder mass defined within the 2010421-01 equipment at a height of 32 in (0.8 m).

10.5. Handling – Manual (2nd)

10.5.1. Following the Concentrated Impact test, perform the second package handling (drop test). Follow the sequence listed below. Make all of the drops from 15 inches except the final drop which is from 30 inches.

Drop Sequence	Orientation	Specific face, edge or corner
1	Edge	Edge 4-6
2	Face	Face 4
3	Face	Face 6
4	Corner	Corner 2-1-5
5	Edge	Edge 2-1
6	Bottom	Face 3, Increase height to 30 inches.

10.6. Record completion of Shipping Test in Appendix I.

11. LABEL INSPECTION

11.1. Inspect labels for clarity and legibility and record pass/fail in Appendix II.

11.2. All visual inspections are to be performed using no magnification, under normal, diffused (indirect) fluorescent lighting, at a distance of 16 - 18 inches, with a maximum of 5-second time limit for visual inspection.

12. ACCEPTANCE CRITERIA

12.1. Shipping Test

12.1.1. Each box shall remain intact and not break open during the test. Indentations on edges or corners are acceptable.

12.2. Label Inspection

12.2.1. The printing of each pouch shall be clear and legible with no smears or missing print.

12.2.2. All intended labeling information is present.

APPENDIX I

Shipping Test Log Sheet

Preconditioning:

Start Date: _____ Chamber Number:_____

Completion Date: _____ Last Calibration:_____

Signature/Date: _____ Calibration due:_____

Drop Test:

Catalog _____ Weight _____ Drop Height: _____

Drop	Orientation	Specific face, edge or	Initials/Date
1	Top	Face 1	
2	Edge	Edge 5-3	
3	Edge	Edge 6-3	
4	Corner	Corner 2-3-5	
5	Corner	Corner 4-3-6	
6	Bottom	Face 3	

Comments: _____

Signature: _____ Date: _____

Compression Test:

Catalog _____ Pounds Force _____

Comments: _____

Signature: _____ Date: _____

Appendix I Continued
Shipping Test Log Sheet

Vibration:

Low Frequency, 40 minutes, Initials_____ High frequency 10 minutes, Initials _____

Completion Date: _____

Signature: _____ Date: _____

Second Drop Test:

Catalog_____Weight _____ Drop Height: _____

Drop	Orientation	Specific face, edge or	Initials/Date
1	Edge	Edge 4-6	
2	Face	Face 4	
3	Face	Face 6	
4	Corner	Corner 2-1-5	
5	Edge	Edge 2-1	
6	Bottom	Face 3, Increase height to 30 inches.	

Comments: _____

Signature: _____ Date: _____

Appendix II
Label Clarity and Legibility Log Sheet

Inspect the product per the protocol and enter the number of units that pass or fail in the box below.

Catalog #	Pass	Fail
Clarity/Legibility		

Comments:_____

_____

_____

Inspected by: Date completed