

**Originator of the Change: B. Mackie**

**Date: 5/7/03**

**New Revision: 16**

<b>Is the Control Plan affected?</b>	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
<b>Is the Process Flow Chart affected?</b>	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
<b>Is the FMEA affected?</b>	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
<b>Is the Characteristic Matrix affected?</b>	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
<b>Is customer notification required?</b>	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
<b>Is customer approval required?</b>	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No

**Description of Change (from what to what):**

Replace "MIP Medical/Implantable Products" in section 2.0 with "AV-AVX-CO-035 Medical/Implantable Products"

**Reason for Change:**

MIP obsoleted and replaced with corporate spec.

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**MASTER PRODUCT SPECIFICATION HRC5000**

**TITLE:** Capacitors, Tantalum, Chip, Implantable Grade,  
Detail Specifications For.

## 1.0 SCOPE

- 1.1 This specification delineates the minimum manufacturing process control and the environmental test requirements for all *AVX Tantalum Corporation* chip capacitors made for use in implantable life support applications.

## 2.0 REFERENCE DOCUMENTS

MIL-PRF-55365	Capacitor, Fixed, Electrolytic (Tantalum), Chip, Established Reliability, General Specification For
MIL-STD-202	Test Methods For Electronic And Electrical Component Parts
AV-AVX-CO-035	Medical/Implantable Products
Procedure 61010	Quality Records
Procedure 61020	Non-conforming Material
Procedure 63010	Design
J-109	TAZ COTS and Military Series Product

## 3.0 PURPOSE

- 3.1 The purpose of this specification is to provide high reliability microminiature tantalum chip capacitors for use in implantable life support and sustaining applications by:

- 3.1.1 Establishing a rigorous screening test schedule designed to detect and eliminate from shipment any capacitor or capacitor test lot that exhibits poor performance or reliability.
- 3.1.2 Establishing a continuous test schedule to determine baseline reliability data for

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specific product shipped under this specification.

3.1.3 Assuring proper lot control and lot traceability procedures are in effect.

3.1.4 Taking appropriate failure analysis and corrective actions as required.

## 4.0 GENERAL PRODUCT REQUIREMENTS

4.1 All product shipped for use in implantable life support applications shall, as a minimum, be subjected to and meet the requirements of MIP and this specification.

4.2 Hot solder dipped product is certified to the requirements of this specification prior to application of the solder. After solder dip, product is electrically and visually 100% re-inspected.

## 5.0 CUSTOM SPECIFICATION

5.1 All applicable customer product specifications must be reviewed by Product Engineering prior to order entry.

## 6.0 SAMPLING AND SHIPMENT PROCEDURES FOR NEW ACCOUNTS/ACTIVITY

6.1 **Initial Sample Evaluation** - Refers to samples for use in initially evaluating the physical and electrical properties of the capacitor devices.

6.1.1 These devices may be shipped "off-the-shelf".

6.1.2 The customer may require special screening of the initial samples. Screening requirements will be determined by Engineering.

6.1.3 These samples are not intended for use in devices actually implanted in humans, and will be labeled as such.

6.2 **Qualification Capacitors** - These capacitors are for use in actual implantable device circuits to qualify the capacitors through production for internal qualification testing of the circuit (to include FDA

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qualification requirements) and for limited, controlled use as prototype implants.

6.2.1 **For qualification samples:** Prior to making delivery and price commitments, the preliminary print review must be completed (see 5.1).

6.2.2 All qualification samples must be subjected to and meet Group A screening requirements prior to delivery.

### 6.3 Normal Production Shipments

NOTE: All testing is to J-spec limits except for special test limits listed in the slashes. This does not apply to limits for Group A or Group C testing unless specifically listed.

6.3.1 All controls and test requirements imposed by the customer and internal requirements will be specified in the appropriate special internal production control documents.

6.3.2 In the event that the Group C data indicates nonconformance to the product specification, failure analysis will be performed, and corrective action and/or customer notification will be implemented as necessary.

## 7.0 PRODUCT LINES

7.1 The approved product lines covered by this specification are TAZ, TBJ and TAC Series Tantalum Chips.

## 8.0 LOT CONTROL REQUIREMENTS

8.1 All data shall be traceable to the raw materials of each individual manufacturing lot.

8.2 All packaging shall be marked with a manufacturing date code. As a minimum, date code shall appear on first level packaging.

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- 8.3 Lot cards, screening and environmental test data, C of C's, and destruct test samples shall be maintained in accordance with internal procedure 61010.
- 8.4 All devices that have successfully met the requirements of this specification shall be maintained in bonded inventory.
- 8.5 Bonded stock with soldered terminations over one year old must be resubmitted to and pass solderability testing prior to shipment.

## 9.0 SCREENING REQUIREMENTS

- 9.1 All manufacturing lots shall be subjected to Group A requirements prior to shipment.
- 9.2 Final electrical requirements shall be as specified in internal documents or the appropriate customer specification.

## 10.0 PRODUCT LINE MONITORING PERIODIC TESTING GROUP

- 10.1 Samples will be accumulated from all shipments of HRC5000 devices. These samples will be tested as follows:
- 10.1.1 Temperature Stability per MIL-PRF-55365, Group A.
- 10.1.2 2K Life test at 125° C per MIL-PRF-55365.
- 10.2 Military conformance sampling shall be used for product line verification, per the following tests:
- 10.2.1 Moisture Resistance per MIL-PRF-55365, Group C.
- 10.2.2 Resistance to Solvents per MIL-PRF-55365, Group C.
- 10.3 Shipments shall not be withheld pending results of these tests.

**GROUP A**

Devices shall be subjected to the following tests:

1. **100% Thermal Shock** -per MIL-STD-202, Method 107, Condition F, except 10 cycles.
2. **100% Voltage Aging** - per MIL-PRF-55365, Weibull "B" failure rate.
3. **100% Electrical Testing** - per documented internal requirements or customer requirements, if tighter.
4. **100% Visual & Mechanical** - per applicable documented internal requirements.
5. **Simulated Functional Test** - per attached flow chart, 20 piece sample per manufacturing lot.
6. **Solderability** - per MIL-PRF-55365, except gold terminations will be tested for minimum 75% coverage.
7. **X-Ray** - per applicable documented internal requirements, 50 piece sample per manufacturing lot.

**SIMULATED FUNCTIONAL TESTING GROUP A**

