



A Zebra Technologies White Paper

Laboratory Testing of Zebra's Z-Band[®] Direct Thermal Antimicrobial Wristbands



Introduction

This document details the laboratory testing completed on Zebra® Z-Band direct thermal antimicrobial-coated wristbands. Independent laboratories and the Zebra Technologies Supplies research and development team tested the wristbands to ensure they meet Zebra's high standards for image durability, scannability and comfort. The tests evaluated the following:

- MR Safety
- Durability
- Potential to cause skin irritation

Since bar coded wristbands provide a convenient way to comply with The Joint Commission's National Patient Safety Goal to "improve the accuracy of patient identification," it is important for wristbands to be readable and scannable during the patient's stay. As you will see, Zebra's Z-Band wristbands were shown to be readable on the first scan. They also proved to be non-irritating. In addition, they do not appear to present an additional hazard or risk to a patient undergoing an MRI procedure.

The following facilities conducted the testing:

- Image Durability and Peel Adhesion: Zebra's Supplies R&D Laboratory—Testing Completed: December, 2006
- Tensile Strength: Zebra's Supplies research and development team utilized Northwestern University's Central Facilities supported by the MRSEC program of the National Science Foundation (DMR-0520513)
- Skin Irritability: Toxikon Corporation, 15 Wiggins Ave. Bedford, MA 01730—Report Date: May, 2006

The next section details the tests' procedures and results.

1. MR Safety

Zebra contracted with an independent MRI testing company to test Zebra's Z-Band wristbands (listed below) to determine if they would present a hazard or risk to a patient undergoing an MRI procedure. The testing on the products included:

- Magnetic field interactions
- MRI-related heating
- Image artifacts

The following Z-Band wristbands underwent testing:

- Z-Band Direct
- Z-Band QuickClip™
- Z-Band Comfort
- Z-Band Soft Infant
- Z-Band 4000
- QuickClips

Notably, these products are made of polypropylene. The direct thermal imaging chemistry is composed primarily of leuco dyes and developers. The inks/varnishes used are UV varnishes and water based inks.

There is no metal content in or on these particular patient identification bands.

Based on the test results, Z-Band wristbands products listed above were determined **"MR-Safe" (MR Safe—an item that poses no known hazards in all MRI environments)** according to the terminology specified in the American Society for Testing and Materials (ASTM) International, Designation: F2503-08: Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. These specific products do not appear to present an additional hazard or risk to a patient undergoing an MRI procedure.

2. Durability Testing

Optimum scanning performance and image durability are important, especially regarding the narrow 5 mil 128 Subset C bar codes that are printed on today's hospital wristbands. A bar code that fails to scan or requires repeated attempts to scan, can both jeopardize patient safety and staff productivity. Zebra's Supplies research and development team tested the image durability of Z-Band direct thermal wristbands to insure optimum image durability and scanning performance.

The image durability of a 5 mil narrow-bar 16 digit Code 128 C bar code printed on a Z-Band wristband at Zebra's recommended darkness and print speed settings was measured by scanning with a MS1690 Focus Area Imaging Bar Code Scanner after exposure to solvents, abrasion and water. For each test performed, a "Pass" or "Fail" designation was noted. Following are definitions of the designations:

- **Pass** = Immediate scan of bar code without repeated attempts
- **Fail** = Failure of bar code to scan or required repeated attempts to scan

Solvents

The following solvents were tested using an AATCC Crockmeter, using a crocking cloth and a Crockmeter heavy arm:

91% Isopropyl Alcohol

50X rubs with a soaked cloth on a 5 mil narrow-bar 16 digit Code 128 C bar code.

All Zebra Wristbands: **Pass**

70% Ethyl Rubbing Alcohol

50X rubs with a soaked cloth on a 5 mil narrow-bar 16 digit Code 128 C bar code.

All Zebra Wristbands: **Pass**

Betadine

100X rubs with a soaked cloth on a 5 mil narrow-bar 16 digit Code 128 C bar code.

All Zebra Wristbands: **Pass**

Purell

50X rubs with a soaked cloth on a 5 mil narrow-bar 16 digit Code 128 C bar code.

All Zebra Wristbands: **Pass**

Abrasion

An abrasion test was conducted using an AATCC Crockmeter, using a crocking cloth and a Crockmeter heavy arm.

1000X rubs with a dry crocking cloth on a 5 mill narrow-bar 16 digit Code 128 C bar code.

All Zebra Wristbands: **Pass**

Water Resistance

The water resistance was tested using a Cimarec Stirring Hot Plate.

The 5 mil narrow-bar 16 digit Code 128 C bar code was immersed in 105° F/40° C water, at stir setting 3.

All Zebra Wristbands: **Pass**. Up to 6 hours.

Tensile Strength

The tensile strength was tested using a MTS Sintech 20/G Materials Testing Workstation, at a speed of 1 inch/minute. This test simulates pulling the wristband off a wrist.

All Zebra Wristbands: Withstand up to 45 pounds of force.

Peel Adhesion

The peel adhesion was tested using an IMASS SP-2000 Slip/Peel Tester at a speed of 12 inches per minute and a peel angle of 180 degrees. This test simulates peeling the wristband apart at the adhesive tab.

All Zebra Wristbands: Withstand up to 55 ounces of force.

3. Skin Irritation Testing

Zebra's Z-Band wristbands were tested for the potential to produce a primary dermal irritation after a single exposure to the skin.

Z-Band wristbands were tested to FDA 21CFR, Part 58, referencing:

- ISO 10993-10, 2002, Biological Evaluation of Medical Devices—Part 10: Tests for Irritation and Delayed-Type Hypersensitivity
- ISO 10993-12, 2002, Biological Evaluation of Medical Devices—Part 12: Sample Preparation and Reference Materials
- ISO/IEC 17025, 2005, General Requirements for the Competence of Testing and Calibration Laboratories

The test articles received a topical 4-hour application of the USP 0.9% Sodium Chloride for Injection (NaCl) and Cottonseed Oil (CSO) extracts of the Z-Band materials. After 72 hours, there were no signs of erythema or edema. Therefore, Z-Band wristbands are not likely to cause dermal irritation and are considered a negligible irritant, according to Toxikon Corporation.

Conclusion

Zebra is committed to providing hospitals with wristbands that meet our high standards for image durability, scannability and comfort. Zebra's Z-Band direct thermal wristbands:

- Do not appear to present an additional hazard or risk to a patient undergoing an MRI procedure.
- Are scannable after repeated exposure to water and common solvents found in hospitals, as well as abrasion.
- Show no signs of erythema or edema when testing for primary skin irritation.

Zebra Technologies is a world leader in bar code, RFID, and ID card printing technologies, including systems installed at healthcare facilities for unit-of-use labeling, prescription label printing, patient wristband printing, materials management, security, and employee identification. Together with its partners, Zebra has the experience, industry knowledge, and specialized products needed for successful hospital implementations. Zebra is also a leader in standards development that actively participates in the work of life sciences industry associations so that it will be prepared to meet the emerging needs of its customers. Contact Zebra at +1 800 423 0442 or visit www.zebra.com for more information about bar code printing solutions for healthcare.



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