

A SATO Holdings Corporation White Paper

**Laboratory Testing of
SATO's Direct Thermal Antimicrobial Wristbands**



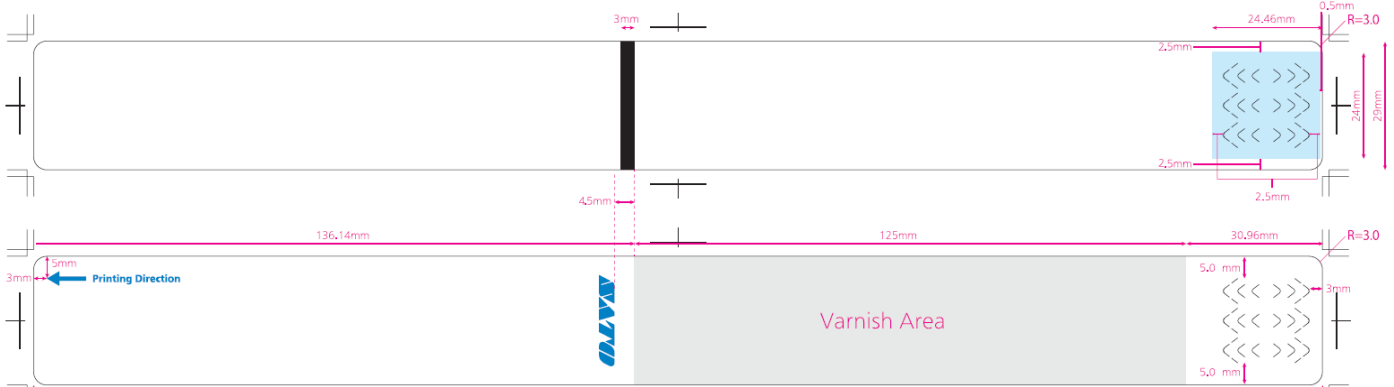
Introduction

This White Paper will present in details the laboratory testing completed on SATO direct thermal wristbands. SATO Printing Co., Ltd and independent laboratories performed extensive testing on SATO's direct thermal wristband line-up to evaluate the following:

- Print Durability and Base Material Resistance
- Data Conservation based on real study (bar code readability)
- Skin Irritation

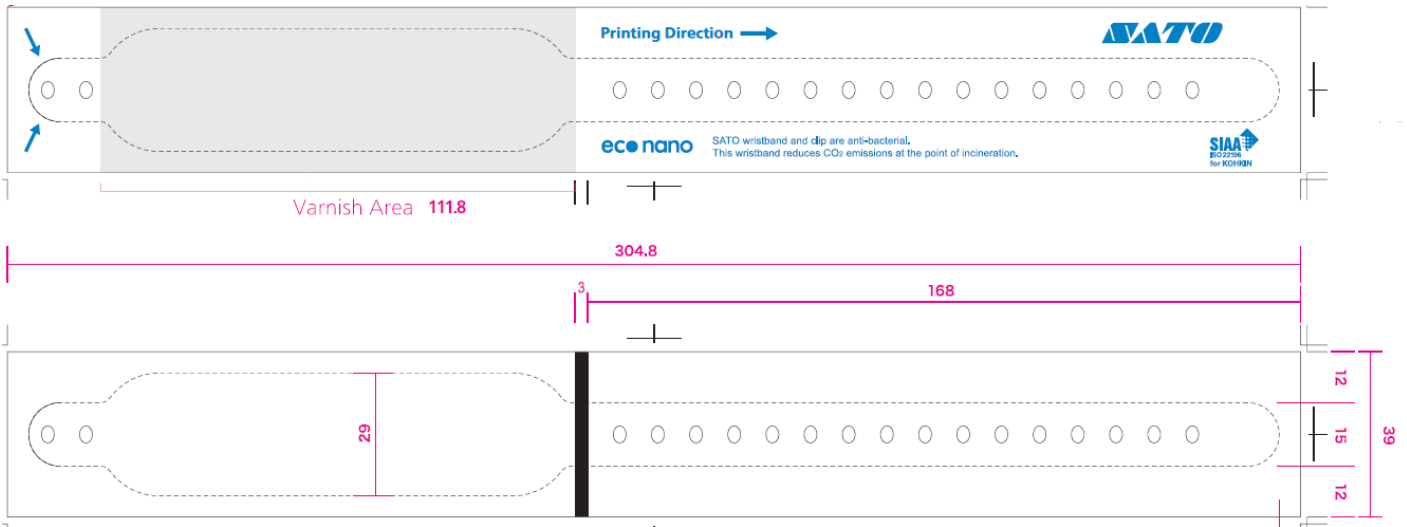
Wristband Line-up Presentation

1. Direct Thermal Adult Wristband with Adhesive Closure



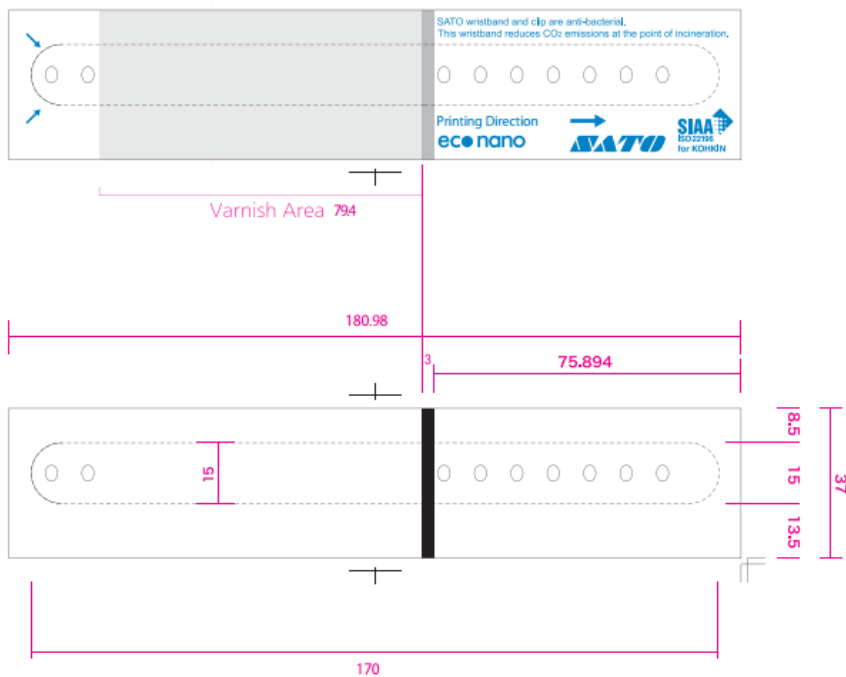
Product Reference	160165141
Print Method	Direct Thermal
Closure Type	Adhesive Fastening with Tamperproof
Patient	Adult
Color	White
Wristband Dimensions	292.1mm x 29mm
Wristband Print Area	125mm x 29mm
Packaging Specification:	100 pieces/roll, 16 rolls/box

2. Direct Thermal Adult Wristband with Clip Closure



Product Reference	060007584
Print Method	Direct Thermal
Closure Type	Clip Fastening
Patient	Adult
Color	White
Wristband Dimensions	295mm x 29mm
Wristband Print Area	108.8mm x 29mm
Packaging Specifications	100 pieces/roll, 6 rolls/box

3. Direct Thermal Child Wristband with Clip Closure



Product Reference	060002722
Print Method	Direct Thermal
Closure Type	Clip Fastening
Patient	Child - Infant
Color	White
Wristband Dimensions	170mm x 15mm
Wristband Print Area	78mm x 15mm
Packaging Specifications	125 pieces/roll, 8 rolls/box

Product Key Points

Direct Thermal Adhesive & Clip Closure Wristband

- Antimicrobial specifications based on ISO standard
- Perfectly fit for bar code printing
- Soft and robust material
- Embossed material on the backside allowing proper skin aeration
- ECONANO® technology to absorb CO₂

Soft Type Clip

- Antimicrobial specifications based on ISO standard
- Strong closure system impossible to open once closed and round-shaped to protect patient skin
- ECONANO® technology to absorb CO₂



SATO Direct Thermal Wristbands and Soft Clips are the world's first patient ID wristbands that use ECONANO technology, which enables users to reduce the CO₂ emission at the point of incineration.

Tested Wristbands Product Code:

Direct Thermal Adult Adhesive Closure	– 160165141
Direct Thermal Adult Clip Closure	– 060007584
Direct Thermal Child Clip Closure	– 060002722

Testing Facilities

- Base Material Resistance & Print Durability Testing: SATO Printing Co., Ltd & Kaken Test Center (Osaka, Japan). Report date: November 2016 & March 2017
- Skin Irritation Testing: Hohenstein Laboratory (74357 Boennigheim, Germany). Report date: February & March 2017

SATO's Wristband Certifications

➤ **Antimicrobial Certification**

SATO's Direct Thermal Wristbands comply with the antimicrobial activity guidelines defined by the JIS Z 2801 : 2010 / ISO 22196 standards.



➤ **Latex Free Certification**

SATO Quality Assurance Center, Ltd certifies that SATO's Direct Thermal Wristbands do not contain natural rubber latex.

➤ **Iron / Iron Oxide Free Certification**

Neither iron nor iron oxide was used in the base material or during the manufacturing process of SATO's Direct Thermal Wristbands.

➤ **Phthalates Free Certification**

Phthalates are neither used nor contained intentionally in SATO's Direct Thermal Wristbands.

Durability & Data Conservation Testing Results

All wristband samples tested were printed with SATO's CT4i Series Printer in Direct Thermal printing mode and in 203 Dpi at the recommended speed and darkness settings.

Data conservation testing was performed by scanning a 1 dot 16 digit Code 128 C bar code (used in hospitals worldwide for patient ID applications). For each following test, a "Pass" (Immediate scan of bar code) or "Fail" (Failure to scan or repeated attempts required to read the bar code) designation was noted.

Test Property

Test Results

Durability to Water

Rubbing with a soaked crocking cloth on a 1 dot 16 digit code 128 C bar code

After 40 Rubs

Pass

Durability to Soap Solution

Rubbing with a soaked crocking cloth on a 1 dot 16 digit code 128 C bar code

After 40 Rubs

Pass

Durability to Abrasion

Rubbing with a dry crocking cloth on a 1 dot 16 digit code 128 C bar code

After 1000 Rubs

Pass

Durability to Hand Sanitizer (Purell®)

Rubbing with a soaked crocking cloth on a 1 dot 16 digit code 128 C bar code

After 40 Rubs

Pass

Durability to Betadine (Isodine)

Rubbing with a soaked crocking cloth on a 1 dot 16 digit code 128 C bar code

After 200 Rubs Pass

Durability to 70% Ethyl Alcohol

Rubbing with a soaked crocking cloth on a 1 dot 16 digit code 128 C bar code

After 40 Rubs Pass

Warm Water Resistance

1KA-Werke GmbH & Co. KG, C-MAG HS7, Cimarec Hot Plate was used, the a 1 dot 16 digit code 128 C bar code was immersed in 105°F/40°C water at stir setting 3

After 24 Hours Pass

After 48 Hours Pass

Tensile Strength

Simulates pulling the wristband off a wrist. Tested at the speed of 1 inch/minute until the wristband breaks

Maximum Force 7Kg/15mm

Resistance & Data Conservation (bar code readability) Testing Results

For this test, 10 volunteers wore SATO's Direct Thermal Wristbands for 2 weeks and performed normal activity during the testing period. Barcode readability and conservation of the wristband properties were evaluated after 1 week and after 2 weeks.

All wristband samples tested were printed with SATO's CT4i Series Printer in Direct Thermal printing mode and in 203 Dpi at the recommended speed and darkness settings.

Data conservation testing was performed by scanning a 5 millimeter narrow-bar 12 digit Code 128 C bar code (used in hospitals worldwide for patient ID applications).

Once the study period was over, each wristband bar code was scanned and rated based on the ANSI specifications for the quality of linear bar codes testing. The American National Standards Institute (ANSI) guidelines provide standard measurement and a letter grade (A, B, C, D, E or F) for each bar code depending on its readability. A grade of C or better is currently accepted as the minimum to ensure immediate scanning without error.

Example of tested wristband:



Testing Conclusions:

After 1 week

After 1 week, all human characters and barcodes printed on wristbands were perfectly readable. The grade of each barcode was evaluated based on ANSI standards and gave the following results: 2 barcodes had A grade (best possible one), 6 barcodes had B grade and only 2 barcodes had C grade.

After 2 weeks

After 2 weeks, 9 wristbands out of 10 were readable. The grade of each barcode was evaluated based on ANSI standards and gave the following results: 4 barcodes had B grade, 2 had C grade, 2 had D grade, 1 had F grade and 1 barcode was not readable anymore.

Skin Irritation Testing

SATO's Direct Thermal Wristbands were tested by an independent laboratory to assess potential irritation to the patients' skin after exposure to the wristband.

SATO's Direct Thermal Wristbands were tested and comply with the following standards/procedures:

- **ANSI/AAMI/ISO 10993-5:2009-10**, Biological Evaluation of Medical Devices – Part 5 (Cytotoxicity Evaluation). Test item is considered “**Non-Cytotoxic**”.
- **HET CAM Test**, Test for skin irritation and tissue compatibility at the chorionallantoic membrane (CAM) of the hen's egg enables the evaluation of a potential risk for skin irritation. After test, the **samples achieved the best score of 0 (not irritative to slightly irritative)**.

Conclusion

SATO Direct Thermal antimicrobial wristbands boast superior durability and resistance and can be scanned without error even after being worn for 1 week. Moreover, clinical tests also show that they are not likely to cause any dermal irritation to the patient's skin.

About SATO

About SATO

SATO (TOKYO:6287) is a leading global provider of Auto-ID solutions that connect people, goods and information. It serves a diverse range of customers, delivering end-to-end solutions that streamline operations, empower workforces and help customers reduce their environmental impact. For the fiscal year ended March 31, 2016, it reported revenues of JPY 105,504 million (US \$880 million). More information about SATO can be found at www.satoworldwide.com or www.linkedin.com/company/sato-worldwide.*

**Conversion is based on an average exchange rate of 1 US Dollar = 120.14 Japanese Yen*

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