A SATO Holdings Corporation White Paper

Laboratory Testing of

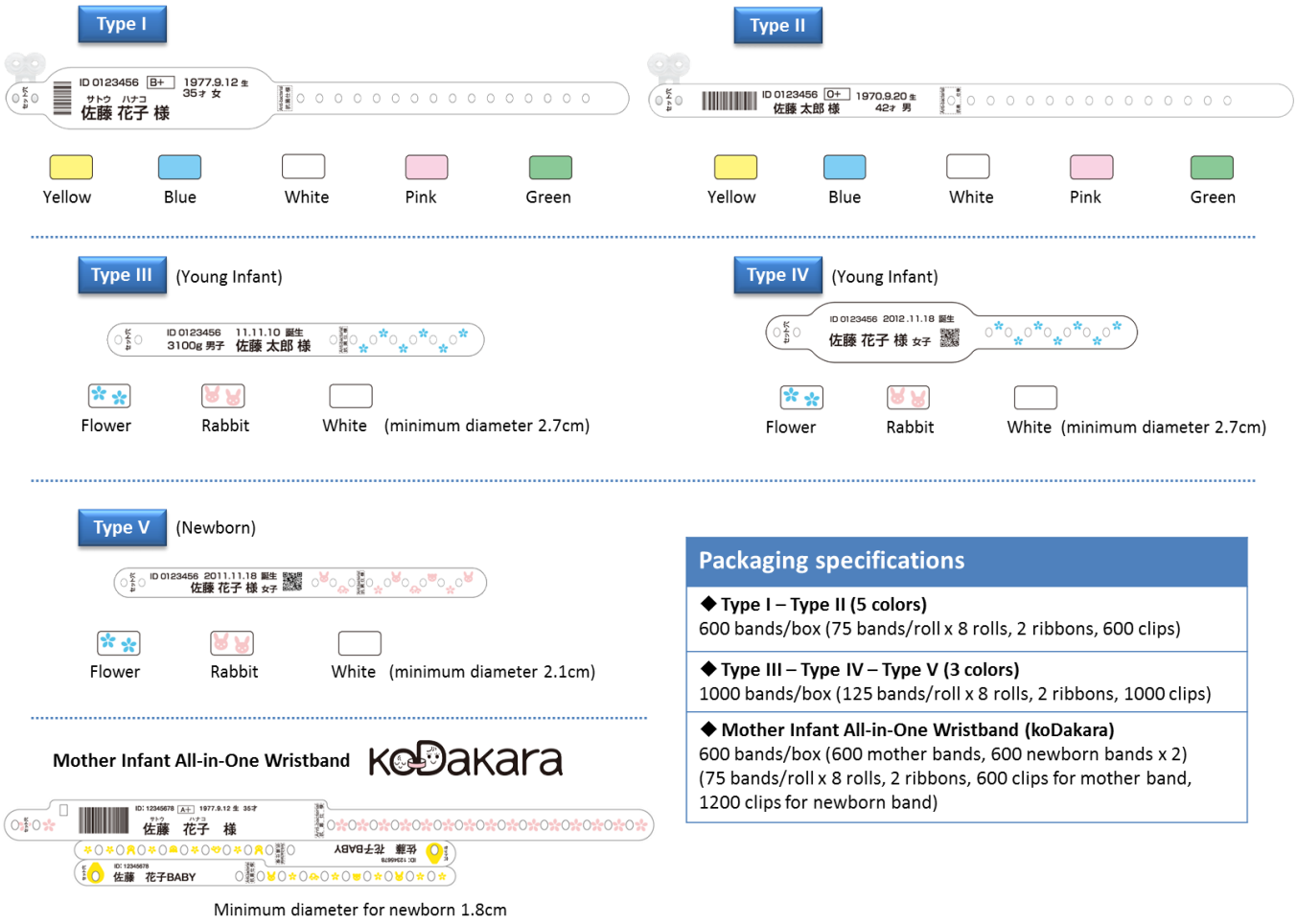
SATO's Thermal Transfer Antimicrobial Wristbands

Introduction

This White Paper will present in details the laboratory testing completed on SATO thermal transfer antimicrobial wristbands. SATO Printing Co., Ltd and independent laboratories performed extensive testing on SATO's thermal transfer 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



Packaging specifications
◆ **Type I – Type II (5 colors)** 600 bands/box (75 bands/roll x 8 rolls, 2 ribbons, 600 clips)
◆ **Type III – Type IV – Type V (3 colors)** 1000 bands/box (125 bands/roll x 8 rolls, 2 ribbons, 1000 clips)
◆ **Mother Infant All-in-One Wristband (koDakara)** 600 bands/box (600 mother bands, 600 newborn bands x 2) (75 bands/roll x 8 rolls, 2 ribbons, 600 clips for mother band, 1200 clips for newborn band)

Product Key Points

Soft Type Wristband

- Antimicrobial specifications based on ISO standard
- Perfectly fit for bar code printing
- Soft and robust material
- Embossed material allowing proper skin aeration
- ECONANO® technology to absorb CO_2

Soft Type Clip

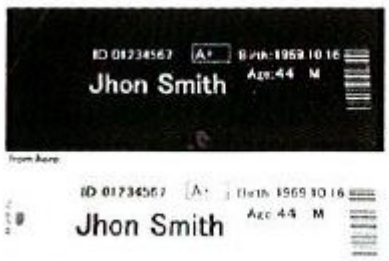
- Antimicrobial specifications
- Strong closure system impossible to open once closed and round-shaped to protect patient skin
- ECONANO® technology to absorb CO_2

SATO Soft Type 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.

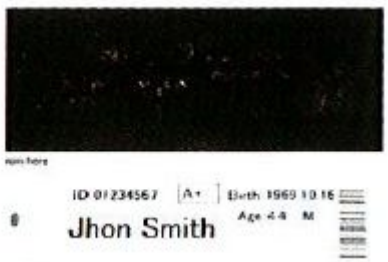
P133A Ribbon

- Resin ribbon specifically designed for thermal transfer printing
- Excellent print resistance to water, soap and alcohol
- Specific material to prevent the leak of personal information after printing

With standard ribbon



With SATO P133A Ribbon



Tested Wristbands Product Code:

Duramark Adult Secure Clip Fastening Antimicrobial Soft Type I White	– 060002601
Duramark Adult Secure Clip Fastening Antimicrobial Soft Type I Yellow	– 060002611
Duramark Adult Secure Clip Fastening Antimicrobial Soft Type I Green	– 060002641
Duramark Adult Secure Clip Fastening Antimicrobial Soft Type I Pink	– 060002631
Duramark Adult Secure Clip Fastening Antimicrobial Soft Type I Blue	– 060002621
Duramark Adult Secure Clip Fastening Antimicrobial Soft Type II White	– 060002521
Duramark Adult Secure Clip Fastening Antimicrobial Soft Type II Yellow	– 060002531
Duramark Adult Secure Clip Fastening Antimicrobial Soft Type II Green	– 060002561
Duramark Adult Secure Clip Fastening Antimicrobial Soft Type II Pink	– 060002551
Duramark Adult Secure Clip Fastening Antimicrobial Soft Type II Blue	– 060002541
Duramark Child Secure Clip Fastening Antimicrobial Soft Type III White	– 060002721
Duramark Child Secure Clip Fastening Antimicrobial Soft Type III Blue Flower	– 060002741
Duramark Child Secure Clip Fastening Antimicrobial Soft Type III Pink Rabbit	– 060002731
Duramark Child Secure Clip Fastening Antimicrobial Soft Type IV White	– 060002771
Duramark Child Secure Clip Fastening Antimicrobial Soft Type IV Blue Flower	– 060002791
Duramark Child Secure Clip Fastening Antimicrobial Soft Type IV Pink Rabbit	– 060002781
Duramark Child Secure Clip Fastening Antimicrobial Soft Type V White	– 060002981
Duramark Child Secure Clip Fastening Antimicrobial Soft Type V Blue Flower	– 060003001
Duramark Child Secure Clip Fastening Antimicrobial Soft Type V Pink Rabbit	– 060002991
Mother Infant All-in-One koDakara Wristband (Open Clip Type)	– 060007541
Mother Infant All-in-One koDakara Wristband (Closed Clip Type)	– 060007551

Testing Facilities

- Base Material Resistance & Print Durability Testing: SATO Printing Co., Ltd & Kaken Test Center (Osaka, Japan). Report date: December 2012
- Skin Irritation Testing: Geneva Laboratories, 1001 Proctor Drive. Elkhorn, WI 53121-0140. Report date: January & February 2013

SATO's Wristband Certifications

- **Antimicrobial Certification**
  SATO's Soft Type Wristbands comply with the antimicrobial activity guidelines defined by the JIS Z 2801 / ISO 22196 standards.

- **Latex Free Certification**
  SATO Quality Assurance Center., Ltd certifies that SATO's Soft Type Wristbands do not contain natural rubber latex.

- **Specifications & Standards for food, food additives, etc.**
  SATO's Soft Type Wristbands and Soft Type Clips comply with the Ministry of Health and Welfare in Japan notification No. 370 of 1959 "Specifications and Standards for food, food additives, etc." (compliance with the conformity criteria)

- **Iron / Iron Oxide Free**
  Neither iron nor iron oxide was used in the base material or during the manufacturing process of SATO's Soft Type Wristbands.

Durability, Resistance and Data Conservation Testing Protocols

All wristband samples tested were printed with SATO's Thermal Transfer CT4i Series Printer using SATO P133A ribbon at the recommended speed and darkness settings. SATO Soft Type antimicrobial clips were used for all durability tests.

Wristband print resistance was tested with an AATTC Crockmeter.

Data conservation testing was performed by scanning a 5 millimeter narrow-bar 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.

For the durability test, 10 volunteers were asked to wear SATO's Soft Type Wristbands for 2 weeks. 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 but some companies can also specify a B grade as a minimum when establishing standards.

Durability & Data Conservation Testing Results

Test Property	Test Results
Durability to Water	
Rubbing with a soaked crocking cloth on a 5 millimeter narrow-bar 16 digit code 128 C bar code	
After 600 Rubs	Pass
After 1000 Rubs	Pass
Durability to Soap Solution	
Rubbing with a soaked crocking cloth on a 5 millimeter narrow-bar 16 digit code 128 C bar code	
After 600 Rubs	Pass
After 1000 Rubs	Pass
Durability to Abrasion	
Rubbing with a dry crocking cloth on a 5 millimeter narrow-bar 16 digit code 128 C bar code	
After 1000 Rubs	Pass
After 2000 Rubs	Pass
Durability to Hand Sanitizer (Purell®)	
Rubbing with a soaked crocking cloth on a 5 millimeter narrow-bar 16 digit code 128 C bar code	
After 200 Rubs	Pass
Durability to Betadine (Isodine)	
Rubbing with a soaked crocking cloth on a 5 millimeter narrow-bar 16 digit code 128 C bar code	

After 600 Rubs	Pass
After 1000 Rubs	Pass

Durability to 70% Ethyl Alcohol

Rubbing with a soaked crocking cloth on a 5 millimeter narrow-bar 16 digit code 128 C bar code

After 600 Rubs	Pass
After 1000 Rubs	Pass

Warm Water Resistance

1KA-Werke GmbH & Co. KG, C-MAG HS7, Cimarec Hot Plate was used, the 5 millimeter narrow-bar 16 digit code 128 C bar code was immersed in 105°F/40°C water at stir setting 3

After 24 Hours	Pass
After 72 Hours	Pass

Cleansing Oil Resistance

1KA-Werke GmbH & Co. KG, C-MAG HS7, Cimarec Hot Plate was used, the 5 millimeter narrow-bar 16 digit code 128 C bar code was immersed in room temperature cleansing oil (KOSE) at stir setting 3

After 24 Hours	Pass
After 72 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	Up to 26.6 lbs

Resistance & Data Conservation (bar code readability) Testing Results

For this testing, 10 volunteers wore SATO's Soft Type Wristbands for 2 weeks and performed normal activity during the testing period. Barcode readability and conservation of the wristband properties were evaluated. Age and gender of the volunteers are as follows:

- Volunteer 1 : 50 years old male
- Volunteer 2 : 58 years old male
- Volunteer 3 : 59 years old male
- Volunteer 4 : 25 years old female
- Volunteer 5 : 45 years old male
- Volunteer 6 : 45 years old female
- Volunteer 7 : 50 years old male
- Volunteer 8 : 58 years old male
- Volunteer 9 : 57 years old male
- Volunteer 10 : 35 years old female

The picture below represents actual wristband samples at the end of the testing period. All bar codes and text based information were still perfectly readable. All bar codes could be read upon first scan and obtained either A or B grade according to ANSI standards.

Skin Irritation Testing

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

SATO's Soft Type Wristbands were tested and comply with the following standards:

- **ANSI/AAMI/ISO 10993-5:2009**, Biological Evaluation of Medical Devices – Part 5 (Cytotoxicity Evaluation). Test item is considered "**Non-Cytotoxic**" and meets ISO test acceptance requirements of no more than Grade 2 Reactivity.
- **ANSI/AAMI/ISO 10993-10:2010**, Biological Evaluation of Medical Devices – Part 10 (Closed Patch Sensitization). Under the conditions of this study, the test article is a **non-sensitizer**.
- **ANSI/AAMI/ISO 10993-10:2010**, Biological Evaluation of Medical Devices – Part 10 (Primary Skin Irritation). Under the conditions of this study, the test **article response category was negligible** (Primary Irritation Index = 0).

Conclusion

SATO thermal transfer antimicrobial wristbands boast excellent durability and resistance and can be scanned without error even after being worn for 2 weeks. Moreover, clinical tests also show that they are not likely to cause any dermal irritation to the patient's skin.

About SATO

SATO is a pioneer and leading global provider of integrated Automatic Identification and Data Collection solutions that leverage barcode and RFID technologies. SATO manufactures innovative, reliable auto-identification systems and offers complete solutions to businesses by integrating hardware, software, media supplies and maintenance services. Customers rely on SATO for accuracy, labor and resource savings helping to preserve the environment.

Founded in 1940, SATO is publicly listed on the first section of Tokyo Stock Exchange in Japan. It has sales and support offices in over 20 countries and is represented globally through a world-class network of partners. For the fiscal year ended March 31, 2013, it reported revenues of JPY 87,256 million (US$ 1.052 billion). More information about SATO Corporation can be found at www.satoworldwide.com.

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