



# SoftTouch™ Antimicrobial Wristbands

## Laboratory Testing

By SATO America

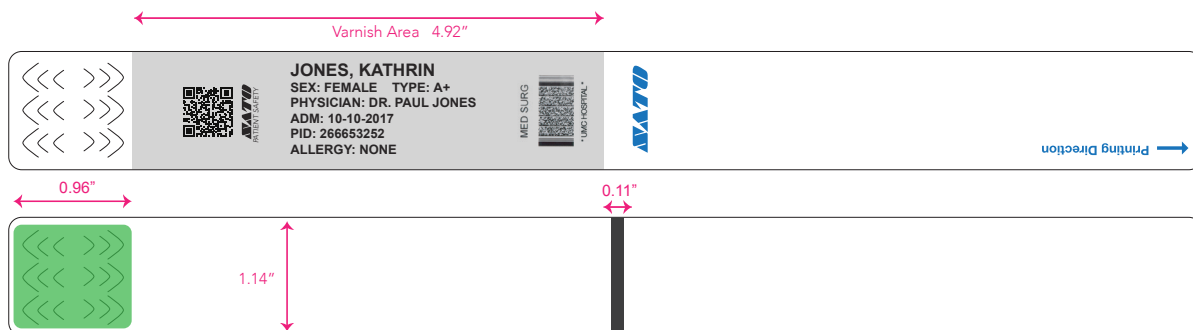
This White Paper presents the results of the laboratory testing completed on SATO direct thermal wristbands. SATO Printing Co., Ltd and independent laboratories performed extensive testing on SATO's direct thermal wristband line-up to evaluate the following:

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

In this updated version V.4, we have added some notes on the use of SATO's UHF RFID Direct Thermal Adhesive Wristband.

## Wristband Line-up Presentation

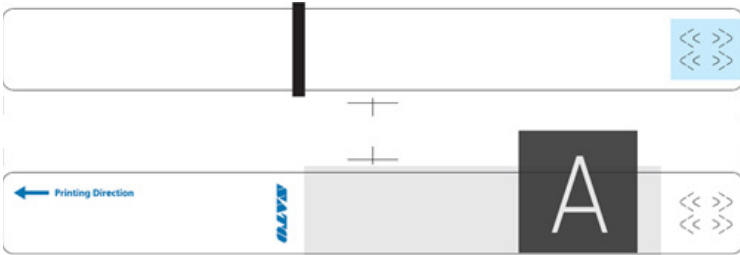
### 1. Direct Thermal Adult Wristband with Adhesive Closure



Product Reference	160165141
Print Method	Direct Thermal
Closure Type	Adhesive Fastening with Tamperproof
Patient	Adult
Color	White
Wristband Dimensions	11.50" x 1.14"
Wristband Print Area	4.92" x 1.14"
Packaging Specifications	100 pieces/roll, 16 rolls/box

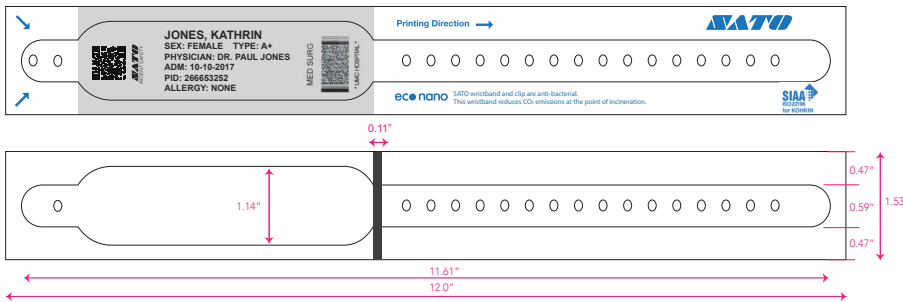


## 2. Direct Thermal Child Wristband with Adhesive Closure



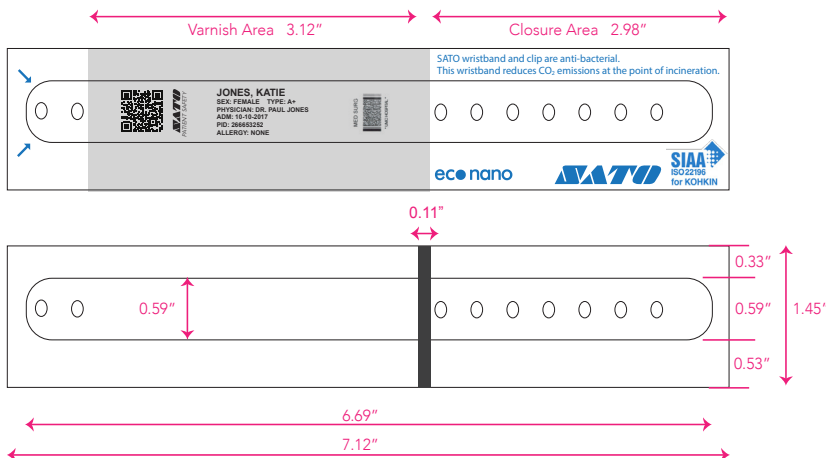
Product Reference	800118153
Print Method	Direct Thermal
Closure Type	Adhesive Fastening with Tamperproof
Patient	Infant
Color	White
Wristband Dimensions	7.37" x 0.78"
Wristband Print Area	3.54" x 0.78"
Packaging Specifications	125pieces/roll 20 rolls/box

## 3. Direct Thermal Adult Wristband with Clip Closure



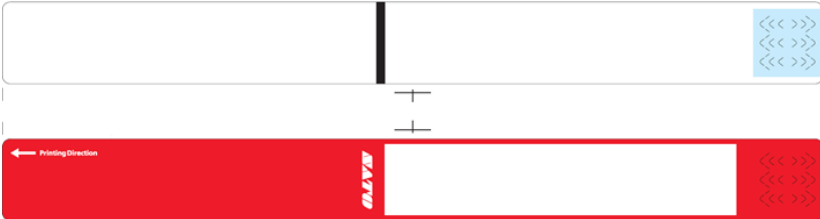
Product Reference	060007584
Print Method	Direct Thermal
Closure Type	Clip Fastening
Patient	Adult
Color	White
Wristband Dimensions	11.61" x 1.14"
Wristband Print Area	4.28" x 1.14"
Packaging Specifications	100 pieces/roll 6 rolls/box

## 4. Direct Thermal Child Wristband with Clip Closure



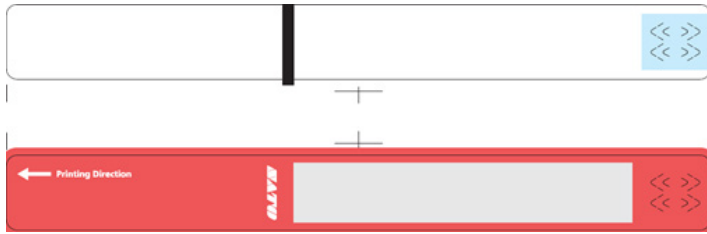
Product Reference	060002722
Print Method	Direct Thermal
Closure Type	Clip Fastening
Patient	Child - Infant
Color	White
Wristband Dimensions	6.69" x 0.59"
Wristband Print Area	3.07" x 0.59"
Packaging Specifications	125 pieces/roll 8 rolls/box

### 5. Direct Thermal Adult Red Wristband with Adhesive Closure



<b>Product Reference</b>	800119368
<b>Print Method</b>	Direct Thermal
<b>Closure Type</b>	Adhesive Fastening with Tamperproof
<b>Patient</b>	Adult
<b>Color</b>	Red
<b>Wristband Dimensions</b>	11.5" x 1.14"
<b>Wristband Print Area</b>	4.92" x 1.14"
<b>Packaging Specifications</b>	100 pieces/roll 16 rolls/box

### 6. Direct Thermal Child Red Wristband with Adhesive Closure



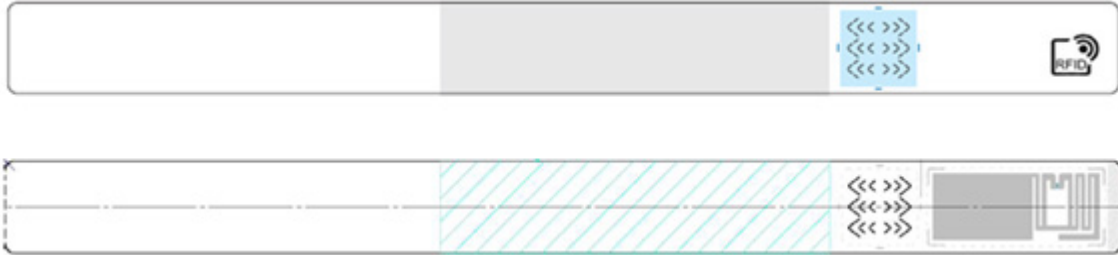
<b>Product Reference</b>	800119369
<b>Print Method</b>	Direct Thermal
<b>Closure Type</b>	Adhesive Fastening with Tamperproof
<b>Patient</b>	Child - Infant
<b>Color</b>	Red
<b>Wristband Dimensions</b>	7.37" x 0.78"
<b>Wristband Print Area</b>	3.54" x 0.78"
<b>Packaging Specifications</b>	125 pieces/roll 20 rolls/box

### 7. Direct Thermal Adult Narrow with Adhesive Closure



<b>Product Reference</b>	8001184022
<b>Print Method</b>	Direct Thermal
<b>Closure Type</b>	Adhesive Fastening with Tamperproof
<b>Patient</b>	Adult
<b>Color</b>	White
<b>Wristband Dimensions</b>	11.46" x 0.78"
<b>Wristband Print Area</b>	5.19" x 0.78"
<b>Packaging Specifications</b>	100 pieces/roll 20 rolls/box

## 8. UHF RFID Direct Thermal Wristband with Adhesive Closure



<b>Product Reference</b>	162014251
<b>Print Method</b>	Direct Thermal
<b>RFID Encoding</b>	UHF, EPC Class1 Gen 2
<b>Closure Type</b>	Adhesive Fastening with Tamperproof
<b>Patient</b>	Adult
<b>Color</b>	White
<b>Wristband Dimensions</b>	14" x 1.14"
<b>Wristband Print Area</b>	4.88" x 1.14"
<b>Packaging Specifications</b>	75 pieces/roll, 16 rolls/box



## Product Key Points

### Direct Thermal Adhesive & Clip Closure Wristband

- Antimicrobial specifications based on ISO standard
- Perfect for barcode printing
- Soft and robust material
- Embossed material on the backside allowing proper skin aeration



### Soft Type Clip

- Antimicrobial specifications based on ISO standard
- Strong closure system makes it impossible to open once closed, and its rounded shape protects the patient's skin

### UHF RFID Wristband (additional key points for RFID feature)

- Antimicrobial specifications based on ISO standard
- Designed to provide optimal patient comfort during hospital stay
- Allows simultaneous barcode printing & RFID encoding
- Optimal read range for hospital location systems

## Tested Wristbands Product Code:

Direct Thermal Adult Adhesive Closure	160165141
Direct Thermal Child with Adhesive Closure	800118153
Direct Thermal Adult Clip Closure	060007584
Direct Thermal Child Clip Closure	060002722
Direct Thermal Adult Red with Adhesive Closure	800119368
Direct Thermal Child Red with Adhesive Closure	800119369
Direct Thermal Adult Narrow with Adhesive Closure	8001184022
UHF RFID Wristband Adhesive Closure	162014251

## 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 barcode (used in hospitals worldwide for patient ID applications). For each following test, a "Pass" (Immediate scan of barcode) or "Fail" (Failure to scan or repeated attempts required to read the barcode) designation was noted.

Test Property	Test Results
<b>Durability to Water</b>	
Rubbing with a soaked crocking cloth on a 1 dot 16 digit code 128 C barcode	
After 40 Rubs	Pass
<b>Durability to Soap Solution</b>	
Rubbing with a soaked crocking cloth on a 1 dot 16 digit code 128 C barcode	
After 40 Rubs	Pass
<b>Durability to Abrasion</b>	
Rubbing with a dry crocking cloth on a 1 dot 16 digit code 128 C barcode	
After 1000 Rubs	Pass
<b>Durability to Hand Sanitizer (Purell®)</b>	
Rubbing with a soaked crocking cloth on a 1 dot 16 digit code 128 C barcode	
After 40 Rubs	Pass



Test Property	Test Results
<b>Durability to Betadine (Isodine)</b>	
Rubbing with a soaked crocking cloth on a 1 dot 16 digit code 128 C barcode	
After 200 Rubs	Pass
<b>Durability to 70% Ethyl Alcohol</b>	
Rubbing with a soaked crocking cloth on a 1 dot 16 digit code 128 C barcode	
After 40 Rubs	Pass
<b>Warm Water Resistance</b>	
1KA-Werke GmbH & Co. KG, C-MAG HS7, Cimarec Hot Plate was used, a 1 dot 16 digit code 128 C barcode was immersed in 105°F/40°C water at stir setting 3	
After 24 Hours	Pass
After 48 Hours	Pass
<b>Tensile Strength</b>	
Simulates pulling the wristband off a wrist. Tested at the speed of 1 inch/minute until the wristband breaks	
Maximum Force	7Kg / 0.59"

## Resistance & Data Conservation (barcode 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 barcode (used in hospitals worldwide for patient ID applications). For each following test, a "Pass" (Immediate scan of barcode) or "Fail" (Failure to scan or repeated attempts required to read the barcode) designation was noted.

Once the study period was over, each wristband barcode was scanned and rated based on the ANSI specifications for the quality of linear barcode testing. The American National Standards Institute (ANSI) guidelines provide standard measurement and a letter grade (A, B, C, D, E or F) for each barcode 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-readable 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.

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.

## 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 \(not irritative to slightly irritative\)](#).

## Precautions

Symptoms such as rash and eczema may appear depending on the constitution of the person wearing a wristband (allergies, sensitive skin, etc.). If you notice any abnormalities on your skin, stop using it immediately, remove it and consult a doctor.

## Storage Conditions

Storage: 32°F to 104°F, 30% to 80%RH

1. Store the product away from sunlight and sources of heat. Ensure that the product is stored in a location where the recommended storage temperature is not exceeded.
2. If the product is stored in a location with excessive humidity or moisture present in storage locations might affect the functioning of the product.



## Notes on RFID Product

1. Please understand that the Product incorporates precise semiconductors and its reading performance varies greatly depending on the circumstances. Therefore, given these characteristics of the Product, it is recommended to conduct a thorough field test on the Product using your reading and writing equipment in advance, and adopt the use of the Product at your own discretion.

- Reading of the data may be affected if the Product is attached to a metallic product or a bottle containing a liquid.
- If the angle of the tag to the antenna changes, the communication performance may be affected.
- If there is an electronic device or equipment or other metallic product which generates noise signal, etc. around the Product, the communication performance may be affected.
- Depending on the temperature or humidity of where the Product is used, the communication may become impossible.

2. Since there are cases where writing of data is not completed because of electricity shortage during writing of data, please make sure that the writing of data has been completed successfully.

3. Breakage of IC chips or data garbling of memory in IC chips may occur due to the circumstances of handling of the Product and external stress (including but not limited to pressure, static electricity, etc.) during operation or transportation or storage or the circumstances of using the Product.

4. In case that we confirm the existence of defects in the Product by a cause attributable to us, we will deliver the same number of the replacement Products. THIS REPLACEMENT IS YOUR SOLE AND EXCLUSIVE REMEDY AND IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE IN CASE OF DEFECTS IN THE PRODUCT AND WE WILL BE EXEMPTED FROM OTHER RESPONSIBILITIES INCLUDING, BUT NOT LIMITED TO, MONETARY COMPENSATION. IN ADDITION, WE WILL IN NO WAY ACCEPT ANY LIABILITY FOR THE READING PERFORMANCE OF THE PRODUCT.

5. Please understand that there is a possibility that the production of base materials or RFID inlay (including IC chips) may be unavoidably discontinued due to their supplier's decision. In case of such discontinuation of RFID inlay or IC chip, we will offer an alternative product to you after mutual discussion.



### **IMPORTANT**

**RFID wristbands should be removed from patients prior to MRI scans, as they contain metallic materials.**



## 1. Handling Instructions

The RFID Wristband includes sensitive microchip. Please follow the precautions below carefully.

1. Do not bend or flex the part of the wristband where the microchip is located. Do not apply excessive force to the part of the wristband where the microchip is located.
2. Do not apply excessive force or shocks to the microchip location when attaching the wristband.
3. Keep the product away from strong magnetic fields and radiation sources as these may cause malfunctions. This product must be removed from patients before entering an area where magnetic resonance imaging (MRI) equipment is in use.
4. Correct operation cannot be ensured if the wristband is stacked with other RFID products.
5. Correct operation cannot be ensured if the wristband is used near a lot of liquid.
6. If the product is modified or processed in any way, this may greatly change the product read range or other characteristics. Test and validate all additional modifications or processing.

## 2. Warranty

The Product has a 12 month warranty and is limited to products that are in their original packaging and stored according to the storage conditions and environment as instructed in this document. If Product is used under high temperature, stored under direct sunlight, affected by chemicals or water, or is damaged by physical stress or strong magnetic fields, the warranty does not apply.

## 3. Limitation of Warranty

SATO will not accept warranty claims in the following cases:

7. In the case SATO has not been notified in a timely manner regarding defective products after receipt.
8. In the case the product has been used after the warranty period has expired.
9. In the case the product is not stored in its original packaging.
10. In the case the product has not been handled and stored according to instructions as laid out in this document.
11. In the case external the product has been damaged due to external factors such as fire, natural disasters malfunctioning electrical equipment or other similar reasons.
12. In the case the product has been modified or processed by a third party.
13. In the case the defect is due to any other reason not under the control of SATO or force majeure.

## 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. More information about SATO Corporation can be found at [www.satoworldwide.com](http://www.satoworldwide.com)



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A SATO Holdings Corporation White Paper

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

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