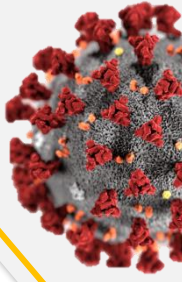




Puri Band Attached Thermometer



PURPOSE

To provide scientific evidence on the effectiveness, safety and cost-effectiveness of Puri Band attached thermometer as a temperature screening and monitoring tools for COVID-19 control.

INTRODUCTION

Establishments such as businesses, transportation systems, and community organizations are developing plans to resume normal or phased operations during the COVID-19 pandemic. These plans may include an initial assessment to identify people who may be infectious in order to limit the spread of COVID-19 infection. Temperature measurement is one of the assessment to determine if a person has an elevated temperature potentially caused by a COVID-19 infection. One method to measure a person's surface temperature is the use of "no-touch" or non-contact temperature assessment devices which do not require physical contact, thus reduce the risk of spreading infection. These non-contact devices can quickly measure and display a temperature reading for a larger number of people can be evaluated individually at points of entry.³

One of the non-contact device is the Puri Band. Puri Band is the Self-Check Temperature Patch that measures body temperature by colour change of a small patch sticker. When attached, the colour of the band changes with body temperature. For normal body temperature, it turns green. If it turns yellow, it means that the person has high fever of more than 37.5 degree. User can simply attach the patch directly to places where body temperature can be easily measured, such as wrists and neck areas. When a sticker is applied to the skin, the color changes instantly in real time according to body temperature.



Figure 1: Puri Band

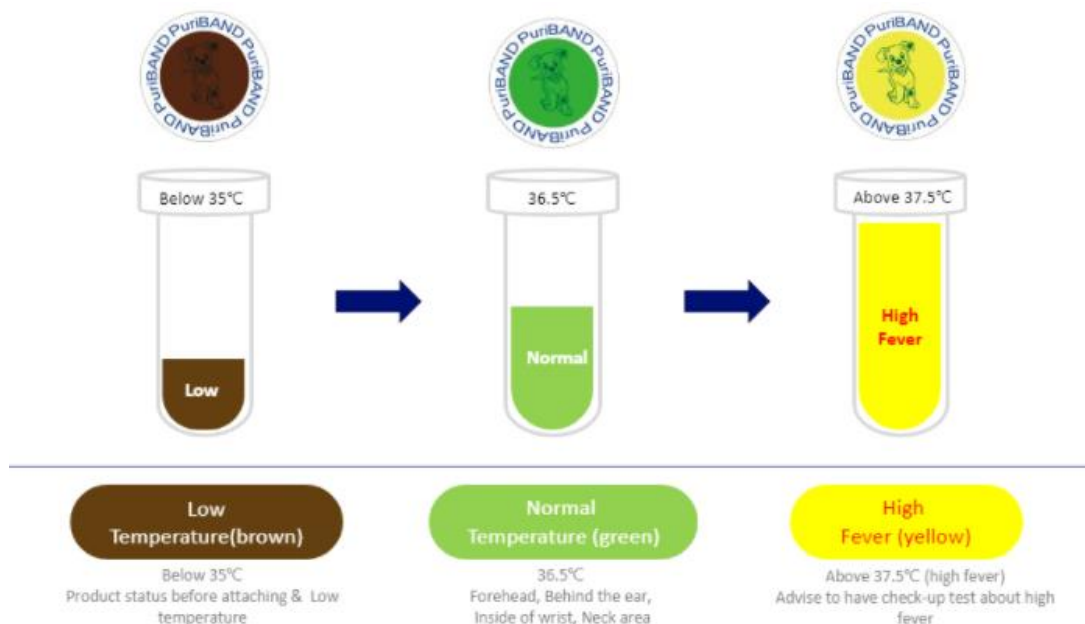


Figure 2: Puri Band colour indication

This color-marked thermometer stickers was manufactured and patented in Seoul, South Korea by PuriTech company under the Korean Medical Devices Regulations with FDA registration Number D40755 under classification Class I (general controls) and was exempted from the premarket notification procedures.

Puri Band allows constant temperature monitoring of a large number of individuals with minimal effort and virtually zero disruptions during work or other daily activities. It will remains effective for 3-4 days and withstand washing or shower. The price of Puri Band on ebay website is RM 82.64 for 1 set with 8 patches.

In Korea, Puri Band have been used widely as part of quarantine packages for air travelers, temperature screening at the airport, daycare centres, kindergastens,schools, nursing homes, hospitals, universities and public venues.

EVIDENCE/INFORMATION SUMMARY

There was no retrievable evidence from the scientific databases such as Medline, EBM Reviews, EMBASE via OVID, PubMed and from the general search engines [Google Scholar and US Food and Drug Administration (US FDA)] on effectiveness and safety of colour-marked thermometer stickers.

Little is known about the colour-marked thermometer stickers mechanism of action. However, according to the Medisafe Technologies Sdn Bhd Quality Assurance Executive, this product measures body temperature using an array of thermochemical cells (dots) which colour tone changes according to body temperature. It has a white fabric on release paper, and an adhesive is applied between them. This adhesive and white fabric are used for disposable bands. It composed of three layers of temperature-sensitive pigment that changes colour depending on the temperature of the white fabric.

Puritech manufacturer from Seoul, South Korea have commissioned Korea Testing Certification (KTC) to conduct a cytotoxicity test on Puri Band. The results were presented as below:

Test items	Units	Test Standard	Results
1. Cytotoxicity test	-	ISO 10993-5, Test for <i>in vitro</i> Cytotoxicity, Test on extracts (1x MEM, 37°C, 24 h)	Grade 2 (Mild) Not more than 20 % of the cells are round and devoid of intracytoplasmic granules, no extensive cell lysis; not more than 50% growth inhibition observable.
2. Guinea pig maximization test	-	ISO 10993:2010, Biological Evaluation of Medical Devices- Part 10: Test for irritation and skin sensitization, 7.5 Guinea pig maximization test	Negative No clinical symptom, death or moribund animals were observed during the experiment. No evidence of causing delayed dermal contact sensitization in the guinea pig.
3. Animal irritation test	-	ISO 10993:2010, Biological Evaluation of Medical Devices- Part 10: Tests for irritation and skin sensitization, 6.3 Animal irritation test	Negative No evidence of significant irritation from test article extract applied to skin of rabbits.

No Puri Band accuracy and sensitivity test information can be retrieved in any scientific databases.

CONCLUSION

There was no evidence retrieved from scientific databases on the effectiveness and safety of Puri Band attached thermometer as a temperature monitoring tool.

This Puri Band thermometer patch has a potential as a continuous body temperature monitoring and screening tool for COVID-19 control. Evaluation on its accuracy comparing to standard thermometer is warranted.

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Based on available evidence up to 22th February 2021

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Disclaimer: This rapid assessment was prepared to provide urgent evidence-based input during COVID-19 pandemic. The report is prepared based on information available at the time of research and a limited literature. It is not a definitive statement on the safety, effectiveness or cost effectiveness of the health technology covered. Additionally, other relevant scientific findings may have been reported since completion of this report.

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