

+LUCKY



INSTRUCTIONS FOR USE Wearable axillary thermometer

NOTICE D'UTILISATION Thermomètre axillaire connecté

MANUAL DE INSTRUCCIONES Termómetro axilar conectado

BEDIENUNGSANLEITUNG Angeschlossenes Axillar thermometer

MANUALE D'ISTRUZIONE Termometro ascellare collegato

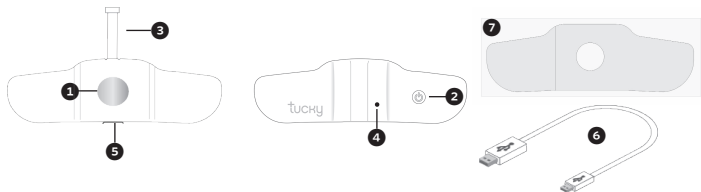
MANUAL DE INSTRUÇÕES Termómetro axilar ligado

GEBRUIKSAANWIJZING Aangesloten axillaire thermometer

دليل المستخدم متصل بالحرارة الإبطية

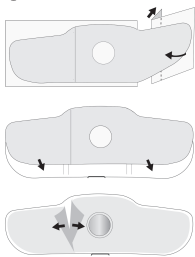
Model: Tucky-21

22300AD, -A June 2020



- 1** Measurement sensor / Sonde de mesure / Sensor / Sensore / Meetsensor / قياس مسبار
2 On-off button / Bouton marche-arrêt / Ein-Ausschalter / Botón de encendido-apagado / Pulsante di accensione-spegnimento / Botão On-Off / Aan-uit-knop / زر تشغيل / إيقاف
3 Micro USB port strip-cap / Languette-capuchon port micro USB / Lasche-Kappe für Micro-USB-Anschluss / Lengüeta-capuchón de puerto micro USB / Languetta-cappuccio porta Micro-USB / Separador da tampa da porta micro USB / Micro USB-poort strip-kap / علامة التيوب فقط، منفذ BSU المصغ
4 On-off LED / Led On-Off / LED zur Betriebsanzeige / Led de funcionamiento / LED di funzionamento / LED de funcionamiento / Aan-Uit-LED / تشغيل / الاضواء
5 USB port / Port USB / USB-Anschluss / Puerto USB / Porta USB / porta USB / USB-poort / BSU منفذ
6 Charger lead / Câble chargeur / Ladekabel / Cable cargador / Cavo di ricarica / Cabo do carregador / Opladkabel / كابل شحن
7 Double-sided adhesive / Adhésif double-faces / Doppelseitigen Klebstoff / Adhesivo de doble cara / il biadesivo / Adesivo dupla face / Dubbelzijdige kleefband / تطبيق اللاصقة على الوجهين على التابلت

A



B



INSTRUCTIONS FOR USE

Tucky-21 is a non-invasive and reusable electronic device for home use and a non-invasive and single patient use in the hospital. This product is intended for non-urgent ambulatory **continuous armpit body temperature monitoring** from ages 29 days and older.

Tucky-21 also allows position monitoring of patient from ages 29 days and older (this is however not part of its medical intended use). It is positioned under the right armpit, as high as possible, with a dedicated double-sided adhesive (ADH-21) and transmits data to the "Tucky" smartphone application.

Temperature monitoring

The thermometer is set in direct mode: it takes the actual axillary temperature, without making adjustment calculations. You should thus **wait about 15 minutes** after placing Tucky under the armpit for the temperature to stabilize. The temperature is displayed with a color code, indicating whether it is normal or not.

Colour / axillary temperature correlation table:			
Green normal temperature	Orange high temperature	Red (alert) Very high temperature	Grey Temperature not representative
From 34.7 to 37.3 °C (93.2 to 98.6 °F)	From 37.3 to 38.4 °C (98.6 to 100.4 °F) default value	Above 38.4 °C (100.4 °F) default value	E.g.: opened arm*
<i>Note: rectal temperature is usually 0.7 °C (1.3 °F) higher than axillary temperature</i>			

*The **arm must be closed** so that the measurements are less disturbed by the environment. The normal temperature varies according to the individual (age, sex, type, skin thickness), the time of day and external factors (ambient temperature, clothing, etc.) [1]. It is therefore normal to notice temperature variations caused by changes in the environment or arm position. In this case, the trend can be interpreted by following the highest values of the last few hours.

An **alert** is issued when the temperature exceeds the "very high temperature" value. This threshold can be modified by the user in the application.

Position monitoring

The device also allows **position monitoring**, especially for babies. An icon on the application indicates whether the baby is in one of the following 4 positions: standing or sitting, lying on his back, lying on his stomach, lying on his side.

An alert is issued when the child turns over on his or her stomach. This alert can be deactivated in the application.

Note: to ensure this functionality, the product must be placed under the right armpit.

[1] KELLY, Greg. Body temperature variability (Part 1) : A review of the history of body temperature and its variability due to site selection, biological rhythms, fitness, and aging. *Alternative medicine review*, 2006, vol. 11, no 4, p. 278.

WARNINGS AND PRECAUTIONS FOR USE

Before using the product, please **read these instructions for use carefully and completely** to ensure reliability of the data.

- Tucky is a measurement tool but is not a diagnostic tool. It is not a substitute for monitoring symptoms or consulting a physician.
- Do not use this thermometer to interpret hypothermia temperatures.
- Tucky should only be applied with the **double-sided adhesive provided** (ADH-21), on clean and cream-free skin. Adhesives are single-use and non-repositionable. During use, ensure that the probe remains in continuous contact with the skin.
- If axillary hairs are present, shave the area to maximize contact between Tucky and the skin.
- In case of heavy sweating or use during sport activities, a single-sided medical adhesive may be added over the device to improve its hold. A list of recommended adhesives is available on the manufacturer's website.
- Do not apply the device on irritated or damaged skin or if an allergy to plastics (elastomer or silicone type) and/or adhesives has been detected in the patient.
- The adhesive should be changed every 24 hours or more frequently depending on skin sensitivity. If the skin shows redness, wait until it disappears before putting the product back on. If irritation occurs, remove the product immediately and seek advice from a health care professional.
- Tucky and adhesives should be used under normal conditions of temperature and humidity (see *"Technical data"*). Otherwise, measurements accuracy cannot be guaranteed.
- The thermometer and adhesives must be transported, stored and put in dry locations, away from direct sunlight, fire, contamination and within the specified temperature and humidity ranges (see *"Technical data"*).
- It must not be immersed in water: remove Tucky before bathing or showering.
- The product has been designed to follow the curvature of the body. **Do not twist it by hand** and do not try to open, repair or modify it. Do not use if damaged.
- Do not use Tucky near strong wave emitting devices (MRI scanners, scanners, portable or mobile RF communication devices) that may interfere with its operation (see *"Electromag. testing"*).
- Do not use Tucky and adhesives beyond their lifespan (see *"Technical Specifications"*).
- Be sure to keep Tucky and its accessories (adhesives and charger cable) away from children's mouth. They must be used by adults.
- The device must never be worn during charging. Its functions are then deactivated.
- Check that your device (smartphone or tablet) is compatible with the application and has Bluetooth® and internet connectivity (see *"Technical data" and list of recommended devices*).
- Before using Tucky, check the time on your phone as the application is based on it.
- Make sure your smartphone or tablet has enough memory to store data.
- The phone paired with Tucky using Bluetooth® must remain within signal range to receive information (see *"Monitor data wherever you are"*).
- The manufacturer may change this manual and product specifications without notice. Refer to the digital version available on the manufacturer's website.

OPERATING INSTRUCTIONS

Charge Tucky

- Before using Tucky for the first time, **charge Tucky** with the supplied cable ④ by connecting it to a computer 5V USB port until the LED turn off (about 2 hours). The autonomy after a full charge is 5 days.

Install the application and create an account

- Download the «Tucky» application from the Apple Store or Google Play Store.
- Create an account by following the instructions, then create one profile per patient.

Note: the data are stored in a certified health data cloud.

Associate Tucky with a patient profile

- Turn on Tucky by pressing the On/Off ② button; LED ④ will blink for 2 seconds (6 times).
- In phone / tablet settings, activate the Bluetooth® function.

Notes: on iPhone, Tucky may not appear in the list of detected Bluetooth® devices. Simply enable Bluetooth®, then exit from iPhone settings.

- In the application, select a profile, approach Tucky to the phone / tablet, press the “Associate” button and accept authorization requests. A temperature is displayed in the banner.

Note: once associated, Tucky reconnects as soon as it's within signal range.

Apply ADH-21 adhesive to Tucky ⑤

- Remove the small part of the paper backing and peel the adhesive ⑦ from the remaining part. Stick it on Tucky's front side, making sure probe edges are covered. Then remove both parts of the clear film.

Place Tucky under the armpit ⑥

- To place Tucky, observe the following points:

- * The micro-USB port ⑤ must be oriented downwards, with strip-cap ③ closed and sensor ① facing the skin,
- * Tucky must be positioned **as high as possible** under the right armpit.

Notes: if axillary hairs are present, shave the area before applying the device. In case of heavy sweating, it is possible to improve Tucky hold by adding a single-sided adhesive strip over it.

- For a better temperature measurement, wear light clothing and wait about 15 minutes with the arm closed until the temperature stabilizes.

Monitor the data wherever you are (2 use cases)

- Below 10m, use the phone / tablet connected to Tucky via **Bluetooth®**.

Notes: if Bluetooth® connection is lost, the application tries to reconnect automatically. Tucky will continue to record the temperature (for 8 hours maximum) and will synchronize with the application as soon as the connection is re-established.

- Above 10m, two phones / tablets connected to the same account are required.

* One must be connected to Tucky via Bluetooth®. It automatically relays information via Internet to the cloud (see “Data Protection”), making them accessible to other devices.

* The other one displays data **from the cloud** without distance limit. A cloud icon on the app indicates this.

Notes: verify that alerts work and are audible by activating “Test alert” on the application.

There is no limit concerning the number of people which can monitor remotely data of the same account.

Turn off Tucky

- To turn off Tucky, press the On/Off button; the LED will lit during two seconds. Otherwise, Tucky will automatically turn off 30 minutes after being removed from the body.

Cleaning and maintenance

- After each use, remove the adhesive and clean Tucky with a cotton soaked with medical alcohol. **Do not use water, abrasive cleaners**, or dishwashing products on Tucky. Not intended to be sterilized.

- To avoid battery issues, **charge Tucky at least once a year**.

TECHNICAL CHARACTERISTICS

Type of product	Direct mode clinical thermometer
Thermometer references Adhesives reference	- TUCKY-21, TUCKY-21W, TUCKY-21Y, TUCKY-21O, TUCKY-21P, TUCKY-21B & TUCKY-21N - ADH-21-E1
Storage / transport conditions	For complete product (including adhesives) or for adhesives only: Temperature: +10 to 27 °C (+50 to 80 °F); Relative humidity: 40 to 60 % For thermometer only: Temperature: -20 to +55 °C (-4 to 131 °F); Relative humidity: 15 to 95 %
Normal conditions of use	Temperature: +15 to 40 °C (59 to 104 °F); Relative humidity: 15 to 95 % (non-condensing) Atmospheric pressure: 76 to 106 kPa
Display resolution	0,1 °C (0,2 °F)
Displayed temperature range	+24 to 44 °C (75 to 111 °F)
Accuracy (maximum laboratory error within the display temperature range)	±0.1 °C (0.2 °F) from 37 to 39 °C (98 to 102 °F); ±0.2 °C (0.3 °F) from 32 to 37 °C (90 to 98 °F) and from 39 to 42 °C (102 to 107 °F); ±0.3 °C (0.5 °F) beyond these ranges.
Power supply	Rechargeable internal Lithium battery not accessible. Capacity: 35 mAh
Charger cable	USB 2.0 Type A male to Micro USB Type B male cable
Charging voltage	5V
Alerts and information	High temperature: >38,4 °C (101,1 °F) (modifiable), Rollover on the belly (deactivated), Battery discharged (<6 %), Tucky detached, Long connection loss (>15min), Error
Bluetooth® technology	BLE 4.2; very low output power (1.35 mW)
Protection class IP22	Protected against solid bodies larger than 12 mm Protected against dripping water up to 15° from vertical
Supplied accessories	Instruction for use, charger cable, double-sided adhesive tape ADH-21
Lifespan	Thermometer: 5 years (500 charge cycles); Adhesives: 5 years
Required equipment	Smartphone or tablet with Bluetooth and internet connectivity. A list of recommended equipment is available on the manufacturer's website
Compatibility	From iPhone 4S, iPad 3 and Android 4.3

The device is intended for use in the electromagnetic environment defined below

ELECTROMAGNETIC EMISSION TESTS	COMPLIANCE	ENVIRONMENT
RF emission (CISPR 11)	Group 1	RF emissions are very low and are not likely to cause interference to nearby electronic equipment
	Class B	Conform
Harmonic current emission	Not applicable	Battery powered

Voltage fluctuation, Emission of Flicker flicker	Not applicable	Battery powered
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IMMUNITY TESTING	TEST LEVEL ACCORDING TO IEC 60601	CONFORMANCE LEVEL
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV on contact ± 2,4,8 and 15 kV in air	Compliant
Radiated RF IEC 60601-4-3	10 V/m from 80 MHz to 2,5 GHz	Compliant
Magnetic field at mains frequency IEC 60601-4-8	30 A/m	Compliant

DATA PROTECTION

Data are stored in a certified health data cloud (HADS) and are processed in accordance with applicable laws for the purpose of monitoring patient's axillary temperatures. You have the right to access, rectify and delete your data, and the right to limit data treatment. For more information, please read the privacy and data protection policy on the manufacturer's website.

AFTER-SALES SERVICE, WARRANTY & INSPECTION

If you have problems using the product, please refer to the troubleshooting section on the manufacturer's website. If the problem persists, contact support and communicate the product serial number available on the packaging label and on the 2D barcode located under the product strip-cap. Applications for reading 2D barcodes are available from the Apple Store and Google Play Store.

Tucky thermometer is under warranty for 2 years from the date of initial purchase from the distributor by the end customer. It covers defects in material and workmanship under normal use in accordance with manufacturer's recommendations. This warranty does not cover defects caused by abnormal or faulty use or resulting from a cause unrelated to the intrinsic qualities of the product. For more information, please refer to the general terms and conditions of sale on the manufacturer's website.

To guarantee the operation and accuracy of the product, it is advisable to have it inspected every 2 years. The cost of this service is defined on the manufacturer's website.

REGULATORY COMPLIANCE

This device complies with European directives and regulations relating to medical devices, radio equipment and restriction of hazardous substances. A copy of the EU Declaration of Conformity is available on the manufacturer's website. Any serious incidents with Tucky should be reported to e-TakesCare (vigilance@e-takescare.com) and the health agency in charge of vigilance incidents.

INFORMATIONS TO USERS IN USA

Federal Communication Commission Interference Statement (FCC ID = 2AWDL-TUCKY21WAA)

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation

INFORMATIONS TO USERS IN CANADA (IC : 26084-TUCKY21WAA)

This device complies with Industry Canada's licence exempt RSSs. Operation is subject to the following two conditions: (1) This device may not cause interference; and (2) This device must accept any interference, including interference that may cause undesired operation of the device.

Radiation Exposure Statement

The product complies with the Canada portable RF exposure limit set forth for an uncontrolled environment and are safe for intended operation as described in this manual. The further RF exposure reduction can be achieved if the product can be kept as far as possible from the user body or set the device to lower output power if such function is available.

INFORMATIONS UTILISATEURS CANADIENS (IC : 26084-TUCKY21WAA)











Cet appareil est conforme aux CNR exemptes de licence d'Industrie Canada. Son fonctionnement est soumis aux deux conditions suivantes : (1) Ce dispositif ne peut causer d'interférences ; et (2) Ce dispositif doit accepter toute interférence, y compris les interférences qui peuvent causer un mauvais fonctionnement de l'appareil.

Déclaration d'exposition aux radiations

Le produit est conforme aux limites d'exposition pour les appareils portables RF pour les États-Unis et le Canada établies pour un environnement non contrôlé. Le produit est sûr pour un fonctionnement tel que décrit dans ce manuel. La réduction aux expositions RF peut être augmentée si l'appareil peut être conservé aussi loin que possible du corps de l'utilisateur ou que le dispositif est réglé sur la puissance de sortie la plus faible si une telle fonction est disponible.

SYMBOL SIGNIFICATIONS

CE marking affixed in 2016

	Manufacturer / Fabricant : e-TakesCare, 35, rue des Chantiers, 78000 Versailles, France www.e-takescare.com
	Direct current / Courant continu
	CE marking / Marquage CE
	Follow the operating instructions / Suivre les instructions d'utilisation
	Apparatus comprising BF-type applied parts / Appareil comportant des pièces appliquées de type BF
	Non-ionizing radiation / Rayonnement non ionisants
	Storage temperature / Température de stockage : +10 to 27 °C (+50 to 80 °F)
	The device, its accessories and its packaging must be recycled in the appropriate way at the end of their use. Please observe local regulations and rules / Le dispositif, ses accessoires et son emballage doivent être recyclés de la façon appropriée au terme de leur utilisation. Veuillez respecter les règlements et règles locaux
	Serial number / Numéro de série
	Catalogue number / Référence catalogue



Manufacturer website:
www.e-takescare.com