QUICK USER GUIDE

BABY MONITOR

biotrend

Model: KOALA

Manufactured by:
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Uruguay 2887 - Victoria
Buenos Aires - Argentina

1. Indications of use

The physiological baby monitor Koala is a device that allows to perceive sounds close to the baby and has a base-sensor dedicated to the prevention and warning of episodes where the physiological indications SpO2, hearth rate, temperature and body position leave the expected values .
It was designed to be used in newborn children up to 18 months.

2. Contraindications and warnings

- It is not designed to be defibrillation tested according to IEC 60601-1: 2005 clause 8.5.5.1.
- Do not use during magnetic resonance imaging sessions.
- The oximetry readings and pulse signals may be affected by certain environmental conditions, by errors in the application of the sensor and by specific conditions of the child.
- Factors that can degrade performance or affect the accuracy of measurements include the following:
    - Excessive ambient light
    - Excessive movement
    - Electrosurgical interference

- Devices that restrict blood flow in the area of application
- Incorrect application of the sensor
- Bad pulse signal
- Venous pulsations
- Anemia or low concentrations of hemoglobin
- Dysfunctional hemoglobin

This device is intended to serve only as an early assistant in the evaluation of the child.

It is necessary that anyone who is about to operate this device carefully read and understand the instructions for use of this manual, in order to understand how to operate it properly following these instructions.

3. Precautions

The Koala is an accessory and is not a substitute of adult supervision.
In case of premature babies, with supplemental oxygen or with a health condition, please consult with the professional to indicate if the Koala is the right device for your child.
Respond immediately to any warning sound.
Inspect the area of application of the sensor every 6 to 8 hours minimum to ensure the correct alignment of the

sensor and the integrity of the skin. The sensitivity of it may vary depending on the clinical condition or skin condition.

4. Content of the box

BASE: The base receives the transmissions of the koala sensor through bluetooth low energy (BLE) and it is connected via WIFI forming a wireless domestic network with the smartphones of the house. It also has an ambient microphone to listen to what happens in your baby's environment.
Also, It is the element that will produce the wireless charge of the Koala sensor (QI) when placing it in the sector for that purpose.

USB CABLE: The base is powered through a USB cable like that for cell phones and must remain powered for the system to work.

KOALA SENSOR: It is the device that senses the different parameters through the BIOTREND SAT technology widely tested in medical environments with its Biotrend BPO250 pulse oximeters. Its high integration technology allows it to have dimensions ideal for newborns, even premature babies in a medical environment, to use it without any problem of size.

GRIP FABRIC: It is a synthetic fabric accessory, totally antiallergenic and widely used in medical products in contact with the skin that ensures the maintenance of the sensor in a safe position in order to avoid false alarms due to changes in the position of it.

6. Instructions for use

6.1. Before placing on the baby

Before using the Koala for the first time, proceed to charge the device and connect it to the WIFI network.
Put the sensor in the base in the existing depression for this purpose. The device is supported on the logo side on the base. This will result in wireless charging of the device.

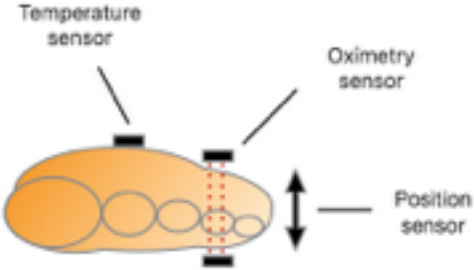
- The first time you charge it, there will be a synchronization between the sensor and the base. During this process of approximately 30 seconds, the indicator ring of the base will blink in white indicating the action. Once completed this will light up in blue color slowly rising and falling its intensity.
- When it is fully charged, the hoop will remain permanently blue.

6.2. Place the sensor in the baby foot

The sensor consists of an emitting LED and a receiver, the signal crosses the foot of your baby allowing to establish the oxygen content in the arterial blood indicating whether the tissue oxygenation process is developing normally (Oximetry). It also allows to calculate the hearth rate and the temperature in the skin of your baby's foot.

6.2.1. Important details in the sensor position

- Functional scheme of the sensor



- The emitter and receiver should be as aligned as possible. A better alignment implies a more reliable measurement.
- Do not place the sensors on the toes. This will generate bad readings. Always place on the instep.

- Try to keep the electronics as close to the skin as possible. Adjust with the grip fabric gently.
- If the base does not turn green on its indicator ring once the sensor is placed and it is flashing yellow, verify that the sensor is positioned correctly.
- For newborn babies use the sensor so that the logo is on the sole of the foot. This will facilitate the adjustment and measurement for small sizes.

6.2.2. Placement of the sensor

- Position the sensor trying to align the emitter and receiver (A perfect alignment is not necessary).
- Verify that the indicator ring on the base lights green.

6.3. Alarms and visual and acoustic indicators

The physiological baby monitor Koala consists of a medical device (Sensor + Base) and a smartphone application that adds listening functionality of the baby environment.

The base is the element that charges the battery of the sensor wirelessly and establishes the communication with it when it is placed on the baby's foot. The sensor is responsible for measuring the parameters, blood oxygen saturation (SpO2), heart rate (PPM), temperature and relative position. When any of these parameters leaves the established values, the base makes light and audible indications to call the attention of the adult in charge of the baby.

6.3.1.Physiological Alarms

EVENT	DESCRIPTION	LIGHT INDICATOR	ACOUSTIC INDICATOR
PULSE LOST	Sensor placed correctly, pulse can not be measured for 20 seconds and no movement is detected during that time. It requires immediate attention.	RED on / off 2 times per second.	10 tones that repeat every 10 seconds
LOW SpO2 / HEART RATE OUT OF RANGE	Sensor placed correctly and the baby has a low level of oxygen in the blood or its heart rate is extremely low or high. It requires immediate attention.	YELLOW on / off 2 times per second	3 tones that repeat every 15 seconds
VERY HIGH OR VERY LOW TEMPERATURE	Sensor placed correctly and the baby has temperature in his foot out of range. It requires immediate attention.	YELLOW on / off 2 times per second	3 tones that repeat every 15 seconds

6.3.2.Technical Failure Indicators

EVENT	DESCRIPTION	VISUAL INDICATOR	AUDIO INDICATOR
SENSOR FAILURE	The sensor is correctly positioned and happens to be not positioned or incorrectly positioned. It requires attention, not necessarily immediately.	YELLOW constantly on	1 tone each 30 seconds
CONNECTION FAILURE	The sensor is not communicating with the base - Connection failure. The measurement is not working. It requires attention, not necessarily immediately. Note: It was connected to the sensor and lost the connection	YELLOW constantly on	1 tone each 30 seconds
MEASUREMENT FAILURE	The sensor is connected, but presents inability to measure SpO2 or BPM for N seconds and motion is detected. It requires attention, not immediately.	YELLOW constantly on	1 tone each 30 seconds

6.3.3.Indications

EVENT	DESCRIPTION	LIGHT INDICATOR	AUDIO INDICATOR
SUCCESSFUL SYNCHRONIZATION	The synchronization between the base and the sensor is completed (Paired)	-	BIRUBIP
SENSOR CHARGING	The sensor is correctly placed in the base for its wireless charging process	BLUE - slowly low and rise its intensity	—
SENSOR FULL CHARGE	The sensor is correctly placed in the base and completed its charging process	BLUE constantly on	—
BASE POWERED	The base is connected to the power supply and without connection to the sensor	WHITE constantly on	—
ALL VALUES IN RANGE AND CONNECTED	The base and the sensor are connected with all the vital signs in range	GREEN constantly on	—

6.3.4. Range of normal values

PARAMETER	VALID RANGE
Blood oxygen saturation (SpO2)	85 % > VALUE > 100 %
Heart rate	60 PPM > VALUE > 200 PPM
Confort skin temperature	16 ºC > VALUE > 39 ºC

6.4. Connect baby monitor from the KOALA app

Read carefully and follow the steps to configure and connect the BABY CALL application. The oximetry, temperature and position sensing device is already working. No shutdown is required for adding the application.
Download the Biotrend Koala APP from Play Store or App Store and install it in your smartphone Android or IOS.

6.5. Associate the KOALA base with WIFI at your home

6.5.1. Router with wps

Wi-Fi Protected Setup™ (WPS) is a feature that lets you easily connect WPS-supported client devices, such as wireless printers, to your router wirelessly. The koala Base has available this kind of configuration.

- Push the wps button in your router 
- Wait 30 seconds while the base is self-configuring.
- Once it is configured a bip bip sounds.

The base is configured and the system is working.

6.5.2. Router without wps, manual configuration

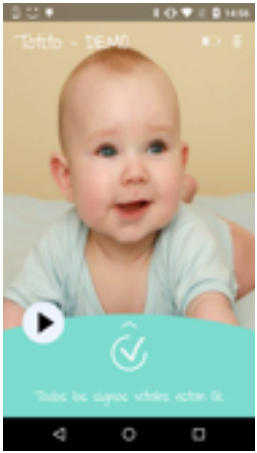
- Open the application from your Android or IOS smartphone
- Disconnect the base from the power supply and reconnect it. This action puts the base waiting to be connected by the smartphone application. Blinking in violet color for 15 seconds. If the base turns white, repeat this action
- From the application Go to menu/configure base

- Go to baby docks. If you do not see a base or list of available bases, you will refresh the screen (by sliding your finger on it from top to bottom)
- Select the one that corresponds (Touching the lamp symbol you receive a sound identifying the base)
- You will be asked for a password, by default it is 1234. This key protects your base from being accessed by another user with the Koala application.
- Go to menu/networks. Add by touching + the wifi of the house.
- Select the one that corresponds
- Add an alias name (for example home)
- Set the WIFI password
- Return to baby docks screen and refresh it until the base change the connexion symbol from bluetooth to wifi.

Once the base is configured the system is working. Each time the base enters the range of that configured WIFI network it will connect automatically.

6.6. Configure Baby and sensor information

At this point parents can upload their baby's data. Sex, date of birth, photo, etc.



6.7. Basic operation with the application

Once the base and the application are connected, it allows parents to listen to all the ambient sounds in their child's environment by touching the play button. When the sensor is not connected, the application is automatically placed as a baby monitor, playing the ambient sounds at the request of the parents.

When the sensor is connected in the application, the auditory and visual indications of the base are reproduced

at the app for the case in which the parents are at a greater distance where they do not perceive the indications of the base.

More information about the application can be consulted in its help section.

6.8. Sensor turning on and off

- The sensor is turned on simply by placing it in the charging base.
- The sensor can be turned off in two ways:
    - Automatically: Removing the sensor from the load base and leave it without movement for 5 minutes. It will turn off automatically to protect its battery.
    - Forced: Place the sensor in the base, wait for the beginning of the charge by flashing the green LED on its orange section. Then a red LED will light up at the other end for 5 seconds. If it is removed from the base in that time the sensor will turn off. Once the red led is off, it goes back into normal operation.

7. Technical specifications

7.1. Base

Power supply	**USB adaptor 100 - 240 V, 50-60 hz**
Dimensions (HxWxD)	**68 x 68 x 16 mm**
Weight	**300 g**
Connectivity	**Bluetooth v4.2 BLE** **WIFI - 802.11 b/g/n** **WEP/WPA/WPA2**
Indications	**Visuals and auditories**

7.2. Sensor

Power supply	**Rechargeable battery - QI (wireless charging)**
SpO2	**0 - 100 %**
Precision	**2 % @ 70 - 100**
BPM (Heart rate)	**20 - 254 bpm**
Precision	**± 3 digits**
Temperature	**0 - 60 ºC**