Babytone

Baby Sleep Clip
Model: BS1

1. Before use

1.1 Warning and Cautions

- The device is not a medical device and is not intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease.
- This product is intended for use with healthy children up to 24 months of age. If your child has a pre-existing medical condition, please consult your doctor before use.
- This product is an aid and should not be substituted for the care and oversight of an adult or consultation with medical professionals.
- Do not use this product as a diagnostic tool.
- Do not use this product to justify unsafe sleep habits.
- Keep the Baby Sleep Clip out of children's mouths.
- For babies with sensitive skin, remove the sensor immediately if redness, swelling, or skin irritation occurs.
- Children can be strangled by cords. Keep cords out of reach (more than 1m/3ft away). Never use extension cords with AC adapters. Only use the DC 5V 1A adapter.
- Movement from external sources such as being pushed in a bassinet or traveling in a vehicle may be detected by the device. The device should not be relied upon where external sources of movement are present.
- The monitored child must sleep in their own separate bed as the device may detect the movement of any other person sharing the bed with the child, and will not send any notification as long as it detects movement.
- Never submerge the device in water or other liquids.
- Do not clean the device with acetone or other volatile solutions.
- Do not drop this device or subject it to strong impact.
- The device and accessories are provided non-sterile.
- Do not place this device in pressure vessels or gas sterilization device.
- Do not dismantle the device, as this could cause damage or malfunctions or impede the operation of the device.

1.2 Guide to Symbols

Symbol	Description
(factory)	Manufacturer
(date)	Date of manufacture
SN	Serial number
(crossed-out bin)	Indicates that the product should not be discarded as unsorted waste but must be sent to separate collection facilities for recovery and recycling.
(hand book)	Refer to instruction manual
MR	MR unsafe
IPX6	Indicate that the product is protected from powerful water jets.
CE	CE marking
EC REP	Authorized representative in the European community
UKCA	UKCA marking
UK REP	UK Responsible Person
FC	Indicates that the product complies with the applicable FCC requirements
((·))	Non-ionizing radiation
(recycle)	Indicates that the marked item or its material is part of a recovery or recycling process.
(Triman)	Our products and packaging can be recycled, don't throw them away! Find where to drop them off on the www.quefairedemesdechets.fr site (Only applicable for French market).
(temp limit)	Temperature limit
(humidity)	Humidity limitation
(pressure)	Atmospheric pressure limitation

1.3 Packing List

- Main unit ×1
- Clip ×2
- User manual ×1
- Quick guide ×1
- Battery ×1
- Battery replacement uncapping tool ×1
- USB magnetic charging cable ×1

2. Introduction

2.1 Intended Use

The product is a wearable clip that can be clipped onto the baby's diaper or pants to easily monitor the baby's respiration, sleeping position, and feeling temperature during sleep, and alert when the range of signs (stomach sleeping or feeling temperature) exceeds the user's setting.

2.2 Contraindication

No contraindications.

2.3 Overview

Temperature probe hole
Indicator light
Clip
Charging contacts
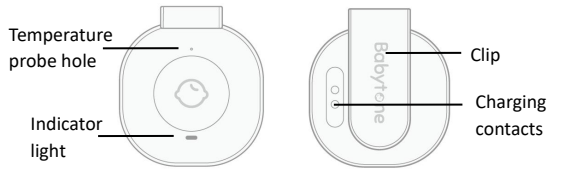
Color	Brightness	Status	Events
Red	High	Fast flashing (every 2s)	Stomach sleeping; detected/high respiratory rate/low respiratory rate
		Fast flashing (3s)	App connection failure
	Low	Slow flashing (every 5s)	Low battery (<20%)
Blue	High	Fast flashing	Connecting to App
		Solid (5s) then off	App Connected
		Solid	Software updating
	Low	Slow flashing	Working mode
Green	High	Single flash	Reminder of shaking the device twice
	Low	Slow flashing	Charging
		Solid	Fully charged

3. Using the Device

3.1 Charging

Charge the device before using to release it from the shipping mode.
Use the magnetic charging cable to charge your device's battery through the computer's USB port or USB charging adapter.
The device automatically enters sleep mode when fully charged.

3.2 Working Modes

On	Device power greater than 5%
Working mode	Shake the device twice to enter working mode.
Sleep mode	The device enters sleep mode if there is no activity detected or the device falls off for more than 10 minutes.
Off	Device power lower than 5%

3.3 Download the App

Download the ViHealth App from iOS App Store or Google Play Store, or scan the QR code below.
Note:
- The ViHealth App is compatible with iOS versions 9.0+ and Android versions 5.0+.
- The communication distance is up to 33ft (10m) in open space. Firewall or obstacles in between may affect the distance dramatically.

3.4 App Connection

Follow the steps below to connect the Baby Sleep Clip to the App:
1. Download the ViHealth App and allow all requested permissions.
2. Sign up a ViHealth account.
3. Enter personal profile information.
4. Ensure the device Bluetooth is on by putting it into charging or working mode.
5. Click the displayed device icon with the right serial number.
6. The connection will be finished in a few seconds.

3.5 Wearing the Baby Sleep Clip

1. Pinch open the clip.
2. Push the clip onto the diaper to its FULL extent.
3. Keep the baby icon in the same direction as your child's body direction to avoid unexpected readings or notifications.

Push · Right Direction · Wrong Direction

Note:
- Snugly fitting sleepwear (diaper/pants/etc) is essential for accurate monitoring. Loose fitting sleepwear may cause lose contact with the child and introduce false notifications.
- Keep the temperature probe hole exposed to air.
- Please keep clothes out of the clip to avoid breakage of the clip or unexpected notifications.
- Please do not wrench the end of the clip as it may break the clip.
- The device can store up to ten sets of data for up to 24 hours each. Please sync data to your phone in time.
- Please keep recording for at least ten minutes or the data will not be saved.

3.6 Real-time Monitoring

The ViHealth App supports monitoring respiration rate, sleeping positions, feeling temperature and abnormal events in real-time on the Dashboard screen.

3.7 Alerts

When recorded data exceeds the preset value, the device alerts via the indicator light and the App sends sound or vibration notifications. You can adjust the settings in the App- [Dashboard]- [Settings].
- Stomach sleeping:
  Turn on/off device alerts
  Adjust the sensitivity of the alert
- Respiration rate:
  Turn on/off device and App alerts
  Adjust the threshold which triggers an alert.
- Feeling temperature (App only):
  Turn on/off App alerts.
  Adjust the unit and thresholds which triggers an alert.
  Adjust the temperature drop value.

3.8 Review Data

Users can review historical recordings in App- [History]. You can select a recording to view detailed information, export the report and share it with others.

4. Maintenance

4.1 Time & Date

When connected to the App, the device time will automatically sync with the phone time.

4.2 Cleaning

- The device is splash-resistant, NOT waterproof. Do not immerse in water. If it gets wet, dry it off immediately.
- Do not leave it in wet diaper for long time, it may cause unexpected temperature reading, or other malfunctions.
- Clean the device by wiping gently with a cloth or cotton ball moistened with water or medical alcohol.

4.3 Accessory Replacement

User can exchange the clip when it is broken. Please follow the steps below.
1. Remove the main unit. Hold the left and right sides of the clip frame and push the main unit outward from the back of the clip.
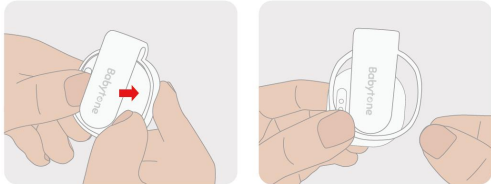
2. Take out the spare clip.
3. Align the triangle symbol on the clip frame with the main unit indicator and press the main unit downward into the frame.
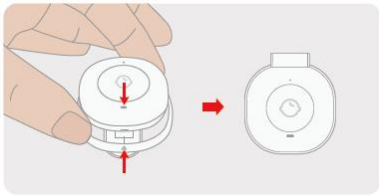
5. Specifications

Environmental	Operating	Storage
Temperature	5 to 45°C	-25 to 55°C
Relative humidity (non-condensing)	10% to 80%	10% to 95%
Barometric	700 to 1060hPa	700 to 1060hPa
Protection against electric shock	Internally powered equipment	
Degree of dust & water resistance	IPX6	
Weight	15g	
Dimension	45.62mm*39.68mm*18.24mm	

	(Clip included)
Battery	Rechargeable Lithium-polymer, 240mAh
Charge time	<4 hours
Battery life	≥84 hours for typical use
Alert source	Stomach sleeping; high/low respiration rate; high/low feeling temperature; falling temperature
Recorded parameters	Respiration rate; sleeping positions; feeling temperature; abnormal events and its time
Data storage	10 sessions, up to 24 hours for each
Wireless	Bluetooth 5.0
Frequency range	2.402 − 2.480 GHz
Max RF power	8 dBm
Expected service life	3 years
Mobile App for iOS	iOS 9.0 or above, iPhone 4s/ iPad 3 or above
Mobile App for android	Android 5.0 or above

6. Troubleshooting

Problem	Possible Cause	Possible Solution
Device does not enter working mode.	Battery may be low.	Charge the device and try again.
	Device might be damaged.	Please contact your local distributor.
The App cannot find the device	The Bluetooth of your phone is off.	Turn on the Bluetooth in the phone.
	The device Bluetooth is off.	Ensure the device is in working or charging mode.
	For **Android**, Bluetooth cannot work without location permission.	Allow location access.
Receive no alerts from the device.	Device falling off	Re-wear the device.
	Device powering off due to low battery	Charge the device.
	Device alert is turned off in the App.	Turn on the Device alerts in the App.

7. FCC statement

FCC ID: 2ADXK-1671

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.

Note: 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.

Note: The Grantee is not responsible for any changes or modifications not expressly approved by the party responsible for compliance. such modifications could void the user's authority to operate the equipment.

The device has been evaluated to meet general RF exposure requirement.

This equipment complies with FCC's RF radiation exposure limits set forth for an uncontrolled environment. This device and its antenna(s) must not be co-located or conjunction with any other antenna or transmitter.

8. Appendix Electromagnetic compatibility

Guidance and manufacturer's declaration – electromagnetic emissions		
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the Pulse Oximeter should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the
Harmonic emissions IEC 61000-3-2	n.a.	

Voltage fluctuations/ flicker emissions IEC 61000-3-3	public low-voltage power supply network that supplies buildings used for domestic purposes.

Guidance and manufacturer's declaration – electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the Pulse Oximeter should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC61000-4-6	3Vrms 150kHz to 80MHz	N/A	Portable and mobile RF communications equipment should be used no closer to any part of the Pulse Oximeter, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = [\frac{3.5}{V_1}]\sqrt{P}$ $d = [\frac{3.5}{E_1}]\sqrt{P}$ 80MHz to 800MHz $d = [\frac{7}{E_1}]\sqrt{P}$ 800MHz to 2.7GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres(m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range. b Interference may occur in the vicinity of equipment marked with the following symbol: ((•))
Radiated RF IEC61000-4-3	10V/m 80MHz to 2.7GHz	10V/m	

NOTE 1 - At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2-These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

b The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,7 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in these frequency ranges.

c Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.

d Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Guidance and manufacturer's declaration – electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15kV air	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines	n.a.	n.a.
Surge IEC61000-4-5	± 1 kV line to line ±2 kV line to earth	n.a.	n.a.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% UT 0,5cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°, 0% UT 1cycle and 70% UT 25/30 cycles Single phase: at 0°	n.a.	n.a.

Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30A/m, 50/60Hz	30A/m, 50/60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: UT is the AC mains voltage prior to application of the test level.

Recommended separation distances between portable and mobile RF communications equipment and the A&D unit			
The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150kHz to 80MHz $d = [\frac{3.5}{V_1}]\sqrt{P}$	80MHz to 800MHz $d = [\frac{3.5}{E_1}]\sqrt{P}$	800MHz to 2.7GHz $d = [\frac{7}{E_1}]\sqrt{P}$
0.01	0.12	0.04	0.07
0.1	0.37	0.12	0.23
1	1.17	0.35	0.70
10	3.70	1.11	2.22
100	11.70	3.50	7.00

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 - At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 - These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Recommended separation distances between RF wireless communications equipment					
The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between RF wireless communications equipment and the device as recommended below, according to the maximum output power of the communications equipment.					
Frequency MHz	Maximum Power W	Distance	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
385	1.8	0.3	27	27	RF wireless communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $E = \frac{6}{d}\sqrt{P}$ Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitter, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: ((•))
450	2	0.3	28	28	
710	0.2	0.3	9	9	
745					
780					
810	2	0.3	28	28	
870					
930					
1720	2	0.3	28	28	
1845					
1970					
2450	2	0.3	28	28	
5240	0.2	0.3	9	9	
5500					
5785					

NOTE 1 - These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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