CONTENTS

Before using the BM-03 Baby Breathing Monitor, please read the instructions and conditions of use carefully, as well as the basic first aid and emergency care procedures for babies!

If you have any doubts about the use of the monitor, please use the contact numbers listed in this manual.

1. INTENDED PURPOSE OF THE PRODUCT

The BM-03 Baby Breathing Monitor is a certified risk class IIb **medical device** that monitors the breathing of infants. It does not serve to restore vital functions, nor is it a therapeutic device. It is not a substitute for proper child care. It is intended for use by health care providers and for child care in the home environment. The purpose of the product is to provide an early warning of **respiratory arrest or decreased respiratory rate** by optical and acoustic signals. It warns against the potential danger of respiratory arrest that may occur in young children (e.g. due to **sudden infant death syndrome - SIDS**) or due to other causes (suffocation, manifestations of illness, etc.). There are no known side effects or other contraindications due to the nature and purpose of use.

The device is not intended for:
- direct or mediated contact with the infant's body,
- the simultaneous monitoring of two infants at once (e.g. twins).

Basic monitor attributes:
- warning against sudden infant death syndrome or other causes of arrest or irregular breathing;
- for home and health care (including placement in incubators);
- for infants from 1 kg and up;
- does not affect or restrict infant movement;
- maximum reliability – automatic function test every time you turn it on, detection of infant position;
- powered by 2 AA batteries (included);
- simple controls, does not require any special maintenance or calibration;
- uncomfortable room temperature indicator;
- night light;
- day and night mode to ensure a good night's sleep;
- portable.

Package contents:
1. control unit,
2. sensor pad with connecting cable,
3. 2 alkaline batteries,
4. accessory – clip for hanging (XA809),
5. accessory – Velcro,
6. accessory – control unit holder (XA810),
7. accessory – stand (XA814).

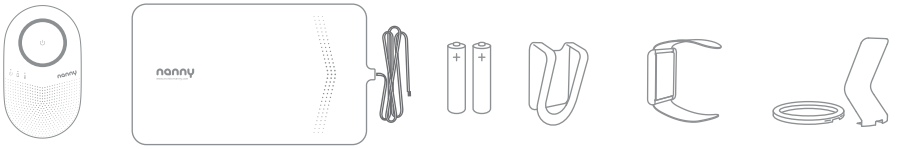


Fig. 2 Package contents

2. FUNCTIONS AND CONTROLS

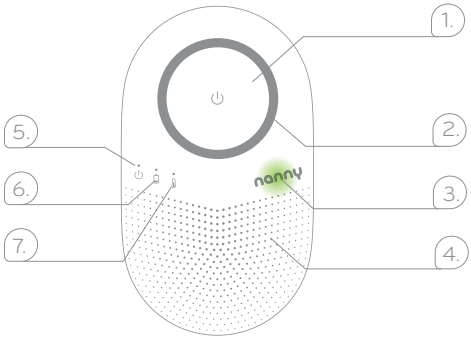


Fig. 3 Control unit – functions and symbols

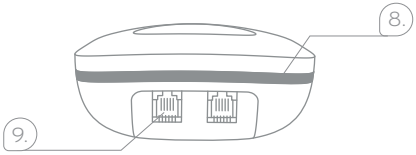


Fig. 4 Control unit – bottom part

1. mechanical button to turn the monitor on/off
2. light indicator of respiration state/alarms
3. NANNY logo – functions as a touch switch for the night light
4. speaker
5. power-on indicator – infant position indicator, transition from standby to active mode and back, mechanical button jam and successful automatic function test
6. low battery level indicator
7. room temperature indicator
8. night light
9. sockets for the pad cable connector

2.1 PRIMARY FUNCTION – BREATHING MONITOR

Based on signals from a sensor pad placed under the child, the device monitors breathing regularity and indicates respiratory arrest. **Inhalation and exhalation** are indicated by a flashing green light around the mechanical button used to switch the monitor on/off. When the **alarm** is triggered, a bright red light flashes around the mechanical button and a loud alarm sounds.

An alarm is triggered if:

A. **No breathing is detected for a period of 20 sec.** A warning is sent 17 seconds after the last detected breath and then the alarm is triggered.
B. **Breathing frequency is lower than 8 respirations per minute.** In such case, the alarm is triggered immediately (without warning).

The alarm can be **switched off** by pressing the mechanical button.

The monitor operates in either active or standby mode. In **active mode**, the monitor senses the baby's breathing movement. In standby mode, the monitor switches to power saving mode and the unit evaluates the signals from the pad to issue baby position warnings.

The transition to standby mode is indicated by an optical and acoustic signal.

If the mechanical button jams, this is an error. If a jam is detected during the automatic function test following transition from standby mode, the control unit will not start. If a mechanical button jam is detected in active mode, a sound and light will indicate this critical malfunction. To reset, release the jammed button. Press the button again to turn off the malfunction warning.

Automatic function test
When switching from standby to active mode, the device automatically tests its functionality. The test checks the battery status, type of pad and age, pad connection, optical and acoustic signalling, and whether the infant position function is activated or not.

Function test results:

A. Flashing of all indicator lights, a short beep and 10 flashes of the power-on symbol = all checks have been carried out correctly and the instrument is fully functional.

B. Flashing of all indicator lights, a short beep, repeated warning beep - see chart - and 10x flashes of the power-on symbol = error has been diagnosed that does not prevent the use of the monitor and maintains its functionality.

Type of warning	Acoustic signal
Infant position monitoring is deactivated	2 beeps
A sensor pad or control unit is connected that may have exceeded its service life	3 beeps

C. **One or two warning beeps, an orange light flashes around the mechanical button used to switch the monitor on/off and the device will not switch on = critical error detected (2 beeps indicate critical battery level, 1 beep indicates that the pad is not connected), the device cannot be used. Correct the error (insert new batteries or connect the pad), then you can use the device again. If the error cannot be eliminated, send the monitor to a service centre.**

2.2 SUPPLEMENTARY FUNCTIONS

2.2.1 DETECTION OF INFANT POSITION ON THE SENSOR PAD

The BM-03 Baby Breathing Monitor in standby mode continuously evaluates the signals from the pad and is thus the only device on the market today that can alert you when a baby has likely been placed on the sensor pad. This helps prevent tragic consequences if a parent or other caregiver forgets to turn the device on and the baby stops breathing.

Warning when the monitor is not switched on
If a parent or other caregiver puts the baby in the crib but forgets to turn on the monitor, the power-on indicator will flash orange and two long beeps will sound after 30 seconds. The light will flash the entire time the device detects stimuli from the mat but has not been switched on.

The user must press a mechanical button to turn the device on, the device will not go from standby to active mode by itself.

Turning the position detection function on and off
The infant position detection function is switched on at the factory. If you wish to switch this function off or on again, hold down the mechanical button before inserting the batteries, then insert the batteries. Keep the switch pressed. After 10 sec, deactivation is confirmed by the power-on indicator beeping and flashing. The function can be reactivated in the same way.

If the position detection function is deactivated, a warning beep sounds twice at the end of the automatic function test.

2.2.2 NIGHT LIGHT

For your convenience, the breathing monitor is equipped with a night light, which is particularly useful when checking on an infant at night.

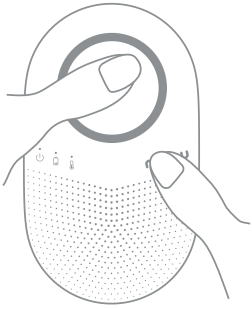


Fig. 5a – Activating/deactivating the night light

Activation and deactivation of the night light function
The night light function is **deactivated at the factory**. To activate it, press the mechanical button for 10 seconds simultaneously with the night light capacitor switch in the centre of the NANNY logo (fig. no. 5a). After activation, the night light will flash three times.

The light function can be deactivated in the same way. The activation and deactivation of the light function can be done only in the standby mode. The light function is completely deactivated if the batteries are low, except if there is an alarm in night mode.

Turning the night light on and off
The night light is turned on/off using the capacitor located in the centre of the NANNY logo (symbol 3 in Fig. 3). Place your fingertip on the centre of the NANNY logo and leave it there for at least 1 sec (Fig. 5 b). There's no need to press, just touch the surface.

The night light shines for 30 sec. If you place your finger on the capacitor switch again **within 20 sec** of activation, the night light will turn off. **After 20 sec** the night light will gradually decrease in intensity. If you touch the capacitor switch again during this period, the night light will shine for another 30 sec, otherwise it will turn off by itself after 30 sec.

In the event of an alarm in night mode, the lamp will automatically turn on.

The night light cannot be turned on when the battery voltage is low. This is indicated by repeated rapid flashing of the low battery indicator light.

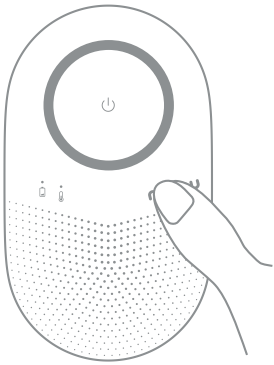


Fig. 5b – Turning the night light on/off

2.2.3 MONITORING ROOM TEMPERATURE

The control unit is equipped with a sensor for measuring the ambient temperature. It indicates when a room is overheated, which can be one of the causes of sudden infant death syndrome. The unit can thus send alerts when the room temperature is likely to be uncomfortable. However, the responsibility for the room temperature and environment lies with the parent or other caregiver (monitor operator).

The temperature is indicated by the flashing thermometer symbol:

If it blinks **blue**, then the room temperature is **below 16.5 °C**. This is a cooler environment that may still be comfortable for you and your baby.
If it blinks **orange**, then the room temperature is **above 28 °C**. It is advisable to lower it by ventilating or turning down the heat to avoid overheating the baby.

2.2.4 DAY AND NIGHT MODE

The device is equipped with an optical sensor to detect day and night or darkness. As a result, the LED indicators will shine at a lower intensity at night than in the daytime to keep parents or other caregivers sleeping soundly.

The device switches between day and night mode automatically.

The sensor identifying night and day may be negatively affected by light that is invisible to the human eye (such as infrared light from a baby monitor camera). Depending on the particular conditions (power of control unit light source, room dimensions, reflectivity of surrounding surfaces, location of the evaluation unit), the indicator diodes may thus illuminate at higher or even full intensity even in apparent darkness. To reduce their intensity properly, we therefore recommend switching off these devices for the night (but always taking into account their intended use).

3. INSTALLATION PROCEDURE

Neither the sensor pad nor the control unit needs to be specially cleaned or disinfected out of the box. Make sure all parts are undamaged before using the monitor. The installation and subsequent reuse of the equipment does not require any temperature tempering.

1. Place the sensor pad under the mattress together with a layer of suitable waterproofing to prevent leakage from areas where the infant will lie. The pad must be placed on a flat surface with the top print facing upwards and must not sag. If the crib has only slats, place the pad on a solid board. The board does not need to cover the entire bottom of the crib - it only needs to extend about 3 cm past the surface of the pad on each side.

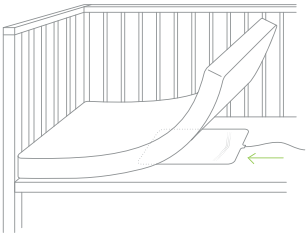
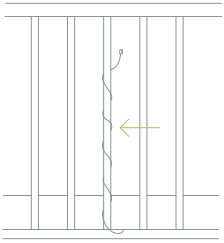


Fig. 6 Placing the sensor pad



2. Route and secure the connecting cable so that it cannot be pulled by the child and at the same time so that it does not form loose sections or loops. If you do not use the full length of the cable, coil up the unused section and fasten it securely with a zip tie. Place the coil out of the infant's reach.

Fig. 7 Securing the connecting cable

3. Remove the battery cover and insert the batteries. The battery polarity for insertion is marked inside the battery compartment.

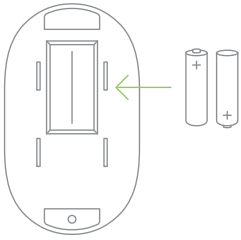
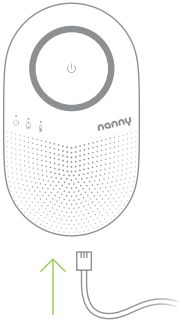


Fig. 8 Inserting batteries



4. Connect the connection cable to any socket of the control unit. The connector must snap and hold when inserted.

Fig. 9 Connecting the connection cable to the control unit

5. For your convenience, the control unit may be secured using the following accessories:

- crib holder with Velcro – you can tighten the Velcro depending on the circumference of the top rail of the crib;
- wall holder with double-sided tape for placement on furniture wall or other fixed surface;
- crib clip;
- control unit stand – e.g. can be placed on a night stand next to the crib.

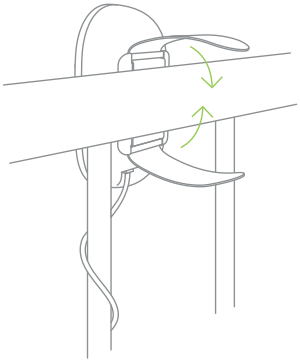


Fig. 10 Holder with Velcro

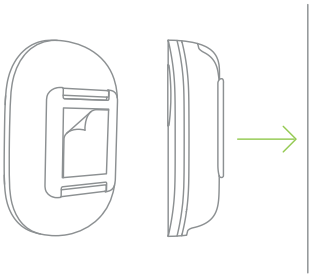


Fig. 11 Holder with double-sided tape

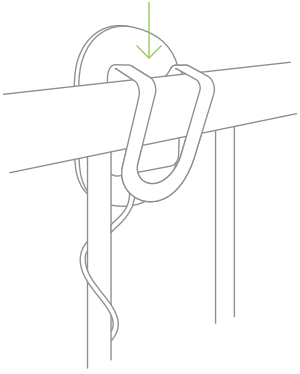


Fig. 12 Crib clip

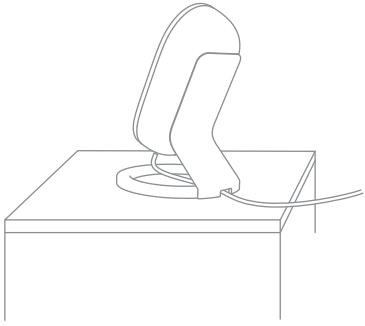


Fig. 13 Stand

Always make sure the control unit is within your hearing range.

6. **Perform a performance test at the installation site – see next section.** Then the monitor is ready to use.

4. MONITOR PERFORMANCE TEST AT THE INSTALLATION SITE

We recommend conducting the performance test daily, or at least whenever changing the location of the crib or monitor.

- When the baby is in the crib, check whether the green light is blinking around the mechanical button. The green light blinks in response to the infant's breathing and movement. The blinking need not be regular – the frequency of blinking corresponds to the movement and respiration of the infant.
- Then remove the baby from the crib and move away from the crib. Wait a few moments for the vibrations of your movements and the mattress to subside.
- If you hear a warning after 17 seconds and an alarm after 20 seconds, the performance test has been successful and you can rely on the monitor's function. Check that the alarm can be heard in all areas where parents or other caretakers are present.

If the green light flashes even when the baby is not in the crib, the monitor is sensing environmental disturbances. Ambient vibrations with a similar frequency can be falsely interpreted by the device as the baby's breathing/movements and must therefore be eliminated to ensure the device is functioning reliably and your baby is safe! Disruptive vibrations can be caused by intensive air flow (fans, air conditioners), people walking near the crib, mechanical vibrations from household appliances, etc. Eliminate disturbances in the vicinity or move the crib!

5. POWER SUPPLY AND BATTERY REPLACEMENT

The device is powered by two alkaline 1.5 V AA batteries. The device monitors battery level and distinguishes between low and critical battery level.

Low battery level is indicated by a flashing red light with the battery symbol. All functions except the night light are maintained. The low battery level light comes on about 2 weeks before the batteries are completely discharged, so that you have enough time to replace them. The batteries must be replaced as soon as possible after the red low battery light is activated.

If **battery level is critical**, the device will beep twice and an orange light will flash around the mechanical button during the automatic function test and the instrument will not switch on. Replace both batteries immediately!

Batteries must be replaced depending on the intensity of use – typically after 4-12 months. Before replacing the batteries, switch off the device by pressing the mechanical button. Remove the battery cover and take out the original batteries.

Remove the batteries once you stop using the monitor completely.

6. SENSOR PAD

The sensor pad is included. It can also be purchased separately as a BM-03D replacement part.

A single sensor pad can be used for an infant up to 6 months old. Once an infant begins rolling around or moving in the crib, the monitored area can be increased by adding a second sensor pad. The control unit has two sensor pad sockets. The sockets are identical, so you can plug the connector into either one in any order.

The device will not switch into active mode unless at least one BM-03D type sensor pad is connected.

If a sensor pad is disconnected in active mode, an alarm immediately sounds. If a pad is disconnected in standby mode, a warning beep sounds 2 times and the orange light around the mechanical button flashes 3 times.

It is advisable to purchase a set with 2 pads. During the first few months of your baby's life, the second pad can be used other places - for example, in another crib, at grandma's, etc. In such case, only the control unit is moved. Once the baby grows, connect the second pad together with the original pad in the baby's crib.

Plug both pads into the sockets on the underside of the control unit. Always ensure that there are no loose cables or loops within reach of the baby.

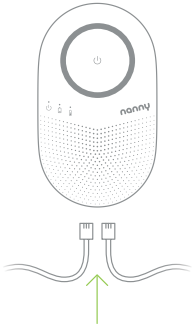


Fig. 14 Connecting two sensor pads to the control unit

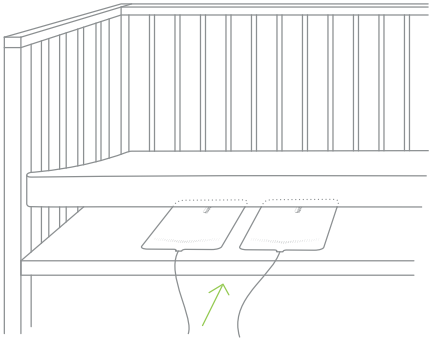


Fig. 15 Using two sensor pads

To monitor twins, a separate breathing monitor is needed for each baby - so you cannot use the same control unit for 2 babies at the same time, even though each will be lying on its own pad. To use the breathing monitor effectively, the babies must always lie in their own cribs, otherwise the monitor may pick up the movements of the other baby.

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6.1 SERVICE LIFE OF SENSOR PAD

The service life of a sensor pad is 2 years, after which it should be replaced.

The BM-03 Baby Breathing Monitor tracks the number of hours the monitor has been in use as an auxiliary indicator - if the pad is likely to have exceeded the specified service life, a warning beep sounds 3 times during each automatic function test. However, the date it was first used is crucial for determining the expiry date.

The sensor in the pad may wear out over time and therefore may not properly sense your baby's movements and breathing. In this case, the monitor may report false alarms that will worry you unnecessarily. While false alarms cannot endanger your child's life or health, you will hear the alarms so often that you may prefer to turn the monitor off or lower your vigilance, putting your child at risk.

7. MAINTENANCE AND CLEANING

The BM-03 Baby Breathing Monitor is not intended for sterilization. Apart from battery replacement and cleaning, the BM-03 does not require any special maintenance. For cleaning, use only water or a mild soap and water solution, a slightly damp cloth (e.g. microfibre) to gently wipe the control unit and sensor pad. It is not necessary to disinfect the BM-03, even between uses by different patients. Keep in mind when cleaning that any moisture penetrating the battery compartment or control unit can damage the device! Also avoid dampened wipes or other materials that may release fibres, which can clog the ports in the control unit.

The frequency of cleaning is not specified by the manufacturer and the frequency of cleaning does not affect the service life of the product. The BM-03 is not a measuring device and is therefore not subject to calibration. It is recommended to occasionally check the sensor pad for the collection of moisture where the pad touches the mattress. It is advisable to turn the mattress 180° once in a while in the crib, or flip it upside down, air it out, etc., to prevent the collection of moisture.

Protect the sensor pad, cable and connectors from mechanical damage (impact, bending, tensile stress, etc.). In case of damage, contact the dealer or the manufacturer's service directly (page 67).

During maintenance, protect the pad, connecting cable and connectors from mechanical damage and penetration of moisture.

8. ALARMS

PHYSIOLOGICAL ALARMS			
Alarm description	**Priority**	**Light indicator**	**Acoustic signal**
Low respiratory rate Number of breaths/respirations lower than 8/min. (evaluated in active mode)	High	Red light blinking around the mechanical button (2.5 Hz, 200 ms light/200 ms pause)	Physiological alarm – sequence of 10 tones of identical frequency and acoustic pressure (50 ms tone/50 ms pause), except: - between the 3rd and 4th tone and the 8th and 9th tone the pause is 250 ms, - between the 5th and 6th tone the pause is 550 ms Before repeating the entire sequence, there is a pause of 2550 ms
Respiratory arrest Stoppage in breathing lasting longer than 20 sec (evaluated in active mode)	High		

TECHNICAL ALARMS			
Alarm description	**Priority**	**Light indicator**	**Acoustic signal**
Unplugging or connecting a sensor pad (evaluated in active mode)	Medium	Yellow light blinking around the mechanical button (0.5 Hz, 1000 ms light/1000 ms pause)	Technical alarm – sequence of 3 tones (200 ms tone/200 ms pause) Before repeating the sequence there is a pause of 2500 ms
Detection of mechanical button jam in active mode (evaluated in active mode)	Medium	Yellow light blinking around the mechanical button (0.5 Hz, 1000 ms light/1000 ms pause) while at the same time the power-on symbol flashes orange (5 Hz, 100 ms light/100 ms pause)	
Reset caused by a circuit that monitors technical malfunctions of the device (evaluated after the unit is turned on)	Medium	Yellow light blinking around the mechanical button (0.5 Hz, 1000 ms light/1000 ms pause)	

If a technical alarm is not turned off in time by the user, the colour of the light indicator changes to red and the number of tones of the acoustic signal increases to 10.

Operator response to alarms
High priority: Immediate operator response required
Medium priority: Immediate operator response required

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9. OPERATOR ALERTS

Event	Light indicator	Acoustic signal
Warning of impending physiological alarm – respiratory arrest (evaluated in active mode)	Orange light blinking around the mechanical button (2.5 Hz, 200 ms light/200 ms pause)	7 x tone (200 ms tone/200 ms pause)
Low battery level	The battery indicator light with the battery symbol flashes red slowly (100 ms light/2 s pause)	No acoustic signal
Critical battery level	The battery symbol light blinks red rapidly (100 ms light/300 ms pause)	No acoustic signal
Detection of **infant position** indicator of the control unit (evaluated in standby mode)	The indicator light with the power-on symbol blinks orange (1 Hz, 500 ms light/500 ms pause)	2 beeps – notification 30 sec after position detection, provided the infant is still detected (1 sec tone)
On/off indicator of the control unit	The indicator light with the power-on symbol blinks 10 times. (100 ms light/100 ms pause)	1 beep / 2 beeps (300 ms tone / 300 ms pause)
Low temperature signal (evaluated in active mode)	The indicator light with thermometer symbol flashes blue (100 ms light/2 s pause) (lasts until low temperature is no longer detected)	No acoustic signal
High temperature signal (evaluated in active mode)	The indicator light with thermometer symbol flashes orange (100 ms light/2 s pause) (lasts until high temperature is no longer detected)	No acoustic signal
Sensor pad disconnected in standby mode (evaluated in standby mode)	Orange light blinks 3 times around mechanical button (100 ms light/100 ms pause)	2 beeps – notification (500 ms tone)
Detection of **mechanical button jam** in standby mode	Indicator light with power-on symbol is permanently orange. When the button is released, the light will turn off.	No acoustic signal
Indication of a successful **automatic function test with no errors detected** (when switching to active mode)	The indicator light with power-on symbol flashes orange 10 times. (100 ms light/100 ms pause)	1 beep (500 ms)
Indication of critical errors **after automatic functional test** (evaluated and signalled when switching to active mode)	Orange light around the mechanical button 2 sec for critical battery level, 1 sec when sensor pad is not connected	2 beeps (500 ms tone) for critical battery level, 1 beep (500 ms tone) when sensor pad is not connected
Warning signal after the automatic function test (evaluated and signalled when switching to active mode)	No light signals	2 beeps when infant position detection is switched off 3 beeps when the control unit or sensor pad has exceeded its service life.

Event	Light indicator	Acoustic signal
Signal for **enabling/disabling the night light** (evaluated in standby mode)	The night light blinks 3 times (300 ms light/300 ms pause)	No acoustic signal
Signal for **deactivation of infant position detection**	The power-on indicator flashes orange 3 times (500 ms light/500 ms pause)	3 notification beeps (1 s tone, 1 s pauza)
Signal for **activation of infant position detection**	The power-on indicator flashes orange twice (1 s light, 1 s pause)	1 notification beep (3 s tone)
Signal for **unsuccessful activation of the night light** or **forced shut down of the night light** due to **low/ critical battery level**	5 red flashes of the battery indicator (100 ms light/100 ms pause)	No acoustic signal
Transition from active to standby mode and back	The power-on indicator flashes orange 10 times (100 ms light/100 ms pause)	2 beeps / 1 beep

10. IMPORTANT NOTES

Use in an incubator	The BM-03 Baby Breathing Monitor can also be used in an incubator. Only the sensor pad can be placed in an oxygen-enriched environment; the control unit must always be placed outside. Before use, check that the incubator does not cause vibrations that could be falsely interpreted as baby breathing/movement.
Monitoring twins	When using the BM-03 Baby Breathing Monitor for twins, a basic requirement is that each baby must have its own crib with separate breathing monitor installed. Therefore, you cannot use the same control unit connected to 2 sensor pads to monitor 2 babies at the same time. To ensure proper function of the device, the cribs must not touch each other.
Infant age	Whether the BM-03 Baby Breathing Monitor can be used depends on infant weight, not age. The manufacturer recommends the Nanny Breathing Monitor for babies from a minimum weight of 1 kg and a maximum weight of 15 kg. Greater baby weights may cause mechanical damage to the sensor.
Proper placement of the control unit	The acoustic signal of the monitor control unit must not be directed towards the infant and must be placed at least 0.5 meters away from the child's head to prevent possible damage to the infant's hearing.
Proper crib placement	The device uses a very sensitive sensor to monitor breathing. The sensor can be affected by vibrations shaking the crib, the floor or even the whole building. Therefore, the crib must not touch a bed in which another person is sleeping and must not touch or be near any equipment that vibrates.
Use in a pram or cradle	We do not recommend such use! Prams or cradles may move spontaneously resulting in false detection of baby movement. The BM-03 Baby Breathing Monitor should only be used where the sleeping area is fixed and does not touch anything.

Use another sensor pad	This medical device is not intended to be connected with any other medical device. The monitor will not turn on if you connect a different type or manufacturer of sensor pad to it. Similarly, the BM-03D sensor pad cannot be used in combination with another type of monitor from another manufacturer.
Mattress	Most commercially available mattresses can be used with the breathing monitor. You can purchase mattresses tested for compatibility with the Nanny breathing monitor at **www.nanny.cz**. The thickness of the mattress should be no more than 12 cm.
Infant supervision – help within reach	Bear in mind that the device can only alert you, but it does not prevent the risk of respiratory arrest per se! If your baby has a medical problem, it is up to you or a doctor to help. Also, do not go too far away from your baby so that you can hear the device and are able to react in the event of an alarm. Do not use the monitor in an environment where you might not hear or see an alarm (too much noise or light). Supervision must only be carried out by persons who can see and hear and are capable of correctly interpreting alarms and helping the infant.
Guarantee	The manufacturer is liable for the operational performance of the BM-03 product if it is installed and used according to this manual and its recommendations, otherwise it is not liable. The manufacturer is not liable for the proper functioning of the product in the event of mechanical or other damage, or if the service life of the product has been exceeded. The manufacturer is not liable for defects in batteries.
Used or rented breathing monitors	The manufacturer strongly discourages the purchase of used or rented breathing monitors. If not handled carefully, the sensor may become less sensitive, resulting in, among other things, a higher incidence of false alarms. The manufacturer is not liable for the proper functioning of the product in these cases.
Modifications of the breathing monitor	Do not open or modify the monitor. Otherwise, the manufacturer cannot guarantee the proper function and utility of the monitor and bears no liability.
Mechanical damage to the device	Do not use the monitor if there is mechanical damage, such as a large part of the plastic cover broken off - this could cause excessive light or siren sound which could harm your child. If indicator symbols are no longer visible, due for example to careless or improper cleaning, only use the device if you can correctly distinguish the light indications of the symbols, or ensure that the symbols are marked in an alternative way (sticker or special mark). Otherwise, send the instrument in for service.
Nearby wireless technologies	Any wireless communication technology devices such as wireless home networks, mobile phones, cordless phones and their base stations, portable stations that may affect the proper operation of the monitor, should be used at least 1 m away from any part of the monitor.
Nearby amateur radio systems	Amateur radio transmitters should be operated at least 10 m away. However, the manufacturer cannot guarantee the proper function of the monitor during such operation due to the variety of equipment types, transmitting powers and antenna systems.
Incidence of serious adverse events	Any serious adverse events arising in association with the BM-03 Baby Breathing Monitor must be reported to the manufacturer and competent national authority.

11. PROBLEMS AND SOLUTIONS

False alarms – the monitor sounds an alarm when the infant is breathing regularly	1. **The infant's breathing motion was not reliably detected by the sensing pad.** • For very young children, you can place the sensing pad directly under the sheet (but always add a waterproof layer to prevent fluid leakage). Such placement will minimize the possibility of false alarms. As soon as the baby starts to move around in the crib, place the sensing pad under the mattress. If the baby is lying in a prone position (with head up as advised by a doctor), it is essential to maintain good physical contact between the baby, the mattress and the sensing pad. Support the slats (not just the mattress) to ensure this condition is met. Or put something under the legs of the crib. • Check that the weight of the mattress actually presses on the sensor pad. The mattress must not be crammed between the crib walls causing it to ‚float' above the crib slats. 2. The sensor pad does not accurately detect the infant's respirations – the sensor in the pad is probably **mechanically damaged** (e.g. due to a fall) or **the pad service life (2 years) has been exceeded** – the sensor pad must be replaced.
No alarm after removing the infant from the crib	The sensor pad is picking up disturbances from the surroundings than must be eliminated. Proceed according to section 4.
When turned on, the device reports low battery level	Make sure you have not used rechargeable batteries (these have a lower voltage and the device interprets this as a low battery level). Only alkaline batteries should be used.
Night light does not light up	The night light is deactivated at the factory - to activate it, follow section 2.2.2 The night light is also deactivated if the battery level is low. If you want to continue using it, replace the batteries.
I have placed the baby on the pad in standby mode, but the unit does not signal that the baby has been placed on the pad.	The monitor is functioning correctly. The monitor is designed to intelligently evaluate stimuli on the pad, where it constantly monitors the environment and tries to distinguish the likely movements of the infant on the pad from the surrounding stimuli. It is also equipped with a timer, where the signal indicating the placement of a baby is only repeated if no excitation has been detected for a certain period of time (10 s) since the previous signal. The monitor therefore detects that a baby may have indeed been placed on the pad before alerting you to the need to switch the monitor to standby mode. Also check whether you have deactivated the infant position function (see section 2.2.1) – this would be indicated by 2 warning beeps when the unit is switched on during the automatic function test.
After inserting the batteries, the automatic function test does not take place, the monitor does not turn on when the mechanical button is pressed.	You have probably inserted batteries with low voltage. Replace both batteries.
The breathing indicator (green circle) is too intense even at low ambient light levels and is distracting during the night.	There is probably an infrared light source in the room (e.g. the infrared light of a baby monitor camera). This radiation is invisible to the human eye but is detected by a sensor in the unit that detects the ambient light level. The source of infrared radiation should therefore be shielded if possible or ideally switched off completely overnight (but always taking into account the purpose of the device).

12. SPECIFICATION OF BM-03 USE

1. Designated health indications

The BM-03 Baby Breathing Monitor can be used for preventive monitoring of breathing activity in healthy individuals (children). The following indications are recommended for monitoring:

- Whooping cough – the monitor is recommended for 1 month after diagnosis - many children have coughing spasms for longer periods of time with the risk of vomiting and the potential threat of inhaling vomit with ensuing consequences.
- Diagnosed apnoea with bradycardia (slowed heart action) below 80 beats per minute. A monitor is recommended for 6 weeks after resolution of symptoms.
- Muscle weakness - may be present in a range of muscular and neurological diseases with varying prognosis. If this is a transient condition, it is recommended to monitor the infant for 6 weeks after symptoms have resolved.
- Respiratory disorder associated with a decrease in blood oxygen content (desaturation), the infant may be either pale or pale/bluish. Monitoring is recommended for 6 weeks after resolution of symptoms.
- Gastroesophageal reflux (stomach contents returning to the oesophagus, possibly to the mouth) can cause breathing problems such as apnoea, slowing of the heart rate or a drop in blood oxygen levels - monitoring is recommended for 6 weeks after symptoms have resolved.
- Proven apnoea longer than 20 s - 6 weeks of monitoring after the end of the apnoea-related condition.
- Infant with an ALTE episode - a condition associated with a combination of apnoea, discolouration of the baby's skin and mucous membranes, change in muscle tension, choking or coughing. Monitoring is appropriate for 6 weeks after an ALTE episode.
- Infants with apnoea of prematurity - a sudden cessation of breathing lasting at least 20 seconds or associated with a slowing of the heart rate (below 80 beats per minute) or a decrease in blood oxygen content in an infant less than 37 weeks of gestational age. Monitoring is recommended until 43 weeks of gestational age and for an additional 6 weeks without the above clinical signs.
- Infants with bradycardia being treated with caffeine, theophylline and similar drugs - monitoring for 6 weeks after the end of treatment.
- Infants with chronic lung disease (bronchopulmonary dysplasia), especially those who require oxygen therapy, CPAP - Continuous Positive Airway Pressure or mechanical ventilation.
- Infants with neurological or metabolic disease affecting respiratory control - the recommended duration of monitoring depends on the individual's medical condition.
- Infants with tracheostomies or anatomical anomalies causing airway vulnerability - the need for monitoring depends on the individual disability.
- Previous sibling died of SIDS - discontinuation of monitoring recommended 1 month after the age of the child who died of SIDS if the monitored child has no clinical signs of impending respiratory failure.
- Monitoring of the infant in the paediatric inpatient ward after an ALTE episode - after discharge, home monitoring is recommended according to the cause of the episode.

2. Target patient population

- Age: from birth to typically 12 months (according to the maximum recommended weight of the child corresponding to a physiological age of up to 2 years, in exceptional cases for non-physiological cases even above 2 years, but always taking into account the recommended maximum weight of 15 kg).
- Recommended patient weight from 1 to 15 kg.
- Medical condition: according to the designated health indications
- Nationality: multiple.
- The patient does not use or control equipment.

3. The BM-03 medical device is not intended for direct or mediated contact with the patient's body.

4. Designated minimum user profile

- Age: 12 and up, with age-appropriate judgement.
- Ability: able to distinguish colours and interpret the meaning of light indicators, able to replace batteries in the device and install the system according to instructions in the manual.
- Language requirements: average ability to read and understand text in native language.
- Experience: basic experience with installing and controlling simple electronic systems with the aid of instructions.
- Other abilities: unimpaired hearing and sight, mentally competent to care for an infant.

5. Intended environment and conditions for use

- Intended for use in healthcare provider and home environments.
- Intended for use under a mattress protected by a waterproof layer to prevent leaking.
- Not intended for direct or indirect contact with the patient
- Not intended for use in vehicles, rocking cradles, prams, hammocks, hanging baskets, and environments that easily transmit shocks and vibrations.
- Not intended to be overloaded beyond the weight limit specified in the instructions, which may lead to unreliable operation.

a. User requirements

- Viewing angle: 45°.
- Viewing distance: 1 to 5 m depending on lighting conditions.
- Ambient lighting conditions: 50 lx to 2500 lx.
- Noise level of 80 dBa emitted 1 m from the device.
- The system is portable when maintaining the designated conditions for use and environment.
- The frequency of use is not limited by the manufacturer.
- It is necessary to respect the service life of the sensor pad, which is 2 years or 14,600 hours, and the control unit, which is 10 years.

b. Surroundings – see Technical information below

13. TECHNICAL SPECIFICATIONS

Power supply	3 V; 2× 1.5 V type AA alkaline battery (LR6)
Quiescent current consumption	106 µA
Consumption during an alarm	270 mA
Low battery	2.46 V ± 0.15 V
Critically low battery	2.2 ± 0.15 V
Alarm breathing frequency	<8 respirations/min. (i.e. <0.13 Hz)
Room temperature measurment range	-40 °C to +85 °C with accuracy ± 0,2 °C
Typical battery life – home health care	6 months (shortened by frequent alarm testing and night light use)
Typical battery life – health care provider	4 months (shortened by frequent alarm testing and night light use)
Sensor pad	Type BM-03D, dimensions max. 300 × 500 × 15 mm
Siren acoustic power	80 dB.m-1 ± 5 % dB.m-1
Control unit – dimensions	max. 140 × 82 × 37 mm, weight 125 g + battery
Operating conditions	+5 °C to +40 °C, Rh 15 % - 93 %, 700 hPa - 1200 hPa
Transport and storage	0 °C to +70 °C, Rh 10 % - 85 %, 700 hPa - 1200 hPa
Resistance to ingress of foreign body	IP31 rating
Service life of sensor pad	2 years, or 14,600 h of running time
Service life of control unit	10 years
System service life	10 years provided the sensor pad is replaced regularly (every 2 years)
In compliance with normative requirements	EN 60601-1:2006 +A11:2011 +A1:2013 +A12:2014 +AC:2014 +A2:2021, EN 60601-1-2:2015 +A1:2021, EN 60601-1-6:2010 +A1:2015 +A2:2021, EN 60601-1-8:2007 +A1:2013 +AC:2014 +A11:2017 +A2:2021, EN 60601-1-11:2015 +A1:2021, EN 10993-1:2020, EN 62366-1:2015 +A1:2020, EN ISO 14971:2019 +A11:2021, EN ISO 13485:2016 +AC:2016 +A11:2021, EN 62304:2006 +A1:2015, EN ISO 18778:2022, EN ISO 15223-1:2021, EN IEC 63000:2018

14. TERMS AND SYMBOLS

	Manufacturer		
ME device	Medical electronic device (with additional component detecting energy from the patient)		
EMC	Electromagnetic compatibility (set of normative requirements for a ME device)		
SIDS	Sudden infant death syndrome		
	Marking of BF type attachment		General warning mark
	General command mark		Reference to user manual instructions
IP31	Device resistance to ingress of foreign body and water (shielding)		
0xxxxynnnnnnn	Product bar code identification; Prefix: 0xxxy product identification (02594 unit; 02593 pad): Suffix: nnnnnnnn serial number		
MD	Medical device		
UDI	UDI (unique device identifier)		
(01)08594052530056 (10)2206310005 (21)00005000000001	(01) = UDI-DI of the medical device (10) = LOT (production batch) (21) = SN (serial number)		

Certified by National Certification Body EZÚ Praha no. 1014.

The product has been clinically evaluated and is listed in the Register of Medical Devices of the Czech Republic as a class IIb medical device.

JABLOTRON a.s. declares that the BM-03 product is designed and manufactured in accordance with government Regulation No. 54/2015 Coll.

JABLOTRON a.s. declares that the BM-03 product is designed and manufactured in accordance with the harmonisation legislation of the European Union: directive 93/42/EEC as last amended. The original Declaration of Conformity can be found at **www.monitornanny.com**.

Do not dispose of batteries in the trash after use, but take them to a collection point. Although the product does not contain any harmful materials, do not dispose of it in normal waste but in special containers or collection yards for the disposal of minor electrical equipment, or hand it over to the dealer or directly to the manufacturer.

MANUFACTURE, SALES AND SERVICE:
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15. EMC COMPATIBILITY OF THE MEDICAL DEVICE

15.1 EMISSIONS LIMITS BY ENVIRONMENT

Phenomenon	Professional health care facility [a]	Home health care [a]
RF emissions by conduction and radiation	CISPR 11	CISPR 11 [c] [d]
Harmonic distortion	see IEC 61000-3-2 [b]	see IEC 61000-3-2
Voltage fluctuations and flicker	see IEC 61000-3-3 [b]	see IEC 61000-3-3

a) For information regarding environment of intended use.

b) This test is not applicable in this environment if the ME equipment and ME systems used are connected to the public power supply and the power supply is otherwise meets the basic EMC standard.

c) ME devices and ME systems intended for use in aircraft shall comply with the RF EMISSION requirements of ISO 7137. Testing for line-propagated RF EMISSIONS shall only be performed for ME devices and ME systems that are intended to be connected to the aircraft's on-board network. ISO 7137 is identical to RTCA DO-160:1989 and EUROCARD ED-14C:1989. The latest versions are RTC DO-160G:2010 and EROCAE ED-14G:2011. Therefore, Section 21 (Category M) of a more recent version such as [39] or [40] should be used.

d) Standards applicable to other modes or EM transport environments. Examples of standards that might apply are CISPR 25 and ISO 7637-2.

15.2 IMMUNITY REQUIREMENTS - INPUT AND OUTPUT THROUGH THE DEVICE'S COVER

Phenomenon	Basic standard for EMC or testing method	Resistance test levels	
		Professional health care facility	Home health care [a]
Electrostatic charge	IEC 61000-4-2	± 8 kV contact charge ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV for air discharge	
RF EM field propagated by radiation [a]	IEC 61000-4-3	3 $V \cdot m^{-1}$ [f] 80 MHz – 2,7 GHz [b] 80 % AM at 1 kHz [c]	10 $V \cdot m^{-1}$ [f] 80 MHz – 2,7 GHz [b] 80 % AM at 1 kHz [c]
Near field from RF wireless communication devices	IEC 61000-4-3	See 8.10.	
Magnetic field of specified network frequencies [d] [e]	IEC 61000-4-8	30 $A \cdot m^{-1}$ [g] 50 Hz or 60 Hz	

a) If an interface is used between the patient physiological signal simulation and the ME device or ME system, it must be located within 0.1 m of the vertical plane of the homogeneous field region in the same orientation as the ME device or ME system.
b) An ME device or ME system that intentionally receives RF electromagnetic energy for its operation must be tested at the receiving frequency. Testing may be performed at other modulation frequencies as determined in the risk management process. This test assesses the basic safety and necessary function of the intended receiver when the ambient signal is in the passband. It is understood that the receiver might not achieve normal reception during the test.
c) Tests may be performed at other modulation frequencies identified in the risk management process.
d) This only applies to ME devices and ME systems with magnetically sensitive components or circuits.
e) During the test, the ME device or ME system may be powered at any nominal input voltage but at the same frequency as the test signal.
f) Before using modulation.
g) This test level assumes a minimum distance of at least 15 cm between the ME apparatus or ME system and the source of the network frequency magnetic field. If risk analysis indicates that the ME device or ME system will be used closer than 15 cm to the source of the network frequency magnetic field, the resistance test level shall be set as appropriate for the minimum expected distance.

15.3 RESISTANCE REQUIREMENTS – INPUT OUTPUT OF DEVICE COVER FROM RF INSTRUMENTS

Test frequency MHz	Band [a] MHz	Service [a]	Modulation [b]	Maximum output W	Distance m	Test level of resistance V.m^{-1}
385	380 to 390	TETRA 400	Pulse modulation [b] 18 Hz	1.8	0.3	27
450	130 to 470	GMRS 460 FRS 460	FM[c] ± deviation 5 kHz 1 kHz sinusoidal waveform	2	0.3	28
710 745 780	704 to 787	LTE Band 13,17	Pulse modulation [b] 217 Hz	0.2	0.3	9
810 870 930	800 to 960	GSM 800/900 TETRA 800 iDEN 820 CDMA 1900 DECT LTE Band 5	Pulse modulation [b] 18 Hz	2	0.3	28
1720 1845 1970	1700 to 1990	GSM 1800/1900 CDMA 1900 DECT LTE Band 1,3, 4, 25 UMTS	Pulse modulation [b] 217 Hz	2	0.3	28
2450	2400 to 2570	Bluetooth WLAN 802.11 b/g/n RFID 2450 LTE Band 7	Pulse modulation [b] 217 Hz	2	0.3	28
5240 5500 5785	5100 to 5800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0.2	0.3	9

NOTE: If necessary to achieve the resistance test level, the distance between the transmitting antenna and the ME device or ME system may be reduced to up to 1 m. According to IEC 61000-4-3, a distance of 1 m is allowed.

a) For some services only uplink frequencies are included.
b) The carrier wave shall be modulated using a rectangular signal fill factor of 50 %.
c) As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used, since although this does not represent true modulation, it would be the worst case.

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