nanny

BM-03 Baby breathing monitor

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CONTENTS

Prior to using the BM-03 Baby breathing monitor, please read the instructions for use and the conditions of its use carefully, as well as the general procedures of first aid and emergency care for children!

If you have any questions about using the monitor, please refer to the contacts provided in this manual.

1. PRODUCT IDENTIFICATION

The BM-03 Baby breathing monitor is **a certified Class IIb medical device** that monitors a baby's breathing. It cannot be used to restore vital functions and is not a therapeutic device. It does not replace proper childcare. It is intended for use by health care providers and for care in the home environment. The product is intended to provide a warning, by an optical and acoustic warning, that the **respiration has stopped or the respiration rate has decreased**. It thus warns of the possible danger of respiratory arrest that may occur in young infants (for example, due to **sudden infant death syndrome - SIDS**) or due to other causes (suffocation, an illness, etc.). Due to the nature and purpose of use, no side effects and other contraindications are known.

The device is not intended for:

- direct contact or transferred contact with the child's body,
- for monitoring two children at once (for example, twins).

Basic characteristics of the monitor:

- warning of sudden infant death syndrome or other causes of respiratory arrest or irregularity;
- health care at home and in a hospital (can be used in an incubator);
- for children over 1 kg;
- does not affect or restrict the child's movement;
- maximum reliability - automatic functionality test every time it is switched on and detection of baby's placement;
- powered by 2 AA batteries (included);
- easy to use, does not require special maintenance or calibration;
- indicates an uncomfortable room temperature;
- night light;
- Day and Night mode to give you a quiet night's sleep;
- easily portable.

Package contents:

1. control unit,
2. sensor pad with connecting cable,
3. 2x alkaline batteries,
4. accessories - clip for hanging (XA809),
5. accessories - Velcro,
6. accessories - control unit holder (XA810),
7. accessories - stand (XA814).

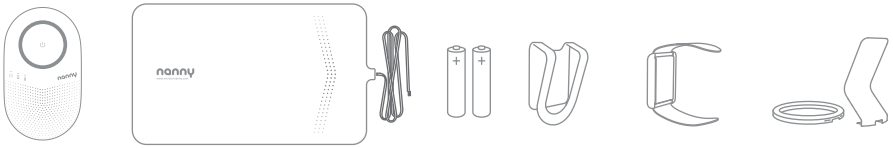

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Fig. 2 Package contents

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2. FUNCTIONS AND CONTROLS

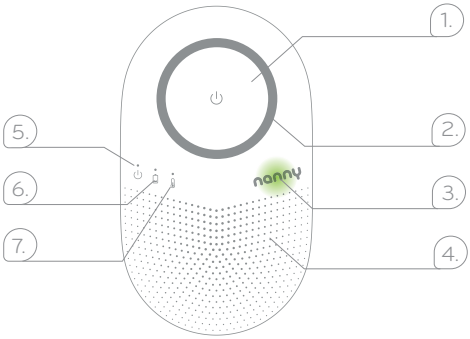

Fig. 3 Control unit - functions and symbols

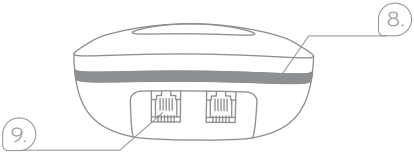

Fig. 4 Control unit - bottom section

1. mechanical on/off button for the monitor
2. optical indication of breathing/alarm conditions
3. the NANNY logo works as a capacitive button for light control
4. speaker
5. indicator light with the power-on symbol - signalling the baby's placement/removal, transition from standby to active mode and back, mechanical button jam and successful automatic functionality test
6. low battery indicator
7. room temperature indicator
8. lamp light
9. sockets for the sensor pad cable connector

2.1 MAIN FUNCTIONS - BREATHING MONITOR

Based on signals from the sensor pad located under the baby, the device monitors the regularity of breathing and signals respiratory arrest. **Inhalation and exhalation** are indicated by a green flash around the monitor's mechanical on/off button. **The alarm** consists of an intense red flash around the mechanical button and a loud acoustic alarm.

The alarm will go off if:

A. **No inhalation is detected for 20 secs.** 17 secs after the last breath is detected, a pre-alarm is triggered and the alarm then goes off.
B. **The breathing rate is less than 8 breaths per minute.** In this case, the alarm goes off immediately (with no pre-alarm).

The first warning alert is in the form of a flashing orange indicator light with the power-on symbol accompanied by a triple beep sounds - If breathing is not detected, after only 10 secs (related to the baby's removal detection function, see par. 2.2.1)

The alarm can be **turned off** by pressing the mechanical on/off button. The monitor operates in active and standby mode. In **active mode**, the monitor detects the baby's breathing movements and additional functions are activated. In **standby mode**, the monitor is switched to power saving mode and the unit evaluates the signals from the pad to be able to draw attention to a baby being placed there.

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

Permanently jammed mechanical button indicates a malfunction. If this fault is detected during the automatic functionality test after the standby mode transition, the function of the evaluation unit will not be triggered. If a mechanical button fault is detected in active mode, a critical failure will be reported visually and acoustically. Release the mechanical button to remove the fault. Press the button once more to turn off the malfunction warning.

Automatic functionality test
When switching from standby to active mode or when inserting the batteries, the device automatically tests its functionality. The test checks the batteries, the correct type of pad is connected and its age, the optical and acoustic signal, the notification for the on/off switch being in the incorrect state for the baby's current absence or presence.

Functionality test results:

A. Flashing of all indicator lights, a short beep and 10x flashes of the indicator light with the power-on symbol = all checks have been carried out correctly and the device is fully functional.
B. Flashing lights and repeated warning beeps = error diagnosed but it does not prevent the monitor from being used and maintaining its functionality.

Type of warning	Acoustic indication
None – the device is fully functional	1x beep
The Switch Guard function is deactivated	2x beep
Connected a sensor pad or control unit with possibly exceeded lifespan	3x beep

C. **One or two warning beeps, orange flashing of the indicator light around the mechanical button designed to turn the monitor on/off and the device does not turn on = critical error detected (2 beeps critical battery condition, 1 beep unconnected sensor pad), device cannot be used. Correct the error (insert new batteries or connect the sensor pad), then you can use the device again. If the error could not be removed, send the monitor to the service center.**

2.2 SUPPLEMENTARY FUNCTIONS

2.2.1 DETECTING WHETHER THE BABY HAS BEEN PLACED ON THE SENSOR PAD OR TAKEN OFF IT (SWITCH GUARD)

When in standby mode the BM-03 Baby breathing monitor continuously evaluates signals from the pad and is thus the only device on the market today to point out that

the baby was most likely placed on the sensor pad. This prevents tragic consequences if a parent or other caregiver forgets to turn on the device and the baby stops breathing.

It can also warn parents or other caregivers if they remove a baby from the cot and forget to turn off the device.

Warning when the monitor is not turned on
If a parent or other caregiver puts the baby in the crib but forgets to turn the monitor on, the indicator with the power-on symbol starts to flash orange and after 30 secs a long beep will sound. The light flashes the entire time the device is evaluating the vibrations on the sensor pad, but the device has not been turned on.

To switch on the device, the user must press the mechanical button, the device will not automatically switch from standby to active mode.

Turning the Switch Guard function off and on
The function of detection of baby's placement is turned on by default. If you wish to turn this function off or on again, hold the mechanical button before inserting the batteries, then insert the batteries. Keep the switch pressed. After 10 secs, the deactivation is confirmed by beeping and the indicator light flashing with the power-on symbol. The function can be reactivated in the same way.

If the Switch Guard function is deactivated, a warning beep will sound 2x at the end of the automatic functionality test.

Removal detection
If a parent or other caregiver takes the baby out of the crib and forgets to switch the device off, the indicator light with the power-on symbol starts to flash orange after 10 secs and a quiet beep will sound 3x. If the device is not switched off, a pre-alarm and then an alarm will sound 17 secs after the last detection.

The same acoustic and visual signal can be noticed even when the baby is in the crib. This means that more than 10 secs have elapsed since the last breath, or the sensor pad has not detected any breathing movement during this time. If breathing movements are not restored, the monitor will sound a pre-alarm and then an alarm 17 secs after the last detection.

2.2.2 NIGHT LIGHT

For your convenience, the breathing monitor is equipped with a light, which is mainly used to check on the baby at night.

Activation and deactivation of the light function
The lamp function is **deactivated by default**. To activate it, simultaneously press the mechanical button and the lamp's capacitive switch, which is located in the middle of the NANNY logo (Fig. 5a), for 10 secs. After activation, the lamp flashes three times.

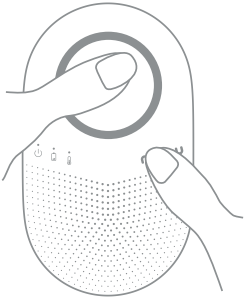

Fig. 5a - Activating/ deactivating the light function

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.

Switching the light on and off
The light is switched on and off using the capacitive switch located in the middle of NANNY logo (symbol no. 3 in Fig. 3). The light is switched on and off by touching the light's capacitive switch which is located in the middle of the NANNY logo. Place your fingertip on the center of the NANNY logo and leave it attached for at least 1 second (Fig. 5b). There is no need to press the switch, just place your finger on the surface.

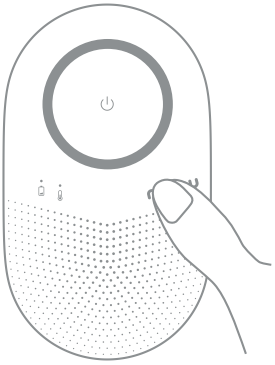

Fig. 5b – Switching the light on and off

The light is on for a period of 30 secs. If you place your finger on the capacitive switch again **within 20 secs** of switching on, the lamp goes out. **After 20 secs**, the lamp will gradually dim. If you place your finger on the capacitive switch again as it dims, the light will be restored for another 30 secs, otherwise it will go out after 30 secs.

If the alarm is triggered in night mode, the lamp will turn on automatically.

The lamp cannot be switched on when the battery voltage is low, which is indicated by repeated rapid flashing of the low battery indicator light.

2.2.3 MONITORING ROOM TEMPERATURE

The evaluation unit is equipped with a room temperature sensor. It serves to indicate the room is overheated, which may be one of the causes of sudden infant death syndrome. The device can thus indicate a room temperature that is quite likely uncomfortable, however, responsibility for the temperature and quality of the environment lies with the parent or other caregiver (monitor operator).

The temperature range is indicated by a flashing indicator light with the thermometer symbol:

Flashing **blue** = the room temperature is **below 16.5 °C**. It is a cooler environment, but it may be comfortable for you and your baby.
Flashing **orange** = room temperature is **higher than 28 °C**. It is advisable to reduce it, for example by airing or turning down the heating, to prevent the baby from overheating.

2.2.4 DAY AND NIGHT MODE

The device is equipped with an optical sensor to detect day and night, or darkness. Thanks to this, the light diodes light up at night with a lower intensity than during the day to ensure parents or other caregivers have a good night's rest.

Day and Night mode switches automatically.

3. INSTALLATION

Neither the sensor pad nor the control unit need to be specially cleaned or disinfected after unpacking. Before using the monitor, make sure that all parts are undamaged. The device does not require temperature adaptation in connection with its installation and subsequent repeated use.

1. Place the sensor pad under the mattress together with a suitable insulating layer against liquid penetration in the places where the baby will be lying. The pad must be placed on a flat surface with the top print facing up and must not be bent. If the cot only has a slat base, support the pad with a solid board. The board does not have to cover the entire lower part of the bed - it is enough if it exceeds the area of the pad by about 3 cm on each side.

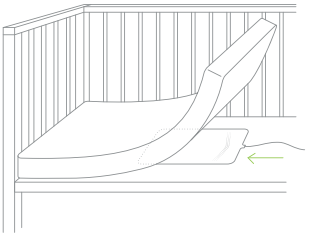

Fig. 6 Location of the sensor pad

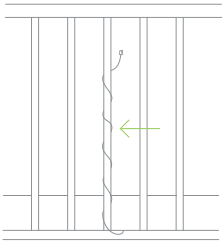

Fig. 7 Securing the connecting cable

2. Route and secure the connecting cable so that the child cannot pull on it and it does not form loose sections or loops. If you do not use the entire length of the cable, roll up the unused part and tighten it tightly with a tie wire. Keep the roll out of the reach of children.

3. Remove the battery cover and insert the batteries. The battery compartment has the polarity marked inside for inserting the battery.

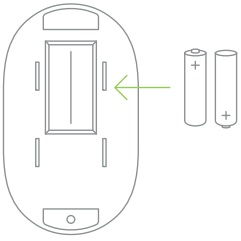

Fig. 8 Inserting the batteries

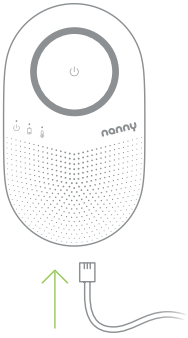

Fig. 9 Connecting the connecting cable to the control unit

4. Connect the connecting cable to any socket in the control unit. The connector must click and hold when inserted.

5. For your convenience, you can hold the control unit with various accessories:

- a cot holder and Velcro - you can tighten the Velcro to the circumference of the upper edge of the cot;
- holder and double-sided adhesive tape to place it on the side of furniture or another solid surface;
- cot clip;
- a stand for the control unit - it can be placed, for example, on the bedside table next to the bed.

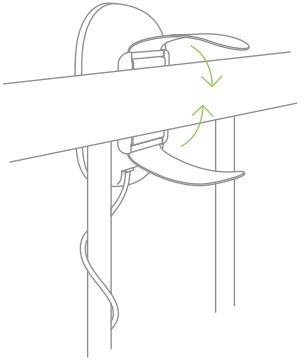

Fig. 10 Holder and Velcro

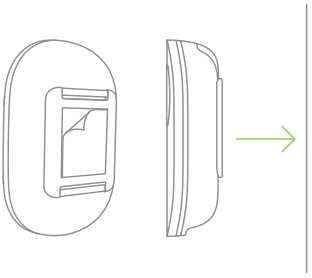

Fig. 11 Holder and adhesive tape

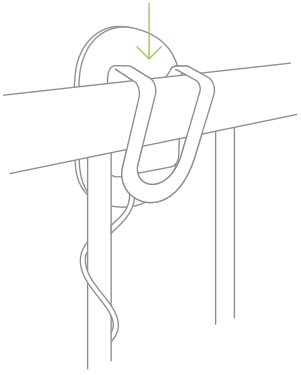

Fig. 12 Cot clip

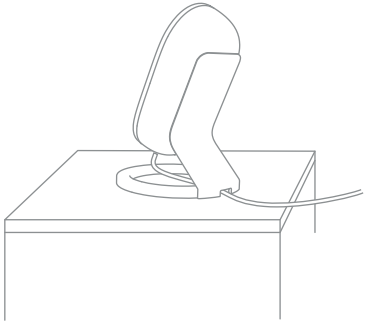

Fig. 13 Stand

Always make sure that you can hear the control unit.

6. **Perform a lifespan test at the installation site - see next section.** The monitor is then ready for use.

4. IN SITU MONITOR LIFESPAN TEST

We recommend performing the lifespan test daily, but at least when changing the location of the bed or monitor.

- Check that the green indicator light around the mechanical button flashes when the child is in the crib. The green indicator light flashes in response to the baby's breathing or movements. The flashing does not have to be regular - the frequency of the flashing corresponds to the baby's movements or breaths.
- Then take the baby out of the cot and move away from the cot. Wait a while for the vibrations from your movements and the mattress to subside.
- If there is a warning after 10 secs, a pre-alarm after 17 secs and an alarm after 20 secs, the lifespan test has been successful and the functionality of the monitor can be fully relied upon. Verify that the alarm sound can be heard in all areas where the parents or other caregivers are present.

If the green light flashes even when the baby is not in the crib, the monitor is detecting a disturbance in the surroundings. Surrounding shocks or vibrations with a similar frequency can be falsely evaluated by the device as the baby's breathing/movements, therefore they must be eliminated in order to ensure the device works reliably and the baby is safe! Disturbance can be caused by intense airflow (fans, air conditioning), walking near the bed, mechanical vibration from household appliances, etc. Eliminate disturbance in the surroundings or relocate the cot!

5. POWER SUPPLY AND REPLACING THE BATTERIES

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

Low battery voltage is indicated by a flashing red indicator light with the battery symbol. All functions except the lamp are retained. The low battery indication lasts for about 2 weeks before the batteries are completely empty, so you have enough time to replace them. The batteries must be replaced as soon as possible after the red low battery indicator comes on.

When the **battery voltage is critical**, an error is indicated by a double beep and an orange flash of the indicator light around the mechanical button during the automatic functionality test and the device is not switched on. Replace both batteries immediately!

The batteries need changing depending on the intensity of use - usually after 4-12 months. Before replacing the batteries, switch off the device by pressing the mechanical button. Remove the battery cover and remove the original batteries.

Remove the batteries when you are not using the monitor at all.

6. SENSOR PAD

The sensor pad is included in the package. It can also be bought separately as a spare part labelled BM-03D.

One sensor pad is enough until the baby is about 6 months old. If the baby starts to climb or move in the cot, the monitored area can be enlarged by attaching a second sensor pad. The control unit contains 2 sockets for connecting the sensor pads. The sockets are identical, so the connector can be connected to either of them in any order.

The device will not be in active mode until at least one BM-03D sensor pad is connected. If any sensor pad is disconnected in active mode, the alarm is sounded immediately.

If any sensor pad is disconnected in active mode, the alarm is sounded immediately. If the pad is disconnected in standby mode, a warning beep will sound and the orange light around the mechanical button will flash 3x.

It is best to buy a set of 2 pads. The second pad can be used in multiple places in the baby's first months of life - for example, in another bed, at its grandparents, etc. In this case, only the control unit is moved. When the baby grows up, the second pad can be attached to the baby's cot together with the original pad.

Both pads are connected to the sockets on the bottom of the control unit. Always keep loose cables or loops out of the baby's reach.

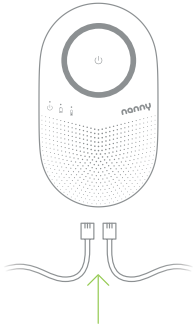

Fig. 14 Connecting two sensor pads to the control unit

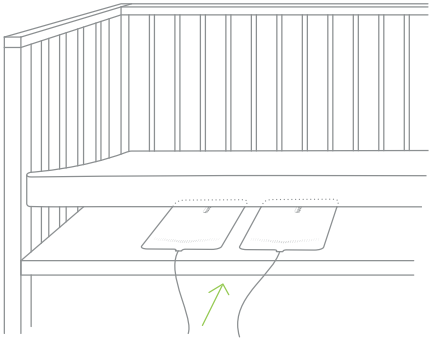

Fig. 15 Using two sensor pads

To monitor twins, a separate breathing monitor is needed for each baby - so it is not possible to use the same control unit for 2 babies at the same time, even though each will lie on its own mat. To use the breathing monitor effectively, babies must always lie in their own cot, otherwise the monitor may detect the other baby's movements.

6.1 LIFESPAN OF THE SENSOR PAD

The lifespan of the sensor pad is set at 2 years, after which the pad must be replaced.

The BM-03 Baby breathing monitor tracks the number of hours the monitor has been in operation as an auxiliary data - if the sensor pad has probably exceeded the specified period of use, 3x warning beeps sound during each automatic functionality test.

However, the date it is put into service is decisive for determining the lifespan.
The sensor in the pad may wear out over time, so it may not correctly sense your baby's movements and breathing. In this case, the monitor may give false alarms that will cause you unnecessary worries. **False alarms** may not endanger your baby's life or health, but you will hear the alarm so often that you might prefer to turn the monitor off or reduce your alertness, which could endanger your child.

7. CLEANING AND MAINTENANCE

The BM-03 Baby breathing monitor is not to be sterilized. The device does not require any special maintenance other than replacing the batteries and cleaning. Only use a slightly damp cloth (e.g. microfiber) with water or a weak soap-and-water solution. Disinfection of BM-03, even between uses by different patients, is not required. Keep in mind that moisture entering the battery compartment or the control unit during cleaning can damage the device! Avoid wet wipes or other materials that may have loose fibres that can clog the holes in the control unit.

The frequency of cleaning is not specified by the manufacturer and the frequency of cleaning does not affect the product's lifespan.

BM-03 is not a device with a measuring function, it does not require calibration.

We simply recommend that you check the sensor pad in the cot from time to time to ensure moisture has not condensed where the pad touches the mattress. It is advisable to turn the mattress 180° in the cot once in a while, or turn it upside down or let it air out, etc.

Protect the sensor pad, supply cable and connector from mechanical damage (bumping, bending, tensile stress, etc.). In case of detected damage, contact the seller.

During maintenance, protect the pad, supply cable and connectors from mechanical damage and moisture entering.

8. ALARM STATES

PHYSIOLOGICAL ALARMS			
Alarm state	**Priority**	**Light indication**	**Acoustic indication**
Low breathing rate Number of inhalations/exhalations less than 8/min. (evaluated in active mode)	High	Red flashing around the mechanical button (2.5 Hz, 200 ms light/200 ms pause)	Alarm - continuous melody 80 $dB.m^{-1}$ ± 5%
Respiratory arrest No respiration for more than 17 secs (evaluated in active mode)	High	Red flashing around the mechanical button (2.5 Hz, 200 ms light/200 ms pause)	Respiratory arrest pre-alarm 7 short tones (200 ms tone/200 ms pause) after 17 secs of not detecting breathing), then alarm after 3 secs from the start of the pre-alarm - continuous melody 80 $dB.m^{-1}$ ± 5%
TECHNICAL ALARMS			
Alarm state	**Priority**	**Light indication**	**Acoustic indication**
Sensor pad disconnected Loss of communication with the pad (evaluated in active mode)	Moderate	Orange flashing around the mechanical button (5 Hz, 100 ms light/100 ms pause)	Technical alarm - high intensity intermittent tone (100 ms tone/100 ms pause)
Mechanical switch jam detected in active mode (evaluated in active mode)	Moderate	Orange flashing around the mechanical button (5 Hz, 100 ms light/100 ms pause) and at the same time the indicator light with the power-on symbol flashes orange (5 Hz, 100 ms light/100 ms pause)	Technical alarm - high intensity intermittent tone (100 ms tone/100 ms pause)
Reset caused by a watchdog that monitors the technical state of the device (evaluated after switching on the unit)	Moderate	Orange flashing around the mechanical button (5 Hz, 100 ms light/100 ms pause)	Technical alarm - high intensity intermittent tone (100 ms tone/100 ms pause)

Operator's response to alarm states
High priority: The need for immediate operator response
Moderate priority: The need for rapid operator response

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9. OPERATOR WARNING

Event	Light indication	Acoustic indication
Low battery	The indicator light with the battery symbol flashes slowly and red (100 ms light/2 s pause)	No acoustic signal
Critically low battery	The indicator light with the battery symbol flashes quickly and red (100 ms light/300 ms pause)	No acoustic signal
Detecting **a child placed** on the pad (evaluated in standby mode)	The indicator light with the power-on symbol flashes orange (1 Hz, 500 ms light/500 ms pause)	1x beep - warning after 30 secs from child presence detection, if the child is still detected (1 sec tone)
Detecting **a child removed** from the pad (evaluated in active mode)	The indicator light with the power-on symbol flashes orange (5 Hz, 100 ms light/100 ms pause) (Ends when breathing detected, but 30x at most)	3 notification beeps (300 ms tone/300 ms pause) (ends when breathing detected, but 3 times at most)
Low temperature indication (evaluated in active mode)	The indicator light with the thermometer symbol flashes blue (100 ms light/2 secs pause). (Lasts until the low temperature is no longer detected)	No acoustic signal
High temperature indication (evaluated in active mode)	The indicator light with the thermometer symbol flashes orange (100 ms light/2 secs pause). (Lasts until the high temperature is no longer detected)	No acoustic signal
Indication that the **sensor pad** is **disconnected** in standby mode (evaluated in standby mode)	3x orange flashes around the mechanical button (100 ms light/100 ms pause)	1x beep - warning (500 ms tone)
Mechanical button jam detecti-on in standby mode (evaluated in standby mode)	Permanent orange glow of the indicator light with the power-on symbol. Releasing the button stops the light.	No acoustic signal
Mechanical button jam detection in active mode.	Indicator light of power-on symbol and indicator light around the mechanical button flash orange. Flashing stops when the button is released and pressed again.	Discontinuous high intensity tone (100 ms tone/100 ms pause)
Indication of a successful **automatic functionality test without detected errors** (when switching to active mode)	10x orange flashes of the indicator light with the power-on symbol (100 ms light/100 ms pause)	1x beep (500 ms)
Error signaling and warning after **automatic functionality test** (evaluated and signaled when switching to active mode)	Critical error detected - 1x orange flashing around the mechanical button (100 ms light/100 ms pause). Warning detected - no light indication.	Acoustic signalling according to the type of error or warning: 2x beeps (500 ms tone) when battery voltage is critical, 1x beep (500 ms tone) when the sensor pad is not connected

Indication to **enable/disable light** functionality (evaluated in standby mode)	3x flashes of the lamp (300 ms light/300 ms pause)	No acoustic signal
Indication of the **function of detection of baby's placement deactivated**	3x orange flashes of the indicator light with the power-on symbol (500 ms light/500 ms pause)	2x notification beeps (1 sec tone, 1 sec pause)
Indication of the **the function of detection of baby's placement activated**	2x orange flashes of the indicator light with the power-on symbol (1 sec light/1 sec pause)	1x notification beep (3 secs tone)
Indication of **unsuccessful light activation** or **light forcibly turned off** due to **low/critically low batteries**	5 x flashes of the indicator light with the battery symbol in red (100 ms light/100 ms pause)	No acoustic signal
Transition from active to standby mode and back	indicator light with the power-on symbol flashes orange 10x (100 ms light/100 ms pause)	No acoustic signal

10. IMPORTANT WARNING

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 located outside. Before use, check that the incubator does not cause vibrations that could be falsely interpreted as the baby's breathing/movement.
Monitoring twins	When using the BM-03 Baby breathing monitor for twins, the basic condition is that each child must have its own cot, in which a separate breathing monitor is installed. Therefore, it is not possible to use the same evaluation unit connected to 2 sensor pads to monitor 2 babies at the same time.
Age of the baby	Use of the BM-03 Baby breathing monitor is not determined by the child's age, but by its weight. The manufacturer recommends BM-03 Baby breathing monitor for children from a min. weight of 1 kg and a max. weight of up to 15 kg. A heavier child may cause mechanical damage to the sensor.
Correctly placing the control unit	The acoustic indicator of the monitor's control unit must not face the child and must be placed at least 0.5 meters away from the child's head to prevent possible damage to its hearing.
Correct placement of the cot	The device uses a very sensitive sensor to sense breathing. Its operation may be affected by shocks to the cot, the floor or even the building. The cot must therefore not touch a bed, in which another person is sleeping, nor must it touch or be in the vicinity of any devices that vibrate.
Use in a pram or cradle	We do not recommend this use! A pram or cradle can move spontaneously, which can lead to "false movements" being detected. It is only possible to use the breathing monitor in places where the sleeping area is fixed and does not touch anything.

Using another sensor pad	This medical device is not intended to be used with other medical devices. The monitor will not turn on if a different type of sensor pad or one from a different manufacturer is connected to it. Likewise, the BM-03D sensor pad cannot be used in combination with another type of monitor from another manufacturer.
Mattresses	Most commonly available mattresses can be used with the breathing monitor. The mattress should be 12 cm thick at most. It is not recommended to use mattresses made of too hard a material (polystyrene foam, etc.), which can more easily absorb interfering shocks from the surrounding air moving.
Baby supervision - help within reach	Please note that the device can only alert you, but it does not of itself prevent the risk of respiratory arrest! If the child has a health problem, it is up to you or the doctor to help it. Likewise, do not move too far away from your child so you cannot hear and be able to respond to an alarm. Do not use the monitor in an environment where you may not hear or see the alarm (an environment that is too noisy or too bright). Supervision must be carried out only by sighted and hearing persons who are able to correctly distinguish the alarm and help the child.
Guarantee	The manufacturer is responsible for the functionality of the BM-03 product if it is installed and used according to this manual and its recommendations, otherwise it does not bear any responsibility. The manufacturer is not responsible for the proper functioning of the product if it has suffered mechanical or other damage or if the product's lifespan has been exceeded. The manufacturer is not responsible for battery defects.
A used or borrowed breathing monitor	The manufacturer strongly discourages buying this product used or getting it from a rental company. If it is handled incorrectly, the sensing device's sensitivity may be reduced leading to, among other things, an increase in false alarms. In these cases, the manufacturer is not responsible for the product's functionality.
Modifying the breathing monitor	Do not open or modify the monitor. Otherwise, the manufacturer cannot guarantee the correct functionality and lifespan of the monitor and assumes no responsibility.
Mechanical damage to the device	Do not use the monitor in case of mechanical damage, such as breakage of a large part of the device's plastic cover - this could cause excessive release of light or sound, which could harm your child. If the indicator symbols are no longer legible, for example due to careless or incorrect 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 marker pen). Otherwise, send the device for service.
Wireless technology in range	Please use wireless communication devices, such as wireless home networks, mobile phones, cordless phones, and their base stations, portable stations, which may affect the proper operation of the monitor, at a distance of at least 1 m from any part of the monitor.
Amateur radio equipment in range	Amateur radio transmitters and their antennas should be at least 10 m away. However, the manufacturer cannot guarantee the proper functioning of the monitor during radio operation due to the various types of equipment, transmission powers and antenna systems.
Incidence of a serious adverse event	Any serious adverse event occurring in connection with the BM-03 Baby breathing monitor should be reported to the manufacturer and the relevant national authority.

11. PROBLEMS AND HOW TO SOLVE THEM

False alarms - the monitor sounds an alarm although the child is breathing regularly	1. Whilst breathing the **child's movement did not reliably reach the sensor pad.** • For very small babies, the sensor pad can be placed directly under the sheet (but always use an insulating pad to prevent liquids leaking into the pad). Placing it here minimizes the likelihood of false alarms. When the baby starts to move in the cot, place the sensor pad under the mattress. If the baby lies in an inclined position (if it should have its head raised as part of a doctor's recommendation), there should be good mechanical contact between the baby, the mattress and the sensor pad. Prop up the cot base (not just the mattress) to meet this condition. Or prop up the back legs of the cot. • Check that the mattress really lies with its entire weight upon the sensor pad. The mattress must not be clamped tightly against the walls of the cot so that it does not "float" above the cot's base. 2. The sensor pad does not sense the baby's breathing properly - the sensor in the pad is probably **mechanically damaged** (for example due to a fall) or **the pad's lifespan has expired** (2 years) - the sensor pad needs to be replaced.
There was no alarm after taking the baby out of the cot	The sensor pad detects disturbance in the surroundings that need to be removed. Follow section 4.
After switching on, the device indicates empty batteries	Make sure you have not used rechargeable batteries (they have a lower voltage and the device evaluates the situation as low batteries). Only alkaline batteries can be used.
The lamp does not light	The lamp is deactivated at the factory - follow section 2.2.2. to activate it. The lamp is also deactivated when the batteries are low. If you want to continue using it, replace the batteries.
I placed the child on the pad in standby mode, but the unit does not signal the child being placed on the pad	This is correct behavior of the monitor. The monitor is equipped with an intelligent evaluation of the stimulation on the pad, which constantly monitors the environment and tries to distinguish the probable movements of the child on the pad from the surrounding stimulation. It is also equipped with a timer, which repeats the signaling of the laying of the baby only if no signal has been detected for a certain time (10 secs) since the previous signaling. Therefore, the monitor will evaluate that the child may have actually been placed on the pad, and only then will it alert you of the possible need to switch the monitor to standby mode. Also check that you have not deactivated the Switch Guard function (see chapter 2.2.1) - this would be signaled by a 2x warning beep after switching on the unit during the automatic functionality test.
When the batteries are inserted, there is no automatic functionality test, the monitor does not turn on when the mechanical button is pressed.	You have probably inserted batteries with a very low voltage state. Replace both batteries.
The baby is in the crib and asleep, yet the indicator light with the power-on symbol randomly flashes orange accompanied by a quiet beeping sound.	This is a correct function of the monitor. The monitor is equipped with a sensor that receives and evaluates the vibrations on the sensor pad caused by breathing. It has an implemented function of detecting the child's removal from the bed. If the pad has not detected any breathing movements for 10 secs, it alerts the user to turn off the monitor. This happens either if the baby has actually been taken out of the crib or has not taken a breath during this time. If the baby does not breathe again or the user does not turn off the unit, in both cases a pre-alarm and then an alarm will be announced after 17 secs (see chapter 2.1).

12. BM-03 SPECIFICATION

1. Designated health indications

The BM-03 Baby breathing monitor can be used to preventively monitor breathing in healthy individuals (children). It is recommended to monitor the following indications:

- Whooping cough - the monitor is recommended for 1 month after diagnosis - however, many children have coughing fits for a longer period of time with the risk of vomiting and the potential threat of inhaling vomit with all the consequences.
- Apnea with bradycardia (slowed heart action) less than 80 beats per minute. The monitor is recommended for 6 weeks after the symptoms disappear.
- Muscle weakness - can be present in a whole range of muscular and neurological diseases with varying prognosis. If it is a transient condition, it is recommended to monitor the infant for 6 weeks after the symptoms disappear.
- Respiratory disorder associated with a decrease in blood oxygen content (desaturation), the infant may be either pale or greyish/bluish. Monitoring recommended for 6 weeks after the symptoms disappear.
- Gastroesophageal reflux (stomach contents returning to the oesophagus, even to the mouth) can cause breathing problems up to apnoea, slowing of the heart rhythm or a drop in blood oxygen levels - monitoring recommended for 6 weeks after symptoms disappear.
- Documented apnoea of more than 20 secs - monitoring for 6 weeks after the apnoea-related condition ends.
- Infant with an ALTE episode - a condition associated with a combination of apnea, a change in the colour of the baby's skin and mucous membranes, a change in muscle tone, choking or gagging. Monitoring appropriate for 6 weeks after an ALTE episode.
- Infants with apnoea of prematurity - breathing suddenly stops for 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' gestation. Monitoring is recommended until 43 weeks' gestation and for a further 6 weeks without the above clinical symptoms.
- Infants with bradycardia being treated with caffeine, theophylline and similar drugs - monitoring 6 weeks after treatment ends.
- Infants with chronic lung disease (bronchopulmonary dysplasia), especially those who need increased oxygen content in the inspired air, 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 severity of the condition.
- Infants with tracheostomies or anatomical anomalies causing vulnerability of the developing airway - the need for monitoring depends on the individual disability.
- Previous sibling died of SIDS - if the monitored child has no clinical signs that threaten respiratory distress, then it is recommended to end monitoring 1 month after the age of the child who died of SIDS.
- Monitoring an infant in a paediatric inpatient ward after an ALTE episode - after discharge, home monitoring is recommended depending on the cause of the episode.

2. Designated patient population

- Age: from birth to typically 12 months (depending on the child's maximum recommended weight corresponding to the physiological age up to 2 years, in exceptional cases, for non-physiological cases, even above 2 years, but always taking into account the recommended maximum weight).
- Recommended patient weight from 1 to 15 kg.
- State of health: according to the specified medical indication.
- Ethnicity: multiple.
- The patient is not a device user (does not control device).

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

4. Minimum specified user profile

- Age: 12 years + , with the ability to judge appropriate to his or her age.
- Knowledge: ability to distinguish the colours and meanings of the signal lights, ability to change batteries in the device and install the device according to the instructions in the manual.
- Language aptitude: average ability to read and understand a text in the native language.
- Experience: basic experience with installing and operating simple electronic devices with the aid of a manual.
- Other abilities: hearing and sighted individual, mentally competent to care for a child.

5. Intended environment and conditions of use

- It is intended for use in healthcare provider and home environments.
- It is designed to be used under a mattress with an insulating pad to protect against permeation.
- Not intended for use in transport means, unlockable cradles, prams, hammocks, hanging baskets, in environments that easily transmit shocks and vibrations.
- Not intended to be overloaded beyond the weight limit specified in the manual which can lead to unreliable operation.

a. User conditions

- Observation angle: 45°.
- Observation distance 1 to 5 m depending on light conditions
- Ambient light conditions: 50 lx to 2500 lx.
- Emitted sound pressure: 80 dBa 1 m from the device.
- The device is portable when keeping to the specified environmental and usage conditions.
- The frequency of use of the device is not limited by the manufacturer.
- It is necessary to respect the lifespan for the sensing pad, which is 2 years or 14600 hours, and the control unit, which is 10 years.

b. Ambient conditions - see Technical data below

13. TECHNICAL SPECIFICATIONS

Power supply	3 V; 2 × 1.5 V alkaline battery type AA (LR6)
Idle consumption	106 µA
Consumption during an alarm	270 mA
Low battery indicator voltage	2.46 V ± 0.15 V
Critically low battery indicator voltage	2.2 V ± 0.15 V
Threshold breathing rate	<8 breaths/min (i.e. <0.13 Hz)
Measuring range for room temperature	-40 °C to +85 °C with an accuracy of ± 0.2°C
Typical battery life - home health care	6 months (this is reduced with frequent alarm testing and using the lamp)
Typical battery life - health care provider	4 months (this is reduced with frequent alarm testing and using the lamp)
Sensor pad	Type BM-03D, dimensions max. 300 × 500 × 15 mm
Acoustic alarm level	80 $dB.m^{-1}$ ± 5 % $dB.m^{-1}$
Electronic control unit - dimensions	max. 140 × 82 × 37 mm, weight 125 g + batteries
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
Ingress protection	IP31
Lifespan of the sensor pad	2 years or 14600 h since it's first use
Lifespan of the control unit	10 years
Lifespan of the device	10 years under the condition of replacing the sensor pad after its lifespan (i.e. every 2 years)
Meets the following standards:	EN 60601-1 ed. 2 2:2007 + A1:2014 EN 60601-1-2 ed. 3:2016 EN 60601-1-6 ed. 3:2010 + A1:2015 EN 60601-1-8 ed. 2:2008 + A1:2013 + A11:2017 EN 60601-1-11 ed. 2:2016 EN ISO 10993-1:2021, EN 62366-1:2019 EN ISO 14155:2021, EN 14971:2020 EN ISO 13485 ed. 2:2016, EN IEC 63000:2019 EN 62304:2006 + A1:2016

14. DEFINITIONS AND SYMBOLS

ME device	Medical electrical device (with attachment that detects energy from the patient)		
EMC	Electromagnetic compatibility (a set of normative requirements for a ME device)		
SIDS	Sudden infant death syndrome		
	Designation of the attachment part type BF		General warning sign
	General mandatory action sign		Refer to instruction manual/booklet
IP31	The device's immunity to the ingress of foreign bodies and water (Ingress protection class)		
	Product identification by barcode, 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 medical device
(10) = LOT (batch number)
(21) = SN (serial number)

Certification performed by the notified body EZÚ Prague No. 1014.

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

JABLOTRON ALARMS a.s. declares that the product BM-03 is designed and manufactured in accordance with the harmonization legislation of the European Union: Directive No. 93/42/EHS, as last amended. The original Declaration of Conformity is at **www.monitornanny.com**

After use, the battery should not be thrown into the bin, but returned to a collection point. Although it is free of any harmful materials, do not dispose of it in normal waste, but in special containers or collection points for the disposal of small electrical equipment, or hand it over to the dealer or directly to the manufacturer.

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15. EMC OF A MEDICAL DEVICE

15.1 EMISSIONS LIMITS BY ENVIRONMENT

Phenomenon	Professional medical facilities [a]	Home health care [a]
RF emissions propagated 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 on the intended use environment.

b) This test is not applicable in this environment if the ME devices and ME systems used are connected to the public power supply network and the power supply is otherwise within the scope of the basic EMC standard.

c) ME instruments and ME systems intended for use in aircraft must meet the requirements of RF EMISSIONS pursuant to ISO 7137. The conducted RF EMISSION test is only performed for ME instruments and ME systems that are intended for connection to an aircraft's on-board network. ISO 7137 is identical to RTCA DO-160: 1989 and EUROCARD ED-14C: 1989. The latest editions are RTCA DO-160G:2010 and EROCAE ED-14G:2011. Therefore, section 21 (category M) of a newer edition, such as [39] or [40], should be used.

d) Standards applied for other modes or the EM transport environments for which they apply. Examples of standards that could 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 test method	Immunity test levels	
		Professional medical facilities	Home health care [a]
Electrostatic discharge	IEC 61000-4-2	± 8 kV or contact charge ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV for air discharge	
RF EM fields propagated by radiation [a]	IEC 61000-4-3	3 $V.m^{-1}$ [f] 80 MHz – 2,7 GHz [b] 80 % AM at 1 kHz [c]	10 $V.m^{-1}$ [f] 80 MHz – 2,7 GHz [b] 80 % AM at 1 kHz [c]
Near fields from RF wireless communication devices	IEC 61000-4-3	see 8.10.	
Magnetic field of specified mains frequencies [d] [e]	IEC 61000-4-8	30 $A.m^{-1}$ [g] 50 Hz or 60 Hz	

a) If an interface is used between the simulation of the patient's physiological signal and the ME device or ME system, it must be located within 0.1 m of the vertical plane of the homogeneous field area in one direction with 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 reception frequency. Testing may be performed at other modulation frequencies determined in the risk management process. This test assesses the basic safety and necessary functionality of the intended receiver when the ambient signal is in the passband. It is understood that the receiver may not achieve normal reception during the test.
c) Testing may be performed at other modulation frequencies determined in the risk management process.
d) Valid only for ME devices and ME systems with magnetically sensitive components or circuits.
e) During the test, the ME instrument or ME system may be supplied with 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 device or ME system and the source of the mains frequency magnetic field. If the risk analysis shows that the ME instrument or ME system will be used closer than 15 cm from the source of the mains frequency magnetic field, the immunity test level must be set as is appropriate for the minimum expected distance.

15.3 IMMUNITY REQUIREMENTS - INPUT AND OUTPUT THROUGH THE DEVICE'S COVER FROM RF DEVICES

Test frequency MHz	Band [a] MHz	Service [a]	Modulation[b]	Maximum output W	Distance m	Immunity test level 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	FMc) ± 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 immunity test level, the distance between the transmitting antenna and the EM device or EM system can be reduced to 1 m. According to IEC 61000-4-3, a distance of 1 m is permitted.

a) For some services, only uplink frequencies are included.
b) The carrier wave must be modulated using a rectangular signal fill factor of 50 %.
c) As an alternative to FM, 50% pulse modulation at 18 Hz can be used, because even if it does not represent real modulation, it would be the worst case.

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