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Киргизия (996)312-96-26-47

Россия (495)268-04-70

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Казахстан (772)734-952-31

Сургут (3462)77-98-35 Тверь (4822)63-31-35 Томск (3822)98-41-53 Tyna (4872)74-02-29 Ульяновск (8422)24-23-59 Уфа (347)229-48-12 Хабаровск (4212)92-98-04 Челябинск (351)202-03-61 Череповец (8202)49-02-64 Ярославль (4852)69-52-93

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Технические характеристики на пульсоксиметры BSM компании DITTMANN



- Precise and quick measurement of arterial oxygen saturation on a finger Pain-free measurement using two beams of light with different wavelengths Measurement and display of pulse rate and pulse intensity as bar graph and wave diagram (plethysmograph)
- Quick and easy application Easily portable thanks to low size and weight Ideal for sports and leisure activities 24 month warranty Contents: 1 Pulse Oximeter BSM 382
- 1 Operating manual, 2 x AAA batteries, 1 lanyard

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Dear customer,



Thank you for purchasing a new Pulse Oximeter BSM 382 and for your trust in our products. To ensure proper functioning and performance of your pulse oximeter, please read the operating manual prior to using your device for the first time. This is to ensure that you can enjoy this article for a long time.

What is pulse oximetry?

Pulse oximetry is a process for non-invasive measurement of arterial blood oxygen saturation as well as the pulse rate and pulse intensity on a human finger. The oxygen saturation determined in this way is referred to as **SpO2** (saturation of peripheral oxygen) and specifies the content of haemoglobin saturated with oxygen in percent.

In order to achieve **precise and reliable measurements**, it is important to be familiar with the operation of the device and information on pulse oximetry. Please read this operating manual carefully!



1.0 Explanation of symbols

The safety symbols illustrated in this operating manual provide information on the proper use of the device and to protect your safety.

The symbols have the following meanings:



Read and observe the operating manual!



Warning/Danger: Improper use leads to a risk of severe injuries, damage and danger of death!



These instructions must be complied with!



Device with type BF application part: Protection against electrical shock by means of leakage currents that conform to standards.

ATTENTION: It is dangerous for users to carry out self-diagnosis and self-treatment based on the measurements determined with this Pulse Oximeter BSM 382. This may lead to the aggravation of diseases. <u>This device can under no</u> <u>circumstances replace proper medical consultation</u> - if in doubt, always consult your physician!

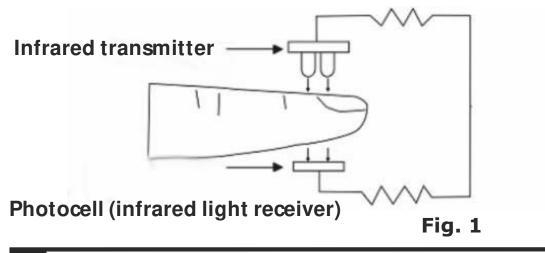


2.0 Application and function

2.1 Application and operational principles

The Pulse Oximeter BSM 382 is a portable measuring device for easy, uncomplicated and precise measurements of arterial oxygen saturation as well as pulse rate and pulse intensity (display as bar and wave chart) at any time. The device features an adjustable acoustic and visual alarm function.

Using the Pulse Oximeter BSM 382, the oxygen saturation level of the arterial haemoglobin (**SpO2**) can be easily measured on a finger. The measurement is carried out by two light sources with different wavelengths being shone through the finger and hitting a photo electrode on the other side. The photo electrode determines which portions of the light have passed through the finger. Depending on the blood oxygen saturation, different portions of the light pass through the finger. Based on these measurements, the device determines the saturation level, making blood samples unnecessary.





Principle of operation:

The Pulse Oximeter BSM 382 carries out two measurements: Firstly, the blood oxygen saturation and secondly, the pulse rate in the finger tip. Additionally, the pulse intensity is displayed as bar graph or wave diagram (plethysmograph). For this purpose, the device is clamped to a finger. Using infrared light, the device can carry out measurements and assess the colour deviation for different levels of blood oxygen saturation to determine the current values. Potential sources of errors due to external influences include external infrared radiation, bad circulation in the fingers and artificial or painted finger nails.

2.2 Pulse Oximeter BSM 382 fields of application

This device is exclusively intended for private use. It is not suitable for commercial application or long-term monitoring.

Fields of application for the Pulse Oximeter BSM 382 for monitoring of oxygen saturation and pulse levels may include:

- Private monitoring of oxygen saturation and pulse levels
- Sport aviation
- Altitude training
- Mountain climbing
- Endurance training
- Sports activities of any kind



2.3 Explanation of measurements

For healthy people, a normal blood oxygen saturation level of between 92 - 98 % is measured. Diseases or conditions leading to blood oxygen saturation **levels** that are **too low** include:

- Pulmonary emphysema
- Asthma
- Reduced respiration
- Circulatory disturbance
- Heart defect
- Blood pH value disturbance
- Low oxygen content in the ambient air (e.g. in high-altitude mountains)
- Increased oxygen consumption, e.g. through physical exercise

Levels of blood oxygen saturation that are **too high** may be caused by particularly quick and deep breathing. The level may increase up to 100 per cent. However, this substantially reduces the carbon dioxide content in the blood potentially influencing the blood pH value balance. Breathing air with an increased oxygen content (e.g. during oxygen therapy) may also lead to increased levels.



2.4 Intended use

The Pulse Oximeter BSM 382 is exclusively to be used according to its intended use: measurement of arterial oxygen saturation and pulse rate and intensity on a human finger. The device is not intended for **long-term monitoring** of patients! The device is not equipped with an interface for connection to other medical monitoring equipment!

This device must <u>not</u> be used by persons (including children) with limited physical, sensory or mental abilities or insufficient experience and/or knowledge unless they are supervised by a person responsible for their safety or have been instructed on using the device.



3.0 Safety instructions



3.1 General safety instructions

- 3.1.1 The device must not be used in case of a defect. Do not try to modify (change), disassemble or repair the device or to replace parts.
- 3.1.2 In case of irregularities during application of the device, immediately stop using the device and consult your physician.
- 3.1.3 Do not carry out any other tasks during measurement.
- 3.1.4 In case of any doubt concerning the application of the device, please consult your physician.
- 3.1.5 Keep this operating manual during the service life of the product and pass it on with the device if it is passed on to third persons. Also make the operating manual available to third persons. The operating manual is an integral part of the device.
- 3.1.6 Misuse and use that does not conform with the intended use of the device must be prevented.
- 3.1.7 Do not drop or shake the device and do not expose it to shocks.
- 3.1.8 To ensure precise measurements, protect the device from dust, corrosive substances, hot surfaces, humidity, dirt and damage.
- 3.1.9 Do not touch the device with pointed or sharp objects.



- 3.2.0 Do not expose the device to direct sunlight or extremely high or low temperatures. Only use and store the device in dry and clean environments.
- 3.2.1 Do not open the device and do not try to repair it in case of defects or damage. This will result in voiding your warranty. The device may only be repaired by authorised specialists.
- 3.2.2 Remove the batteries from the device if it is not used for longer periods of time to prevent damage due to leaking batteries.
- 3.2.3 Do not use or store the device in locations with extremely high or low ambient temperatures or in extremely dry or humid environments as this may lead to inaccurate measurements.
- 3.2.4 The device must not be disinfected with hot steam or boiling water. For information on disinfection, cleaning and care, please refer to page 34.

3.3 Environmental restrictions of the BSM 382

3.3.1 Do not use the device in humid or wet environments or shortly after transferring it from a cold to a hot and humid environment. During application, keep away the device away from any liquids and do not immerse it in liquids at any time.



- 3.3.2 The device must not be used during magnetic resonance imaging or computer tomography!
- 3.3.3 **WARNUNG** Risk of explosion! Do not use the device in flammable atmospheres, with flammable anaesthetics or other flammable substances and gases or near explosive substances!
- 3.3.4 The device must only be used in environments free from dust, shocks, vibrations and corrosive and flammable substances.
- 3.3.5 During application, the device may cause interferences for other electrical equipment. Do not use it in the vicinity of other electrical equipment.
- 3.3.6 Do not use any mobile phones in the vicinity of the device while carrying out measurements. Please note that mobile RF (radio frequency) communication equipment (e.g. mobile phones) may disturb medical electrical equipment.
- 3.3.7 When using the device, always observe a safety distance of at least 1.5 m to shortwave or microwave equipment or radio frequency surgical instruments.
- 3.3.8 Medical electrical equipment is subject to special safety requirements regarding EMC (electromagnetic compatibility). Please note the EMC instructions (page 37 - 45) for installation and commissioning of the device.



3.4 Application by children and teenagers

- 3.4.1 Keep the device away from children and teenagers under the age of 18.
- 3.4.2 Supervise children to prevent them from playing with the device.
- 3.4.3 Keep the device away from children. Small parts or batteries may be swallowed and lead to suffocation. Children may be injured when using the device.
- 3.4.4 The device is not suitable for babies, children under the age of 4 and for persons weighing less than 15 kg!

3.5 Important application information

- 3.5.1 This pulse oximeter cannot replace medical consultation or treatment! The measurements are only to be used for comparison. In case of health problems, always seek medical consultation!
- 3.5.2 **WARNING:** The device <u>must **not be used**</u> **for long-term monitoring** of patients (e.g. in intensive care units)! The device is **not** equipped with an interface for connection to other medical monitoring equipment!
- 3.5.3 **WARNING:** Do not look into the measuring beam of the device. This could cause damage to your eyes!



- 3.5.4 Do not use the device if it is damaged. Using damaged devices may cause injuries, serious danger and inaccurate measurements.
- 3.5.5 Always keep the device clean and dry and avoid damage. Only in this way can accurate measurement results be ensured.
- 3.5.6 Regularly check the device for damage or defects that could impair the safety and functioning of the device.
- 3.5.7 In case of unusually low measurements or measurements that do not correspond to your personal perception, repeat the measurement. If in doubt, seek medical consultation!
- 3.5.8 The device requires approx. 8 seconds to determine the measurement. Only measurements that are properly displayed are reliable. Fluctuating measurements are not significant. For some persons, the device cannot determine any reliable measurements.
- 3.5.9 Do not use the device on wounds, skin rash, fresh scars or painful areas.
- 3.6.0 Do not attach the device to the same finger for longer periods of time to prevent pressure injuries. In case of pressure pain, stop the application immediately. The application on children and persons who cannot make themselves understood as well as persons with circulatory and sensory disorders in the application area requires special attention!



- 3.6.1 Stop using the device in case of intolerance or allergic reactions (e.g. latex allergy) caused by components of the device.
- 3.6.2 Before carrying out any measurements with the device, make sure that the fingers are clean, dry and oil-free.
- 3.6.3 Colour on the fingers (dirt, tattoos) may lead to incorrect measurements.
- 3.6.4 Nail polish on the finger nails and nails that are too long or artificial may make measurements impossible or lead to incorrect measurements.
- 3.6.5 Fingers that are too thin or too cold may lead to incorrect measurements. In this case, use the thumb and ensure that it is inserted deeply enough into the device or warm up the fingers.
- 3.6.6 Make sure that there are no obstacles between the measuring elements (optical sensors) in the device.
- 3.6.7 The optical sensors of the device must be protected from any contamination. Contamination may lead to incorrect measurements.
- 3.6.8 If the device displays unclear or fluctuating values, remove the device from the finger and reattach it to repeat the measurement.
- 3.6.9 Measurements of the oxygen saturation in the arterial haemoglobin may be influenced by strong ambient lighting.



4.0 Questions regarding pulse oximetry

4.1 What is pulse oximetry?

Pulse oximetry enables non-invasive measurements of arterial oxygen saturation as well as pulse rate and pulse intensity. The measurement is carried out by two light sources with different wavelengths (660 nm red light and 940 nm infrared light) which are shone through the finger and hit a photo electrode on the other side determining the potions of the light that have passed through the finger. Depending on the blood oxygen saturation, different portions of the light pass through the finger. Based on these measurements, the device determines the saturation level.

4.2 Advantages of non-invasive pulse oximetry

The measurement of the arterial oxygen saturation level using the Pulse Oximeter BSM 382 is uncomplicated, non-invasive (no blood sample needs to be taken) and can be carried out almost everywhere at any time due to the small size and low weight of the device. Another advantage is that pulse rate and pulse intensity are simultaneously determined and displayed. The Pulse Oximeter BSM 382 can be extremely useful, particularly for activities that may lead to deterioration in arterial blood oxygen saturation (mountain climbing, aviation, hang gliding, paragliding, endurance sport, etc.) but also for private checks and during sports and leisure activities of any kind.



4.3 Conditions that could influence the measurement

Please observe the following circumstances as these may influence the measurement or lead to incorrect measurements:

- 4.3.1 There must be no dirt, nail polish or tattoos on the finger or finger nail.
- 4.3.2 The finger must be inserted deeply enough into the device with the finger nail pointing upwards to the display side of the device.
- 4.3.3 The finger used for measurement must not be moved and the person who the measurement is being carried out must stay calm.
- 4.3.4 No arterial or venous lines must be connected to the arm of the finger which the measurement is being carried out on and no blood pressure cuffs may be used.
- 4.3.5 Strong ambient lighting from fluorescent lamps, infrared lamps and heating devices or direct sunlight is to be avoided.
- 4.3.6 Medication such as dopamine, procaine, lidocaine and butacaine may strongly influence the measurement.
- 4.3.7 For patients suffering from severe anaemia or anaemic or toxic oxygen deficiency, the measurements may be incorrect.
- 4.3.8 Incorrect measurements may occur due to severe hypothermia, shock and low blood pressure as well as poisoning which influences the oxygen binding capacity of the haemoglobin.



5.0 Scope of supply (packaging content)



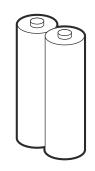


1 x Pulse Oximeter BSM 382 i



1 x Lanyard

1 x Operating manual

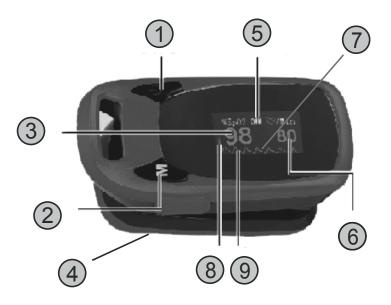


2 x AAA batteries

Please check all components directly after unpacking for completeness of the scope of delivery and damage. Do not use the device in case of damage or if the operating manual is missing!



6.0 Device front and LED display



- 1. **ON/OFF** button for activation or manual deactivation of the measurement process
- 2. M configuration button for display switching and setting visual and acoustic alarms
- 3. Colour display (OLED display)
- 4. Battery compartment at the back of the device
- 5. Battery symbol / warning indicator (
) in case of low batteries
- 6. Pulse rate display
- Pulse intensity display as pulse chart (plethysmograph)
- 8. Pulse intensity display as bar graph
- Display of the measured arterial oxygen saturation level (%SpO2)



7.0 Starting up the device

7.1 Inserting the batteries

Press on the arrow-shaped surface on the battery compartment cover on the back of the device and slide the cover off. Insert 2 batteries (type AAA) in the correct position (+ and - pole) according to the marking in the centre of the battery compartment (refer to **fig. 2**). **WARNING:** Make sure that the batteries are inserted correctly according to their polarity! <u>Incorrectly inserted</u> <u>batteries may damage the device!</u> Afterwards, reattach the battery compartment cover by sliding it until it locks in place and closes flush with the device housing.

<u>Battery types:</u> The Pulse Oximeter BSM 382 requires alkaline batteries type AAA. <u>Do not use</u> <u>rechargeable batteries!</u>



7.2 Battery warning indicator

If the batteries of the device are low, the battery symbol 5 () only displays one bar. In this case, please insert new batteries (also refer to point 10.0 on pages 31 - 33).



7.3 Lanyard attachment

Guide the thin black section of the lanyard through the opening in the device housing. Open the latch of the thin black lanyard and guide the light grey lanyard and the clip lock through to create a loop. Tighten this loop until the lanyard is securely attached to the bar at the housing (refer to **fig. 3**). If required, the device can be quickly detached from the lanyard by pushing together the two lateral clips of the black clip lock and pulling the device off the lanyard. To attach it, reconnect the two parts of the black clip lock until it locks in place.



Fig. 3

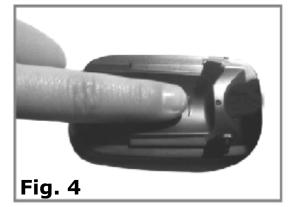


8.0 Device operation

Step 1: Open the device like a clothes peg, insert a finger completely into the opening (refer to **fig. 4**) and close the device by releasing the back. The device is now securely attached to the finger. **NOTE:** Please note that the finger must be inserted with the finger nail facing upwards (towards the display side)!

Step 2: Press the O ON/OFF button 1 to activate the measurement process. "Oximeter" appears briefly on the display and the measurement is started. After approx. 8 seconds, the determined arterial oxygen saturation levels (%SpO2) (9) and the pulse rate (6) are displayed as well as the pulse intensity wave diagram (plethysmograph) (7) and bar graph (8) on the display (refer to fig. 5). As long as the device remains attached to the finger, the measurements are continuously updated.

NOTE: During the measurement, <u>stay calm and</u> <u>do not move the finger</u> as this may lead to incorrect measurements.







Step 3: To complete the measurement, remove the device from the finger by pushing on the peg ends. After approx. 15 seconds, the device is switched off automatically. The device can also be switched off manually by pressing the ⁽⁾ ON/OFF 1 button for approx. 2 seconds.

WARNING: The device is not intended for **longterm monitoring** of patients! The device is **not** equipped with an interface for connection to other medical monitoring equipment!

8.1 Display switching

Press the M 2 configuration button to turn the display in four different directions and to set a total of six different display modes. Press the M 2 configuration button briefly to switch the display in the order illustrated in **fig. 6** (see below).

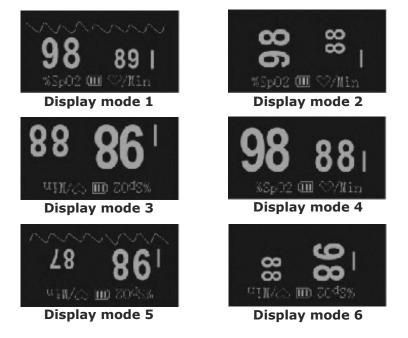


Fig. 6



8.2 Activation/deactivation of the alarm function

If the **alarm function** is <u>activated</u>, an acoustic or visual alarm is triggered if the values go above or below adjustable upper or lower limits. To activate this, switch on the device and hold down the M (2) configuration button until the Settings/Alm **Setup** mode is displayed and release the button (2). The star-shaped cursor is now displayed next to **Alm Setup**. Briefly press the **M** (2) configuration button to move it to the Alm entry. Next to the star-shaped cursor, off is displayed (this means that the alarm function is deactivated). When you hold down the M(2) configuration button, the setting <u>alternates</u> between **on** and **off**. Switch on the alarm function by releasing the configuration button when **on** is displayed (refer to fig. 7).

	Settings		
Alm Setu	р		
Alm Beep	on off	*	
Restore	011		
	Exit		

Fig. 7

To switch off the alarm function, proceed similarly and set the function from **on** to **off**. To save the selected settings, move the star-shaped cursor to the **Exit** entry by pressing the configuration button 2 and hold down the button 2 until the measurements are displayed again. The selected settings are now saved.



8.3 Activation/deactivation of the acoustic function

If the acoustic function is activated, the pulse rate is not only displayed visually but also indicated acoustically by an acoustic signal which emits at the pulse rate. To activate it, switch on the device and hold down the M(2) configuration button until the Settings/Alm Setup mode is displayed and release the button (2). The starshaped cursor is now displayed next to Alm **Setup**. Briefly press the **M** (2) configuration button to move it to the **Beep** entry. Next to the starshaped cursor, off is displayed (this means that the acoustic function is deactivated). When you hold down the M (2) configuration button, the setting alternates between **on** and **off**. Switch on the acoustic function by releasing the configuration button when **on** is displayed (refer to fig. 8).

Settings				
Alm Setup				
Alm	on			
Веер	on	*		
Restore				
Exit				

Fig. 8

To switch off the acoustic function, proceed similarly and set the function from **on** to **off**. To save the selected settings, move the star-shaped cursor to the **Exit** entry by pressing the configuration button (2) and hold down



the button 2 until the measurements are displayed again. The selected settings are now saved.

RESET function: Deleting settings

If **OK** is displayed in the **Settings/Alm Setup** menu next to the **Restore** entry, all settings in the **Settings/Alm Setup** and the **Settings/Sound Setup** menus correspond to the <u>factory settings</u> (refer to page 46). If any settings have been changed and saved in the menus, **OK** is not displayed.

To restore the adjustable values in the **Settings/Alm Setup** and **Settings/Sounds Setup** menus to the factory settings, press the **M** (2) configuration button to move the star-shaped cursor down to the **Restore** entry and hold down the button until **OK** is displayed next to the starshaped cursor (refer to **fig. 9**). By doing this, all previously set values are <u>returned to the factory</u> <u>settings</u>. Press the **M** configuration button twice to return to the menu.

Settings			
Alm Setup			
Alm	on		
Веер	off		
Restore		*	ОК
Exit			

Fig. 9



8.4 SpO2 alarm settings (oxygen saturation)

The Settings/Sound Setup menu allows you to set the blood oxygen saturation limit values in % at which acoustic (acoustic signal) and visual alarms (blinking of the measurement) are triggered. In the range of 50 % - 100 %, a lower and an upper limit can be set. To do so, switch on the device and hold down the M(2) configuration button until the Settings/Sounds Setup mode is displayed and release the button (2). The starshaped cursor is now displayed next to **Sounds Setup**. Press the **M** (2) configuration button briefly to move the cursor down to the SpO2 Alm Hi entry to set the upper alarm limit next to the starshaped cursor. To do so, hold down the M(2)configuration button until the lowest limit (**50**%) is displayed. As you hold down the button, the displayed value increases in **single steps** to a maximum of 100 % (refer to fig. 10).

Se	ttings		
Sounds Setup			
Sp02 Alm Hi	100		
Sp02 Alm Lo	94		
PR Alm Hi	130		
PR Alm Lo	50		
+/-		+	F
	Exit		

Fig. 10



Release the button 2 when the desired value is reached and move the star-shaped cursor down to the **SpO2 Alm Lo** entry by pressing the button again. Adjust the <u>lower alarm limit</u> next to the star-shaped cursor in the same way as the upper alarm limit. Make sure that the upper limit is higher than the lower limit. To save the selected settings, move the star-shaped cursor to the **Exit** entry by pressing the configuration button 2 and hold the button 2 down until the measurements are displayed again. The settings are now saved.

8.5 Pulse rate alarm settings

The Settings/Sound Setup menu allows you to set the limit values of the pulse rate per minute at which acoustic (acoustic signal) and visual alarms (blinking of the measurement) are triggered. In the pulse rate per minute range of 5 - 250, a lower and an upper limit can be set. However, as the device can only measure a pulse rate of more than 30 beats per minute, the minimum limit should be set to at least 30 beats per minute. To adjust the limits, switch on the device and hold down the M(2) configuration button until the Settings/Sounds Setup mode is displayed and then release the button (2). The star-shaped cursor is now displayed next to **Sounds Setup**. Briefly press the **M** (2) configuration button three times to

GB

move the cursor down to the PR Alm Hi entry to adjust the upper alarm limit next to the starshaped cursor. To do so, hold down the M(2)configuration button until the lowest limit of **5** is displayed. As you hold down the button (2), the displayed limit increases in steps of five to a maximum value of **250** before starting at **5** again. Release the button (2) when the desired value (e.g. **130**, refer to **fig. 11**) is reached and move the star-shaped cursor down to the **PR Alm Lo** entry by pressing the configuration button (2) again. Adjust the lower alarm limit next to the star-shaped cursor in the same way as the upper alarm limit. Make sure that the upper limit is higher than the lower limit. To save the selected settings, move the star-shaped cursor to the Exit entry by pressing the configuration button (2) and hold the button (2) down until the measurements are displayed again. The settings are now saved.

Settings				
Sounds Setup	-			
Sp02 Alm Hi	100			
Sp02 Alm Lo	90			
PR Alm Hi	130*			
PR Alm Lo	50			
+/-		+		
	Exit			

Fig. 11



SETTINGS +/- under Settings/Sounds Setup

Press the M (2) configuration button to move the star-shaped cursor down to the +/- entry to set whether all adjustable values in the

Settings/Sounds Setup menu are adjusted in increasing or decreasing order. To do so, hold the M 2 configuration down and the setting next to the star cursor will <u>alternate</u> between + and -. Release the configuration button if the required entry is displayed. If + is displayed next to the star-shaped cursor, all adjustable values in the Settings/Sounds Setup menu can be adjusted in <u>increasing</u> order (refer to fig. 12). If - is displayed next to the star-shaped cursor, all adjustable values in the Settings/Sounds Setup menu can be adjusted in <u>decreasing</u> order (refer to fig. 13).

Settir	ngs	
Sounds Setup		
Sp02 Alm Hi	100	
Sp02 Alm Lo	94	
PR Alm Hi	130	
PR Alm Lo	50	
+/-	* +	Fig. 12
Exi	t	
Settir	ngs	
Sounds Setup	0	
Sp02 Alm Hi	100	
Sp02 Alm Lo	94	
PR Alm Hi	130	
PR Alm Lo	50	
+/-	* =	Fig. 13
+/-		

GB

9.0 Device disposal

9.1 The service life of the device is approx. 3 years. If the Pulse Oximeter BSM 382 is to be recycled, it has to be disposed of according to legal regulations. For this purpose, consult your local administration or a disposal company. The Pulse Oximeter BSM 382 is to be disposed of according to the Waste Electrical and Electronic Equipment Directive 2002/96/EC (WEEE).

10.0 Battery change and information

- 10.1 **Battery types:** The Pulse Oximeter BSM 382 requires alkaline batteries type AAA. <u>Do</u> <u>not use rechargeable batteries!</u>
- 10.2 **Battery change:** Press on the arrowshaped surface on the battery compartment cover on the back of the device and slide the cover off. Insert 2 batteries (type AAA) in the correct position (+ and - pole) according to the marking in the centre of the battery compartment (refer to **fig. 14** on **page 32**). **WARNING:** Make sure that the batteries are inserted correctly according to their polarity! <u>Incorrectly inserted batteries may damage the device!</u>



Fig. 14

Afterwards, reattach the battery compartment cover by sliding it until it locks in place and closes flush with the device housing.



- 10.3 <u>Battery disposal:</u> Do not dispose of empty batteries with household waste! Dispose of empty batteries at an electronics retailer or a public collection point. Consumers are legally obliged to return empty batteries.
- 10.4 <u>These signs mark batteries containing</u> <u>hazardous substances</u>: **Pb** = contains lead, **Hg** = contains mercury, **Cd** = contains Cadmium.
- 10.5 Batteries can be life-threatening if swallowed. Keep the device and its batteries away from children. If a battery has been swallowed, seek medical attention immediately.
- 10.6 If a battery has leaked, avoid any contact with skin, eyes and mucous membranes. Rinse the affected areas immediately with plenty of clear water and immediately seek medical attention!



- 10.7 Batteries must not be charged (except rechargeable batteries), disassembled, burnt or short-circuited.
- 10.8 Protect batteries from high temperatures. Take out the batteries of the device if they are low or if the device is not to be used for a longer period of time. This way, damage due to leaking batteries can be avoided.
- 10.9 Always replace all batteries. Do not use different types of batteries, brands, rechargeable batteries or batteries with different ratings.



11.0 Cleaning and care

- 11.1 Always keep the surface of the device free from dust and dirt. Prior to cleaning the device, switch it off and remove the batteries. To clean the housing, use a dry, soft cloth. In case of heavier soiling, clean the device with a slightly dampened cloth with some mild cleaning agent. Afterwards, let the device dry completely. Do not attempt to clean the device using abrasives, benzene or solvents! Make sure that no fluids can enter the device!
- 11.2 Do not immerse the pulse oximeter in water or any other fluids! Do not pour any fluids on the device and ensure that no cleaning agents remain on the device.
- 11.3 For disinfection, a suitable commercial disinfectant or 75 % alcohol can be used. Afterwards, let the device dry completely.
- 11.4 After cleaning, store the device at room temperature at a clean and dry location. Do not expose the device to extreme temperatures, humidity, direct sunlight or shocks!
- 11.5 Make sure that the optical sensors of the device are free of dirt. Only in this way can accurate measurement results be ensured.



12.0 Technical defects

Defect	Cause	Solution
The device is switched on but no values or data are displayed (or	The finger is not positioned correctly in the device.	Insert the finger correctly in the device accor- ding to the user instructions.
oxygen saturation and pulse rate cannot be displayed correctly).	The oxygen saturation or pulse rate is too low to be measured properly.	Try to carry out a measurement again. If you are sure that the device is working properly, seek medical advice immediately!
The displayed values (oxygen saturation and pulse rate) are fluctuating or	The finger is not positioned deeply enough in the device.	Insert the finger correctly in the device accor- ding to the user instructions.
not stable.	The finger is shaking or the user is moving.	Make sure that the finger stays still in the device and that the user does not move.



12.0 Technical defects

Defect	Cause	Solution
The device cannot be switched on.	There are no batteries in the device or the batteries are incorrectly positioned.	Check whether the batteries are inserted (at the correct polarity). If not, position the batteries correctly at the correct polarity (refer to page 31 and following).
	The batteries are empty or low.	Replace the batteries. Observe the correct polarity (refer to page 31 and following).
	The device is defective.	Contact your dealer / customer service.
The display switches off automatically.	The device is auto- matically switched off after approx. 5 seconds.	This is normal - no defect!
	The batteries are low.	Replace the batteries. Observe the correct polarity (refer to page 31 and following).



Table 1 - Guide and manufacturer declaration - electromagnetic emissions - for all DEVICES AND SYSTEMS (refer to 6.8.3.201 a) 3).

Guide and manufacturer declaration – electromagnetic emissions

The (DEVICE or SYSTEM) is intended for use in the electromagnetic environment specified below. The customer or the user of the (DEVICE or SYSTEM) should assure that it is used in such an environment.

Emissions test	Complianc e	Electromagnetic environment - guide
RF emissions CISPR 11	Group 2	The (DEVICE or the SYSTEM) uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

Guidelines and manufacturer declaration – electromagnetic emissions

The BSM 382 is intended for use in the environment specified below. The customer or the user of the BSM 382 should assure that it is used in such an environment.



Emissions test	Conformity	Electromagnetic environment - guide
RF emissions according to CISPR 11	Group 2	THE BSM 382 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions according to CISPR 11	Class B	The BSM 382 is suitable for use in all establishments, including
Harmonics emissions according to IEC 6100-3- 2	Not applicable	domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/ flicker emissions according to IEC 6100-3- 3	Not applicable	



Guidelines and manufacturer's declaration – electromagnetic immunity

The BSM 382 is intended for use in the electromagnetic environment specified below. The customer or the user of the BSM 382 should assure that it is used in such an environment.

Immunity test	IEC 60601- test level	Confor mity level	Electromagnetic environment – guidelines
Electrostati c discharge (ESD) according to IEC 61000-4-2	± 6 kV contact discharge ± 8 kV air discharge	Not applicabl e ± 8 kV air discharg e	Floors should be wood, concrete or laid with ceramic tiles. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/b urst according to IEC 61000-4-4	± 2 kV for mains lines ± 1 kV for input/out put lines	Not applicabl e	Mains power quality should be that of a typical residential, commercial or hospital environment.



Immunity test	IEC 60601- test level	Confor mity level	Electromagnetic environment – guidelines
Surges according to IEC 61000-4-5	± 1 kV symmetri cal voltage ± 2 kV asymmet rical voltage	Not applicabl e	Mains power quality should be that of a typical residential, commercial or hospital environment.
Voltage dips, short interruption s and voltage variations of the power supply according to IEC 61000-4- 11	< 5 % UT (> 95 % voltage dip of UT) for $\frac{1}{2}$ periods 40 % UT (60 % voltage dip of UT) for 5 periods 70 % UT (30 % voltage dip of UT) for 25 periods < 5 % UT (> 95 % voltage dip of UT) for 5 s	Not applicabl e	Mains power quality should be that of a typical residential, commercial or hospital environment. If the user of the BSM 382 requires continued operation during power line interruptions, it is recommended that the BSM 382 be powered from an uninterruptible power supply or a battery.



Immunity test	IEC 60601- test level	Confor mity level	Electromagnetic environment – guidelines
Power frequency (50/60 Hz) magnetic field according to IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

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

Guidelines and manufacturer's declaration – electromagnetic immunity

The BSM 382 is intended for use in the electromagnetic environment specified below. The customer or the user of the unit should assure that it is used in such an environment.

Immunity test	IEC 60601- test level	Confor mity level	Electromagnetic environment – guidelines
			Portable and mobile RF communications equipment should be used no closer to any part of the [device or system] including cables than the recommended separation distance calculated from thefrequency of the equation appropriate to the transmitter.



Guidelines and manufacturer's declaration – electromagnetic immunity			
Immunity test	IEC 60601- test level	Confor mity level	Electromagnetic environment – guidelines
			Recommended separation distance:
Conducted RF disturbance s according to IEC 61000-4-6	3 Vrms 150 kHz to 80 Mhz	3 Vrms	d = 1.2 √₽
Radiated RF disturbance s according to IEC 61000-4-3	3 V/m 80 MHz to 2.5 Ghz	3 V/m	d = 1.2 80 MHz to 800 MHz √₽
			Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance



13.0 Information on electromagnetic

Guidelines and manufacturer's declaration – electromagnetic immunity			
Immunity test	IEC 60601- test level	Confor mity level	Electromagnetic environment – guidelines
			in meters (m). Field strengths from fixed RF transmitters as determined by an electromagnetic site survey (a) should be less than the conformity level in each frequency range (b). Interference may occur in the vicinity of equipment marked with the following symbol.

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

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



a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment as a result of fixed RF transmitters, an electromagnetic site survey is recommended. If the measured field strength in the location in which the BSM 382 is used exceeds the applicable RF compliance level above, the BSM 382 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the BSM 382.

b. Not applicable over a frequency range of 150 kHz to 80 Mhz.

Recommended separation distance between portable and mobile RF communications equipment and the [DEVICE or SYSTEM]

The BSM 382 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the BSM 382 can help to prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the BSM 382 as recommended below, according to the maximum output power of the communications equipment.



Rated maximum	Separation distance according to frequency of transmitter in meters		
output power of the transmitter in Watt	150 kHz to 80 Mhz d = 1.2 P	80 Mhz to 800 Mhz d = 1.2 /P	800 Mhz to 2.5 Ghz d = 2.3 √P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the separation distance can be estimated using the equation applicable to the respective column, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 To calculate the recommended safe distance of transmitters in the frequency range 80 MHz to 2.5 GHz, an additional factor of 10/3 has been applied to reduce the probability of disturbance from a mobile/portable communications device which is inadvertently brought within the patient area.

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



14.0 Technical data

Model/type: Dimensions (LxWxH): Weight:

Material: Power supply:

Power consumption:

Measuring method:

Measuring duration: Display: **Resolution:**

Energy-saving functions:

BSM 382 Approx. 74 x 37 x 38 mm Approx. 50 g (incl. batteries) Plastic, metal 3.0 V DC, 2 x AAA batteries (V = volt, DC =direct current) < 30 mA (mA =milliampere) Contactless infrared measurement approx. 8 seconds OLED colour display 1 % for SpO2 and 1 bpm for pulse rate (bpm = beats per minute) The device is switched off automatically approx. 15 seconds after removing it from the finger Approx. 20 hours with a set of full alkaline batteries

Operating time:

Factory settings:

Alarm default values Haemoglobin saturation: Pulse rate:

<u>Alarm Setup</u> Alm: Beep:

Upper limit: 100 Lower limit: 94 Upper limit: 130 Lower limit: 50

on off



14.0 Technical	data
MEASURING DATA: Oxygen saturation:	
Measuring range:	35 % - 100 % (per cent)

uring range: **Resolution:** Measuring accuracy:

Optical sensors:

Pulse measurement:

Measuring range:

Measuring accuracy: Pulse intensity:

10 nm) nm = nanometer 30 bpm - 250 bpm (bpm = beats per minute) +/-2 bpm Illustration by bar graph and wave diagram

1 %

2 %

(plethysmograph): higher amplitude = stronger pulse)

from 70 % - 100 %: +/-

Wavelength 940 nm (+/-

Red light: Wavelength

660 nm (+/-2 nm)

Infrared light:

Operating conditions:

Atmospheric pressure: 700 hPa - 1060 hPa (hectopascal) 5 °C - 40 °C at 15 % - 80 % relative

Storage/transport data:

50°C -10°C -

80%

Atmospheric pressure:

humidity

Storage/transport temperature: -10 °C to 50 °C at 15 % - 80 % relative humidity 700 hPa - 1060 hPa (hectopascal)



14.0 Technical data

LOT

SN

2014-08





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Devices of protection:

Device nameplate:

Batch designation: LOT V4714BSM382 Serial number: SN 00001 (consecutive number) Date of manufacture: 2014-08 (year, month) The BSM 382 device is certified according to EU Directive 93/42/ECC for Medical Devices. Manufacturer: Handelshaus Dittmann GmbH, Kissinger Straße 68, D-97727 Fuchsstadt/Germany. Protection against electrical shock according type BF (Body Float). Application device type BF with increased protection against electrical shock to the body, however, not directly to the heart. Apply dry and store **IPX4** Against General mutual water

BSM 382, Puls-Oximeter 3 V DC, 2 x Typ AAA Handelshaus Dittmann GmbH Kissinger Straße 68 D-97727 Fuchsstadt/Germany V4714BSM382 2014-08 Keep dry C C 0123

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15.0 Warranty

This Pulse Oximeter BSM 382 has been developed and manufactured with great care.

The legal warranty period for the product is 24 months from date of purchase for material or manufacturing errors. Please keep the receipt as proof of purchase of the Pulse Oximeter BSM 382 in case you need to make warranty claim.

The warranty shall not include:

- Damage due to incorrect use
- Defects already known to the customer at the time of purchase
- Wear parts
- Damage due to unauthorised modifications and personal negligence of the customer

After expiry of the warranty period, defective devices can be sent to the address specified on the following page. Repairs after expiry of the warranty period are at the owner's expense.



15.0 Warranty

In case of technical difficulties, questions or warranty claims regarding this device, please contact us:

PLEASE NOTE:

In case of complaints about the device, please first contact the responsible service centre! If required, the service centre will ask you to return the device. UNPAID shipments will not be accepted by the service centre! Архангельск (8182)63-90-72 Астана (7172)727-132 Астрахань (8512)99-46-04 Барнаул (3852)73-04-60 Белгород (4722)40-23-64 Брянск (4832)59-03-52 Владивосток (423)249-28-31 Вологоград (844)278-03-48 Вологда (8172)26-41-59 Воронеж (473)204-51-73 Екатеринбург (343)384-55-89 Иваново (4932)77-34-06 Ижевск (3412)26-03-58 Иркутск (395)279-98-46 Казань (843)206-01-48 Калининград (4012)72-03-81 Калуга (4842)92-23-67 Кемерово (3842)65-04-62 Киров (8332)68-02-04 Краснодар (861)203-40-90 Красноярск (391)204-63-61 Курск (4712)77-13-04 Липецк (4742)52-20-81

Киргизия (996)312-96-26-47

Магнитогорск (3519)55-03-13 Москва (495)268-04-70 Мурманск (8152)59-64-93 Набережные Челны (8552)20-53-41 Нижний Новгород (831)429-08-12 Новокузнецк (3843)20-46-81 Новосибирск (383)227-86-73 Омск (3812)21-46-40 Орен (4862)44-53-42 Оренбург (3532)37-68-04 Пенза (8412)22-31-16

Россия (495)268-04-70

Пермь (342)205-81-47 Ростов-на-Дону (863)308-18-15 Рязань (4912)46-61-64 Самара (846)206-03-16 Санкт-Петербург (812)309-46-40 Саратов (845)249-38-78 Севастополь (8692)22-31-93 Симферополь (3652)67-13-56 Сочи (862)225-72-31 Счароль (8652)20-65-13

Казахстан (772)734-952-31

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