Audio Signals

No	Name	LCD Display	Sound	Control
1	Power on	All symbols	Beep for 2 second	Press for 1 second
		software version		
		start measure		
2	Pulse search	The icon ♥ flickers	X	X
3	Max./ Min SpO2 and Pulse rate warning	High or Low and yellow backlight flickers	Beep-beep sounded repeatedly	Default
			Mute for temporary, will beep-beep sounded after two minutes.	mode
			Mute before power off	mode
4	Probe failure alert	shows on the screen and yellow back light flicker	Beep-beep sounded repeatedly	X
5	Low battery alert	shows on the screen and yellow backlight flickers.	Beep-beep-beep sounded repeatedly for 1 minute and power off/	x
6	Automatic Off	X	Beep-beep sounded and then power off	After pulse is undetectable for around 1 minutes.
7	Unable measure	Blood saturation & pulse rate appears (- -) and yellow backlight flickers.	Beep- beep sounded repeatedly.	X
8	Data Updated Period	Less than 2 seconds.	X	X
9	Alert Condition Delay	Less than 8 seconds for SpO2. Less than 16 seconds for pulse rate.	X	X
10	Alert Signal Delay	Less than 1 second for SpO2 and pulse rate	X	X

Specification

SpO2

Measuring range	35% – 100% (the resolution is 1%)
Accuracy	70% – 100%: ±2 %; 35% – 69%: unspecified

Pulse Rate

Measuring range	30 – 250 bpm (the resolution is 1 bpm)
Accuracy	30 – 250 ± 3 digits

Probe Type

Probe model	Rossmax PA100, PB100, PC100, PD100, PF100
Extension cord	Rossmax PE100
Optical Sensor	The wavelength of red LED is 660 nm and Infrared LED is 905/880 nm with maximum optical output power of 4 mW/sr.

Electrical Specification

Battery	AA * 4 (Alkaline)
Battery Life	Continually for 15 hours with 4 alkaline batteries

Environmental conditions

Operation Condition	Temperature: 5°C – 40°C (41°F – 104°F), Relative Humidity:15% – 95%(non condensing), Atmospheric pressure: 700hPa ~ 1060hPa
Storage / Transport Condition	Temperature: -25°C – 70°C (-13°F – 158°F), Relative Humidity:15% – 90%(non condensing), Atmospheric pressure: 700hPa ~ 1060hPa Note: The condition of -25°C or 70°C back to use should stand for 3 hours at room temperature.
Dimension	Size: 14.5(L) x 7.25(W) x 2.25cm(H)
Weight	About 150g (without the batteries)
Standard	IEC/EN60601-1, IEC/EN60601-1-2, IEC/EN60601-1-11, ISO80601-2-61

Symbol Descriptors

	Manufacturer
SN	Serial number

EC REP	EU representative
	Type BF (Body Floating)
IP Classification	IP22: Protected against foreign objects and moisture
CE	CE Mark
	Warning: the symbol on this product means that it's an electronic product and following the European directive 2012/19/EU the electronic products have to be dispose on your local recycling centre for safe treatment.

Troubleshooting

Symptoms	Check points	Corrections
SpO2 or Pulse rate cannot displayed	The icon "- -" shows on the screen	Place the finger properly and try again
	This icon shows on the screen means probe dysfunction	Be sure"Rossmax" probe is connected to the device correctly.
	Applied finger improperly	Place the finger properly and try again
SpO2 or Pulse rate are not displayed stably	Finger is shaking or body is moving	Keep body steady
	Applied finger improperly	Place the finger properly and try again
No display when the bottom is pressed	Batteries run down	Replace with new batteries
	Batteries inserted incorrectly	Re-insert batteries
The display disappears suddenly	The device will auto power off when it gets no signal	Normal
	Low battery	Replace with new batteries

⚠ Note: If the unit does not work, return it to your dealer. Under no circumstance should you disassemble and repair the unit by yourself.

Warning

• This device is not intended for use by people (including children) with restricted physical, sensory or mental skills or a lack of experience and/or a lack of knowledge, unless they are supervised by a per- son who has responsibility for their safety or they receive instructions from this person on how to use the device. Children should be supervised around the device to ensure they do not play with it.
• This device only for spot-checking, but not medical result evaluation.
• This device is designed to determine the percentage of arterial oxygen saturation of functional hemoglobin. Factors that may degrade pulse oximeter performance or affect the accuracy of the measurement include the following:
 - Do not apply the pulse oximeter on the same arm as a blood pressure cuff, arterial catheter or infusion line (s).
 - Excessive light, such as sunlight or direct home lighting.
 - Not steady at the site of application. (e.g. term-bling)
 - Moisture in the device
 - Improperly applied device
 - Finger is too large or too small to fit into the device.
 - Poor pulse quality
 - Venous pulsations
 - Anemia or low hemoglobin concentrations
 - Cardio green and other intravascular dyes
 - Carboxyhemoglobin
 - Methemoglobin
 - Dysfunctional hemoglobin
 - Artificial nail or fingernail polish
 - On fingers with anatomical changes, oedemas, scars or burns.
 - The conditional of probe. Use only the Rossmax approved pulse oximeter sensor, cable and accessories. These parts are not reprocessed. Use of other sensors, cable and accessories can result in inaccurate readings.
• Using the device for long periods may cause pain for people with circulatory disorders. Reposition the device (probe) at least once every 4 hours to allow the patient's skin to breath and to check patient's condition regularly.
• Do not use the device near flammable or explosive gas mixtures.
• Do not use the device during an MRI or CT scan, be used no closer than 30 cm (12 inches) to any part of the [ME EQUIPMENT or ME SYSTEM], including cables specified by the manufacturer.
• The device will be affected by electromagnetic interference during operation.
• A warning that other cables and accessories may negatively affect EMC performance.
• The device may not work when circulation is reduced. Warm or rub the finger, or re-position the device.
• This device is a precision electronic instrument and must be repaired by qualified technical professionals. Field repair of the device is not possible. Do not attempt to open the case or repair the electronics. Opening the case may damage the device and void the warranty.
• Do not overextend the device's spring.
• A functional tester cannot be used to access the accuracy of a pulse oximeter monitor.
• Do not self-diagonse or self-medicate on the basis of the measurements without consulting your doctor. In particular, do not start taking any new medication or change the type and/or dosage of any existing medication without prior approval.

• Do not look directly inside the housing during the measurement. The red light and the invisible infra-red light in the probe are harmful to your eyes.
• Please be aware that user with susceptible skin.
• As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.
• A warning regarding stacking and location close to other equipment.
• Do not reuse or disinfect disposable SpO2 probe. (only for PD100).
• A warning to the effect that the responsible organization or operator needs to verify the compatibility of the monitor, probe, and cable before use, otherwise patient injury can result.
• The oximeter is calibrated in the factory before sale, there is no need to calibrate it during its life cycle.

Cleaning

1. Please clean the surface of the device before using. Wipe the device with medical alcohol (70% isopropyl alcohol) first, and then let it dry in air or clean it by dry clean fabric.
2. Using the medical alcohol to disinfect the product after use, prevent from cross infection for next time use.
3. The best storage environment of the device is -25°C ~ 70°C ambient temperature and not higher than 90% relative humidity.
Note: 1. Do not sterilize, autoclave or immerse this device in liquid. Do not pour or spray any liquids onto the device.
2. Do not use caustic or abrasive cleaning agents, or any cleaning agent containing ammonium chloride or isopropyl alcohol.

Maintenance

Recommends user to return this device to the manufacturer perform the following checks every 24 months.
• Inspect the equipment for mechanical and functional damage or deterioration.
• Ensure all user interface keys and accessories function normally.
Note: Manufacture use Index 2 SpO2 simulator to verify operation of the pulse oximeter equipment.

EMC guidance and manufacturer's declaration

Recommended separation distances between portable and mobile RF communications equipment and the ME equipment			
The Handheld Pulse Oximeter is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Handheld Pulse Oximeter can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Handheld Pulse Oximeter as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter / W	Separation distance according to frequency of transmitter / m		
	150 kHz to 80 MHz , d=[3.5/V1] √P	80 MHz to 800 MHz , d=[3.5/E1] √P	800 MHz to 2,5 GHz , d=[7/E1] √P
0.01	0.1	0.1	0.2
0.1	0.4	0.4	0.7
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	11.7	11.7	23.3

Declaration — electromagnetic emissions		
The Handheld Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the Handheld Pulse Oximeter should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Handheld Pulse Oximeter uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Handheld Pulse Oximeter is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power Harmonic emissions supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	N/A	
Voltage fluctuations/Flicker emissions IEC 61000-3-3	N/A	

Declaration — electromagnetic emissions and immunity — for EQUIPMENT and SYSTEMS that are use in the professional healthcare facility environment or in the home healthcare environment			
The Handheld Pulse Oximeter declaration — electromagnetic immunity			
The Handheld Pulse Oximeter system is intended for use in the electromagnetic environment specified below. The customer or the user of the Handheld Pulse Oximeter system should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms ; 6 Vrms ; 150 kHz to 80 MHz	N/A	Portable and mobile RF communications equipment should be used no closer to any part of the EQUIPMENT or SYSTEM including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Interference may occur in the vicinity of equipment marked with the following symbol.
Radiated RF IEC 61000-4-3	3 V/m ; 10V/m ; 80 MHz – 2.7 GHz l 80%	3 V/m ; 10V/m ; 80 MHz – 2.7 GHz ; 80%	
Proximity fields from RF wireless Communications equipment IEC 61000-4-3	27 V/m	385 MHz	27 V/m	385 MHz	
	28 V/m	450 MHz	28 V/m	450 MHz	
	9 V/m	710 MHz	9 V/m	710 MHz	
		745 MHz		745 MHz	
		780 MHz		780 MHz	
	28 V/m	810 MHz	28 V/m	810 MHz	
		870 MHz		870 MHz	
		930 MHz		930 MHz	
	28 V/m	1720 MHz	28 V/m	1720 MHz	
		1845 MHz		1845 MHz	
		1970 MHz		1970 MHz	
	28 V/m	2450 MHz	28 V/m	2450 MHz	
	9 V/m	5240 MHz	9 V/m	5240 MHz	
		5500 MHz		5500 MHz	
		5785 MHz		5785 MHz	

Declaration — electromagnetic immunity			
The Handheld Pulse Oximeter system is intended for use in the electromagnetic environment specified below. The customer or the user of the Handheld Pulse Oximeter system should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5 kV ±1 kV differential mode ±2 kV common mode	N/A	Mains power quality should be that of a typical commercial or hospital environment.

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % U₂; 0, 5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U₂; 1 cycle and 70 % U₂; 25/30 cycle Single phase: at 0°	N/A	Mains power quality should be that of a typical commercial or hospital environment. If the user of the EQUIPMENT or SYSTEM requires continued operation during power mains interruptions, it is recommended that the EQUIPMENT or SYSTEM be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

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rossmax
Model: **SA210**

rossmax
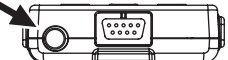
EN Handheld Pulse Oximeter

www.rossmax.com

Introduction

Rossmax Handheld Pulse Oximeter is used to measure oxygen saturation in blood (SpO2) and pulse rate, also to issue warnings immediately. It is a non-invasive device intended for spot-check of adults, child, and infants with corresponding probe applied at home, hospital and clinics. The probe contains a dual light source and a photodetector.

Attention: Consult the accompanying documents. Please read this manual carefully before use. Please be sure to keep this manual.

Name/ Functions of each part

No.	Item	Purpose
1	Pulse strength	
2	Probe icon	
3	LCD backlight button	For light on/ off
4	Sound button	For Heartbeat sound loud volume lower volume silence
5	Time	Shows the time
6	SpO2 **%SpO₂** icon	**High** High SpO2 **Low** Low SpO2
7	Pulse Rate **Pulse min.**	**High** High Pulse Rate **Low** Low Pulse Rate
8	UP/DOWN button	For adjust/view all setting/ memory **M** memory icon
9	Set button	For view/ adjust default setting
10	Alert button	Alert off / Alert pause
11	Power button	Power on/ off
12	Battery compartment	For install or replace batteries Full batteries out of batteries
13		it's for data transmission.

Battery installation

1. Use thumb to slide battery cover out.
2. Insert or replace 4 "AA" batteries according to the (+/-) polarity.
Caution: Need to replace when the batteries icon " " is blinking on display/ while pressed the function button and nothing appears on display.
Caution: Batteries may leak or explode if used or disposed of improperly. Remove batteries if the device will be stored for long time. Do not use different types or brand of batteries at the same time.
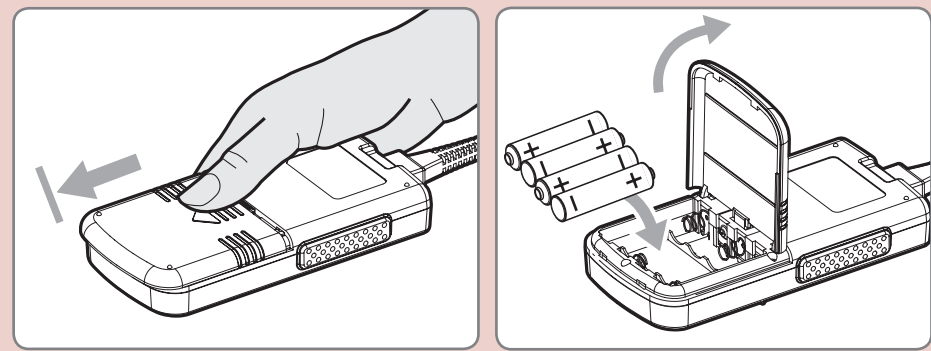
Probe connection

Rossmax PA100/ PC100 or compatible probe is used. (Please install carefully.)
Caution: It may damage the efficiency of the device if not apply with a Rossmax compatible probe.
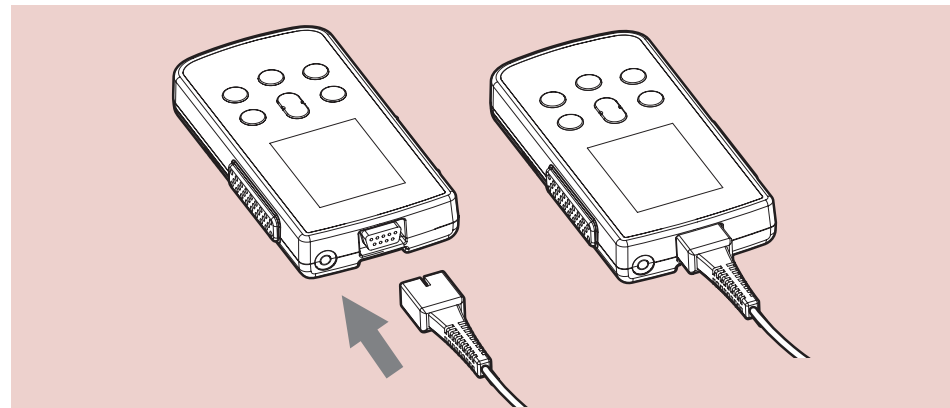
How to measure

1. Press the Power On button for 1 second, when the device activates, the beep sound will last for 2 second.
Note: After the device activates, the software version will pop up directly. For first time activates, it will directly jump to time setting. (Please refer to setting instruction.)
2. Information of software version appears; insert one finger to probe, nail side up, for self-test.
Notes: The device will turn itself off automatically after 1 minute idling with two beep sounded.
3. The pulse strength shows " ", pulse oximeter begins its measurement.
Notes: The heartbeat is sounded though the buzzer. If need to become silence mode, press the sound button and the LCD screen will have the sound icon shown. If need the heartbeat sound, press the sound button to exit.
4. Your SpO2 and pulse rate values will appears on the screen after few seconds.
Notes: 1. Don't remove your finger until the measurement is completed.
2. Any other problems or unrecognized icon, please refer to trouble shooting.

Preview Default Setting

1. Press the SET button 1 second to preview default setting value.
2. Press to exit preview default mode or wait for 3 second for automatically.
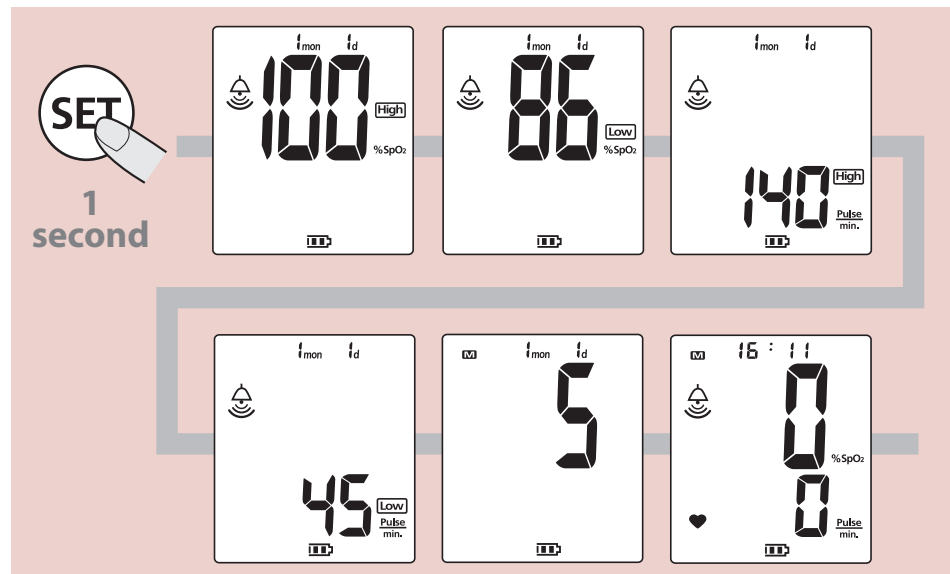

How to Change Default Setting
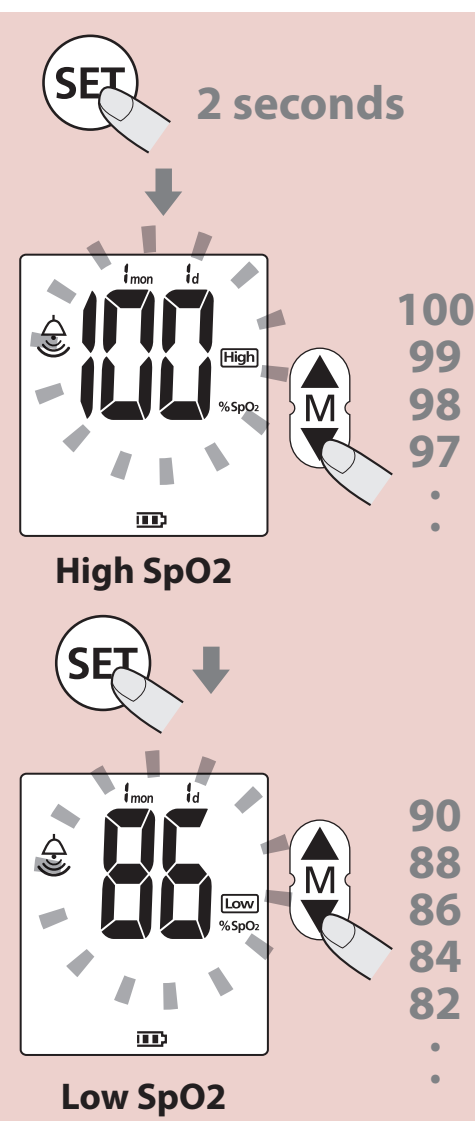
Press the SET button 2 second to enter the set up mode and change default. For jump to next setting, press SET after finishing. To exit, press or wait for 10 second.

SPO2 mode
• To setup Max SpO2 rate, press SET to enter, and it shows **High** as picture and press / button for adjustment. To set up Min SpO2 rate, press SET , and it shows **Low** as picture and same as max setting.
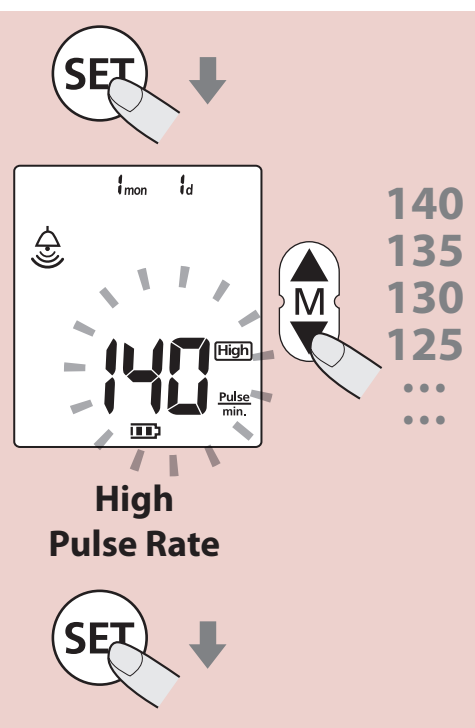
Pulse Rate mode
• To setup Max Pulse rate, press SET to enter, and it shows **High** as picture and press / button for adjustment. To set up Min Pulse rate, press SET , and it shows **Low** as picture and same as max setting.
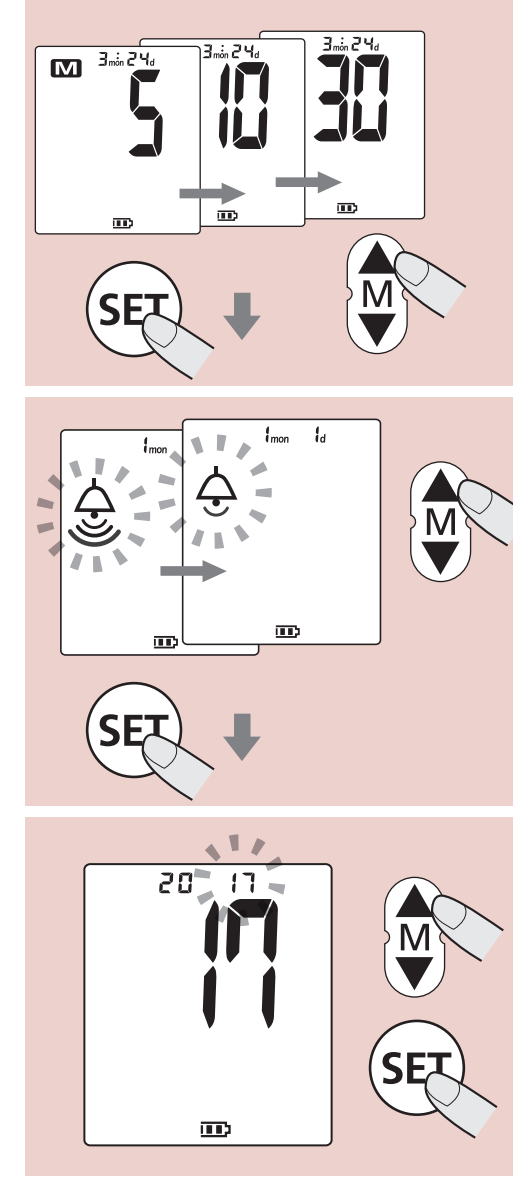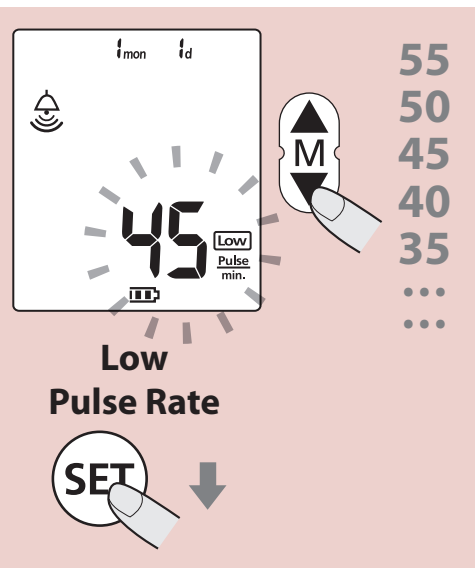
Memory interval mode
1. Optional of SA210: 5 / 10 / 30 / 60 minutes.
2. While the memory mode, the **M** memory interval mode appears on the screen. To change the default, press / to change (5)-(10)-(30)-(60) or (60)-(30)-(10)-(5) minutes.


Sound volume control
• For the control of sound volume, for loud volume, for lower volume. To change the sounds volume, Press / to change --> .

Time Setup
• To set up the time, it starts from year as picture, and press / to adjust. Following the same frequency for month, date, hour to minutes.

Warning: Press or wait for 10 seconds to exit, the setup value will be reserved. Please check the setting value before use.

Memories reading and delete

Enter the memory mode with the or to read the SpO2 and pulse rate in memory mode.
Note: When entering the memory reading mode, the **M** will appear on the screen.
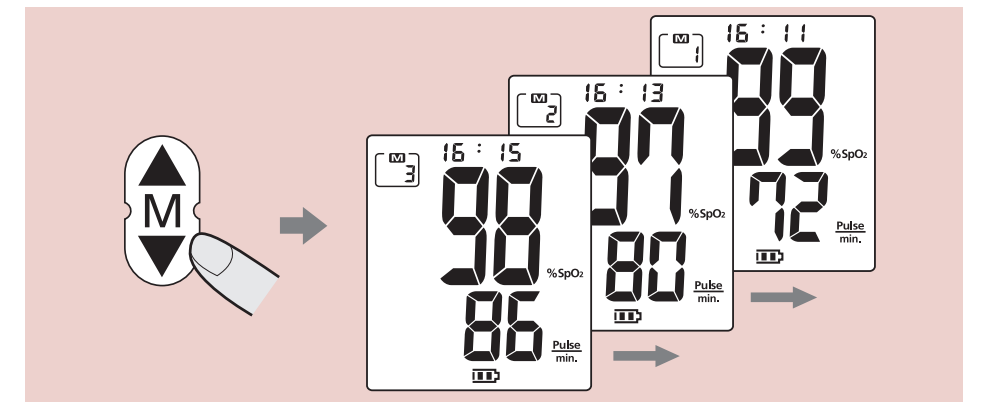
Press SET for two second during the memory reading mode, it will enter the memory delete mode. The screen show and means not to delete any data, while the screen with and , it means to delete data.
Caution: The deleted data could not be restored.

2 seconds to clean data