bluepoint MEDICAL



SMARTsat® Technology

Handheld Pulse Oximeter OxyTrue ® A

User Manual

OxyTrue®A with SMARTsat® technology - **User Manual**

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CE **0482**

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Table of Contents

1 Intended Use - Warnings 5
1.1 Contraindications 7
2 Controls – Symbols – Display Modes 8
2.1 Controls and User Interfaces 8
2.2 Display Modes and Displayed Data 9
2.3 Symbols and Indicators 10
2.4 Audible Indicators 11
2.4.1 Pulse Tone (Beep) 11
2.4.2 Alarm Signals and Priorities 11
2.4.3 Battery Alarm 11
2.4.4 Audible Alarm Volume 11
3 Preparation for Use 12
3.1 Battery Installation 12
3.2 Connecting the SpO_2 Sensor 12
3.3 Switching on the Device 13
3.4 Commencing Monitoring 13
3.5 Switching off the Device 13
4 Screen Contents – Menu Structure 13
4.1 Main Menu 13
4.1.1 Submenu: Alarm Settings 14
4.1.2 Submenu: Data Management 15
4.1.3 Submenu: Setup 16
4.1.4 Default Start Settings 18
4.2 Other 18
4.2.1 Volume Control Shortcut 18
4.2.2 Power-Save Mode 18
5 Troubleshooting guide 18
5.1 Adverse effects on SpO_2 measurement accuracy 18
5.2 Error Message – Cause - Corrective Action 19
5.3 Problem – Cause - Corrective Action 19
5.4 Problems with EMI (Electromagnetic Interference) 20
6 Maintenance – Cleaning – Testing 20
7 Symbol Definitions 22
8 Technical Specifications 23
9 Clinical studies 25
10 Reporting of serious incidents 26
11 Scope of delivery and order numbers 26

1 Intended Use - Warnings

The OxyTrue® A handheld pulse oximeter with silicone cover is intended for continuous or spot check monitoring of functional arterial oxygen saturation (SpO_2) and pulse rate of adult, paediatric, infant and neonatal patients.

To be used by trained healthcare professionals only. For use in the home care environment the user may use the device after instruction by, or under supervision of, a trained healthcare professional.

Depending on the SpO_2 sensor connected, the OxyTrue® A may be used in hospital, hospital type facilities, transport, emergency care and mobile environments; as well as in the home care environment (see section 11 for more detail on sensors and field of application).

Warning:
Warnings are identified by the WARNING symbol shown above. Warnings alert the user to potential serious outcomes, such as death, injury, or adverse events to the patient or user.

Warning:
Do not make any clinical judgments based solely on the OxyTrue® A. The monitor is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms. The interpretation of the measurement values should be done only by trained healthcare professionals.

Warning:
Explosion hazard, do not use OxyTrue® A in the presence of flammable anaesthetic mixtures with air, oxygen or nitrous oxide.

Warning:
Routinely monitor the patient to ensure that the OxyTrue® A is functioning and the sensor is correctly placed.

Warning:
Pulse oximetry measurements and pulse signals can be affected by certain environmental conditions e.g. electromagnetic disturbances, sensor application errors, and certain patient conditions. See the appropriate sections of chapter 5 for specific safety information. Equipment performance lost or degraded due to electromagnetic disturbances is described in detail in chapter 5.4.

Warning:
Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Warning:
Portable radio frequency communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30cm (12 inches) to any part of the OxyTrue® A, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Warning:

Certain physiological conditions, medical procedures, and external agents may interfere with the monitor's ability to detect and display accurate measurements. (Chapter 5.1 provides information on possible interferences)

Warning:
For the measurement, the SpO_2 monitor uses red and infrared light with specific fixed wavelengths. Consider that these wavelengths might influence diagnostic parameters of other optical applications. The utilized wavelengths are listed in the instructions for use of the specific sensor.

Warning:
If you are uncertain about the accuracy of any measurement, check the patient's vital signs by alternative means, then ensure that the OxyTrue ® A is functioning correctly.

Warning:
The use of accessories, sensors, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emission or decreased electromagnetic immunity of this equipment and result in improper operation.

Warning:
In high ambient light conditions it is required to shield the sensor application site with opaque material. Excessive ambient light may result in inaccurate measurements.

Warning:
Do not silence/ pause the audible alarm function, if patient safety could be compromised.

Warning:
The OxyTrue® A is a prescription device to be operated only by trained personnel. The monitor is for attended monitoring only.

Warning:
Do not adjust, repair, open, disassemble, or modify the OxyTrue® A. Damage to the device may result in degraded performance and/or patient injury.

Warning:
As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement, strangulation, or injury to the patient.

Warning:
The OxyTrue® A is not defibrillator proof. Remove the sensor from the patient throughout defibrillation or whilst an electrosurgical unit is in use, so as to avoid shock to the caregiver or patient.

Warning:
Disconnect the OxyTrue® A and sensor from the patient throughout computed tomography. During the active irradiation period, the reading might be inaccurate.

Warning:

Disconnect the OxyTrue® A and sensor from the patient throughout magnetic resonance imaging (MRI) scanning. Induced electrical current could potentially cause burns.

Warning:
Pulse oximeter equipment measurements are statistically distributed. Only about two-thirds of measurements can be expected to fall within ± A_{rms} of the measured values by a CO-Oximeter. To verify the function of pulse oximeter probes a functional tester like Index II or equivalent can be used.

Warning:
A functional tester (like Index II or equivalent) may not be used to validate SpO_2 accuracy. A functional tester can be used to verify the function of pulse oximeter probes.

Warning:
Do not change the batteries or clean the device or sensors whilst in use or connected to a patient.

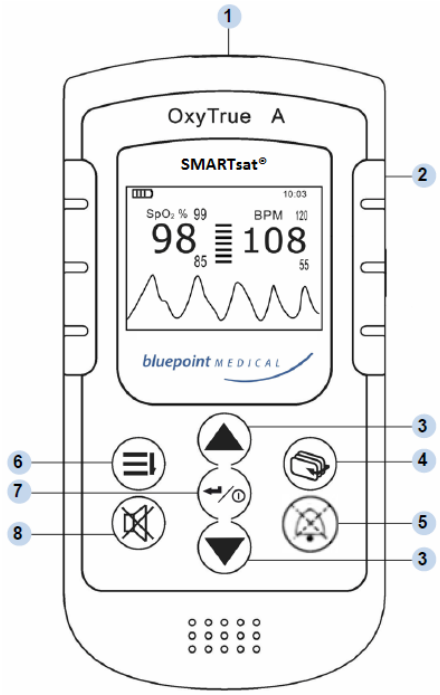
Warning:
Risk due to barely audible alarms.
The user must remain within the hearing range of the acoustic alarm signal. This permits quick recognition and handling of the alarm.

1.1 Contraindications

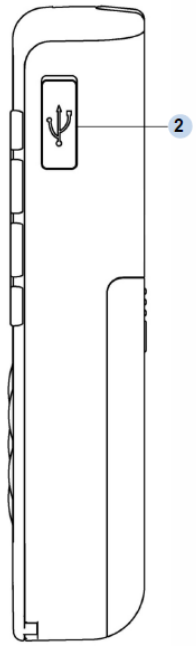
There are no known contraindications to the use of the device.

2 Controls – Symbols – Display Modes

2.1 Controls and User Interfaces



Front view



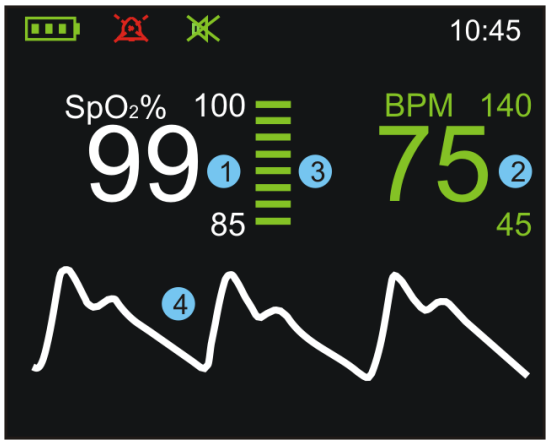
Side view

No.	Symbol	Features/Button	Function
1		Sensor Port	Port for SpO_2 sensor
2		USB	USB 2.0 interface
3		Arrow Buttons (up/down)	Multifunction buttons used for 1. Scrolling through menu items. 2. Increasing/decreasing parameter values. 3. From monitoring display modes: can be used as shortcuts to volume/display power save mode
4		Display Mode	Toggles between various display modes
5		Audible alarm pause	Audible alarm On/Off. The audible alarm can be paused for a maximum period of two minutes. Optical alarm remains activated.
6		Menu	Menu selection
7		ENTER button, On/Off	Confirms selection To turn on the device: press and hold power button briefly. To turn off the device: press and hold power button for approx. 3 seconds.
8		Pulse Tone	Turns pulse tone and switch on tone On/Off

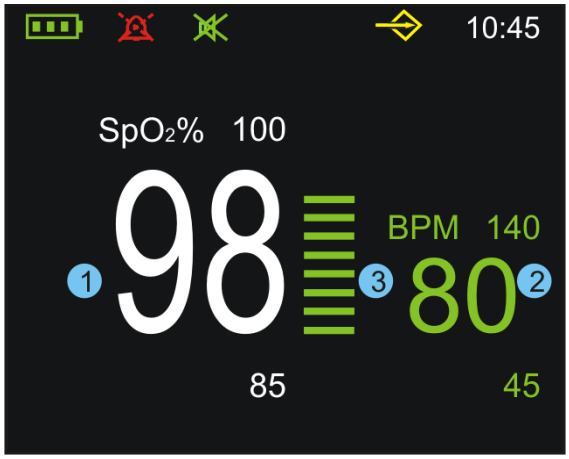
2.2 Display Modes and Displayed Data

Toggling Between Display Modes

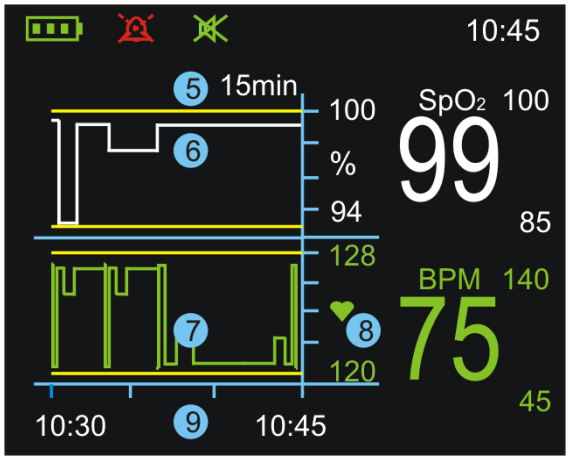
The operator can toggle between various display modes by pressing  button.



Display 1



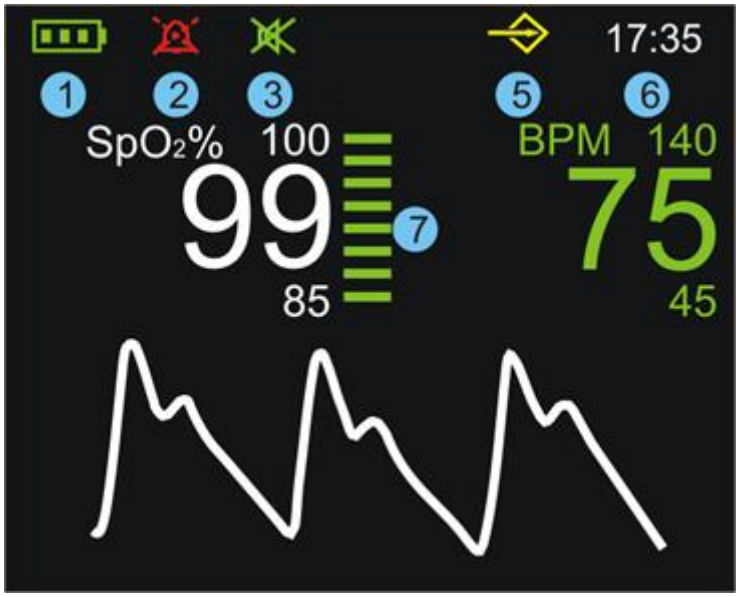
Display 2



Display 3 to 5: Trend
15, 30 and 240-minute trend, parallel to ongoing measurement

1. The SpO_2 value shows the blood oxygen saturation level expressed as a percentage. The small numbers shown immediately above and below the measured value on the right side indicate the upper and lower alarm limits.
2. Pulse rate in beats per minute. The small numbers immediately above and below the measured value on the right side indicate the upper and lower alarm limits.
3. Normalized bar graph for pulse amplitude. Indicates the dynamic pulse amplitude and rate. The colour of the bar graph is an indicator for signal quality (refer to 2.3)
4. Normalized pulse waveform (plethysmogram). The reading is automatically adjusted to the pulse strength; therefore, a waveform of good amplitude should be visible at all times.
5. Time-interval of trends
6. Trend waveform for SpO_2 with continuous upper and lower alarm limits in yellow
7. Trend waveform for pulse rate with continuous upper and lower alarm limits in yellow
8. Pulse indicator
9. Start and end times

2.3 Symbols and Indicators



No.	Symbols/Indicators	Definition
1		Battery level indicator. The three segments represent the battery charge level. The symbol flashes red when the battery capacity is low.
2		Audible alarm pause indicator. The audible alarm can be paused for a maximum period of two minutes. Optical alarm remains activated.
3		Pulse tone off. Start tone off at next switch on.
5		Memory symbol. The device's memory for measurement data is full. No new data can be stored. Old data can be erased or overwritten.
6	17:35	Current time, displayed in 12h or 24h format.
7		Normalized pulse amplitude bar graph representing the heart rate. The colour of the bar graph is an indicator for signal quality. - Green: good signal quality, very accurate measurement. - Yellow: average signal quality, measurement may be inaccurate. - Red: poor signal quality, value has not been updated for a maximal duration of 28s. After 28s the "Bad signal quality" high priority alarm is generated (refer to section 2.4.2)

2.4 Audible Indicators

2.4.1 Pulse Tone (Beep)

During monitoring a pulse beep is audible for every detected pulse. The pitch of the pulse tone is dependent on the measured SpO_2 value. A higher pitch is indicative of higher oxygen saturation. The pulse tone volume can be adjusted under the menu item “Volume”. The pulse tone can be also silenced using the button. Pressing the button a second time will reactivate the pulse tone.

2.4.2 Alarm Signals and Priorities

The OxyTrue® A differentiates between alarms of high, medium and low priority. An alarm of higher priority will always override alarms of respective lower priority. Vice versa, an alarm of high priority cannot be silenced by a following alarm of lower priority.

Priority	Audio Signal Sequence (repeatedly)	Alarm Cause
High	BEEP_BEEP_BEEP___BEEP_BEEP 1 seconds pause BEEP_BEEP_BEEP___ BEEP_BEEP 3 seconds pause	- Bad signal quality (no pulse signal found) - SpO_2 below 60 % - Battery low (last two minutes before switch off)
Medium	BEEP_BEEP_BEEP 5 seconds pause	- Violation of the SpO_2 or pulse alarm limits - Battery low (see 2.4.3)
Low	BEEP_BEEP 16 seconds pause	- Probe off - No sensor - Ambient light - Sensor fault - Device defective - Data memory full

2.4.3 Battery Alarm

When the device is switched on and a critically low battery level is detected, it will not start operating and a “Low battery” message will be displayed.

If the batteries reach a critically low level during monitoring, the battery indicator will start to flash yellow and an audible warning signal of medium priority will be generated. After one minute, the battery indicator turns red and an audible warning signal of high priority is generated. This warning signal will remain active for two minutes, at which point the device will automatically switch off.

2.4.4 Audible Alarm Volume

The alarm volume is not adjustable; however, it is possible to pause the audible alarm for a maximum period of two minutes using the audible alarm pause  button. The audible alarm is silent during alarm pause, the optical alarm remains activated.

3 Preparation for Use

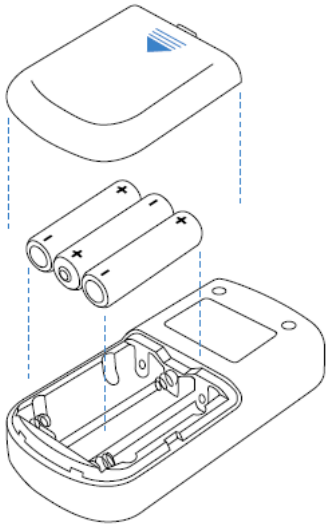
Caution:
The use of rechargeable instead of alkaline batteries may cause a shorter operating time of the device.

Caution:
Ensure that the speaker is clear of any obstruction and that the speaker holes are not covered. Failure to do so could result in an inaudible alarm tone.

Caution:
Remove the batteries if the device is to be stored, transported or not used for a long period of time.

3.1 Battery Installation

- Slide down the cover of the battery compartment on the rear panel of the device.
- Insert three batteries (1.5 Volt, AA), ensuring the correct orientation in accordance with the polarity markings.
- Slide the battery compartment cover back into initial position to close.



Warning:
Batteries may leak or explode if used or disposed of improperly. Please dispose of in accordance with your local ordinances and regulations.

Warning:
Explosion hazard, do not use AA rechargeable Lithium-ion batteries.
Use only Alkaline (1.5 Volt, Type AA LR6) or rechargeable NiMh AA (1.2 Volt, Type AA HR6, 1200 mAh)

3.2 Connecting the SpO_2 Sensor

Insert the sensor cable into the sensor port located on the top edge of the device, ensuring correct orientation of the sensor connector and the port.

Visual check
Before beginning operation, ensure that the device and sensor are not damaged.

Warning:
Do not use sensors or cables that appear to be damaged. Do not use a sensor when optical components are exposed. Do not use a device that appears damaged. Replace monitor immediately in cases of visible damages.

Warning:
Ensure that the speaker is clear of any obstruction and that the speaker holes are not covered. Failure to do so could result in an inaudible alarm tone.

3.3 Switching on the Device

Press and hold the on/off button ⏎/⏻ briefly until an opening 'welcome screen' appears. The device performs a self-test. After the power on self-test is successfully completed the device is ready for monitoring. A start tone will sound after power on, provided the pulse tone has not been switched of before.

3.4 Commencing Monitoring

Once the sensor is connected and correctly positioned on the patient, monitoring begins automatically. Refer to the sensor 'Instructions For Use' to determine if an appropriate sensor is being used, and if it is applied correctly. Ensure that the monitor is providing a reading and that the pulse tone can be switched on and off to verify proper operation.

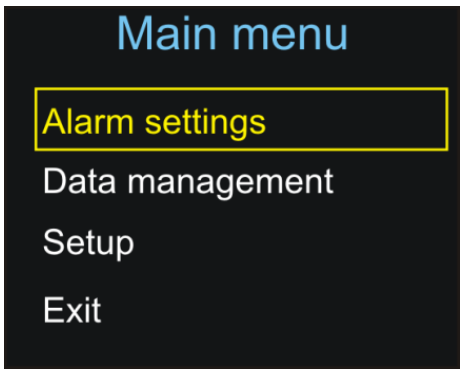


3.5 Switching off the Device

Press and hold the on/off button ⏎/⏻ for approx. three seconds to switch off the device. The OxyTrue® A device will also power off automatically after two minutes when not in patient monitoring use, provided no alarm condition is present.

4 Screen Contents – Menu Structure

4.1 Main Menu



All important and frequently used settings are accessible through the main menu, which can be opened by pressing the button ☰.

Navigating the Menu

Use the buttons ▲▼ to scroll through menu items. The currently selected menu item is highlighted by a coloured frame. Press the ⏎/⏻ button to confirm your selection.

Entering Data
In some submenus it is possible to adjust a certain parameter. In this case the parameter can be increased or decreased using the arrow buttons. The value will increase or decrease more quickly when the respective button is held down. Press the ⏎/⏻ button to confirm the new value.

Exiting Menu and Returning to Display
Press the display button at any time, in any menu to return immediately to the monitoring display.
If no button has been pressed for more than 30 seconds, the device will automatically return to the monitoring screen.

4.1.1 Submenu: Alarm Settings

4.1.1.1 General Information

The alarm limits for SpO_2 and pulse can be set individually. The current alarm limits are shown as small numbers above and below the measured values on the right side. If a measured value either exceeds the upper limit or falls below the lower limit, visual and audible alarms will be triggered immediately.

Visual alarm
When an alarm has been triggered the critical value will turn yellow together with the violated alarm limit and the critical value flashes. An alarm will also be triggered if the sensor is removed from the application site, if the signal remains poor over a long period of time or if the sensor is disconnected from the device, provided that valid measurement data has been recorded beforehand.

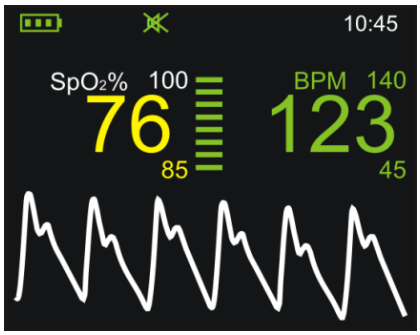
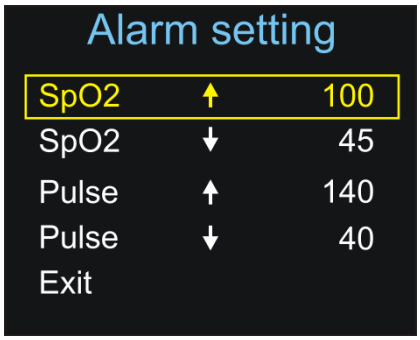


Figure: Visual alarm which was triggered by a violation of the lower SpO_2 alarm limit.

Caution:
Do not set alarm limits to extreme values that can render the alarm system useless.

4.1.1.2 Adjust Settings



Selection with ▲▼ buttons Selection/confirmation with button ⏎/⏻

Alarm Settings
Setting of the upper and lower alarm limits of the SpO_2 and pulse rate. “Off” deactivates the alarm limit. After restarting the device, the default alarm limits will be reset.

4.1.2 Submenu: Data Management

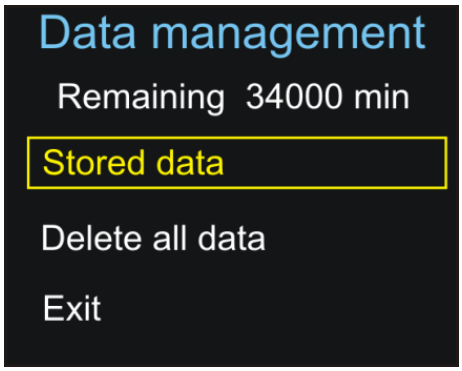
4.1.2.1 General Information

Recording Data

The OxyTrue® A device can store more than 560 hours of monitoring data. Each individual data set, regardless of its actual length, uses at least 15 minutes of memory space. A new data set is generated automatically each time the device is turned on. When the device is turned off, all of the measurements that were taken are automatically stored in the devices memory, together with the respective alarm limits, date and time. The device warns the user when the memory is almost full by displaying the symbol. A maximum of 50 data sets can be stored in the memory. After this maximum has been reached the oldest data set is overwritten upon confirmation by the user. Stored data sets can be retrieved and erased under the menu item "Data management". The data sets can be stored and processed with the user-friendly OxyTrue® A PC-Software.

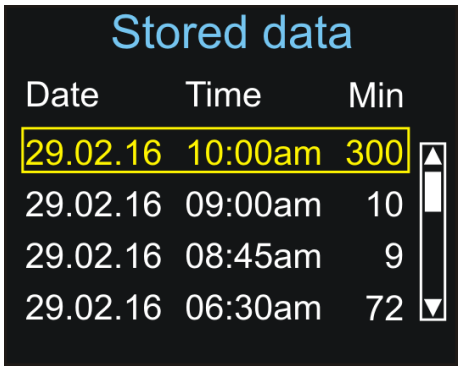
Stored data will not be erased when the batteries are removed temporarily.

4.1.2.2 Data



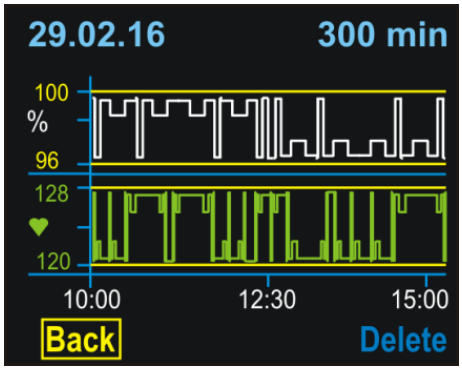
Used Data Management menu to

- view remaining recording time in minutes
- access list of stored data sets
- delete all data in memory



Stored Data menu

List of all stored data sets. Retrieve selected data set by pressing the button.

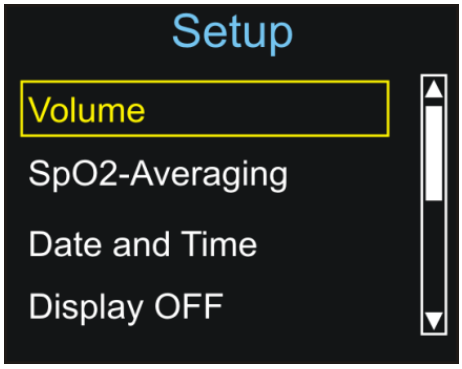


Select "Back" to return to the list of stored data or "Delete" to erase the data set shown.

The stored measurements are displayed in graphic form together with the date, start time and duration of the recording. The SpO_2 reading is shown in white, and the pulse reading in green. The yellow lines represent the respective alarm limits.

4.1.3 Submenu: Setup

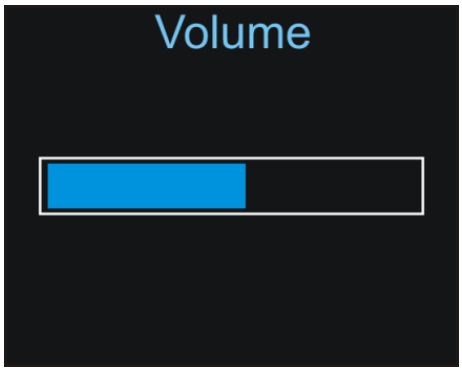
4.1.3.1 General Information



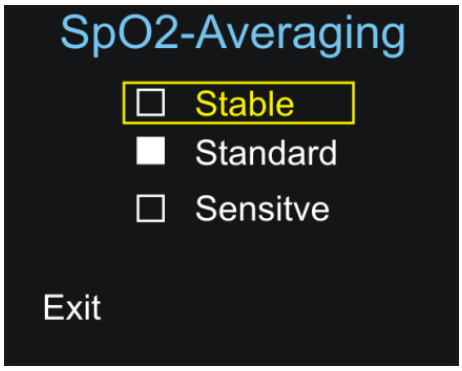


This submenu offers access to various device settings; confirm selection by pressing the ↵/ⓘ button.

4.1.3.2 Adjusting Settings



Adjust the pulse tone volume using the ▲▼ buttons. Confirm new settings by pressing the ↵/ⓘ button.



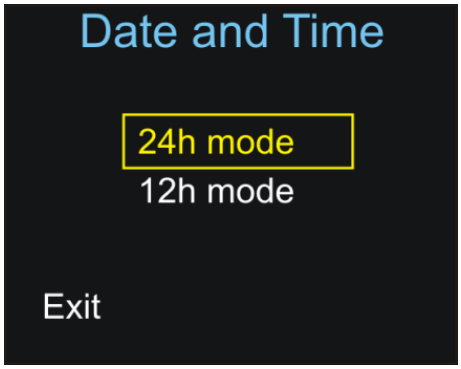
Stable: When this setting is selected any strong and sudden variations in data will not immediately affect the reading (data incorporated over time); minor irregularities have little or no effect on the displayed reading.

Standard: Averaging parameters used for this setting are between those of the stable and sensitive settings.

Sensitive: The reading is more sensitive to irregularities but reacts very quickly to any changes in measured parameters.

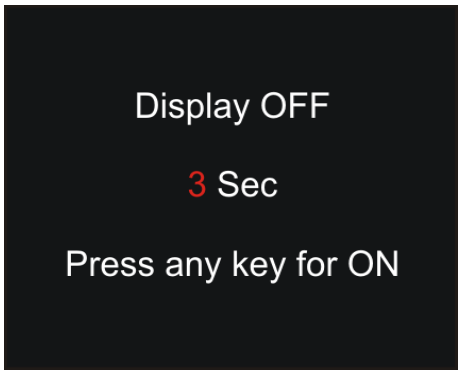
Effects of the SpO_2 mean settings on the response time of the measurement:

Response Time Mode	Motion performance	Average response time
Stable	Highly motion resistant	11 sec
Standard (default)	Motion resistant	8 sec
Sensitive	Reduced motion resistance	5 sec





First, select between 12h mode and 24h mode; then set date and time. Settings for date and time are not erased when the batteries are temporarily removed.

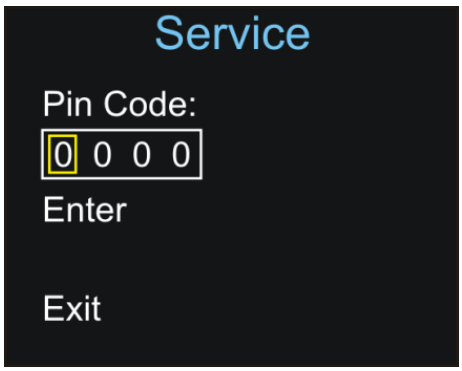


Select display off to enter the Power Save Mode through the menu (refer to 4.2.2).

Note: Switching off the display during long measurement episodes such as over-night monitoring can prolong the battery life considerably!



Depending on the firmware, up to ten different language options are available here for selection. All messages and menus will be displayed in the selected language.



Service:
The Service submenu is protected by a PIN code; only authorised service personnel can access this menu (only available in English).

4.1.4 Default Start Settings

Changed settings are in effect only as long as the monitor remains on. Once the monitor has been turned off, at the next start up, the default settings will be in effect. The start-up defaults can be changed in the PIN protected Service Menu. Only authorized service personnel have access.

The language and setting of *pulse tone off* are not reset during a restart of the device, the settings selected before will be stored.

4.2 Other

4.2.1 Volume Control Shortcut

If the ▲ button is pressed during any monitoring display mode the volume control screen will open. Adjust the volume using the ▲▼ buttons. Confirm new setting by pressing the ↵/⏻ button.

4.2.2 Power-Save Mode



The display can be turned off to save power and extend battery life. This can be accomplished by pressing the ▼ button once. A countdown will start, after which the display will be switched off. The device is now in economy power mode. The pressing of any button will reactivate the display. If an alarm is triggered, the display will be turned on automatically.

5 Troubleshooting guide

5.1 Adverse effects on SpO_2 measurement accuracy

Warning:
Physiological conditions, medical procedures, or external agents that may degrade pulse oximeter performance or affect the accuracy of the measurement include the following:

- Incorrect applications of the sensor
- Externally applied colouring agents such as nail polish or artificial nails
- Intravascular dyes
- Placement of the sensor on an extremity with blood flow restrictors (arterial catheters, blood pressure cuffs, infusing lines, etc.)
- Failure to shield the sensor site in high ambient light conditions
- Excessive patient activity
- Low perfusion
- Venous pulsations
- Anaemia or low haemoglobin concentrations
- Cardiac dysrhythmia like extrasystole or atrial / ventricular fibrillation

- Dysfunctional haemoglobin, e.g. caused by a carbon monoxide intoxication
- Electromagnetic interference
- Electrosurgical interference

5.2 Error Message – Cause - Corrective Action

“No sensor!” or **“Sensor disconnected!”**
The sensor is not connected properly to the device.
– Check sensor connection.

“Probe off!”
The sensor has been removed from the monitoring site.
– Check that the sensor is properly attached to the patient.

“Low battery!”, **battery symbol flashing red**
The batteries are almost completely discharged.
– Replace batteries immediately.

“Sensor fault!”
The connected sensor is either defective or not compatible with the device.
– Check sensor.

“Device defective!”
Fatal device error, e.g. resulting from improper handling, such as use with computer tomography.
– Contact authorised service personnel or your local sales representative.

“Too much ambient light!”
High ambient light sources near the sensor, e.g. surgical lights.
– Shield sensor more effectively from external light.

“Bad signal quality”
Poor-quality pulse signal, for example as a result of low perfusion.
– Move the sensor to a different site on the patient or provide more effective monitoring conditions.

5.3 Problem – Cause - Corrective Action

Problem: There is no response to the Power button.
Cause – Corrective Action: Ensure that the Power button is fully depressed. The batteries may be missing, discharged, or oriented incorrectly. Install new batteries.

Problem: No pulse signal found or the pulse signal cannot be found anymore
Cause – Corrective Action:

a) Check the patient. Check the sensor instructions for use to determine if an appropriate sensor is being used and if it is applied correctly. Check sensor and extension cable connections. Test the sensor on another subject. Try another sensor or extension cable.

b) **Perfusion may be too low** for the monitor to track the pulse. Check the patient. Change the sensor site. Try another sensor. Test the monitor on a subject with good perfusion.

c) **Interference due to patient** activity may be preventing the monitor from tracking the pulse. Keep the patient still, if possible. Verify that the sensor is securely applied and replace it if necessary. Change the sensor site.

d) **The sensor may be too tight**, there may be interference due to ambient light, or the sensor may be on an extremity with a blood pressure cuff, arterial catheter, or intravascular line. Reposition sensor, as necessary.

e) **Electromagnetic interference** may be preventing the monitor from tracking the pulse. Remove the source of interference.

Problem: No pulse tone
Cause – Corrective Action: Continue to listen for the pulse beep tone as the monitor is used. If it does not sound with each pulse it indicates one of the following: Pulse beep volume is off. – Switch volume on. Speaker/audio has malfunctioned - Signal is corrupted. OxyTrue® A has stopped functioning. – Contact authorised service personnel or your local sales representative.

5.4 Problems with EMI (Electromagnetic Interference)

This device has been tested and found to comply with the limits for medical devices according to DIN EN 60601-1-2 and ISO 80601-2-61. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

Due to the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in healthcare environments it is possible that high levels of such interference due to close proximity or strength of a source may result in disruption of performance of this device. Examples of noise sources in healthcare environments that could cause electromagnetic interference include:

- Electrosurgical units
- Cellular / Mobile phones
- Mobile two-way radios
- Electrical appliances
- High-definition televisions (HDTVs)

The pulse waveform can be obscured by electromagnetic interference. During such interference measurements may seem inappropriate or the monitor may not seem to operate correctly.
Disruption may be evidenced by erratic readings, cessation of operation or other incorrect functioning.
In case the SpO_2 or pulse rate accuracy is lost or degraded due to EM disturbances, the device will display the message „Bad Signal Quality“ and a high priority alarm will sound. It is also possible that due to EM disturbances, the device will falsely give low priority alarm and display the message “Probe off!“ or “Sensor fault!“.
If this occurs, the operating environment should be surveyed to determine the source of disruption and the following actions taken to eliminate the source:

- Turn equipment in the vicinity off and on to isolate the offending equipment.
- Reposition or relocate the interfering equipment.
- Increase the distance between the interfering equipment and this equipment.

The monitor generates uses, and radiates radio frequency energy. Failure to follow these instructions may cause harmful interference with other devices in the vicinity.

6 Maintenance – Cleaning – Testing

Maintenance
The monitor requires no calibration. Repair or service of the device may only be performed by authorised service personnel with service qualification by the manufacturer. If service is necessary, contact the manufacturer or your local sales representative. The contact address and phone numbers are listed on the last page.

Caution: *There are no user-serviceable parts inside the OxyTrue® A. The cover should only be removed by authorised service personnel.*

Caution: *Follow local, state and national governing ordinances and recycling instructions regarding disposal or recycling of the device and device components, including batteries.*

Cleaning

Use a soft cloth dampened with either a commercial, nonabrasive cleaner, or a solution of 70% alcohol in water. Lightly wipe the surface of the monitor.

Caution:
Clean contaminated and/or dirty equipment before returning, following the cleaning procedure described below.

Caution:
Clean the device separately from the sensors. For instructions on cleaning pulse oximeter sensors, refer to the respective sensor instructions for use.

Caution:
Do not use caustic or abrasive cleaning agents on the device or the sensors.

Caution:
Do not immerse the OxyTrue® A in any liquid. Do not spray, pour, or spill any liquid on the OxyTrue® A, its accessories, connectors, switches, or openings in the enclosure as this may damage the monitor.

Note: Clean the OxyTrue® A once per week or more frequently if the handled by multiple users.

Disinfection

Use a soft cloth saturated with a solution of 10% chlorine bleach in tap water.

Caution:
The device may not be sterilized either with superheated steam or with hot air!

Caution:
Do not autoclave or immerse the device or sensors in liquid. Do not expose the device or components to excessive moisture or liquids.

Testing

Test of the alarm system

In order to trigger an alarm for test purposes during monitoring set the upper alarm limit of SpO_2 or pulse rate below the currently indicated measurement value. The device will react with a visual and an audible alarm.

Test of the measurement accuracy

The only reliable method of testing the measurement accuracy of a SpO_2 monitor is the clinical validation of the measurement data, indicated by the system monitor with sensor on the basis of a blood gas analysis. During extensive clinical studies, the monitor combined with the approved sensors evidenced the accuracy required.

Warning:
A functional tester cannot be used to assess the accuracy of a pulse oximeter monitor or sensor.

7 Symbol Definitions

	Accompanied with "**Warning:** *Supplementary text*." within this document. Warnings indicate potential harmful conditions that may lead to injury or death.
	Accompanied with "**Caution:** *Supplementary text*." within this document. Cautions indicate conditions that may lead to damage to or malfunction of the device.
Note:	Denoted as "**Note:** *Supplementary text*." within this document. Notes inform the user to relevant facts and conditions in connection with the device.
	Consult User Manual for detailed operating information.
	Consult accompanying documents for important safety-related information.
	Manufacturer
	Type BF applied parts
	Catalogue number / Part number
	Serial number
	Temperature limitation
	Indicates that the transport package has to be kept out of heated areas.
	Humidity
	Fragile, handle with care
	Do not dispose in the consumer waste. Electrical and electronic equipment shall be collected and recycled in accordance with (Directive 2002/96/EC).
CE 0482	CE-Conformite Europeene authorization mark. 0482-notified body
IP32	IP Code (International Protection Rating) according to IEC 60529. *IP3X*: protection against tools, wires or similar objects with Ø > 2.5 mm, protection against solid foreign bodies with Ø > 2.5 mm. *IPX2*: Protection against vertically falling water drops (up to a 15° angle) provided the device is in the intended position of use with the display facing the top while placed on the back.
	Not made with natural rubber latex.
	Not made with DEHP.
UDI	Unique device identifier

8 Technical Specifications

Measurement Range	
SpO_2 (Functional oxygen saturation)	Displayed measurement range: 0 – 100 %
Pulse Rate	Displayed measurement range: 20 – 300 bpm (beats per minute)
Perfusion Index (infrared percentage modulation)	Functional range: 0,1 – 20 % (no motion)
Accuracy	
SpO_2 (Functional oxygen saturation)	70 – 100 %: $A_{rms} \leq 2\%$ (no motion, incl. low perfusion[3])[1, 4] 60 – 80% : $A_{rms} \leq 2\%$ (no motion, incl. low perfusion[3]) [1, 4] 70 – 100 %: $A_{rms} \leq 3\%$ (motion condition)[2] <60%: unspecified
Pulse Rate (20 – 300 bpm)	$A_{rms} \leq$ 2bpm (no motion, incl. low perfusion[3]) [5] $A_{rms} \leq$ 3bpm (motion condition[2])
Range of Alarm limits	
SpO_2	45–100 %
Pulse Rate	20–300 bpm.
Average sound pressure level of the alarm signal at a distance of 1 m:	
Low priority alarms	58 dB(A)
Medium priority alarms	60 dB(A)
High priority alarms	62 dB(A)
Display (TFT colour display, 65000 colours, 128 x 160 pixels, 1.77")	
Data displayed	Oxygen saturation, pulse rate, plethysmogram, bar graph, short-term and longterm trends.
Indicators	Signal quality, pulse amplitude, battery status, audible alarm pause, sensor detection, sensor disconnection.
Expected service life	
OxyTrue® A	5 years
Reusable SpO_2 sensors	2 years
Reaction times First displayed value after application)	
Display of first value	The time until the first value is displayed after application is depending on the measurement conditions (perfusion, motion artefacts) and is in the following range: SpO_2: 3 to 7 s; Pulse Rate: 5 to 8 s.
Data update period	Typically, the displayed data update period is 1s. The data update is delayed in case no new valid data is available, e.g. due to excessive signal distortion. The longest data update period is 28 s.
Alarm delay	The sum of alarm conditioning and signal generation delay is less than 1s.

1) Because pulse oximeter measurements are statistically distributed, only about two-thirds of measurements can be expected to fall within ± Arms of the measured values by a co-oximeter.

2) Tested with all Fluke Index II Oximeter tester motion patterns with pattern specific motion frequency of 0,5Hz to 6Hz at perfusion PI: 0,65% to 5% including non-repetitive motion and motion repeating every 0,5Hz.

3) Tested with Fluke ProSim 8 Oximeter tester at infrared percentage modulation PI: 0,7% to 0,1%

4) Applies to reusable SMARTsat® sensors, refer to sensor instructions for use for sensor specific accuracy claims

5) Tested with Fluke ProSim 8 Oximeter tester throughout the pulse rate range of 20 – 300bpm

Trend Information	
Long-term Trends	up to 560 hours
Short-term Trends	15 min / 30 min / 240 min

Environmental Conditions	**Operating conditions**	**Transport and storage**
Temperature	0 to +40°C	-40 to +70°C
Relative humidity	15 to 95% RH non-condensing	
Altitude	620 to 1060 hPa (620 hPa corresponding to an altitude of 4000m)	

Miscellaneous	
Construction	Class IP32 degree of protection against foreign bodies and water provided the device is in the intended position of use with the display facing the top while placed on the back. For the classification of the sensor see instruction for use.
Electrical safety	Internally battery powered / Type BF applied part (including attached SpO_2 sensor probes)
Classification	Class IIb device, in accordance with MDD 93/42/EEC
Dimensions	(L x W x H): 11.8 x 6 x 2.5 cm
Weight	approx. 160 g (with batteries, without sensor)
Power Supply	3 Alkaline batteries (1,5 Volt, Type AA LR6) Alternative: 3 rechargeable NiMh batteries, 1,2 Volt, Typ AA HR6, 1200 mAh
Battery Life	Battery life with 3 full alkaline batteries typically provides 36h of monitoring (no alarms and at 25°C)
Data Memory	More than 560 hours, maximum 50 datasets
Communication interface	
USB 2.0	**ONLY** connect devices via USB which provide safety extra low voltage 5V DC and double isolation according to IEC 60601-1 or IEC 60950-1.
Intended use	The data downloaded by this interface are not intended to be used in prevention, diagnosis, or treatment of any disease. The intention of this interface is to provide data for professional users in wellness and health applications for example sport, fitness, and relaxation management. Control of the monitor using the interface is not possible. It's use is limited to download of measurement data with the OxyTrue-Data-Download-SW.

Applied Standards
IEC 60601-1, Ed. 3.1 (Basic safety)
IEC 60601-1-2, Ed 4.0(Electromagnetic compatibility)
EN ISO 80601-2-61:2019 (Pulse Oximeters)
IEC 60601-1-8 (Ed. 2.1) (Medical alarm monitors)EN ISO 10993-1:2020; EN ISO 10993-5:2009; ISO 10993-10:2021; EN ISO 10993-23:2021 (Biocompatible sensors)

Note: This product complies with ISO 10993-1, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing.
Note: This device is not made with natural rubber latex or DEHP.

9 Clinical studies

SpO_2 Accuracy:
The SpO_2 accuracy is validated by clinical tests with the OxyTrue®A with SMARTsat® technology monitor. These controlled hypoxia studies are conducted on a pool of 12 consenting subject volunteers at an independent research laboratory. The pool consists of equally distributed healthy female and male subjects that are of age 21 to 32, with skin tones ranging from light to dark. The measurement values of the sensors were compared with those of the co-oximetry in the subjects over the specified functional oxygen saturation range.
The accuracy is stated in terms of the root-mean-square (A_{rms}) difference between measured values (SpO_2) and reference values (SaO_2) for all subjects and relates to the ISO 80601-2-61 Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment.

The table below presents the detailed measurement results of the study for each representative sensor respectively.

Table 1: SpO_2 accuracy validation results - OxyTrue® A with SMARTsat® technology

	A_{rms} % SpO_2 by SaO_2-Rang				
Sensor type	**70–100 %**	**60-70%**	**70–80 %**	**80–90 %**	**90–100 %**
SC7500 [1]	1,6	2,4	1,7	1,8	1,5
SF7500	1,5	2,0	1,7	1,4	1,4
W7500	1,6	2,4	1,9	1,5	1,3
EP7500	1,8	3,3	2,3	1,7	1,4
10-AP [2]	2,4	3,4	2,6	2,3	2,1

Note: Because pulse oximeter measurements are statistically distributed, only about two-thirds of measurements can be expected to fall within ± Arms of the measured values by a co-oximeter.

1) Results apply to equivalent sensors SCM7500 and SCP7500
2) Results apply to equivalent sensors 10-PP, 10-IP. 10-NP

Modified Bland and Altman plots (SpO_2- SaO_2) versus SaO_2) for each combination of representative SpO_2 sensor with OxyTrue®A are listed in the sensor specific instructions for use. The plots show the data for all subjects pooled, including upper 95 % and lower 95 % limits of agreement.

Warning:
A functional tester (like Index II or equivalent) may not be used to validate SpO_2 accuracy. A functional tester can be used to verify the function of pulse oximeter probes.

10 Reporting of serious incidents

If there is a *serious incident* in connection with the use of this product, this should be reported.

The incident should be reported to the manufacturer and the health authority or the competent authority for the installation site of the product.

A *serious incident* is when there is a **death or a temporary or permanent serious deterioration in the health of a patient, user or other person.**

Send an email to the following manufacturer address: **prrc@bluepoint-medical.com**

When doing so, please provide the following information:

- Order number and model designation of the product as indicated on the product
- Serial number/batch number of the product
- Date of the *serious incident*
- Description of the *serious incident*, including its impact on the patient or any injury
- Your contact details (institution, address, contact name (substitute), title and phone number)

11 Scope of delivery and order numbers

Scope of delivery:

OxyTrue® A with SMARTsat® technology **complete device:**
1 x OxyTrue® A with SMARTsat® technology, pulse oximeter
1 x Reusable SpO_2 sensor (selectable, see order numbers*)
1 x Lanyard
1 x Silicone protector
3 x AA batteries
1 x USB data cable
1 x User manual and PC software (CD-ROM)
1 x Quick start guide
1 x Hard Shell Carry Case

*** Order numbers - OxyTrue® A** with SMARTsat® technology **complete device:**

Order number/ Reference number	**Sensor style**
9020112001-SC	SoftCap® SpO_2 sensor, large (SC7500)
9020112001-SCM	SoftCap® SpO_2 sensor, medium (SCM7500)
9020112001-SCP	SoftCap® SpO_2 sensor, small (SCP7500)
9020112001-W	SoftWrap® SpO_2 sensor (W7500)
9020112001-SF	SoftFlap® SpO_2 sensor (SF7500)
9020112001-EP	Earprobe SpO_2 sensor (EP7500)

Indicate language version when ordering:

Language version	**Language**
Central Europe version	GB, DE, ES, FR, HU, IT, NL, PL, PT, ZA
Scandinavian version	GB, DK, FI, SE, NL
Special European Character version	GB, GR, RU, TR
Asian version	GB, JP, KOR

Accessories and replacement parts validated for use in healthcare facilities, on transport and in the homecare environment:

Order number	**Type**	**Product**
6020132004	SC7500	SoftCap SpO_2 sensor - Large (>20kg), 3rd generation soft sensor, 1.2m silicone cable
6020132010	SCM7500	SoftCap SpO_2 sensor - Medium (>20kg) , 3rd generation soft sensor , 1.2m silicone cable
6020132300	SCP7500	SoftCap SpO_2 sensor - Small (10 - 20kg) , 3rd generation soft sensor , 1.2m silicone cable
6020132002	SF7500	SoftFlap SpO_2 sensor, finger clip sensor with ambient light shield, 1.2m PVC cable
6020132006	W7500	SoftWrap SpO_2 sensor, 3rd generation soft sensor
6020132254	EP7500	Ear Probe SpO_2 sensor , 1.2m cable
1020122059	–	Universal Mounting Kit, V-adapter with female pole-mount thread
6020122001	–	Carrying case: Carrying bag for main unit and sensor, with shoulder strap “YELLOW”
1020122060	–	Universal Pole-Mount Adapter: Adapter with vertical and horizontal adjustment
1020122056	–	OxyTrue® A Silicone Protective Cover
8020122001	–	OxyTrue® A Hard shell Transportation Case (HD)

Accessories and replacement parts validated for use only in healthcare facilities:

Order number	**Type**	**Product**
6020131194	10-AP	Adult Plaster Disposable SpO_2 Sensor, box with 24 pcs.
6020131197	10-PP	Paediatric Plaster Disposable SpO_2 Sensor, box with 24 pcs.
6020131199	10-IP	Infant Plaster Disposable SpO_2 Sensor, box with 24 pcs.
6020131201	10-NP	Neonatal Plaster Disposable SpO_2 Sensor, box with 24 pcs.
1020132275	XT6500	Extension Cable, 1.2m cable length, PVC cable
1020122058	XT6501	Extension Cable, 2.4m cable length, PVC cable
1020122057	–	USB Data Cable
1020410001	–	CD-ROM OxyTrue® A PC-Software

Additional sensors and accessories are available upon request.

Contact information of your Sales Representative:

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