ENVITEC
by Honeywell

Pulse oximeter MySign®S

Technical Documentation

066-07-1002197_GA_MySignS_FDA-0

USA

Subject to technical changes!

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This manual was created with great care - should you nevertheless find conflicting details during use of the system, we request that you inform us in a brief message so that we can correct the discrepancies as quickly as possible.

We reserve the right to make changes to the product due to advancements in optical or other technologies that are not reflected in the information and figures in this technical documentation. All trademarks mentioned in the text are registered trademarks of the respective owners and are recognized as protected.

This manual is subject to revision by EnviteC-Wismar GmbH.

The latest edition of this technical documentation can be downloaded from our web page www.envitec.com.

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1 General information

The pulse oximeter MySign® S may only be used by operators with sufficient knowledge and due consideration of this technical documentation and the operating manual. The system must only be used for the purpose described.

Symbols used in this manual

Danger of death, serious injury or considerable material damage if the relevant safety measures are not observed.

Important information about the product or a specific part of the manual which should be read with particular attention.

Commissioning

Always note whether there is any damage to the unit, sensor or adapter cable before starting the system it up. Do not use units, sensors or adapter cables if damaged.

Storage and packaging

The MySign® S and SpO2 sensors must be stored in their original packaging at temperatures of between -25 °C and 70 °C.

Maintenance

The pulse oximeter must only be maintained and serviced by the hospital/dealer's technical service personal or by EnviteC-Wismar GmbH staff.

Disposal

In accordance with Directive 2002/96/EC (WEEE), the manufacturer will accept the return of the electrical and electronic device for proper disposal after dismantling!

MR Unsafe

MR Unsafe – keep away from magnetic resonance imaging (MRI) equipment.

2 Safety information

Unit

- The MySign® S may not be operated in atmospheres that pose explosion risks.
- The MySign® S may not be used during defibrillation.
- A defective unit may not be used. Parts that are broken, worn out or contaminated must be replaced.
- The MySign® S and all accessory parts may only be used by persons who have the appropriate education to guarantee proper handling.
- Portable and mobile RF (radio frequency) communication devices (e.g. mobile phones) can interfere with and disrupt electrical medical devices. Additional information about electromagnetic compatibility (EMC) can be found in this manual or on our homepage.
- Medical electrical equipment needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in this Operating Manual.
- MySign® S is not suitable for operation in the vicinity of MRI devices or X-ray radiation and may not be operated in the above environments.
- Exceeding the operating parameters or disregarding the measurement conditions will lead to incorrect measurements or, in severe cases, damage to the MySign® S
- Incorrect use or positioning of the sensors can result in measurement errors and can lead to constriction of body parts by the sensor cable, shearing off of skin portions by the sensor, etc.
- Only the sensors and accessory parts approved by EnviteC-Wismar GmbH may be used with the MySign® S. Sensors and accessories must be in flawless condition. The use of foreign articles can lead to functional failures or loss of biocompatibility and may endanger the patient.
- The use of accessories, transducers and cables other than those specified could result in increased EMC emissions or decreased EMC immunity. See section “15. Order Information” for details.
- The equipment should not be used adjacent to or stacked with other equipment and if adjacent or stacked use is necessary, the equipment should be observed to verify normal operation in the configuration in which it will be used.
- The taking of medications that alter the blood color, the administration of intravascular dyes (such as methylene blue or indocyanine green and other dyes) or a high level of dysfunctional haemoglobin (e.g. carbon monoxide poisoning) can significantly falsify the measurement result.
- MySign® S is intended to support a diagnosis. MySign® S may only be used for determination of a diagnosis within the context of other clinical evidence and symptoms. A clinical evaluation based solely on the use of MySign® S is not permitted.
- MySign® S is delivered in an appropriate shipping packaging. Do not use MySign® S or the compatible sensors if one of the parts exhibits transport damage or other damage.
- When using the system with patients, the system may not be connected to a computer by the data cable.
- The setting of extreme alarm limits can override the alarm function, which could be dangerous for the patient.

Rechargeable battery

- Do not throw into fires.
- Do not damage or change the battery's structure in any way.
- Do not allow to come into contact with fluids.
- Do not store with other metallic objects as this could cause the battery to short-circuit.

Risk of Electrostatic Discharge

- Usage in environments with synthetic floor materials (e.g. carpeting) or a relative humidity below 30% is not recommended. Environments with antistatic floor materials are to be preferred.
- If the unit is used in environments with synthetic floor materials, a relative humidity below 30% or if you are in doubt, discharge any static electricity you may be carrying by touching a grounded metallic surface or item before touching the unit.

Sensor

- Do not use sensors if damaged.
- Do not put any mechanical stress (through pulling, stretching or twisting) onto the sensor cable.

Unit

- This technical documentation is considered part of the unit. Precise compliance with the technical documentation and the operating manual is a requirement of proper use and correct handling of the unit as well as for ensuring the safety of the patient and user.
- Read the technical documentation and the operating manual carefully and completely, as information that concerns multiple sections is only included once.
- EnviteC only considers itself responsible with regard to the safety, reliability and function of the units if the assembly, extensions, reconfigurations, changes and repairs are performed by EnviteC or by a party expressly authorized for this by EnviteC and the unit is used in accordance with the operating manual and the technical documentation.
- If the unit is not used for a prolonged period of time, the capacity of the battery must be checked before mobile use and charged first, if necessary.
- Should reasons exist to doubt the accuracy of the measurement, the vital functions of the patient must first be examined in another way and then inspect the functionality of the MySign® S.
- The device must be positioned such that the optical and acoustic alarm signals can be recognized from a minimum distance of 4 m.

Rechargeable battery

- Do not dispose of batteries as household waste.

Sensor

- Before using the sensors, carefully read the associated operating manual as well as all warnings and other instructions.
- When selecting the sensor, consider the weight and activity level of the patient. Also evaluate whether there is sufficient blood circulation at the application site.
- Movement artifacts can falsify the measurement result. Make certain that the application site is kept still.
- The sensor should be protected from heavy exposure to light since this can cause measurement errors. If the signal quality is not sufficient after about 10 seconds, try affixing the sensor at a different application site.
- Check sensor and application at least every 4 hours for proper functioning (check position and patient skin for damage), and reposition if necessary.
- The sensor contains no latex. The materials used in manufacturing are free of natural latex proteins. The materials that come into contact with the patient have undergone extensive biocompatibility testing.

Essential Performance

Essential Performance is performance, the absence or degradation of which, would result in an unacceptable risk, and includes the following functionalities:

- Accuracy of blood oxygen saturation (SpO2) measurement
- Accuracy of pulse rate measurement
- Alarm indication
- Alarm adjustment within safe limits and silence/pause
- Indication of measured results (saturation, pulse) and associated alarm limits on displays

3 Designated use and functional description

3.1 Indications for use (designated purpose)

MySign® S is a handheld pulse oximeter with accessory sensors indicated for continuous non-invasive monitoring of the functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate for adult and pediatric (excluding neonatal and infant) patients in hospitals, hospital-type facilities, and mobile units. For professional use only.

The device is calibrated to functional oxygen saturation.

The areas in the hospital where the unit can be used include general nursing wards, operating rooms, areas for special procedures and intensive care units both in hospitals and in hospital-like institutions. Hospital-like areas include, for example, out-patient clinics, sleep laboratories, care facilities, surgical centers and day clinics.

MySign® S allows for comprehensive basic monitoring of SpO2 and pulse rate including:

- Configuring of upper and lower alarm limits
- Standard alarm limits
- Visual and audible monitoring

The monitor provides retrospective access to the monitoring data via a USB connection to a PC utilizing the optional MySign PC Software.

The data is stored by the monitor in a trend and event database. It is possible to display trend tables (vital parameters), store them on a central server for documentation or print them out at any location. The measurements can also be displayed as a trend diagram.

The sensors are applied to the corresponding body parts of the patient, such as the finger. Based on the measurement values, pulse-oximetric oxygen saturation (SpO2), pulse rate, pulsation index and the quality of these signals are made available to the user.

The MySign® S may only be used by persons who have the appropriate education to guarantee proper handling.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

3.2 General functional principles and conditions

The technology of non-invasive pulse oximetry is based on two principles. On one hand, the color of the blood influenced by oxygen saturation is determined at the two wavelength ranges of red and infra-red (spectrophotometry). On the other hand, the quantity of arterial blood in tissue (and therefore also the light absorption of this blood) varies during the pulsation caused by the ejection of blood from the heart into the arteries (plethysmography).

The color difference caused by the blood saturation can be attributed to the optical properties of the hemoglobin molecule, or more precisely, to the organic hem component. The hemoglobin is responsible for transporting oxygen in the blood via oxygenation (O2Hb).

The oxygen can be released again; i.e. the blood is deoxygenated (oxygen saturation decreases), losing its red color accordingly. As a result, the absorption of red light is more heavily influenced, and the absorption of infra-red light is less influenced. The pulsation of the arterial blood flow, which changes the blood volume during the systole and diastole and thereby alters the light absorption, is used for determination of the arterial oxygen saturation.

Because only the change in light absorption is evaluated, non-pulsing but absorbing substances such as tissue, bone and venous blood have no effect on the measurement. One red and one infra-red diode serve as light sources for the measurement. The receiver is a photodiode.

The pulse oximeter measures the ratio of the red and infra-red pulsating absorption, which correlates directly with oxygen saturation, and displays the oxygen saturation on this basis. In addition, the time intervals between pulsations are converted into a pulse rate and also displayed.

3.3 Signal quality, pulsation index, disruptions

The pulse oximeter requires a measurable pulse wave in order to correctly determine oxygen saturation values and pulse rate values. If no or only a very weak pulse wave is detected, incorrect values may be obtained.

The values can also be incorrect if significant movement artifacts occur. The displayed measurement values only lie within the defined precision range if the bar graph (signal quality indicator) is shown in blue.

Signal quality:

Blue = Good

Yellow = Moderate

Orange = Poor

The sensor's reading will only be accurate if it is correctly positioned. If attached incorrectly, the sensor's light signal will not be aimed straight at the tissue, which can affect the SpO2 reading.

Pulsation Index (PI): PI is a measure of the level of blood pulsation in the tissue and is defined as the quotient of the pulsatile (I_{AC}) and non-pulsatile (I_{DC}) components of the infra-red light. PI values below 1 can result in measurement errors.

Utility of PI: Adequate blood flow (pulsation) at the application site is required for a correct measurement. The pulsation index (PI) is a general indicator of the pulsation strength obtained at the measurement site, and provides an additional means of signal quality assessment.

Testing of PI: The pulsation index has been evaluated by testing the MySign® S monitor and sensors with a listed pulse oximeter simulator at pulse modulation levels ranging from 0.2% to 20%.

The pulsation may be negatively influenced by, for example, the use of blood pressure cuffs, arterial catheters, arterial occlusion or overly tight application of the sensor. Venous pulsation or defibrillation can also affect the measurement result.

The artifact leveling (AL) is used to suppress movement artifacts for the SpO2 and pulse rate parameters. In addition, the pulse rate is checked for plausibility with a deviation suppression (DS) function.

The MySign® S is calibrated to pulse-oximetric hemoglobin oxygen saturation with dyshemoglobin-free blood based on reference measurements via fractional saturation measurement (CO-oximeter). If the level of dysfunctional hemoglobin is high, the precision of the measurement is impaired. Intravascular dyes, nail polish and artificial fingernails can also impair the precision of the measurement.

In addition, the measurement precision can be impaired by strong ambient light or direct sunlight. In such cases, the sensor can be covered.

If you doubt the precision of the measurement, check the vital signs of the patient with the help of other methods. Then make certain that the MySign® S is functioning properly.

4 Commissioning

4.1 Unpacking and testing the delivery

If the shipping box is damaged, notify your shipper. Unpack the MySign® S and its accessories. If a part is missing or damaged, contact the customer service of EnviteC or your local EnviteC dealer.

4.2 Parts list

1 x pulse oximeter MySign® S

1 x operating manual unit

1 x CD technical documentation unit

1 x USB cable

4.3 Function test

Verify the proper functioning of the MySign® S before using it the first time. Do this by following the further instructions in section 6.1.

4.4 Installation

Connect the SpO2 sensor to the MySign® S unit as shown below.

Note the arrow on the sensor plug and the unit socket to ensure the correct connection orientation. Otherwise the contacts could be damaged and correct functioning cannot be guaranteed!

4.5 Charging the battery

The battery must be fully charged before using the MySign® S for the first time. It can be charged either at an external power supply or a USB port on a computer.

4.5.1 Charging the battery at an external power supply

The battery can only be charged at an external power supply using a suitable wall power supply with a USB port (EnviteC Part No.: 1001829). When using the EnviteC external power supply, charging the battery takes around 4 hours and is completed as soon as the battery symbol is shown as full.

4.5.2 Charging on a USB port

To charge the battery at a USB port, connect it to the USB port on the computer using the enclosed cable. As the charge current at the port is only around 500 mA, it can take up to 6 hours to charge the battery at a computer.

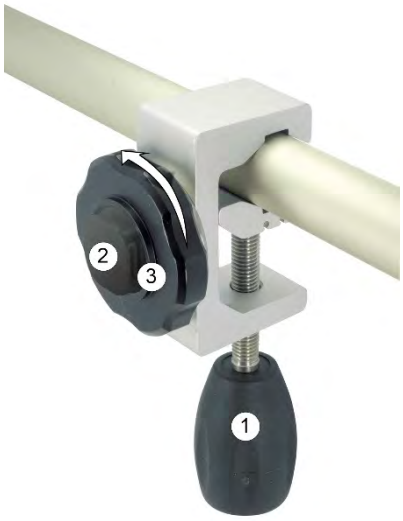
- Only use power supplies that correspond to the system's specifications (see “13. Technical specifications”)!
- For more information on the position of the battery indicator, see section “5.2 Display”.

To charge the battery, open the cover on the USB port of the MySign® S, insert the USB cable (data cable / Part No. 1001815) and connect it to the USB port on a computer or the external power supply.

4.6 Set up / mounting

The MySign® S must be set up / mounted as per the requirements at the place of use, on an even surface or using the universal holder (optional, Part No. 1001801) for all profiles.

Fold out the support provided on the MySign® S ② and set up the unit.



Hold the fixed tension arm against the bed frame, for example, and attach the holder by turning the threaded spindle ① in a clockwise direction.

Now insert the holder's mounting plate into the guide ② on the back of the MySign® S and fasten by turning the hand wheel ③ in a counter-clockwise direction.

The device must be positioned so that the optical and acoustic alarm signals can be recognized from a minimum distance of 4 m.

5 Operating elements and symbols

The system is operated using the membrane keys on the front. All of the system's status and error messages are shown in plain text on the illuminated screen.

Front

Back

No.	Description	No.	Description
①	Housing	⑥	ON/OFF key
②	Display	⑦	Sensor socket
③	Operating keys	⑧	Sound emitter
④	USB port	⑨	Support
⑤	Alarm LED red/yellow		

5.1 Keys and LEDs

Function keys 1 + 2 (depending on menu)

Example:

Function 1 Function 2

Select key UP
For selecting menu items and changing parameters
(Pulse sound ➔ louder)

Select key DOWN
For selecting menu items and changing parameters
(Pulse sound ➔ quieter or off)

Main menu or home key
Opens the main menu or brings you back to the main screen

“Pause audio alarm” key with yellow LED
Acknowledges an alarm ➔ Mutes it for 120 seconds
Pressing this key briefly twice (double-click) fully switches off the **current** audio alarm.

Switches the audio alarm **off**!

LED on ➔ as soon as the audio alarm has been switched off.
LED flashes ➔ as soon as the reminder signal has also been switched off.

ON/OFF key
For switching the unit on / off

Alarm LED red/yellow
Visual signals, see “10. Alarm signals”

5.2 Display

No.	Description
1	Date and time indicator
2	Patient type: Shows the preset patient type (adult or child). Also see section “Patient type”.
3	ID (identification): Shows the current measurement series number. Also see section “Measurement series”
4	Symbols: See additional table for explanation (5.4)
5	Battery status indicator: See section “Alarm messages”
6	Pulse sound volume: Shows the current volume of the pulse sound. This can be adjusted or switched off with the select keys “UP” and “DOWN”.
7	Current SpO2 measurement value
8	Upper SpO2 alarm limit
9	Lower SpO2 alarm limit
10	Current pulse measurement value
11	Upper pulse alarm limit
12	Lower pulse alarm limit
13	Bar graph: Shows the plethysmogram as a bar graph and indicates the signal quality with color changes. Blue means good signal quality, yellow moderate and orange poor. See also section “Precision, disruptions”
14	Pulsation index (PI): A the ratio of the pulsatile signal (i.e. due to blood pulsation) to the non-pulsatile signal obtained at the measuring site. < 1 means poor/low pulsation at the measurement site.
15	Information field: Also see “Information” section.
16	Description of the function keys

5.3 Symbols on the label

Follow the instructions given in the operating manual!

Manufacturer + date of manufacture

PN Product number

SN Serial number

MR Unsafe

IP54 Protected against spray water and dust

Unit corresponds to type BF – Not protected from the effects of defibrillators

Follow the disposal instructions!

CE Conformité Européenne (European conformity)

5.4 Symbols shown on the display


Key lock ON


Key lock OFF


View


Data memory


Alarm settings


General settings


Help


Up


Down


Audio alarm off

Audio alarm off only for current alarm

Pause sound

Application indicator
(see also section “Application indicator)


Patient type


Sensor off


Plug disconnected


Sensor defective


Battery symbol


Mains operation/charge


Connecting the system to a computer


Flag for marking within a dataset


Error (yellow = minor / red = severe)

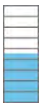
Alarm condition
(Symbol to display an alarm condition)


Information


Info

Low level priority warning


Medium level priority warning


Bar graph signal quality


Switch off


For pulsation index (PI) bar graph
see section 11


Pulse sound volume


Pulse (heart beat)


Pulse sound off


Function off


Function on

6 Operation

All functions of the unit and the necessary initial configuration are described in this section.

6.1 Switching the unit on / off

Once the unit has been switched on, it will automatically test all of its internal functions and components. While performing these tests, the symbol “Follow the operating manual” appears on the display for about 3 seconds.

A signal tone is also emitted during the function test, and all LEDs (alarm and audio alarm paused) are activated. If you do not hear or see these indications, repeat the switching-on process. If the problem persists, please contact customer service.
The sensor is also checked during the function test, so ensure it is connected. However, it is not checked for accuracy.

Switching on the unit

Hold down the key for around 1 second.

The unit will be ready to take measurements after approx. 5 seconds.

Example: Information displayed while the unit is being switched on:

The device personalization is shown if this has been entered using the MySign® PC software.

If the measurement data have been personalized using the computer's software, the screen will display a prompt asking whether this data is to be copied over after the unit has been switched on.

If this prompt regarding copying the personalized measurement data is not confirmed within 2 minutes, they are not copied. In that case, the system will generate a new measurement series record.

Switching off the unit
The unit will show a countdown for the shutdown process, starting with the number 3. If the ON/OFF key is released at any time during the countdown, the countdown is stopped and the unit stays on.

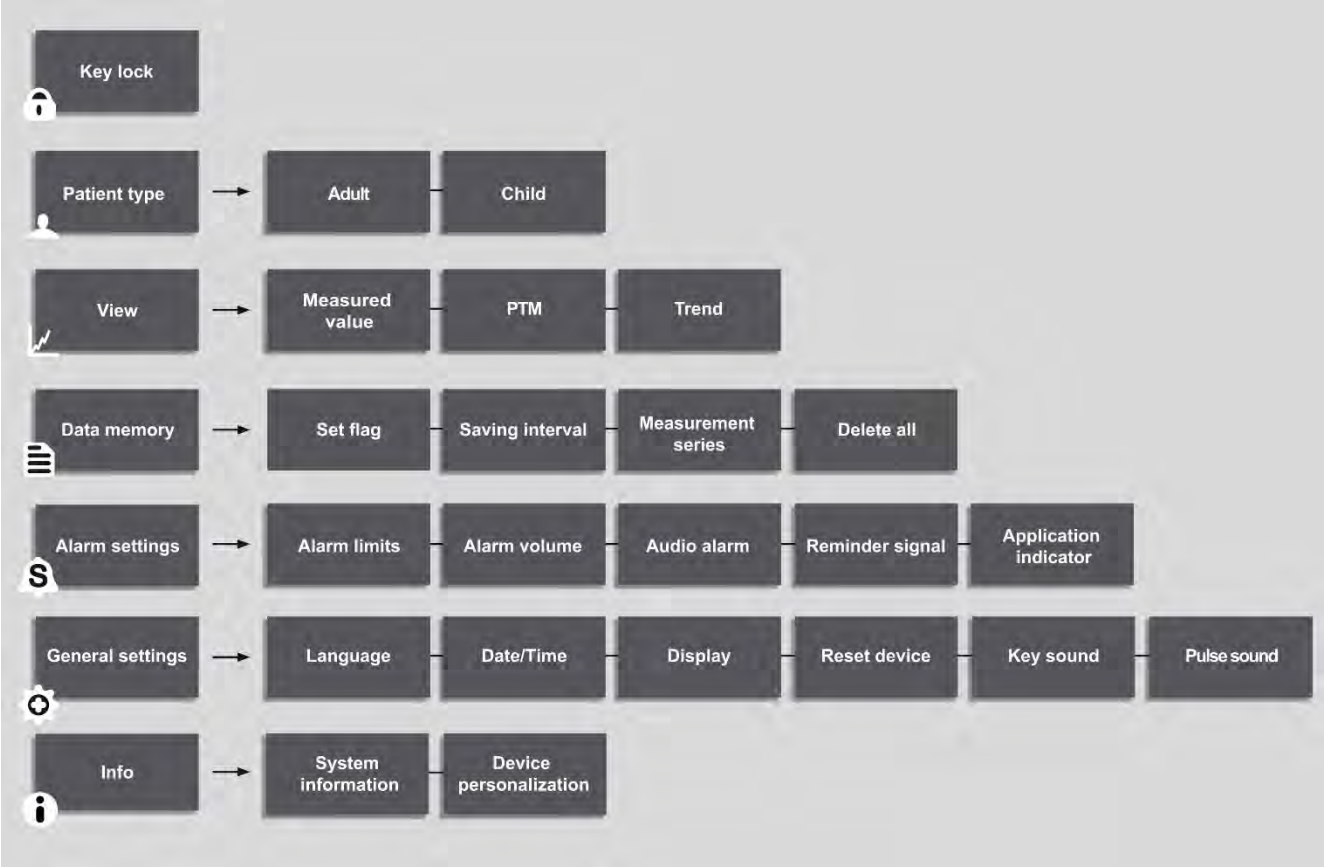
Hold the key pressed for about 3 seconds

Example: Information displayed while the unit is being switched off:

Once the unit has been switched off, the data from the measurements that have been performed are stored inside the unit's memory and can be viewed again at a later time.

6.2 Main menu

Overview



6.3 Key lock

For this, the keys are locked to prevent changes from being made to the device settings.

Select “Key lock” from the main menu.

Deactivate the key lock by pressing “Unlock ?”.

Confirm the subsequent query by pressing “OK”.

The keys are now unlocked and can be used to operate the unit.

6.4 Patient type

Various initial settings can be configured for specific groups of persons in the “Patient type” menu.

Adult

SpO2 alarm limits:	
Upper	Lower
100 %	90 %
Pulse alarm limits:	
Upper	Lower
120 bpm	50 bpm

Child

SpO2 alarm limits:	
Upper	Lower
100 %	90 %
Pulse alarm limits:	
Upper	Lower
140 bpm	75 bpm

6.5 View

The properties of the unit display can be modified in the “View” menu. One differentiates here between “Measured value”, “PTM (plethysmogram)” and “Trend”.

The display can also be modified with function key 2 (right) “View”.

Select “View” in the main menu.

Once this menu has opened, you will be able to select from any of the above modes.

6.5.1 Measured value

In this display mode, the currently measured SpO2 and pulse values as well as the pulsation index and signal quality are displayed. To view an overview of the measurements that have already been performed, go to “Measurement series” in the “Data memory” menu.

Select “Measured value” from the “View” menu.

Horizontal position ➔ Measurement value view

When holding the unit horizontally, the measurement value will also be displayed horizontally.

6.5.2 PTM

In this mode, the unit will show both the “Measured value” and “Plethysmogram”.

Select “PTM” from the “View” menu.

Horizontal position ➔ PTM view

When holding the unit horizontally, the PTM view will also be displayed horizontally.

6.5.3 Trend

In this mode, the system will show the current measurement and a time line showing the trend of the measurements taken over the past three hours. This gives a comprehensive overview of any changes in the measurements.

Select “Trend” from the “View” in the menu.

Horizontal position ➔ Trend view

When holding the unit horizontally, it will extend the measurement period shown to 4 hours.

6.6 Data memory

The data memory contains the data from previous measurements. These recordings are listed by ID or chronologically by start and end date.

Select “Data memory” from the main menu.

Once the “Data memory” menu has opened, you will be able to select from a number of different functions.

Changing the battery does not affect the data stored in the memory.

6.6.1 Set flag

This function can be used to insert flags into the data memory in order to, for example, document the administration of medications.

Select “Set flag” from the “Data memory” menu.

“Flagged” appears for a brief time on the display, and the flag is indicated in “Trend” view as a vertical, dotted line.

6.6.2 Save interval

You can configure here the time interval at which the unit should save measurement values. The save interval can be set between 5 s and 60 s.

6.6.3 Measurement series

A measurement series comprises all of the measurements (SpO2 and pulse) that are taken during one measuring cycle. A new measuring cycle is started every time the unit is switched off and on, and each new series of measurements is assigned a separate ID.

The measurement values are saved at the configured save interval.

Select “Measurement series” from the “Data memory” menu.

Then select a measurement series. It is also possible to move within the measurement series using the arrow keys.

The data can also be displayed graphically. The “Zoom” function changes the time axis of the graph.

Low level priority warning (e.g. battery charge low)

Medium level priority warning
(e.g. value below lower alarm limit)

Flagged

For additional information on the priority levels, see section “8. Alarm messages”.

6.6.4 Delete all

Deletes all of the measurement data stored in the unit and starts a new measurement series.

Select “Delete all” from the “Data memory” menu.

6.7 Alarm settings

The alarm settings contain all configuration options for alarms.

Select “Alarm settings” from the main menu.

Once the “Alarm settings” menu has opened, you will be able to select from a number of different options.

6.7.1 Alarm limits

The alarm limits are the upper and lower limits for SpO2 and pulse such that an integrated signal device will indicate an alarm if the values are outside of this range.

Select “Alarm limits” from the “Alarm settings” menu using the select key.

The value can be changed by pressing the select key.

Switch to the next value by pressing the function key “Next”. At the last value (lower pulse alarm limit), all changes are confirmed and accepted with “OK”.

You can move back one step with the function key “Back” until eventually leaving the alarm settings.

The alarm limits can also be changed with the function key 1 (left) “Alarm limits”.

6.7.2 Alarm volume

This function can be used to individually adjust the volume for the audio alarms and reminder signal.

Select “Alarm volume” from the “Alarm settings” menu.

Use the selection keys to adjust the alarm volume.

Then confirm by pressing the right function key.

6.7.3 Audio alarm

This is where the audio alarm for all messages can be switched on and off.

Select “Audio alarm” from the “Alarm settings” menu.

This is switched on or off with the right function key.

Other options:

1. The audio alarm can be paused for 120 s directly on the unit with the key “Pause audio alarm” (LED lights (above the “Pause audio alarm” key) + symbol dashed yellow + 120s).
2. Double-pressing the key “Pause audio alarm” will only switch off the audio alarm for the currently applicable alarm condition (LED lights + symbol yellow).
3. By simultaneously pressing the “Pause audio alarm” key and , the audio alarm can be switched off entirely (LED lights + symbol red).

We advise against switching the audio alarm off.

Even when the audio alarm is switched off, a reminder signal is emitted every 4 minutes, unless this has also been additionally switched off.

6.7.4 Reminder signal

The reminder signal is emitted every 4 minutes if the audio alarm has been switched off and an alarm condition exists. This function can be switched on or off under “Alarm settings”. Switching off the reminder signal requires a code (set at the factory to 2012), which can be entered using the “UP” and “DOWN” select keys.

When the reminder signal and the audio alarm have been switched off, the yellow LED above the “Pause audio alarm” key flashes.

Select “Reminder signal” from the “Alarm settings” menu.

This is switched on or off with the right function key.

We advise against switching the reminder signal off.

6.7.5 Application indicator

Indicates how long the SpO2 sensor has been used at the same application point (e.g. index finger).

The application indicator is given in hours from 0 - 8. The display starts as soon as the sensor is placed or re-applied. This function can be switched on or off under “Application indicator”.

Select “Application indicator” from the “Alarm settings” menu.

This is switched on or off with the right function key.

The symbol flashes if more than 4 hours have passed. After 8 hours, the following symbol >8h is shown.
The time is only reset to zero by the error message “Sensor off”.

Check sensor and application at least every 4 hours for proper functioning (check position and patient skin for damage), and reposition if necessary. For older people, it is recommended that checks are performed after just 2 hours to prevent bruises from forming.

Switching the unit off and back on interrupts the time measurement, which begins again at 0 hours.

6.8 General settings

The unit's main settings can be configured in the “General settings” menu. The settings can also be configured using the supplied software.

Select “General settings” from the main menu.

Once the “General settings” menu has opened, you will be able to select from a number of different options.

6.8.1 Language

This menu item can be used to select the required language.

Select “Language” from the “General settings” menu.

Now select the corresponding language.

6.8.2 Date/Time

The date and time are shown in the international format.

- Date: ➔ YYYY-MM-DD (year – month – day)
- Time: ➔ HH:MM (hours : minutes)

Select “Date/Time” from the “General settings” menu.
Pressing the key again will enable you to change the next value.

The change is entered using the select keys and confirmed with “OK”.

6.8.3 Display

This menu can be used to adjust the brightness settings, the automatic reduction of the display brightness (auto-off) and the auto-rotation (rotation of the display when the unit is rotated).

Select “Display” from the “General settings” menu. The corresponding menu item can be opened using the selection keys and pressing function key 2 again.

Use the selection keys to configure these functions.

6.8.4 Reset device (factory setting)

Here, the unit can be reset to the factory settings or user settings. The user settings are defined using the PC software.

Factory settings	
Pulse sound	3
Alarm sound	On
Alarm sound volume	7
Reminder signal	On
Application indicator	On
Key sound	On
Patient type	Adult
SpO2 upper limit	100
SpO2 lower limit	90
BpM upper limit	120
BpM lower limit	50
View mode	Measurement value
Display brightness	8
Auto-off (display)	1 (when not connected to power supply)
Auto-rotation	Off
Saving interval	10 s
Language	English

6.8.5 Key sound

This menu can be used to switch on or off the audio signal that is sounded when a key is pressed.

Switch the function “Key sound” on or off in the “General settings” menu.

6.8.6 Pulse sound

This menu can be used to switch on or off the audio signal for the pulse.

Switch the function “Pulse sound” on or off in the “General settings” menu.

In the normal measurement mode, the volume of the pulse sound can be changed or switched off with the select keys (UP / DOWN).

6.9 Info

This menu can be used to call up information about the unit and the sensor.

Select “Info” in the main menu.

Once the “Info” menu has opened, you will be able to select from a number of different options.

6.9.1 System information

The system information menu contains the most important data about the system.

Unit

- Serial number
- Software version
- Hardware version
- Date of manufacture

Module 1

- Serial number
- Software version

Select “System information” from the “Info” menu.

6.9.2 Device personalization

Freely selectable start text, which can be changed using the PC software. For example, information can be entered identifying the department to which the unit belongs.

7 EnviteC SpO2 sensors and accessories

The SpO2 sensors are transmission sensors and contain two LEDs as well as a photodiode for this spectrum.

Wavelengths

- Reusable sensors: 660/890 nm at 3.5 - 4.5 mW
- Disposable sensors: 660/890 nm at 2.5 - 3.5mW

The sensors are individually detected by MySign® S for the best possible measurement precision.

7.1 Selection and application of a sensor

Before using the sensors, carefully read the associated operating manual as well as all warnings and other instructions.

Never use damaged sensors. Never use a sensor with unprotected optical components.

Only use sensors approved by EnviteC for SpO2 measurements.

When selecting the sensor, consider the weight and activity level of the patient. Also evaluate whether there is sufficient blood circulation at the application site.

The sensor should be protected from heavy exposure to light since this can cause measurement errors. If the signal quality is not sufficient after about 10 seconds, try affixing the sensor at a different application site.

7.2 Overview of EnviteC sensors and cables

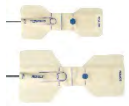
Directly connected sensors (plug C74)

				
SoftTip® Large R-3211-12 MySign®	**SoftTip® Medium** RM-3211-12 MySign®	**SoftTip® Small** RS-3211-12 MySign®	**FingerClip** F-3211-12 MySign®	**Ear sensor** ES-3211-12 MySign®
SoftTip® Large R-3211-31 MySign®	**SoftTip® Medium** RM-3211-31 MySign®	**SoftTip® Small** RS-3211-31 MySign®	**FingerClip** F-3211-31 MySign®	**Ear sensor** ES-3211-31 MySign®

Sensors connected via an adapter cable (plug C60)

Extension and adapter cables
X-4211-3 MySign®

Extension and adapter cables
X-4211-1 MySign®

					
SoftTip® Large R-3212-9 MySign®	**SoftTip® Medium** RM-3212-9 MySign®	**SoftTip® Small** RS-3212-9 MySign®	**FingerClip** F-3212-9 MySign®	**Ear sensor** ES-3212-9 MySign®	**Disposable sensor** DA-2211-1 MySign®
					Disposable sensor DP-2211-2 MySign®

The display of both the SpO2 value and the pulse rate can be influenced by certain ambient conditions, errors in the application of the sensors and certain patient conditions.

A list of the part numbers can be found in the section “Order information”. A current list of the approved sensors can be found at www.envitec.com.

8 Maintenance / cleaning

The unit is maintenance-free and therefore does not need to be inspected at specific intervals with regard to its measuring function or safety. The unit automatically tests all of its functions every time it is switched on and will show any faults it detects. The unit also continuously monitors all of its functions while operating.

Always check the unit, the sensor, the charging equipment and all cables for external damage before use.

The unit may only be serviced by EnviteC or service personnel that have been trained by EnviteC.

Repairs

In the unlikely event that your system will need to be repaired, please contact your dealer or send the system and all of its accessories to the following address:

EnviteC-Wismar GmbH
Service
Alter Holzhafen 18
23966 Wismar, Germany

To speed up the repair process, please obtain an RMA (Return Material Authorization) number through our website, www.envitec.com, under Service / Returns.

Please state your RMA number in all your correspondence!

Cleaning and disinfection of the MySign® S

Only perform a wipe disinfection by gently wiping the unit with a soft, disposable cloth soaked with isopropyl alcohol.

Keep the battery cover closed when cleaning and disinfecting the unit! Do not allow moisture to enter the unit. The electrical contacts inside the unit (battery) and at the USB port must be clean and dry at all times to ensure that the unit will function properly.

Cleaning and disinfecting SpO2 sensors

Follow the instructions in the respective sensor operating manual.

The sensors should be cleaned and disinfected after every use on the patient in order to prevent cross-contamination.
Do not put any mechanical stress (through pulling, stretching or twisting) onto the sensor cable.

8.1 Replacing the battery

Only batteries (Part No. 1001734) of the following type may be used:

- Li-ion 3.6 V DC
- 2900 mAh

To replace a faulty battery, remove the screw ① and push down the cover ②. Now take off the cover and remove the battery connection cable ③ and the battery ④.

The MySign® S may not be operated with regular, non-rechargeable batteries.

The battery connection cable has reverse polarity protection. The unit settings (such as date/time) are saved for at least 5 minutes while the battery is being replaced. After this time, all settings must be reconfigured.

Disposing of the unit, SpO2 sensor, battery

Do not dispose of the unit, SpO2 sensor or battery as household waste. Please return all of these to EnviteC clearly labelled “Entsorgung (Please dispose of)”.

EnviteC-Wismar GmbH
Alter Holzhafen 18
23966 Wismar, Germany
Germany

Danger of explosion!
Do not throw batteries into fire or force them open.

8.2 Replacing the sensor

1. Remove the sensor
2. Disposing of the sensor
3. Connect a new sensor and check its functions

Note the arrow on the sensor plug and the unit socket to ensure the correct connection orientation. Otherwise the contacts could be damaged and correct functioning cannot be guaranteed!

9 PC software

The integrated USB port can be used for exchanging data between a computer and MySign® monitor. The steps for connecting the relevant cables for exchanging data and for charging the battery from the computer port are identical (see section “Commissioning”).

It is only possible to transfer data to a computer once the software has been installed.

The software can be used for:

- Reading and displaying measurement data
- Saving and uploading measurement data
- Updating the unit firmware
- Personalizing the data records
- Configuring the MySign® monitor
- Personalizing the MySign® monitor

The MySign® PC software is intended for reading, documenting and managing the data stored in the MySign® monitor as well as for personalizing and configuring the MySign® monitor by connecting it to the PC via a USB connection. The PC software is not intended for diagnosis and analysis purposes. No measuring is possible while the MySign® monitor is connected to a PC.

No fundamentally essential or safety-relevant functions of the MySign® monitor can be changed in the MySign® monitor configuration.

Please refer to the “Help” section of the PC software for more information on operation and the functions of the PC software.

Connecting the MySign® monitor to the PC software

- Start up the software application
- Connect the PC to the MySign® monitor with a USB cable
- Switch on the monitor

Press “OK” to connect the monitor to the PC software.

If the prompt “Connect to PC” does not appear on the unit, please disconnect the USB plug for at least 3 seconds and then re-connect it.

Connecting the monitor to the PC software will interrupt the current measurement!
It is not possible to conduct any measurements while connected to the PC.

10 Alarm messages

Visual signals		Audio signals	Description	Priorities
	Glowing yellow	---	**Charge level of the battery too low (remaining time about 2 hours)** The battery must be charged as soon as possible.	!
+	Flashing yellow, red symbol	3 x every 10 s	**Critical charge level of the battery (remaining time about 15 min.)** The battery must be charged immediately.	!!
+  +	Glowing yellow	3 x every 15 s	**Plug disconnected** Check sensor plug. Replace sensor, if necessary.	!
+  +	Glowing yellow	3 x every 15 s	**Sensor off** Check the correct seat of the sensor at the application site (e.g. finger). Re-apply, if necessary.	!
+  +	Glowing yellow	3 x every 15 s	**Sensor defective** Check sensor. Replace sensor, if necessary.	!
+	Flashing yellow, orange symbol	---	**Poor signal quality** Check the correct seat of the sensor at the application site (e.g. finger). Re-apply, if necessary.	!
+	Flashing yellow	every second	**Pulse search too long** Check the correct seat of the sensor at the application site (e.g. finger). Re-apply, if necessary.	!!
+ Lower SpO2 or pulse alarm limit	Flashing yellow	**After 10 s delay** 3 x every 10 s	**Oxygen concentration or pulse too low** Check the supply of oxygen to the patient as well as the position of the sensor and function of the unit.	!!
+ Upper SpO2 or pulse alarm limit	Glowing yellow	**After 10 s delay** 3 x every 15 s	**Oxygen concentration or pulse too high** Check the supply of oxygen to the patient as well as the position of the sensor and function of the unit.	!

Description of the priorities

! Low level priority warning

!! Medium level priority warning

11 Info

"Information field" display	Cause	Remedy
PI + < 1 Flashing	**Pulsation index (PI) below 1** Poor blood flow at the application point.	Improve blood flow or select another location to apply the sensor.
Pulse search	Indication that the pulse signal has not yet been detected.	As soon as a pulse signal has been detected, this message will disappear.
Ambient light	Indicates that there is too much ambient light and the measuring signal is therefore not accurate.	The ambient light should be reduced, e.g. the sensor could be covered with a cloth.

12 Error Descriptions and Troubleshooting

Fault indicator	Possible cause	Remedy
Self-test (critical)		
Hardware XXXX	Internal hardware fault	Switch the unit off and then on again. If the fault persists, please contact customer service.
Rechargeable battery	Battery charge too low, no battery connected or battery faulty	Check and charge the battery or replace it if necessary.
Self-test (non-critical)		
Time	Time was reset	Set the time again. If the fault persists, please contact customer service.
Memory	Internal memory error (“Data memory” menu item missing)	Switch the unit off and then on again. If the fault persists, please contact customer service.
Settings	Battery was removed for too long or internal memory error.	Check settings (e.g. language) and change, if necessary. If the fault persists, please contact customer service.

Critical errors jeopardize the unit's reliability, which is why it will switch itself off.

In all other cases, it will still be possible to continue to use it, although with restrictions.

13 Technical specifications

All of the specifications apply to the following standard conditions: Ambient temperature of 1013 hPa, 25°C dry ambient air.

Display area	:	Saturation (SpO2) 1 to 100% Pulse rate (PR) 0 to 300 BPM Pulsation index (PI) below 0.1 to 20
Precision*	:	Saturation +/- 2% (70 to 100%, without disrupting movement) Pulse rate +/- 3 BPM (30 to 250 BPM, without disrupting movement)
Display	:	Time interval for updating the data on the display: 300 ms Plethysmogram: Amplitude = 75% of the display area
Operating temperature	:	0°C – 40°C
Storage temperature	:	-25°C – 70°C
Operating humidity	:	30 – 95% rel. humidity (non-condensing), for operation outside this range refer to the safety information **Risk of Electrostatic Discharge**
Ambient pressure	:	700 to 1060 hPa
Rechargeable battery	:	Li-ion 3.6 V 2900 mAh
Operating time per charge	:	> 18 hours (standard settings) > 24 hours with auto-off activated Function with the lowest display brightness setting
Charger	:	Mini-USB type B, protection class II Input: AC 110V - 230V / 50 – 60 Hz / 125 mA Output: DC 5V / ≥ 1 A / < 15 W IEC 60601-1 / IEC 60950-1
Charging time	:	Approx. 4 hours
Device behavior during battery charging	:	Full functionality guaranteed
Display	:	2.8" multicolor TFT
Dimensions (unit)	:	160 x 72 x 39 mm (L x W x H)
Protection class	:	IP54
Impact resistance	:	IK 05
Weight	:	Approx. 320 g (with sensor*)
Interface	:	USB 2.0 (socket Mini-USB type B)
Alarm functions	:	Monitoring the alarm limits and unit functions (visual and audio)

Alarm limits	:	Can be adjusted to between **SpO2:** Upper limit: 51 % - 100% Lower limit: 50 % - 99% **Pulse:** Upper limit: 31 - 250 BPM Lower limit: 30 – 249 BPM
Alarm sound	:	55 – 75 dB (A)
Pulse sound	:	Sound frequency variable (depending on measured SpO2 value)
Application indicator	:	From 0 to 8 hours
Data memory	:	Max. 96 h with a storage interval of 10 s (Storage interval can be changed from 5 s to 60 s) Measurement values, date, time, alarm limits, events
Personalization	:	Unit and data in connection with MySign® software (e.g. name, ward, patient ID)
Protection class	:	II, type BF
Class	:	IIb
CE marking	:	CE 0123
Standards	:	This unit complies with the requirements of MDD 93/42/EEC concerning medical devices and the corresponding standards. **It also complies with:** DIN EN 1789 Medical vehicles and their equipment - Ambulances

* with SoftTip® R-3211-12 MySign®

Subject to technical changes!

** General accuracy statement - refer to the sensor specific clinical accuracy described below for detailed information.*

13.1 Clinical Accuracy

The MySign® S has been clinically evaluated for accuracy in accordance with ISO 80601-2-61. Testing was performed in healthy adult volunteers providing informed consent in an institutionally approved clinical protocol, with arterial blood samples measured by co-oximetry as the reference samples.

The MySign® S has been clinically evaluated with the following SpO2 sensor types:

- F-3212-9 Reusable FingerClip SpO2 Sensor
- ES-3212-9 Reusable EarClip SpO2 Sensor
- R-3212-9 SoftTip Reusable Rubber Finger Sensor
- DW-2211-6 Disposable Adhesive Tape Sensor
- DS100A Nellcor Finger Clip Sensor (NOTE: third party sensor not manufactured by EnviteC)

In total the sensor types above are representative of the construction of the MySign® S full sensor product offerings for FingerClip, EarClip, SoftTip, and disposable sensors. The reported accuracy for each sensor type is listed in the table and in the graphical plots below.

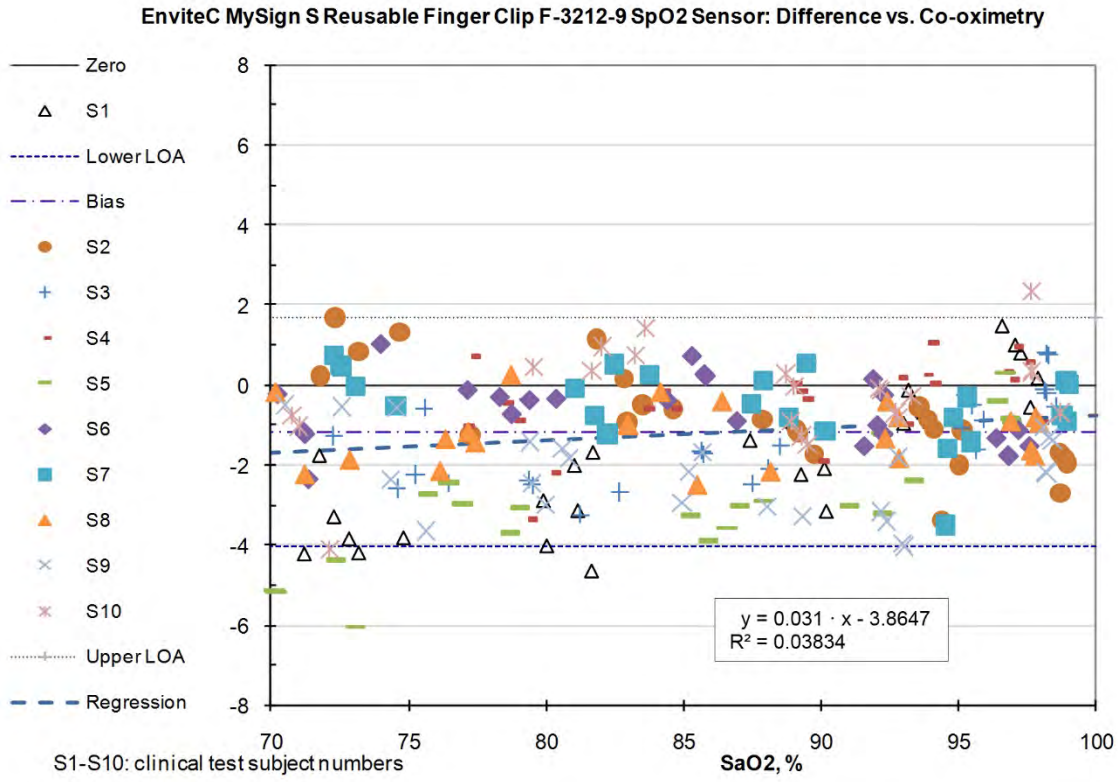
Parameter	F-3212-9	ES-3212-9	R-3212-9	DW-2211-6	DS100A
A_{RMS} 70-80%	2.35	2.90	1.85	2.41	2.41
A_{RMS} 80-90%	2.09	1.33	1.73	2.14	1.44
A_{RMS} 90-100%	1.50	1.33	1.40	1.90	1.48
A_{RMS}[1] 70-100%	**1.86**	**1.98**	**1.60**	**2.01**	**1.79**
Upper 95% LOA[2]	1.673	3.937	2.063	2.331	3.989
Lower 95% LOA	-4.050	-3.888	-3.559	-4.465	-2.444

1. A_{RMS} is root mean square error. This value is expected to contain about 2/3 of the oximeter.
2. LOA is Limits of Agreement – expresses the 95% confidence interval upper and lower boundaries.

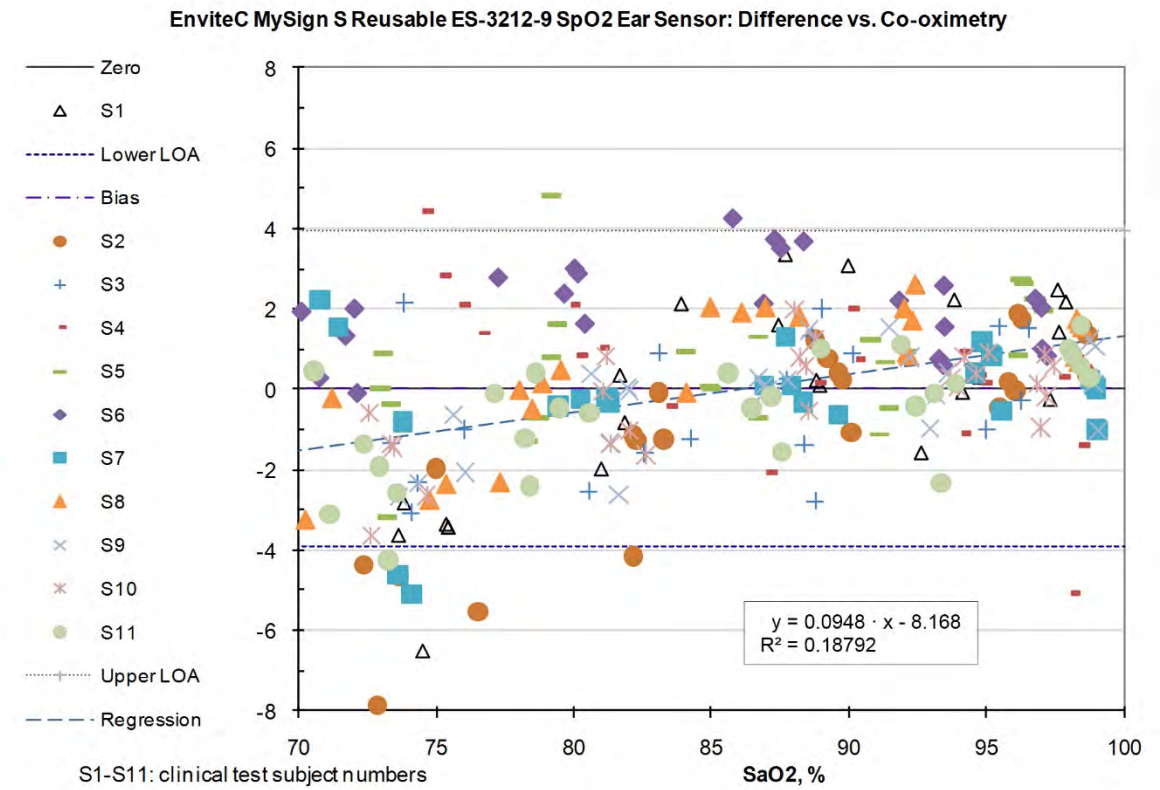
Graphical error plots for each sensor type are provided below, and have been constructed with reference to BLAND, J. M., ALTMAN, D. G. Agreement Between Methods of Measurement with Multiple Observations Per Individual. Journal of Biopharmaceutical Statistics, 17:4, 571 – 582

Refer to the respective user manuals for each sensor type for more information.

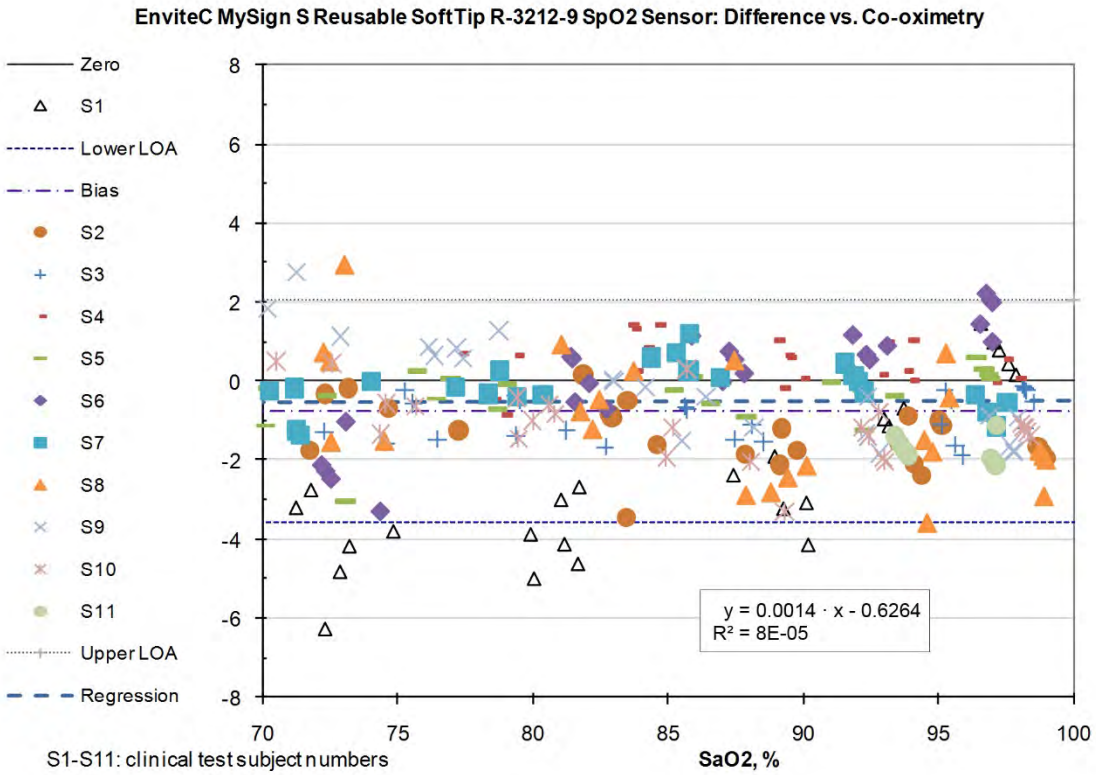
F-3212-9 Reusable FingerClip SpO2Sensor



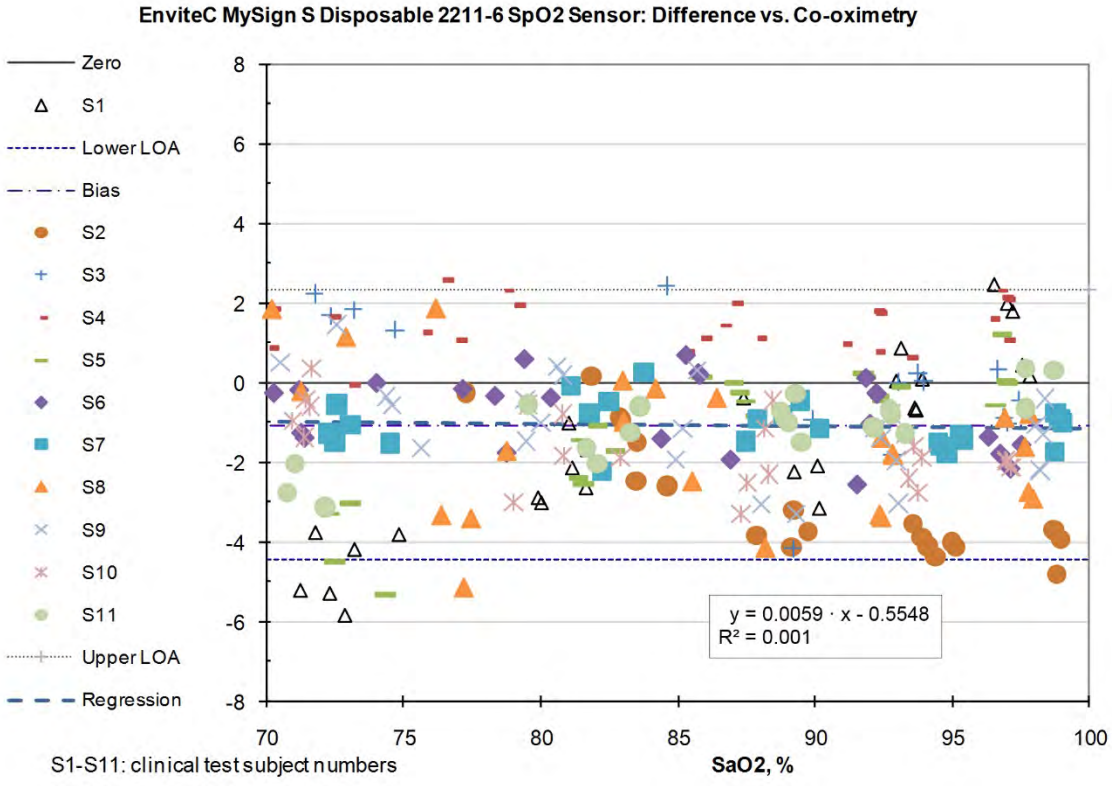
ES-3212-9 Reusable EarClip SpO2 Sensor



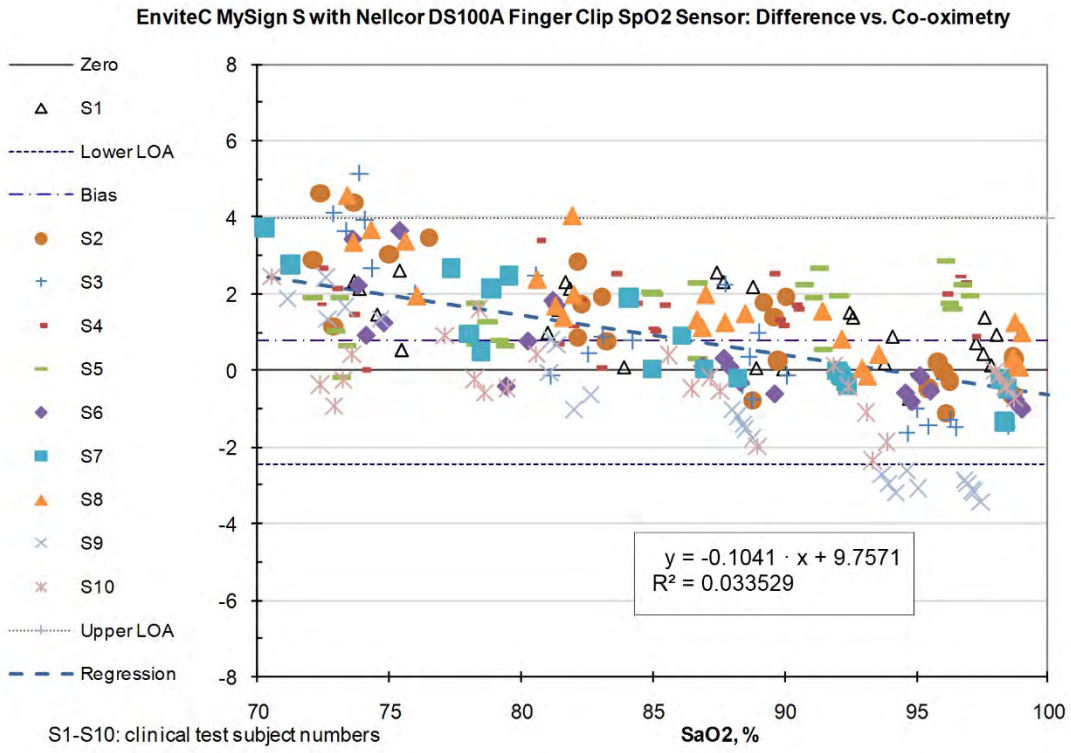
R-3212-9 SoftTip Reusable Rubber Finger Sensor



DW-2211-6 Disposable Adhesive Tape Sensor



DS100A Nellcor Finger Clip Sensor



The third party Nellcor[1] DS-100A has been validated for use on the MySign S. The DS-100A **is not manufactured by EnviteC**.

Refer to the manufacturer's DS-100A instructions for use for more information on this sensor.

[1] Nellcor is a registered trademark of Covidien Inc. (Mansfield, MA, USA)

14 Warranty

As of the purchase date, EnviteC offers a two year warranty for faults arising from material or manufacturing defects. Excepted from this are the battery and the SpO2 sensor (see the General Terms of Business).

Faults that are covered by warranty will be corrected within the framework of our warranty conditions. EnviteC offers no warranty if the operator endangers the functioning of the device through failure to heed the operating manual and technical documentation, inappropriate handling, improper use or unauthorized modifications or repair attempts. In these cases, the liability is transferred to the operator!

Transport to customer service and back for repairs not covered under warranty takes place at the customer's expense.

Please contact your dealer if you wish to make a warranty claim!

To return the unit directly to EnviteC under the warranty, you will need an RMA (Return Material Authorization) number (please always state this number in all of your correspondence!)

through our website, www.envitec.com, under Service / Returns.
Once you have obtained this number, please send the unit along with all accessories to the following address:

EnviteC-Wismar GmbH
Service
Alter Holzhafen 18
23966 Wismar, Germany
Germany

Warranty claims are only accepted on presentation of the purchase receipt!

15 Order information

Description	Part number
MySign® FDA without Sensor [1)]	1002197
Accessories	
Data cable (Mini-USB type B)	1001815
MySign® battery	1001734
MySign® power supply (Mini-USB 5 V / 1.5 A)	1001829 (optional)
MySign® holder	1001801 (optional)
MySign® S CD	1002036
MySign® software	1002080 (optional)

SpO2 sensors	Part number
SoftTip® Large R-3211-31 MySign® FDA	1002198
SoftTip® Large R-3211-12 MySign® FDA	1002199
SoftTip® Medium RM-3211-31 MySign® FDA	1002200
SoftTip® Medium RM-3211-12 MySign® FDA	1002201
SoftTip® Small RS-3211-31 MySign® FDA	1002202
SoftTip® Small RS-3211-12 MySign® FDA	1002203
FingerClip F-3211-31 MySign® FDA	1002204
FingerClip F-3211-12 MySign® FDA	1002205
Ear sensor ES-3211-31 MySign® FDA	1002206
Ear sensor ES-3211-12 MySign® FDA	1002207

SpO2 sensors with adapter cable	Part number
Extension and adapter cables X-4211-3 MySign® FDA	1002208
Extension and adapter cables X-4211-1 MySign® FDA	1002209
SoftTip® Large R-3212-9 MySign® FDA	1002210
SoftTip® Medium RM-3212-9 MySign® FDA	1002211
SoftTip® Small RS-3212-9 MySign® FDA	1002212
Ear sensor ES-3212-9 MySign® FDA	1002213
FingerClip F-3212-9 MySign® FDA	1002214
Disposable sensor DA-2211-1 MySign® FDA	1002215
Disposable sensor DP-2211-2 MySign® FDA	1002216

[1)] The power supply (Part No. 1001829) is not included and must be ordered separately if needed.

The SpO2 sensors (previous page) and SpO2 sensors with adapter cable listed above have been tested to comply with applicable emissions and immunity requirements. Representative sensors of each type were tested with the maximum cable length of 390 cm, which includes the X-4211-3 Extension and Adapter Cable maximum length of 300 cm plus the connected SpO2 sensor maximum length of 90 cm.

The use of accessories, transducers and cables other than those specified could result in increased EMC emissions or decreased EMC immunity.

16 EMC Declaration

Manufacturer`s Declaration – Electromagnetic Emissions IEC 60601-1-2
for the Equipment or System MYSIGN S

General information requirements of IEC 60601-1-2 sect. 5.2 Instructions for use:

5.2.1.1) Requirements applicable to all EQUIPMENT and SYSTEMS: Instructions for use shall include the following:

a) a statement that MEDICAL ELECTRICAL EQUIPMENT needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the ACCOMPANYING DOCUMENTS;
b) a statement that portable and mobile RF communications equipment can affect MEDICAL ELECTRICAL EQUIPMENT.

Table 1: Guidance and manufacturer`s declaration - electromagnetic emissions

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

Table 2 and 4: Guidance and manufacturer`s declaration - electromagnetic immunity

Guidance and manufacturer`s declaration electromagnetic immunity			
The MYSIGN S is intended for use in the electromagnetic environment specified below. The customer or the user of the MYSIGN S 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	**± 6 kV** contact **± 8 kV** air	**± 6 kV** contact **± 8 kV** air	If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Bursts IEC 61000-4-4	**± 2 kV** power supply lines	**± 2 kV** power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surges IEC 61000-4-5	**± 1 kV** differential mode **± 2 kV** common mode	**± 1 kV** differential mode **± 2 kV** common mode	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	**> 95 %** dip in U_T/ 0,5 cycles **60 %** dip in U_T/ 5 cycles **30 %** dip in U_T/ 25 cycles **> 95 %** dip in U_T/ 5 sec.	**> 95 %** dip in U_T/ 0,5 cycles **60 %** dip in U_T/ 5 cycles **30 %** dip in U_T/ 25 cycles **> 95 %** dip in U_T/ 5 sec.	Mains power quality should be that of a typical commercial or hospital environment. If the user of the MYSIGN S requires continued operation during power mains interruption, it is recommended that the [Equipment or System] be powered from an UPS or a battery.
magnetic field Power frequency (50/60) Hz magnetic field IEC 61000-4-8	**3 A/m**	**30 A/m**	Power frequency magnetic fields should be at levels characteristics of a typical location in a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6	**V_1 = 3 V** 150 kHz – 80 MHz	**6 V**	Portable and mobile communications equipment should be used no closer to any part of the MYSIGN S, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **$d = 0.6 \sqrt{P}$** for V1 = 6 V
Radiated RF IEC 61000-4-3	**E_1 = 3 V/m** 80 MHz – 2.5 GHz	**20 V/m**	**$d = 0.18 \sqrt{P}$** 80 MHz to 800 MHz **$d = 0.35 \sqrt{P}$** 800 MHz to 2,5 GHz Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a], should be less than the compliance level in each frequency range. Interference [b] 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 due to fixed RF transmitters, an electromagnetic side survey should be considered. If the measured field strength outside the location in which the MYSIGN S is used exceeds the compliance level, the MYSIGN S should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as relocating or using another location of the MYSIGN S.

b) Over the frequency range from 150 kHz to 80 MHz the field strength should be lower than 6 V/m.

Table 6: Recommended separation distances between portable and mobile RF communications equipment and the equipment or system – for equipment or systems that are not life-supporting

Recommended separation distances between portable and mobile RF communication equipment and the MYSIGN S			
The MYSIGN S is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the MYSIGN S can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the MYSIGN S 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 – 80 MHz $d = 0.6 \sqrt{P}$	**80 MHz – 800 MHz** $d = 0.18 \sqrt{P}$	**800 MHz – 2.5 GHz** $d = 0.35 \sqrt{P}$
0.01	0.06	0.02	0.04
0.1	0.18	0.06	0.11
1	0.58	0.18	0.35
10	1.8	0.55	1.1
100	5.8	1.8	3.5

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

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

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