

V-Sign™ Sensor 2

REF VS-A/P/N

Carbon Dioxide Tension and
Oxygen Saturation Sensor

Reusable / Nonsterile / Waterproof

Directions for Use



Introduction

SenTec's V-Sign™ Sensor 2 is intended for continuous PCO₂, SpO₂/PR monitoring. The V-Sign™ Sensor 2 provides superior performance, is robust, reliable and requires comparatively low maintenance. It combines within a patented digital sensor design the optical components needed for 2-wavelength, reflectance pulse oximetry with the components needed to measure PCO₂.

Indications/Contraindications

The V-Sign™ Sensor 2 (VS-A/P/N) is indicated for use when continuous non-invasive monitoring of carbon dioxide tension, oxygen saturation, and pulse rate are required for adult and pediatric patients. In neonatal patients the use of the V-Sign™ Sensor 2 is indicated for carbon dioxide tension monitoring only. The V-Sign™ Sensor 2 is for use only with SenTec instruments and instruments that contain SenTec monitoring technology or are licenced to use SenTec sensors (SenTec-compatible instruments).

Instructions for use

Preparation - Membrane change

The membrane and the electrolyte of the V-Sign™ Sensor must be changed regularly. The monitor requests a membrane change if required. Additionally, the membrane of the sensor must be changed if it is damaged, does not have a tight fit, or if there is trapped air or dry electrolyte under the membrane. For further information refer to the Instruction Manual for the SenTec Digital Monitoring System (SDMS), the Membrane Changer Directions for Use for detailed membrane change instructions, and the Technical Manual for the SDM or contact the manufacturer of the instrument.

Preparation - Calibration

The PCO₂ segment of the V-Sign™ Sensor 2 must be calibrated regularly. The monitor requests a sensor calibration if required. Between monitoring it is recommended to store the sensor in the docking station. This will ensure that the sensor is ready for use, as the sensor will automatically be calibrated as needed. For further information refer to the Instruction Manual for the SDMS and the Technical Manual for the SDM or contact the manufacturer of the instrument.

Patient Application of the V-Sign™ Sensor

The choice of the sensor attachment accessory depends on the patient's age, the parameters to be measured and the skin condition at the measurement site. For additional information and detailed sensor application directions please refer to the Instruction Manual for the SDMS or the Quick Reference Guide of the SDMS or - in case of use with a SenTec-compatible instrument - to the instrument's manual or contact the manufacturer of the instrument.

Warning: The measurement of SpO₂ and PR with SenTec TC Sensors is only defined on sites specified by the manufacturer (refer to the instrument's manual). In order to avoid erroneous readings and false alarms of SpO₂ and PR, ensure that the appropriate patient type (Adult) is selected. Ensure to disable the parameters SpO₂/PR for sensor application on other measurement sites.

Warning: The use of temperatures higher than 41°C requires special attention to patients with susceptible skin, e.g. neonates, geriatric patients, burn victims, patients with skin diseases.

CAUTION: A flat, well-perfused area of intact skin is needed (centrally located sites are preferable). Avoid placement over large superficial veins or areas of skin breakdown or edema.

Cleaning and Disinfection

CAUTION: The use of other cleaning and disinfection procedures other than those recommended here may result in permanent damage to the sensor.

CAUTION: Do not remove the membrane of the sensor for cleaning and disinfection.

CAUTION: Wiping and/or the application of mechanical force in general can damage the sensor membrane or the sensor cable mechanically. Wipe the sensor carefully and inspect the condition of the membrane and sensor cable after cleaning and/or disinfection.

The V-Sign™ Sensor 2 must be cleaned before inserting it into the docking station in order to remove any gel residues or other soils such as blood, protein, or mucous that could contaminate the docking station, cause cross-infections between different patients and/or gas leakage during calibration.

In order to remove all foreign substances, the sensor should be cleaned prior disinfection.

Important: The cleaning and disinfection solutions listed here have been tested for their suitability for the V-Sign™ Sensor. The below listed name brand products for cleaning and disinfection may be substituted by other name brand products of equivalent composition. However, as there are many factors (contact time, force applied during wiping etc.) that can influence the functionality of the sensor, it is the responsibility of the user to test the functionality of the sensor after cleaning and/or disinfection. SenTec recommends using 70% Isopropanol.

Table 1: Low Level Disinfection	
Brand name/ manufacturer	Cleaning procedure
WEBCOL Alcohol Prep Pads (Kendal); 70% Isopropanol	Carefully wipe all SenTec TC Sensor surfaces and the cable with alcohol wipes and allow to dry.
Mikrozid (Schülke Mayr) pre-soaked wipes; 25% Ethanol, 35% Isopropanol	
Kodan® forte (Schülke&Mayr); 45,0 g 2-Propanol, 10,0 g 1-Propanol, 0,20 g Biphenyl-2-ol, 30% H2O2	Carefully wipe all surfaces of the SenTec TC Sensor and the cable with wipes soaked Kodan forte. Wait 5 min. Remove all Kodan forte residues using 70% Isopropanol. Allow to dry.
Gigasept® AF (Schülke&Mayr); 15 g Didecylidimethylammoniumchlorid, 10 g Phenoxypropanole, 6,9 g Aminoalkylglycine; 15 – 30% non-ionic tensides.	Carefully wipe all surfaces of the SenTec TC Sensor and the cable with wipes soaked in 4% solution (e.g. 960 ml deionized water plus 40 ml Gigasept AF). Note that the 4% dilution has a shelf-life of 7 days. Wait 15 min. Remove all Gigasept residues using 70% Isopropanol. Allow to dry.

Terralin Protect (Schülke&Mayr) 22 g Quaternäre Ammoniumverbindungen, Benzyl-C12-16-alkyldimethyl-, Chloride, 17 g 2-Phenoxyethanol, 0,9 g Aminoalkylglycine, 5 – 15% non-ionic tensides.	Carefully wipe all SenTec TC surfaces and the cable with wipes soaked in 2% solution (e.g. 980 ml deionized water plus 20 ml Terralin Protect). Wait 15 min. Remove all Terralin residues using 70% Isopropanol. Allow to dry.
Prevantics™ Device Swab (PDI); 3.15% Chlorhexidine Glucuronate (w/v) and 70% Isopropyl Alcohol (v/v)	Carefully wipe all SenTec TC Sensor surfaces and the cable with the pre-soaked PDI wipe for 5 seconds. Let dry for 5 seconds. Remove all PDI residues using 70% Isopropanol. Allow to dry.
Sanoclean AR (Sanosil); 1.5% Hydrogen Peroxide (0.003% Silver)	Carefully wipe all SenTec TC Sensor surfaces and the cable with wipes soaked in Sanoclean AR (note: the commercial solution is ready to use, no further dilution required), Wait 15 minutes. Remove all Sanoclean residues using 70% Isopropanol. Allow to dry.
Dismozon plus (Bode Chemie); Magnesium Monoperoxyphthalat 958 mg/g	Carefully wipe all SenTec TC Sensor surfaces and the cable with wipes soaked in 3.6% solution (e.g. 36g of Dismozon granulate per liter of deionized water). Note: The diluted solution has a shelf-life of 8h. Wait 15 min. Remove all Dismozon residues using 70% Isopropanol. Allow to dry.
Microbac Forte (Bode Chemie); 20% Benzyl-C12-18-alkyldimethylammoniumchloride; 5% N-(3-Aminopropyl)-N-dodecylpropan-1,3-diamin	Carefully wipe all SenTec TC surfaces and the cable with wipes soaked in 2% solution (e.g. 980 ml deionized water plus 20 ml Microbac Forte). Wait 15 min. Remove all Microbac Forte residues using 70% Isopropanol. Allow to dry.
Super Sani Cloth (PDI); 0.25% n-alkyl dimethyl ethylbenzyl ammonium chlorides 0.25% n-alkyl dimethyl benzyl ammonium chlorides	Carefully wipe all SenTec TC Sensor surfaces and the cable with the pre-soaked PDI wipe. Wait 2 minutes. Remove all PDI residues using 70% Isopropanol. Allow to dry. CAUTION: This cleang agent is potentially aggressive to the skin. Thus, sensor membrane must be changed after cleaning to ensure optimal skin compatibility.
CaviCide or CaviWipe (METREX® RESEARCH CORPORATION) 0.28% Diisobutyl-phenoxyethoxyethyl dimethyl benzyl ammonium chloride; Isopropanol	Spray CaviCide or CaviWipe directly onto the sensor/cable surface. Allow surface to remain visibly wet for 3 minutes. Remove all CaviCide or CaviWipe residues using 70% Isopropanol. Allow to dry. CAUTION: This cleang agent is potentially aggressive to the skin. Thus, sensor membrane must be changed after cleaning to ensure optimal skin compatibility.

Table 2: High Level Disinfection	
Brand name/ manufacturer	Cleaning procedure
Cidex OPA (J&J) (*); 0.55% ortho-Phthalaldehyde Note: Requires pre-cleaning using an enzymatic cleaner: ENZOL (J&J) or Prolystica (Steris); Subtilisin	First, remove debris using an enzymatic detergent: Soak the Sensor and the desired length of cable in enzymatic solution for 5 minutes. Rinse the sensor and the cable briefly in deionized water. Blot dry carefully. Soak the Sensor and the desired length of cable in CIDEX OPA solution for 12 minutes. Soak the SenTec TC Sensor and the desired length of cable 3x for 2 minutes in sterile or deionized water (renew after each soaking cycle). Carefully wipe all surfaces of the SenTec TC Sensor and cable with 70% Isopropanol. Allow to dry. CAUTION: Sensor membrane must be changed after cleaning to ensure optimal sensor monitoring performance.

Sani Cloth Bleach (PDI); Sodium Hypochloride 0.63% Approx. 6000 ppm available free chlorine	Carefully wipe all SenTec TC Sensor surfaces and the cable with the pre-soaked PDI wipe. Wait 4 minutes Remove all PDI residues using 70% Isopropanol. Allow to dry.
Clorox Healthcare Bleach Germicidal Wipes ; 5500 ppm Sodium Hypochloride	⚠ CAUTION: Do not use bleach cleaners on sensor surfaces without or with defect membrane. This may damage the PCO ₂ unit. ⚠ CAUTION: Bleach is potentially aggressive to the skin. Thus, sensor membrane must be changed after cleaning to ensure optimal skin compatibility.
Mikrozid® PAA wipes (Schülke & Mayr); 0.07% Per-Acetic acid; Hydrogen Peroxide, Acetic acid	Carefully wipe all SenTec TC Sensor surfaces and the cable with the pre-soaked Mikrozid PAA wipes. Wait 15 min. Remove all Mikrozid PAA residues using 70% Isopropanol. Allow to dry.

Applying force, e.g. during wiping, can damage the sensor cable and sensor membrane mechanically. After cleaning, verify that the membrane is not damaged and that there are no air bubbles between membrane and sensor surface. The membrane ring must be securely seated on the sensor. In case of damages, trapped air or loose fit the membrane must be changed. Do not use the sensor if there is any visible damage.

Important: Always calibrate the sensor after cleaning and/or disinfection.

Note: For further information please refer to the Instruction Manual for the SDMS or contact the manufacturer of the instrument.

Compatibility of V-Sign™ Sensor 2 with different instruments

Before starting a measurement, please check the sensor's compatibility with the connected instrument.

Connnection to SDM: The V-Sign™ Sensor 2 requires firmware versions SMB V07.00.4 and MPB V05.00.06 or newer. The SMB and MPB version of the monitor may be found in the SDM menu "System Information". Please contact your local SenTec representative for firmware upgrade information.

Other SenTec-compatible instruments: Consult individual manufacturers for compatibility of particular instruments and sensor models. Each manufacturer of SenTec-compatible instruments is responsible for determining whether and under what conditions its instruments are compatible for safe and effective use with each SenTec sensor model. This may include different specifications and/or warnings, cautions, or contraindications. Refer to the instrument's manual or consult manufacturer for complete instructions for use of this sensor with their SenTec-compatible instrument.

Accuracy

For accuracy specifications of the V-Sign™ Sensor 2 when used with SenTec monitors refer to the Technical Specifications in the Technical Manual of the SenTec Digital Monitor. For accuracy specifications of the V-Sign™ Sensor 2 when used with SenTec-compatible instruments refer to the instrument's manual or contact the instrument manufacturer.

Useful life

Under normal wear and tear the expected life time of the V-Sign™ Sensor is typically 18 months.

WARNINGS

- Sensors are designed for use with specific monitors. The user and/or operator must verify the compatibility of the monitor, sensor, and cables before use or

- patient injury may result.
- Failure to handle/apply the V-Sign™ Sensor 2 properly may cause inaccurate measurements.
- Keep the V-Sign™ Sensor 2 (as well as any discarded parts) out of reach of children under the age of 5 years. The sensor is small enough to be swallowed and may block the trachea.
- Ensure that the V-Sign™ Sensor 2 is physically intact, with no broken or damaged parts. Discontinue use immediately if any defects are noted.
- Do not touch the V-Sign™ Sensor 2 membrane with any sharp-edged objects or your fingernails. Damage of the sensor membrane will cause inaccurate measurements.
- Do not alter or modify the V-Sign™ Sensor 2.
- To ensure accurate data verify that the sensing elements on the V-Sign™ Sensor 2 membrane-face are completely covered by the measurement site.
- Carefully route and fix sensor cables to reduce the possibility of patient entanglement or strangulation.
- Do not use the V-Sign™ Sensor 2 during MRI scanning. Conducted current may cause burns. Also, the V-Sign™ Sensor 2 may affect the MRI image, and the MRI unit may affect the accuracy of oximetry measurements.
- The sensor can be kept on the patient during defibrillation, burns are possible under very rare circumstances.
- Physically separate the sensor and cables from electro-surgical equipment during electro-surgery. Do not place the sensor between cutting and counter electrode.
- Any change in cutaneous PcoCO₂ may be due to either a change in arterial PCO₂, or due to a change in skin blood flow under the V-Sign™ Sensor 2. Cutaneous PcoCO₂ only reflects arterial PCO₂ at relatively high local blood flow.
- Do not expose the V-Sign™ Sensor 2 to strong ambient light such as direct sunlight, surgical lamps, infrared warming lamps, and phototherapy lights during clinical use. This may cause inaccurate measurements. In such cases, cover the sensor with an opaque material.
- Excessive motion may compromise the performance of the V-Sign™ Sensor 2.
- SpO₂ readings may be falsely low in the presence of tricuspid valve insufficiency (mixture of arterial and venous values) due to retrograde venous pulsations.
- The pulsations from intra-aortic balloon support can be additive to the pulse rate on the oximeter pulse rate display. Verify pulse rate against ECG heart rate.
- Intravascular dyes may lead to inaccurate SpO₂ measurements.
- Elevated levels of Methemoglobin (MetHb) and/or Carboxyhemoglobin (COHb) will lead to inaccurate SpO₂ measurements.
- Furthermore, the following situations may result in reduced accuracy of the V-Sign™ Sensor 2 readings: dysfunctional hemoglobins, anemia, intravascular dyes, low perfusion at the measurement site, venous pulsations, certain cardiovascular pathologies, skin pigmentation, externally applied coloring agents, prolonged and/or excessive patient movement, exposure of the sensor to high ambient light levels, defibrillation.
- Ensure to select the upper alarm limit for SpO₂ carefully and in accord with accepted clinical standards. High oxygen levels may predispose a premature infant to develop retinopathy.
- Always apply sensor on intact and dosed skin sites. Pierced earlobes may result in incorrect tPCO₂ measurements. Do not apply to injured skin. Avoid placement over large superficial veins.
- After observation of any skin irritations, do not apply the V-Sign™ Sensor 2 to the same measurement site. Unless the patient's local skin perfusion and physiological condition improved significantly do not apply the sensor to any other measurement site.
- The recommended/ default application duration per measurement site (site time) is 8 hours but longer site times are possible (up to 12 hours). Refer to the Technical Manual for the SDM (when used with SenTec-compatible instruments refer to the instrument's manual) for further information. Exercise extreme caution and assess the measurement site at least every 2 hours with poorly

- perfused patients.
- Regularly inspect the sensor. Do not use the sensor if there is any visible damage to the sensor housing, sensor membrane, sensor cable or if the color of the ring around the glass electrode has a metallic luster. Change the sensor membrane if it is damaged or missing, has a loose fit, or if there is trapped air or dry electrolyte under the membrane.
- Check disposables monthly and replace any expired products.
- For additional warnings, cautions and/or contraindications when using the V-Sign™ Sensor 2 with SenTec-compatible instruments, refer to the instrument's manual or contact the instrument manufacturer.

CAUTIONS

- Federal law (U.S.) restricts this device to sale by or on the order of a physician.
- WEEE Disposal: European consumers are obliged by law to dispose Waste Electrical and Electronic Equipment (WEEE) according to the WEEE Directive: 1. All electrical and electronic waste must be stored, collected, treated, recycled and disposed of separately from other waste. 2. Consumers are obliged by law to return electrical and electronic devices at the end of their service lives to the public collection points set up for this purpose or point of sale. Details to this are defined by the national law of the respective country. Note: By recycling materials or other forms of utilizing old devices, you are making an important contribution to protecting our environment.
- Druing transport: store sensor with membrane and protected from light/radiation.
- Do not clean the sensor in an ultrasonic cleaner.
- Do not immerse the connector of the sensor cable in any liquid solution.
- Do not sterilize any parts of the sensor by irradiation, steam, ethylene oxide, plasma or autoclav method.
- Always clean the sensor surface before insertion into the docking station or the Membrane Changer.
- Avoid bending and tearing the sensor cable or the application of any other mechanical force (e.g. during cleaning), mechanical damage could result.

Warranty

To obtain information about a warranty (and warranty exclusions), if any, for this product, contact SenTec AG, your local SenTec representative or the manufacturer or the manufacturer's local representative of the SenTec-compatible instrument.

Patents/Trademarks/Copyright

International Industrial Design No. DM/054179, Japanese Design No. 1137696, U.S. Design Patent No. D483488, Canadian Patent No. 2466105, European Patent No. 1335666, German Patent No. 50111822.5-08, Spanish Patent No. 2278818, Hongkong Patent No. HK1059553, U.S. Patent No. 6760610, Chinese Patent No. ZL02829715.6, European Patent No. 1535055, German Patent No. 50213115.2, Spanish Patent No. 2316584, Indian Patent No. 201300, Japanese Patent No. 4344691, U.S. Patent No. 7862698, SenTec™, V-Sign™, OxVent™, V-STATS™, V-CareNet™, V-Check™, Staysite™, Advancing Noninvasive Patient Monitoring™ and Illuminate Ventilation™ are trademarks of SenTec AG / © 2019 SenTec AG. All rights reserved. The contents of this document may not be reproduced in any form or communicated to any third party without the prior written consent of SenTec AG. While every effort is made to ensure the correctness of the information provided in this document, SenTec AG assumes no responsibility for errors or omissions. This document is subject to change without notice.