Intended Use, Principles of Operation and Limitations

Intended Use of the SenTec Digital Monitoring System (SDMS)

The SenTec Digital Monitoring System (SDMS) – consisting of the SenTec Digital Monitor (SDM), sensors and accessories (p. 10) – is indicated for continuous, noninvasive monitoring of carbon dioxide tension and oxygen tension as well as oxygen saturation and pulse rate in adult and pediatric patients. In neonatal patients the SDMS is indicated for carbon dioxide and oxygen tension monitoring only. Oxygen tension monitoring is contraindicated for patients under gas anesthesia.
The SDMS is indicated for use in clinical and non-clinical settings such as hospitals, hospital-type facilities, intra-hospital transport environments, clinics, physician offices, ambulatory surgery centers and – if under clinical supervision – home environments. The SDMS is for prescription use only.

Note: The above phrasing corresponds to an abbreviated version of the SDMS' Intended Use. Please refer to the current issue of the Technical Manual for the SDM (HB-005752) for the full phrasing of the SDMS' Intended Use.

Transcutaneous PCO_2 and PO_2

Principles of Operations of tcPCO_2 and tcPO_2

Carbon dioxide (CO_2) and Oxygen (O_2) are gases that readily diffuse through body and skin tissue and, therefore, can be measured by an adequate noninvasive sensor being applied at the skin surface. If the skin tissue beneath the sensor site is warmed up to a constant temperature local capillary blood flow increases, metabolism stabilizes, gas diffusion improves and, hence, reproducibility and accuracy of CO_2/O_2 measurements at the skin surface improves.

CO_2 tensions measured at the skin surface ($PcCO_2$) are usually consistently higher than arterial PCO_2 values ($PaCO_2$) in patients of all ages. It is therefore possible to estimate $PaCO_2$ from the measured $PcCO_2$ using an adequate algorithm. $TcPCO_2$ designates an estimate of $PaCO_2$ calculated from the measured $PcCO_2$ with an algorithm developed by J.W. Severinghaus. The 'Severinghaus Equation' first corrects $PcCO_2$ measured at the sensor temperature (T) to 37 °C by using an anaerobic temperature factor (A) and then subtracts an estimate of the local 'Metabolic Offset' (M).

Note: Hence, the $tcPCO_2$ values displayed by the SDM are corrected/normalized to 37 °C and provide an estimate of $PaCO_2$ at 37 °C. On the SDM and throughout this manual (unless explicitly stated otherwise) '$tcPCO_2$' is displayed/labeled as 'PCO_2'.

In newborns PO_2 measured at the skin surface (PcO_2) correlates with arterial PO_2 (PaO_2) almost in a one to one relationship at a sensor temperature of 43 to 44 °C, whereby the accuracy of PcO_2 compared to PaO_2 is best up to PaO_2 of 80 mmHg (10.67 kPa), above which it increasingly tends to read lower than PaO_2 (especially in adults).

As target PaO_2 levels in newborns are usually below 90 mmHg (12 kPa), a correction of PcO_2 values measured at a sensor temperature of 43 to 44 °C is normally not necessary. $TcPO_2$ designates an estimate of PaO_2 and corresponds to the measured PcO_2. The recommended (and default) 'Sensor Temperature' and 'Site Time' for SenTec TC Sensors depend on the selected patient type and the enabled parameters and are summarized in the following table:

Patient Type	PO_2 enabled	Recommended Sensor Temperature [°C]	Recommended Site Time [hrs]
Neonatal (if younger than term birth + 12 months)	No	41.0	8.0
	Yes	43.0	2.0
Adult/ Pediatric	No	42.0	8.0
	Yes	44.0	2.0

Note: On the SDM and throughout this manual (unless explicitly stated otherwise) '$tcPO_2$' is displayed/labeled as 'PO_2'.

Good to know!
Warming the skin tissue beneath the sensor to a constant temperature improves accuracy as it a) increases capillary blood flow/induces local arterialization, b) stabilizes metabolism, and c) improves gas diffusion through skin tissue. With increasing sensor temperature the application duration ('Site Time') must be evaluated carefully and adjusted accordingly to reduce the risk of burns. Special attention must be given to patients with sensitive skin at the sensor site (p. 20).

Please refer to Technical Manual for the SDM (HB-005752) and the references cited therein for additional information on transcutaneous blood gas monitoring.

Limitations of $tcPCO_2$ and $tcPO_2$

The following clinical situations or factors may limit the correlation between transcutaneous and arterial blood gas tensions:

- Hypo-perfused skin tissue beneath the sensor site due to low cardiac index, circulatory centralization (shock), hypothermia (e.g. during surgery), use of vasoactive drugs, arterial occlusive diseases, mechanical pressure exercised on measurement site, or inadequate (too low) sensor temperature.
- Arterio-venous shunts, e.g. ductus arteriosus (PO_2 specific).
- Hyperoxemia (PaO_2 > 100 mmHg (13.3 kPa)) (PO_2 specific).
- Inadequate measurement site (placement over large superficial veins, on areas with skin edema (e.g. oedema neonatorum), skin breakdown, and other skin anomalies).