

TCM5 FLEX monitor Specifications

Hardware

Display

Screen: 9" color, capacitive, multi-touch TFT, 800 x 480 pixels, 16:9 ratio Display options: trend view, detail view Screen update rates: Numeric data values (SpO₂, pulse rate, tc*p*CO₂, tc*p*O₂, heating power): 1/sec Trend data range (depends on time axis scale): 1 pixel / 2 sec to 1 pixel / 96 sec Viewing angle adjustment: -10° / 0° / +8°

Operating conditions

Ambient temperature: 5-40 °C (41 - 107 °F) Relative humidity: up to 90 %, non-condensing Atmospheric pressure: 525 - 800 mmHg (700 - 1060 hPa) Built-in barometer: Range: 375-825 mmHg or 50-110 kPa Accuracy: ±5 mmHg or 0.67 kPa Power: 100-240 V, 50-60 Hz, 55-85 VA (max.) Rechargeable Lithium Ion battery, Type RRC2040 Typical operating time: 4 hours per charge at 25 °C

Dimensions

TCM5 monitor

270 mm
152 mm
188 mm
2.5 kg, 2.3 kg (without battery)

Software

Measuring range

Transcutaneous carbon dioxide tension/tcpCO₂: 5-200 mmHg or 0.7-26.7 kPa Transcutaneous oxygen tension/tcpO₂: 0-800 mmHg or 0.0-99.9 kPa Oxygen saturation/SpO₂: 0-100 % (70-100 % with ±3 digits) Pulse rate: 25-240 bpm

Calibration

Automatic calibration Calibration gas: CO₂: 7.5%, O₂: 12% , N: 80.5% Integrated calibration chamber Maximum interval between two calibrations is set to 12 hours.

Patient data storage

Up to 1 year of measuring data in 1-sec data intervals Download of stored patient data to USB storage

Connectivity

Network connection: Ethernet 10/100 Base-T full duplex USB: 3x USB 2.0 (1x side, 2x rear), Type-A (USB 1.1 compatible) Isolated serial output: USB 2.0, Type-B (USB 1.1 compatible) & RS 232 Isolated Nurse call output: relay contact normally open (calling, closed, not calling, opened), 60V, 2.5A Isolated analog output: 0-1000 mV Data protocol: MonLink (2.0, TCM4 series, TOSCA500, MicroGas 7650)

Interface with third-party products

Polysomnographs: Alice 5/6, Embla, Embletta Gold and other. Patient monitoring systems: Philips, General Electric (GE), Mindray Mounting system: compatible to GCX mounting system USB storage: Data export

Site timer

Indication of remaining measuring time Measuring time elapsed: clock triggers an alarm (and sensor temperature is off after 15 min)

Alarm level

OFF, 1-10 (1 is minimum) OFF: only available in Sleep mode

Languages

English, French, German, Czech, Danish, Dutch, Estonian, Finnish, Hungarian, Italian, Japanese, Lithuanian, Chinese, Norwegian, Polish, Portuguese, Romanian, Russian, Slovak, Spanish, Swedish, Turkish

tc Sensor 92, tc Sensor 84 and tc Sensor 54

Sensor performance (in vitro)

tc Sensor 92

Measurement principle:

Stow-Severinghaus-type tcpCO_2 sensor combined with Masimo SET $\ensuremath{^{\otimes}}$ SpO_2 pulse oximetry

Conditions: sensor temperature of 43.0 °C, calibration interval: 12 h

tcpCO₂:

Accuracy: (5-200 mmHg): \pm 5 mmHg Response time: (0-90%): \leq 70 sec Drift: \leq 0.5%/h Linearity: at 1 and 10% CO₂: better than 1 mmHg or 0.13 kPa at 33% CO₂: better than 5 mmHg or 0.67 kPa

SpO₂:

Accuracy: (70-100%): ± 3 digits

Pulse rate:

Accuracy: (25-240 bpm) \pm 3 bpm SpO₂ and pulse rate: signal averaging 2, 4, 8, 10, 12, 14 and 16 sec Data update rate: 1 per second

tc Sensor 54

Measurement principle:

Stow-Severinghaus-type tcpCO₂ sensor

Conditions: sensor temperature of 43.0 °C, calibration interval: 12 h

tcpCO₂: Accuracy: (5-200 mmHg): \pm 5 mmHg Response time: (0-90%): ≤ 70 sec Drift: ≤ 0,5%/h Linearity: at 1 and 10% CO₂: better than 1 mmHg or 0.13 kPa at 33% CO₂: better than 3 mmHg or 0.40 kPa

Interference by anesthetic gases (in vitro)

tcpCO₂:

75% N₂O, 2% Halothane, 2% Enflurane, 2% Isoflurane, 2% Desflurane, 2% Sevoflurane: negligible

Sensor dimensions

Diameter: 15 mm or 0.6 in Height: 8 mm or 0.3 in Weight: 3 g or 0.1 oz Sensor cable length: 3 m or 9.8 ft, shielded, flexible, polyurethane coated

Compliance

The TCM5 monitor complies with the following standards: IEC 60601-1 (general safety), IEC 60601-1-2 (EMC), IEC 60601-1-6 (usability),

IEC 60601-1-8 (alarms), IEC 60601-2-23 (transcutaneous monitors), ISO 80601-2-61 (pulse oximeters), ISO 14971 (Risk Management), IEC 62366 (usability engineering) IEC 62304 (Software in medical devices), ISO 10993-1 (biocompatibility), EN1041 (information supplied by manufacturers), ISO 15223-1 (Symbols).

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tc Sensor 84

Measurement principle:

Stow-Severinghaus-type tcpCO2 sensor combined with Clark-type tcpO2 sensor

Conditions: sensor temperature of 43.0 °C, calibration interval: 12 h

tcpCO₂:

Accuracy: (5-200 mmHg): \pm 5mmHg Response time: (0-90%): \leq 70 sec Drift: \leq 1%/h Linearity: at 1 and 10% CO₂: better than 1 mmHg or 0.13 kPa, at 33% CO₂: better than 5 mmHg or 0.67 kPa

tcpO₂:

Accuracy: $(0-20.9 \% O_2): \pm 5 \text{ mmHg}$ (20.9-100 % $O_2): \pm 10 \%$ Response time: $(0-90\%): \le 25 \text{ sec}$ Drift: $\le 1\%/h$ Linearity: at 0% O_2 : better than 1 mmHg or 0.13 kPa at 20.9% O_2 : better than 3 mmHg or 0.4 kPa at 50% O_2 : better than 5 mmHg or 0.67 kPa at 90% O_2 : better than 25 mmHg or 3.33 kPa

tcpO₂:

 $75\%~N_2O{:}{<}10~mmHg~or~1.33~kPa$ 2% Halothane: approx. 200 mmHg or 26.67 kPa 2% Enflurane, 2% Isoflurane, 2% Desflurane, 2% Sevoflurane: negligible

Biocompatibility

Not made with natural rubber latex.

This product complies with the requirements of the Medical Device Directive 93/42/EEC.

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