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# Additional information

## Patient safety
The instruments comply with IEC 60601-1:1988, IEC 60601-1-2:2001, IEC 60601-2-23:1999.
The following test house has approved the instrument: CSA in Canada according to CAN/CSA-C22.2 No. 601.1-M90, 601.1S1-94, 601.1B-98, and UL std. No. 601.2.23-98 and 60601-1.

Type BF equipment (body floating) 

CE
This product complies with the requirements of the Medical Device Directive 93/42/EEC June 1993 (Class IIa).

## EMC
This product complies with the requirements of the harmonized standard EN60601-1-2:2001, “Collateral standard: Electromagnetic compatibility – requirements and test”.

## EMC emission
EN55011:1998, level A.

## EMC immunity
As stated in EN60601-1-2:2001, the immunity has been tested according to the IEC 61000 series.
(See also IEC 60601-2-23:1999).

## Performance
This product complies with the IEC 60601-2-23:1999.

## Materials
All materials are latex-free.

## Languages
Danish, Dutch, English, French, German, Greek, Italian, Japanese, Portuguese, Russian, Spanish and Swedish.

## Make the most of transcutaneous monitoring
For more information on Radiometer’s transcutaneous monitors and support services, visit www.radiometer.com/tc.

For more clinical information on transcutaneous monitoring, visit www.bloodgas.org.

## Sales companies:

| *Country:* | *Radiometer representative:* | *Telephone:* | *E-mail:* | *Website:* |
|---|---|---|---|---|
| Australia: | Radiometer Pacific Pty. Ltd. | (+61) 3 9259 2222 | sales@radiometer.com.au | www.radiometer.com.au |
| Canada: | Radiometer Canada | (+1) 877 414 0447 (toll free) | info@radiometercanada.com | www.radiometer.ca |
| China: | Radiometer China | (+86) 21 6128 6466 | pol@radiometer.com.cn | www.radiometer.cn |
| Denmark: | Radiometer Danmark | (+45) 38 27 28 29 | rdan@radiometer.dk | www.radiometer.dk |
| France: | Radiometer S.A.S. | (+33) 1 49 44 35 50 | marketing@radiometer.fr | www.radiometer.fr |
| Germany: | Radiometer GmbH | (+49) 2154 8180 | info@radiometer.de | www.radiometer.de |
| Ireland: | Radiometer Ireland Ltd. | (+353) 1 888 3611 | sales@radiometer.ie | www.radiometer.ie |
| Japan: | Radiometer K.K. | (+81) 3 5777 3500 | salesdep@radiometer.co.jp | www.radiometer.co.jp |
| The Netherlands: | Radiometer Nederland BV | (+31) 79 361 4593 | info@radiometer.nl | www.radiometer.nl |
| New Zealand: | Radiometer New Zealand | (+64) 9 574 1400 | sales@radiometer.co.nz | www.radiometer.co.nz |
| Poland: | Radiometer Sp. z o. o. | (+48) 22 518 02 40 | info@radiometer.pl | www.radiometer.pl |
| Portugal: | Radiometer Ibérica, S.A. | (+351) 214 12 39 70 | rapor@radiometer.es | www.radiometer.pt |
| Spain: | Radiometer Ibérica, S.A. | (+34) 91 655 99 50 | resp@radiometer.es | www.radiometer.es |
| Switzerland: | Radiometer GmbH | (+41) 44 723 38 60 | info@radiometer.ch | www.radiometer.ch |
| United Kingdom: | Radiometer Ltd. | (+44) 1293 517 599 | sales@radiometer.co.uk | www.radiometer.com |
| USA: | Radiometer America Inc. | (+1) 800 736 0600 (toll free) | info@radiometeramerica.com | www.radiometeramerica.com |
| Other countries: | Radiometer International Sales Division | (+45) 38 27 38 27 | isd@radiometer.dk | www.radiometer.com |



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# TCM400
# Specifications

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# Parameter configuration

| Type | Parameters | Units | Ranges |
|---|---|---|---|
| Measured | | | |
| Transcutaneous oxygen tension | tc$pO_2$ | mmHg<br>kPa | 0-2000<br>0-266.7 |
| Electrode heating | Power | mW | 10-650 |
| Calculated | | | |
| Regional Perfusion Index | RPI | - | 0-3 |

# Monitor data

| | |
|---|---|
| Display options: | Normal view (numeric), Trend table view, Trend curve view |
| Display update: | Every 2 sec. |
| Print reports: | Trend table, Trend curve |
| Barometer: | 375-825 mmHg, 50-110 kPa |
| Calibration: | Ambient air or calibration gas |
| Start-up time: | Max. 1 min. |
| Time: | Date, Clock |
| Timer: | Range: 0-99 hours, increments: 1 sec/1 min |

## Power requirements

| | |
|---|---|
| Voltage: | 90-264 VAC |
| Frequency range: | 47-63 Hz |
| Power consumption: | 70 VA (max.) |

## Monitor battery

| | |
|---|---|
| Type: | Rechargeable Pb battery |
| Duty period: | 1 hour typical per charge at 25 °C |
| Recharging time: | Approx. 8 hours at 25 °C |

## Sensor temperature settings

| | |
|---|---|
| Setting: | 37-45 °C |
| Increments: | 0.5 °C |
| Accuracy: | ± 0.1 °C (excluding sensor) |

# Dimensions

## Monitor and module dimensions

| | Monitor | | $O_2$ Module | |
|---|---|---|---|---|
| Height: | 16 cm | 6.3“ | 3.5 cm | 1.4” |
| Width: | 30.8 cm | 12.1“ | 14.5 cm | 5.7” |
| Depth: | 23 cm | 9.1“ | 14.8 cm | 5.8” |
| Weight: | 4 kg | 8.8 lbs | 0.22 kg | 0.5 lbs |

## Electrode dimensions (E5250)

| | | |
|---|---|---|
| Diameter: | Ø 15 mm | 0.6” |
| Height: | 11.3 mm | 0.44” |
| Weight: | 2.9 g | 0.1 oz |

# IT solution

## Computer specifications

6½" TFT, full VGA (640 x 480) color touch screen
AMD Geode GX1, 300 MHz (Pentium Class)
Windows CE 4.2
64 MB RAM
48 hours' storage of measuring data

## Interface possibilities

| | |
|---|---|
| Serial line: | EIA232, (RS232) |
| Printer output: | USB 1.0, HP PCL3 or higher |

# Sensor specifications

## E5250

| | |
|---|---|
| $O_2$ cathode: | 25 µm Platinum |
| $O_2$ anode (reference): | Silver |
| Measuring principle: | Transcutaneous Clark-type $O_2$ electrode |

# Sensor performance (at 43 °C)

## E5250

| | |
|---|---|
| Response time $pO_2$: | < 11 sec (10 % to 90 % response) |
| Max. drift per hour: | < 1.0 % |
| Linearity at 0 % $O_2$: | Better than 1 mmHg |
| Linearity at 90 % $O_2$: | Better than 25 mmHg (equal to 4 %) |

# Accessories

## Fixation rings (904-891)

| | |
|---|---|
| Diameter: | 30 mm |
| Adhesive material: | Medical grade Acrylic adhesive |
| Ring material: | PVC |
| Contact solution: | 1.2-propanediol and deionized water |

## Membranes (904-308)

| | |
|---|---|
| Membrane material: | PP membranes |
| Electrolyte solution: | 1.2-propanediol, potassium chloride, sodium hydrogen carbonate and deionized water |

## TCC3 calibration unit (optional)

| | | |
|---|---|---|
| Height: | 8 cm | 3.15" |
| Width: | 12 cm | 4.7" |
| Depth: | 23 cm | 9.0" |
| Weight: | 1.9 kg | 4.2 lbs |

| | |
|---|---|
| Calibration: | 1-point |
| Calibration gas: | 5 % $CO_2$ and 20.9 % $O_2$, balance $N_2$ |
| Gas flow: | 8 mL/min ±2 mL/min |
| Automatic shut-off: | After 5, 10, 15, 20, 50 minutes, as desired |
| Battery type: | 1.5 Alkaline, IEC type LR6 |