

FeNO measuring system

Vivatmo pro

FEATURES

| Handheld | |
|---|---|
| Measuring range | 5 ppb to 300 ppb |
| Linearity | $r^2 \geq 0.99$, slope 1.00 ± 0.05 , intercept ± 5 ppb |
| Accuracy for 10 seconds measurement mode | ± 5 ppb for < 50 ppb, $\pm 10\%$ for ≥ 50 ppb, $\pm 15\%$ for ≥ 160 ppb expressed as the upper/lower confidence limit of 95 % |
| Precision for 10 seconds measurement mode | ± 5 ppb for < 50 ppb, $\pm 10\%$ for ≥ 50 ppb, $\pm 15\%$ for ≥ 160 ppb expressed as 1 SD for replicate measurements with the same instrument |
| Lifetime | At least 5,000 measurement trials calibration-free |
| Memory capacity | 1,000 measurements on handheld. All measurements stored on basestation. |
| 6 seconds measurement mode | For children ages 7 - 11 years old who are not able to complete a 10 second measurement mode |

SPECIFICATIONS

| Basestation (F 09G 100 168) | |
|-----------------------------|--|
| Display | 7 inch 16:10, 1024 x 600 pixel touchscreen |
| Weight | 1350 g |
| Dimensions | 265 mm x 213mm x 160 mm |
| Electrical safety | ME device with external supply, tested according to EN 60601-1 IP 20 for basic safety |
| Wireless charging | Charging w/ constant current up to 220 mA followed by constant voltage up to 4.2V stopping when fully charged. |
| Data transfer | Ethernet 10/100MB, WLAN 2.4 GHz b/g/n internal: Bluetooth® Smart (Low Energy), 2.4 GHz |



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PRAXISDIENST
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Handheld (F 09G 100 078)

| | |
|-------------------------------------|---|
| Sensing technology | Chemical field-effect transistor (Chem-FET) to measure nitrogen dioxide that is converted from nitric oxide by disposable mouthpiece. |
| Power source | Customized Vivatmo pro - Rechargeable Li-Ion Battery, 3.6V battery: accessory; compartment lid: detachable part |
| Weight | 170 g |
| Data Transfer | Bluetooth® Smart (Low energy); 2,4 GHz frequency band |
| Dimensions | 4.0 cm x 5.4 cm x 22.4 cm |
| Electrical safety | ME device with internal supply, tested according to EN 60601-1, IP20 for basic safety |
| Applied Part | Type B as per EN 60601-1 for handheld and disposable mouthpiece when attached |
| Max. surface temp. | 58°C, touch time < 60 seconds |
| Electromagn. emission | CISPR11 Group 1 (battery operated) |
| Electromagn. immunity | IEC 61000-4-2, IEC 61000-4-3 (battery operated), IEC 61000-4-8 |
| Useful life of rechargeable battery | At least 40 measurement trials when fully charged |

| Power supply (accessory) | |
|--------------------------|---|
| Model type | UE electronic, model number UE36LCP-240150SPA |
| Input voltage | 100 - 240 VAC, 50 - 60 Hz |
| Output power range | < 25 W |
| Output voltage | 24 V |

| Disposable Mouthpiece (accessory) | |
|-----------------------------------|---|
| Single-time use | Measurement limited to 5 measurement trials within 15 min |
| Useful life | Limited by expiration date |

ENVIRONMENTAL CONDITIONS

| | Operation | Transport and Storage between uses |
|--|----------------------|--|
| Temperature | +15°C to +27°C | <u>Transportation:</u> -20°C to +60°C for a maximum of 72 hours <u>Storage:</u> +5°C to +27°C |
| Relative humidity (non-condensing) | 15 % to 60 % | <u>Transportation:</u> ≤ 85 % for a maximum of 72 hours <u>Storage:</u> 10 % to 60 % |
| Air pressure (corresp. to 0 - 2,000 m a.s.l.) | 780 hPa to 1,100 hPa | 780 hPa to 1,100 hPa |
| Ambient NO concentration | < 100 ppb | |

ELECTROMAGNETIC COMPATIBILITY (EMC)

Vivatmo pro complies with EN60601-1-2:2015 with the objective to avoid insecure product situations. This standards regulate the levels of immunity against electromagnetic interferences and the maximum electromagnetic emission values for medical equipment. Vivatmo pro manufactured by the company complies with the standard guidance and manufacturer's declaration – electromagnetic emissions EN60601-1-2:2015 both in terms of immunity and of emissions and does therefore not need any service and maintenance regarding EMC and ESD over lifetime. Vivatmo pro basestations with a date of manufacture before 1st November 2018 comply with EN 61326-1:2013 for EMC.

Note that portable and mobile HF communication systems may interfere with this device. Do not staple or use the device close to mobile phones or other devices generating electrical or electromagnetic fields. This could result in malfunction of the medical device and may create a potentially insecure situation. Portable RF communication devices (including peripherals such as antenna cables and external antennas) are not to be used closer than 30 cm next to any part of the Vivatmo pro system.

Guidance and manufacturer's declaration – electromagnetic emissions

The Vivatmo pro is intended for use in the electromagnetic environment specified below. The customer or the user of Vivatmo pro should assure that it is used in such an environment.

| Emissions test | Compliance | Electromagnetic environment – Guidance |
|-----------------------|------------|--|
| RF emissions CISPR 11 | Group 1 | The Vivatmo pro uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| RF emissions CISPR 11 | Class B | The Vivatmo pro is suitable for use 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. |

Guidance and manufacturer's declaration – electromagnetic immunity

| Immunity test | IEC 60601 Test level | Compliance level | Electromagnetic environment – Guidance |
|---|-----------------------------|-----------------------------|--|
| Electrostatic discharge (ESD) IEC 61000-4-2 | ±8 kV contact ±15 kV air | ±8 kV contact ±15 kV air | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %. |
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 | 30 A/m | 30 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |
| Radiated RF IEC 61000-4-3 | 10 V/m 80 MHz to 2.7 GHz | 10 V/m 80 MHz to 2.7 GHz | |

Test specifications for immunity test against high-frequent radio-based electronic communications systems

| Test frequency MHz | Modulation ^b | Immunity testing level V/m |
|-----------------------|---------------------------------------|-------------------------------|
| 385 | Pulse modulation 18 MHz ^b | 27 |
| 450 | FM (± 5 kHz Deviation, 1 kHz Sine) | 28 |
| 710 | | |
| 745 | Pulse modulation 217 MHz ^b | 9 |
| 780 | | |
| 810 | Pulse modulation 18 MHz ^b | 28 |
| 870 | | |
| 930 | | |
| 1720 | Pulse modulation 217 MHz ^b | 28 |
| 1845 | | |
| 1970 | | |
| 2450 | Pulse modulation 217 MHz ^b | 28 |
| 5240 | | |
| 5500 | Pulse modulation 217 MHz ^b | 9 |
| 5785 | | |

^b The carrier must be modulated by a square-wave signal with a duty cycle of 50 %.

REACH REGULATION

Vivatmo pro can contain following substances of the actual candidate list of the EU REACH regulation 1907/2006 in a concentration above 0.1 %: Lead-monoxide.

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