

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

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 IEC 60601-1, IP20 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



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 IEC 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 (battery operated), FCC Part 15 Class B
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. These 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 <i>pro</i> 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 <i>pro</i> 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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