FeNO monitoring system
Vivatmo *me*

FEATURES

Vivatmo *me*	
Measuring range	5 ppb to 300 ppb
Accuracy	±5 ppb below 50 ppb, ±10 % ≥50 ppb, ±15 % ≥ 160 ppb expressed as the upper/lower confidence limit of 95 %
Precision	±5 ppb below 50 ppb, ±10 % ≥50 ppb, ±15 % ≥ 160 ppb expressed as one standard deviation for replicate measurements with the same instrument
Lifetime, Device service life	1,000 measurements
Memory capacity	1,000 measurements

SPECIFICATIONS

Handheld	
Sensor	Chemical field-effect transistor
Display	Digital LCD display
Power source	4 AAA batteries 1.5 V, Useful life of batteries: Alkalin up to 25 attempts, lithium/ iron disulfide up to 60 attempts
Weight	170 g
Dimensions	4.0 cm x 5.4 cm x 22.4 cm
Package contents	Vivatmo *me* device, package of 5 disposable mouthpieces, 4 AAA batteries, protective cap, Instructions for use

Disposable Mouthpiece (accessory)	
Single use	Measurement within 15 minutes after opening the pouch. Useful life limited to 5 attempts and expiration date.
Shelf life	2 years from manufacturing.

Limitations of the System: Exchange your Vivatmo me at the latest 3 years after manufacturing date.

ELECTRONICAL AND SAFETY INFORMATION

Applied part	Type BF as per EN 60601-1-11 for handheld and disposable mouth-piece when attached
Maximum surface temperature	58 °C, touch time < 60 seconds
Electrical safety	ME device with internal supply, tested as per EN 60601-1-11 IP 22 (protection against solid particles >12,5 mm and ingress of dripping water when tilted up to 15°) for basic safety but not for function
Data transfer	Bluetooth® Smart (low energy), 2.4 GHz frequency band
Electromagnetic emissions	CISPR 11 Group 1 (battery operated)
Electromagnetic immunity	EN 61000-4-2, EN 61000-4-3 (battery operated), EN 61000-4-8

REACH REGULATION

Reporting Requirement according to Article 33 of the REACH Regulation No. 1907/2006: The pump within our product contains lead monoxide.

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ENVIRONMENTAL SPECIFICATIONS

	Operation	Transportation / Storage between uses
Temperature	+15 °C to +27 °C	+5 °C to +27 °C
Relative humidity (non-condensing)	15 % to 60 %	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)

Important information regarding electromagnetic compatibility (EMC)
This device complies with EN60601-1-2:2015 for EMC with the objective to avoid insecure product situations. This standard regulates the levels of immunity against electromagnetic interferences and the maximum electromagnetic emission values for medical equipment. This medical device manufactured by the company complies with the standard 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.

Please note that portable and mobile HF communication systems may interfere with this device even if compliant with CISPR emission requirements. Do not stack the device or use any mobile phones or other devices generating strong electrical or electromagnetic fields. This could result in malfunction of the medical device and may create a potentially insecure situation. Portable RF communication devices are not to be used closer than 30 cm next to the device.

Guidance and manufacturer's declaration – electromagnetic emissions

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

Emissions test	Compliance	Electromagnetic environment – Guidance
RF emissions CISPR 11	Group 1	The Vivatmo *me* 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 *me* 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.
Harmonic emissions IEC 61000-3-2	n/a	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	n/a	

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Guidance and manufacturer's declaration – electromagnetic immunity			
The Vivatmo *me* is intended for use in the electromagnetic environment specified below. The customer or the user of the Vivatmo *me* should assure that it is used in such an environment.			
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%.
Electrical fast transient/burst IEC 61000-4-4	n/a	n/a	n/a
Surge IEC 61000-4-5	n/a	n/a	n/a
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	n/a	n/a	n/a
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.
Notes: U_T is the AC mains voltage prior to application of the test level.			

Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment – Guidance**
Conducted RF IEC 61000-4-6	10 Vrms 150 kHz to 80 MHz	n/a	Portable and mobile RF communications equipment should be used no closer to any part of the Vivatmo *me* including cables, than the recommended separation distance calculated form the equation applicable to the frequency of the transmitter. **Recommended separation distance:** d = $1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m 80 MHz to 2.7 GHz	d = $1.2\sqrt{P}$ 80 MHz to 800 MHz d = $2.3\sqrt{P}$ 800 MHz to 2.7 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 

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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 [b] 18 MHz	27
450	FM ± 5 kHz Deviation 1 kHz Sine	28
710 745 780	Pulse modulation [b] 217 MHz	9
810 870 930	Pulse modulation [b] 18 MHz	28
1720 1845 1970	Pulse modulation [b] 217 MHz	28
2450	Pulse modulation [b] 217 MHz	28
5240 5500 5785	Pulse modulation [b] 217 MHz	9

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

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