Fischer ANalysen Instrumente GmbH

Technical Data Sheet

Modell	**HeliFAN*plus*** (FANci3)
Manufacturer	Fischer ANalysen Instrumente GmbH
Address	Brahestraße 25-27, 04347 Leipzig, Germany
Product type	In vitro diagnostic medical device
Class	Other device

Intended Use

The breath test analyzer HeliFAN*plus* is a nondispersive infrared spectrometer. It is for determining the ratio of the natural isotopes ^{13}C and ^{12}C in gases containing CO_2.
The main application field of the analyzer is at the clinics, at the physician's office laboratories and at gastroenterologists for investigating metabolic processes and diagnosing infectious or metabolic diseases.

General Specifications

Dimensions	Width:	350 mm
	Depth:	210 mm
	Height:	240 mm
Weight	9 kg	
Unit construction	Table top unit with screwed casing. The analyzing unit is hermetically sealed.	
Casing	Sheet steel housing with plastic case.	
Gas processing	All gases are transported within the analyzer by the integrated feed pump. The surrounding air destined for rinsing is lead across a coarse filter to protect the analyzer. CO_2–free air (zero gas) is produced by piping surrounding air through an absorber containing soda lime.	
Gas ports	Four sample ports for breath bags from which measuring gas is pumped into the analyzer; inlet port for rinsing gas; gas outlet. Optional I/O port for automatic sample feeder connection.	
Protection classification	IP 20 acc. EN 60529	
Electric connections	• Control and data I/O (USB jack type B) • AC power inlet (switched IEC 320 plug)	

Environmental Specifications

Operating condition	Ambient Temperature:	+15 … +35 °C
	Altitude:	-400 … 2200 meters o.S.L.
	Relative Humidity:	< 75 % (non-condensing)
Storage condition	Ambient Temperature:	+5 … +45 °C
	Altitude:	-400 … 4800 meters o.S.L.
	Relative Humidity:	< 75 %

Power Specifications

Electrical power	~ 100 … 250 V AC, 47 … 63 Hz
Power consumption	26 W (95 W max.)
Fuses	Main fuses in appliance inlet: 2 x 1 A slow blow / 250 V Fuse on power supply: 1 x 3 A slow blow / 250 V

Measuring Data

Measurement span	$^{13}CO_2$: 80 … 800 ppm $^{12}CO_2$: 0.8 … 8 vol.–%
Delta range (^{13}C δ)	-50 … 250 ‰
Time behavior	Tempering analyzer to 55 °C: 1 h until working temperature (55 °C) is reached 8 h to reach maximal stability (uninterrupted duty recommended) Measuring time per sample: 2.5 minutes (typ.)
Sample gas consumption[1)]	Sample container: 12 ml Breath bag: 30 ml (min.)
Accuracy[1)]	± 0.4 δ‰, ± 10 % of target DOB
Repeatability[1) 2)]	Inter-day and intra-day SD < 0.4 δ‰
Diagnostic Sensitivity	97.8 % (^{13}C UBT with IRMS as gold standard)
Diagnostic Specificity	98.9 % (^{13}C UBT with IRMS as gold standard)
Analytical Sensitivity[1) 3)]	LOD = ± 1.2 δ‰
Analytical Specificity[1) 3)]	max. delta diff.: < 0.7 δ‰ (cross sensitivity to relative humidity)
Linearity[1)]	max. deviation of the target DOB value: $R^2 > 0,98$

1) sample CO_2 concentration > 1.5 vol–% (with FANas > 3.0 vol-%)
2) at DOB ≤ 40 δ‰
3) Delta range (^{13}C δ) -40 … 0 ‰

Stability	Semi-automatic drift compensation by integrated comparison media Zero point adjustment: by internal generated CO_2-free air End point adjustment: built-in calibration cells (to be checked once a year)
Influence effects	Associated gas / transverse sensitivity: compensated by filtering and internal electronic correction Temperature influence: ≤ 1% of the measured value per 10 K ambient temperature Atmospheric pressure influence: zero point: no influence sensitivity: ≤ 0.2 % of the measured value per 1 % change of pressure
Gas inlet conditions	Temperature: +15 °C … +40 °C Pressure inside the measuring chambers: max. 200 hPa overpressure Flow rate: given by the internal gas feed pump (typ. 10 l/h)