4000 Respiratory Monitor Regulatory Notices

Warnings and Advisory Notices:

Note: Please read all this information before using this Vitalograph device. A full set of instructions, including cleaning instructions, is available at www.vitalograph.co.uk.

- This Vitalograph device is intended to measure lung function, primarily for single patient use at home under medical supervision, or for use in clinic, where SafeTway or Bacterial Viral Filter disposable mouthpieces must be used.
- Take care not to block the mouthpiece with the tongue or teeth. A 'spitting' action or coughing will give false readings.
- If used at home symptoms must take precedence over device measurements*.
- If the device is used for longer than its specified life, the accuracy of the device may deteriorate.
- Before use, ensure that the batteries do not exceed their shelf life, as indicated on the batteries.
- Store in a clean dry place.
- Cleaning & disinfecting: The outer surfaces should be cleaned every week, more often if necessary. The use of an ordinary alcohol wipe is recommended, with special attention to the mouthpiece area.

** If the patient at home thinks that the device is not reading correctly, they must advise the healthcare professional immediately.*

The device must be taken to separate collection at the product end-of-life.
Do not dispose of these products as unsorted municipal waste.

Warranty

Your Vitalograph device is guaranteed for one year*. Replace if it is faulty, otherwise replace the unit every three years.

**Excepting accidental / transit damage or inappropriate use of the device.*

FDA Notice:

Caution: Federal Law restricts this device to sale by, or on the order of a physician.

CE Notice

Marking by the symbol CE 0086 indicates compliance of this device to the Medical Devices Directive of the European Community. Such marking is indicative that the Vitalograph device meets or exceeds the referenced technical standards.

The Vitalograph device 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.

The Vitalograph device is battery operated and 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.

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

- 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 magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
- Interference may occur in the vicinity of equipment marked with the following symbol - (((•))).

Technical Specifications

Material:	PC/ABS
Accuracy:	Better than ± 3% (FEV1 & FEV6), ± 10% (PEF)
Flow Impedance (as applicable):	Better than 0.15kPa/L/s at 14L/s
Measurement Range:	PEF: 25 – 840 L/min BTPS FEV1: 0 – 9.99 L BTPS FEV6: 0 – 9.99 L BTPS
Safety & Performance Standards:	EN ISO 23747:2007, ATS/ERS Guidelines 2005
Electromagnetic emissions:	CISPR 11 Group 1 (battery operated)
Electromagnetic immunity:	IEC 61000-4-2, IEC 61000-4-3 (battery operated)
Sensor:	Stator/rotor
Power Supply:	AAA batteries
Operating Temperature:	17 – 37°C

Recommended separation distances between portable and mobile RF communication equipment and the system

The Vitalograph device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the system as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz $d = 1.2\sqrt{P}$**	**800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$**
0.01	0.1m	0.1m	0.2m
0.1	0.4m	0.4m	0.7m
1	1.2m	1.2m	2.3m
10	3.7m	3.7m	7.4m
100	11.7m	11.7m	23.3m

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (w) according to the transmitter manufacturer.

NOTE 1 *At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies..*

NOTE 2 *These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.*

Declaration of Conformity

Product: 4000 Respiratory Monitor

Vitalograph hereby ensures and declares that the above product associated with this user manual, is designed and manufactured in accordance with the following QMS regulations and standards:

- European Medical Devices Directive {MDD} 93/42/EEC. This device, classified as 2a as per Annex IX of MDD 93/42/ EEC, meets the following provisions of Annex II of the Medical Devices Directive as per Article 11, section 3a, excluding point 4 of Annex II. This device complies with the EMC Directive 89/336/EC, conformance demonstrated by following standard EN60601- 1-2:2001. Equipment classification: Residential.
- Canadian Medical Device Regulation {CMDR}
- FDA Quality System Regulation {QSR} 21 CFR 820.
- EN ISO 13485: 2016. Medical devices. Quality management systems. Requirements for regulatory purposes.

CE 0086

Certifying Body {for 93/42/EEC and CMDR}: British Standards Institute {BSI}
Certificate Nos. CE 00772, MD 82182, FM 83550

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