

In2itive e-Diary

Next generation eCOA platform
with integrated respiratory assessment



The In2itive™ e-Diary is a robust handheld medical device with a high resolution touchscreen for gathering eCOA data. Using Vitalograph®'s proven Fleisch Pneumotachograph flowhead, the In2itive e-Diary provides accurate measurement of respiratory endpoints in clinic or home settings.

Fully integrated wireless communications allow automatic secure transmission of data to the study web portal. Uploaded data is available for instant review of site and subject performance. The In2itive e-Diary is a fully validated class II (USA) and IIa (EU) medical device meeting or exceeding all technical requirements for cyber-security and data protection.

Features

- Large, responsive touchscreen
- Fleisch pneumotachograph flowhead for respiratory endpoints e.g. FEV1 and PEF
- Customizable alerts, reminders, and workflows to fit study protocols
- Date/time stamps on all data and results
- Cellular/Mobile option transmits results direct to Vitalograph web portal
- Automatic secure end-to-end encrypted data transmission
- Live spirometry quality feedback
- Subject management via web portal or PC software
- Integrated animated training module
- Password protected
- CE marked and FDA cleared



The device can host any ePRO, eCOA or sponsor questionnaire using text, VAS, images, tick box, radio buttons, etc.

Pre integrated & validated ePROs:

Respiratory - asthma

ACQ	MAPI
AQLQ(S)12+	MAPI
AQ20	Prof P Jones
ACT	Quality Metric

Respiratory - COPD

EXACT	Evidera
EXACT E-RS	Evidera
CAT	GSK

Health status

EQ5D-3L	Euroqol
EQ5D-5L	Euroqol

Technical Specification

Product:	Vitalograph 2120 In2itive e-Diary
Dimensions:	186 mm x 81 mm x 48 mm net
Weight:	0.3 kg net
Communications:	Minimum USB 2.0 Integrated Cellular/Mobile (optional)
Power Supply:	Universal Input 100 -240V, 50-60 Hz or USB Power 5V/500mA (as supplied) 3.7V Lithium-ion polymer battery
Flow Detection Principal:	Fleisch type Pneumotachograph capable of giving linear signals throughout the entire physiological range.
Volume Detection:	Flow integration sampling @ 100Hz
Volume Accuracy:	±3% or ±0.05L of the reading (ISO 26782:2009).
Flow Measurement Range:	Max. flow rate ±14 L/s Min. flow rate ±0.02 L/s
PEF Accuracy:	±10% or ±10L/min of the reading (ISO 23747:2015)
Back Pressure:	Less than 0.1kPa/L/sec @ 14L/s (ATS/ERS 2019)
Performance Standards: (the device meets or exceeds)	ATS/ERS 2019, ISO 23747:2015 & ISO 26782:2009
Safety Standards:	EN 60601-1:2006+A1:2013 with US deviations
EMC Standards:	EN 60601-1-2:2015
Home Use Standards:	EN 60601-1-11:2015
QA/GMP Standards:	EN ISO 13485, FDA 21 CFR 820, CMDR SOR/98-282 & JPAL

Vitalograph (font), Vitalograph® and In2itive™ are trademarks or registered trademarks of Vitalograph Ltd.
All other trademarks and trade names are those of their respective owners.