

Precision Diary Spirometer

Micro Diary



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The CareFusion Micro Diary is an electronic data capture Spirometer, specially designed to provide a modern alternative to mechanical PEF meters and paper Diary cards for objective monitoring in clinical trials. Using the CareFusion digital volume transducer, with its proven accuracy and stability, plus an easy to use keypad entry and on screen text display, the CareFusion Micro Diary is ideal for patients to use at home. The Micro Diary Spirometer can be programmed with your specific protocol requirements using the comprehensive PC based Windows software and recorded data rapidly transferred to or via a PC.

Design Innovation

The CareFusion Micro Diary is a compact, hand-held electronic data capture Spirometer, specially designed for patient PEF and spirometry monitoring at home. Featuring the CareFusion digital volume transducer, with its proven accuracy and reproducibility, each unit is individually calibrated to ATS/ERS 2005 standards for diagnostic devices on a waveform generator and routine calibration is not required. The tactile universal keypad and easy to read backlit graphics display, ensures ease of use by all subjects.

Protected Data Retrieval

To comply with FDA requirement 21 CFR Part 11 ensuring secure data entry, the Micro Diary can be PIN number protected for regulatory clinical trial requirements. Data can be retrieved via the Micro Diary serial port either directly to a PC, or remotely using a modem and results can be printed directly at the investigator's site or exported into a central database.

Easy to Use Software

The unit is supplied complete with easy to use, comprehensive PC based Windows software for clinical researchers and data managers to configure to a trial specific protocol and is activated by the subject according to the investigators' protocol, allowing any sequence of pre-determined commands to be executed at specified times. 'Blow 'commands with incentive settings and quality check messages can be displayed on screen to encourage good, reproducible patient technique. Full symptom questions can also be viewed on a scrolling screen display and responses may be obtained using numeric, visual analogue or yes/no scoring systems. The Micro Diary incorporates optional patient reminder alarm and low readings warning features.



Specifications

Micro Diary

| Measurements: | PEF, FEV1, FVC/FEV6 |
|---------------|--|
| Display: | 64x100 pixel LCD |
| Resolution: | 10ml Volume |
| Volume Range: | 0 to 8.0 Litres |
| Flow Range: | 0.2 to 15.00 Litres/Second |
| Accuracy: | +/- 3% to ATS/ERS Standardisation |
| Keypad: | l, ←, ↑, ↓, Del |
| Interface: | USB |
| Memory: | Typically >1 year of recording |
| Power supply: | 3v Lithium coin cell - 600mAh |
| Dimensions: | 130x57x37 |
| Weight: | 100gms (including batteries) |
| Software: | Windows compatible 2000, XP, Vista 32, 64 |

Features

- Full question display large screen
- PIN number protection
- Optional quality check messages
- Measures and stores PEF, FEV₁, FVC/FEV₆
- Option to store flow/volume loops from recorded blows
- Universal, easy to use keypad entry
- Secure audit trail for regulatory clinical trials

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