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Title: Office spirometry: (Un)reliability of some handheld spirometers

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Body: Spirometry is considered the gold standard to diagnose COPD and several handheld spirometers were introduced for use by general practitioners. We tested 13 commonly available handheld spirometers and compared their performance to a Jaeger Masterscreen PFT being considered the gold standard. Spirometry was performed according to ATS-ERS criteria and was recorded twice with handheld and Masterscreen (in random order) on 17 to 27 patients referred for routine spirometry testing. Bland-Altman analysis and comparison of FEV1/VC ratios were the main outcome variables. Results: Two devices overestimated FVC significantly and one device underestimated FVC and FEV1 (see Table). Only 5 out of 13 handheld spirometers measured all FEV1/VC ratios within 10% of those measured by the gold standard. We conclude that some handheld devices unreliably measure FEV1 and/or FVC resulting in a false positive detection of airway obstruction or a false negative result.

| | FVC | FEV1 | Δ FEV1/FVC > 10% |
|---------------------------------|-----------------|-----------------|---------------------------|
| Device | LoA (L) | LoA (L) | (%) |
| SpiroPro, Jaeger, GE | -0.222 - +0.350 | -0.267 - +0.205 | 5 |
| Spirobank, MIR, IT | -0.349 - +0.654 | -0.258 - +0.288 | 5 |
| Blue Spiro, Medisoft, BE | -0.044 - +0.764 | -0.328 - +0.214 | 33 |
| One Flow, Clement Clarke, UK | -0.500 - +0.913 | -0.315 - +0.152 | 13 |
| Spiro2000, Medikro OY, FI | -0.421 - +0.336 | -0.366 - +0.238 | 0 |
| Pocket-Spiro USB100, MEC, BE | -0.418 - +0.224 | -0.423 - +0.076 | 9 |
| PC-Spiro, MCT Ganseman, BE | -1.087 - +0.321 | -0.671 - +0.234 | 26 |
| SDS 104, Schiller, SZ | -0.556 - +0.374 | -0.477 - +0.166 | 0 |
| SpiroCard, QRS Diagnostics, USA | -0.394 - +0.251 | -0.282 - +0.116 | 0 |
| EasyOne, NDD, SZ | -0.532 - +0.404 | -0.347 - +0.173 | 4 |
| Spiro USB, Micromedical, UK | -0.389 - +0.413 | -0.342 - +0.193 | 10 |

| | | | |
|---------------------------------|-----------------|-----------------|---|
| SpiroPerfect™, Welch Allyn, USA | -0.494 - +0.362 | -0.304 - +0.174 | 0 |
| Spirostik, Geratherm, GE | -0.420 - +0.407 | -0.323 - +0.182 | 0 |

LoA: Limits of Agreement