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Title: Quality of home spirometry data in asthmatic patients

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Body: Introduction In clinical trials, spirometry measurements may be taken at home using electronic diaries (e-Diaries) with integrated spirometers, for use as safety and/or efficacy endpoints. The accuracy of this data is of particular importance¹. Previous clinical trials have used an older Vitalograph e-Diary, where limited feedback was given to patients. Aim To determine the repeatability of domiciliary PEF and FEV₁ data collected using the new Vitalograph In2itive e-Diary™ in an international multi-centre, double blind, placebo controlled clinical trial in patients with asthma. Method 174 patients were instructed by trained staff to record spirometry measurements at home, twice a day. If the patient did not meet the ATS/ERS 2005 Repeatability criteria, the e-Diary provided instant feedback that the respiratory efforts were not consistent and asked the patient to perform another test. Results

	Number of Sessions	% Acceptable Session	
		PEF	FEV ₁
In2itive e-Diary	35,615	95	97
Previous device	113,098	85	63

Repeatability Criteria: PEF: 2 highest results < 40 L/min difference FEV₁: 2 highest results < 150ml difference Conclusions Providing instant feedback to the patients on the In2itive e-Diary resulted in achieving higher repeatability for PEF and FEV₁ data compared to the previous device. Further feedback messages could potentially help to provide even more reliable efficacy and safety data from home spirometry, as well as helping to bridge the gap between in-clinic spirometry results and home based measurements. References 1. Harrison Aleck, Watson Elizabeth. Huff and puff; repeatability of serial home PEF & FEV1 recordings in a pharmaceutical trial. Eur Respir J 2010; 36: S54: E3967.

