COMPARISON BETWEEN AN ULTRA-PORTABLE, LOW-COST HYDROGEN BREATH ANALYSIS DEVICE AND AN EXISTING GOLD-STANDARD DEVICE

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Background: Hydrogen Breath Testing (HBT) is a clinically validated technology used to identify the presence of carbohydrate malabsorption, which is of particular relevance in functional gastrointestinal disorders (such as IBS and SIBO). Conventional HBT tools and the necessary consumables are expensive and the tests are time-consuming, which can limit their utility in a clinical environment. *AIRE (FoodMarble Digestive Health, Dublin, Ireland)*, a low-cost, app-connected HBT device, which requires no consumables and which offers ease-of-use benefits, allows breath testing to be performed at home, thus enabling a more time and cost-effective physician-patient interaction and treatment pathway for functional gastrointestinal disorders.

Methods: 14 (9 males) healthy adult volunteers mean age 31 (23-43) yrs, were enrolled. Breath tests were performed by each volunteer using two *AIRE* devices and the results were compared against those of a *QuinTron BreathTracker SC analyser* (QuinTron Instruments, Milwaukee, WI), a reference standard benchtop device. A baseline reading was recorded using each device prior to the ingestion of 10g of lactulose, a non-absorbable carbohydrate substrate. Each volunteer took a breath reading every five minutes, sequentially switching between each device, such that over a 15-minute interval, three breath samples were recorded, each with a different device. Over the course of three hours, this yielded 39 data points per volunteer. The five minute gap between breath samples across devices was chosen to ensure a recovery in alveolar H_2 concentrations between exhalations. The H_2 concentrations from each device were compared at 15-minute intervals, using concentration plots created for each volunteer and device, by linearly interpolating the H_2 concentrations over time. The exclusion criteria for analysis was a baseline breath concentration of >15ppm on any of the devices. One volunteer was excluded from the final data analysis due to a high H_2 baseline leaving 13 subjects for analysis. The H_2 concentrations recorded by the *QuinTron* device were used to adjudicate where malabsorption had occurred. In instances where there was a >20ppm increase in H_2 over the initial baseline (Pimentel et al, Am J Gastroenterol. 2000;95:3503–3506), the test was considered positive, otherwise it was considered negative.

Results: There was diagnostic agreement in 13 out of 13 (12 positive and one negative) cases between *AIRE and QuinTron devices.*

Discussion: Initial testing on healthy volunteers suggests that the portable *AIRE* device may offer results comparable to those delivered by a gold-standard benchtop device in IBS patients. Further larger population studies are planned with IBS patients, which will use two *AIRE* devices as well as two benchtop devices, to better account for inter-device variability in both cases.

Figure 1: Size comparison between AIRE device and a "quarter" coin (i.e. 0.25 USD).