VALIDATION METHANE AND HYDROGEN PORTABLE BREATH ANALYZER AIRE2 THROUGH CALIBRATION GASES

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INRODUCTION

Assessment of hydrogen and methane levels in breath is widely used as breath test for diagnosis of carbohydrate malabsorbtion, lactose intolerance , syndrome of intestinal bacterial overgrowth (SIBO). Usually such test is performed in clinical settings with the sophisticated analytical devices (gas chromatographs and others). The modern trend in medicine – move from the hospital to home of the patient demands portable, easy to use devices which are important for personalized recommendations on the healthy nutrition.

The expanding range of personalized devices is marketed to help in achieving health benefits and sustaining behavioural changes. The first device for such purpose (AIRE) was developed by the FoodMarble company in Ireland. This study presents portable breath tests validation. Considered test measure exhale human hydrogen and methane and estimate gastrointestinal fermentation level. The result of estimation is presented as "Score" from 0 to 10. "Score" is sum of "Hydrogen level" and "Methane level". The study was conducted with four devices. The flow controller RRG-2 maintained the humidity flow at a certain level with an accuracy of ±1.2%. The humidity accuracy was 1.7%.

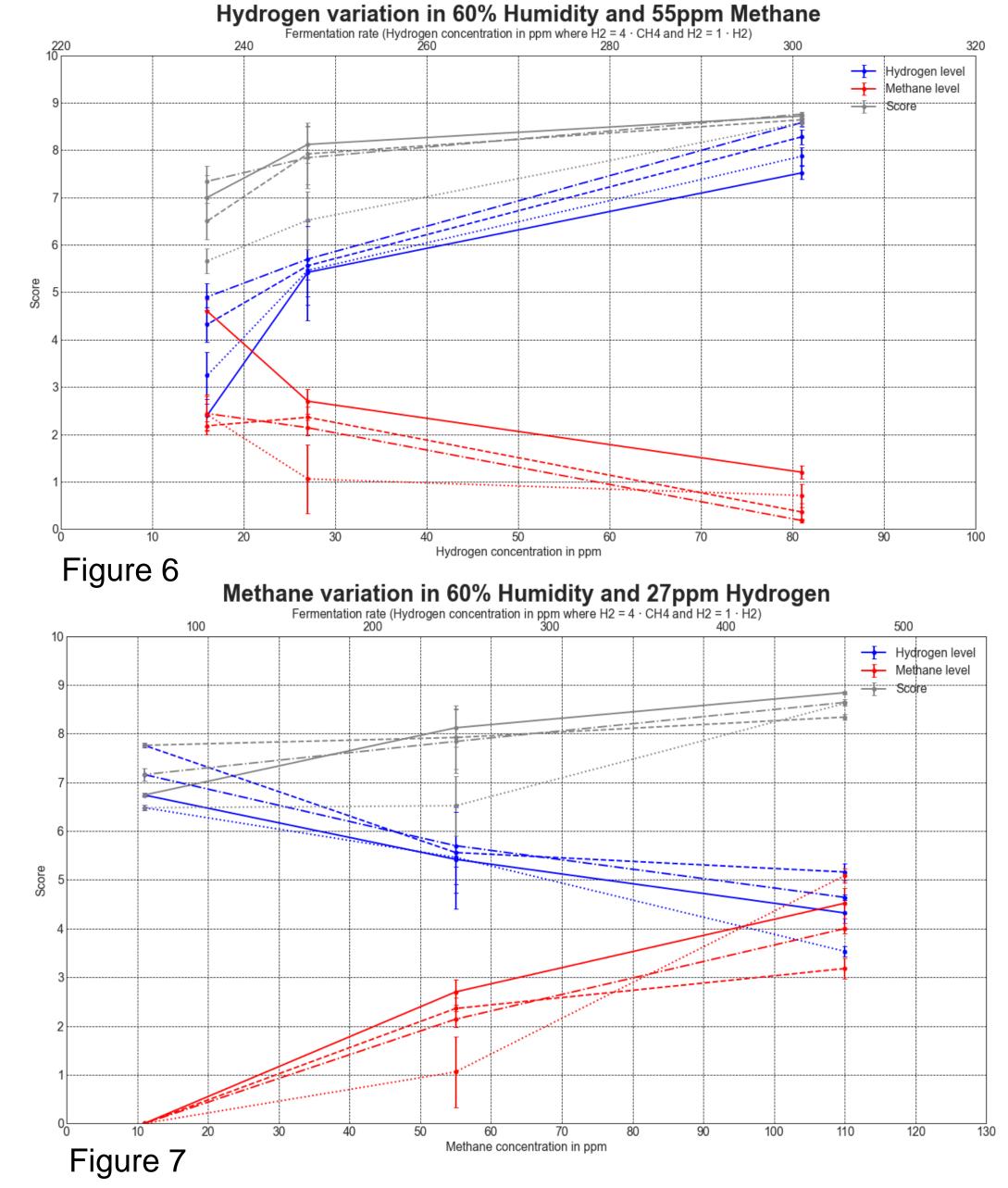
Different gas concentrations achieved through particular stand for gas flow mixing. Stand accuracy completeness depends on flow controller accuracy. Bronkhost LOW- Δ P-FLOW and IQ+FLOW series have 1% accuracy [3]. Dry air generator was GVH – 2,0-3,5. As a result estimated uncertainty of calibration gas preparation is no more than 5%.

RESULTS

Following characteristics were received (on the top of the plot indicate fermentation level or equivalent hydrogen according to equation 1):

(1)

- Only two out of the four devices are sensitive to both dry and humid methane concentrations of 55 ppm and 110 ppm. There is complete insensitivity to low methane concentrations (less than 55 ppm) in dry air. This insensitivity is due to the devices ignoring the gas flow and failing to initiate the measurement procedure.
- There is a wide "Score" deviation both within a single device and between different devices.
- Hydrogen is detected in the readings even though it is not present in the gas mixture.



OBJECTIVES

Validation of the H2-detecting AIRE device was performed by comparing the H2-values of exhaled air samples from volunteers obtained by the AIRE and the Quintron Gas Chromatograph [1].

Disadvantages of this study are:

- Different time sampling methods. Five seconds exhale after three seconds holding breath for AIRE is not standard Sampling alveolar air on exhale finish to flexible bag.

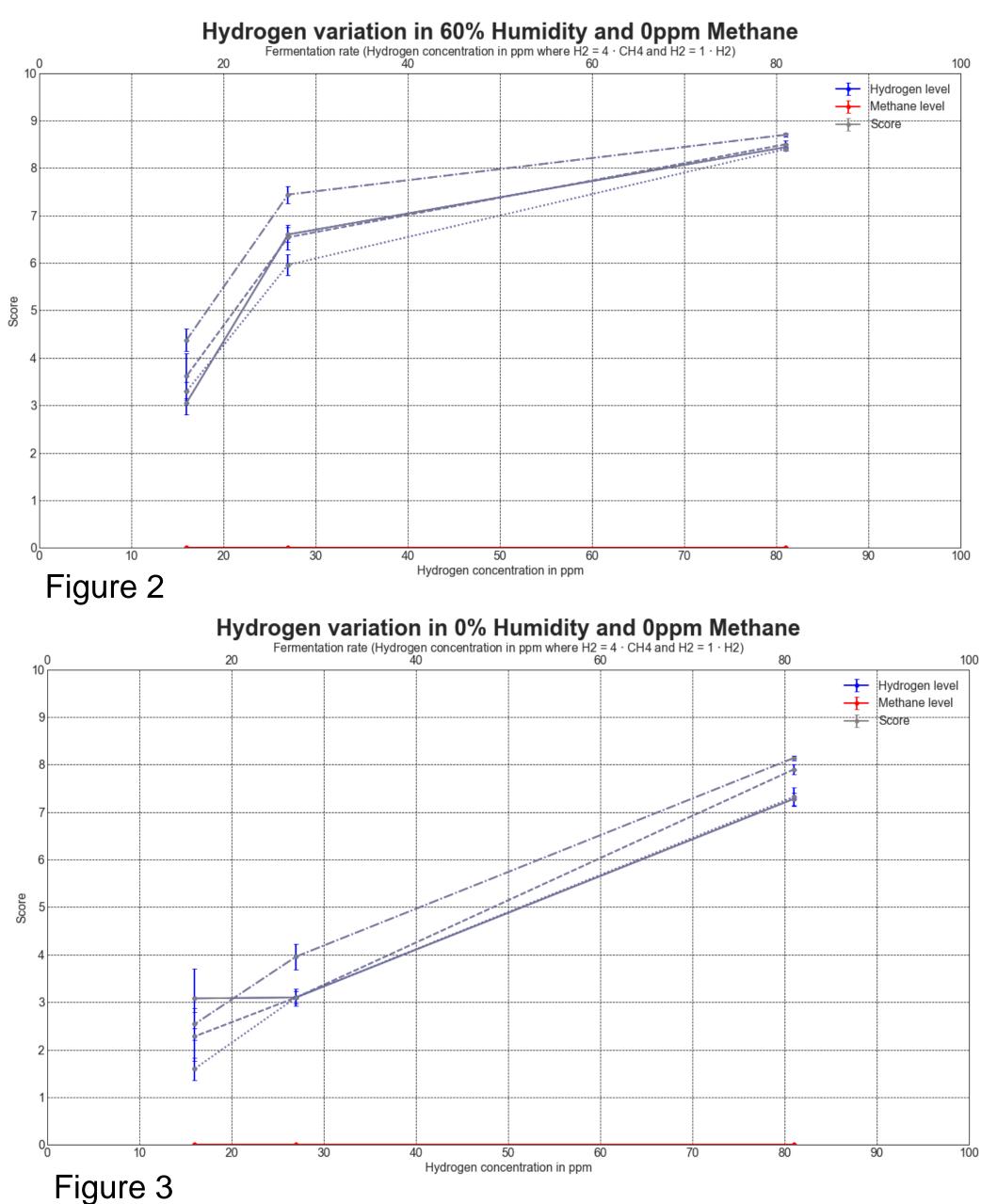
- Hydrogen variability, depends of flow rate, breath depth and closeness sample to alveolar space influents validation results Itis incorrect to use human exhale gas as referent validation sample.

Here we proposed to validate AIRE2 by using calibration gas with known parameters: hydrogen, methane concentration and humidity level.

METHODS

Different gas concentrations of H2 and CH4 in the dry and 60% humidity air were produced by the gas flow mixing set-up. H2 (16, 27 and 81 ppm) and CH4 (11, 55 and 110 ppm) concentrations were used separately and in different combinations.

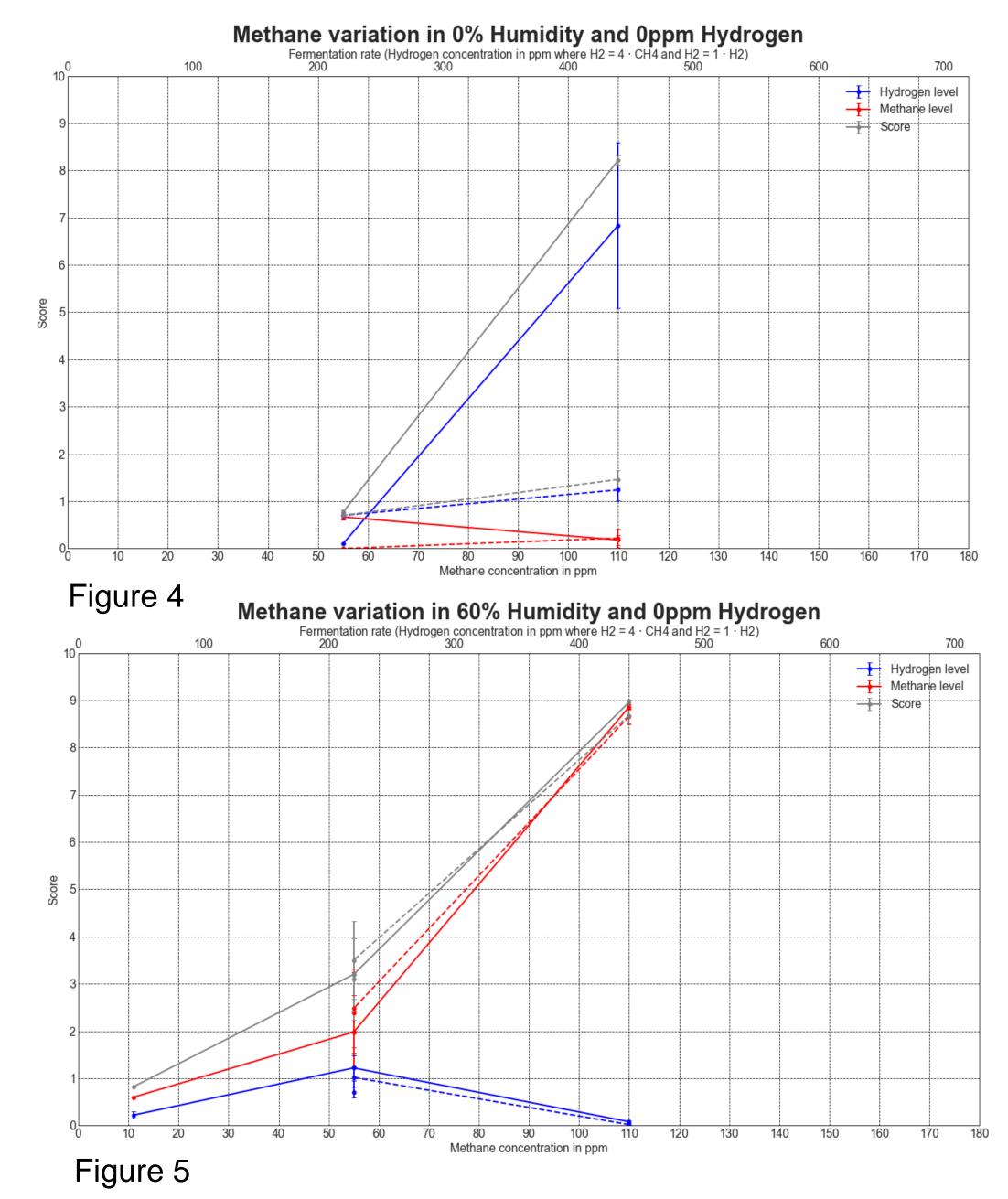
$$H_{2eq} = H_2 + 4 \cdot CH$$



There is a zero "Methane level" for an 11 ppm methane concentration in the presence of 27 ppm hydrogen across all devices.
Similar concentrations of both gases do not influence the "Score" in the same way. Hydrogen has the highest weight in the "Score" formation, with a 27 ppm hydrogen concentration corresponding to a full 5.5 "level."
An increase in methane or hydrogen in the mixture has a minor effect on the "Score," primarily altering the balance between the "Hydrogen level" and the "Methane level."



- It is evident that the characteristics for hydrogen in dry air are more linear compared to those in humid air.
- The standard deviation for low hydrogen concentrations is greater than at other concentration levels. Methane was not detected in this setup.
- The deviation between devices is larger in humid air than in dry air, with a difference of about 1.5 in humid air and approximately 1 "Score" in dry air at a concentration of 27 ppm.
- The characteristic in humid air is higher on the "Score" axis compared to dry air, with a difference of about 1-1.5.



CONCLUSIONS

Level of Hydrogen unlike methane affects more the "Score" level or fermentation level. So, there is on figure 6 or 7 27 ppm Hydrogen concentration (about 5.5 "level" on figures) is in about 2 times higher in "level" then 55ppm methane concentration (about 2.5 "level" on figures). This is contrary to methane in recalculation on equivalent hydrogen (fermentation level) which taken with coefficient 4 [4]

In the conduct of experiments we have noted that measure procedure is depended on the smartphone operational system. It is mean about interruption interval between measurements. When devise associated with Android smartphone this interval equals 5 minutes while with iOS it is 15 minutes. This interval declared as minimum period of sensor recovery.

In addition, while methane gas validation in dry air without hydrogen it has been found that 2 out of 4 AIRE 2 devices ignored 55ppm and 110 ppm concentration and 4 out of 4 ignored 11ppm concentration. It is similar to wet air case except for 11ppm could detected by 1 out of 4 devices. Ignoring here is lack of start the measuring procedure. Supposedly this is because methane sensor TGS2611 using in the AIRE2. According, to technical documentation such methane sensors have working range in 500-10000ppm, it is 5 times higher than top concentration methane limit in the human breath.

The error in gas concentrations was checked using the GastroCH4eck breath monitor (Bedfont®, UK) and was found to be within $\pm 5\%$ [2]. Four AIRE2 devices were calibrated in parallel using Bluetooth connections to three iPhones and one Android smartphone, with mobile applications installed from the vendor's website (www.foodmarble.com). All measurements were repeated five times for each gas mixture. The result of each measurement was displayed on the smartphone as a fermentation rate in proprietary units ("Score" from 1 to 10).

Methane and hydrogen gas cylinders were used with concentrations of 2540 ppm and 6250 ppm, respectively. The concentration uncertainty is about 3%. A Cellkraft Humidifier P-2 was used as the humidity generator.

References

[1] Shrestha A. et al. Validity of a portable breath analyser (AIRE) for the assessment of lactose malabsorption //Nutrients. – 2019. – T. 11. – Nº. 7. – C. 1636 [2] GastroCH4ECK® Gastrolyzer® USER MANUAL [3] https://www.bronkhorst.com/int/products/gas-flow [4] Christl S. U. et al. Production, metabolism, and excretion of hydrogen in the large intestine //Gastroenterology. – 1992. – T. 102. – Nº. 4. – C. 1269-1277