Study Report

SPECTROPHON Dehydration Monitor Accuracy Evaluation

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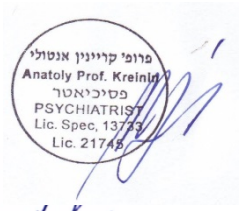

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1. Study information and Objective

Reduced physical activity is considered as a risk factor for obesity, diabetes, cancer and depression. A proper exercise program can mitigate cognitive and physical decline associated with ageing [1,2,3,4]. Existing general guidelines for physical activity are not universal or appropriate for every person. A personalized approach based on a subject age and unique combination of different physiological parameters would serve as a solution for finding optimal training protocols for individuals. Hence, monitoring basic physiological and biochemical parameters and obtaining information reflecting the body metabolic state is necessary for health status estimation to develop the abovementioned personally-oriented training protocols. Dehydration Body Monitor (DBM) developed by Spectrophon LTD can measure sweat lost, salt concentration in sweat, and sweating dynamics, which can be used for personal physical status monitoring. This is important not only for controlling appropriate body hydration level but also for keeping kidneys "healthy" [5]. Currently, only few DBM tools are available on the market, so there is a growing need for new effective accurate real-time DBM sensors.

The main **objective** of current study is to estimate the accuracy of Spectrophon DBM incorporated in smartwatch Samsung Gear S2 and sport band Samsung Gear Fit2. The secondary **aim** of the study is to evaluate the safety-in-use of Spectrophon DBM.

Study variables and end points:

Volume of sweat produced during exertion – 4 times per experiment

Total salt in sweat – 4 times per experiment (not relevant for the current study)

Visual examination of the skin contacting the sensor - at the end of the experiment

2. Test Facility

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3. Tested device

Name: Dehydration Body Monitor
Source: Spectrophon, LTD
Model: SP-DBM
Firmware version: 1.5

4. Experimental Design

Healthy adults (n=200) in different age and gender groups were recruited for the study. Samsung Gear S2 smartwatch with Spectrophon DBM attached to the bottom of the smartwatch were placed on the right wrist of each participant. At the same time, Samsung Gear Fit2 sport band with Spectrophon DBM attached to the bottom of the band was placed on the left wrist of the participant. Each participant was subjected to moderate physical activity. Data from Samsung Gear S2 and Samsung Gear Fit2 was obtained simultaneously. In parallel, subject weight was also monitored using commercially available digital balancers (Shekel B-200-P).

The evaluation of the measurement accuracy of the Spectrophon DBM was defined as the difference between subject weight change during the exertion (due to sweating and water consumption) and the volume of sweat detected by Spectrophon DBM.

All experiments were conducted indoors under ambient temperature (18^{o}C) and humidity (40-60%) .

4.1. Experimental groups:

Number of subjects: 200

Age range: 18-50+

18-25 years: 50 participants

26-35 years: 50 participants

36-45 years: 50 participants

46-50 years: 50 participants

4.2. Inclusion criteria:

1. Age: older than 18, both gender.
2. Ability and willingness to sign an informed consent form for participation in the study.

Exclusion criteria:

1. Presence of cardiologic or vascular disease.
2. Evidence of any other serious medical disorder.
3. Pregnancy

5. Procedures:

Participants were weighed prior to the experiment (no clothing after maximal drying) and then subjected to physical activity (walking on the treadmill).

5.1. Activity protocol:

T0: Initiate exercise

T1: T0+15 min - Stop exercise, Rest

T2: T0+25 min - Initiate exercise

T3: T0+40 min – Stop exercise, Rest

T4: T0+50 min - Initiate exercise

T5: T0+65 min – Stop exercise

T6: T0+75 min - Initiate exercise

T7: T0+90 min – Stop exercise

Total duration of study: 90min.

5.2 Intensity of exercises:

Participants could choose high or low intensity of exertion:

a. High: 0:00-0:01 – preparation;

0:01-0:05 – 5.5km/h;

0:05-0:10 – 6.0km/h;

0:10-0:15 – 6.5km/h;

b. Low: 0:00-0:01 – preparation;

0:01-0:05 – 5.0km/h;

0:05-0:10 – 5.5km/h;

0:10-0:15 – 6.0km/h;

5.3 Data recording:

After DBM application was activated, DBM started recording data (sweat rate and total salt in sweat) every 20 sec. and automatically saved results into archive on a mobile phone linked to Samsung Gear S2 or Samsung Gear Fit2 by Bluetooth. Manual recording of data was conducted during breaks (between phases T1-T2, T3-T4, T5-T6 and after T7).

Participants were also weighed during each break (no clothing after maximal drying).

5.4. Drinking

During the procedure, subjects could drink up to 500 ml of water. The weight of the bottle was measured and recorded after drinking during breaks. The difference was subtracted to the weight loss calculation.

5.5 Restrictions:

In this experiment, we avoided:

a. Urination during test (empty before T0)
b. Weight loss should not exceed 2%

Participants could cancel the experiment at any point of the procedure if desired.

6 Results

Most participants (97%) chose high intensity level of exertion. Only 1 participant was not able to finish the procedure due to a prior leg trauma (not related to the current experiment).

In the first days of the experiment, there were difficulties with data recording of Spectrophon DBM incorporated in Samsung Gear Fit2 due to conflict between DMB software and software monitoring energy consumption. The problem was quickly solved by DBM software update.

Subject skin was examined after the procedure to ensure: no allergic reaction or any other reaction related to hypersensitivity caused by DBM. No adverse skin reactions were observed.

There was no significant difference between data obtained from Samsung Gear S2 and Samsung Gear Fit2. In both cases the difference between weight loss measured using commercially available balancers Shekel B-200-P and sweat rate measured by Spectrophon DBM did not exceed 20% in 95% of all samples.

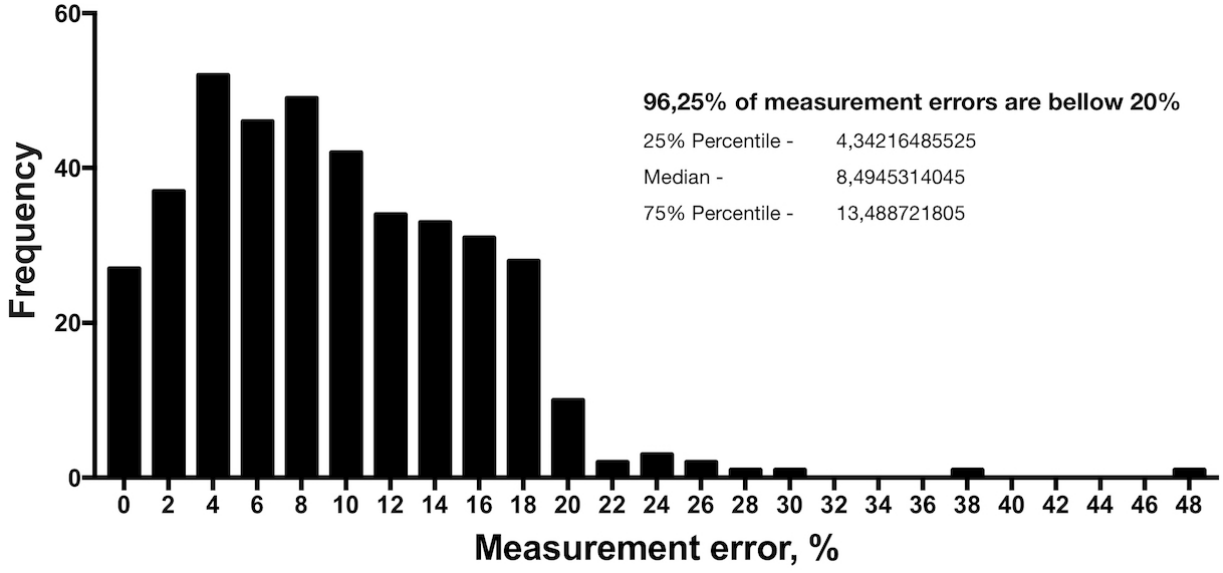

Fig.1 Frequency of Measurement Errors (all datasets combined)

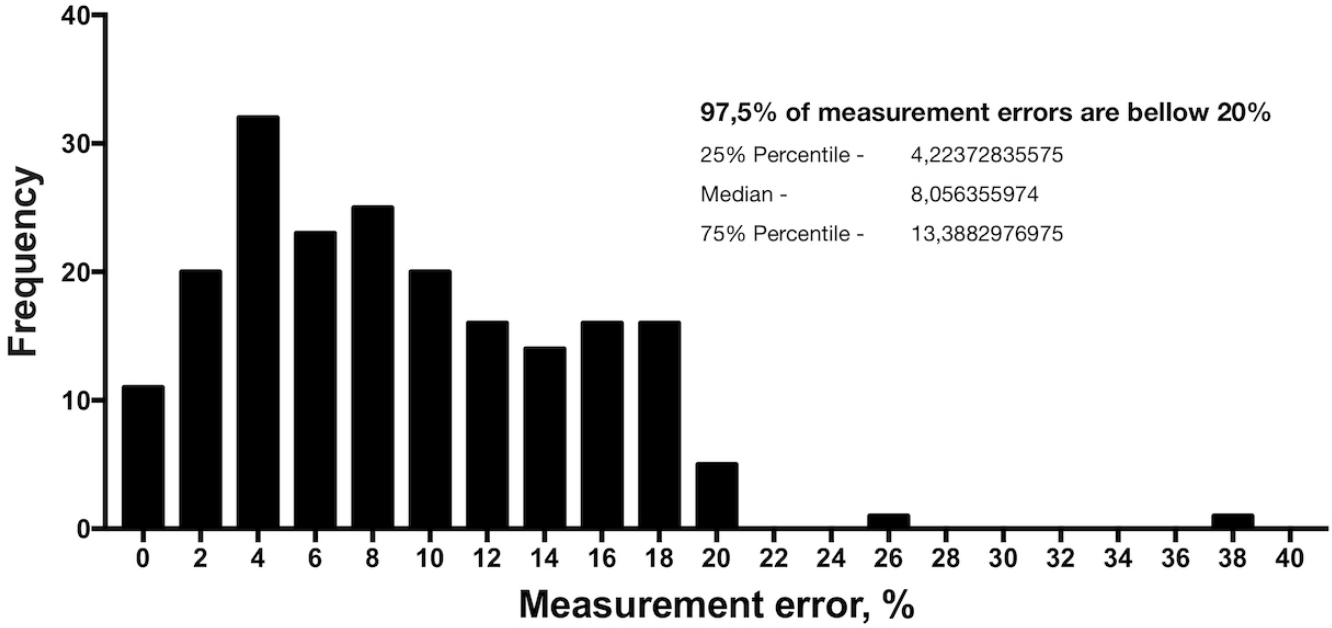

Fig.2 Frequency of Measurement Errors (Samsung Gear S2)

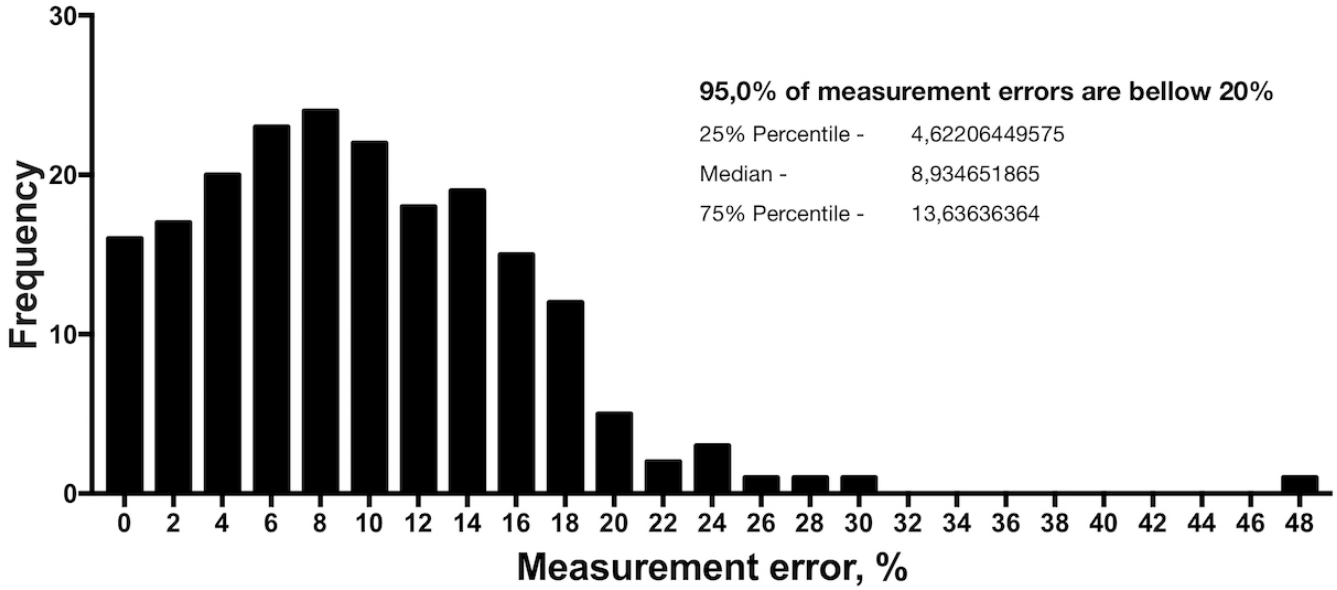

Fig.3 Frequency of Measurement Errors (Samsung Gear Fit2)

7 Summary

Out of 200 measurements conducted by Spectrophon DBM, less than 5% differed from the real weight loss for more than 20%. Most of these differences may be explained by incorrect procedure following by the participant (short removal of the tested devices, unplanned buttons push, not complete drying before weighing etc.).

Obtained results allowed us to conclude that DMB developed by Spectrophon LTD is an accurate tool for sweat rate measurement

8 References

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