WHITE PAPER

Determination of precision for the seca medical Body Composition Analyzer 514/515 (seca mBCA) in Caucasian adults

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Introduction

The seca mBCA uses the Bioelectrical Impedance Analysis (BIA) method. The medical device is validated against respective gold standard reference methods and consists of clinically investigated reference data for the interpretation of normal values.
The accuracy and precision of the BIA method -amongst others- are affected by instrumentation, client factors, technical skill and environmental factors. In order to determine the precision of the seca mBCA multiple measurements with different users and devices need to be undertaken and matched against each other.

Study objective

Aim of the study is to show the precision of the device amongst the three important elements of variability:

1. **repeatability**
   variability across successive measurements within a short time period taken by the same operator and the same device.
2. **between-device precision**
   variability across measurements taken by the same operator, but different devices
3. **between-operator precision**
   variability across measurements taken by the same device, but different operators

Subjects and methods

Nine Caucasian men and women (BMI 21.1-25,7 kg/m^2) aged 24-51 years were recruited at the Institute of Human Nutrition and Food Science in Kiel, Germany.
For the measurements three series are were conducted as follows:

1. Four subjects with three consecutive measurements per subject performed by operator I on one device
2. Four subjects with three consecutive measurements per subject performed by operator I and additionally operator II one device
3. Four subjects with three consecutive measurements per subject performed by operator I on one device and three consecutive measurements of the same subjects performed by operator I on another device

In total this set-up generated N=60 measurements.
The measurements were carried out with the seca mBCA at frequencies of 5 kHz and 50 kHz and delivered values for the BIA parameters fat free mass (FFM), total body water (TBW), extracellular water (ECW) and phase angle (φ).
As a result of the clinical validation of the seca mBCA against respective gold standards reference methods with 124 Caucasian subjects the standard errors of estimation (SEE) shown in table 1 were calculated.

Table 1 SEE for BIA results measured in the device validation study

parameter	SEE
TBW [l]	1.35
FFM [kg]	1.91
ECW [l]	0.78

TBW, Total body water; FFM, fat free mass; ECW, extracellular water; SEE, standard error of estimation

The SEE for φ is determined with 0.5° by the manufacturer.
All mentioned standard errors of estimate were defined as acceptance limits for the measurements undertaken in this precision study.

Results

Basic characteristics of the Caucasian study subjects are listed in table 2:

Table 2 Descriptive characteristics of the Caucasian study population in Kiel (MW ±SD)

Subject ID	gender	weight [kg]	height [m]	BMI
S_80	male	89.45	1.897	24.9
S_137	male	82.2	1.870	23.5
S_138	male	88.05	1.852	25.7
S_144	male	83,75	1.890	23.5
S_146	male	76.35	1.800	23.6
S_147	female	59.3	1.670	21.3
S_148	female	61.5	1.700	21.1
S_150	female	70.15	1.760	22.6
S_151	female	71.25	167.3	25.5

BMI, Body Mass Index

In the following figures the above listed limits (+/- SEE) for each parameter and the mean values for each subject are shown.

Series for repeatability measurements

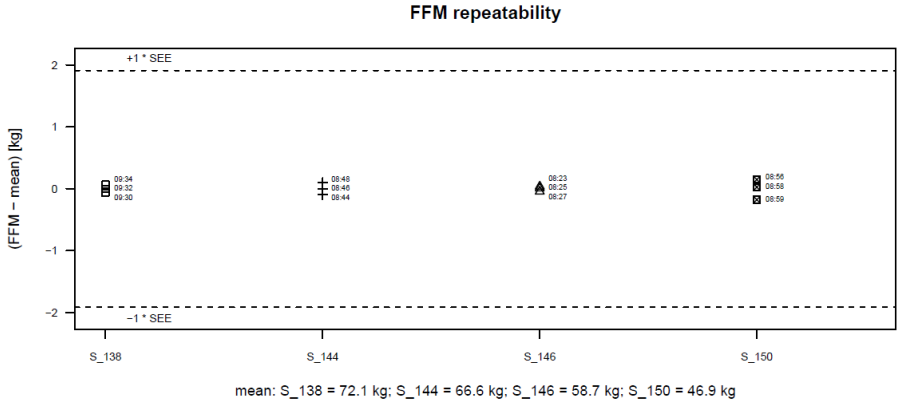

Figure 1 FFM results on repeatability

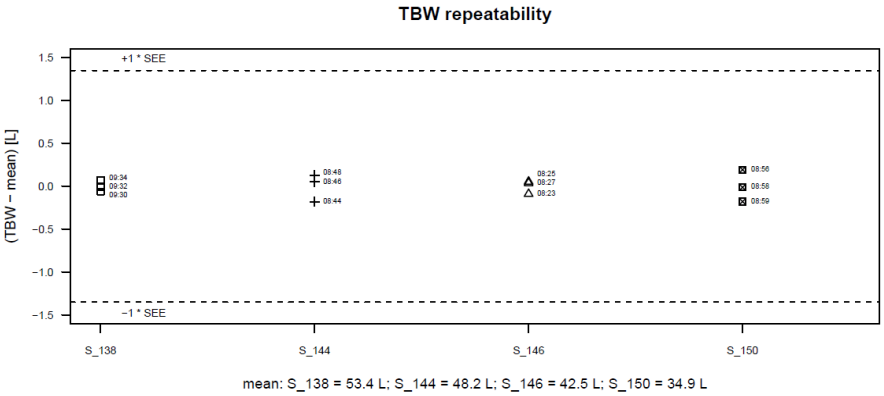

Figure 2 TBW results on repeatability

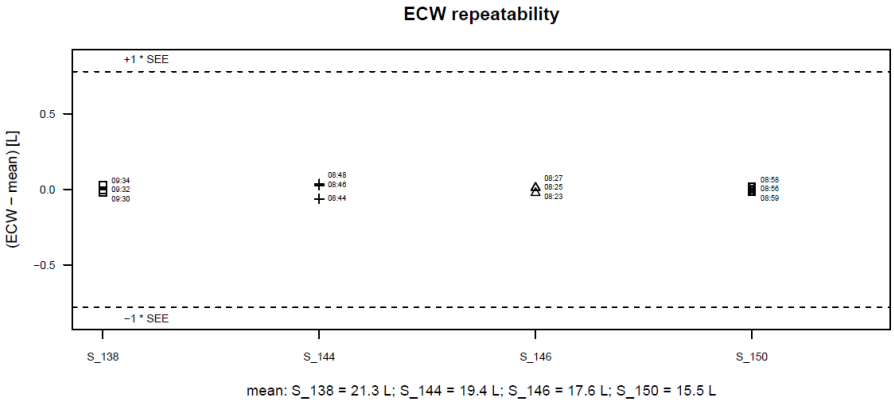

Figure 3 ECW results on repeatability

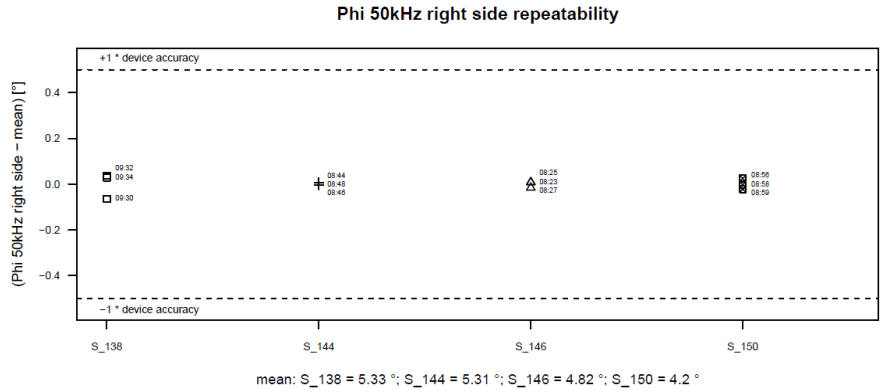

Figure 4 φ right side results on repeatability

Series for between operator measurements

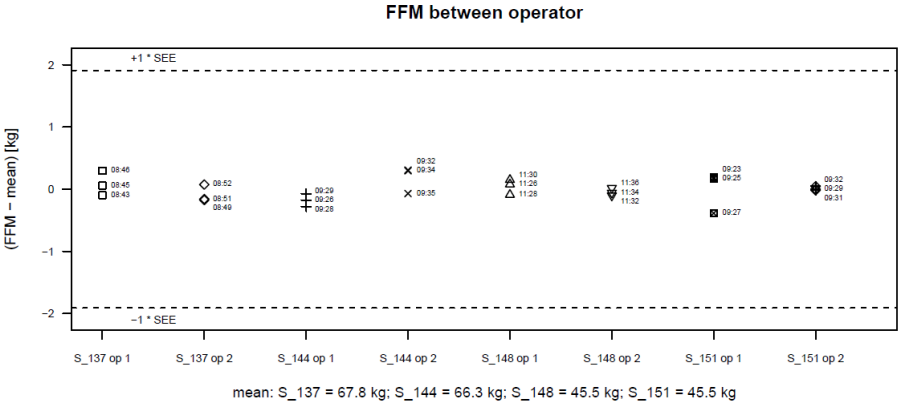

Figure 5 FFM results between operator

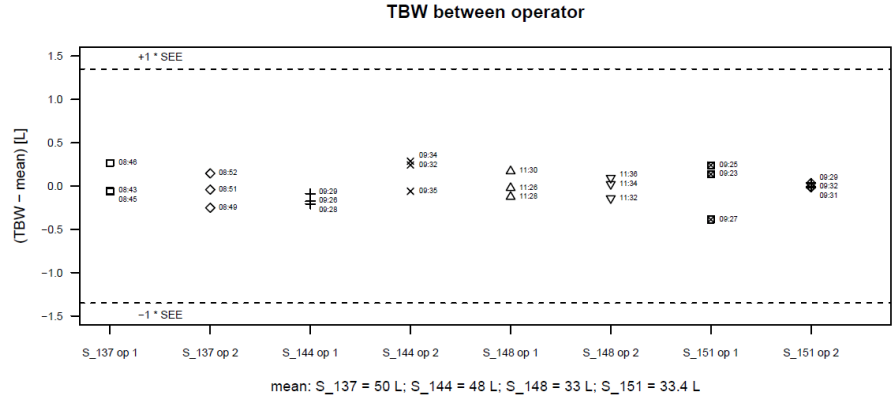

Figure 6 TBW results between operator

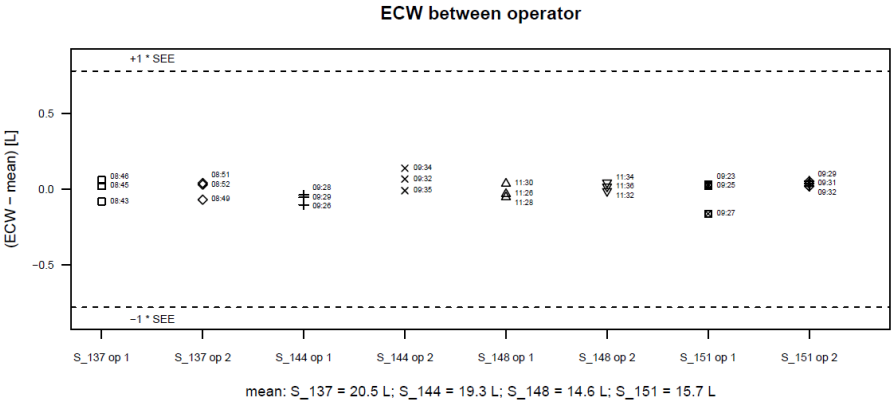

Figure 7 ECW results between operator

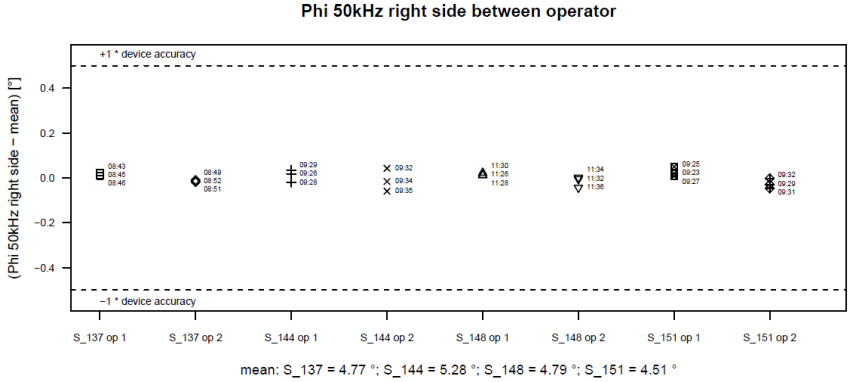

Figure 8 φ right side results between operator

Series for between device measurements

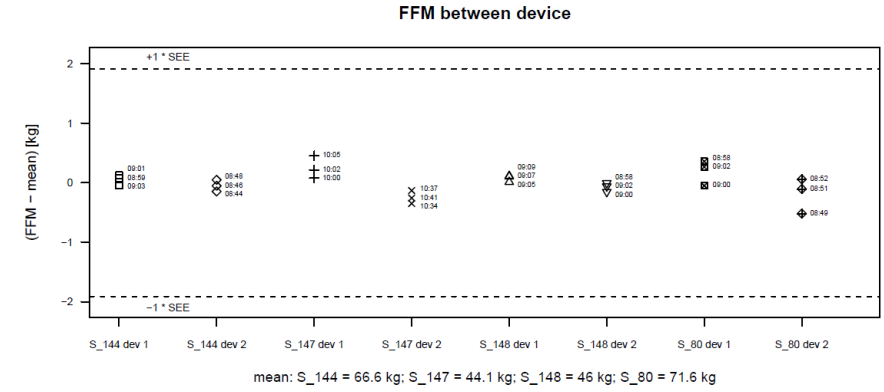

Figure 9 FFM results between device

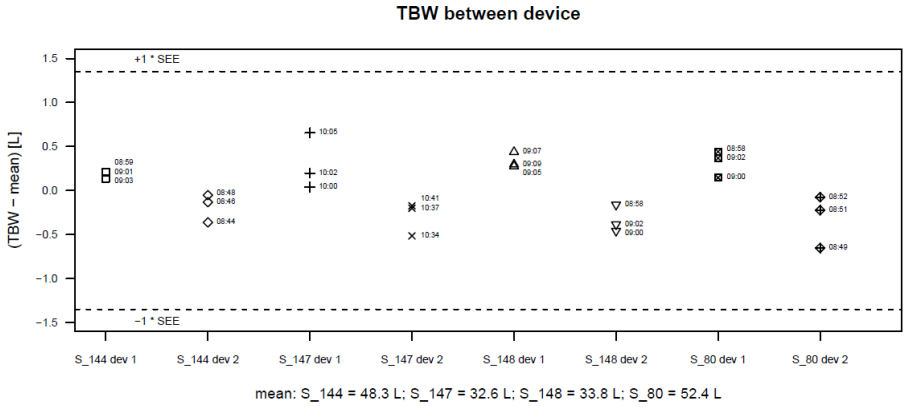

Figure 10 TBW results between device

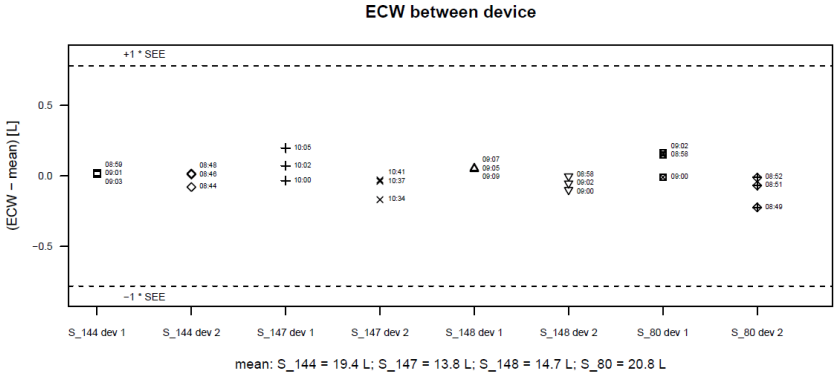

Figure 11 ECW results between device

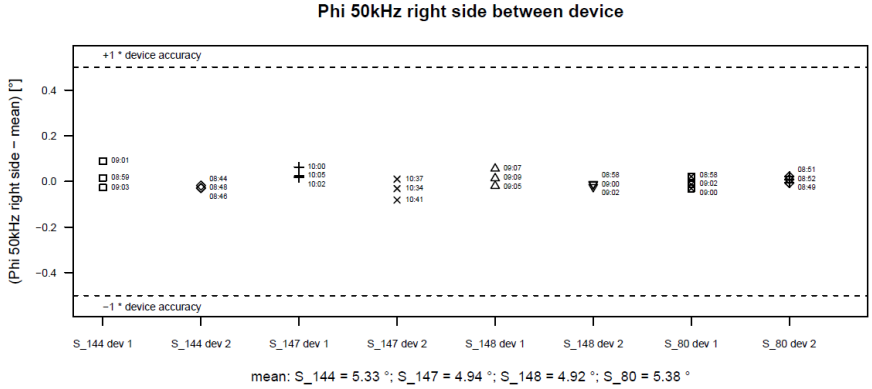

Figure 12 φ right side results between device

Conclusion

All results generated for the subjects S_80; S_137, S_138, S_144, S_146, S_147 S_148, S_150 and S_151 are within the defined acceptance limits.
The validated eight-electrode, segmental multifrequent seca mBCA BIA device which estimates the body composition in adults in various ethnic populations therefore is a clinically precise device regarding repeatability across different operators and devices to measure FFM, FM, TBW, ECW and φ.