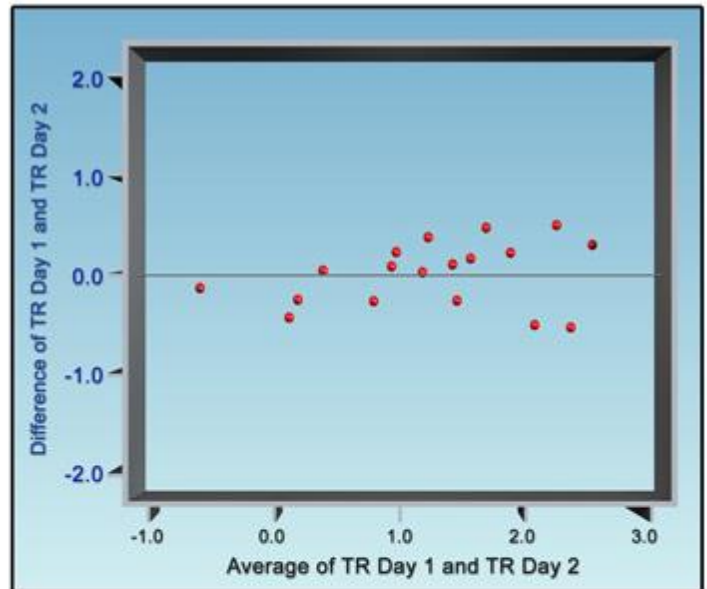
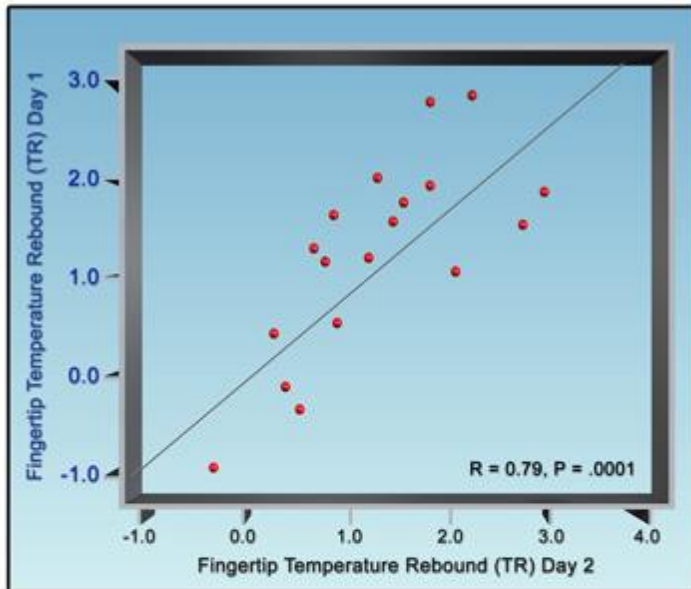


Reproducibility and Repeatability of VENDYS® Measurements



Variable	D	SD _D	CV (%)	CR (%)	ICC	P value
Heart Rate	0.47	0.054	11.4	10.6	0.7	0.01
Mean Arterial Pressure	0.44	0.038	8.7	7.5	0.79	0.0005
Start Temperature	0.51	0.036	7.1	7.1	0.81	0.0001
DTM (VENDYS®) Indices of Vascular Reactivity						
TR° C	0.209	0.012	5.7	2.4	0.82	0.0001
AUC	0.292	0.014	4.8	2.8	0.83	0.0001

D: mean absolute difference; SD_D: SD of mean differences; CV: coefficient of variability $[(SD_D/D)*100]$; CR: coefficient of repeatability $[(SD_D * 1.96)*100]$; ICC: Intra-class Correlation Coefficient.

Reproducibility and Variability of Vascular Reactivity Measurement using Digital Thermal Monitoring

Background: Previous studies demonstrated that Digital Thermal Monitoring (DTM) of vascular reactivity, a new test for vascular function assessment, is well-correlated with Framingham Risk Score, coronary calcium score and CT angiography. This study evaluates the variability and reproducibility of DTM measurements. We hypothesized that DTM is reproducible and its variability falls within the accepted range of clinical diagnostic tests. A fully automated DTM device (VENDYS, Endothelix Inc., Houston) was used for repeated measurement of vascular reactivity and endothelial function in 18 healthy volunteers (age 35±4 years, 74% male) after 24hours. All subjects underwent overnight fasting, and the test was preceded by 30 minute rest in a supine position inside a dimmed-room with temperature 22°C to 24 °C. The measurements were obtained during and after a 2 minute supra systolic arm-cuff occlusion induced reactive hyperemia procedure. Post cuff-deflation adjusted temperature rebound (TR) and AUC (area under the temperature curve), DTM indices of vascular function, were studied. Day to day coefficient of repeatability was 7.1 % for baseline temperature, 7.5% for mean blood pressure and 10.6% for heart rate. The coefficient of repeatability (CR) of TR and AUC were 2.4% and 2.8%, respectively. In a controlled-environment, the repeatability of DTM is excellent. DTM can be used as a reproducible and operator-independent test for measurement of vascular function in clinical trials and cardiovascular risk assessment clinics.