BSX Answers to DCR Questions:

1. Question: What are the accuracy and precision of the results compared with blood tests?

BSXinsight is over 95% accurate at identifying lactate threshold. It uses novel algorithms and proprietary machine learning techniques built from literally hundreds (n=800+) of individual athlete tests to achieve this industry standard level of accuracy.

This means that across all athletes whom we've tested at BSX Laboratories we were able to identify lactate threshold using BSXinsight with 5% or less deviation from what independent professional assessment determined it to be using traditional blood sampling methods. In other words, those error measurements represent the percent deviation from what the blood tests determined lactate threshold to be using blood draws, and what BSXinsight determined it to be.

The BSXinsight was not only accurate but demonstrated extremely high precision. The Thresholds determinations had a the standard deviation that was about less than one half of the increment between states, which was for example, approximately 10 watts for power. This is on par with what is commonly reported in the scientific literature for traditional blood lactate testing.

2. Question: How does the length of the test impact my results?

A good Endurance (Lactate Threshold) Test is designed to bring an athlete to maximal effort within about 25-30 minutes which amounts to about 8-10 stages that are three minutes in duration. This is a tried and true method followed by human performance experts and Centers around the world based on the best way to track the blood lactate changes. (Admittedly there are other protocols in existence that vary in length of stage and rate of exertional increase. In general, these produce clinically comparable results).

In order to visually identify the accumulation of lactate in the blood the traditional test was designed to take the athlete through 5-7 stages of effort below aerobic threshold where lactate is not changing appreciably, 2-3 stages transitioning to the anaerobic threshold where lactate concentrations are increasing and then 1-3 stages above their anaerobic threshold where the major lactate accumulation occurs.

The biosignals that the BSXinsight collects, which are correlated to the lactate concentrations by our proprietary algorithm, allow the calculation of aerobic and anaerobic threshold, which correspond to the initial increase and accumulation of lactate respectively.

The effort level you start from is important to a successful Endurance Test. If an athlete does not exercise at the correct number of stages in each of the three ranges previously described (above/at/below threshold) then the underlying changes in the muscle tissue will not be detectable, just as a traditional blood lactate testing would not be able to detect the accumulation of lactate in the blood. There is no difference here between the blood and optical approach.

BSXinsight identifies optical changes in muscle biosignals (principally SmO_2 but also including a variety of other indicators) to determine lactate threshold both aerobic and anaerobic. Since BSX algorithms are looking for biological 'transitions' or features that tightly correlate with what is commonly referred to as Threshold, extending far beyond this point provides little value and it is advised from a safety perspective to end the Test. Following the same logic, ending a test prior to this transition point will not result in a successful test result.

Our extensive testing has shown that athletes have varying ability to push themselves to and beyond the physiologic events we commonly call lactate threshold. In order to accommodate for these athlete specific variations and generate training zones that are tailored to that individual, we have identified quantifiable adjustments that can be made in the event an athlete continues to exert well beyond.

3. Question: How large are (and what are the causes of) typical variations of the LT output that are not caused by changes in athletic fitness?

Retrospective analysis of all of the test data collected at BSX Laboratories, as well systematic review of the scientific literature on traditional blood lactate demonstrates that repeated testing can in some cases produce threshold determination for athletes that vary by 5-10 watts for both blood and optical measurements. Historically, researchers attribute this reported variation to a number of factors of which physical and mental fatigue, blood sampling technique and nutrition have been verified to play a major role. One of the major benefits of testing with BSXinsight is the absence of sampling technique as an error source and hence the potential for greater reliability on the data. For best results, it is advisable to wait at least 24h after any extraneous physical exercise before performing an Endurance Test and to make sure you are of typical mental / physical energy.

4. Question: Can the BSXinsight be worn on other muscles?

Initial development of BSXinsight was optimized for and calibrated around the calf muscle. For Endurance testing it is critical that the sensor be worn only at that site. For daily training, however, BSXinsight can be worn on any muscle. Regardless of the muscle that you choose to measure, it is important the BSXinsight is securely yet comfortably worn. Attaching too loosely can result in excessive motion artifact that will decrease the quality of the data. Similarly, attaching too tightly can restrict blood flow producing undesirable discomfort as well as harm to the data.

It is also important to note that the included BSXinsight calf sleeve comes with advanced light blocking technology to allow outdoor training, even in the harshest lighting environments. When measuring from other muscle groups, it is important to make sure that external light is effectively blocked.

When comparing for day to day consistency, it is best if the BSXinsight is attached to the same site using the same method each time. Variations in muscle selection, measurement site, and method of attachment can produce variations in the reported data. This isn't necessarily a bad thing, but it must be noted and accounted for when attempting to compare various data sources. For example, different muscles will produce different SmO2 profiles depending on their level of recruitment during an activity.

5. Question: How repeatable are BSXinsight SmO_2 measurements?

When considering repeatability, two types are of importance: baseline and dynamic. Baseline repeatability is defined as the SmO2 readings when the device is worn at rest while dynamic repeatability is defined as the recorded variation in SmO2 when athletes perform the same physical activity under the same initial conditions (e.g., starting from a rest state).

BSXinsight has been measured to demonstrate best in industry baseline repeatability. It also shows the best absolute dynamic repeatability (i.e., the standard deviation of the SmO_2 change during exercise). It will be noted that BSXinsight slightly underperforms the competition in measurements of relative dynamic repeatability (i.e., the standard deviation of SmO_2 change divided by the mean amplitude of the change). This is due to the fact that the competition exaggerates (artificially amplifies) the amount of SmO2 variation recorded during an activity.

A rule of thumb to remember when evaluating the repeatability of SmO2 data with BSXinsight is the *2-3-7 rule* (see actual numbers below). This simply means that when comparing data from the same athlete at the same location, one can expect up to 2% variation (actually, 1.6%) under identical physiologic conditions. The BSXInsight device monitors the muscle directly below the sensor and is sensitive to localized variations in oxygenation. Therefore, when monitoring SmO_2 values from the same athlete on contralateral muscle groups 3% of SmO_2 variation are typically seen. When the same muscle group is measured between two different athletes, the reported person-to-person variation is about 7%, in a repeatable way (that is, different people have consistently different baselines).

Table 1: Expected standard deviations for SmO_2 baseline variations when using the BSXInsight device.

% Variation	**Event**
1.6%	same calf, short term
2.8%	same calf, long term
2.4%	contralateral calf, short term
3.3%	contralateral calf, long term
7.2%	different athlete subject

Table 2: Expected short-term contributions to baseline variation (same calf).

Independent sources of variation	**Value (% pts)**
Device	0.05
Short-term physiological changes	0.47
Small placement-to-placement variation	1.53
Short-term baseline std. dev.	**1.60**

Table 3: Expected long-term contributions to baseline variation (same calf).

Independent sources of variation	Value (% pts)
Device	0.05
Small placement-to-placement variation	1.53
Longer-term physiological variation	2.31
Long-term baseline std. dev.	**2.77**

Table 4: Expected short-term contributions to baseline variation (contralateral calf).

Independent sources of variation	Value (% pts)
Device	0.05
Short-term physiological changes	0.47
Typical placement-to-placement variation	2.35
Typical short-term baseline std. deviation	**2.40**

Table 5: Expected long-term contributions to baseline variation (contralateral calf).

Independent sources of variation	Value (% pts)
Device	0.05
Typical placement-to-placement variation	2.35
Longer-term physiological variation	2.31
Total long-term baseline std. deviation	**3.30**

6. Question: Does the BSXinsight measure absolute or relative SmO_2?

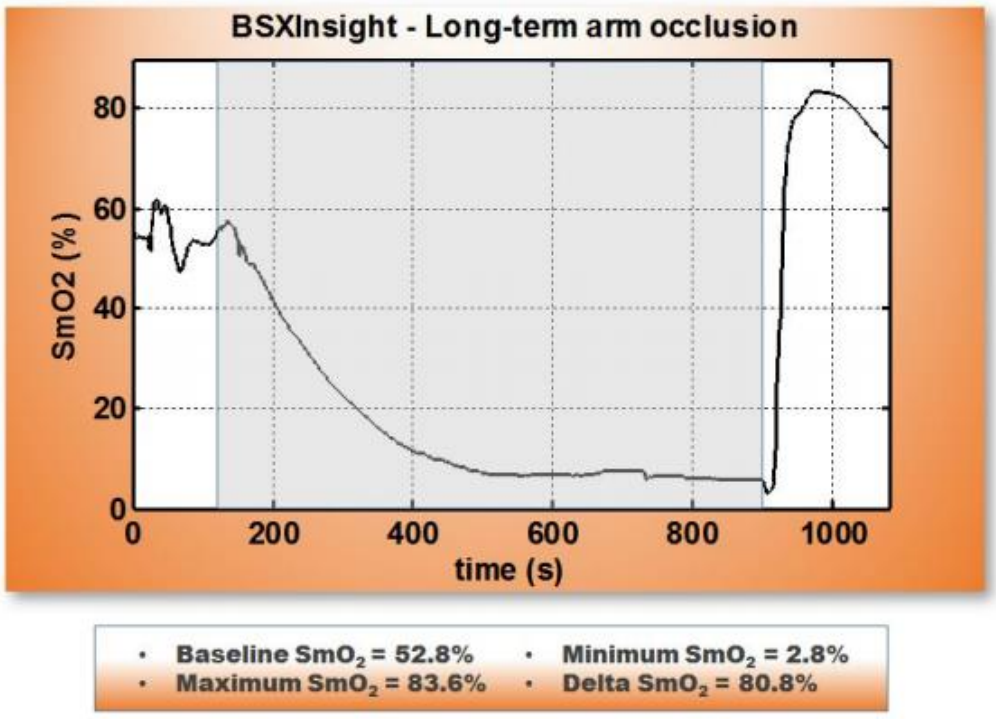
The BSXinsight is calibrated for absolute measurements within a range from 0% to 100%, where 0% indicates that all hemoglobin in the tissue volume directly below the sensor have completely given out all their oxygen and, thus, consist of deoxyhemoglobin, while 100% indicates that all hemoglobin in the tissue directly below the sensor are completely oxygenated (oxyhemoglobin).

7. Question: How accurate are the SmO2 values reported by the BSXinsight?

As covered in a previous topic, BSXinsight Gen2 SmO_2 are calibrated for absolute measurements within a range from 0% to 100%, where 0% indicates that all hemoglobin in the tissue volume directly below the sensor have completely given out their oxygen and, thus, consist of deoxyhemoglobin, while 100% indicates that all hemoglobin in the tissue directly below the sensor are oxygenated (oxyhemoglobin).

The Figure below shows SmO_2 values monitored in the forearm during a long-term arterial occlusion. During long occlusion living tissue continues to consume oxygen to sustain its metabolic processes, up to the point when all oxygen has been consumed. Once the occlusion is terminated oxygenated blood rushes to re-oxygenate the arm, leading to high oxygenation values. In the experiment below we see a minimum SmO_2 value of 2.8% and a maximum (after occlusion) value of 83.6%, demonstrating the BSXinsight's ability to monitor the full range of oxygenation values in tissue.

Comparing those values to an expected baseline of 80.6% (using arterial and venous values available in the literature for example, from Medbo[1] or Bloos[2]), and an absolute minimum oxygenation level of 0%, we see that the range of 2.8% to 83.6% is very close to the expected range, with a maximum deviation of 2.8% and 3% at the lowest and highest values, respectively.



References

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2. F. Bloos and K. Reinhart, "Venous oximetry," in Intensive Care Med. , v. 31, pp. 911–913 (2005)