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14. ABSTRACT

Purpose. The validity and the reliability of using intestinal temperature (Tint) via ingestible temperature sensors (ITS) to measure core body temperature have been demonstrated. However, the effect of elapsed time between ITS ingestion and Tint measurement has not been thoroughly studied. Methods: Eight volunteers (six men and two women) swallowed ITS 5 h (ITS-5) and 29 h (ITS-29) before 4 h of varying intensity activity. Tint was measured simultaneously from both ITS, and Tint differences between the ITS-5 and the ITS-29 over the 4 h of activity were plotted and compared relative to a meaningful threshold of acceptance (+ .25ºC). The percentage of time in which the differences between paired ITS (ITS-5 vs ITS-29) were greater than or less than the threshold of acceptance was calculated. Results: Tint values showed no systematic bias, were normally distributed, and ranged from 36.94ºC to 39.24ºC. The maximum Tint difference between paired ITS was 0.83ºC with a minimum difference of 0.00ºC. The typical magnitude of the differences (SE of the estimate) was 0.24ºC, and these differences were uniform across the entire range of

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Influence of Sensor Ingestion Timing on Consistency of Temperature Measures

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ABSTRACT

GOODMAN, D. A., R. W. KENEFICK, B. S. CADARETTE, and S. N. CHEUVRONT. Influence of Sensor Ingestion Timing on Consistency of Temperature Measures. *Med. Sci. Sports Exerc.*, Vol. 41, No. 3, pp. 597–602, 2009. **Purpose**: The validity and the reliability of using intestinal temperature (T_{int}) via ingestible temperature sensors (ITS) to measure core body temperature have been demonstrated. However, the effect of elapsed time between ITS ingestion and T_{int} measurement has not been thoroughly studied. **Methods**: Eight volunteers (six men and two women) swallowed ITS 5 h (ITS-5) and 29 h (ITS-29) before 4 h of varying intensity activity. T_{int} was measured simultaneously from both ITS, and T_{int} differences between the ITS-5 and the ITS-29 over the 4 h of activity were plotted and compared relative to a meaningful threshold of acceptance (±0.25°C). The percentage of time in which the differences between paired ITS (ITS-5 vs ITS-29) were greater than or less than the threshold of acceptance was calculated. **Results**: T_{int} values showed no systematic bias, were normally distributed, and ranged from 36.94°C to 39.24°C. The maximum T_{int} difference between paired ITS was 0.83°C with a minimum difference of 0.00°C. The typical magnitude of the differences (SE of the estimate) was 0.24°C, and these differences were uniform across the entire range of observed temperatures. Paired T_{int} measures fell outside of the threshold of acceptance 43.8% of the time during the 4 h of activity. **Conclusions**: The differences between ITS-5 and ITS-29 were larger than the threshold of acceptance during a substantial portion of the observed 4-h activity period. Ingesting an ITS more than 5 h before activity will not completely eliminate confounding factors but may improve accuracy and consistency of core body temperature. **Key Words:** GASTROINTESTINAL MOTILITY, INTESTINAL TEMPERATURE, MEANINGFUL THRESHOLD OF ACCEPTANCE, TELEMETRY

Monitoring core body temperature is one of the best methods to reduce the risk of heat injury in athletic, occupational, and military settings. The manner in which core body temperature is measured represents a balance between accuracy, reliability, and logistical practicality. The "gold standard" of measurement in experimental research settings is a thermistor or a thermocouple probe inserted into the esophagus (3,20) and, in field settings, the rectum (19,25). However, these approaches are largely impractical for field use when continuous core body temperature measurements are needed. The advent of ingestible temperature sensors (ITS), which transmit intestinal temperature (T_{int}), has allowed for the continuous monitoring and recording of core body temperature without the logistical limitations imposed by laboratory techniques designed principally for constrained data collection.

The validity and the reliability of using T_{int} via ITS as a surrogate for core body temperature have been demonstrated under controlled conditions (4,5,7–9,18,21,31). Gant et al. (9) found good agreement between T_{int} and T_{rec} during intermittent exercise 10 h after ITS ingestion, and they concluded that T_{int} measures were reliable between repeated trials when allowing 10 h between ingestion and measurement. O'Brien et al. (21) compared T_{int} to both rectal (T_{rec}) and esophageal (T_{eso}) temperatures during rest and exercise as well as during warm and cold water immersion. They concluded that 12 h after ingestion, T_{int} measures via an ITS were valid measures of core body temperature relative to T_{rec} and T_{eso} but suggested that ITS measures could be influenced by temperature variations along the GI tract. Although ITS measures of T_{int} have been shown to be valid and reliable, mitigating factors such as movement of the ITS within the GI tract may limit the use of ITS in measuring core body temperature for comparison between repeated trials.

Gastrointestinal motility is unpredictable and can play a large role in transit time of an ITS device out of the stomach and within the GI tract itself. The rate of GI motility is determined acutely by numerous factors such as dietary content including the use of caffeine, alcohol, and medication

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(23,24,26), exercise (13,16), time of day (26), emotional state (26), and dehydration (30), and by additional factors such as age (11,17,26), sex (11,26), training and fitness (14,22), or nicotine inhalation (17). As these factors are difficult to control, the transit time and the location of an ITS device within the GI tract could be highly variable and may alter T_{int} measures. Using standardized procedures to reduce the influence of some of these factors may decrease the variability of GI motility. McKenzie and Osgood (18) observed ITS transit times of 12.5 to 134.5 h (~0.5–5.5 d) and suggest that volunteers ingest an ITS at the same time every day to ensure no data loss when measuring T_{int} over extended periods.

The timing of ITS ingestion can alter T_{int} measures such that they are not valid compared with conventional measures. Manufacturers of ITS devices recommend ingestion 3–5 h before exercise (HQinc, Palmetto, FL, and Minimitter Inc., Bend, OR). Inside this 3- to 5-h window, the amount of time the ITS resides within or near the stomach may affect T_{int} values due to food and fluid consumption (15,27,31). It is also possible that T_{int} values will differ along the GI tract during rest and exercise when the elapsed time between ITS ingestion and T_{int} measurements is extended beyond 5 h. Discrepancies between T_{int} measured via ITS and other measures of core body temperature (T_{rec}, T_{eso}) have been reported and range from 0.2°C to 2.2°C when an ITS is ingested 2–9 h before T_{int} measurement (5,15,27). Although the authors speculated as to the reason for the range of temperature differences observed, they did not specifically address that the discrepancies may have been due to differences in the amount of time elapsed between ingestion and measurement of T_{int}. More recently, Wilkinson et al. (31) reported that 5 h is sufficient time to eliminate effects of cold fluid ingestion for the majority of volunteers but suggest that an ITS be ingested 10 h before exercise to completely eliminate these effects. Gant et al. (9) supports the 10-h ingestion timing before activity to allow more time for the progression of the ITS along the GI tract where motility and differences between T_{int} and T_{rec} may be decreased. However, 10 h may result in the loss of an ITS in some volunteers if the measurement period extends beyond 12 h (18,21), thus requiring ingestion of a second ITS.

To date, the only study we are aware of where volunteers ingested two ITS many hours apart is reported by Wilkinson et al. (31). Volunteers ingested a pair of ITS 11.5 h apart for the purpose of identifying and observing transient temperature differences (>2.0°C) due to cold water ingestion over time. This report demonstrated that the majority of ITS are unaffected by cold fluid ingestion 5 h after ingestion; however, it does not provide data regarding the level of agreement between paired ITS after 5 h. The purpose of the current study was to quantify the agreement between a pair of ITS ingested 24 h apart by determining the amount of time the temperature differences would be greater than typical diurnal variations, and precision of the ITS device itself.

METHODS

Volunteers. All volunteers were provided informational briefings and gave voluntary and informed written consent to participate. Investigators adhered to policies for protection of human subjects as prescribed in Army Regulation 70-25 and US Army Medical Research and Materiel Command Regulation 70-25. The research was conducted in adherence with the provisions of 32 CFR Part 219. The study protocol was approved in advance by the Human Use Review Committee at the US Army Research Institute of Environmental Medicine and the Human Subjects Research Review Board at the US Army Medical Research and Materiel Command (USAMRMC). Eight volunteers (two female) were included in the analysis. An additional five volunteers participated but were not included in the analysis. The volunteers ranged in age from 18 to 32 yr. All volunteers were members of the United States Army, were of a moderate to high fitness level, and took part in physical training on a regular basis.

Study design. The investigation took place over three consecutive days in the Mojave Desert. Because this study was conducted in the field without laboratory access, no attempt was made to calibrate ITS as has been suggested by numerous publications (4,9,21,27,31). Therefore, we administered the ITS per the manufacturer specifications. Figure 1 presents the time line of an individual day of the study. Each morning, after breakfast, volunteers orally ingested an ITS (VitalSense Jonah Ingestible Capsule; Minimitter Inc.). From 1300 to 1700 h, volunteers performed structured, intermittent activities that included light, moderate, and high intensity exercise while carrying a load of approximately 15 kg. This structured activity occurred in ambient temperatures of 38–46°C and was designed to elicit elevations in T_{int}, which were recorded approximately every min on a portable data recorder (VitalSense Monitor, Minimitter Inc.) for each volunteer. On the second day, volunteers ingested a second ITS (24 h after the ingestion of the previous ITS), and T_{int} measures were recorded simultaneously from both ITS using dual channels of the same VitalSense Monitor. On the third day, three male volunteers retained both of the previously ingested ITS and performed the same procedures as the previous 2 d for observational

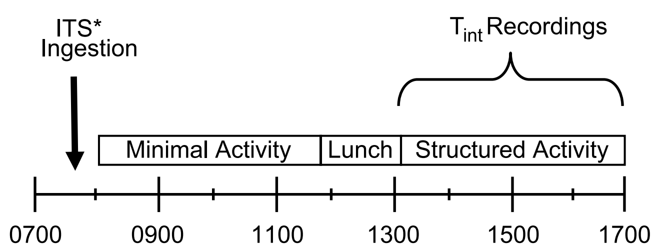

FIGURE 1—Individual day time line. T_{int} recordings were collected approximately every minute during the 4-h structured activity (1300–1700 h each day). Observations on days 1, 2, and 3 were of ITS in the GI tract for 5 h (ITS-5), 29 h (ITS-29), and 53 h, respectively. *T_{int} recordings for day 1 were limited to a single ITS.

purposes. No dietary, lifestyle, or nutritional restrictions were imposed, except to abstain from alcohol. Throughout all experimental testing, the eight volunteers included in the analysis were provided with cold water and permitted to drink *ad libitum* but exhibited no transient decreases of T_{int} often associated with cold fluid consumption as described by Wilkinson et al. (31). The additional five volunteers, who participated in the structured activities, were not included in the analysis because ITS-5 exhibited transient decrease in T_{int} from cold fluid ingestion (n = 1) (8) or they expelled an ITS less than 29 h after ingestion (n = 4). Upon completion of all testing, investigators verified that the ITS telemetry signal was no longer present before volunteers were allowed to remove the "MRI incompatible" safety wristband.

ITS comparisons. At the beginning of the 4-h structured activity on the second day, the ITS ingested the previous day was in the GI tract for 29 h (ITS-29), and the ITS ingested that morning was in the GI tract for 5 h (ITS-5). During the 4-h structured activity period, comparisons were made between simultaneous T_{int} recordings for each pair of ITS (ITS-29 vs ITS-5). It has been established that the rate of motility decreases along the GI tract such that an object, such as a bolus of food, or ITS, located in the lower small intestine would undergo less motility compared with one in the upper small intestine and greater motility compared with one in the colon (26). Therefore, this analysis was grounded on the premise that the ITS-29, in the GI tract for 29 h, would be more established within the lower GI tract whereas ITS-5 would reside somewhere in the upper GI tract (9). As an additional observation, the three male volunteers who had not expelled the previously ingested ITS by the third day allowed for a comparison of T_{int} from an ITS ingested 53 h (ITS-53) and 29 h (ITS-29) before the 4-h period of structured activity.

Criteria for T_{int} comparisons. Criteria for T_{int} comparisons between the ITS ingested 24 h apart were made using a meaningful threshold of acceptance of ±0.25°C. This threshold was determined to be meaningful by the typical day-to-day variability in rectal temperature when controlling for time of day as well as the precision of the ITS device itself. Consolozio et al. (6) reported ±0.25°C as the typical standard deviation of normal resting rectal temperatures in a large group of volunteers (n > 80). The precision of the ITS used in this study was ±0.10°C (Minimitter Inc.). For the purpose of this study, the range of acceptance was chosen such that it was larger than the precision of the instrumentation and approximately equal to normal core body temperature variability. This same difference is small enough to allow detection of differences commonly considered to have physiological and psychological consequences (10) as well as differences commonly associated with circadian and ovulatory core body temperature rhythms (7,28,29).

Data analysis. To determine the percent of time that ITS measures were outside of the threshold of acceptance, we calculated the difference between the recorded T_{int} for each pair of ITS approximately every minute. T_{int} differences were plotted against time for each volunteer. The time intervals when T_{int} differences were >0.25°C and ≤0.25°C were compared with the entire time and expressed as a percent. This analysis is very similar to the simple and intuitive nonparametric Bland–Altman (1) approach to assess agreement between two measures. Data gaps for each subject >5 min were not included in the analysis. Regression analysis was used to compare agreement between ITS-29 and ITS-5 (r^2) and to determine the magnitude (SEE) and the uniformity (residuals vs predicted) (12) of the differences across the range of core body temperatures observed. The observational comparison of three male subjects on the third day was examined in similar fashion, but with a descriptive aim only, due to the small number of subjects.

RESULTS

Recorded T_{int} values from all ITS ranged from 36.94°C to 39.24°C. Linear regression analysis revealed 67% explained variance between ITS-29 and ITS-5. The typical magnitude of the differences (SEE) was 0.24°C, and these differences were uniform across the entire range of observed temperatures as determined using both runs test and visual inspection (12). However, the maximum T_{int} difference between these paired ITS was as high as 0.83°C with a minimum difference of 0.00°C. T_{int} differences between paired ITS for each volunteer are plotted against time in Figure 2. T_{int} differences between ITS-29 and ITS-5 (Fig. 2) for all eight volunteers were within the ±0.25°C threshold of acceptance 56.2% of the time. The remaining 43.8% of the time, T_{int} differences were outside of the threshold of acceptance with a mean difference of 0.40°C. The individual volunteer ITS pair percentages outside of the threshold of acceptance for ITS-29 versus ITS-5 ranged from 0.0% to 81.8% with a mean percentage of 45.0% (SD = 28.6%). We also observed that the T_{int} differences between ITS-53 and ITS-29 for three volunteers were within the threshold of acceptance 81.5% of the time. The individual ITS pair percentages outside of the threshold of acceptance for these ITS pairs ranged from 8.0% to 29.8% with a mean percentage of 18.8% (SD = 10.9%).

DISCUSSION

The purpose of this study was to determine whether ingestion timing of an ITS would alter T_{int} measures beyond typical diurnal variations and the precision of the ITS device itself. To determine whether a meaningful difference of ±0.25°C existed between two ITS devices ingested 24 h apart, T_{int} measures were compared during 4 h of activity of varying intensity. Five hours after ingestion of a second ITS, T_{int} differences were outside of the threshold of acceptance for 43.8% of the time with a mean difference of 0.40°C.

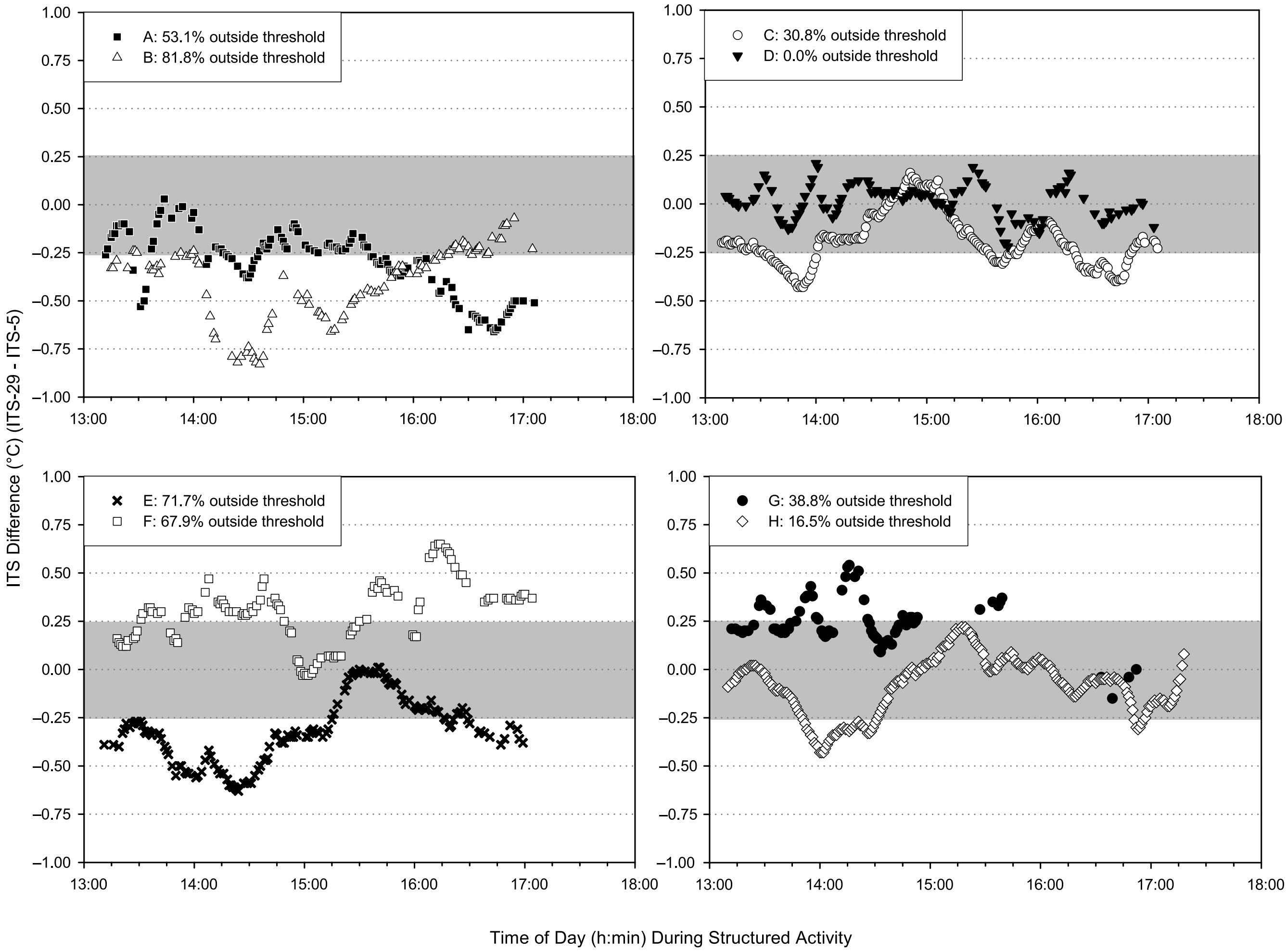

FIGURE 2—ITS T_{int} differences (ITS-29 minus ITS-5) by time for each volunteer (A–H) during structured activity. Two volunteers are presented per graph. Meaningful threshold of acceptance (±0.25°C) is highlighted.

The differences observed between ITS-29 and ITS-5 may be due to differences in location along the GI tract. As contents move farther along the GI tract, motility slows (26) and ITS are likely subject to less temperature variability. Although the literature supports this notion, comparing both ITS with another measure of core body temperature (T_{rec} and T_{eso}) is needed to confirm this phenomenon. Although only observed in three individuals, ITS-53 versus ITS-29 were within the threshold of acceptance, a larger percentage of time (82.5%) of the 4-h observation, further supporting our contention. Most investigators who have allowed ≥10 h between ITS ingestion and measurements (9,21) report temperature differences between T_{int} and T_{rec} similar (0.2–0.3°C) to the threshold of acceptance in the current investigation. Conversely, reports of differences as large as ~2.2°C between T_{int} and T_{rec} are possibly explained by shorter time between ingestion and activity, coupled with cold fluid ingestion (5,27).

Core temperature differences outside of the established threshold of acceptance may impact volunteer safety, athlete performance, and conclusions drawn from experimental research. The ITS difference greater than 0.25°C chosen for the threshold of acceptance of the current study is similar to several publications that identify differences between T_{rec} and T_{int} greater than 0.27°C (5,9,15,31) as meaningful. The consequence of temperature differences between paired ITS has the same implications as differences between a single ITS and T_{rec}. Although the average absolute difference in temperature between ITS-29 and ITS-5 appears acceptable (r^2, SEE, uniform residuals), a closer inspection shows that 5 h after ingestion of an ITS, T_{int} falls outside the threshold of acceptance 43.8% of observed time. Measuring and recording temperatures outside of the threshold of acceptance may place volunteers/athletes at increased risk for heat injury (10), result in degraded cognitive and physical performance (10), limit effect size of research protocols, or fail to identify documented diurnal and menstrual variations (7,28,29).

The analysis used in the current study used linear regression (12) and a method akin to the simplified nonparametric Bland–Altman approach (1) to compare agreement between ITS-29 and ITS-5. This combination affords both a conventional (12) and a simplified (1) but highly interpretable means for comparison. By plotting the error between ITS measures against time (Fig. 2), differences relative to the threshold of acceptance could be determined at any given moment over the 4-h period. Two recent publications (5,9) used conventional Bland–Altman analysis (2) to conclude that T_{int} is a valid measure of core body temperature, using T_{rec} as the criterion standard. Both authors report correlation values (r) >0.85 and similar mean biases that are well within the respective precision described therein, which suggests that these methods of analyses may provide useful clinical information. Despite similar conclusions, these two studies report drastically different 95% limits of agreement. Gant et al. (9) reported a 95% limits of agreement of ±0.22°C and Casa et al. (5) reports ±0.99°C. Although these 95% limits of agreement signify the relatively narrow and wide spread of the data, respectively, little information is conveyed relative to a meaningful difference. By applying a nonparametric analysis to the Bland–Altman plots of these two studies (1), all data points can be compared with the same meaningful value, which allows for an equivalent comparison of these analyses to the current study. By using the same threshold of acceptance as that designated herein (±0.25°C), we find that approximately 41% of the temperature differences reported by Casa et al. (5) are within the threshold of acceptance, whereas approximately 85% of the temperature differences reported by Gant et al. (9) are within the threshold of acceptance. Methodological differences between those two studies and the current study, such as elapsed time after ingestion and drinking cold fluids, may help to explain the differences in percentages of agreement.

The timing of ITS ingestion will affect temperature variability between ITS and other measures of core body temperature, including a second ITS. At minimum, ideal timing would allow for an ITS to travel enough distance into the intestines to avoid effects of fluid ingestion while simultaneously ensuring that the ITS is not expelled. Five hours is sufficient to eliminate the effects of fluid ingestion for the majority of volunteers (31), although 10 h of ingestion timing before activity appears to be the consensus of current ITS research to eliminate effects of fluid ingestion (9,31) and to ensure that the ITS is not passed (18,21). By ingesting a second ITS 5 h before activity, the current study demonstrates that the difference between ITS-5 and ITS-29 is within the threshold of acceptance for a much smaller percentage of time (56.2%) than the temperature differences between T_{rec} and ITS ingested 10 h before activity (approximately 85%), as reported by Gant et al. (9). These results reinforce the notion that ingesting an ITS 10 h before activity would provide a higher level of agreement compared with 5 h. Interestingly, ingesting an ITS 29 h before activity does not appear to be more advantageous than ingesting an ITS 10 h before activity. The current study does not provide a comprehensive analysis of the advantages or limitations of using ITS for research nor clinical purposes.

CONCLUSION

The timing for ingestion of an ITS is critical for accurate and reliable core body temperature monitoring. This study shows that T_{int} measured 5 h after ingestion may still differ significantly (>0.25°C) from T_{int} measured 29 h after ITS ingestion. Although gastrointestinal motility is highly variable and strongly influenced by numerous, difficult to control factors, it appears that in many cases T_{int} agreement with other core body temperature measures is improved when more than 5 h are allowed to elapse between ITS ingestion and measurement. Coaches, athletic trainers, and researchers must balance their need for accuracy and safety with the limitations of ingestion of an ITS.

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The views, opinions, and/or findings in this report are those of the authors and should not be construed as official Department of the Army position, policy, or decision unless so designated by other official designation. The results of the present study do not constitute endorsement by ACSM. All experiments were carried out in accordance to state and federal guidelines.

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