Accuracy and Performance of Continuous Glucose Monitors in Athletes

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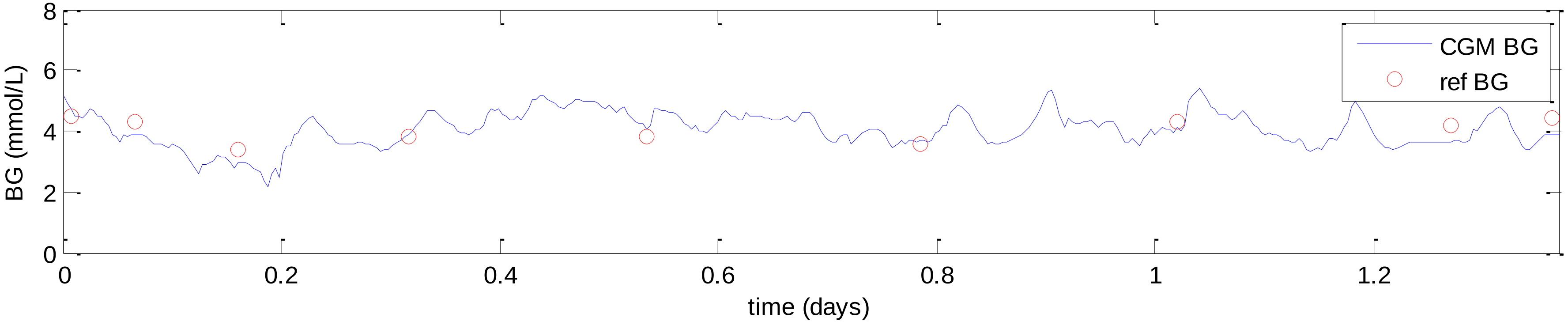
Background

Continuous Glucose Monitors (CGMs)

The CGM consists of a pager-like monitoring device that receives information from a sensor inserted under the skin that detects glucose in the interstitial fluid.

- Originally designed to help Type 1 diabetics manage blood glucose levels
- Recently used in the Intensive Care Unit (ICU) and Neonatal Intensive Care Unit (NICU) to detect hypoglycaemia in at-risk babies
- CGM accuracy is dependent on Blood Glucose (BG) calibration measurements entered into the device every four times a day
- Much more frequent measure of blood glucose (5 minutely) but performance trade offs

(www.medtronic.com)



Why?

Optimisation of an athlete's BG has the potential to

- Increase race performance – knowing when and what to eat during racing
- Speed recovery – Optimal replacement of glycogen stores
- Aid training - as blood glucose can reflect metabolic and inflammatory conditions

However, before these benefits can be realized the accuracy and performance of CGM devices in active athletes must be evaluated

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Background

Recalibration of CGM data

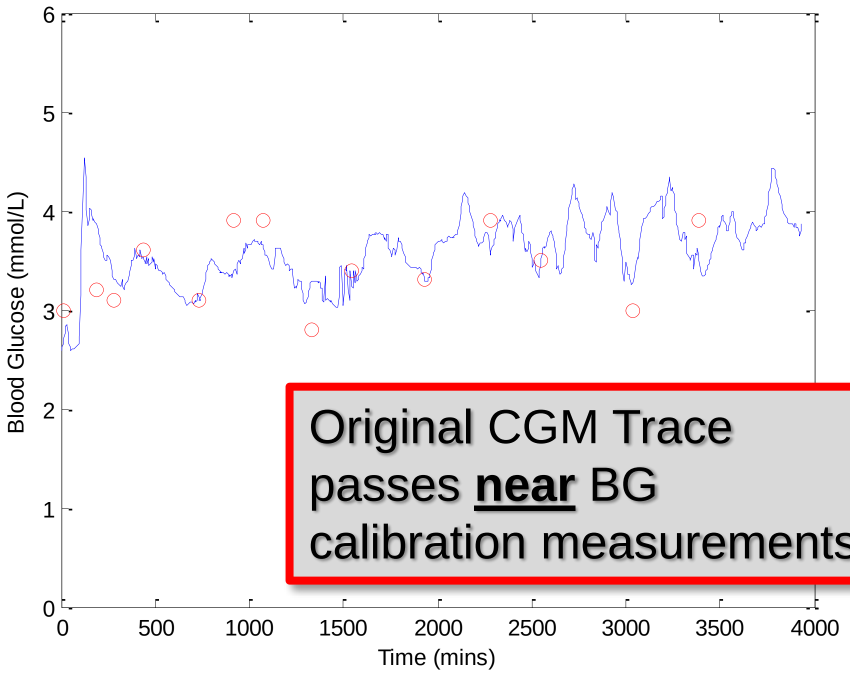
Blood Glucose = slope * (electric current- offset)

Linear Regression Calibration

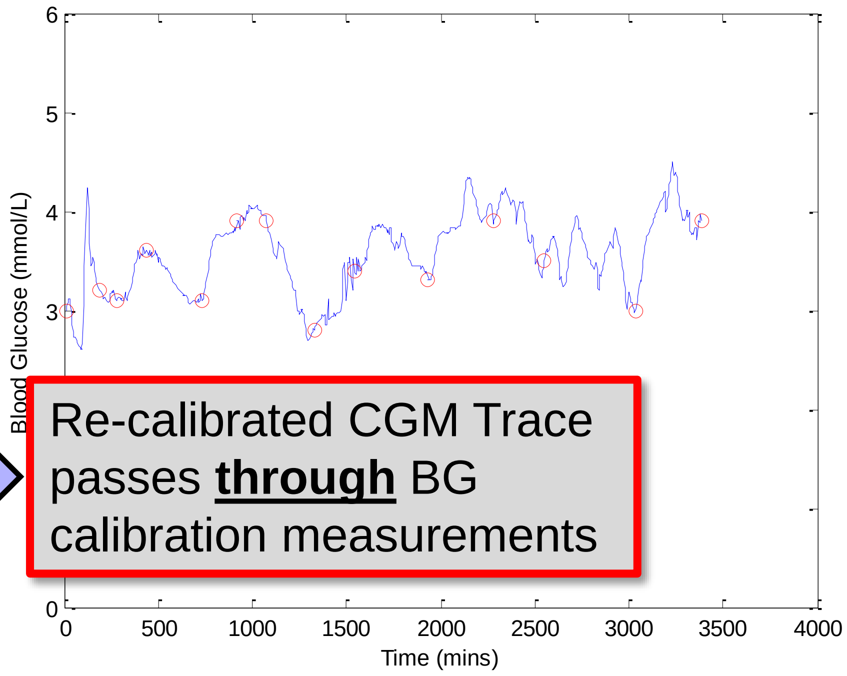
The CGM uses linear regression techniques combined with smoothing. This is a typical “built-in” method of calibration.

Linear Interpolation Calibration

A Re-calibration algorithm was used to make better use of the accurate blood glucose measurements.



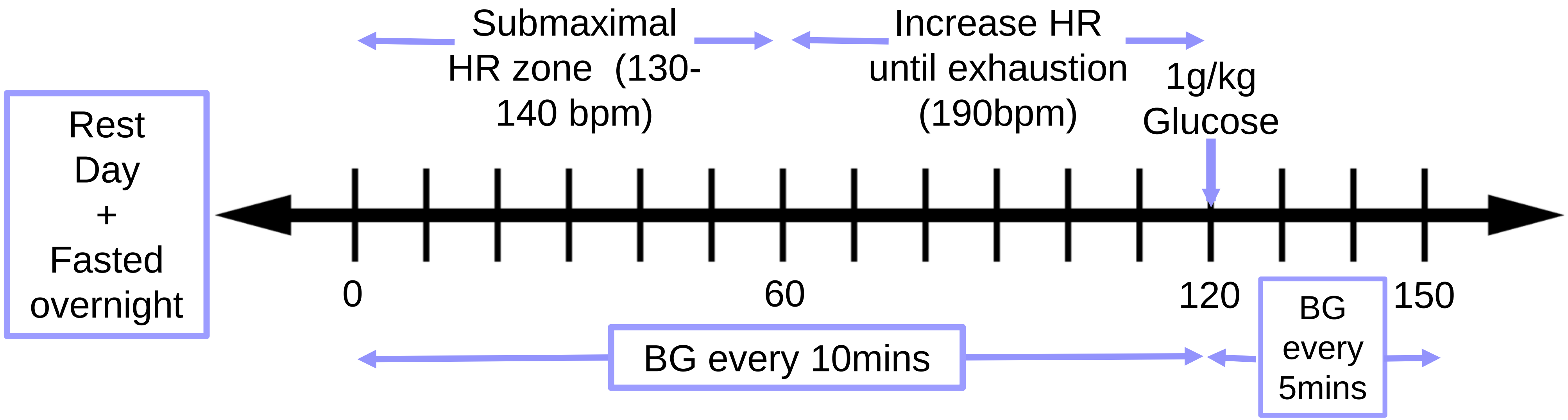
Original CGM Trace passes **near** BG calibration measurements



Re-calibrated CGM Trace passes **through** BG calibration measurements

Procedure

Two fasting exercise tests were carried out 3 days apart:



At a later date, ‘**fasting sedentary tests**’ were carried out.

Analysis

Mean absolute relative difference (MARD) and Offset was calculated between reference BG measurements collected during the fasting tests and the CGM trace:

$$MARD = mean\left(abs\left(\frac{CGM - BG}{BG}\right)\right) * 100$$

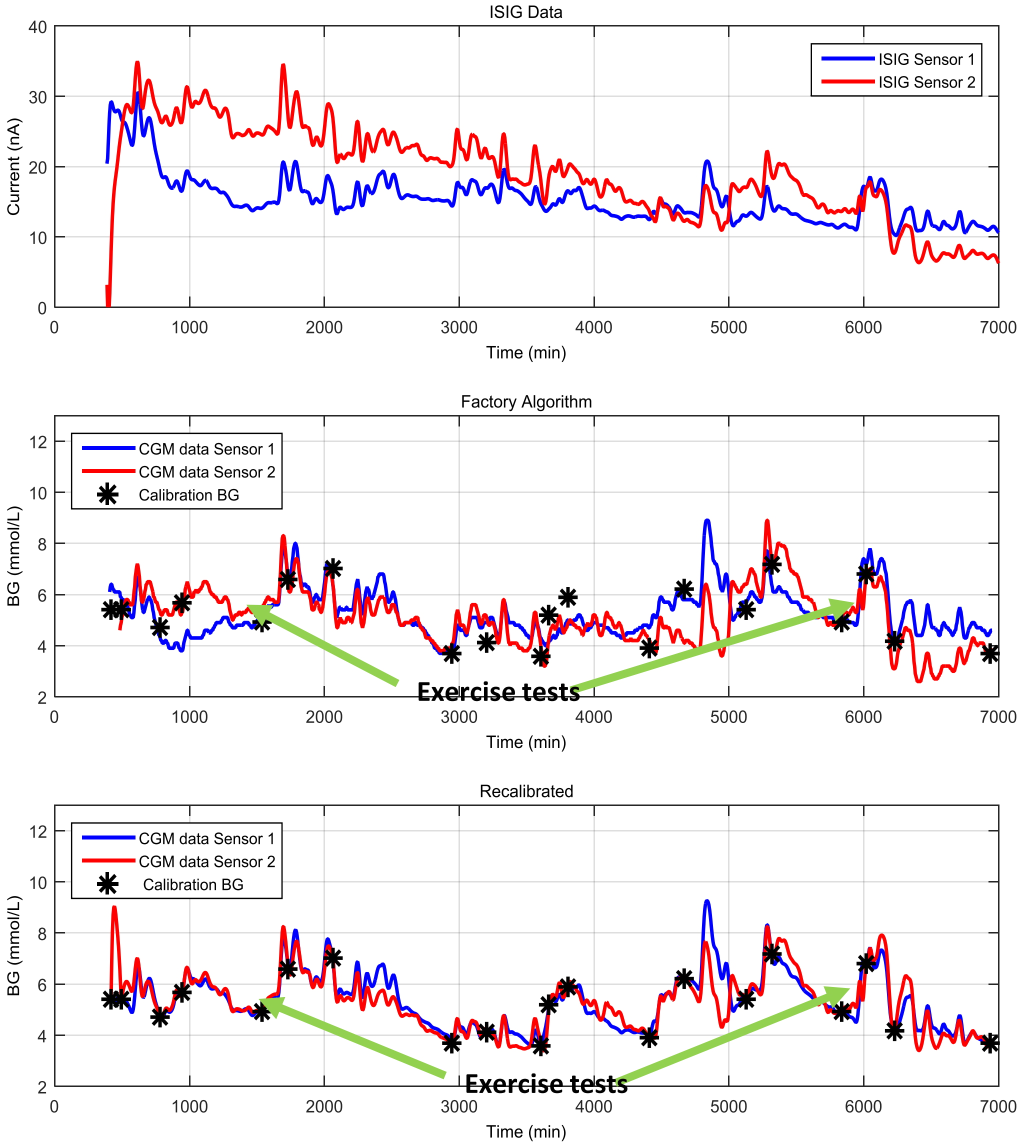
$$Offset = CGM - BG$$

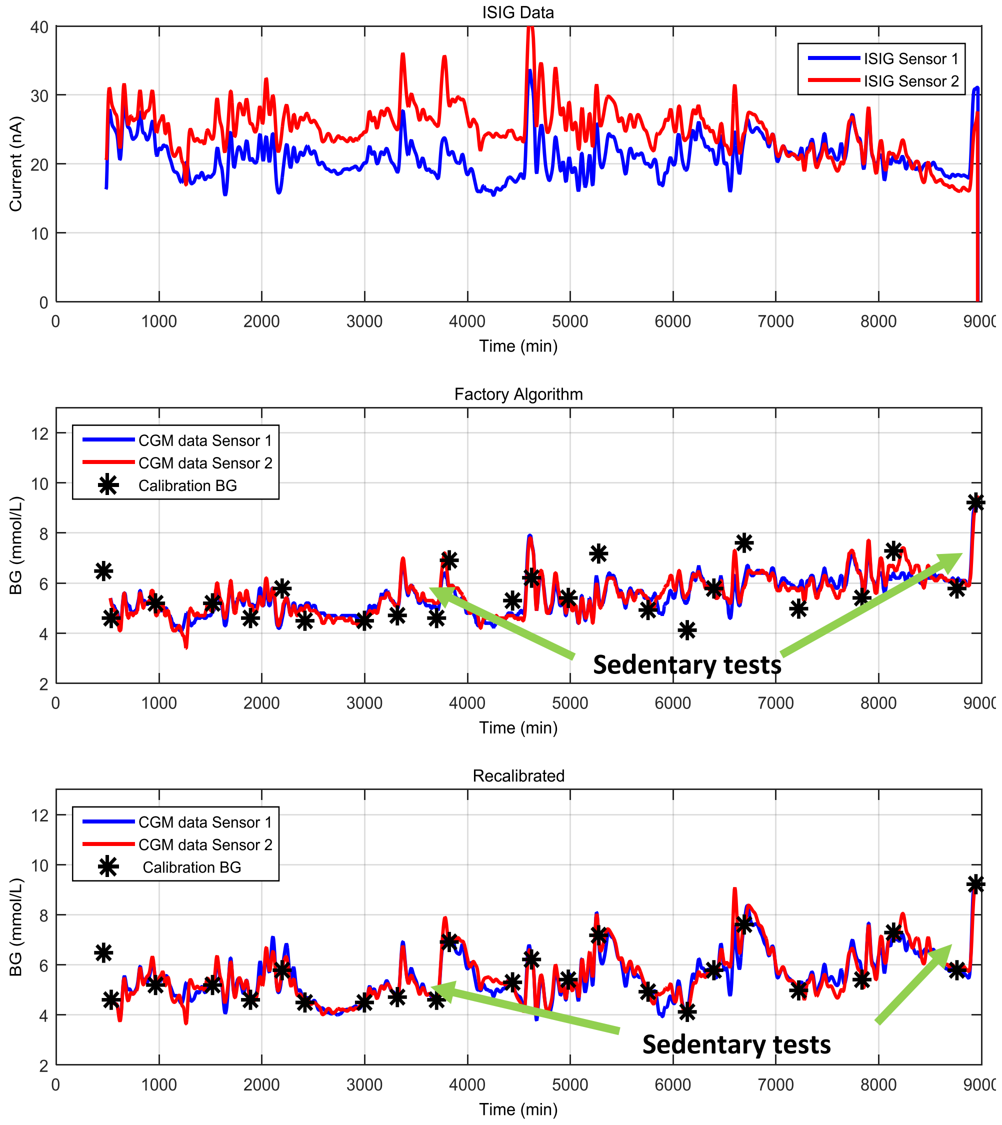
These metrics were assessed during:

- the exercise or sedentary phase only (0 – 120mins)
- Including the glucose bolus subsequent to these phases. (0 – 150mins)

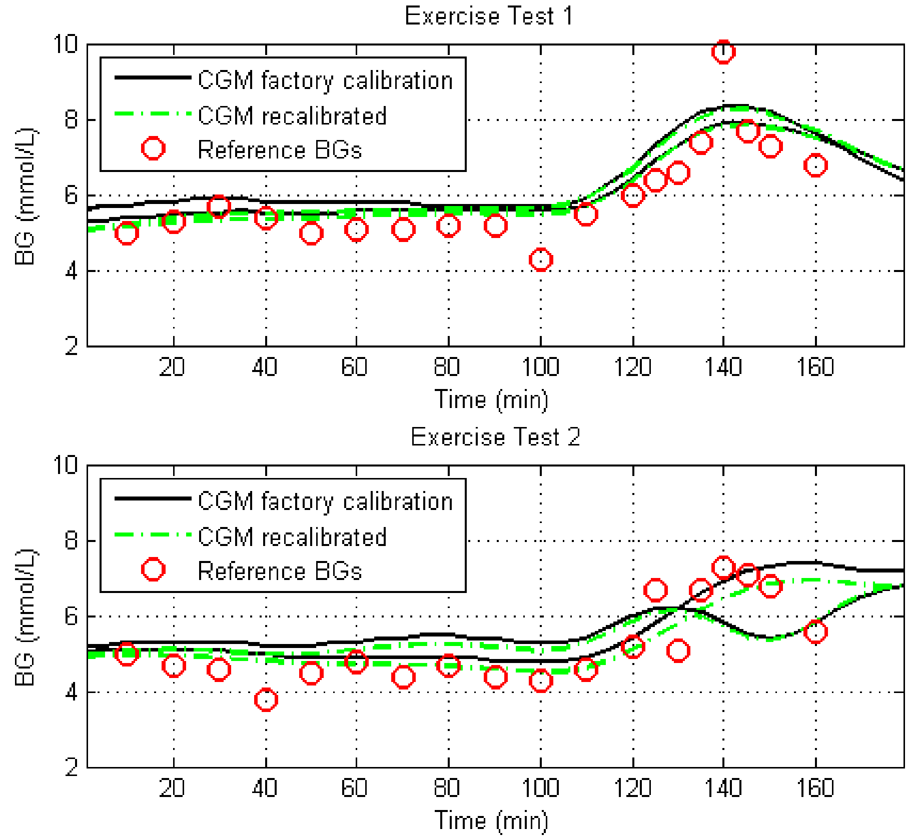
Results

CGM Traces





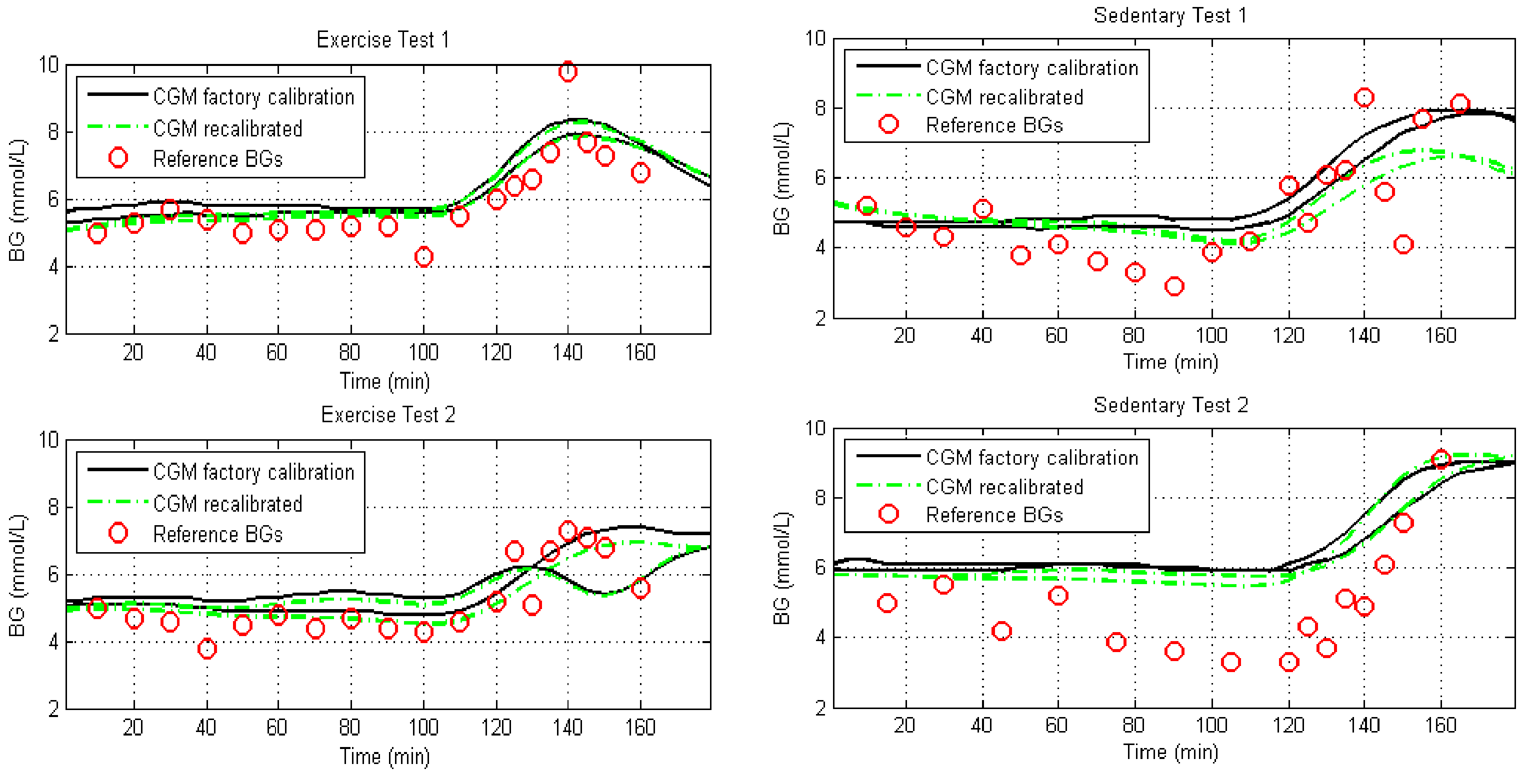
Results – Exercise Performance



		Exercise Fasting Test 1		Exercise Fasting Test 2		MEDIAN [IQR]
		Sensor 1	*Sensor 2*	*Sensor 1*	*Sensor 2*	
Recalibrated	**MARD (%)** exercise + glucose bolus	7.07	10.1	7.37	12.9	8.74 [7.15 12.2]
	MARD (%) exercise Only	6.64	8	5.01	11.8	7.32 [5.42 10.9]
Algorithm	**MARD (%)** exercise + glucose bolus	8.55	12.6	10.1	16.9	11.4 [8.9 15.8]
	MARD (%) exercise Only	8.73	12.9	8.67	17.9	10.8 [8.69 16.7]

During Exercise MARD are equivalent if not better than the performance reported for CGM in diabetic subjects – 10.8 [8.7 – 16.7] % median [IQR] or 7.3 [5.4 – 10.9] % with recalibration

Results – Sedentary Performance



		Exercise Fasting Test 1		Exercise Fasting Test 2		MEDIAN [IQR]
		Sensor 1	*Sensor 2*	*Sensor 1*	*Sensor 2*	
Recalibrated	**MARD (%)** exercise + glucose bolus	7.07	10.1	7.37	12.9	8.74 [7.15 12.2]
Recalibrated	**MARD (%)** exercise Only	6.64	8	5.01	11.8	7.32 [5.42 10.9]
Algorithm	**MARD (%)** exercise + glucose bolus	8.55	12.6	10.1	16.9	11.4 [8.9 15.8]
Algorithm	**MARD (%)** exercise Only	8.73	12.9	8.67	17.9	10.8 [8.69 16.7]
		Sedentary Fasting Test 1		**Sedentary Fasting Test 2**		
		Sensor 1	*Sensor 2*	*Sensor 1*	*Sensor 2*	
Recalibrated	**MARD (%)** exercise + glucose bolus	18.6	17.8	35.9	34.9	26.4 [17.6 35.2]
Recalibrated	**MARD (%)** exercise Only	18.1	16.9	37.3	41.5	25.1 [16.9 35.4]
Algorithm	**MARD (%)** exercise + glucose bolus	22.4	18.8	40.8	37.6	30 [21.5 38.4]
Algorithm	**MARD (%)** exercise Only	21.6	18.8	43	44.8	32.3 [20.9 43.5]

Sedentary tests obtained worse performance attributed to two main factors:

- The reference measurements most likely biased during the sedentary test due to low apparent skin and leading to BG meters reading lower than expected values
- Interstitial fluid is not actively pumped like blood. It relies on muscle movement to circulate and mix.

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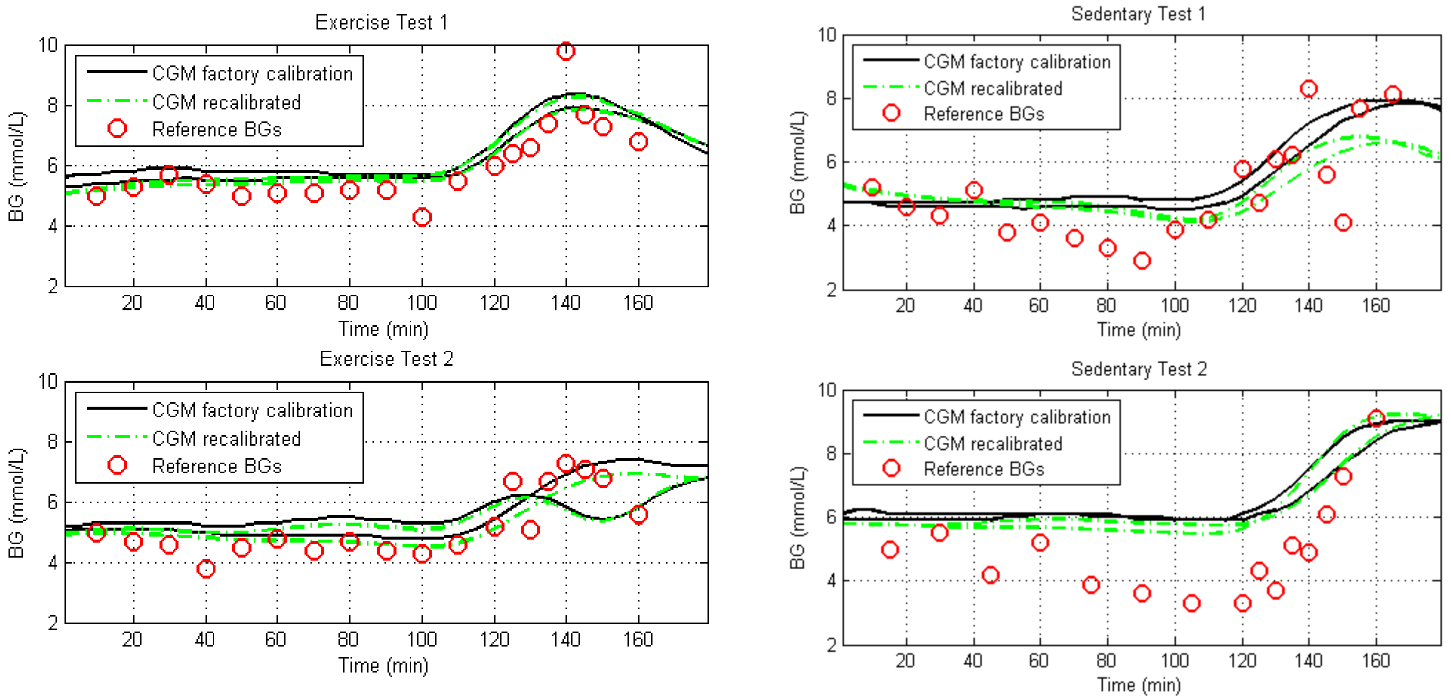
Result - Bias



- There is a consistent positive bias evident, whether it be exercising or sedentary, or when applying the recalibration algorithm or the factory algorithm.

		Exercise Fasting Test 1		**Exercise Fasting Test 2**	
		Sensor 1	*Sensor 2*	*Sensor 1*	*Sensor 2*
Recalibrated	**Offset** exercise + glucose bolus	0.3 [0.1 0.4]	-0.1 [-0.7 0.4]	0.03 [-0.1 0.3]	0.2 [-0.6 0.5]
	Offset exercise Only	0.3 [-0.002 0.3]	0.3 [-0.1 0.4]	0.2 [-0.05 0.3]	0.5 [0.2 0.7]
Algorithm	**Offset** exercise + glucose bolus	0.4 [0.2 0.5]	0.7 [0.5 0.8]	0.4 [0.1 0.5]	0.7 [-0.3 1.0]
	Offset exercise Only	0.4 [0.2 0.5]	0.6 [0.5 0.7]	0.4 [0.2 0.5]	0.8 [0.7 1.0]

		Sedentary Fasting Test 1		**Sedentary Fasting Test 2**	
		Sensor 1	*Sensor 2*	*Sensor 1*	*Sensor 2*
Recalibrated	**Offset** exercise + glucose bolus	0.3 [-0.4 1.0]	0.3 [-0.8 0.8]	1.7 [0.9 2.1]	1.6 [0.7 2.1]
	Offset exercise Only	0.4 [-0.05 1.0]	0.4 [-0.1 0.9]	1.6 [0.6 2.1]	1.8 [0.7 2.3]
Algorithm	**Offset** exercise + glucose bolus	0.7 [-0.03 1.2]	0.4 [-0.3 0.9]	1.9 [1.0 2.5]	1.7 [0.9 2.3]
	Offset exercise Only	0.7 [-0.4 1.1]	0.5 [-0.3 0.9]	1.9 [0.8 2.5]	1.9 [0.9 2.5]

Limitations

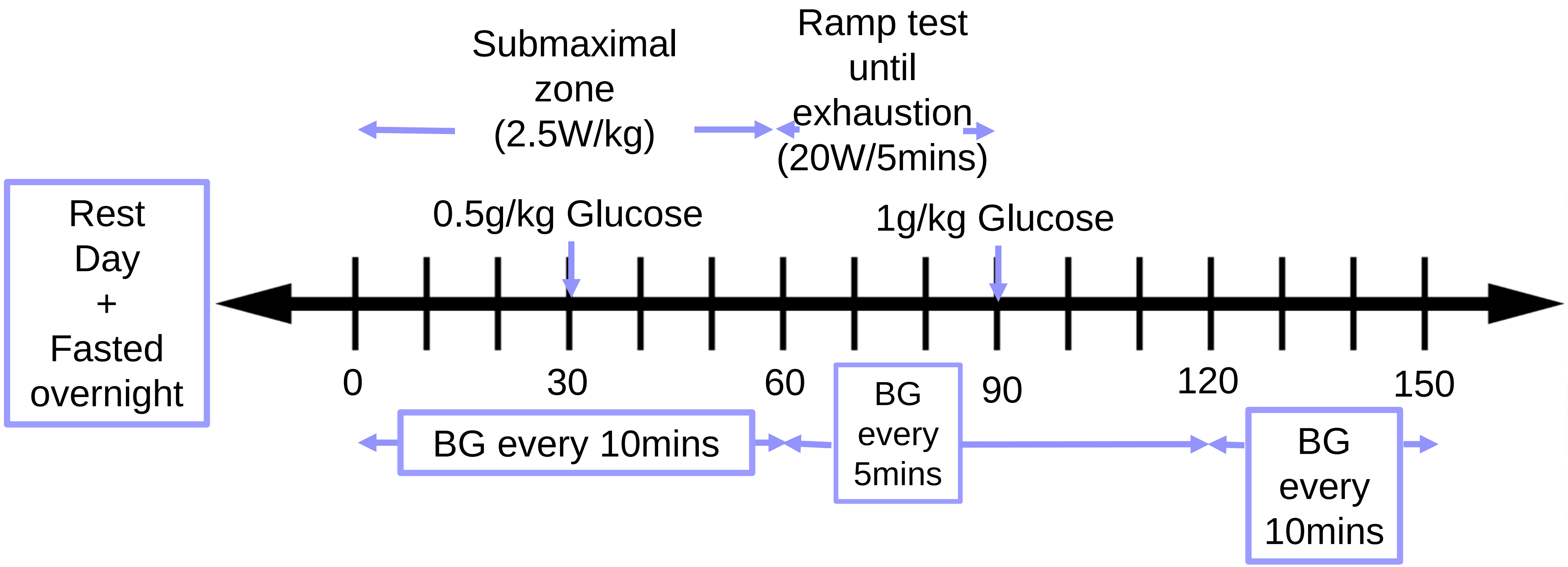
The small data set is a major limitation of this study, **however**:

Based on the results of this study an Athlete trial plan was formed to further test the performance of CGM devices:

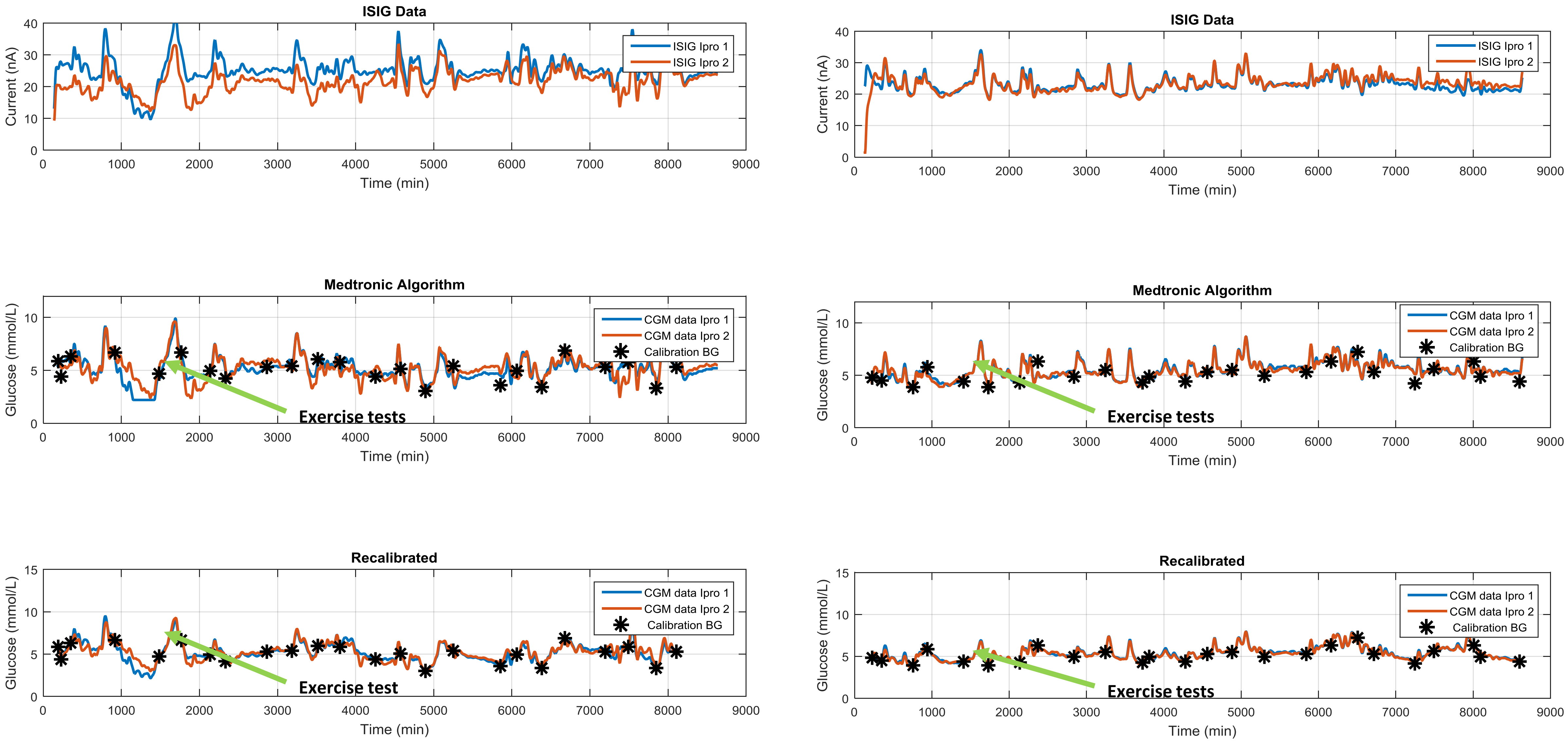
- 10 fit, healthy adults with a resting heart rate of 60 beats per minute (bpm) or lower
- Participants will have 2 Ipro2 CGM devices (Medtronic Minimed, Northridge, CA, USA) inserted in to their abdomen at least 24 hours before undertaking an exercise test

Protocol

- Very Similar protocol to the first exercise test



Interim Results



Interim Results

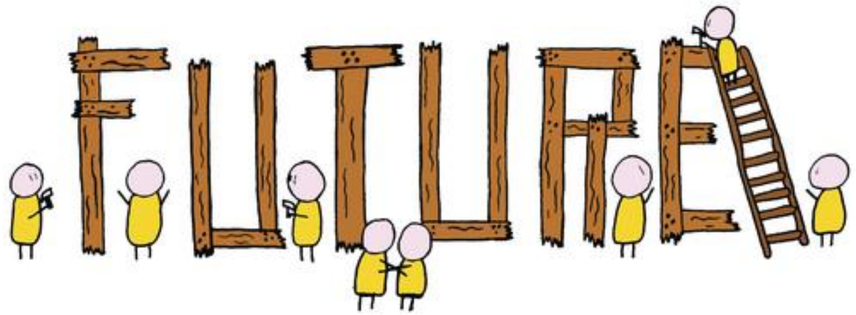
MARD	SG1	SG2	SG1 recal	SG 2 recal	Median[IQR]
ATH01	11.2	13.4	32.5	12.4	12.9 [11-28]
ATH02	15.2	14.9	9.3	11.5	13.2 [9.8-15]
ATH03	9.0	8.9	6.8	7.7	8.3 [7.0-9.0]
ATH04	12.3		13.8		13.0
ATH05	13.8	11.9	10.8	11.3	11.6 [11-13]
ATH06	12.7	13.8	15.7	17.3	14.8 [13-17]
ATH07	11.1	32.3	22.4	17.9	20.2 [13-30]
ATH08	10.6	14.2	7.5	16.0	12.4 [8.3-16]
Median [IQR]	11.8 [11-14]	13.8 [12-15]	12.3 [7.9-21]	12.4 [11-17]	

- 8/10 Subjects enrolled so far
- Very similar performance between recalibration algorithm and factory algorithm
- Very good performance across the board.
- Offset no longer evident

Conclusions

- Good Performance seen with CGM during exercise - Sensors agree well with each other and reference measurements
- During sedentary periods the accuracy of the monitors was reduced - This decrease in accuracy is likely related to the fact interstitial fluid is not actively pumped like blood. It relies on muscle movement to circulate and mix.
- These result show real promise for using CGM to help optimize BG levels in an athletic active cohort
- These differences in performance also provide insight into how these devices might be more optimally used in the target, more sedentary cohort.

Future work



- **Develop Athlete Specific Metabolic Model:**
  - Create Endogenous insulin secretion Model
  - Create Endogenous glucose production Model
  - Examine the sensitivity of SI to change in other glucose metabolism parameters

- **Develop a protocol to optimise Athletes Blood Glucose using CGM values**
  - Develop robust control methods to modelled variation and CGM dynamics

Acknowledgements

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Questions??