THE VALIDITY OF SELECT PHYSICAL ACTIVITY TRACKING DEVICES DURING VARYING PHYSICAL ACTIVITY INTENSITY RANGES AND MODALITIES IN PERSONS WITH AND WITHOUT TYPE ONE DIABETES.

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Abstract:

The primary purpose of this study was to examine the validity of two high cost physical activity trackers, the Zephyr Bioharness^{TM}, and the Metria Armband by Vancive, to differentiate physical activity (PA) intensities and modalities using heart rate (HR), breathing frequency (BR), and energy expenditure (EE), when compared to indirect calorimetry using the Cosmed Fitmate^{TM} and the discrete component open circuit spirometry system. The secondary purpose of this study was to examine the validity of two low cost physical activity trackers the Garmin Vivofit2, and the Mio Fuse to differentiate between PA intensities and modalities using HR and EE, compared to indirect calorimetry from the Cosmed Fitmate^{TM} and the discrete component open circuit spirometry system. The study outcomes revealed that during the light-to-moderate intensity exercise session; i) the EE, as assessed by the Metria, was significantly different from the Fitmate with a mean overestimate of 0.64 kcals · minute^{-1}; ii) the HR, as assessed by the Bioharness, was significantly different from the Polar monitor (HR monitor used with FM) with a mean underestimate of 4.73 bpm and; iii) the BR, as measured by the Bioharness, was significantly different from the Fitmate with a mean underestimate of 9.49 breathes/minute. During the intermittent moderate-to-vigorous intensity exercise session; i) the EE, as assessed by the Metria, was significantly different from the Fitmate with a mean overestimate of 0.33 kcals · minute^{-1}; ii) the HR, as assessed by the Bioharness, was significantly different from the Polar monitor with a mean underestimate of 0.6 bpm and; iii) the BR, as measured by the Bioharness, was significantly different from the Fitmate with a mean underestimate of 2.85 breathes/minute. During the vigorous-to-maximal intensity exercise session: i) the EE, as assessed by the Metria, was significantly different from the Fitmate with a mean underestimate of 1.78 kcals · minute^{-1}; ii) the HR, as assessed by the Bioharness, was not significantly different from the Polar monitor

with a mean overestimate of 1.61 bpm and; iii) the BR, as measured by the Bioharness, was significantly different from the Fitmate with a mean underestimate of 5.61 breaths/minute. It is concluded that, despite the statistical significance compared to the criterion comparators, wearable technology that differentiates physical activity intensities and modalities is most promising for estimates of EE and HR. Therefore, whether persons are interested in; becoming habitually active, increasing the current level of PA, or improving quality of life with a chronic condition such as T1D, the higher cost PA trackers are the better choice given their ability to differentiate between PA intensities and modalities.

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List of Abbreviations

AP: Artificial Pancreas

ATP: Adenosine-Triphosphate

BR: Breathing Rate

CGM: Continuous Glucose-monitoring Device

EE: Energy Expenditure

HR: Heart Rate

METs: Metabolic Equivalents

NIH: National Institute of Health

PA: Physical Activity

T1D: Type One Diabetes/Diabetic

VO_2: Oxygen Consumption/Aerobic Power

VO_2max: Maximal Oxygen Uptake/Maximal Aerobic Power

Chapter 1: Literature Review

1.0 Introduction

Primary Prevention and Secondary Disease Management with Physical Activity Participation

The concept of habitual physical activity (PA) participation as a therapy for primary disease prevention and secondary disease management is far from novel, and dates back to the 1950's with the work of Morris (Morris, 1953; Morris, 1953) and Paffenbarger in the 1970's (Paffenbarger 1975; Paffenbarger, 1978). These studies assessed the relative risk of death resulting from physical inactivity and sedentarism (Powel, 1987; Berlin, 1990; Lee, 1995, 2000; Wannamethee, 1995; Kohl 2001; Oguma; 2002; Warburton, 2006). In addition, there has been undisputable evidence from more recent work discussing the benefits of habitual PA participation for primary disease prevention and secondary disease management. Such that, it has been proposed that there is a linear relationship between increases in PA participation and health status (Warburton, 2006). PA is an umbrella term that encompasses all non-structured activities of daily living, leisure or recreational PA and structured exercise for the purposes of improving aspects of physical and physiological fitness (Bouchard, 1990, 1994).

The increased prevalence of sedentarism and hypokinetic diseases along with the strong supporting evidence of the effectiveness of PA interventions, has underscored the need for prescriptive PA participation intervention strategies. The success of these intervention strategies are dependent on the individuals' physical and physiological attributes, level of motivation, ability to stay committed, and the ability to accurately quantify the PA that the individual is participating in, as they may need to meet specific energy expenditure (EE) thresholds (Marcus, 1994). Effective EE thresholds for reductions in incidence for type 2 diabetes has been documented to be as low as 500 kcal (Manson, 1992; Gregg, 2003), while increases of 2200 kcal

was associated with plaque reductions in persons with heart disease (Hambrecht, 1993; Franklin, 2003). This evidence supports the importance of quantifying an individual's EE from a PA bout, as well as the importance of a customized PA regime.

Furthermore, the level of motivation an individual's ability to stay committed will affect their adherence and compliance to the PA prescription, and in turn the effectiveness of the PA intervention. To facilitate this, it has been shown that self-regulation strategies, such as self-monitoring, goal-setting, reinforcements, and self-corrective actions increase PA participation in a variety of populations (Bandura, 1991). All of the above could be effected by a number of different factors that a wearable PA monitoring and/or motivational device could provide. Based on the Transtheoretical model of behavior change, it is known that a person will commonly progress through six stages of change; precontemplation, contemplation, preparation, action, maintenance, and termination (Prochaska, 1997). The time spent in each of the respective stages does not have to be linear, and an individual may progress through the first 3 stages rather quickly until they find themselves in the action phase (Marcus, 1994). An individual's stage of change refers to their readiness to engage in regular PA. The process of change includes' five cognitive and behavioral strategies that one uses as they progress from the first to last stage (Marcus, 1992). Wearable technology that monitors or promotes PA may serve as a critical tool to keep an individual motivated to support ones cognitive and behavioral processes toward achieving a behavior change. It has been demonstrated that real-time data visualization from a wearable technology device during PA provides enhanced awareness and motivation to the wearer. Additionally, when the output of these devices is integrated with a social sharing platform, the level of motivation is further enhanced (Consolvo, 2006; Toscos, 2006; Ali-Hasan,

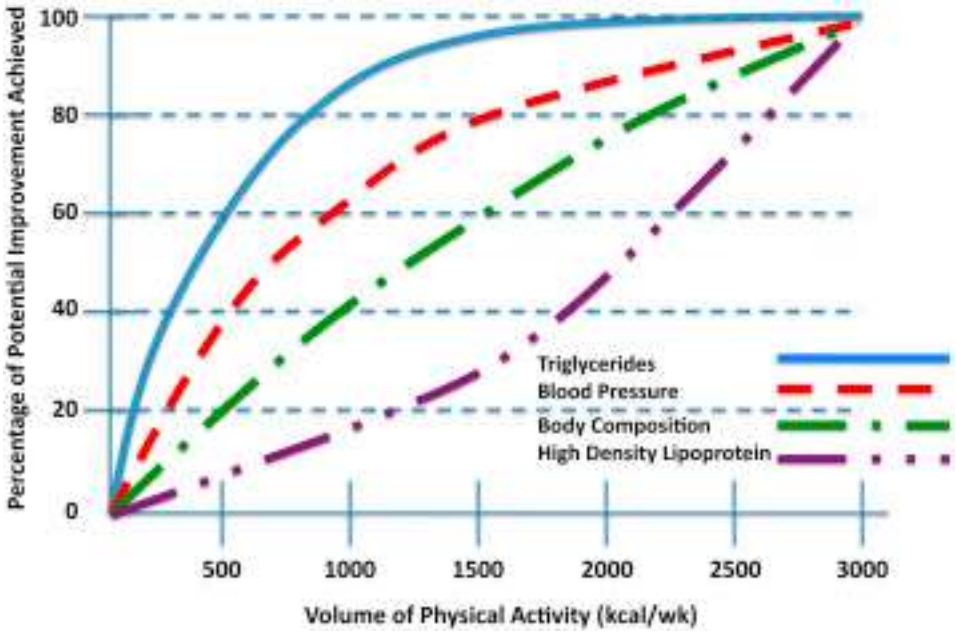
2006; Lin, 2006). Emerging evidence supports that both conscious awareness and PA participation tracking reinforce behavior change.

The ability of wearable technology devices to quantify volume of PA is based on the manufacturers proprietary formulas and the testing that these devices undergo during development. Although the precision of these devices has been questioned, they are considered to be sufficiently accurate for use with populations interested in increasing their PA participation (Albinali, 2010). These devices can also aid in understanding and achieving exercise prescriptions. The global public health messages recommend that individuals should engage in thirty minutes or more of moderate intensity PA on most days of the week, accumulating 1000-2000 kcal/week, should reduce their sitting time, as well as, maximize their activities of daily living (Giannuzzi, 2003; Gledhill, 2003; Warburton 2006). Throughout the day, an individual encounters different physical demands, thereby varying their daily EE. Therefore, if an individual was to become aware of their increase in sedentarism, they may be more inclined to proactively participate in PA, if they are outfitted with a device that provides both visual and physical alerts (Consolvo, 2006; Toscos, 2006; Ali-Hasan, 2006; Lin, 2006).

For the purposes of secondary disease management, PA and exercise prescriptions are strongly dependent on the exercise-related risk. Risk stratification can be accomplished by applying evidence based screening tools such as the annually updated PAR-Q+ (e.g. 2015 PAR-Q+ and when applicable, the ePARmed-X+ (www.eparmedx.com) (Balady, 2000; Bredin, 2013; Fletcher, 2001). Individuals stratified as low-risk may be prescribed a PA and/or exercise prescription similar to that of a healthy individual. Moderate-to-high risk individuals should follow a strictly individualized PA and exercise prescription which is characteristic of a lesser intensity, thus a lower accumulated EE. Nonetheless, cumulative small amounts of PA are

beneficial in order to enable maintenance of independent living and counteract any co-morbidities (Gledhill, 2003). Providing individuals with chronic conditions with the ability to monitor their PA intensity and EE via wearable technology can greatly improve the efficacy of secondary prevention. It is known that with as little as 500 kcal/week individuals can see improvements by as much as 20% in some physiological health markers, as illustrated in Figure 1. Figure 1 illustrates that much of the improvement in some health benefit indicators is achieved at lower volumes of physical activity participation (e.g., triglycerides and blood pressure), while much of the improvement in other health benefit indicators comes at higher volumes of participation (e.g., high-density lipoproteins). The 'volume' of physical activity is simply the sum of all bouts of physical activity, regardless of how short the duration. Assuming a person expends 100 kcal/15 minutes. Figure 1 also illustrates how the Volume of Physical Activity in kcal/per week relates to daily and weekly time commitment (over 5 days) (Gledhill, 2003, Jamnik 2015)

Figure 1: Theoretical relationship between physical activity and various determinants of health status as proposed by Gledhill and Jamnik.



kcal/week	500	1000	1500	2000	2500	3000
Minutes/day	15	30	45	60	75	90
Minutes/week	75	150	225	300	375	450
Hours/week	1 ¼ hr.	2 ½ hr.	3 ¾ hr.	5 hr.	6 ¼ hr.	7 ½ hr.

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Although there are many acute and chronic benefits associated with PA participation both the quantity and quality of the PA play integral roles in the benefits that can be realized. The exercise prescription must be mode and load dependent which corresponds with the FITT principle; frequency, intensity, time, and type (Pollock, 1998). More importantly, the exercise bout should be; specifically geared towards the individual's goals, include variation and periodization to minimize desensitization and maximize training adaptations (Ratamess, 2009). All of the above principles must be considered when delivering a customized PA and/or exercise

prescription protocol, as different conditions, diseases and co-morbidities will require varying stimuli or dosage to maximize the benefits of the PA (Warburton, 2006).

Type one diabetes (T1D) is a common autoimmune disease, which is typically diagnosed in children as young as ten years of age. This is a critical time in a child's growth and development and when the child begins to adopt habits which they would employ for the remainder of their lives. However, T1D can be diagnosed as early as the first year of life. According to the Canadian Diabetes Association, there are 2.7 million Canadians living with diabetes or prediabetes and 5-10% (135,000 - 270,000) have T1D (DIAMOND PROJECT GROUP 2006, DiaMond 2000; CDA). Furthermore, the Public Health Agency of Canada has reported that Canada was found to have one of the highest incidence rates of T1D for children under 14 years of age (DIAMOND PROJECT GROUP 2006, DiaMond 2000). All persons with T1D depend on a customized insulin injection regime, as the individuals' pancreas is no longer able to produce insulin. The inability to produce insulin is a direct result of the autoimmune destruction of the pancreatic beta-cells (Alberti, 1998; Maahs, 2010; Shugart, 2010). As the cells begin to diminish in number, the individual's pancreas loses the ability to produce and secrete insulin, resulting in insulin deficiencies and dysglycemia complications. Unfortunately, the field of diabetic management is far from black and white when it comes to standardized insulin dosing. Individuals with T1D must learn and adapt to their body's glycemic fluctuations. There are many documented complications associated with extreme blood glucose levels, which exacerbate the development and severity of future diabetes related conditions (Chu, 2011). The ever-present challenge to attenuate glycemic fluctuations underscores the need for appropriate insulin dosing. Some of the major hurdles associated with insulin injections include; injecting too much or too little, as well as the events that follow the last insulin dose administration.

Technological advancements and medical engineering laboratories are developing devices that continuously monitor blood glucose levels and communicate with an individuals' insulin pump. This device is commonly known as a continuous glucose-monitoring device (CGM), which is designed for persons with T1D to avoid or minimize the traditional finger prick-lancet method. The CGM design has the potential to eliminate fears of hypo/hyperglycemia in T1D, specifically during PA participation, as it could remove the inconvenience of individuals having to temporarily suspend their exercise bouts to measure their blood glucose levels. While, it is widely acknowledged that regular PA participation is important for preventing and managing a wide range of chronic diseases and conditions including T1D (Bouchard, 1988, 1992; Kesaniemi, 2001). In the context of T1D, PA participation is a paradox owing to the unpredictable and consequent hypo/hyperglycemic outcomes. Although this device seems to be highly convenient and safe, there are a few shortcomings to this technology that should be noted. The major limitation of the CGM is its accuracy, which is related to method of measurement (Vaddiraju, 2010). The accuracy of the CGM is affected by the methods of measurement, as the device only assumes blood glucose levels based on the current (partial) presence of glucose concentration which has diffused into the individuals' interstitial fluid, from the bloodstream (Boyne, 2003, Kulcu 2003).

The National Institute of Health (NIH) and other funders are currently supporting the development of a closed-loop artificial pancreas (AP), which is a device that acts similarly to an insulin pump, but does not require any user-input, thereby minimizing the risks associated with diabetic hypo/hyperglycemia and other related complications (Riddell, 2015; Turksoy, 2015). Ideally, in order for the AP to accurately function it must be paired with a CGM and a PA intensity monitoring device. It should be noted that the applications of PA intensity monitoring

devices are not limited to T1D. These PA intensity monitoring devices will undoubtedly become increasingly essential in primary prevention and secondary disease management across the lifespan.

1.1 Overview of Physical Activity

PA encompasses activities of daily living, active transport, structured exercise, specialized skilled movement, and sports participation (WHO, 2010). The inherent rate of energy demand imposed by PA participation aligns with "global intensity spectrum descriptors" such as: very light, light, light-to-moderate, moderate, moderate-to-vigorous, vigorous and vigorous-to-maximal and maximal (Gledhill, 2003; Jamnik and Gledhill 2015; Norton, 2010). The body's ability to effectively respond to the varying intensities along the PA spectrum is highly dependent upon the continuous interplay between the aerobic and anaerobic metabolic systems (Gastin, 2001). Although both metabolic systems contribute to total metabolism, the greater or lesser shared reliance of the two metabolic systems in meeting the energy requirements is dictated by both the PA intensity and duration. At low continuous rates of energy demand the aerobic metabolic system is dominant, and as the rate of energy demand progressively increases there is a concomitantly greater reliance on both the aerobic and anaerobic metabolic systems regardless of whether the PA is continuous or intermittent in nature (Åstrand, 2003). In summary, the practice of stratifying PA as aerobic, aerobic-anaerobic versus anaerobic is simply intended to underscore the dominance of an energy system in resynthesizing the energy required to meet the imposed energy demand. It is necessary to underscore that use of metabolic descriptors to classify PA intensities, while convenient, is overly simplistic and can be misleading.

1.2 Benefits of Physical Activity

The benefits of PA for persons with and without T1D should be noted as they largely assist in many positive health outcomes for both populations. The benefits of habitual PA are the same for persons with and without T1D (Chu, 2011; Guelfi, 2005). The common T1D specific benefits include; increased glucose control plus management, the effectiveness of insulin (Herbst, 2007; Riddell, 2004), improved glucose uptake (Norris, 1990) resulting in lower blood glucose levels plus glycated hemoglobin (HbA1C), and reduced risks for diabetic complications such as nephropathy, retinopathy, and neuropathy (CDA). Other non-disease specific benefits include, but are not limited to; improved body mass management, reduced risks for osteoporosis, reduced risks for cancer, increased quality of life (QOL), improved self-esteem. (Warburton, 2006), improved blood pressure (Chu, 2011), and improved blood lipid profile (Campaigne, 1985; Laaksonen, 2000).

1.3 Aerobic Physical Activity

Typically, aerobic activity is characterized as light-to-moderate and moderate-to-vigorous intensity PA, which may be performed continuously or intermittently, but dependent on an individual's aerobic capacity and power. An example of light-to-moderate intensity PA would be purposeful walking at a 15 to 20-minute mile pace 3.5 – 3.7 mph (5.6- 5.9 km/h) or light jogging, 5 - 6 mph (8 -10 km/h), which would be associated with an intensity around 3 to 5 metabolic equivalents (METs), 50 to 75 percent of an individual's age-predicted maximum heart rate, 20 – 59% of heart rate reserve, or up to 50% of an individual's VO_2 max, or 10 - 13 out of 20 on the original the Borg subjective Rating of Perceived Exertion scale (RPE) (Åstrand, 2003; Jamnik, 2011; Warburton, 2006; Borg, 1992).

1.4 Aerobic-Anaerobic Physical Activity

Aerobic-anaerobic plus anaerobic PA classically consists of intermittent moderate-to-vigorous and vigorous-to-maximal intensity bouts of PA such as sprints or maximal lifts, interspersed with light-to-moderate intensity PA or a passive recovery period. This activity is associated with moderate-to-vigorous intensities of 6 – 7 METs and corresponds to 50 to 75 percent of an individuals' VO_2 max, and vigorous-to-maximal intensities corresponds to upwards of 6 to 10+ METs and corresponds to 75 to 100 percent of an individual's maximum heart rate or approximately 60% or more of an individual's maximal oxygen uptake (VO_2 max), or 16 - 20 out of 20 on the original the Borg subjective RPE scale. The energy demand required upon the initiation of such activity is fulfilled by combination of the anaerobic and aerobic metabolic systems. The dominance of the anaerobic metabolic system allows for high muscle phosphagen and anaerobic glycolysis to meet the high-energy demands throughout the intense bout of PA (Åstrand, 2003).

1.5 Monitoring PA: Established and Emerging Self-Wear Technology and Accelerometers

Recently there has been an exponential increase in the popularity and implementation in self-wear technology (Murakami, 2016). Self-wear technology can be divided into different categories including PA trackers, sleep trackers, and sleep management devices. Some self-wear devices have the ability to perform under multiple categories. The measurements provided by this technology are primarily used to quantify an individual's EE and provide an overview of their PA patterns (Achten, 2003). Self-wear technology devices are designed to measure an individuals' EE, keeping individuals motivated and on track to achieving their fitness training goals. There are an abundance of products on the market which vary in their respective

accuracies and measurement techniques (device name, mean absolute percent error); BodyMedia Fit 9.3%. Fitbit Zip 10.1%, Fitbit One 10.4%, Jawbone Up 12.2%, Actigraph 12.6%, DirectLife 12.8%, NikeFuel Band 13.0%, and Basis B1 Band 23.5% (Lee, 2014)

Typically, the devices operate using proprietary formulas and assumptions, which are based on the wearers' heart rate (HR), accelerometry (step counts or CPM) or a combination of the two which associate with common relative PA intensities as described using percent heart rate reserve, percent HR_{max}, RPE, and METs (Table 1). To date, next to indirect calorimetry, electronic HR monitors have proven to be the most accurate and reliable for monitoring PA intensity and EE (Swain, 1997; Achten, 2003). Additional technologies attempt to capture other parameters such as skin temperature, near body ambient temperature, breathing rates/frequencies, heat flux, sweat rate and accelerations in triaxial planes to also quantify EE. It is important to note, that the major inherent limitations of these devices lies in their accuracy and reliability (Murakami, 2016).

Table 1: Harmonization of different expressions of relative intensities for aerobic exercise prescription for activities lasting 30 to 60 min.

Intensity	%HRR	%HR_{max}	RPE	METs	MET min·wk^{-1}	Breathing rate	Body temperature	Example activity
Sedentary	<20	<50	<10	<3	<450*	Normal	Normal	Sitting watching TV, working on the computer
Light effort	20–39	50–63	10–11	3–4	450–600	Slight increase	Starting to feel warm	Dusting, light gardening
Moderate effort	40–59	64–76	12–13	5–6	750–900†	Greater increase	Warmer	Brisk walking
Vigorous effort	60–84	77–93	14–16	7–10	1050–1500‡	More out of breath	Quite warm	Jogging
Very hard effort	>84	>93	17–19	>10	>1500	Greater increase	Hot	Running fast
Maximal effort	100	100	20			Completely out of breath	Very hot, perspiring heavily	Sprinting all-out

Note: The shaded area identifies intensity levels that are required for health. Adapted from Warburton et al. 2006a; %HRR, % heart rate reserve; %HR_{max}, % maximum heart rate; RPE, rating of perceived exertion; MET, metabolic unit relative to resting metabolism.

*3 METs × 30 min × 5 days = 450 MET min·week^{-1}.

†6 METs × 30 min × 5 days = 900 MET min·week^{-1}.

‡10 METs × 30 min × 5 days = 1500 MET min·week^{-1}.

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Accelerometry-based devices measure the body's acceleration in up to three planes, and are commonly referred to as triaxial accelerometers. The three orthogonal planes are anteroposterior, mediolateral, and vertical, thus, attempting to account for individuals' acceleration in all planes of movement. Most accelerometers rely on multiple piezoelectric

sensors to complete these measurements (Chen, 2005). The piezoelectric acceleration sensor detects acceleration when the sensor undergoes a degree of deformation based on its internal components. The sensor is able to differentiate in accelerations based on the geometry (cross-sectional area and length), material property (stiffness), and the positioning of the seismic mass on its beam. In order for the accelerations to be measured in various planes, several unidirectional translational accelerometer units must be mounted orthogonally to one another. A major limitation of most piezoelectric accelerometers is that they can only reliably detect dynamic events (Togowa, 1998; Chen, 2005). For example, the accelerometers may not accurately detect movement when a person is exercising on a stationary cycle ergometer or a road bike.

Although these devices are not as accurate as traditional laboratory practices, and may never be, there is certainly no doubt about the accessibility and practicality of these efficient and affordable devices. For monitoring PA intensity in the general population, the information that is provided with the respective degree of error is sufficiently accurate to draw some conclusions (Lee, 2013; Lee, 2014). Thus, these devices can successfully serve as valuable tools for primary prevention and secondary disease management with PA participation. Given the well documented benefits of habitual PA participation on, cardiovascular disease, peripheral arterial disease, diabetes, cancer, hypertension, obesity, depression and osteoporosis) and premature death, (Powel, 1987; Berlin, 1990; Lee, 1995, 2000; Wannamethee, 1995; Kohl 2001; Oguma; 2002; Warburton, 2006) it becomes evident that the pairing of PA participation with wearable technology may enhance disease prevention and management.

1.6 Blood Glucose Instabilities in T1D and Exercise

Given the importance of PA participation, it is imperative to understand the potential glycemic fluctuations and triggers a person with T1D could encounter. A physically active individual with T1D can experience hypo- or hyperglycemia dependent on PA modality and intensity. In general, when persons participate in PA, there are a number of physiological responses and metabolic pathway adjustments which allow for the energy demands to be met. These include, but are not limited to, increases in VO_2, rate of lactate production plus clearance, and motor unit recruitment which collectively work towards supporting the resynthesis of adenosine-triphosphate (ATP) (Knuttgen, 1972). For most PA, the energy demands are typically met through the breakdown of muscle glycogen to glucose via aerobic and aerobic-anaerobic metabolic pathways (Saltin, 1971). For persons without T1D, the maintenance of blood glucose is accomplished by counter-regulatory responses of glucagon and insulin. The secreted glucagon triggers the release of glucose from the liver, into the bloodstream, via the breakdown of glycogen in the Cori cycle. This process of hepatic glucose production is mediated by insulin (Gallen, 2005; Landt, 1985; Wasserman, 1994; Zinker, 1999). As all individuals with T1D lack the ability to produce insulin, they must rely on exogenous injections to supply it. Therefore, it is vital to the exercising individual, with T1D, to ensure adequate amounts of insulin prior to initiating any form of PA.

It is known, that sustained light-to-moderate intensity aerobic PA typically results in hypoglycemia in persons with T1D (Guelfi, 2005). Given the presence of too much insulin, the individual could experience an accelerated rate of glucose uptake into the muscle (Riddell, 2006; Toni, 2006; Tonoli, 2012). In this instance, hypoglycemia is as of a result of the depletion of

muscle carbohydrate stores, which is the primary substrate needed to resynthesize the ATP, required for the sustained low-to-moderate intensity bout of PA.

Hypoglycemia is characterized as low blood glucose levels; usually less than 70 mg/dl or 3.9 mmol/l (ADA, 2015). Hypoglycemia in persons with T1D can be induced by PA participation, too much insulin, and/or lack of glucose ingestion (Cryer, 2003). The symptoms of hypoglycemia are, but are not limited to; nervousness, anxiety, irritability, confusion, shakiness, lightheadedness, hunger, nausea, blurred or impaired vision, seizures, coma, and death (National Institute of Diabetes and Digestive and Kidney Diseases, 2008). Unfortunately, in the short term, hypoglycemia is far more severe compared to high blood glucose levels (hyperglycemia). In order to quickly rebound the hypoglycemic state, the individual must ingest 15 grams of fast-acting simple carbohydrates, or if unconscious, exogenous glucose must be administered (CDA, ADA 2015). The importance of safe blood glucose monitoring and management is critical for the health, well-being, and quality of life of individuals with T1D. The underlying factors of hypoglycemia could be any single variable or combination of the following variables; excessive carbohydrate depletion, lack of carbohydrate ingestion prior to activity, or hyperinsulinemia (Tuominen, 1995, Rabasa-Lhoret, 2001).

In contrast, the performance of aerobic-anaerobic or anaerobic PA typically demands a vigorous-to-maximum effort, inherently resulting in hyperglycemia and in an extreme situation, ketoacidosis (Jain, 2006; Riddell, 2006; Toni, 2006; Tonoli, 2012). Evidence suggests that the observed increases in blood glucose during anaerobic or anaerobic-aerobic activity PA are a consequence of the interplay between energy resynthesis and the presence of stress hormones such as epinephrine. Hyperglycemia is characterized by fasting blood glucose levels above 126 mg/dl or 7 mmol/l (ADA, 2015). In persons with T1D, the consequent hyperglycemia is

attributed to insulin insufficiency (Purdon, 1993, Sigal, 1996, Marliss, 2002, Wasserman, 2002, Bussau, 2006). Given the insulin insufficiency, and resultant inability of muscles to take up glucose, this results in a greater reliance on free fatty acids for ATP resynthesis. In extreme situations, the increase of free fatty acid breakdown results in the production of ketone byproducts, thus initiating ketoacidosis. An unchecked ketoacidotic state will hinder PA participation due to the decrease in blood pH (Jain, 2006; Riddell, 2006). A person with T1D can experience hyperglycemia as of a result of diet, i.e. too much carbohydrate ingestion, and/or a lack of insulin, or vigorous or maximal intensity PA including exercise, or stress. The symptoms for severe hyperglycemia include shortness of breath, fruity breath, increased thirst, and frequent urination. If hyperglycemia goes untreated, persons with T1D can become ketoacidotic, which could potentially cause a diabetic shock or coma (WHO, 2016).

Emerging evidence supports that the participation in intermittent moderate-to-vigorous intensity and vigorous-to-maximum intensity bouts of PA appear to be more effective in attenuating undesirable glycemic fluctuations for T1D (American Diabetes Association, 2004; Bussau, 2006; Bussau, 2007; Robertson, 2009). The PA bout should ideally consist of an individual performing whole body aerobic PA interspersed by whole body anaerobic- aerobic and anaerobic PA to offset the negative effects of each activity which could induce hypo/hyperglycemia. Therefore, it is imperative for physically active persons with T1D to understand the associated glycemic risks and the respective strategies to attenuate the potential adverse effects (Guelfi, 2005).

Chapter 2: The Accuracy and Sensitivity of Select Exercise Intensity Devices During Varying Exercise Modalities in Persons With and Without Type One Diabetes.

Statement of Contributions:

Loren Yavelberg was responsible for the data collection, recruitment, data analysis and writing process.

Dr. Veronica Jamnik and Dr. Michael Riddell had assisted with the data collection, overseeing the investigation, refining the hypothesis, advising and valuable insight and direction

Dessi Zaharieva assisted in subject recruitment for the persons with T1D, measuring blood glucose and blood lactate.

Collegues such as Robert Gumieniak, Chip Rowan, Ryan Hancock and the M.FSc. had assisted with the data collection.

2.0 Purpose

Advances in PA "sensing" self-wear technology have emerged that quantify movement via, accelerometry, global position satellite, etc. to gauge the relative PA intensity. There is an abundance of products on the market which all vary in their measurement techniques, costs and accuracies (e.g., Polar and Garmin HR monitors, Fitbit, Nike FuelBand, Sense-Wear, Jawbone). This study was precipitated by the needs of persons interested in developing an artificial pancreas (AP). These persons were seeking to obtain electrical signals that aligned with real-time physiological responses, obtained during varying PA intensities and modalities. These findings also play an integral part in customized primary disease management, secondary disease prevention, PA prescriptions, the enhancement of current knowledge of EE, HR, BR, and shine light on the novel uses of currently available technology and wearable technology. Therefore, the purpose of this study was to evaluate the validity of EE, HR, BR from two high cost pieces of wearable technology which could potentially be used in a future AP investigation, along with two other low cost consumer-based PA activity trackers, during varying PA intensities and modalities. Given the effects of PA on glucose fluctuations in persons with type 1 diabetes (T1D) depending on the volume of PA (i.e., aerobic, anaerobic, mixed), this variability in glucose responses to PA makes the development of AP systems challenging and particularly underscores the need for accurate PA intensity "sensing" self-wear technology. It was important to assess the accuracy of these devices in both healthy and clinical populations for targeted primary prevention and secondary disease management. The two pieces of high cost hardware included the Zephyr Bioharness and the Metria Armband, while the two low cost consumer-based products included the Garmin VivoFit 2 and the Mio Fuse. The aim was to examine the validity of these activity trackers during varying exercise intensities plus modalities in persons with and

without T1D using EE, HR, and BR. This was accomplished by comparing the primary outcome, EE, using indirect calorimetry via the open circuity spirometry from the discrete component system and a metabolic unit (Cosmed Fitmate, Cosmed, Italy). The HR from the PA tracking devices was compared to the HR obtained with the Polar Unit (Polar Electro, Kemeple, Finland). The primary outcome of interest was EE obtained from each of the devices while the secondary outcomes included HR and BR. Given that EE is a common variable in all of the devices it was used as a measure of primary outcome (Table 2). Table 2 summarizes the variables that are measured by each device. For this investigation: i) the discrete component system and the Fitmate measured HR, EE, BR and oxygen consumption were measured, ii) the Metra only measured EE, iii) the Bioharness measured HR and EE, iv) the Garmin Vivofit2 measured EE, and v) the Mio Fuse measured EE. All devices were compared to the criterion standard variables assessed using the discreet component open-circuit spirometry system in the left column.

Table 2: Variables that are measured by each device. All devices were compared to the criterion standard in the left column.

	Measured Variables					
Variable	**Discrete Component System**	**Fitmate**	**Metria**	**Bioharness**	**Garmin VivoFit2**	**Mio Fuse**
Heart Rate (bpm)	√	√		√	√	√
Energy Expenditure (kcal/min)	√	√	√ (KJ)	√	√	√
Breathing Rate (b/m)	√	√		√		
Oxygen Consumption	√	√				
Heart Rate Variability				√		
Accelerometry			√	√		√
Sleep Quality + Duration			√		√	
Posture				√		
Peak Acceleration				√		
Skin Temperature			√			

*Energy expenditure is reported but not recorded on the Bioharness, along with Heart Rate from the Garmin Vivofit2 and Mio Fuse.

2.1 Hypothesis

It was hypothesized that EE recorded from the devices would accurately differentiate PA intensities within all wearable technology devices. The secondary outcomes, HR, BR and Direct VO_2, were used to confirm the PA intensity differentiation.

2.2 Methods

All protocols were reviewed and approved by the Human Participants Review Sub-Committee at York University's Office of Research Ethics. Throughout the study there were no adverse events to report on.

2.2.1 Study Participants and Requirements

A total of twenty-five male and female study participants were recruited including 8 persons with T1D. The study participants were between the ages of 18-55 (24.75 ± 7.58). Those participants with T1D must have been using an insulin pump for at least six months prior to participating in the study, and were not part of any other clinical trials or taking medications for any reason which would alter their diabetes management. Study participants did not have any physical ailments which would contraindicate participation in the study (e.g. cardiomyopathies, neuropathy, other diabetes-related complications), and were screened by a certified exercise physiologist using the evidence-based screening tools, the 2015 PAR-Q+ and ePARmed-X+ (www.eparmedx.com) for exercise contraindications and risk stratification.

2.2.2 Laboratory Based Physical and Physiological Fitness Assessment

Once recruited, the participants were randomly assigned to the PA order, to minimize order effects. There was a maximum of 5 test days in the laboratory. On the initial test day each participant underwent an incremental-to-maximal effort treadmill test for the determination of aerobic fitness or power (VO_2 max) using the criterion discrete component system (n=18) or Fitmate (n=19) open circuit spirometry. A subset of the study participants (n=14, 7 males and 7 females), who had their VO_2 max determined by the discrete component system repeated the incremental-to-maximal effort treadmill test using the Fitmate metabolic unit, on a fifth day. This

was used to confirm that the measured variables from the Fitmate metabolic unit were both accurate and reliable. This permitted the Fitmate metabolic unit to be used as the criterion device for the measurement of interest during the exercise sessions. In addition, anthropometric data including height, body mass, percent body fat, skinfolds, waist circumference and pre-exercise blood pressure were collected. Study participants had their body mass measured upon each visit (Seca Alpha Scale, Modell 770, Germany). Percent body fat was measured, without shoes, using bioelectrical impedance analysis (Tanita scale, model TBF-612, Arlington Heights, Illinois). Height was measured without any footwear, using a wall-mounted stadiometer. Waist circumference (WC) was measured using the standard National Institute of Health (NIH) protocol, which entails the tape measure being placed around the waist, on the skin, at the level of the iliac crest. Skinfolds were measured using Harpenden fat calipers (Baty International, Burgess Hill, England) according to the PALM (Jamnik and Gledhill, 2015). The skinfold sites included the Tricep, Bicep, Subscapularis, Iliac Crest and Medial Calf. The composite body composition was derived from the measurements of body mass index (BMI) (Metric: BMI= $\frac{kg}{h\,(m^2)}$, English: BMI= $\frac{lb}{h\,(in^2)} * 703$), sum of the five skinfolds (SO5S), and the NIH WC. In summary, the BMI and SO5S provide an indication of the overall amount of body fat and the WC provides information on visceral or central adiposity. The composite body composition score is used to estimate the health-risk attributable to body composition and this is accomplished by using graduated WC and SO5S within and across each BMI category (Jamnik and Gledhill, 2015).

Pre-exercise blood pressure and pulse rate measurements were determined in the seated position, in a private room, using an automated device (BpTRU Medical Devices Ltd. BC Canada). Following a five-minute sitting rest period, the BpTRU™ recorded six sequential

measurements, one minute apart. The BpTRU™ device generated average values for the pre-exercise systolic plus diastolic blood pressures and pulse rate using the last five of the six measurements. Although not required, all hypertensive values would have been re-evaluated using the auscultatory blood pressure method.

2.2.3 Data Collection Process

The incremental-to-maximal effort treadmill test for the determination of VO_2max followed the same loading sequence for all participants, but was terminated based on their respective capacities. The protocol was designed with a built in warm-up, and workload was increased every two minutes. The protocol was initiated at 3.5 mph (5.6 kph) - 1% elevation and then progressed accordingly; 5 mph (8.0 kph) - 1% elevation, 6 mph (9.7 kph) - 1% elevation, 6.5 mph (10.5 kph) - 1% elevation, then subsequent workloads consisted of the same speed (6.5 mph) with increases of 2% in elevation every 2 minutes. When the study participants were no longer able to continuously run, an active recovery was initiated, which allowed them to slow down to a lower intensity of 3.5 mph - 1% elevation for 2 minutes. Subsequently, the attainment of VO_2 max was confirmed using a discontinuous protocol. Thus, the participants exercised at higher workloads for 2 minutes, followed by another active recovery. This protocol sequence was repeated until the VO_2 of the subsequent workload was equal to or lower than the previous, indicating maximum oxygen intake (Lupton, 1923, Gledhill, 1994; Howley, 1995). This can also be referred to as supramaximal testing, where the individual was not taken to a peak, but rather a true max where the VO_2 of the more difficult task was lower than the previous (Jacobs, 1983; Gledhill 1994). The VO_2 was determined from measurements obtained during the last thirty seconds of each workload via direct analysis of mixed expired gases. The initial treadmill test was completed using the gold-standard discrete open circuit spirometry Tissot tank system, while

the final test was completed using the Fitmate metabolic unit, Cosmed Fitmate, in order to ensure validity in the hardware.

The discrete open circuit spirometry system was comprised of; a 120L Tissot gasometer collection tank (Warren E Collins LTD. Braintree, Massachusetts), rapid response oxygen and carbon dioxide gas analyzers (Applied Electrochemistry, Model S-3A and CD-3S, Sunnyvale, California), a hose, two-way y-valve (Ewald Koegal Co, San Antonio Texas), mouthpiece and nose plugs. The mouthpiece was positioned between the participants' gums and teeth and they were required to breathe in and out of the mouthpiece throughout the VO_2 collection period with their noses plugged. The Y-valve allowed the participants to freely inhale atmospheric air, then directly exhale air into the hose then tank, where the gasses mixed and collected. Once the expired gases were collected they were then analyzed using the gas analyzers which worked in tandem to each other. The collected variables; minute ventilation, fractions of expired carbon dioxide and oxygen, were then used to calculate the participants' VO_2. The other variables of interest included BR (b/m), HR (bpm), and EE (kcals) was estimated from VO_2 $L \cdot min^{-1}$, where for every liter of consumed oxygen the EE is approximately 4.86 kilocalories per minute (Péronnet, 1991). The VO_2 max test was terminated if the study participant could no longer complete the workload as a result of volitional fatigue, or if the above VO_2 max criteria was met. This was to be determined by the qualified exercise physiologist present at the time.

The portable metabolic unit (Fitmate), worked similarly to the discrete component system by using expired gas analysis, but differed in gas collection and calculation techniques. The study participant was outfitted with a face mask which was held in place by a headpiece. While the study participant was exhaling, a flowmeter and oxygen sample line, attached to the face mask, collected data on breathing rate, volume of air, and the fractional concentration of oxygen.

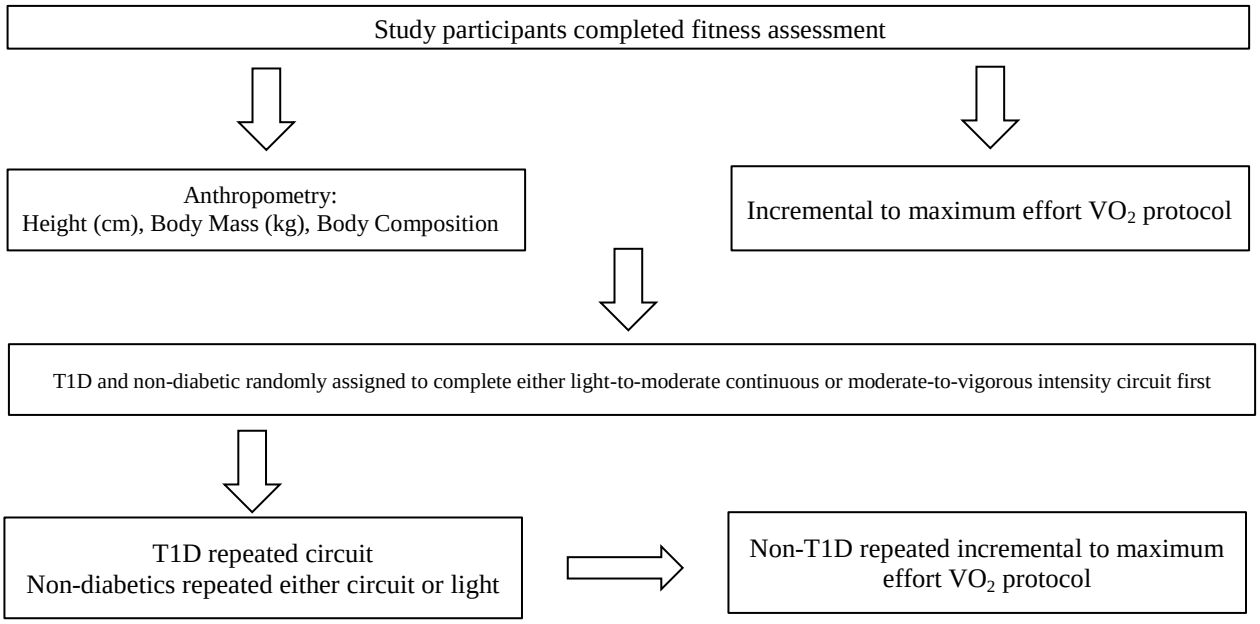
Unlike the discrete component system, the Fitmate only analyzed the expired oxygen and assumed the associated carbon dioxide concentration based on proprietary formulas. The Fitmate metabolic unit was also able to internally calculate the participants' provided breath-by-breath VO_2. The other variables of interest included BR (b/m), HR (bpm), and EE (kcals) was estimated from VO_2 $L \cdot min^{-1}$, where for every liter of consumed oxygen the EE is approximately 4.86 kilocalories per minute (Péronnet, 1991). The identical test termination criteria were applied, as stated above. The criterion pulse (heart) rate was measured throughout using a Polar HR monitor (Polar Electro, Kempele, Finland).

All study participants were instrumented with the; i) Bioharness chest strap for the measurements of HR (bpm) and BR (b/m), ii) Metria armband for the measurement of EE (kJ), iii) and the Garmin chest strap or Mio wrist band for the measurements of HR (bpm) and total EE (kcals). The Metria Armband was worn on the study participants' non-dominant upper arm and collected information on the individuals' Skin Temperature, PA Intensity, Activity Levels, and EE. While the Zephyr Bioharness, was worn on the study participants' upper body in the form of t-shirt or chest strap and collected information on HR, HR variability, BR, Posture, Activity Level, Peak Acceleration, Speed and Distance. Both devices are non-invasive, and persons with T1D exercised while wearing their own insulin pumps in addition to the wearable technology. Both consumer-based fitness trackers also measure HR and EE. The Garmin VivoFit2 measures HR through a conventional chest strap, while the Mio fuse measures HR through reflection photoplethysmography using green 530nm wavelength light.

Following the initial test day, each group participated in the remaining 4 activity days in a differing order. The purpose of this was to exclude any training order effects. The exercise days consisted of a continuous light intensity treadmill based continuous exercise session or a

calisthenics-based circuit exercise session. The exercise intensities were predetermined for each activity day, based on the participants' VO_2 max, as determined on the initial visit. The study participants repeated either the intermittent circuit or continuous light activity days on the remaining two activity days (Figure 2). This ordering of activity would allow the researchers to monitor accuracy on a test-retest basis. All measurements and exercises were performed in the Human Performance Laboratory at York University.

Figure 2: Summary of Laboratory Measures



VO_2, HR and RPE were continuously measured during the continuous light-to-moderate intensity PA which consisted of walking on the treadmill for 40 minutes, at a speed and grade that elicited 40-50% of the study participant's VO_2 max. Blood glucose was measured every ten minutes for participants with T1D. On a subset of study participants, finger prick blood lactate was measured every ten minutes to confirm the PA intensity (Lactate Scout, EKF Diagnostics,

Wales, UK). The exercise collection was terminated based on a blood glucose cut-point of 3.5 mmol/l.

VO_2, HR and RPE were also measured throughout the circuit activity day which included: walking on a treadmill for 4 minutes, performing a circuit of the following exercises: marching on the spot with high knees (using the arms) 45 sec; squats with a front sweep (reps/60 sec); 4 Jumping Jacks; quadruped (aka as the bird dog) (30 sec); 2 Jumping Jacks; 4 push-ups followed by a 20 sec prone forearm plank; marching on the spot with high knees/30 sec); 8 kg ball lift to platform at chest height/60 sec; 4 pushups, followed by a 20 sec prone forearm plank, 4 minutes of vigorous intensity cycling; repeating the circuit above; walking on a treadmill for 4 minutes; repeating the circuit above; and finishing with 8-10 minutes of cycling at a vigorous intensity, to ensure all activity days were 40 minutes in duration. The intensity of the circuit ranged from moderate-to-vigorous (50-75% of VO_2max) and vigorous-to-maximum (75-100% of VO_2max). All four exercise sessions were supervised by qualified exercise professionals (Certified Exercise Physiologists). Blood glucose was measured every ten minutes for participants with T1D. On a subset of study participants, finger prick blood lactate was measured every ten minutes to confirm the PA intensity. The exercise collection was terminated based on a blood glucose cut-point of 3.5 mmol/l.

2.3 Data Analysis

A subset of study participants (n=14) repeated the incremental-to-maximal effort treadmill VO_2 on two separate occasions. On one occasion, the incremental-to-maximal effort treadmill VO_2 was completed using the metabolic unit (Fitmate), and on the second occasion the identical incremental-to-maximal effort treadmill VO_2 protocol was administered using the discrete component system. The results from both systems using the final thirty seconds of each

workload were aggregated and compared. This step was essential to ensure that the measured variables of interest from the Fitmate metabolic unit were valid during the light-to-moderate intensity 40-50% VO_2max continuous exercise and moderate-to-vigorous intensity 51-75% VO_2max intermittent circuit exercise sessions. The Fitmate metabolic unit variable outcomes were deemed accurate if the variables of interest were not significantly different at the 95% confidence level, compared to that of the discrete component system.

The results of the incremental-to-maximal effort treadmill VO_2 protocol were used to demarcate the following exercise intensity ranges: light-to-moderate intensity 40-50% VO_2max, moderate-to-vigorous intensity 51-75% VO_2max, vigorous-to-maximum intensity 76-100% VO_2max (Garber, 2011). These exercise intensities align with the approximate harmonized classification of exercise intensities as shown in Table 3.

Table 3: Shows the approximate classification of exercise intensity using relative and absolute methods commonly used in practice. Adopted American College of Sports Medicine (14), Howley (173), Swain and Franklin (344), Swain and Leutholtz (346), Swain et al. (347), and the US Department of Health and Human Services (370

	Cardiorespiratory Endurance Exercise											Resistance Exercise
	Relative Intensity				Intensity ($\%VO_{2max}$) Relative to Maximal Exercise Capacity in METs			Absolute Intensity	Absolute Intensity (MET) by Age			Relative Intensity
Intensity	%HRR or $\%VO_2R$	$\%HR_{max}$	$\%VO_{2max}$	Perceived Exertion (Rating on 6–20 RPE Scale)	20 METs $\%VO_{2max}$	10 METs $\%VO_{2max}$	5 METs $\%VO_{2max}$	METs	Young (20–39 yr)	Middle-aged (40–64 yr)	Older (≥65 yr)	% 1RM
Very light	<30	<57	<37	<Very light (RPE < 9)	<34	<37	<44	<2	<2.4	<2.0	<1.6	<30
Light	30–39	57–63	37–45	Very light–fairly light (RPE 9–11)	34–42	37–45	44–51	2.0–2.9	2.4–4.7	2.0–3.9	1.6–3.1	30–49
Moderate	40–59	64–76	46–63	Fairly light to somewhat hard (RPE 12–13)	43–61	46–63	52–67	3.0 to 5.9	4.8–7.1	4.0–5.9	3.2–4.7	50–69
Vigorous	60–89	77–95	64–90	Somewhat hard to very hard (RPE 14–17)	62–90	64–90	68–91	6.0–8.7	7.2–10.1	6.0–8.4	4.8–6.7	70–84
Near–maximal to maximal	≥90	≥96	≥91	≥Very hard (RPE ≥ 18)	≥91	≥91	≥92	≥8.8	≥10.2	≥8.5	≥6.8	≥85

Table adapted from the American College of Sports Medicine (14), Howley (173), Swain and Franklin (344), Swain and Leutholtz (346), Swain et al. (347), and the US Department of Health and Human Services (370).
HR_{max}, maximal HR; $\%HR_{max}$, percent of maximal HR; HRR, HR reserve; VO_{2max}, maximal oxygen uptake; $\%VO_{2max}$, percent of maximal oxygen uptake; VO_2R, oxygen uptake reserve; RPE, ratings of perceived exertion (48).

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The breath-by-breath data from the Fitmate metabolic unit were also aggregated into minute-by-minute values to coincide with the data outputs from the wearable technology, for each respective exercise day. A Paired t-test analysis was performed using SPSS 23.0 was used for all the analysis, with a threshold for statistical significance set at $p \leq 0.05$ a priori, and the

Fitmate metabolic unit was used as the criterion standard for comparison. The comparisons were completed for the variables of interest (HR, BR, EE) between devices to determine accuracy and reliability.

Bland-Altman analyses were conducted to determine and illustrate bias using Prism 6. The Bland-Altman analysis examines the agreement between the two measurement procedures conducted on the same variable at the same time (Altman, 1983). The analyses were performed such that the difference of the secondary devices, B, compared to the criterion, A, divided by the average of the criterion (Difference B - A / Average).

2.4 Results

2.4.1 Study Participants' Characteristics

Study participants consisted of a total of 25 study participants, 14 males and 11 females, 18-55 years of age (24.75 ± 7.58), of those, 8 were persons with T1D. The participants with T1D had been using an insulin pump for at least six months prior to participating in the study. The anthropometric, physical and physiological fitness profiles of all groups and sub-groups are reported in Table 4. A significant difference was observed ($p=0.045$) in Peak exercise HR between non-diabetic (ND) females and females with T1D, likely due to the older age of one of the female study participants in the T1D group.

Table 4: Anthropometric, physical and physiological fitness profiles of both groups.

	Male		Female	
	ND *(n=10)*	**T1D** *(n=4)*	**ND** *(n=7)*	**T1D** *(n=4)*
Variable	**Mean ± SD**	**Mean ± SD**	**Mean ± SD**	**Mean ± SD**
Age (yr)	21 ± 1.6	23 ± 9.2	24 ± 6.0	34 ± 13.5
Height (cm)	175.3 ± 5.9	180.3 ± 5.9	164.4 ± 3.5	169.5 ± 10.6
Body Mass (kg)	79.9 ± 7.9	76.5 ± 3.4	64.4 ± 8.3	71.3 ± 9.9
BMI (kg/m^2)	26.0 ± 2.2	23.6 ± 2.2	23.8 ± 2.7	24.7 ± 1.5
Body Fat (%)	19.3 ± 5.1	13.1 ± 6.9	30.1 ± 6.2	31.2 ± 2.7
Sum of 5 Skinfolds (mm)	53.3 ± 27.1	35.3 ± 10.5	82.1 ± 27.8	79.1 ± 13.8
Waist Circumference (cm)	84.9 ± 7.9	80.5 ± 3.3	83.2 ± 5.2	87.3 ± 6.6
Body Composition				
Health Benefit Zone Rating	Very Good	Excellent	Very Good	Very Good
VO_2max ($mL \cdot kg^{-1} \cdot min^{-1}$)	49.9 ± 4.3	55.9 ± 6.7	42.0 ± 7.7	38.1 ± 1.9
Peak HR (bpm)	200 ± 3.7	203 ± 3.6	199 ± 3.9	182 ± 15.7*

ND represents persons without diabetes and T1D represents study participant with Type One Diabetes
Health Benefit Zone Rating is a function of the composite body composition score using graduated NIH waist circumference, and sum of 5 skinfolds within and across each body mass index category. Very good indicates that body composition falls within a range that is generally associated with considerable health benefits. An excellent rating indicates that the body composition falls within a range that is generally associated with enhanced health benefits. *Significant difference was observed (p=0.045) in Peak exercise HR between non-diabetic females and females with T1D, due to the older age of one of the female study participants.

2.4.2 Statistical Analysis and Data Interpretation

Given the portability of the Fitmate metabolic unit and its need for use during the free-movement circuit exercise sessions, the researchers had to confirm that the Fitmate metabolic unit was in fact accurate. This was accomplished by using a sub-set of the 25 study participants (n = 14, male = 7, female = 7) who repeated the identical incremental-to-maximal effort VO_2 protocol on two separate occasions. The data was averaged for the final thirty seconds of each two-minute workload. A paired t-test analysis was performed using SPSS 23.0 to compare the Fitmate metabolic unit outcomes using the criterion discrete component system. There were no significant difference between the two measurement systems for the VO_2 max values ($p = 0.565$). The co-relation between the two system for the incremental-to-maximum VO_2 values was $r = 0.967 \pm 0.03$. There were no significant differences for the maximum breathing rate ($p = 0.407$). The co-relation between the two systems for the maximum breathing rate values was, $r = 0.921 \pm$

0.04. Statistical analyses were only performed on the grouped data. No statistical analyses were conducted for sex differences and between ND and persons with T1D, due to the low number of study participants in the sub-groups. The average VO_2 max and maximum BR for all study participants who repeated the incremental-to-maximum VO_2 protocol are represented in Table 5.

Table 5: Discrete Component System versus Metabolic Unit (Fitmate) Accuracy for VO_2 max and maximal Breathing Rate (Mean ± SD)

	Max VO_2($mL \cdot kg^{-1} \cdot min^{-1}$)		Max BR (b/min)	
	Discrete Component System	**Fitmate Metabolic Unit**	**Discrete Component System**	**Fitmate Metabolic Unit**
Males (n=7)	48.35 ± 4.48	48.34 ± 4.72	57.86 ± 9.63	56.09 ± 10.94
Females (n=7)	39.60 ± 3.58	38.11 ± 4.34	50.71 ± 11.01	49.72 ± 12.31
Grouped (n=14)	43.97 ± 5.99	43.23 ± 6.87	54.29 ± 10.61	52.90 ± 11.67

No significant differences were found

2.4.3 Comparison between wearable technology devices for Energy Expenditure, Heart Rate, and Breathing Rate during the incremental-to-maximal effort VO_2 protocol

The results from the incremental-to-maximal effort VO_2 protocol using the Fitmate metabolic unit were averaged for every minute to create a common comparison time frame, given that the different wearable technology devices collected data at different time frequencies (Bioharness every second and Metria every minute). A paired t-test analysis was performed to determine if significant differences were observed for the variables of interest (EE, HR, BR) between each of the devices at the following intensities; light-to-moderate intensity <50% of VO_2max (Table 6), moderate-to-vigorous intensity 51-75% of VO_2max (Table 7), and vigorous-to-maximum intensity 76-100% of VO_2max (Table 8). No statistical analyses were conducted for sex differences and between ND and persons with T1D, due to the low number of study participants in the sub-groups.

Table 6 contains the EE, HR, and BR data during the light-to-moderate intensity (40-50% VO_2max) portion of the incremental-to-maximum VO_2 protocol using the Fitmate, Metria, and Bioharness. For each variable, the number of study participants (N) per group were reported. In addition, for each variable the number of data points (n) plus the associated means and standard deviations were reported. For each of the variables the statistical analyses were only performed on the grouped data. No statistical analyses were conducted for sex differences and between ND and persons with T1D, due to the low number of study participants in the sub-groups. Significant differences were observed between the Fitmate metabolic unit and the Metria for EE ($n = 53$, $p < 0.001$). The Metria overestimated the EE in the light-to-moderate intensity portion of the the incremental-to-maximal effort VO_2 protocol. Significant differences were also observed between the Fitmate metabolic unit and Bioharness for HR ($n = 76$, $p < 0.001$) and BR ($n = 73$, $p = 0.004$). The Bioharness underestimated both the BR and HR in the light-to-moderate intensity portion.

Table 6: Comparison of Energy Expenditure, Heart Rate, and Breathing Rate between devices during the light-to-moderate intensity portion of the incremental-maximum effort VO_2 protocol (Mean ± SD)

	Energy Expenditure					Heart Rate				Breathing Rate			
	N	n	Fitmate	N	Metria	N	n	Polar	Bioharness	N	n	Fitmate	Bioharness
Males	10	23	7.32 ± 1.99	6	7.72 ± 2.48	10	34	111.24 ± 14.07	109.36 ± 15.84	10	34	22.87 ± 5.71	22.07 ± 7.67
Females	6	12	5.04 ± 1.05	4	5.28 ± 1.38	6	21	123.16 ± 12.11	124.14 ± 15.79	6	18	28.22 ± 5.50	22.59 ± 6.55
Persons with Diabetes													
Males	2	8	6.07 ± 1.57	2	7.43 ± 2.81	2	8	119.08 ± 14.08	114.77 ± 12.00	2	8	20.46 ± 3.49	26.92 ±13.22
Females	3	10	5.99 ± 1.85	2	6.35 ± 2.40	3	13	135.11 ± 3.00	117.89 ± 17.64	3	13	26.34 ± 6.43	21.79 ± 5.87
Grouped	21	53	6.38 ± 2.01	6	6.71 ± 2.41**	10	76	116.57 ± 14.43	115.97 ± 17.38**	10	73	25.14 ± 6.19	22.29 ± 7.17*

** Denotes a significant difference in Energy Expenditure ($p < 0.001$), Heart Rate ($p < 0.001$), and * for Breathing Rate ($p < 0.05$). N denotes the number of study participants per group. n denotes the number of data points used in the statistical analyses.

Table 7 contains the EE, HR, and BR data during the moderate-to-vigorous (51-75% VO_2max) intensity portion of the incremental-to-maximum VO_2 protocol using the Fitmate, Metria, and Bioharness. For each variable, the number of study participants (N) per group are reported. In addition, for each variable the number of data points (n) and the associated means and standard deviations are reported. For each of the variables the statistical analyses were only performed on the grouped data. No statistical analyses were conducted for sex differences and between ND and persons with T1D, due to the low number of study participants in the sub-groups. Significant differences were observed between the Fitmate metabolic unit and Metria for EE ($n = 37$, $p < 0.001$). Significant differences were also observed between the Fitmate metabolic unit and Bioharness for BR ($n = 64$, $p < 0.001$) and HR ($n = 64$, $p < 0.001$).

Table 7: Comparison of Energy Expenditure, Heart Rate, and Breathing Rate between devices during the moderate-to-vigorous intensity portion of the incremental-maximum effort VO_2 protocol (Mean ± SD)

	Energy Expenditure					Heart Rate				Breathing Rate			
	N	n	Fitmate	N	Metria	N	n	Polar	Bioharness	N	n	Fitmate	Bioharness
Males	10	17	12.58 ± 2.34	6	13.27 ± 2.07	10	33	155 ± 14	150 ± 18	10	33	40.58 ± 18.29	29.14 ± 7.54
Females	6	11	8.12 ± 1.17	4	8.78 ± 1.30	6	22	154 ± 14	150 ± 21	6	22	36.94 ± 4.74	30.12 ± 6.44
Persons with Diabetes													
Males	2	4	11.96 ± 2.73	2	13.53 ± 0.84	2	4	151 ± 11	147 ± 11	2	4	25.22 ± 2.75	18.72 ± 5.00
Females	3	5	8.52 ± 1.16	2	7.78 ± 1.33	3	8	149 ± 17	153 ± 28	3	8	33.74 ± 4.45	32.45 ± 5.95
Grouped	21	37	10.68 ± 2.91	14	11.32 ± 2.86**	21	67	155 ± 14	150 ± 19**	21	67	39.04 ± 14.27	29.55 ± 7.06**

**Denotes a significant difference in Energy Expenditure ($p < 0.001$), Heart Rate ($p < 0.001$), and Breathing Rate ($p < 0.001$). N denotes the number of study participants per group. n denotes the number of data points used in the statistical analyses.

Table 8 contains the EE, HR, and BR data during the vigorous-to-maximal (76-100% VO_2max) intensity portion of the incremental-to-maximum VO_2 protocol using the Fitmate, Metria, and Bioharness. For each variable, the number of study participants (N) per group are reported. In addition, for each variable the number of data points (n) and the associated means and standard deviations are reported. For each of the variables the statistical analyses were only performed on the grouped data. No statistical analyses were conducted for sex differences and between ND and persons with T1D, due to the low number of study participants in the sub-groups. Significant differences were observed between the Fitmate metabolic unit and Metria for EE ($n = 191$, $p < 0.001$) and the Fitmate metabolic unit and Bioharness for BR ($n = 267$, $p < 0.001$) and HR ($n = 267$, $p = 0.038$).

Table 8: Comparison of Energy Expenditure, Heart Rate, and Breathing Rate between devices during the vigorous-to-maximum intensity portion of the incremental-maximum effort VO_2 protocol (Mean ± SD)

	Energy Expenditure					Heart Rate				Breathing Rate			
	N	n	Fitmate	N	Metria	N	n	Polar	Bioharness	N	n	Fitmate	Bioharness
Males	10	86	15.82 ± 3.69	6	13.50 ± 2.64	10	124	179 ± 13	179 ± 14	10	124	49.49 ± 21.30	37.22 ± 7.85
Females	6	49	10.82 ± 2.28	4	9.78 ± 1.78	6	95	174 ± 17	178 ± 15	6	95	46.54 ± 8.16	41.05 ± 7.00
Persons with Diabetes													
Males	2	24	18.02 ± 5.82	2	14.58 ± 2.65	2	12	186 ± 12	185 ± 11	2	12	42.59 ± 10.74	33.81 ± 11.07
Females	3	32	11.01 ± 1.95	2	9.28 ± 1.92	3	36	171 ± 14	170 ± 18	3	36	42.89 ± 4.05	41.37 ± 4.47
Grouped	21	191	13.70 ± 4.02	14	11.92 ± 2.95**	21	267	177 ± 15	178 ± 14	21	267	48.18 ± 16.80	38.93 ± 7.72**

**Denotes a significant difference in Energy Expenditure, and Breathing Rate ($p < 0.001$). N denotes the number of study participants per group. n denotes the number of data points used in the statistical analyses.

Bland-Altman Analysis

Bland-Altman analyses were conducted to determine and illustrate bias using GraphPad Prism 6. The Bland-Altman analysis examines the agreement between the two measurement procedures conducted on the same variable at the same time (Altman, 1983). The analyses were performed such that the difference of the secondary devices, B, compared to the criterion, A, divided by the average of the two devices [Difference (B – A) / Average $\frac{B+A}{2}$)].The results for EE during the light-to-moderate intensity), moderate-to-vigorous intensity (51-75% VO_2max), vigorous-to-maximal intensity (76-100% VO_2max), portion of incremental-maximum effort VO_2 protocol are displayed in Figures 3a, 3b, 3c, respectively. The results for HR during the light-to-moderate intensity), moderate-to-vigorous intensity (51-75% VO_2max), vigorous-to-maximal intensity (76-100% VO_2max), portion of incremental-maximum effort VO_2 protocol are displayed in Figures 4a, 4b, 4c, respectively. The results for BR during the light-to-moderate intensity), moderate-to-vigorous intensity (51-75% VO_2max), vigorous-to-maximal intensity (76-100% VO_2max), portion of incremental-maximum effort VO_2 protocol are displayed in Figures 5a, 5b, 5c, respectively.

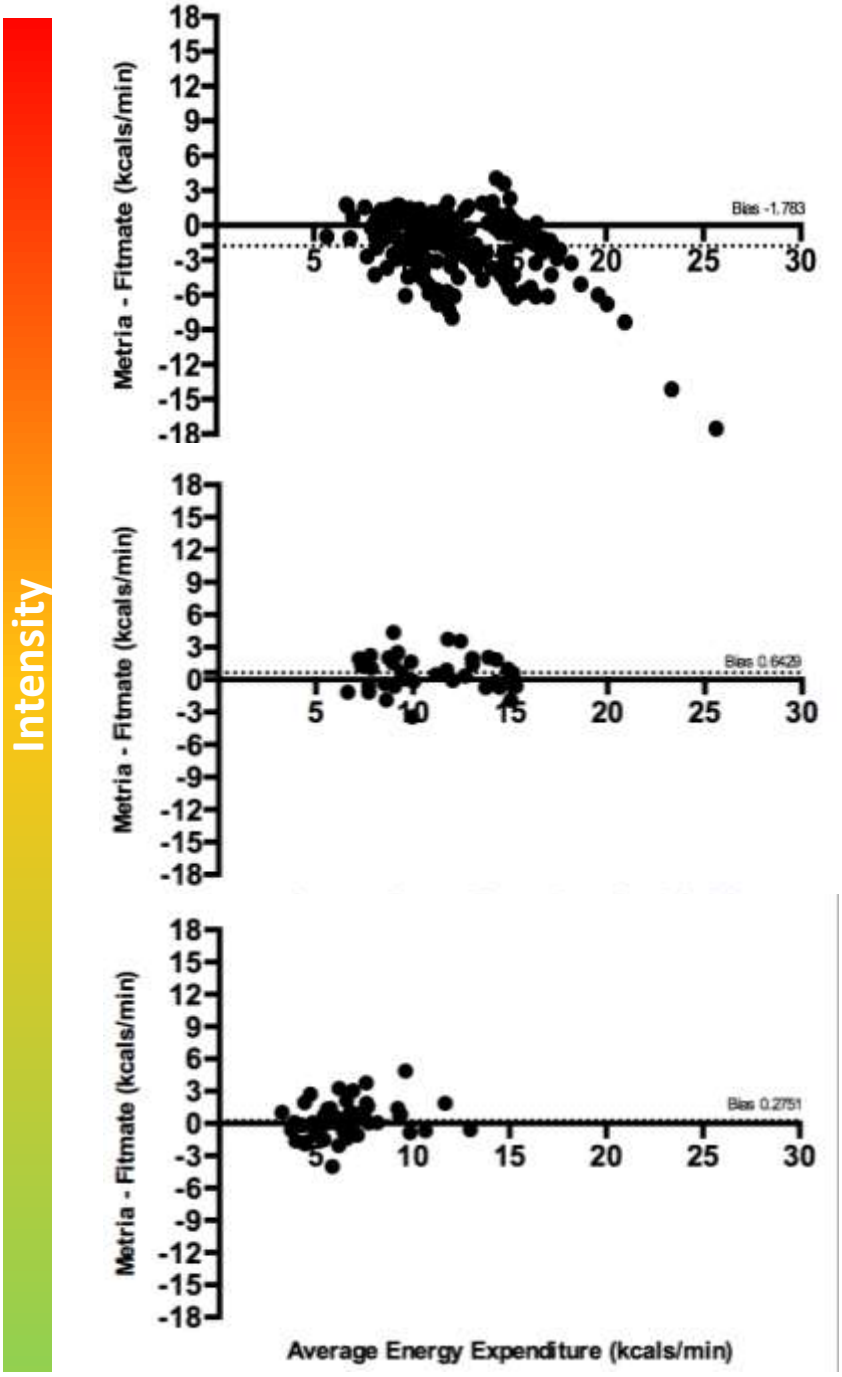
Bland-Altman plots for the Fitmate versus Metria during the light-to-moderate intensity (40-50% VO_2max), moderate-to-vigorous intensity (51-75% VO_2max), vigorous-to-maximal intensity (76-100% VO_2max), portions of incremental-maximum effort VO_2 protocol for Energy Expenditure

Figure 3a contains the results from the Bland-Altman plot for the Fitmate metabolic versus the Metria during the light-to-moderate intensity portion of the incremental-maximum effort VO_2 protocol for EE. The results demonstrate that the Metria has a bias of 0.28 ± 1.62 kcals · minute^{-1} with 95% limits of agreement from -2.91 – 3.46 kcals · minute^{-1}. This indicates that on average the Metria overestimates the EE by 0.28 kcals · minute^{-1}.

Figure 3b contains the results from the Bland-Altman plot for the Fitmate metabolic unit versus the Metria during the moderate-to-vigorous intensity portion of the incremental-to-maximum effort VO_2 protocol for EE. The results demonstrate that the Metria has a bias of 0.64 ± 1.65 kcals · minute^{-1} with 95% limits of agreement from -2.59 – 3.87 kcals · minute^{-1}. This indicates that on average the Metria generally overestimates the EE by 0.64 kcals per minute.

Figure 3c contains the results from the Bland-Altman plot for the Fitmate metabolic unit versus the Metria during the vigorous-to-maximal intensity portion of the incremental-maximum effort VO_2 protocol for EE. The results demonstrate that the Metria has a bias of -1.78 ± 2.77 with 95% limits of agreement from -7.22 – 3.65. This indicates that on average the Metria generally underestimates the EE by 1.78 kcals per minute.

Maximal



Light

Figure 3c

Figure 3b

Figure 3a

Bland-Altman plots for the Polar versus Bioharness during the light-to-moderate intensity (40-50% VO_2max), moderate-to-vigorous intensity (51-75% VO_2max), vigorous-to-maximal intensity (76-100% VO_2max), portions of incremental-maximum effort VO_2 protocol for Heart Rate

Figure 4a contains the results from the Bland-Altman plot for the Polar versus the Bioharness during the light-to-moderate intensity portion of the incremental-maximum effort VO_2 protocol for HR. The results demonstrate that the Bioharness has a bias of -0.60 ± 7.86 bpm with 95% limits of agreement from -16.01 – 14.82 bpm. This indicates that on average the Bioharness generally underestimates the HR by 0.60 bpm.

Figure 4b contains the results from the Bland-Altman plot for the Polar versus the Bioharness during the moderate-to-vigorous intensity portion of the incremental-maximum effort VO_2 protocol for HR. The results demonstrate that the Bioharness has a bias of -4.73 ± 11.07 bpm with 95% limits of agreement from -26.42 – 16.96 bpm. This indicates that on average the Bioharness generally underestimates the HR by -4.73 bpm.

Figure 4c contains the results from the Bland-Altman plot for the Fitmate metabolic unit versus the Bioharness during the vigorous-to-maximal intensity portion of the incremental-maximum effort VO_2 protocol for HR. The results demonstrate that the Bioharness has a bias of 1.45 ± 11.56 with 95% limits of agreement from -21.20 – 24.11. This indicates that on average the Bioharness generally overestimates the HR by 1.45 bpm.

Maximal

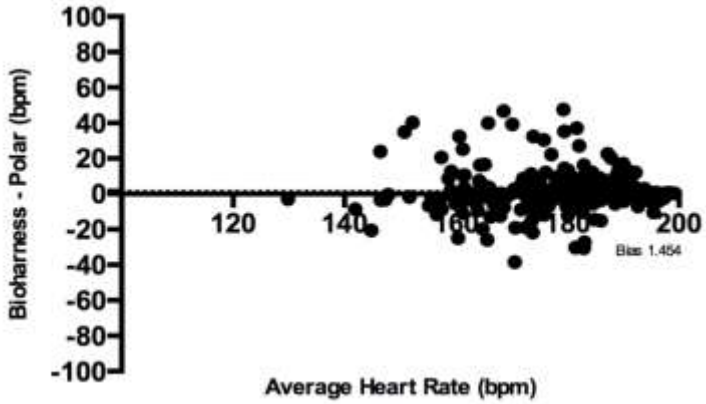


Figure 4c

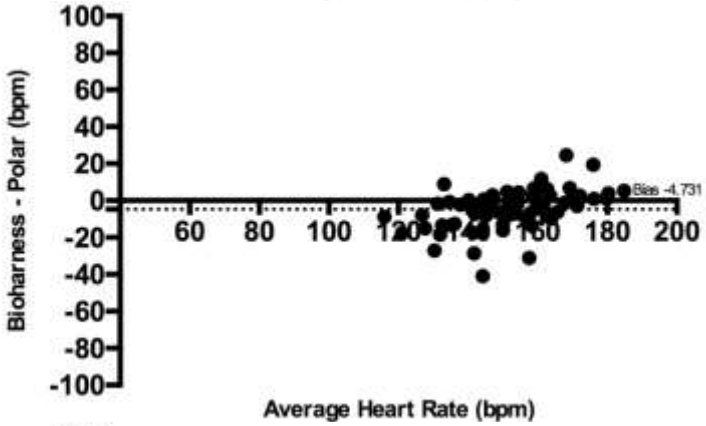


Figure 4b

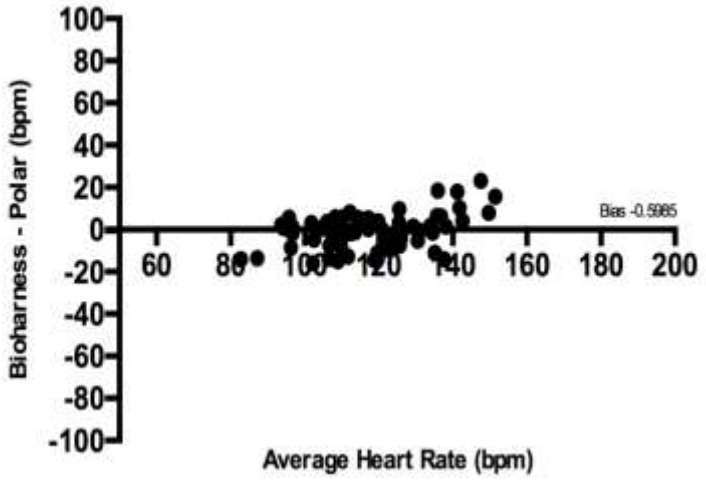


Figure 4a

Light

Bland-Altman plots for the Polar versus Bioharness during the light-to-moderate intensity (40-50% VO_2max), moderate-to-vigorous intensity (51-75% VO_2max), vigorous-to-maximal intensity (76-100% VO_2max), portions of incremental-maximum effort VO_2 protocol for Breathing Rate

Figure 5a contains the results from the Bland-Altman plot for the Fitmate metabolic versus the Bioharness during the light-to-moderate intensity portion of the incremental-maximum effort VO_2 protocol for BR. The results demonstrate that the Bioharness has a bias of -2.85 ± 7.765 breaths/min with 95% limits of agreement from -18.04 – 12.34 breaths/min. This indicates that on average the Bioharness generally underestimates the BR by 2.85 breaths/min.

Figure 5b contains the results from the Bland-Altman plot for the Fitmate metabolic unit versus the Bioharness during the moderate-to-vigorous intensity portion of the incremental-maximum effort VO_2 protocol for BR. The results demonstrate that the Bioharness has a bias of -9.49 ± 11.97 with 95% limits of agreement from -32.96 – 13.98. This indicates that on average the Bioharness generally underestimates the BR by 9.49 breaths/minute.

Figure 5c contains the results from the Bland-Altman plot for the Fitmate metabolic unit versus the Bioharness during the vigorous-to-maximal intensity portion of the incremental-to-maximum effort VO_2 protocol for BR. The results demonstrate that the Bioharness has a bias of -5.61 ± 8.34 breaths/min with 95% limits of agreement from -21.96 – 10.73 breaths/min. This indicates that on average the Bioharness generally underestimates the BR by 5.61 breaths/minute.

Maximal

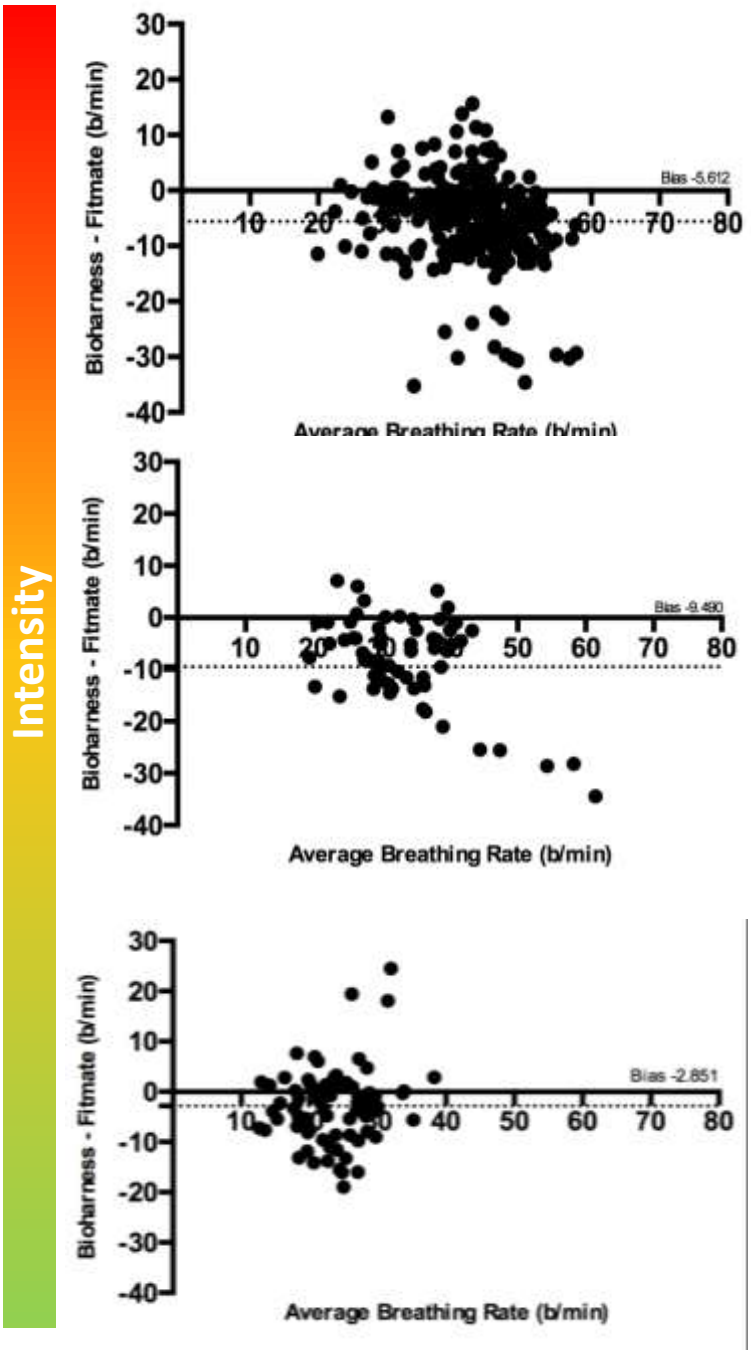


Figure 5c

Figure 5b

Figure 5a

Light

A paired t-test analysis was performed (Table 9) for total EE reported from each of the consumer devices versus the Fitmate metabolic unit, in order to examine the accuracy of the Garmin VivoFit 2 and the Mio Fuse. No significant differences were observed for either of the devices, compared to the Fitmate ($p < 0.05$).

Table 9: Accuracy of Consumer Based Wearable Technology for Total Energy Expenditure during the incremental-to-maximum effort VO_2 protocol (Mean ± SD)

	N	Fitmate	Garmin	N	Fitmate	Mio
Grouped	4	278.07 ± 77.39	327.00 ± 139.38	4	212.42 ± 102.25	381.00 ± 150.08

No significant differences were observed for either of the devices compared to Fitmate ($p < 0.05$). N denotes the number of study participants per group.

2.4.4 Circuit Exercise Data

To determine whether or not the select devices were accurate during moderate-to-vigorous intensity free motion PA, the results from the 40-minute circuit were examined. The data was averaged for every minute to create a common time variable, as different devices collected data at different frequencies (Bioharness every second and Metria every minute). For each variable, the number of study participants (N) per group are reported. In addition, for each variable the number of data points (n) plus the associated means and standard deviations are reported in Table 10. There were significant differences in EE ($p < 0.001$), HR ($p<0.001$), and BR ($p = 0.001$). In addition, all variables were underestimated relative to the criterion standard measurements. Varying sample sizes for EE derived from the Metria were due to equipment malfunction. Reliability was also investigated by examining the data of those individuals who repeated the circuit under similar conditions on a separate day. The descriptive statistics (Mean ± SD), results from the paired t-test analysis, unit difference, and percent difference are contained in Table 10, 11, and 12 for EE, HR, and BR, respectively.

Table 10 contains the EE, HR, and BR data during the first circuit trial using the Fitmate metabolic unit, Metria, and Bioharness. For each variable, the number of study participants (N) per group are reported. In addition, for each variable the number of data points (n) and the associated means and standard deviations are reported. For each of the variables the statistical analyses were only performed on the grouped data. No statistical analyses were conducted for sex differences and between ND and persons with T1D, due to the low number of study participants in the sub-groups. Significant differences were observed between the Fitmate metabolic unit and Metria for EE ($n = 604$, $p < 0.001$), HR ($n = 873$, $p < 0.001$) and Bioharness for BR ($n = 872$, $p = 0.001$).

Table 10: Energy Expenditure, Heart Rate, and Breathing Rate during the first circuit trial (Mean ± SD)

	Energy Expenditure					Heart Rate				Breathing Rate			
	N	n	Fitmate	N	Metria	N	n	Polar	Bioharness	N	n	Fitmate	Bioharness
Males	10	229	9.26 ± 2.42	6	7.01 ± 3.65	10	387	146 ± 22	147 ± 21	10	388	33.02 ± 7.17	27.97 ± 6.70
Females	7	157	6.45 ± 1.32	4	5.33 ± 6.28	7	271	160 ± 21	155 ± 22	7	271	35.58 ± 7.38	29.24 ± 7.61
Persons with Diabetes													
Males	3	120	9.38 ± 1.60	4	6.72 ± 1.69	3	116	164 ± 21	157 ± 22	3	116	33.63 ± 7.33	27.25 ± 6.49
Females	3	98	7.43 ± 1.48	3	5.44 ± 1.62	3	98	145 ± 20	146 ± 22	3	98	38.95 ± 6.02	31.87 ± 6.46
Grouped	23	604	8.32 ± 2.34	17	6.25 ± 2.56**	23	872	153 ± 23	151 ± 22**	23	873	34.46 ± 7.38	28.63 ± 7.05*

**Denotes a significant difference in Energy Expenditure, and Heart Rate ($p < 0.001$). *Denotes a significant difference in Breathing Rate ($p = 0.001$). N denotes the number of study participants per group. n denotes the number of data points used in the statistical analyses.

Table 11 contains the test-retest reliability data of the study participants who repeated the circuit on two separate occasions, using the Fitmate metabolic and Metria for Energy Expenditure. The number of study participants (N) per group are reported. In addition, the number of data points (n) plus the associated mean and standard deviation are reported. The statistical analyses were only performed on the grouped data. During circuit trials 1 and 2 there was a significant difference between the Fitmate and Metria for EE. However, there were no significant differences between circuit trials 1 and 2 for the kcals · minute^{-1}using the Fitmate metabolic unit. Similarly, there were no significant differences between circuit trials 1 and 2 for the kcals · minute^{-1} using the Metria. The unit difference for EE was calculated for each device by subtracting the Circuit Trial 1 value from the Circuit Trial 2 value. Percent difference was calculated for circuit trials 1 and 2 for the Fitmate metabolic unit. Percent difference was calculated for circuit trials 1 and 2 for the Bioharness. No statistical analyses were conducted for sex differences and between ND and persons with T1D, due to the low number of study participants in the sub-groups.

Table 11: Test-retest Energy Expenditure data from study participants who repeated the circuit exercise session on two separate occasions (Mean ± SD)

			Energy Expenditure							
			Circuit Trial 1		Circuit Trial 2		Unit Difference (C1 – C2)		% Difference (C1 & C2)	
	N	n	Fitmate	Metria	Fitmate	Metria	Fitmate	Metria	Fitmate	Metria
Males	2	0	8.700 ± 1.26	-	8.79 ± 1.20	-	-0.09 ± 0.75	-	-1.41 % ± 9.06	-
Females	3	0	6.57 ± 1.40	-	6.25 ± 1.00	-	0.32 ± 1.05	-	2.54 % ± 19.99	-
Persons with Diabetes										
Males	4	21	9.21 ± 1.44	6.84 ± 1.36	9.45 ± 1.91	6.63 ± 1.94	-0.24 ± 1.56	0.21 ± 1.54	-3.07 % ± 18.19	2.82 % ± 22.07
Females	2	14	7.47 ± 1.44	5.15 ± 1.23	7.71 ± 1.38	5.38 ± 0.96	-0.24 ± 0.85	-0.22 ± 1.41	-4.01 % ± 10.91	9.18 % ± 29.12
Grouped	11	35	7.99 ± 1.76	6.25 ± 1.53*	8.07 ± 1.90	6.20 ± 1.71*	-0.41 ± 2.11	0.60 ± 3.49	- 1.29 % ± 15.94	-1.98 % ± 25.42

No significant differences were observed for the Metria compared to Fitmate ($p < 0.05$).

"-" Denotes no data

Table 12 contains the test-retest reliability data of the study participants who repeated the circuit on two separate occasions, using the Fitmate metabolic and Bioharness for Heart Rate. The number of study participants (N) per group were reported. In addition, the number of data points (n) plus the associated mean and standard deviation were reported. The statistical analyses were only performed on the grouped data only. During circuit trial 1 there was a significant difference between the Fitmate and Bioharness for HR. There was a significant difference between circuit trials 1 and 2 for the HR using the Fitmate metabolic unit. There was no significant difference between circuit trials 1 and 2 using the Bioharness. The unit difference for HR was calculated for each device by subtracting the Circuit Trial 1 value from the Circuit Trial 2 value. Percent difference was calculated for circuit trials 1 and 2 for the Fitmate metabolic unit. Percent difference was calculated for circuit trials 1 and 2 for the Bioharness. No statistical analyses were conducted for sex differences and between ND and persons with T1D, due to the low number of study participants in the sub-groups.

Table 12: Test-retest Heart Rate data from study participants who repeated the circuit exercise session on two separate occasions (Mean ± SD)

			Heart Rate							
			Circuit Trial 1		Circuit Trial 2		Unit Difference (C1 – C2)		% Difference (C1 & C2)	
	N	n	Polar	Bioharness	Polar	Bioharness	Polar	Bioharness	Polar	Bioharness
Males	2	14	135 ± 17	136 ± 17	127 ± 16	127 ± 16	8 ± 4	9 ± 3	6 % ± 2	7 % ± 2
Females	3	20	156 ± 20	144 ± 21	154 ± 17	155 ± 18	2 ± 19	-12 ± 16	1 % ± 13	-9 % ± 13
Persons with Diabetes										
Males	4	21	162 ± 21	155 ± 22	152 ± 23	154 ± 23	10 ± 15	-7 ± 40	6 % ± 10	1 % ± 8
Females	2	14	145 ± 20	148 ± 19	146 ± 19	142 ± 21	-1 ± 7	6 ± 7	-1 % ± 5	4 % ± 5
Grouped	11	69	152 ± 22	146 ± 21*	147 ± 22	14 ± 22	5 ± 14*	-3 ± 25	3 % ± 9*	0 % ± 10.35

*Denotes a significant difference in Heart Rate ($p < 0.05$), between the test-retest for the Fitmate. N denotes the number of study participants per group. n denotes the number of data points used in the statistical analyses.

Table 13 contains the test-retest reliability data of the study participants who repeated the circuit on two separate occasions, using the Fitmate metabolic and Bioharness for BR. The number of study participants (N) per group were reported. In addition, the number of data points (n) plus the associated mean and standard deviation were reported. The statistical analyses were only performed on the grouped data. During circuit trials 1 and 2 there was a significant difference between the Fitmate and Bioharness for BR. However, there was no significant difference between circuit trials 1 and 2 using the Fitmate metabolic unit for BR. Similarly, there was no significant difference between circuit trials 1 and 2 using the Bioharness for BR. The unit difference for BR was calculated for each device by subtracting the Circuit Trial 1 value from the Circuit Trial 2 value. Percent difference was calculated for circuit trials 1 and 2 for the Fitmate metabolic unit. Percent difference was calculated for circuit trials 1 and 2 for the Bioharness. No statistical analyses were conducted for sex differences and between ND and persons with T1D, due to the low number of study participants in the sub-groups.

Table 13: Test-retest Breathing Rate data from study participants who repeated the circuit exercise session on two separate occasions (Mean ± SD)

			Breathing Rate							
			Circuit Trial 1		Circuit Trial 2		Unit Difference (C1 – C2)		% Difference (C1 & C2)	
	N	n	Fitmate	Bioharness	Fitmate	Bioharness	Fitmate	Bioharness	Fitmate	Bioharness
Males	2	14	30.98 ± 6.27	26.64 ± 5.83	28.50 ± 7.47	25.77 ± 6.43	2.47 ± 5.85	0.87 ± 6.10	6.42 % ± 22.13	0.38 % ± 26.19
Females	3	20	35.19 ± 5.67	28.90 ± 5.83	34.44 ± 6.27	30.00 ± 5.77	0.75 ± 4.51	-1.10 ± 3.44	1.62 % ± 12.51	- 2.09 % ± 11.89
Persons with Diabetes										
Males	4	21	32.86 ± 7.55	26.82 ± 5.26	31.53 ± 5.56	27.68 ± 5.31	1.33 ± 5.21	-1.95 ± 8.77	1.66 % ± 16.63	-2.09 % ± 11.80
Females	2	14	38.012 ± 5.21	32.45 ± 5.06	39.70 ± 4.77	31.61 ± 4.95	-0.78 ± 3.82	0.85 ± 4.10	-2.61 % ± 10.59	2.09 % ± 11.26
Grouped	11	69	34.38 ± 6.79	28.56 ± 5.82**	33.75 ± 7.12	28.48 ± 6.13**	0.96 ± 4.91	-0.60 ± 6.23	1.75 % ± 15.77	-1.62 % ± 15.97

**Denotes a significant difference in BR ($p < 0.001$), for circuit trial 1 between the Fitmate metabolic unit and Bioharness. **Denotes a significant difference in BR ($p < 0.001$), for circuit trial 2 between the Fitmate metabolic unit and Bioharness. N denotes the number of study participants per group. n denotes the number of data points used in the statistical analyses.

Bland-Altman Analysis

Bland-Altman analyses were conducted to determine and illustrate bias using GraphPad Prism 6. The Bland-Altman analysis examines the agreement between the two measurement procedures conducted on the same variable at the same time (Altman, 1983). The analyses were performed such that the difference of the secondary devices, B, compared to the criterion, A, divided by the average of the two devices [Difference (B – A) / Average $\frac{B+A}{2}$)]. The results for EE, HR, BR during the 40-minute circuit are displayed in Figures 6, 7, 8, respectively.

Figure 6 contains the results from the Bland-Altman plot for the Fitmate metabolic unit versus the Metria during the Circuit Trial 1 for EE. The results demonstrate that the Metria has a bias of -2.49 ± 2.34 with 95% limits of agreement from -7.07 – 2.10. This indicates that on average the Metria generally underestimates the EE by 2.49 kcals.

Figure 6: Bland-Altman plot for the Fitmate metabolic unit versus Metria during the 40-minute circuit for Energy Expenditure

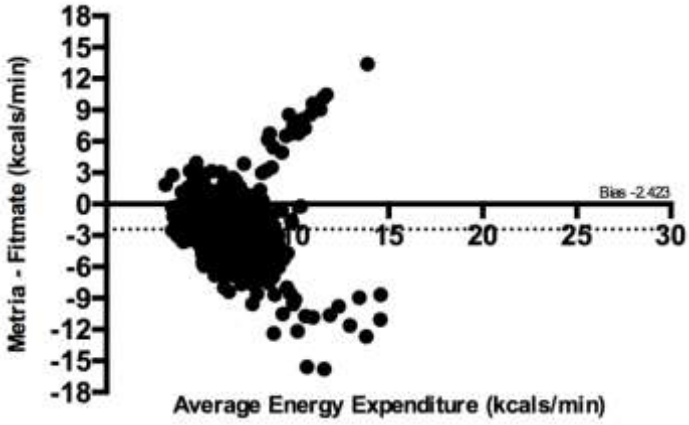


Figure 7 contains the results from the Bland-Altman plot for the Fitmate metabolic unit versus the Bioharness during the Circuit for HR. The results demonstrate that the Bioharness has a bias of -2.01 ± 13.04 bpm with 95% limits of agreement from -27.57 – 23.56 bpm. This indicates that on average the Bioharness generally underestimates the HR by 2.01 bpm.

Figure 7: Bland-Altman plot for the Fitmate metabolic unit versus Bioharness during the 40-minute circuit for Heart Rate

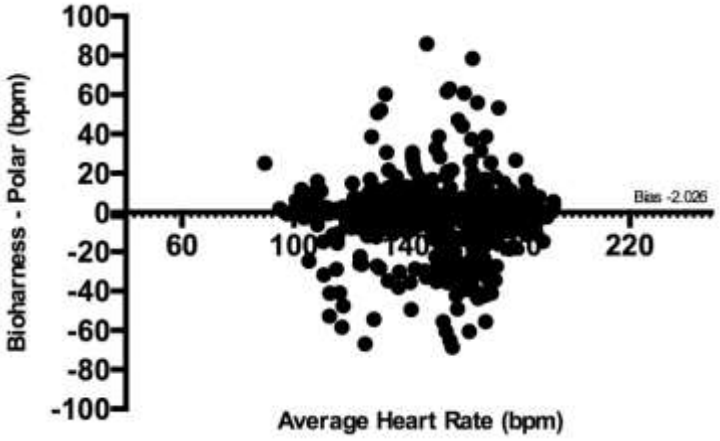
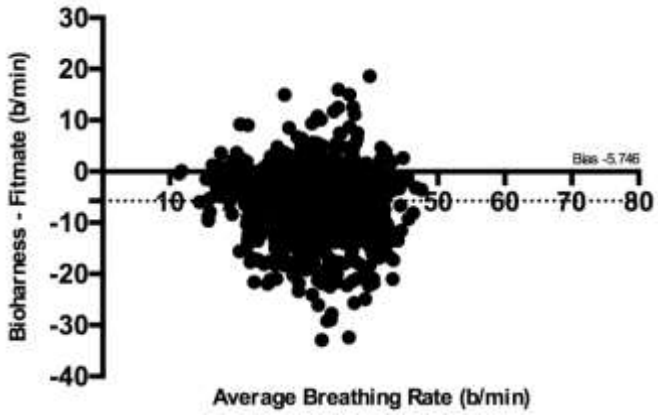


Figure 8 contains the results from the Bland-Altman plot for the Fitmate metabolic unit versus the Bioharness during the Circuit for BR. The results demonstrate that the Bioharness has a bias of -4.96 ± 4.91 breaths/min with 95% limits of agreement from -14.58 – 4.67 breath/min. This indicates that on average the Bioharness generally underestimates the BR by 4.96 breaths/min.

Figure 8: Bland-Altman plot for the Fitmate versus Bioharness during the 40-minute circuit for Breathing Rate



In addition to the Metria and Bioharness, the Garmin VivoFit 2 and Mio Fuse, were also examined during the circuit free motion activity. The accuracy of the total EE reported from these devices was determined using a paired t-test analysis. The results are summarized in Table 14, along with the Mean ± SD for the variables of interest (EE). No significant differences were observed for either of the devices, compared to the Fitmate metabolic unit ($p < 0.05$). The statistical analyses should be interpreted with caution given the small sample sizes.

Table 14: Accuracy of Consumer Based Wearable Technology for Energy Expenditure during Circuit (Mean ± SD)

	N	Fitmate	Garmin	N	Fitmate	Mio
Grouped	7	343.38 ± 50.81	310.43 ± 201.80	5	297.92 ± 56.00	431.00 ± 234.29

No significant differences were observed for either of the devices compared to Fitmate ($p < 0.05$).

2.4.5 Continuous Light-to-Moderate Intensity Treadmill Activity

The accuracy of the wearable technology was examined during the 40-minutes of continuous light-to-moderate intensity treadmill activity. The data was averaged for every minute to create a common time variable as different devices collected data at different frequencies. The results of the paired t-test analysis, as well as Mean ± SD for the variables of interest (EE, HR, BR), can be found below in Table 15. There was a significant difference in EE ($p < 0.001$) and HR ($p < 0.001$). Varying sample sizes in the EE from the Metria are due to equipment malfunction. Reliability was also investigated by examining the data of those individuals who repeated the continuous light-to-moderate intensity treadmill activity under similar conditions. Note that persons with T1D did not repeat the continuous light-to-moderate intensity protocol for safety purposes. The descriptive statistics (Mean ± SD), results from the paired t-test analysis, unit difference, and percent difference are contained in Table 16, 17, and 18 for EE, HR, and BR, respectively.

Table 15 contains the EE, HR, and BR data during the continuous light intensity treadmill activity using the Fitmate, Metria, and Bioharness. For each variable, the number of study participants (N) per group were reported. In addition, for each variable the number of data points (n) plus the associated mean and standard deviation were reported. For each of the variables the statistical analyses were performed on the grouped data. No statistical analyses were conducted for sex differences and between ND and persons with T1D, due to the low number of study participants in the sub-groups. Significant differences were observed between the Fitmate metabolic unit and Metria for EE ($n = 670$, $p < 0.001$) and Bioharness for HR ($n = 974$, $p < 0.001$).

Table 15: Initial trial for the continuous light-to-moderate intensity activity for Energy Expenditure, Heart Rate, and Breathing Rate (Mean ± SD)

	Energy Expenditure					Heart Rate				Breathing Rate			
	N	n	Fitmate	N	Metria	N	n	Polar	Bioharness	N	n	Fitmate	Bioharness
Males	10	233	8.76 ± 1.25	6	8.17 ± 1.91	10	388	127 ± 11	128 ± 14	10	388	26.82 ± 5.48	27.07 ± 5.78
Females	7	160	6.23 ± 0.77	4	6.01 ± 1.42	7	279	137 ± 11	140 ± 19	7	279	28.98 ± 6.59	28.58 ± 7.16
Persons with Diabetes													
Males	4	159	8.52 ± 2.55	4	8.19 ± 2.16	4	159	131 ± 15	130 ± 19	4	159	24.50 ± 6.49	25.43 ± 6.62
Females	3	118	6.45 ± 1.21	3	5.27 ± 1.81	3	148	113 ± 16	114 ± 16	3	148	31.77 ± 4.27	30.41 ± 3.96
Grouped	24	670	7.68 ± 1.87	17	7.15 ± 2.13*	24	974	129 ± 15	130 ± 18*	24	974	27.68 ± 6.26	27.65 ± 6.36

*Denotes a significant difference in EE ($p < 0.001$) and HR ($p < 0.001$). N denotes the number of study participants per group. n denotes the number of data points used in the statistical analyses.

Table 16 contains the test-retest data of the study participants who repeated the light-to-moderate intensity activity on two separate occasions, using the Fitmate metabolic and Metria for EE. The number of study participants (N) per group are reported. In addition, the number of data points (n) plus the associated mean and standard deviation are reported. The statistical analyses were only performed on the grouped data. During light trials 1 and 2 there was a significant difference with the Fitmate metabolic unit for EE. However, there were no significant differences between light trials 1 and 2 for the kilocalories/min using the Metria. The unit difference for EE was calculated for each device by subtracting the Light Trial 1 value from the Light Trial 2 value. Percent difference was calculated for light trials 1 and 2 for the Fitmate metabolic unit. Percent difference was calculated for light trials 1 and 2 for the Metria. No statistical analyses were conducted for sex differences and between ND and persons with T1D, due to the low number of study participants in the sub-groups.

Table 16: Test-retest Energy Expenditure data from study participants who repeated continuous light-to-moderate intensity activity session on two separate occasions (Mean ± SD)

			Energy Expenditure							
			Light-Moderate Intensity Trial 1		Light-Moderate Intensity Trial 2		Unit Difference (L1 – L2)		% Difference (L1 & L2)	
	N	n	Fitmate	Metria	Fitmate	Metria	Fitmate	Metria	Fitmate	Metria
Males	8	233	8.66 ± 1.20	8.18 ± 1.91	9.01 ± 1.35	8.12 ± 1.87	-0.35 ± 1.32	0.06 ± 1.61	-5.27 % ± 17.69	-3.63 % ± 22.13
Females	4	157	6.41 ± 0.74	6.03 ± 1.42	7.21 ± 1.64	6.27 ± 1.42	-0.80 ± 1.46	-0.24 ± 1.19^{+}	-12.99 % ± 24.07	-6.95 % ± 26.40
Grouped	12	390	7.91 ± 1.51	7.31 ± 2.02	8.41 ± 1.68	7.38 ± 1.87	-0.51 ± 1.38*	-0.06 ± 1.46	-7.88 % ± 20.38*	-3.63 % ± 22.13

*Denotes a significant difference in the Fitmate metabolic unit for EE ($p < 0.001$) between light trials 1 and 2 using. N denotes the number of study participants per group. n denotes the number of data points used in the statistical analysis.

Table 17 contains the test-retest data of the study participants who repeated the light-to-moderate intensity activity on two separate occasions, using the Fitmate metabolic and Bioharness for Heart Rate. The number of study participants (N) per group are reported. In addition, the number of data points (n) plus the associated means and standard deviations are reported. The statistical analyses were only performed on the grouped data. During light-to-moderate intensity continuous trials 1 and 2 there was no significant difference with the Fitmate metabolic unit for HR. Similarly, during the light-to-moderate intensity continuous trials 1 and 2 there was no significant difference with the Bioharness for HR. However, there was a significant difference between light trials 1 and 2 for the HR using the Fitmate metabolic unit. There was also a significant difference between light trials 1 and 2 for the HR using the Bioharness. The unit difference for HR was calculated for each device by subtracting the Light Trial 1 value from the Light Trial 2 value. Percent difference was calculated for light trials 1 and 2 for the Fitmate metabolic unit. Percent difference was calculated for light trials 1 and 2 for the Bioharness. No statistical analyses were conducted for sex differences and between ND and persons with T1D, due to the low number of study participants in the sub-groups.

Table 17: Test-retest Heart Rate data from study participants who repeated continuous light-to-moderate intensity activity session on two separate occasions (Mean ± SD)

			Heart Rate							
			Light-Moderate Intensity Trial 1		Light-Moderate Intensity Trial 2		Unit Difference (L1 – L2)		% Difference (L1 & L2)	
	N	n	Polar	Bioharness	Polar	Bioharness	Polar	Bioharness	Polar	Bioharness
Males	8	310	129 ± 11	128 ± 13	129 ± 13	132 ± 17	2 ± 11	-4 ± 20	1 % ± 8	-4 % ± 16
Females	4	157	139 ± 13	136 ± 15	132 ± 15	134 ± 13	8 ± 10	2 ± 12	5 % ± 7	1 % ± 10
Grouped	12	467	132 ± 13	131 ± 14	129 ± 13*	133 ± 16*	4 ± 11*	-2 ± 18*	2 % ± 8*	-2 % ± 14*

*Denotes a significant difference in the Fitmate metabolic unit for EE ($p < 0.001$) between light trials 1 and 2 using. N denotes the number of study participants per group. n denotes the number of data points used in the statistical analysis

Table 18 contains the test-retest data of the study participants who repeated the light-to-moderate intensity activity on two separate occasions, using the Fitmate metabolic unit and Bioharness for BR. The number of study participants (N) per group are reported. In addition, the number of data points (n) plus the associated mean and standard deviation are reported. The statistical analyses were only performed on the grouped data. Between light-to-moderate intensity trials 1 and 2 there was a significant difference with the Bioharness for BR. However, there was no significant difference between light-to-moderate trials 1 and 2 for the BR using the Fitmate metabolic unit. The unit difference for BR was calculated for each device by subtracting the light-to-moderate intensity Trial 1 value from the Light-to-moderate intensity Trial 2 value. Percent difference was calculated for light-to-moderate intensity trials 1 and 2 for the Fitmate metabolic unit. Percent difference was calculated for light trials 1 and 2 for the Bioharness. No statistical analyses were conducted for sex differences and between ND and persons with T1D, due to the low number of study participants in the sub-groups.

Table 18: Test-retest Breathing Rate data from study participants who repeated continuous light-to-moderate intensity activity session on two separate occasions (Mean ± SD)

			Breathing Rate							
			Light-Moderate Intensity Trial 1		Light-Moderate Intensity Trial 2		Unit Difference (L1 – L2)		% Difference (L1 & L2)	
	N	n	Fitmate	Bioharness	Fitmate	Bioharness	Fitmate	Bioharness	Fitmate	Bioharness
Males	8	310	27.94 ± 4.87	28.00 ± 5.79	27.92 ± 4.28	27.54 ± 5.09	-0.02 ± 4.94	0.53 ± 6.43	-1.72 % ± 17.12	-0.89 % ± 22.87
Females	4	157	29.09 ± 8.24	28.02 ± 8.84	29.27 ± 6.63	31.27 ± 5.28	-0.18 ± 6.45	-3.24 ± 8.79	-6.62 % ± 33.59	-24.54 % ± 51.36
Grouped	12	467	28.33 ± 6.23	28.01 ± 6.96	28.38 ± 5.23	28.80 ± 5.44*	-0.06 ± 5.49	-0.74 ± 7.52*	- 3.37 % ± 24.06	- 8.88 % ± 36.85*

*Denotes a significant difference in the Bioharness metabolic unit for BR ($p < 0.001$) between light-to-moderate trials 1 and 2 using. N denotes the number of study participants per group. n denotes the number of data points used in the statistical analysis.

Bland-Altman Analysis

Bland-Altman analyses were conducted to determine and illustrate bias using GraphPad Prism 6. The Bland-Altman analysis examines the agreement between the two measurement procedures conducted on the same variable at the same time (Altman, 1983). The analyses were performed such that the difference of the secondary devices, B, compared to the criterion, A, divided by the average of the two devices [Difference (B – A) / Average $\frac{B+A}{2}$)]. The results for EE, HR, BR during the continuous 40-minute light-to-moderate intensity are displayed in Figures 9, 10, 11, respectively.

Figure 9 contains the results from the Bland-Altman plot for the Fitmate metabolic unit versus the Metria during the 40-minute continuous light-to-moderate intensity PA for EE. The results demonstrate that the Metria has a bias of -0.52 ± 1.72 kcals · minute^{-1} with 95% limits of agreement from -3.88 – 2.85 kcals · minute^{-1}. This indicates that on average the Metria generally underestimates by 0.52 kcals · minute^{-1}.

Figure 9: Bland-Altman plot for the Fitmate metabolic unit versus Metria during the 40-minute continuous light-to-moderate intensity physical activity intensity for Energy Expenditure

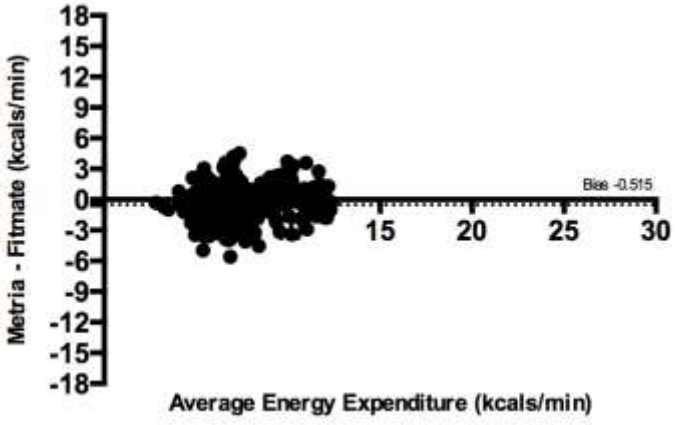


Figure 10 contains the results from the Bland-Altman plot for the Fitmate versus the Bioharness during the 40-minute continuous light-to-moderate intensity PA for HR. The results demonstrate that the Bioharness has a bias of 1.05 ± 8.48 bpm with 95% limits of agreement from -15.57 – 17.67 bpm. This indicates that on average the Bioharness generally overestimates by 1.05 bpm.

Figure 10: Bland-Altman plot for the Fitmate metabolic unit versus Bioharness during the 40-minute continuous light-to-moderate intensity physical activity for Heart Rate

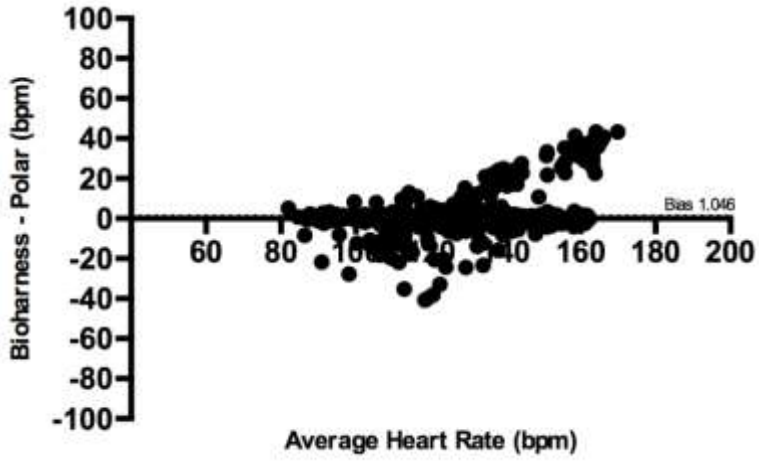


Figure 11 contains the results from the Bland-Altman plot for the Fitmate metabolic unit versus the Bioharness during the 40-minute continuous light-to-moderate intensity PA for BR. The results demonstrate that the Bioharness has a bias of -0.02 ± 4.56 breaths/min with 95% limits of agreement from -8.96 – 8.92 breaths/min. This indicates that on average the Bioharness generally underestimates by 0.02 breaths/min.

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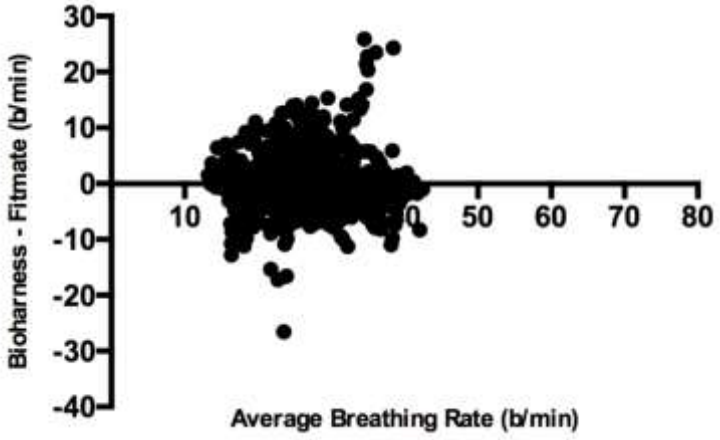
Figure 11: Bland-Altman plot for the Fitmate metabolic unit versus Bioharness during the 40-minute continuous light-to-moderate intensity physical activity for Breathing Rate



In addition to the Metria and Bioharness, the Garmin VivoFit 2 and Mio Fuse, were also examined during the continuous light-to-moderate intensity treadmill activity. The accuracy of the total EE reported from these devices was determined using a paired t-test analysis. The results are summarized in Table 19, along with the Mean ± SD for EE. A significant difference was observed for the Garmin device, compared to the Fitmate ($p < 0.001$). The statistical analyses should be interpreted with caution given the small samples size.

Table 19: Accuracy and Reliability of Consumer Based Wearable Technology for Energy Expenditure during continuous light activity (Mean ± SD)

Light-to-moderate Trial 1						
	N	**Fitmate**	**Garmin**	**N**	**Fitmate**	**Mio**
Grouped	5	355.19 ± 39.67	174.00 ± 28.53*	6	255.30 ± 55.80	277.00 ± 136.31
Light-to-moderate Trial 2						
	N	**Fitmate**	**Garmin**	**N**	**Fitmate**	**Mio**
Grouped	2	324.17 ± 26.19	114.50 ± 54.45	1	419.93	496.00

A significant difference was observed for the Garmin device compared to the Fitmate ($p<0.001$).

2.5 Discussion

The primary purpose of this study was to examine the validity of two high cost PA trackers, the Zephyr Bioharness and the Metria Armband by Vancive, to differentiate exercise intensities plus modalities using the following variables: EE (kcals · minute^{-1}), HR (bpm), and BR (b/min). A secondary purpose was to also examine the validity of two low cost PA trackers to differentiate exercise intensities plus modalities using the following variables: EE (kcals · minute^{-1}) and HR (bpm). It was hypothesized that EE recorded from the devices would accurately differentiate PA intensities and modalities within all wearable technology devices. The results from the statistical analyses support the hypothesis for the use of EE as a valid and reliable variable for the differentiation of i) PA intensity ranges and ii) continuous light-to-moderate versus intermittent moderate-to-vigorous and vigorous-to-maximal circuit-based PA modalities.

In order to determine validity across different wearable technology devices the researchers had to initially define an accurate comparator. Since the Fitmate metabolic unit was chosen as the comparator for this investigation, it was vital to determine the validity and reliability of the Fitmate metabolic unit at varying exercise intensity ranges. This was completed by having participants repeat the initial incremental-to-maximal VO_2 protocol under the same conditions and sequencing using the criterion measure for VO_2, the discrete component open circuit spirometry system and therefore a criterion estimate of EE (kcal·min^{-1}). The results of these two completed trials were statistically tested and no significant differences were found, thus deeming the Fitmate as an appropriate comparator for assessing the validity and reliability of the Bioharness, Metria, Garmin and Mio devices. The Fitmate metabolic unit is designed to use the Polar Unit for the determination of HR. Therefore, the Polar unit was used during the two incremental-to maximal VO_2 trials and was used as the criterion reference for HR's obtained

from the Bioharness, Garmin and Mio devices. The metabolic unit, Cosmed Fitmate, and discrete component system, had good correlation for both VO_2 ($r = 0.92 \pm 0.04$) and BR $r = 0.97 \pm 0.03$. The statistical analyses demonstrated that the HR from the various devices was only significantly different from the Polar unit at light-to-moderate intensity PA, but not practically significant, therefore, allowing the researchers to use the Fitmate during free-motion activity. The researchers had also completed multiple Bland-Altman analyses to indicate that these devices were operating within practically significant ranges based on the 95% Limits of Agreement.

In addition to the statistical analyses, the researchers were able to confirm the PA intensity during the sessions by obtaining blood lactate samples from a subset of study participants. At rest, an individual's blood lactate typically ranges between 0.5 to 2.2 mmol/L (Gollnik, 1986; McGee 1992). As an individual participates in more intense forms of PA, there will be an increase of metabolites and byproducts due to the greater reliance on the anaerobic system. At maximal intensities, an individual can have blood lactate values ranging between 20 and 25 mmol/L (Mainwood, 1985). The blood lactate values during the continuous light-to-moderate intensity PA were 1.61 ± 1.11 mmol/L, $n = 48$. The blood lactate values during the intermittent moderate-to-vigorous circuit were 6.02 ± 4.00 mmol/L, $n = 49$. Therefore, the blood lactate values had confirmed the PA intensity from each of the respective exercise sessions.

Furthermore, the researchers were also able to confirm the PA intensities during the sessions by live monitoring of the study participants heart rate from the Polar receiver and Bioharness and by asking the study participants to self-report their rating of perceived exertion using the original Borg subjective Rating of Perceived Exertion scale (RPE) (BORG, 1982). The original Borg subjective RPE scale ranges from 6 to 20, where 6 is "very, very light" and 20 is "very, very hard". Typically, at rest, individual's self-report an RPE of 6. Once the individuals

began to exercise at a light-to-moderate intensity they self-reported an RPE ranging between 10 to 13. During more vigorous bouts of PA, individuals self-reported an RPE ranging between 16 to 20. During the investigation, the self-reported RPE values and their respective descriptors aligned with the both PA sessions, intermittent moderate-to-vigorous intensity circuit and continuous light-to-moderate intensity. Therefore, the PA intensity from each of the respective sessions was again reinforced by the self-reported RPE using the original Borg subjective ranges.

The study outcomes revealed that during the light-to-moderate intensity exercise session the i) EE, as assessed by the Metria, was significantly different from the Fitmate and on average overestimated by 0.64 kcals · minute^{-1}, ii) HR, as assessed by the Bioharness, was significantly different from the Polar unit and on average underestimated by 4.73 bpm and iii) BR, as measured by the Bioharness, was significantly different from the Fitmate metabolic unit and on average underestimated by 9.49 breathes/minute. This is summarized in (Table 20).

The study outcomes also revealed that during the moderate-to-vigorous intensity exercise session the i) EE, as assessed by the Metria, was significantly different from the Fitmate with a mean overestimate of 0.33 kcals · minute^{-1}, ii) HR, as assessed by the Bioharness, was not significantly different from the Polar Unit with a mean error of 0.6 bpm and iii) BR, as measured by the Bioharness, was significantly different from the Fitmate metabolic unit with a mean underestimate of 2.85 breathes/minute. This is summarized in (Table 20).

Additionally, the study outcomes revealed that during the vigorous-to-maximal intensity exercise session the i) EE, as assessed by the Metria, was significantly different from the Fitmate with a mean underestimate of 1.78 kcals · minute^{-1}, ii) HR, as assessed by the Bioharness, was significantly different from the Fitmate with a mean overestimate of 1.61 bpm and iii) BR, as

measured by the Bioharness, was significantly different with a mean underestimate of 5.61 breathes/minute. This is summarized in (Table 20).

It is important to note that, despite the statistical difference compared to the criterion measures, the estimates are still practically relevant, more commonly referred to as clinically significant. As shown in Table 20, this can be applied to the practical significance of the EE where a mean error of 1.78 kcals · minute^{-1} will not impose that much of a difference in a thirty minute vigorous-to-maximal intensity PA session, where the EE can be upwards of 13 kcals · minute^{-1}. In reference to HR, a mean underestimate of 0.6 bpm in HR is not practically significant nor can most equipment measure to this degree of specificity. At most, an underestimate of 4.73 bpm at a moderate-to-vigorous intensity PA where the HR can range between 140-160 bpm, is still within the 95% Limits of Agreement.

Table 20 contains a summary of the statistical significance, over or under reporting, device intensity estimation, and the corresponding practical significance during a thirty-minute workout for the Metria and Bioharness during all PA intensity ranges. The statistical significance values were taken from the paired t-test analyses completed during the incremental-to-maximum VO_2. The results of the statistical analyses for all PA ranges were reflected during the incremental-to-maximum VO_2. The over and under estimation is reported in reference to the Fitmate portable metabolic unit. The practical significance 95% CI is based on the results from the Bland-Altman analyses, respective to the PA intensity and is reported in EE kcals per minute (kcals · minute^{-1}). The practical significance percent error, is the mean bias reported from the Bland-Altman analyses, divided by the mean value of the Fitmate portable metabolic unit, multiplied by 100. The practical application or impact is in reference to a thirty-minute workout. For EE, the kcals reported are total kcals that would be either over or under estimated for a

thirty-minute exercise session. For HR, the value reported is in beats per minute and would represent an over or under estimation of that value every minute. For BR, the value reported is in breathes per minute and would represent an over or under estimation of that value every minute.

Table 20: Summary table including PA intensity, device estimation, statistical significance and practical significance.

Metria Energy Expenditure compared to Fitmate metabolic unit

Intensity	Over/ Under	Statistical Significance	Practical Significance (95% CI) (kcals · minute^{-1})	Practical Significance (percent error)	Practical Application for a 30 minute workout) (kcals)
Light-to-moderate	∧	$p < 0.001$	-2.91 – 3.46	4.39	8.4
Moderate-to-vigorous	∧	$p < 0.001$	-2.59 – 3.87	5.99	19.2
Vigorous-to-maximal	∨	$p < 0.001$	-7.22 – 3.65	12.99	-53.4

Bioharness Heart Rate compared to Polar Unit

Intensity	Over/ Under	Statistical Significance	Practical Significance (95% CI) (bpm)	Practical Significance (percent error)	Practical Application (bpm)
Light-to-moderate	∨	$p < 0.001$	-16 – 15	0.5	0.6
Moderate-to-vigorous	∨	$p < 0.001$	-26 – 17	3.06	-4.73
Vigorous-to-maximal	∧	-	-21 – 24	0.82	1.45

Bioharness Breathing Rate compared to Fitmate metabolic unit

Intensity	Over/ Under	Statistical Significance	Practical Significance (95% CI) (breaths/min)	Practical Significance (percent error)	Practical Application (breaths/min)
Light-to-moderate	∨	$p < 0.05$	-18.04 – 12.34	11.33	-2.85
Moderate-to-vigorous	∨	$p < 0.001$	-32.96 – 13.98	24.31	-9.49
Vigorous-to-maximal	∨	$p < 0.001$	-21.96 – 10.73	11.64	-5.61

Based on the data obtained from the Fitmate metabolic unit at light-to-moderate intensity PA the average EE was 6.38 kcals · minute^{-1}, which would result in a total EE of 191.4 kcals for a thirty-minute exercise session. Thus, an overestimation of 8.4 kcals from the Metria is only an error of 4.39%, which does not pose any threats to the PA tracking devices' ability to differentiate light-to-moderate intensity PA. Moreover, during the moderate-to-vigorous intensity PA, the average EE was 10.68 kcals · minute^{-1}, which would result in a total EE of 320.4 kcals for a thirty-minute exercise session. Thus, an overestimation of 19.2 kcals from the Metria in this same time frame will only cause an error of 5.99%, which does not pose any threats to the PA tracking devices' ability to differentiate moderate-to-vigorous PA intensity. Also, during the vigorous-to-maximal intensity PA, the average EE was 13.70 kcals · minute^{-1}, which would result in a total EE of 411 kcals for a thirty-minute exercise sessions. Thus, an underestimation of 53.4 kcals from the Metria in this same time frame will only cause an error of 12.99%, which will also not pose any threats to the PA tracking devices' ability to differentiate vigorous-to maximal PA intensity.

As for the HR variable from the Polar unit, at light-to-moderate intensity PA the average HR was determined to be 116.57 bpm. Thus, an underestimation of 0.6 bpm from the Bioharness is only an error of 0.51%, which does not pose any threats to the PA tracking devices' ability to differentiate light-to-moderate intensity PA. Moreover, during the moderate-to-vigorous intensity PA, the average HR was determined to be 154.77 bpm. Thus, an underestimation of 4.73 bpm from the Bioharness in this same time frame will only cause an error of 3.06%, which does not pose any threats to the PA tracking devices ability to differentiate moderate-to-vigorous intensity PA. Also, during the vigorous-to-maximal intensity PA, the average HR was determined to be 176.80 bpm. Thus, an overestimation of 1.45 bpm from the Bioharness in this same time frame

will only cause an error of 0.82%, which does not pose any threats to the PA tracking devices' ability to differentiate vigorous-to-maximal intensity PA.

For the final secondary variable, BR, at light-to-moderate intensity PA the average BR was determined to be 25.14 breaths/min. Thus, an underestimation of 2.85 breaths/min from the Bioharness is only an error of 11.34%, which will not pose any threats to the PA tracking devices ability to differentiate light-to-moderate intensity PA. Moreover, during the moderate-to-vigorous intensity PA, an individual's BR would typically be 39.04 breaths/min. Thus, an underestimation of 9.49 breaths/min from the Bioharness in this same time frame will only cause an error of 24.31%, which will also not pose any threats to the PA tracking devices ability to differentiate moderate-to-vigorous intensity PA. Also, during the vigorous-to-maximal intensity PA, an individual's HR would typically be 48.18 breaths/min. Thus, an underestimation of 5.61 breaths/min from the Bioharness in this same time frame will only cause an error of 11.54%, which will also not pose any threats to the PA tracking devices ability to differentiate vigorous-to-maximal intensity PA.

It is important to note some of the setbacks pertaining to product limitations, as well as how they had potentially affected two of the variables of interest, HR and BR. The HR measure was effected when subjects were required to wear three chest bands to measure the exercise HR. In addition, the HR chest bands would at times move, throughout varying exercises and collection periods, resulting in occasional erroneous values. Study participants were only required to wear multiple chest bands when they were assigned to a group who wore an additional chest band for the Garmin VivoFit, the other two chest bands were from the Bioharness and Polar unit. Erroneous values were not observed when only two chest bands were worn. Moreover, the HR data pertaining to reliability could have also affected by natural day-to-

day variations based on factors that the researchers could not control for such as; sleep duration and quality, hydration, caffeine, and familiarity of the exercise (Ewing, 1991; Achten, 2003). Also, due to technological design, the HR from some of the PA tracking devices experienced a lag time when the study participants were transitioning between different intensity exercises and movements, which could not be corrected for (Achten, 2003).

It was observed that BR was at times also affected by product limitations when study participants were in prone positions or had moved from prone to standing. The transition between orthogonal planes had affected BR as of a result of the Bioharness measurement methods. The BR was measured in this device via stretch transducers built into the band, designed to pick up movements in the upper torso from inspiration and expiration. When the study participants were in 'problematic' positions the BR was at times lower than expected, due to the decreased band tension, resulting in missed breaths. This can be reinforced upon examining the difference in error between the continuous light-to-moderate intensity treadmill activity and intermittent moderate-to-vigorous intensity circuit activity. During the continuous light-to-moderate intensity treadmill activity, the movement between the orthogonal planes was minimal, and the study participant was simply required to walk on the treadmill. This minimal movement yield almost identical results for BR between the Fitmate and Bioharness, unlike the circuit activity. A simple but unlikely solution could be to pre-emptively over tighten the respective chest bands, but this may be uncomfortable and restricting for the study participants. Aside from the validity of this variable, it in it of itself is not a strong reflection of PA intensity. It is known that BR can be affected by a number of different factors such as the activity at hand, number and size of the working muscles, as well as the VO_2. Typically, BR and intensity are assimilated through the talk test (Persinger, 2004).

Although the above variables may have been affected by these limitations, statistical analyses of the low cost Garmin VivoFit 2 and Mio Fuse indicate that these PA tracking devices provide valid estimates of EE but not HR during continuous light-to-moderate intensity steady state and circuit based moderate-to-vigorous intensity PA. As well, at certain points in the investigation the researchers were underpowered and unable to determine whether or not the low cost consumer based devices truly reported valid and reliable findings. The findings should be interpreted with caution given the small sample size. Despite being underpowered, the results of other investigations reveal similar outcomes, in terms of percent error (Lee, 2014).

In conclusion wearable technology that differentiates PA intensity and modalities appears most promising for estimates of EE and HR. Although the results for EE were at times statistically significant, it is important to note that the values are still within practical/clinical significance, thus supporting the hypothesis for the use of EE as a critical variable in the differentiation of PA intensity ranges and modalities. In order to enhance accuracy, the supplementation of an additional robust variable such as HR should be used in conjunction with EE to refine the differentiation of PA intensity ranges. While some variables may misclassify the PA intensity range, this could pose potential threats to clinical populations who may require more precise PA intensity monitoring while exercising. For example, the potential coupling of such devices with the AP to further improve blood glucose management for persons with T1D, whether they are habitually active or want to become more physically active. The results of this study build on those previously published supporting some differences in the EE reported from wearable technology devices. Based on the findings of this investigation it appears that, the higher cost PA tracking devices that track more physiological variables present more validity. Therefore, whether persons are interested in; becoming habitually active, increasing the current

level of PA, or persons with a chronic condition such as T1D, the higher cost PA trackers are the better choice given their ability to differentiate between PA intensities and modalities.

2.6 Limitations

During this investigation a number of set-backs were associated with product design, hardware malfunction, and ethical blood glucose cut-points. At times, device malfunction could have been due to either mechanical or natural and inevitable flaws (i.e. battery), causing some devices to not operate as intended. As of a result of this disruption, the data extracted from the Fitmate or Metria was inoperative and resulted in lower sample sizes at times. The suspected cause of malfunction in the Fitmate could have been due to an exhausted oxygen sensor, damaged oxygen sample line, or file saving errors. Although the former can be at times avoided, the latter could not be. At various times, the researchers were able to determine whether or not the Fitmate was operating accurately and act accordingly, but at others it was unavoidable, as this issue had arisen mid-collection. The issue was primarily unavoidable during the intermittent moderate-to-vigorous intensity circuit collection as the study participants had worn the Fitmate in a closed and secured backpack.

Malfunction in the Metria was unavoidable and only discovered upon data upload. This is due to the inability of the device to communicate with an external component until it was removed from the body. Given that some study participants had worn the device for up to 72+ hours unsupervised, proper device care and management was out of the researchers control. The device was intended to be sweat and water-resistant but had proven to be otherwise at times. Another potential cause of malfunction in the Metria could have been due to battery life. Since the devices come in a stand-by mode from the manufacturer, some devices may have had a

shorter life remaining due to the already consumed battery. Depending on the situation, even though the battery had died, the researchers were able to extract some but not all of the collected data. The researchers had attempted to solve this issue by affixing two Metria units above each other, but this proved to be rather expensive and at times, unnecessary.

Given the special subset population and strict ethical cut-offs in this investigation, there were times that the data collection had to be prematurely terminated to avoid ethical violation, even though this may have not lead to any adverse effects. Premature termination of the data collection primarily occurred during the light treadmill based continuous activity for reasons stated above, but had also occurred in one subject during the circuit. Although glycemic fluctuations may have been instigated from the activity, the researchers were unable to control for this due to the complexity of the disease, thus dietary corrections, diversity of physiological and physical fitness and exercise tolerance of the study participants.

2.7 Implications

Through this investigation the researchers were able to share their newly found knowledge with the scientific community and those interested in exercise as a primary disease prevention and secondary disease management strategy. This study was precipitated by the needs of persons interested in developing an AP. These persons were seeking to obtain electrical signals that aligned with real-time physiological responses obtained during varying PA intensity ranges and modalities. These findings may play an integral part in customizing primary disease prevention and secondary disease prevention PA prescriptions as well as, shine light on the novel uses of currently available body sensing technology. The results of this investigation aid in the understanding PA prescriptions, as well as, improve compliance to the PA prescription, with a goal to enhance the PA intervention. Given that lack of time is often cited as a justification for

sedentarism, individuals with the ability to quantify their PA participation effort could be less hesitant to justify lack of time, upon experiencing the simplicity of expending more energy. Generally, people tend to seek rewards for their accomplishments, and are often turned away when they feel otherwise. The simplicity and convenience of some currently available wearable technology devices can aid in bridging this gap of immediate gratification and feeling of accomplishment from PA participation. With further research in this area, wearable technology devices that are able to accurately differentiate varying PA intensities and modalities can successfully be utilized for clinical purposes (AP), and more accurately in primary disease prevention and secondary disease management.

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Appendices

Appendix A: 2015 PAR-Q+

2015 PAR-Q+

The Physical Activity Readiness Questionnaire for Everyone

The health benefits of regular physical activity are clear; more people should engage in physical activity every day of the week. Participating in physical activity is very safe for MOST people. This questionnaire will tell you whether it is necessary for you to seek further advice from your doctor OR a qualified exercise professional before becoming more physically active.

GENERAL HEALTH QUESTIONS

Please read the 7 questions below carefully and answer each one honestly: check YES or NO.	**YES**	**NO**
1) Has your doctor ever said that you have a heart condition ☐ OR high blood pressure ☐?	☐	☐
2) Do you feel pain in your chest at rest, during your daily activities of living, **OR** when you do physical activity?	☐	☐
3) Do you lose balance because of dizziness **OR** have you lost consciousness in the last 12 months? Please answer **NO** if your dizziness was associated with over-breathing (including during vigorous exercise).	☐	☐
4) Have you ever been diagnosed with another chronic medical condition (other than heart disease or high blood pressure)? **PLEASE LIST CONDITION(S) HERE:**	☐	☐
5) Are you currently taking prescribed medications for a chronic medical condition? **PLEASE LIST CONDITION(S) AND MEDICATIONS HERE:**	☐	☐
6) Do you currently have (or have had within the past 12 months) a bone, joint, or soft tissue (muscle, ligament, or tendon) problem that could be made worse by becoming more physically active? Please answer **NO** if you had a problem in the past, but it ***does not limit your current ability*** to be physically active. **PLEASE LIST CONDITION(S) HERE:**	☐	☐
7) Has your doctor ever said that you should only do medically supervised physical activity?	☐	☐

If you answered NO to all of the questions above, you are cleared for physical activity.
Go to Page 4 to sign the PARTICIPANT DECLARATION. You do not need to complete Pages 2 and 3.

- Start becoming much more physically active – start slowly and build up gradually.
- Follow International Physical Activity Guidelines for your age (www.who.int/dietphysicalactivity/en/).
- You may take part in a health and fitness appraisal.
- If you are over the age of 45 yr and **NOT** accustomed to regular vigorous to maximal effort exercise, consult a qualified exercise professional before engaging in this intensity of exercise.
- If you have any further questions, contact a qualified exercise professional.

If you answered YES to one or more of the questions above, COMPLETE PAGES 2 AND 3.

Delay becoming more active if:

- You have a temporary illness such as a cold or fever; it is best to wait until you feel better.
- You are pregnant - talk to your health care practitioner, your physician, a qualified exercise professional, and/or complete the ePARmed-X+ at **www.eparmedx.com** before becoming more physically active.
- Your health changes - answer the questions on Pages 2 and 3 of this document and/or talk to your doctor or a qualified exercise professional before continuing with any physical activity program.

2015 PAR-Q+

FOLLOW-UP QUESTIONS ABOUT YOUR MEDICAL CONDITION(S)

1. Do you have Arthritis, Osteoporosis, or Back Problems?

If the above condition(s) is/are present, answer questions 1a-1c If **NO** ☐ go to question 2

1a.	Do you have difficulty controlling your condition with medications or other physician-prescribed therapies? (Answer **NO** if you are not currently taking medications or other treatments)	YES ☐ NO ☐
1b.	Do you have joint problems causing pain, a recent fracture or fracture caused by osteoporosis or cancer, displaced vertebra (e.g., spondylolisthesis), and/or spondylolysis/pars defect (a crack in the bony ring on the back of the spinal column)?	YES ☐ NO ☐
1c.	Have you had steroid injections or taken steroid tablets regularly for more than 3 months?	YES ☐ NO ☐

2. Do you have Cancer of any kind?

If the above condition(s) is/are present, answer questions 2a-2b If **NO** ☐ go to question 3

2a.	Does your cancer diagnosis include any of the following types: lung/bronchogenic, multiple myeloma (cancer of plasma cells), head, and neck?	YES ☐ NO ☐
2b.	Are you currently receiving cancer therapy (such as chemotheraphy or radiotherapy)?	YES ☐ NO ☐

3. Do you have a Heart or Cardiovascular Condition? *This includes Coronary Artery Disease, Heart Failure, Diagnosed Abnormality of Heart Rhythm*

If the above condition(s) is/are present, answer questions 3a-3d If **NO** ☐ go to question 4

3a.	Do you have difficulty controlling your condition with medications or other physician-prescribed therapies? (Answer **NO** if you are not currently taking medications or other treatments)	YES ☐ NO ☐
3b.	Do you have an irregular heart beat that requires medical management? (e.g., atrial fibrillation, premature ventricular contraction)	YES ☐ NO ☐
3c.	Do you have chronic heart failure?	YES ☐ NO ☐
3d.	Do you have diagnosed coronary artery (cardiovascular) disease and have not participated in regular physical activity in the last 2 months?	YES ☐ NO ☐

4. Do you have High Blood Pressure?

If the above condition(s) is/are present, answer questions 4a-4b If **NO** ☐ go to question 5

4a.	Do you have difficulty controlling your condition with medications or other physician-prescribed therapies? (Answer **NO** if you are not currently taking medications or other treatments)	YES ☐ NO ☐
4b.	Do you have a resting blood pressure equal to or greater than 160/90 mmHg with or without medication? (Answer **YES** if you do not know your resting blood pressure)	YES ☐ NO ☐

5. Do you have any Metabolic Conditions? *This includes Type 1 Diabetes, Type 2 Diabetes, Pre-Diabetes*

If the above condition(s) is/are present, answer questions 5a-5e If **NO** ☐ go to question 6

5a.	Do you often have difficulty controlling your blood sugar levels with foods, medications, or other physician-prescribed therapies?	YES ☐ NO ☐
5b.	Do you often suffer from signs and symptoms of low blood sugar (hypoglycemia) following exercise and/or during activities of daily living? Signs of hypoglycemia may include shakiness, nervousness, unusual irritability, abnormal sweating, dizziness or light-headedness, mental confusion, difficulty speaking, weakness, or sleepiness.	YES ☐ NO ☐
5c.	Do you have any signs or symptoms of diabetes complications such as heart or vascular disease and/or complications affecting your eyes, kidneys, **OR** the sensation in your toes and feet?	YES ☐ NO ☐
5d.	Do you have other metabolic conditions (such as current pregnancy-related diabetes, chronic kidney disease, or liver problems)?	YES ☐ NO ☐
5e.	Are you planning to engage in what for you is unusually high (or vigorous) intensity exercise in the near future?	YES ☐ NO ☐

2015 PAR-Q+

6. Do you have any Mental Health Problems or Learning Difficulties? *This includes Alzheimer's, Dementia, Depression, Anxiety Disorder, Eating Disorder, Psychotic Disorder, Intellectual Disability, Down Syndrome*

If the above condition(s) is/are present, answer questions 6a-6b — If **NO** ☐ go to question 7

6a.	Do you have difficulty controlling your condition with medications or other physician-prescribed therapies? (Answer **NO** if you are not currently taking medications or other treatments)	YES ☐ NO ☐
6b.	Do you **ALSO** have back problems affecting nerves or muscles?	YES ☐ NO ☐

7. Do you have a Respiratory Disease? *This includes Chronic Obstructive Pulmonary Disease, Asthma, Pulmonary High Blood Pressure*

If the above condition(s) is/are present, answer questions 7a-7d — If **NO** ☐ go to question 8

7a.	Do you have difficulty controlling your condition with medications or other physician-prescribed therapies? (Answer **NO** if you are not currently taking medications or other treatments)	YES ☐ NO ☐
7b.	Has your doctor ever said your blood oxygen level is low at rest or during exercise and/or that you require supplemental oxygen therapy?	YES ☐ NO ☐
7c.	If asthmatic, do you currently have symptoms of chest tightness, wheezing, laboured breathing, consistent cough (more than 2 days/week), or have you used your rescue medication more than twice in the last week?	YES ☐ NO ☐
7d.	Has your doctor ever said you have high blood pressure in the blood vessels of your lungs?	YES ☐ NO ☐

8. Do you have a Spinal Cord Injury? *This includes Tetraplegia and Paraplegia*

If the above condition(s) is/are present, answer questions 8a-8c — If **NO** ☐ go to question 9

8a.	Do you have difficulty controlling your condition with medications or other physician-prescribed therapies? (Answer **NO** if you are not currently taking medications or other treatments)	YES ☐ NO ☐
8b.	Do you commonly exhibit low resting blood pressure significant enough to cause dizziness, light-headedness, and/or fainting?	YES ☐ NO ☐
8c.	Has your physician indicated that you exhibit sudden bouts of high blood pressure (known as Autonomic Dysreflexia)?	YES ☐ NO ☐

9. Have you had a Stroke? *This includes Transient Ischemic Attack (TIA) or Cerebrovascular Event*

If the above condition(s) is/are present, answer questions 9a-9c — If **NO** ☐ go to question 10

9a.	Do you have difficulty controlling your condition with medications or other physician-prescribed therapies? (Answer **NO** if you are not currently taking medications or other treatments)	YES ☐ NO ☐
9b.	Do you have any impairment in walking or mobility?	YES ☐ NO ☐
9c.	Have you experienced a stroke or impairment in nerves or muscles in the past 6 months?	YES ☐ NO ☐

10. Do you have any other medical condition not listed above or do you have two or more medical conditions?

If you have other medical conditions, answer questions 10a-10c — If **NO** ☐ read the Page 4 recommendations

10a.	Have you experienced a blackout, fainted, or lost consciousness as a result of a head injury within the last 12 months **OR** have you had a diagnosed concussion within the last 12 months?	YES ☐ NO ☐
10b.	Do you have a medical condition that is not listed (such as epilepsy, neurological conditions, kidney problems)?	YES ☐ NO ☐
10c.	Do you currently live with two or more medical conditions?	YES ☐ NO ☐

PLEASE LIST YOUR MEDICAL CONDITION(S) AND ANY RELATED MEDICATIONS HERE: _____

GO to Page 4 for recommendations about your current medical condition(s) and sign the PARTICIPANT DECLARATION.

2015 PAR-Q+

If you answered NO to all of the follow-up questions about your medical condition, you are ready to become more physically active - sign the PARTICIPANT DECLARATION below:

- It is advised that you consult a qualified exercise professional to help you develop a safe and effective physical activity plan to meet your health needs.
- You are encouraged to start slowly and build up gradually - 20 to 60 minutes of low to moderate intensity exercise, 3-5 days per week including aerobic and muscle strengthening exercises.
- As you progress, you should aim to accumulate 150 minutes or more of moderate intensity physical activity per week.
- If you are over the age of 45 yr and **NOT** accustomed to regular vigorous to maximal effort exercise, consult a qualified exercise professional before engaging in this intensity of exercise.

If you answered **YES** to **one or more of the follow-up questions** about your medical condition:

You should seek further information before becoming more physically active or engaging in a fitness appraisal. You should complete the specially designed online screening and exercise recommendations program - the **ePARmed-X+ at www.eparmedx.com** and/or visit a qualified exercise professional to work through the ePARmed-X+ and for further information.

Delay becoming more active if:

- You have a temporary illness such as a cold or fever; it is best to wait until you feel better.
- You are pregnant - talk to your health care practitioner, your physician, a qualified exercise professional, and/or complete the ePARmed-X+ **at www.eparmedx.com** before becoming more physically active.
- Your health changes - talk to your doctor or qualified exercise professional before continuing with any physical activity program.

- You are encouraged to photocopy the PAR-Q+. You must use the entire questionnaire and NO changes are permitted.
- The authors, the PAR-Q+ Collaboration, partner organizations, and their agents assume no liability for persons who undertake physical activity and/or make use of the PAR-Q+ or ePARmed-X+. If in doubt after completing the questionnaire, consult your doctor prior to physical activity.

PARTICIPANT DECLARATION

- All persons who have completed the PAR-Q+ please read and sign the declaration below.
- If you are less than the legal age required for consent or require the assent of a care provider, your parent, guardian or care provider must also sign this form.

I, the undersigned, have read, understood to my full satisfaction and completed this questionnaire. I acknowledge that this physical activity clearance is valid for a maximum of 12 months from the date it is completed and becomes invalid if my condition changes. I also acknowledge that a Trustee (such as my employer, community/fitness centre, health care provider, or other designate) may retain a copy of this form for their records. In these instances, the Trustee will be required to adhere to local, national, and international guidelines regarding the storage of personal health information ensuring that the Trustee maintains the privacy of the information and does not misuse or wrongfully disclose such information.

NAME _____ DATE _____

SIGNATURE _____ WITNESS _____

SIGNATURE OF PARENT/GUARDIAN/CARE PROVIDER _____

For more information, please contact
www.eparmedx.com
Email: eparmedx@gmail.com

Citation for PAR-Q+
Warburton DER, Jamnik VK, Bredin SSD, and Gledhill N on behalf of the PAR-Q+ Collaboration. The Physical Activity Readiness Questionnaire for Everyone (PAR-Q+) and Electronic Physical Activity Readiness Medical Examination (ePARmed-X+). Health & Fitness Journal of Canada 4(2):3-23, 2011.

Key References
1. Jamnik VK, Warburton DER, Makarski J, McKenzie DC, Shephard RJ, Stone J, and Gledhill N. Enhancing the effectiveness of clearance for physical activity participation: background and overall process. APNM 36(S1):S3-S13, 2011.
2. Warburton DER, Gledhill N, Jamnik VK, Bredin SSD, McKenzie DC, Stone J, Charlesworth S, and Shephard RJ. Evidence-based risk assessment and recommendations for physical activity clearance: Consensus Document. APNM 36(S1):S266-s298, 2011.

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Appendix B: Consent Forms

Informed Consent Form

Study name: The accuracy and sensitivity of select exercise intensity devices during varying exercise modalities in persons with and without Type 1 Diabetes.

Researchers:
Researcher name: Loren Yavelberg, Masters Candidate, Graduate Program in Kinesiology and Health Science, Email address loreny@yorku.ca, Office phone 416-736-2100 ext. 77236

Researcher name: Dr. Veronica Jamnik, Associate Professor, Room 358 Norman Bethune College, York University, Email address ronij@yorku.ca, Office phone 416-736-2100 ext. 22995

Purpose of the research:
The purpose of this project is to examine the accuracy and reliability of select wearable exercise technologies that estimate physical activity intensity and energy expenditure. The pieces of hardware include the Zephyr Bioharness, Metria Armband, Mio Fuse, and Garmin Vivo Fit 2. The accuracy, sensitivity and reliability of these technologies in measuring physiological markers will be examined during varying physical activity/exercise intensities plus modalities. These physical activity/exercise intensities are similar to those you would encounter while participating in a fitness class or while walking slowly or walking purposefully or while jogging or shovelling snow or raking leaves or mowing the lawn using a push mower.

What you will be asked to do in the research:
Their will be a maximum of 5 non-consecutive visits to the laboratory. On the initial test day and on the fifth (last) day you will undergo an incremental-to-maximal effort treadmill test for the determination of your aerobic fitness (VO2max). At the initial visit the following measurments will also be carried out: height, body mass, resting blood pressure plus pulse rate, sum of 5 skinfolds, waist circumference and percent body fat using a bioelectric impedance device (eg. Tanita Scale).

Following the initial test day, you will participate in the remaining 3 activity days in a differing order. The purpose of this is to minimize any order effect. The exercise days consist of a light intensity continuous exercise session and a moderate-to-vigorous intensity calisthenic based circuit (aka body weight) exercise session. The relative exercise intensities will be predetermined for each activity day, based on the your aerobic fitness (VO_2)max which will be determined on the initial visit. All measurements and exercises will be performed in the Human Performance Laboratories at York University Rooms 126 and 120 Norman Bethune College.

On the light intensity continuous activity exercise day you will be walking on the treadmill for 40 minutes at a speed and grade that is equivalent to 40-50% of your aerobic fitness (aka as your VO_2 max). During this session VO_2, heart rate and rating of perceived exertion will be monitored continuously.

On the circuit exercise day you will be exercising at moderate-tovigorous intensity while performing the following activities: starting with walking on a treadmill for 4 minutes, performing a circuit of the following exercises: marching on the spot with high knees (using the arms) 45 sec; squat with front sweep (reps/60 sec); 4 Jumping Jacks; quadruped (aka as the bird dog) (30 sec); 2 Jumping Jacks; 4 push-ups followed by a 20 sec prone forearm plank; marching on the spot with high knees/30 sec); 8 kg ball lift to platform at chest height/60 sec; 4 pushups, followed by a 20 sec prone forearm plank, 4 minutes of vigorous intensity cycling; repeating the circuit; walking on a treadmill for 4 minutes; repeating the

circuit; and finishing with 8-10 minutes of cycling at a vigorous intensity. During this session VO_2, heart rate and rating of perceived exertion will be monitored continuously.

You will also be required to repeat one of the exercise sessions (light intensity treadmill or moderate-to-vigorous intensity calisthenic (aka body weight) exercise circuit a second time. All five exercise sessions will be supervised by qualified exercise professionals (Certified Exercise Physiologists).

Risks and Discomforts:
As with any strenuous physical activity, there some known risks of participation which include, but are not limited to: dizziness, fatigue, nausea, lightheadedness, loss of consciousness, hypoglycemia, abnormal blood pressure, increased breathing, increased heart rate, increased blood pressure, chest pain, leg cramps, and extremely rare cases – death. Every possible precaution will be taken to avoid such instances, including the use of pre-participation medical risk assessments. All exercise will be supervised by a Certified Exercise Physiologist trained in standard first-aid procedures including Cardio Pulmonary Resuscitation (CPR) and Automatic External Defibrillator (AED). Therefore, in the event of an emergency standard first-aid emergency procedures will be initiated as per the York University Medical Emergency Procedures.

Benefits of the Research and Benefits to You:
By participating, you will provide the researchers with valuable information pertaining to the accuracy, sensitivity and reliability of this wearable technology being used to later implement them in Artificial Pancreas of Type 1 Diabetics. The benefits to you include the opportunity to become familiar with using wearable exercise technology, experience unique fitness testing as well as the exposure to various forms of exercise intensity plus modalities. The benefits of exercise include possible improved weight management, improved blood glucose control, improved cardiovascular and musculoskeletal health, improved self-appearance and elevated self-confidence.

Voluntary Participation: Your participation in the study is completely voluntary and you may choose to stop participating at any time. Your decision not to volunteer will not influence the relationship you may have with the researchers or study staff or the nature of your relationship with York University either now, or in the future.

Withdrawal from the study: You can stop participating in the study at any time, for any reason, if you so decide. Your decision to stop participating, or to refuse to answer particular questions, will not affect your relationship with the researchers, York University, or any other group associated with this project. In the event you withdraw from the study, all associated data collected will be immediately destroyed wherever possible.

Confidentiality: All the information that you supply during the research will be held in confidence in a password protected manner and your name will not appear in any report or publication. All archived data will be removed of any personal identifiers. The paper data will be filed and electronic data will be archived on password protected computers for at least 7 years after publication. The data will be safely stored in Dr. Jamnik's laboratory which has restricted access and only select research staff will have access to this information. Confidentiality will be

provided to the fullest extent possible by law.

Questions about the research? If you have any questions about the research in general or about your role in the study, please feel free to contact the researchers by telephone or by email. This research has been reviewed and approved by the Human Participants Review Sub-Committee, York University's Ethics Review Board and conforms to the standards of the Canadian Tri-Council Research Ethics guidelines. If you have any questions about this process, or about your rights as a participant in the study, your may contact the Senior Manager and Policy Advisor for the Office of Research Ethics, 5th Floor, York Research Tower, York University, telephone 416-736-5914 or e-mail ore@yorku.ca or Dr. Veronica Jamnik, Associate Professor, Room 358 Norman Bethune College, York University, Email address ronij@yorku.ca, Office phone 416-736-2100 ext. 22995 or Loren Yavelberg , Masters of Science Graduate Student, Room 124 Norman Bethune College, Office Phone 416-736-2100 ext. 77236 Email: loreny@yorku.ca or the Graduate Program in Kinesiology and Health Science, 341 Norman Bethune College, York University, Telephone: 416-736-5728, Fax: 416-736-5774, Email: kahs@yorku.ca

Legal rights and signatures:

I _____ consent to participate in the study conducted by Dr. Veronica Jamnik and Loren Yavelberg MSc student. I have understood the nature of this project and wish to participate. I am not waiving any of my legal rights by signing this form.

☐ I am of legal age and I do not require the assent of a care provider: parent, guardian or care provider. My signature below indicates my consent.

Signature _____ **Date** _____
Participant

OR

☐ I am less the legal age and I require the assent of a parent, guardian or care provider. The care provider's signature below indicates consent for my participation in this study.

Signature _____ **Date** _____
Parent/Guardian/Care Provider

Signature _____ **Date** _____
Principal Investigator

Appendix C: Data Sheets

Participant Information Sheet

Name:_____ **DOB:** dd / mm / yyyy /

Male or **Female** (circle) **Age:** _____

Height:_____ cm **Weight:**_____ kg

Dominant Hand: Right or **Left**

Resting BP & HR: AVG: _____/ _____ mmHg

Right:

1) _____/_____ mmHg _____BPM 4) _____/_____ mmHg _____BPM

2) _____/_____ mmHg _____BPM 5) _____/_____ mmHg _____BPM

3) _____/_____ mmHg _____BPM 6) _____/_____ mmHg _____BPM

Resting BP & HR: AVG: _____/ _____ mmHg

Left:

1) _____/_____ mmHg _____BPM 4) _____/_____ mmHg _____BPM

2) _____/_____ mmHg _____BPM 5) _____/_____ mmHg _____BPM

3) _____/_____ mmHg _____BPM 6) _____/_____ mmHg _____BPM

Skinfolds

Bicep: _____/_____ Tricep: _____/_____ Subscapularis: _____/_____

Illiac Crest: _____/_____ Medial Calf: _____/_____ %BF: _____

NIH WC: _____

Date:

VO_2 Max Data Sheet

Name:_____ Age: _____ Height _____cm Weight:_____kg

Work Load	Tissot Temp	Initial Stick (cm)	Final Stick (cm)	Time of sample collection (seconds)	F_EO_2 %	F_ECO_2 %	V_E ($L \cdot min^{-1}$) (STPD)	VO_2 ($L \cdot min^{-1}$) (STPD)	VO_2 ($mL \cdot kg^{-1} \cdot min^{-1}$) (STPD)	HR (bpm)		BR	
3.5 - 0													
5 - 1													
6 - 1													
6.5 - 1													
6.5 - 3													
6.5 - 5													
6.5 - 7													
6.5 - 9													
6.5 - 11													

Study Participant Name: _____ Date: _____

DOB (mm/dd/year) _____ Height (cm) _____ Body Mass (kg) _____

Global Start Time: _____

4 minutes *walking* followed by the following circuit:

Resistance Exercise	FITMATE Time (Min:Sec)	HR (bpm)	BR	RPE	Blood Glucose (mmol/L)	Lactate (mmol/L)
Marching on spot w/ high knees (using arms) 45 sec		|	|			
Squat with front sweep (reps for 60 sec)		|	|			
4 jumping jacks		|	|			
Quadruped for 30 sec		|	|			
2 jumping jacks		|	|			
4 pushups, followed by 20 sec prone forearm plank		|	|			
Marching on spot w/ high knees for 30 sec		|	|			
8 kg ball lift for 60 sec		|	|			
4 Pushups, followed by 20 sec prone forearm plank		|	|			

4 min *cycling* followed by the following circuit:

Resistance Exercise	FITMATE Time (Min:Sec)	HR (bpm)	BR	RPE	Blood Glucose (mmol/L)	Lactate (mmol/L)
Marching on spot w/ high knees (using arms) 45 sec		|	|			
Squat with front sweep (reps for 60 sec)		|	|			
4 jumping jacks		|	|			
Quadruped for 30 sec		|	|			
2 jumping jacks		|	|			
4 pushups, followed by 20 sec prone forearm plank		|	|			
Marching on spot w/ high knees for 30 sec		|	|			
8 kg ball lift for 60 sec		|	|			
4 Pushups, followed by 20 sec prone forearm plank		|	|			

4 min *walking* followed by the following circuit:

Resistance Exercise	FITMATE Time (Min:Sec)	HR (bpm)	BR	RPE	Blood Glucose (mmol/L)	Lactate (mmol/L)
Marching on spot w/ high knees (using arms) 45 sec		|	|			
Squat with front sweep (reps for 60 sec)		|	|			
4 jumping jacks		|	|			
Quadruped for 30 sec		|	|			
2 jumping jacks		|	|			
4 pushups, followed by 20 sec prone forearm plank		|	|			
Marching on spot w/ high knees for 30 sec		|	|			
8 kg ball lift for 60 sec		|	|			
4 Pushups, followed by 20 sec prone forearm plank		|	|			

4-10 min *cycling* to finish 40 min total protocol

Study Participant Name:__________ Date:_______

DOB (dd/mm/year) ___/___/___ Height (cm) _______ Body Mass (kg):__________

Time of Day		FITMATE Time (min:sec) Start time	HR (bpm)	Breathing Rate	RPE	VO_2 At specified time
	Prepping the study participant					
	Treadmill walking					