Validity of mHealth devices and applications: Do we need standards?

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Integration Framework (Lobeló et al.)
Overview of Issues

BACKGROUND ON WEARABLES AND STANDARDIZATION ISSUES
Wang et al.
Rock Health, 2014

Biosensing wearable products being created today could not have existed even three years ago

- Bluetooth Low Energy radio
  First device to implement BLE was the iPhone 4S in 2011

- Wireless charging coil
  Qi standards-based products first hit market in 2013

- MEMS accelerometer
  Price has fallen 4X in the last five years

Offloaded computation
Signal processing from sensors is handled in cloud via iPhone

Source: Product and app rendering courtesy of Spire, Inc.
Note: Spiro product is launching June 17th, 2014
“It’s a crowded market, but there’s a growing tail of opportunity for biosensing wearables. We’re also pretty confident this space will continue to develop as tech giants like Apple, Samsung, and Google start playing in the sandbox”

Source: Rock Health review of 75+ companies (companies are selected, not comprehensive)
Wang et al. 2014

We identified three axes—functionality, reliability, and convenience—on which companies should innovate in order to provide consumers with high utility. Moreover, as biosensing wearables advance across all these three axes, there is significant potential to disrupt not only the consumer electronic markets but also the healthcare markets.

Note: We strongly object to the overuse of the phrase “disruptive innovation”; however, we feel that it describes both the market dynamics as well as popular backlash against the category.
Wang et al. 2014

**COMpletely Fragged**
Attempts at consumer/industry platforms for integrating biosensing wearables

- **Example Platforms**
  - RunKeeper
  - Jiff
  - myfitnesspal
  - REDBRICK HEALTH
  - tactio
  - The Activity Exchange
  - VALIDIC

- **Use Case**
  - **Individual Wellness**
  - **Corporate Wellness**
  - **Remote Patient Management**
    - Providers
  - **Consumer Engagement and Analytics**
    - Payers, biopharma
  - **Data Normalization and Transport**
    - Agnostic (API)

- **Target Customer**
  - Consumers
  - Payers

**Biosensing Wearables**

Note: Devices and platforms are selected, not comprehensive
How can the complex data from a diverse array of devices be processed and harmonized to most effectively (and efficiently) inform clinical decision making and referral to behavior change applications?
Comparisons with other ‘Vital Signs’

- **Blood Pressure**
  - Many Devices
  - **Standard Metrics**
    - Systolic BP (mmHg)
    - Diastolic BP (mmHg)

- **Physical Activity**
  - Many Devices
  - **Various Metrics**
    - MVPA (min)
    - TEE / AEE (kcal)
    - Steps

For EIM applications, compliance with PA guidelines is critical. Indicators of EE (e.g. MetMin) offer most promise for standardization.
Complexities of Physical Activity Assessment

- Physical activity can only be "assessed"
  - Not technically "measureable"
- Physical activity is highly variable
  - Varies from day to day
- Physical activity is multi-dimensional
  - Type / Intensity / Duration / Time
- Physical activity is a ‘relative’ term
  - Movement data only captures absolute amount
    - Standardization by EE / METS enables tracking of both absolute and relative intensity
Existing Standards

- Consumer Trade Association (CTA) has established guidelines for some wearable devices (sleep and steps)

ANSI serves as the "accreditation" body.
Overview of CTA ‘Step’ Report

- **Standardized Protocol:**
  - Treadmill
    - Walking / Running
  - Video Record
    - Manual step count

- **Criterion for “Accuracy”:**
  - Within 10% MAPE
    (Mean Absolute Percent Error)

\[
MAPE = \left(\frac{100}{n}\right) \times \sum_{i=1}^{n} \left| \frac{T_i - E_i}{T_i} \right|
\]
Existing Standards - FDA

- International Medical Device Regulators Forum developed guidelines that also capture issues with wearable
  - Software as a Medical Device (SaMD) Group
Key Terms in SaMD Report

- **Accuracy**: degree of closeness of measurements of a quantity to that quantity's true value.

- **Precision**: related to reproducibility and repeatability, is the degree to which repeated measurements under unchanged conditions show the same results.

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(a) Low precision, low accuracy

(b) High precision, low accuracy

(c) High precision, high accuracy
SaMD: Key Categorical Distinctions

Importance of accuracy, precision and analytic sensitivity depend on how the information will be used.
Personal Experiences and Reflections

ACCURACY AND PRECISION OF WEARABLE MONITORS
Back to the Model
Physical Activity Assessments

*(Improving the Validity of Accelerometry)*

Accelerometry-based activity monitors provide a good balance between validity and feasibility.

Monitors must be calibrated and validated against other criterion measures.

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Diaries
Self-reports
Pedometers
HR monitors
Accelerometers
Direct observation
Indirect Calorimetry
DLW
Evolution of Accelerometry-Based Activity Monitors

Calorimetric Validation of the Caltrac® Accelerometer During Level Walking

The primary purpose of this study was to compare the Caltrac® accelerometer output with measured energy expenditure (EE). Twenty-five volunteers (10 men, 15 women) walked on a level motor-driven treadmill at four different speeds (54, 81, 104, and 130 m·min⁻¹) with the Caltrac® device affixed to the waistline. Each of the four experimental trials lasted eight minutes, and the testing was completed within an hour. During the test, oxygen consumption ($V_o_{2}$) (in L·min⁻¹ and in mL·kg⁻¹·min⁻¹) and nonprotein respiratory exchange ratio were monitored by the Beckman Horizon metabolic cart. The accelerometer output at the end of each exercise bout was also monitored and subsequently divided by 8 to convert the readings to counts·min⁻¹. The mean $V_o_{2}$ (L·min⁻¹) at steady state (ie, 6th-8th minutes of exercise) was converted to a caloric value. We obtained a moderate correlation coefficient ($r$) of .76 between the accelerometer output and the $V_o_{2}$ (mL·kg⁻¹·min⁻¹) and a high correlation coefficient of .92 between the EE and the accelerometer readings. The Caltrac® accelerometer output (counts·min⁻¹) was significantly higher ($p < .01$) than the EE (kcal·min⁻¹) at the four walking speeds. The difference between the accelerometer output and the EE ranged from 13.3% to 52.9%. The data were further analyzed with linear, polynomial, multiple, and stepwise regression models. The results of the analyses revealed that the Caltrac® accelerometer output is a valid predictor of EE during level walking when the appropriate regression equation is used to adjust the values. Because the accelerometer device tends to overestimate EE, the raw accelerometer readings should be applied with caution. [Balogun JA, Martin DA, Clendenin MA: Calorimetric validation of the Caltrac® accelerometer during level walking. Phys Ther 69: 501-509, 1989]
Examples of Early Activity Monitors

- Original Actigraph (MTI/CSA)
  - 1 dimensional

- Actical
  - Omni-directional and small

- Biotrainer
  - “bi-directional”

- Tritrac
  - 3-dimensional version of Caltrac
Evolution of the Actigraph Activity Monitor

- **7164 Monitor**
  - piezoelectric cantilever beam

- **GT1M (~ 2005) - ADXL320**
  - 2 axis MEMS capacitative accelerometer
  - Enabled detection of static and dynamic accelerations.

- **GT3X (~ 2009) - ADXL320**
  - 3 axis MEMS with altimeter

- **GT3X+ (~2012)**
  - Sampled at 12 bit ADC (30-100 Hz)
  - Output in Raw G’s (range: +/- 6G)
Innovations in Activity Monitoring

- **Smaller, more powerful sensors**
  - Wearable / Portable Sensors
- **Increased data storage**
  - Higher sampling rates
  - Longer data collection
- **Merging with other technology**
  - GPS technology
  - Wireless signal transfer
- **Multi-sensor (HR / Heat)**
  - Improved precision
- **Increased utility of software**
  - Advanced data processing capabilities
  - Pattern recognition technology
SenseWear Armband

- Worn over the triceps muscle
- Non-invasive
- Wireless
- Multi-sensor activity monitor
  - 3-axis accelerometer
  - Heat flux
  - Galvanic skin response (GSR)
  - Skin temperature
  - Near body ambient temperature
Biking

Heat Flux

Energy Expenditure

Total EE
897 cal

Active EE (3.0 METs)
561 cal

Physical Activity (3.0 METs)
1 hr 33 min

Average METs
2.5

Step Count
2079

Lying Down
53 min

Sleep
42 min

Sleep Efficiency%
79%
Walking
Lift
Sit/Desk
Drive
Baseball catch

Energy Expenditure
Heat Flux
Acceleration

Total EE
649 cal
Includes off-body estimate of 0 cal

Active EE (3.0 METs)
419 cal
1 hr 5 min

Physical Activity (3.0 METs)

Average METs
2.5

Step Count
3969

Lying Down
Not detected

Sleep
Not detected

Sleep Efficiency
N/A
Validation Research with the SenseWear Armband

- Criterion Measures
  - Observation
  - Indirect Calorimetry
  - Doubly Labeled Water

- Designs
  - Laboratory Based
  - Free Living Studies

- Comparisons of Algorithms Over Time
Example of Doubly-Labelled Water Protocol

Day 0
- Baseline
- Time x0 – (DLW dosage)
- x0 + 1.5-Hr
- x0 + 3.0-Hr
- x0 + 4.5-Hr
- x0 + 6.0-Hr

Day 7
- Time x7
- x7 + 1.5-Hr

Day 14
- Time x14
- x14 +1.5-Hr
### Sensewear DLW Studies

- **Adults** (Johannsen, 2010)¹
  - Total Error: 22 kcal/day
  - MAPE: 8.3%

- **Youth** (Calabro, 2012)²
  - Total Error: 44 kcal/day
  - MAPE: 11.7%

- **Seniors** (Calabro et al., 2010)³
  - Total Error: -21.5 kcal/day
  - MAPE: 8.0%

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Considerations with WAMs

- Monitor location
  - Wrist is comfortable for consumers
  - Wrist is not ideal for modeling PA

- Differences across Monitors
  - Consumer Monitors
  - Research Grade Monitors

Available monitors use different sensors and different methods to provide different information in different formats with different accuracy.
PERSPECTIVES ON CONSUMER MONITORS
### Pilot Study on Consumer Monitors (2012-13)

Multiple monitors / Oxycon Mobile Criterion / Simulated Free Living Activity

<table>
<thead>
<tr>
<th>Monitor</th>
<th>Position</th>
</tr>
</thead>
<tbody>
<tr>
<td>BodyMedia Fit</td>
<td>Right Arm</td>
</tr>
<tr>
<td>BodyMedia Fit</td>
<td>Left Arm</td>
</tr>
<tr>
<td>Fitbit</td>
<td>On Right side belt</td>
</tr>
<tr>
<td>DirectLife</td>
<td>Chest with a necklace chain</td>
</tr>
<tr>
<td>DirectLife</td>
<td>On right side belt</td>
</tr>
<tr>
<td>Gruve</td>
<td>Left side belt</td>
</tr>
<tr>
<td>Omron</td>
<td>Left side belt</td>
</tr>
<tr>
<td>KAM</td>
<td>Right side belt</td>
</tr>
<tr>
<td>Polar HR</td>
<td>Chest</td>
</tr>
<tr>
<td>GPS/Foot pod</td>
<td>Wrist</td>
</tr>
</tbody>
</table>

![Image of a person wearing multiple devices]
Pilot Study Results: Mean Absolute Percent Error
Validation Study: Instruments

- Oxycon Mobile: Portable metabolic analyzer as the criterion measure.

- Consumer-Based Activity monitors
  1) BodyMediaFit (BMF): Research Monitor
  2) DirectLife (DL):
  3) Fitbit One (FO):
  4) Fitbit zip (FZ):
  5) Jawbone UP (JU):
  6) Nike+Fuel Band (NFB):
  7) Basis B1 Band (BB):
  8) ActiGraph (ACT): Research Monitor
<table>
<thead>
<tr>
<th>Activity</th>
<th>Speed (mph)</th>
<th>Time (min)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treadmill (walking)</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>Treadmill (Jogging)</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Treadmill (Running)</td>
<td>7</td>
<td>5</td>
</tr>
<tr>
<td>Sitting</td>
<td>No control</td>
<td>5</td>
</tr>
<tr>
<td>Sweeping</td>
<td>Self pace</td>
<td>5</td>
</tr>
<tr>
<td>Step exercise</td>
<td>Self pace</td>
<td>5</td>
</tr>
<tr>
<td>Stationary bike (100 watt)</td>
<td>Self pace</td>
<td>5</td>
</tr>
<tr>
<td>Walking around the building</td>
<td>Self pace</td>
<td>5</td>
</tr>
<tr>
<td>Climbing stairs (two full second floor)</td>
<td>Self pace</td>
<td>5</td>
</tr>
<tr>
<td>Walking around the building with a backpack (15 kg)</td>
<td>Self pace</td>
<td>5</td>
</tr>
<tr>
<td>Riding a car</td>
<td>More than 20 mph</td>
<td>5</td>
</tr>
<tr>
<td>Cool down</td>
<td>No control (without sitting)</td>
<td>5</td>
</tr>
<tr>
<td>Total</td>
<td>12 activities</td>
<td>71 minutes</td>
</tr>
</tbody>
</table>
Consumer Study 1 - Results

Validity of Consumer-Based Physical Activity Monitors

JUNG-MIN LEE	extsuperscript{1}, YOUNGWON KIM	extsuperscript{2}, and GREGORY J. WELK	extsuperscript{2}

	extsuperscript{1}School of Health, Physical Education and Recreation, University of Nebraska at Omaha, Omaha, NE;
	extsuperscript{2}Department of Kinesiology, Iowa State University, Ames, IA

Overall, the performance of these consumer-based monitors is quite impressive, as most had MAPE values between 10% and 15%. The performance is especially noteworthy, considering the diverse range of activities tested in the study.

*Fitbit One, Fitbit Zip, and BodyMedia Fit provide total energy expenditure (TEE = AEE).
*Add measured resting EE to Activity EE provided by Basis, Nike+Fuel Band, DirectLife, Jawbone Up, and ActiGraph (Frederick 2011, Equation).
## Sample Media Report

<table>
<thead>
<tr>
<th>Fitness Band</th>
<th>Price</th>
<th>Tracks</th>
<th>Error Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>BodyMedia Fit</td>
<td>$99</td>
<td>Sleep, Sweat, Calories</td>
<td>9.3%</td>
</tr>
<tr>
<td>Fitbit Zip</td>
<td>$59</td>
<td>Steps, Calories, Distance</td>
<td>10.1%</td>
</tr>
<tr>
<td>Fitbit One</td>
<td>$99</td>
<td>Steps, Calories, Stairs, Sleep</td>
<td>10.4%</td>
</tr>
<tr>
<td>Jawbone UP</td>
<td>$149</td>
<td>Steps, Calories, Stairs, Sleep</td>
<td>12.2%</td>
</tr>
<tr>
<td>Actigraph</td>
<td>$225</td>
<td>Acceleration, Energy Expenditure, Met Rates, Steps, Heart Rate, Sleep, Light Levels</td>
<td>12.6%</td>
</tr>
<tr>
<td>DirectLife</td>
<td>$199</td>
<td>Movement, Calories</td>
<td>12.8%</td>
</tr>
<tr>
<td>Nike Fuel Band</td>
<td>$119</td>
<td>Movement, Nike FuelPoints</td>
<td>13.0%</td>
</tr>
<tr>
<td>Basis Band</td>
<td>$199</td>
<td>Activity, Sleep, Stress and Heart Rate</td>
<td>23.5%</td>
</tr>
</tbody>
</table>
New(er) Consumer-Based Activity Monitors

● BodyMedia FIT Core 2: Criterion
● Fitbit Flex
● Jawbone UP & 24
● Polar loop
● Garmin Vivofit
● Nike+Fuel Band
● Basis B1 Band
● Withings Pulse
● Misfit Shine
Study 2 Design

- Simulated Workout Protocol (80 Minutes)
  - 20 minutes **sedentary activity**
    - Self selected (e.g. typing, writing, TV, computer, read)
  - 25 minutes **aerobic exercise** on treadmill
    - Self selected speed
  - 25 minutes **resistance exercises** (Circuit Training)
    - Self selected exercises, resistance and repetitions

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**Comparison of Consumer and Research Monitors under Semistructured Settings.**

Bai Y¹, Welk GJ, Nam YH, Lee JA, Lee JM, Kim Y, Meier NE, Dixon PM.
Study 2 - Validity of Consumer Monitors (Mean Absolute Percent Error)

<table>
<thead>
<tr>
<th>Device</th>
<th>Mean Absolute Percent Error (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Actigraph GT3X+</td>
<td>16.7%</td>
</tr>
<tr>
<td>BodyMedia Core</td>
<td>15.3%</td>
</tr>
<tr>
<td>Fitbit Flex</td>
<td>16.8%</td>
</tr>
<tr>
<td>Jawbone Up24</td>
<td>18.2%</td>
</tr>
<tr>
<td>Misfit Shine</td>
<td>30.4%</td>
</tr>
<tr>
<td>Nike Fuelband SE</td>
<td>17.1%</td>
</tr>
</tbody>
</table>
Study 2 - Validity of Consumer Monitors (Mean Absolute Percent Error – by activity)

Selected Consumer Monitors

- Actigraph GT3X+
- BodyMedia Core
- Fitbit Flex
- Jawbone Up24
- Misfit Shine
- Nike Fuelband SE
## Study 2: Mean Error

<table>
<thead>
<tr>
<th></th>
<th>Total Error</th>
<th>SB Error</th>
<th>AE Error</th>
<th>RE Error</th>
</tr>
</thead>
<tbody>
<tr>
<td>AG3X</td>
<td>-11.9 (59.3)</td>
<td>5.8 (21.5)</td>
<td>20.5 (47.5)</td>
<td>-38.3 (25.4)</td>
</tr>
<tr>
<td>BMC</td>
<td>35.5 (44.5)</td>
<td>3.9 (6.1)</td>
<td>16.3 (30.3)</td>
<td>15.4 (25.9)</td>
</tr>
<tr>
<td>FBF</td>
<td>20.4 (54.0)</td>
<td>-5.5 (22.5)</td>
<td>51.9 (44.1)</td>
<td>-25.5 (20.6)</td>
</tr>
<tr>
<td>JU24</td>
<td>-23.1 (63.5)</td>
<td>-11.0 (8.1)</td>
<td>35.3 (58.4)</td>
<td>-47.2 (22.1)</td>
</tr>
<tr>
<td>MF</td>
<td>72.4 (87.2)</td>
<td>-5.7 (7.6)</td>
<td>109.5 (83.8)</td>
<td>-30.8 (21.7)</td>
</tr>
<tr>
<td>NFS</td>
<td>-42.3 (55.1)</td>
<td>-6.5 (7.1)</td>
<td>-9.2 (43.7)</td>
<td>-26.3 (22.9)</td>
</tr>
<tr>
<td>PL</td>
<td>67.6 (152.3)</td>
<td>2.2 (43.8)</td>
<td>14.3 (80.8)</td>
<td>48.9 (76.6)</td>
</tr>
</tbody>
</table>
Study 3

- Comparison of Apple Watch and Fitbit Charge HR
- Integration of HR with accelerometer data should theoretically improve the accuracy but it hasn’t been empirically tested with these monitors yet.
Results of Study 3: Energy Expenditure

- MAPE (overall trial):
  - Apple Watch: 15.2%
  - FitBit Charge HR: 32.9%

Apple Watch slightly underestimated EE but approached “equivalence” while Fitbit overestimated Error for Light and MVPA was considerably higher for FitBit than Apple Watch.
Results of Study 3:
Heart Rate

- MAPE Values (by intensity):
  - Apple Watch HR (N/A)
  - FitBit Charge HR:
    - Sedentary: 7.2%
    - Light: 10.1%
    - MVPA: 8.4%

Fitbit achieved statistical “equivalence” with criterion measure for all 3 intensities.
Results of Study 3: Steps

- **MAPE Values (Aerobic Activity / MVPA):**
  - Apple Watch: 6.2%
  - FitBit Charge HR: 9.4%

Protocol differed from CTA criteria but both monitors met the threshold for accuracy (i.e. < 10%) for aerobic activity.

Not for light or overall activity.
Summary of Consumer Monitors

- Considerable variability in accuracy of consumer monitors
- Accuracy, data resolution and export functionality limit utility for clinical applications
- Differing methods and lack of transparency complicates comparisons (Black Box)
NEW FRONTIERS IN RESEARCH
GRADE MONITORS
Machine Learning Methods
Sojourns:
(Example of Pattern Recognition Methods)

A Method to Estimate Free-Living Active and Sedentary Behavior from an Accelerometer

KATE LYDEN¹, SARAH KOZEY KEADLE¹, JOHN STAUDENMAYER², and PATTY S. FREEDSON¹
¹Department of Kinesiology, University of Massachusetts, Amherst, MA; and ²Department of Mathematics and Statistics, University of Massachusetts, Amherst, MA

A conceptually sound and well tested approach based on detecting naturally occurring bouts
“Sojourns Including Posture (SIP)”: An Enhancement of Sojourns

- Innovative extension of Sojourns that capitalizes on postural data from ActivPAL

![Graphs and images showing accelerometer output and posture changes over time.](Image)
Other Novel Approaches: Sedentary Sphere

Assessing Sedentary Behavior with the GENEActiv: Introducing the Sedentary Sphere
Summary of New Era in Accelerometry Research

- **Raw data** offers promise for standardization
- **Open source** methods enable more powerful analyses and sharing
- **Pattern recognition and machine learning** approaches offer advantages over standard regression equations but systematic approaches are needed to ensure progress
Considerations with ‘Raw’ Data for EIM and mHealth Applications

- The use of ‘raw’ accelerometer data provides potential for collection of ‘agnostic’ physical activity data.

- Data processing methods are complex and require advanced computing methods.
Changing Complexity

1440 samples/day
(1 per minute)

8,640,000 samples/day
(100 hz)
Standardizing Processing of Raw Data are Evolving

- Hildebrand et al. (2014) developed mgcutpoints for acceleration.
- Van Hees developed R-Coding to facilitate processing.

Age-Group Comparability of Raw Accelerometer Output from Wrist- and Hip-Worn Monitors

Maria Hildebrand¹, Vincent T. Van Hees², Bjorge Hermann Hansen¹, and Ulf Ekelund¹,³
Potential for Streamlining Raw Data Processing

- Additional research is needed to understand issues with raw data.

- Application of “Memory Mapping” technology offers promise for standardizing the “input” datasets to expedite processing.

- Cloud-based processing could standardize outcomes for integration.
Summary of Wearables

Or?
And?
Option 1: Multiple Monitors / Different Processing

Data processing and Standardization

Clinical outcome prediction algorithm

Standardization of processed outcome data through APIs
Option 2: Multiple Monitors / Standard Processing
Stages for Standardization

1. Logical Observation Identifiers Names and Codes (LOINC)
2. Hierarchical Data Format (HDF) v5
3. Application Programming Interface (API)
4. Logical Observation Identifiers Names and Codes (LOINC)
Exciting Times are Certainly Ahead!

Thanks!

Greg Welk – gwelk@iastate.edu
Metria IH1 (Patch monitor)

- Adhesive, Disposable, Water-proof monitor

- Based on same technology as the Sensewear Technology
  - Multiple embedded sensors
    - 3-axis accelerometer
    - Galvanic Skin Response
    - Temperature sensors

- Designed for clinical applications
Lab testing
Validation Results

Agreement between Armband and Metria for Individual Days (kcal/day)

<table>
<thead>
<tr>
<th>Day</th>
<th>Corr(r)</th>
<th>MAPE</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>.94</td>
<td>6.0</td>
</tr>
<tr>
<td>3</td>
<td>.89</td>
<td>7.7</td>
</tr>
<tr>
<td>4</td>
<td>.92</td>
<td>6.4</td>
</tr>
<tr>
<td>5</td>
<td>.93</td>
<td>7.1</td>
</tr>
<tr>
<td>6</td>
<td>.89</td>
<td>7.0</td>
</tr>
<tr>
<td>7</td>
<td>.90</td>
<td>8.6</td>
</tr>
</tbody>
</table>
Validation Results

Mean Absolute Percent Error (Relative to Oxycon Mobile) values for the armband and Metria for four specific activities

Correlations between Oxycon Mobile and both Armband and Metria for four specific activities
Summary of PATCH Study

- New non-invasive (disposable) monitoring technology (Metria IH1) offers potential for streamlining data collection

- The Metria IH1 offers potential for clinical applications and physician based counseling on physical activity