LITMUS | HEALTH

DEVICE CENSUS REPORT

Vol. 1: Extraclinical Wearables

Introduction

The use of real world data in clinical research is here to stay. But how does one best acquire these data?

A few years ago our Chief Technology Officer at Litmus, clearly frustrated, screamed aloud to no one in particular, “Will someone please just sell us a dumb bucket of sensors?!”

Driving him was how much proprietary “black box” data processing takes place on top of the raw signal wearables detect. In almost every case we would happily trade “smart” bells and whistles for raw, unfettered data access. This is also the sentiment of most researchers with whom we work and strategize.

For our inaugural Device Census report, we surveyed 179 individual brands; many of those brands have more than one device in the market. None of them are perfect.

Factors like price, form factor, battery life, and connectivity certainly matter. But for researchers incorporating real life data into studies and trials, the type, origin, and distribution of the data coming off these devices are the most important factors. In addition to this market analysis, we have published an academic review of wearables in oncology research that touches on many of these critical elements[1].

In this report we introduce the notion of a device transparency score. This score indicates how open the device maker is about the data they produce and make available. Is the researcher given raw or derived data, or has the data been processed through an algorithm first? If so, what does that transformation comprise? Is the data’s provenance clear? Is the device identifier and serial number available in the data?

Is the data well-documented? What is the status of the the device maker’s application programming interface (API)? Does data come across in JSON format? Does the company have a software development kit (SDK)? How easy will it be to get started as a developer or integrator?

Accounting for these issues and developing a transparency score will help inform researchers to understand the quality of the data. While device accuracy is important, what is more critical is how to measure and account for data quality and consistency.

At Litmus, we are passionate about the need to have access to the most raw and transparent data available, as the metrics being derived are critical to patient care and research.

Heart rate (HR) data was required for inclusion in this report, for reasons we explain. At the end of this report, we append a few “Devices to Watch” that don’t include HR but nonetheless make a strong argument for use in research.

This report will always be a work-in-progress. The market for these devices is evolving rapidly - in fact, we had just finished our first version of the report when we had to immediately go back and edit and add information that had arrived during the report’s production. We will provide updates to this Volume 1 of our Device Census twice a year or more often if a new device announcement merits the addition of new information. We will always clearly indicate the date of latest revision. While this report is not meant to include a list of supportive literature on the topic of wearables and research, we did find a few references compelling enough to list here[2],[3], while other references are linked directly from the text.

As educated consumers and users, you can help us by letting us know about new devices launching, as well as any changes you notice in hardware and software alike. We’re treating this report and the database behind it as a shared community resource. Please help us make it even better.

Lastly, note that this report only surfaces the top 15 devices we found and graded. You are always welcome to write us for data about a device that didn’t make the cut; we’ll be prompt in a reply about what we know: ***hello@litmushealth.com***

Thanks to a generous contract Litmus recently won with the NIH and NCI, we’re going to be able to make our full results available online in a browsable web application. We’re already planning Volume 2, focused on devices that are not body worn.

Thanks for downloading and reading. Enjoy, and good luck!

Parameters and Limitations

INCLUSION CRITERIA

This report is the first volume in a series intended to assist clinical researchers in incorporating sensors and telemetric data into study design. There are over 170 brands and manufacturers in the health and wellness sensor space. For inclusion in this volume, a device needed to be:

- External and wearable, as opposed to ingestible or environmental
- Intended to capture continuous or near-continuous data, as opposed to form factors only suited to workouts, or sensors that go into sleep mode except during workouts, for instance
- Primarily intended to capture data about a human, rather than its environment
- Intended to capture data beyond a clinical setting
- Focused on real-world data, including Average Daily Living and Physical Activity Intensity

We termed the set of devices matching these criteria **"extraclinical wearables."**

BRANDS WITH EXTRACLINICAL WEARABLES:

ActiGraph, Activinsights, Amazfit, Apple, Atlas, Bellabeat, Biovotion, Byteflies, CamNTech, Empatica, Fitbit, Fossil, Garmin, Honor, Huawei, iHealth, Komodo Technologies, LG, Lief, LifeTrak, MC10, Mio, Misfit, Moov, Myzone, Nevo, New Balance, Nixon, Onitor, Oura, Pavlok, Polar, Runtastic, Samsung, Scosche, Spire, Striiv, Suunto, Tigra Sport, Timex, UnaliWear, VitalConnect, WellBe, Whoop, Withings, Xiaomi

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We additionally took the stance that the following were of the utmost importance for clinical research:

- Battery life, which is crucial to participant adherence
- Presence of at least one variety of motion sensor (e.g. accelerometer), and heart rate
- Access to the hardware by way of SDK, or to minimally transformed data by way of developer API
- Ease of integration, including documentation, user manuals, and customer support

Heart rate data need not be an end in itself to be valuable in a clinical research context. For instance, activity intensity models that incorporate heart rate data are likely to be more accurate than those that rely exclusively on forward speed or spikes in accelerometer readings.

REGULATORY

Where evaluation criteria would differ by country—regulatory information and ratings, price, etc.—this report takes a U.S.-centric view. Data provenance is approached through the lens of 21 CFR Part 11, privacy through HIPAA, and approvals are limited to the FDA. Compliance and transparency regarding other regulations was noted, but given lower priority.

It is also important to consider the role of the Institutional Review Board (IRB) in approving the use of wearables in a clinical study. For instance, in our experience, some IRBs are hesitant to approve GPS tracking of participants where it is not explicitly tied to a relevant endpoint, and in all cases, patient consent is a priority.

Even when extraclinical devices are intended for research, they have limitations that should be respected in the study design. Internet-connected or near-field communication (NFC) devices should not be relied upon for a "hard real-time" purpose, for instance. Use of a wearable in a way that could qualify it as a "significant risk device" (21 CFR 812.3(m)) is subject to IRB determination of non-significant risk, or FDA exemption.

Limitations

INDUSTRY CHURN

By far, the most significant drawback to this report is the rate at which the industry experiences turnover. During the course of researching and writing this report, companies merged, divisions closed, startups pivoted away from hardware to focus on software, wearables were introduced and discontinued. Nearly one-fourth of the candidates had to be revised because of changes before publication, and we expect this report to require frequent updates.

This signals a risk to the “freshness” of our findings, but more importantly, it makes it very difficult to recommend devices that are currently supported that have also been validated by the research community. This is especially true for consumer wearables, where iteration is not only a means of driving new sales, but also allows for perpetual market segmentation as trends shift. Because these consumer wearable companies are competitive with one another, they are not particularly forthcoming about changes to their hardware, software, or algorithms. It would be reasonable to assume, for instance, that if an older model was validated for step count, newer models are at least as accurate. Unfortunately, it remains an assumption, so long as companies only volunteer that their step counting algorithm is now “better.”

HARDWARE

A related, and unexpected, limitation of this report is the lack of transparency surrounding the embedded sensors themselves. Specifications for consumer wearables are sufficiently vague that it is oftentimes impossible to disambiguate an accelerometer from a gyroscope, or an altimeter from a barometer. Furthermore, it is not possible to ascertain if a particular wearable has consistent use of an accelerometer or gyroscope during its entire production run - in fact, it is likely that the actual type and manufacturer of these sensors may change over the course of a device’s production lifetime without any transparency to the consumer. Additionally, consumer wearables companies engage in branding of hardware, software, algorithms, and combinations thereof that further obscures what is “under the hood.” Access to raw, untransformed data is exceedingly rare, so the types of data available from any given wearable do little to clarify its actual components.

USE OF MULTIPLE DEVICES AND ‘BRING YOUR OWN DEVICE’

Researchers might be tempted to design studies around a participant’s concurrent use of multiple unipurpose devices in the interest of cost or longer battery life, or to design “bring your own device” (BYOD) studies that restrict participation to the owners of wearable devices that have already been scientifically validated. Unfortunately, it would be difficult, if not impossible, to standardize the data collected from across different devices or platforms. Algorithms are opaque, sample rates vary, the accuracy of timestamps is often difficult to interrogate. Furthermore, many validated devices are no longer in production and may not be supported by the company. For these reasons, we caution against attempting to align data from devices not intended to work together. The misalignment of non-normalized time series data by even fractions of a second could affect statistical power.

Top 15 Wearables for Clinical Research

PREFACE

The finalists are presented in alphabetical order. Only one wearable was selected for review from each of the consumer (non-research) brands, with a bias toward newer models; note that one of the brand's other devices may be more suitable to a given study.

We originally intended to emphasize comfort of devices in the interest of participant compliance, but ultimately decided that the inclusion of heart rate data was more important. The conflict lies in the fact that optical heart rate sensors must be worn snugly against the skin, which means most of these devices are not breathable and care should be taken to avoid skin irritation, even if the materials are hypoallergenic.

The Aesthetic Score below is a fairly subjective measure from 1 (low) to 5 (high). There are sleek but facile devices—epitomized by overpriced designer smartwatches, hideous workhorses, and everything in between. Though appearance may play a role in patient compliance, it is important to note that beauty is fleeting, in this market. Take, for instance, the Mira and Caeden Sona bracelets , whose looks couldn't spare them the fate of so many wearables. Any study that doesn't plan to order all devices upfront should focus on staying power, over looks.

The Transparency Score, measured in Low/Medium/High, is intended to provide researchers with an overall sense of how hard it will be to incorporate the wearable into a study. How much is known about the company's algorithms and models? Is the developer documentation good? Is the user manual detailed and helpful? Essentially, we intend it as an indicator of how much time your team might spend on hold, if you choose that device.

Below is a cross-walk of terms that may be helpful in understanding these reviews:

WHAT'S BEING MEASURED?	SIMILAR/EQUIVALENT TERMS	RELATED TO
Capacitance	Bioimpedance, biopotential, touch sensor	Body fat, muscle mass, wear/in use
Optical heart rate, PPG	Photoplethysmography (PPG), blood volume pulse (BVP), bioimpedance plethysmography	Pulse, heart rate, heart rate variation (HRV), interbeat interval (IBI)
Position tracking	Global Positioning System (GPS), Global Navigation Satellite System (GLONASS)	Location, distance (straight line), distance (displacement)
Skin conductivity	Galvanic skin response (GSR), electrodermal activity (EDA), bioimpedance	Stress, electrolyte levels
Temperature sensor	Thermometer, thermopile	Skin temperature, ambient temperature, operating temperature, wear/in use

ACTIGRAPH

ActiGraph's data analysis platform provides access to minimally transformed data and validated algorithms and models, making it the most transparent supplier on our Top 15 list by a wide margin. Both activity monitors are FDA cleared, as is the new CentrePoint Insight watch covered in our Honorable Mention section. The places where ActiGraph falls short are: no built-in heart rate sensor (but they do sell a compatible heart rate monitor), sparse information about the accompanying belts and bands, and aesthetics.

GT9X LINK

Rx only: Yes

Customer: Researchers

Wear location: Wrist, waist, ankle, thigh

Embedded sensors: Two 3-axis accelerometers, gyroscope, inclinometer, magnetometer, thermometer

Measures: Heart rate/pulse when used with a compatible Bluetooth heart rate monitor, sleep, wear/in use, steps, proximity (Bluetooth), movement, rotation, position, skin temp

Avg. battery life: 1 - 14 days

Connectivity: USB, Bluetooth

Aesthetic score *(1 - 5, low - high)*: 2

Transparency score: High

MSRP: N/A.

The ActiGraph Link is a research wearable that has been on the market since 2014. It features a unique Inertial Measurement Unit (IMU) option that engages additional sensors to detect position and rotation beyond what most appendage-worn wearables are able to measure. Capturing IMU data significantly lessens battery life.

WGT3X-BT

Rx only: Yes

Customer: Researchers

Wear location: Wrist, waist, ankle, thigh

Embedded sensors: 3-axis accelerometer, capacitance, ambient light

Measures: Heart rate/pulse when used with a compatible Bluetooth heart rate monitor, sleep, wear/in use, steps, proximity (Bluetooth), movement, position

Avg. battery life: 12 - 27 days

Connectivity: USB, Bluetooth

Aesthetic score *(1 - 5, low - high)*: 1

Transparency score: High

MSRP: N/A.

The ActiGraph wGT3X-BT is a research wearable that has been on the market since 2013. It has 34 mentions on PubMed, making it a rare example of a validated wearable that is not (yet) being phased out.

APPLE WATCH SERIES 4 GPS

Rx only: No

Customer: Consumers

Wear location: Wrist

Embedded sensors: accelerometer, altimeter, GPS/GLONASS, gyroscope, ambient light, PPG

Measures: Heart rate/pulse, wear/in use, activity, steps, sleep

Avg. battery life: 18 hours

Connectivity: Wi-Fi, Bluetooth

Aesthetic score (1 - 5, low - high): 4

Transparency score: Medium

MSRP: $399+

The Apple Watch Series 4 with GPS (as opposed to GPS + Cellular) is, famously, a smartwatch. While it might be trendy enough to incentivize participants to comply with protocols over the course of long trials, the steep price is hard to justify for research, especially with battery life under 24 hours. We have included it because we agree with Rock Health that Apple seems serious about creating a platform for health, including its recent foray into EHR accessibility.

That said, there remains plenty of room for improvement to the platform. Apple's open-source, research-focused framework, ResearchKit, does not currently include: background sensor data collection (though other APIs on iOS support this); a mechanism for secure communication between your app and your server (you will need to provide this); the ability to schedule surveys and active tasks for your participants; or, a defined data format for how the ResearchKit framework structured data is serialized. Hopefully, their recent extension of ResearchKit GitHub privileges to select, external developers will result in expedited improvements.

ATLAS SHAPE

Rx only: No

Customer: Consumers

Wear location: Wrist

Embedded sensors: accelerometer, PPG

Measures: Steps, sleep, distance, activity, heart rate

Avg. battery life: 3 - 5 days

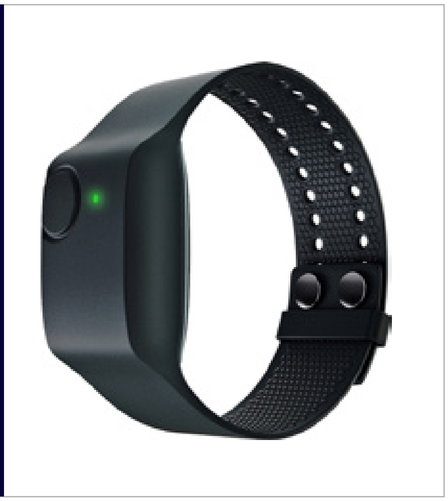
Connectivity: Bluetooth

Aesthetic score *(1 - 5, low - high)*: 3

Transparency score: Medium

MSRP: $99.99

Atlas has a well-documented API, assuming it's kept up to date, and seems willing to engage in high-touch relationships with health care professionals, based on its page addressed specifically to them. They additionally encourage researchers to contact them "to learn more about accessing our library of Machine Learning and AI algorithms." The Atlas Shape and Wristband 2 are excellent choices within the workout coaching and training realm, but their fitness focus may be disruptive to studies with other endpoints. For an additional $100, the shinier Wristband 2 includes a gyroscope, but the form factor is not conducive to continuous wear. Additionally, the Wristband 3 has been pending for some time now, which may herald the deprecation of Wristband 2. Both extant models are heavily discounted from their original MSRP, so be sure to check the site for updates.



EMPATICA E4

Rx only: Yes

Customer: Researchers

Wear location: Wrist

Embedded sensors: 3-axis accelerometer, skin conductivity, PPG, real-time internal clock, thermometer

Measures: Acceleration, blood volume pulse, electrodermal activity, skin temperature, interbeat interval

Avg. battery life: 20 - 36 hours

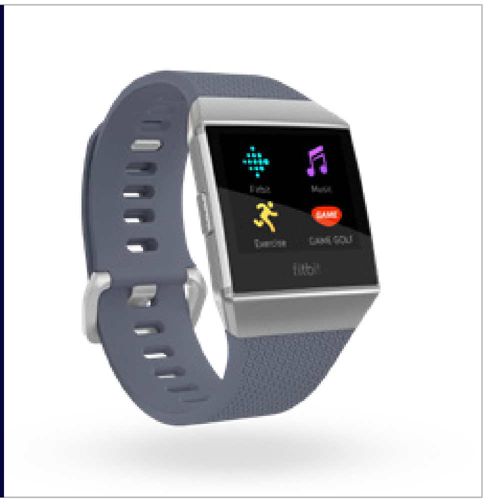
Connectivity: USB, Bluetooth

Aesthetic score *(1 - 5, low - high)*: 2

Transparency score: High

MSRP: $1690

Empatica also offers a much cheaper ($249) consumer wearable, the Embrace, which is FDA cleared for the detection of seizure activity but does not include a heart rate sensor. The E4 is FDA cleared and 21 CFR Part 11 compliance is possible with the E4, with use of the Empatica SDK. Empatica's devices appear in several peer-reviewed papers, but only one features the E4, presumably because it is nearly seven times the price of the Embrace.



FITBIT IONIC

Rx only: No

Customer: Consumers

Wear location: Wrist

Embedded sensors: 3-axis MEMS accelerometer, altimeter, GPS/GLONASS, ambient light, PPG, thermopile

Measures: Steps, heart rate/pulse, active vs. stationary, sleep

Avg. battery life: 4 - 5 days

Connectivity: Bluetooth

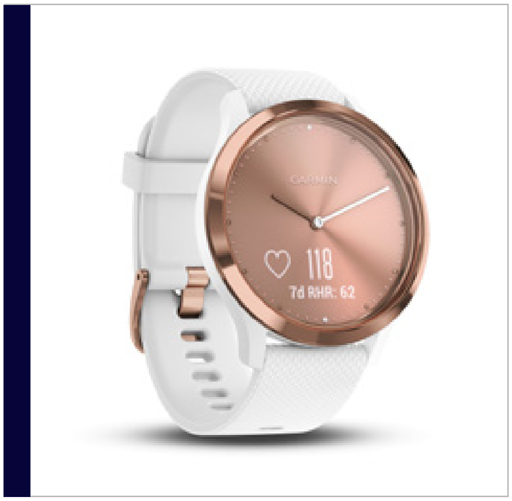
Aesthetic score *(1 - 5, low - high)*: 3

Transparency score: Medium

MSRP: $269.95

The Ionic has impressive battery life for a smartwatch, and especially for one with onboard position tracking. Researchers who aren't interested in GPS data and can abide one day less battery life may be interested in the lower-priced Versa. While Fitbit devices are often reviewed and compared in research papers (over 300, at this time), this new model returns no PubMed entries.

Researcher access to Fitbit currently requires submission of an application, and our developer team has encountered a number of opportunities for better documentation and communication. On the plus side, Fitabase is a wealth of Fitbit-related information, and the Quantified Self movement's mindshare regarding the devices is substantial. For these reasons, we have given it a Transparency Score of Medium.



GARMIN VIVOMOVE HR

Rx only: No

Customer: Consumers

Wear location: Wrist

Embedded sensors: accelerometer, altimeter, PPG

Measures: Steps, heart rate/pulse, distance, activity

Avg. battery life: 5 - 14 days

Connectivity: USB, Bluetooth, ANT+

Aesthetic score (1 - 5, low - high): 5

Transparency score: Medium

MSRP: $199.99+

The sleek, long-lived Garmin Vivomove HR is one of a number of currently-supported Garmin wearables. Thanks to a recent update, the Vivomove HR and other models with heart rate monitoring can now be configured to alert the wearer of an elevated heart rate at rest, which may be particularly useful in trials studying tachyarrhythmias. Garmin wearables have been used and studied in clinical research, though to a lesser extent than Fitbit; this new model doesn't turn up any PubMed results yet, either. Research teams should note that Garmin's SDK employs a proprietary language called "Monkey C."

HUAWEI BAND 3 PRO

Rx only: No

Customer: Consumers

Wear location: Wrist

Embedded sensors: 6-axis accelerometer, PPG, infrared wear sensor, low-power GPS

Measures: Activity, heart rate/pulse, wear/in use, sleep

Avg. battery life: 20 days

Connectivity: Bluetooth

Aesthetic score (1 - 5, low - high): 4

Transparency score: Low

MSRP: $69.99 (may be affected by exchange rate)

Huawei is a Chinese company, which might account for some lack of support and transparency on the English language website. Many of their FAQ documents are unavailable, their SDK is "coming soon," and their API reference isn't public. Huawei claims that their TruSleep model has been validated by the Center for Dynamical Biomarkers (DBIOM) at Beth Israel Deaconess Medical Center, but we could find no peer-reviewed papers to that effect. That said, it is one of the more affordable options that includes heart rate, so the trade-offs might be right for your study. If you're looking for more sensors, the pricier Watch 2 boasts an additional compass and barometer, as well as ambient light sensor and capacitance.

OURA

Rx only: No

Customer: Consumers

Wear location: Finger

Embedded sensors: accelerometer, gyroscope, PPG, temperature sensor

Measures: Heart rate/pulse, HRV, IBI, pulse amplitude variation (related to blood pressure), activity, sleep, respiration, body temperature

Avg. battery life: 7 days

Connectivity: Bluetooth

Aesthetic score (1 - 5, low - high): 5

Transparency score: High

MSRP: $299+

The second generation new Oura Ring takes 8 - 12 weeks to ship and fulfillment would potentially be an issue with well-powered studies, but it is an impressive piece of hardware. It boasts week-long battery life and enough memory to store up to 6 weeks of data onboard. It has good UX around syncing and (cordless!) charging. The form factor is legitimately beautiful, non-allergenic, seamless, water-resistant, and durable. It detects heart rate, HRV, sleep stages, and nocturnal body temperature, which may be of interest where menstrual cycles are implicated. The company's blog provides some amount of transparency about the science and tech, and there is an Oura Cloud API that appears to be well-documented.

POLAR A370

Rx only: No

Customer: Consumers

Wear location: Wrist

Embedded sensors: 3-axis accelerometer, GPS via phone, PPG

Measures: Heart rate/pulse, activity, steps, sleep

Avg. battery life: 4 days

Connectivity: Micro USB, Bluetooth

Aesthetic score *(1 - 5, low - high)*: 3

Transparency score: Medium

MSRP: $149.95

Presently, Polar offers five devices for 24/7 activity tracking with heart rate, 2 with continuous heart rate. Researchers interested in accurate GPS tracking, at the expense of battery life, may wish to employ the Polar M430 instead of the A370. There are 478 PubMed IDs (PMIDs) for "Polar heart rate," at the time of this publication, none for "Polar A370." Though we acknowledge not all of these results pertain to the Polar brand activity trackers, it does seem to be one of the better-studied brands. Additionally, there is some insight into their hardware design and models on the Polar Blog.

SAMSUNG GEAR FIT2 PRO

Rx only: No

Customer: Consumers

Wear location: Wrist

Embedded sensors: accelerometer, barometer, GPS, gyroscope, PPG

Measures: Heart rate/pulse, steps, sleep, activity

Avg. battery life: 3.5 days

Connectivity: Bluetooth

Aesthetic score *(1 - 5, low - high)*: 4

Transparency score: Medium

MSRP: $199.99

The Samsung Galaxy Watch, Gear Sport, Gear S3, Gear S2, and Gear Fit2 all have about three days of battery life and include some grouping of standard sensors. We selected the Fit2 Pro because it is the most recent iteration of the Fit2, and the other series are far pricier. One of the interesting quirks of the Gear App is that it has options to track your caffeine and water intake, in addition to allowing entry of goals.

SPIRE HEALTH TAG

Rx only: No

Customer: Consumers

Wear location: Waist (belt), chest (bra)

Embedded sensors: 3-axis accelerometer, PPG, “proprietary thoracic excursion sensor”

Measures: Heart rate/pulse, stress, sleep, activity, respiration

Avg. battery life: 18 months (then discard and replace Health Tag)

Connectivity: Bluetooth

Aesthetic score *(1 - 5, low - high)*: 4

Transparency score: Medium

MSRP: $49 per 1 - $299 per 8

Spire’s Health Tag represents a unique entry in our Top 15. It clips onto clothing and can be tossed into the wash still attached, making it one of the most durable and discreet wearable products. Its 18 months of battery life are also second to none. The app—which is available for iOS and Android, in spite of what parts of the website say—focuses on stress levels, as measured by a proprietary sensor that tracks the movements of your torso to deduce breathing patterns. Better communication about Spire’s API and product would only make this wearable more enticing.

STRIIV APEX HR

Rx only: No

Customer: Consumers

Wear location: Wrist

Embedded sensors: accelerometer, PPG

Measures: Heart rate/pulse, sleep, steps, activity

Avg. battery life: 7 - 12 days

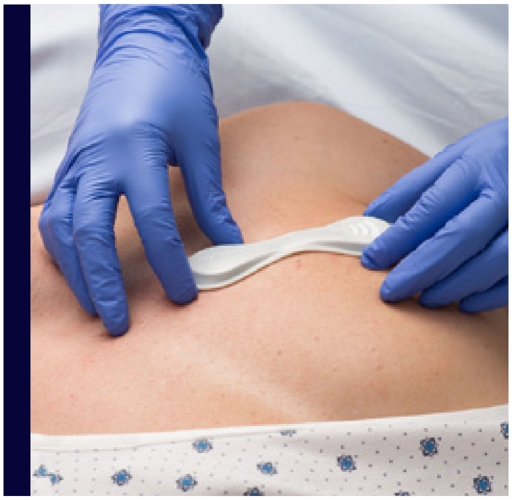
Connectivity: Bluetooth

Aesthetic score *(1 - 5, low - high)*: 4

Transparency score: Low

MSRP: $129.99

The Striiv Apex HR is a smartwatch that claims to record continuous heart rate data with a battery life of seven to 12 days, depending which part of their website you consult. An interesting facet of this wearable is the "on-wrist journaling" option, which allows users to log their food and liquid intake, current weight, medications they ingest, etc. Because of this built-in "habit" log and the substantial battery life, the Apex HR makes our Top 15 in spite of low transparency. We were unable to find a detailed user manual, though there are some answered FAQs on their support portal. Additionally, there does not appear to be any developer documentation, but they are integrated with Validic.



VITALCONNECT VITALPATCH

Rx only: Yes

Customer: Researchers

Wear location: Chest

Embedded sensors: 3-axis MEMS accelerometer, ECG/EKG, thermistor

Measures: Heart rate/pulse, HRV, respiration, posture, position, skin temperature, steps, activity

Avg. battery life: 96 hours (then replace)

Connectivity: Bluetooth

Aesthetic score *(1 - 5, low - high)*: 3

Transparency score: High

MSRP: N/A

VitalPatch is the only adhesive wearable to make our Top 15. This FDA-cleared research wearable has only just begun to show up in peer-reviewed papers; we expect to see more as they wrap up ongoing trials. VitalConnect is not as publicly forthcoming as ActiGraph about the particulars of their data analysis platform, but they do promise a near real-time stream of data to allow physicians to remotely monitor patients with the goal of preventing re-admission to hospitals.

WITHINGS STEEL HR

Rx only: No

Customer: Consumers

Wear location: Wrist

Embedded sensors: 3-axis MEMS accelerometer, PPG

Measures: Heart rate/pulse, steps, sleep, activity, distance

Avg. battery life: 5 - 25 days

Connectivity: Bluetooth

Aesthetic score *(1 - 5, low - high)*: 4

Transparency score: Medium

MSRP: $179.95

Having sold two years prior, Withings recently bought its wearables line back from Nokia Health. A search for Withings returns 30 papers on PubMed, and the Withings API looks to be well documented. We have conservatively awarded a Medium score on transparency, with the hope that their models will be discussed in more detail in future publications. Battery life is five days in “workout mode,” which enables continuous heart rate monitoring.

Top 15 Wearables for Clinical Research

IN ALPHABETICAL ORDER

- ActiGraph GT9X Link
- ActiGraph wGT3X-BT
- Apple Watch Series 4 GPS
- Atlas Shape
- Empatica E4
- Fitbit Ionic
- Garmin Vivomove HR
- Huawei Band 3 Pro
- Oura
- Polar A370
- Samsung Gear Fit2 Pro
- Spire Health Tag
- Striiv Apex HR
- VitalConnect VitalPatch
- Withings Steel HR

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Honorable Mention

There are several products that deserve honorable mention.

Activinsights has a line of GENEActiv wrist-worn accelerometers, with added ambient light and temperature sensors, that record for up to one month before recharging is required. In addition to raw data output and validated algorithms, the platform boasts open source analytics, open data protocols, open SDKs. GENEActiv does not collect heart rate data.

ActiGraph has recently released the **CentrePoint Insight Watch**, an FDA cleared Class II device. What it lacks in heart rate data, it makes up for in real-time data transfer. From ActiGraph CTO Jeremy Wyatt: “The Insight Watch is the first device able to capture the high-resolution, unadulterated source signal from the accelerometer over the air using BLE5, a faster version of Bluetooth.”

The **Bellabeat Leaf** is a well-liked, non-wrist wearable with an explicit women’s health focus. It can be clipped to clothing, or worn as a necklace or bracelet. It doesn’t track heart rate, but the app allows for menstrual cycle tracking and the battery lasts up to 6 months. It appears the API is still pending.

The **Biovotion Everion** wrist-worn wearable and **Byteflies Sensor Dot** adhesive wearable are impressive, sensor-packed devices, from Switzerland and Belgium, respectively. We hesitate to recommend them for general use in U.S. studies given their relative nascency and the potential for hiccups in the coordination of fulfillment or support, but encourage researchers to consider them on a case-by-case basis.

The Canadian **Komodo Technologies AIO Sleeve** is a compression sleeve that might be of particular interest in studies where a compression sleeve would be worn or prescribed anyway. Its specs include 24-bit ECG/EKG, 12-bit 3-axis accelerometer (100 Hz), 2MB RAM, Bluetooth connectivity, 7 days’ worth of battery, and a form factor that is antimicrobial and breathable. It tracks heart rate, heart rate variation (HRV), pulse ox, sleep, steps/distance, and energy expenditure (MET). We left this impressive wearable off because we could not find evidence of a developer portal, and our inquiry about the same has not received a reply as of the publication date.

The **Lief Smart Patch** may be of interest in behavioral health studies. The ECG patch measures heart rate variability, respiration, and activity, with the goal of enabling “heart rate variability biofeedback.”

Lastly, we want to note that Mio Global (now **PAI Health**) is getting out of the hardware game to focus on their validated Personal Activity Intelligence (PAI) score software. As with other brands who have done the same, their wearables will be available until they sell out. Expect to see PAI software running on Lenovo wearables in the future.

Big Names

Largely because we elected to screen for heart rate sensors, developer portals, and long battery life, you may have noticed that there are some big names in wearables that are absent above. They are noted below, in alphabetical order.

LG’s website makes it difficult to find its wearables, and if there is an extant developer portal, we could find no trace of it.

Microsoft’s Band appears to have been discontinued without fanfare in 2016.

Misfit has one model, the Vapor, with optical heart rate, but its battery only lasts one day.

New Balance’s RunIQ suffers the same fate.

Runtastic is a subsidiary of **Adidas**, which very recently announced big changes to its digital sports division. It is not yet clear whether Runtastic hardware will be phased out during the transition.

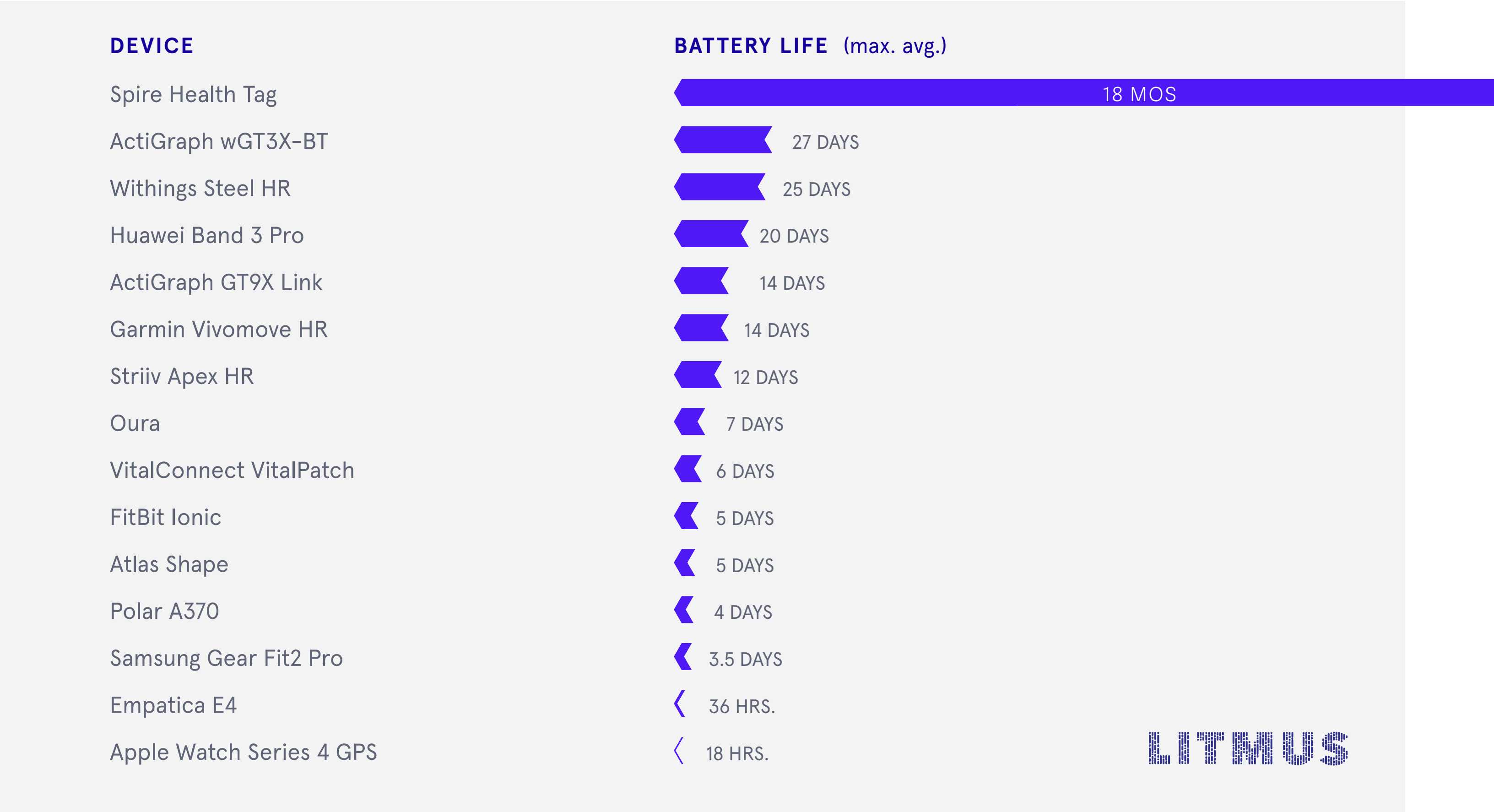
TomTom's website seems to indicate that it is not currently selling any fitness trackers or fitness watches, which is a shame because the Touch Cardio + Body Composition device's use of bioimpedance to estimate body fat versus lean muscle composition brought something interesting to the table.

Xiaomi makes notably cheap wearables, but offers no official SDK (though there is an unofficial one on GitHub), nor any other resources for developers.

References

1. Cox, S. M., Lane, A. & Volchenboum, S. L. Use of Wearable, Mobile, and Sensor Technology in Cancer Clinical Trials. JCO Clinical Cancer Informatics 1–11 (2018).
2. Henriksen, A. et al. Using Fitness Trackers and Smartwatches to Measure Physical Activity in Research: Analysis of Consumer Wrist-Worn Wearables. J. Med. Internet Res. 20, e110 (2018).
3. Nakanishi, M. et al. Estimating metabolic equivalents for activities in daily life using acceleration and heart rate in wearable devices. Biomed. Eng. Online 17, 100 (2018).

Device Battery Life



Device Census Report

Top 15 Wearables for Clinical Research (In alphabetical order)

DEVICE	RX ONLY	CUSTOMER	WEAR LOCATION	EMBEDDED SENSORS	MEASURES	AVG. BATTERY LIFE	CONNECTIVITY	AESTHETIC SCORE (1 - 5, LOW - HIGH)	TRANSPARENCY SCORE (LOW, MED, HIGH)	MSRP
ACTIGRAPH GT9X LINK	Yes	Researchers	Wrist, waist, ankle, thigh	Two 3-axis Accelerometers, gyroscope, inclinometer, magnetometer, thermometer	Heart rate/pulse when used with a compatible Bluetooth heart rate monitor, sleep, wear/in use, steps, proximity (Bluetooth), movement, rotation, position, skin temp	1 - 14 days	Bluetooth, USB	2		N/A
ACTIGRAPH WGT3X-BT	Yes	Researchers	Wrist, waist, ankle, thigh	3-axis accelerometer, capacitance, ambient light	Heart rate/pulse when used with a compatible Bluetooth heart rate monitor, sleep, wear/in use, steps, proximity (Bluetooth), movement, position	12 - 27 days	Bluetooth, USB	1		N/A
APPLE WATCH SERIES 4 GPS	No	Consumers	Wrist	accelerometer, altimeter, ECG, GPS/GLONASS, gyroscope, ambient light, PPG	Heart rate/pulse, wear/in use, activity, falls, steps, sleep	18 hours	Bluetooth, USB	4		$399+
ATLAS SHAPE	No	Consumers	Wrist	accelerometer, PPG	Steps, sleep, distance, activity, heart rate	3 - 5 days	Bluetooth	3		$99.99
EMPATICA E4	Yes	Researchers	Wrist	3-axis accelerometer, skin conductivity, PPG, real-time internal clock, thermometer	Acceleration, blood volume pulse, electrodermal activity, skin temperature, interbeat interval	20 - 36 hours	Bluetooth, USB	2		$1690
FITBIT IONIC	No	Consumers	Wrist	3-axis MEMS accelerometer, altimeter, GPS/GLONASS, ambient light, PPG, thermopile	Steps, heart rate/pulse, active vs. stationary, sleep	4 - 5 days	Bluetooth	3		$269.95
GARMIN VIVOMOVE HR	No	Consumers	Wrist	accelerometer, altimeter, PPG	Steps, heart rate/pulse, distance, activity	5 - 14 days	Bluetooth, USB, ANT+	5		$199.99+
HUAWEI BAND 3 PRO	No	Consumers	Wrist	6-axis accelerometer, PPG, infrared wear sensor, low-power GPS	Activity, heart rate/pulse, wear/in use, sleep	20 days	Bluetooth	4		$69.99**
OURA	No	Consumers	Finger	accelerometer, gyroscope, PPG, temperature sensor	Heart rate/pulse, HRV, IBI, pulse amplitude variation (related to blood pressure), activity, sleep, respiration, body temperature	7 days	Bluetooth	5		$299.99+
POLAR A370	No	Consumers	Wrist	3-axis accelerometer, GPS via phone, PPG	Heart rate/pulse, activity, steps, sleep	4 days	MICRO USB, Bluetooth	3		$149.95
SAMSUNG GEAR FIT2 PRO	No	Consumers	Wrist	accelerometer, barometer, GPS, gyroscope, PPG	Heart rate/pulse, steps, sleep, activity	3.5 days	Bluetooth	4		$199.99
SPIRE HEALTH TAG	No	Consumers	Waist (belt), chest (bra)	3-axis accelerometer, PPG, "proprietary thoracic excursion sensor"	Heart rate/pulse, stress, sleep, activity, respiration	18 mos	Bluetooth	4		$49 per 1 - $299 per 8
STRIIV APEX HR	No	Consumers	Wrist	accelerometer, PPG	Heart rate/pulse, sleep, steps, activity	7 - 12 days	Bluetooth	4		$129.99
VITALCONNECT VITALPATCH	Yes	Researchers	Chest	3-axis MEMS accelerometer, ECG/EKG, thermistor	Heart rate/pulse, HRV, respiration, posture, position, skin temperature, steps, activity	96 hrs	Bluetooth	3		N/A
WITHINGS STEEL HR	No	Consumers	Wrist	3-axis MEMS accelerometer, PPG	Heart rate/pulse, steps, sleep, activity, distance	5-25 days	Bluetooth	4		$179.99

Bluetooth USB MICRO USB

*when used with a compatible Bluetooth heart rate monitor
**affected by exchange rate
***assumed

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