Validating Room Location within the Home for Functional Measures from Digital Health Technologies

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Abstract—Digital health technologies have the potential to measure how a patient feels and functions with low patient burden e.g.: to provide real-world evidence of the benefit of a novel treatment. Despite this potential, traditional wearable devices, e.g. actigraphy, do not provide location-activity information which may improve the validity of these measures relative to established clinical measures. We describe a system that combines a wearable bracelet with Bluetooth-low-energy environment beacons to help localize and provide environmental context to that wearable data, and therefore provide a more clinically relevant measure of function. We describe an initial validation of the accuracy of the location information provided by this system in a study of 5 different real living environments of different size and layout, each collecting data over multiple days and recording their actual location in their home every 15 minutes in a diary. The results are presented in a confusion matrix. Mean overall accuracy was 94.0% (range 88.8-98.8%), which is sufficient to enable construction of more meaningful outcomes for patients than activity alone. For example, to determine if someone is moving around their home more, if they are getting outside more, if they are spending more time in bed, etc. It may be possible to improve location accuracy further with more sophisticated analysis of the beacon data.

Keywords—actigraphy, functional measures, location, beacons, digital health technologies, wearables.

I. INTRODUCTION

It is increasingly recognised that making measurable differences to how someone feels and functions is as important as treating the underlying cause of the disease or extending their life expectancy. Showing that a treatment provides a meaningful patient benefit is also important when deciding to reimburse or prescribe a treatment. It is common to use patient reported outcomes (PRO) to collect this patient led information in studies. Data recorded through PRO are however subjective, can be unreliable in patients with cognitive impairment, and as data is collected only intermittently, interpretation of the results can be challenging.

Digital health technologies (DHTs) such as actigraphy devices are widely used in clinical research. Data reflecting what a person is doing day-to-day in their natural home environment should provide an objective, high-frequency measurement that can complement PROs. However, the impact of DHTs has sometimes been limited, particularly for conditions where functional status and PROs are of primary importance. Although established clinical assessments are imperfect, they remain the reference standard, and it is challenging to demonstrate that DHTs are equivalent or better in practice. There are concerns about the validity of the data and the impact of sources of variability [1,2]. In their home environment, a person's activities and behavior are influenced by that environment (indoors or outdoors, which room) and whether they live alone [3]. While accelerometer data can determine the level of activity, it is hard to define the locus of activity more precisely and thus associate the activity measurements with outcomes or endpoints meaningful to the

The FDA recently published guidance documents intended to facilitate the use of systematic approaches to collect meaningful patient input that can better inform medical product development and regulatory decision-making [4]. They illustrate a shift towards endpoints that measure a Meaningful Aspect of Health (MAH). This is defined as: "Aspect of a disease that the patient a) does not want to become worse, b) wants to improve or c) wants to prevent."

For many conditions, this may be the ability to do day to day activities such as the shopping, meet with friends and family or perform other tasks around their home. Capturing every single activity is impractical and inefficient. Measurements should focus on particular contexts of use and be disease specific, e.g., someone with arthritis may be more focused on measures that reflect mobility while someone with dementia may wish to retain independence. Without additional information it is not possible to make a link between raw activity measures from a wearable device and

meaningful daily activities. However, adding location to the activity information, immediately enables the construction of more meaningful outcomes for people than activity alone. For example, to determine if someone is moving around their home more, if they are getting outside more, if they are spending more time in bed, etc. The measurement of location to improve activity specificity is the focus of this paper.

Alzheimer's Disease and Related Disorders (ADRD) provide a useful case study. Functional assessment is arguably the most important measure for all ADRD research since the determination of whether a person has or has become demented by definition, requires knowing if or when there is functional impairment. Simply stated, if there is no functional impairment, there is no dementia.

We describe here an approach to determine the room location at home of a study participant or whether the participant has left their home. The same approach could also be used if two people are wearing a bracelet to measure social interaction from the time that those people are together. We focus on assessing the accuracy with which Bluetooth Low Energy (BLE) beacons can be used to determine location. The approach described adds no extra burden to the participant over traditional wearables but has the potential to transform the value of the data collected to enable smaller studies to be carried out. The technology can be deployed anywhere, without the need for internet or cellular connection.

II. TECHNOLOGY

The technology evaluated comprises BLE beacons that communicate with a bracelet worn by the participant (Panoramic Digital Health). The received signal strength indicator (RSSI) from a uniquely identified beacon provides an estimate of the proximity to the beacon. In addition, each beacon contains the sensors in Table 1. An "advertising packet" is transmitted by the beacon each 700msec containing the beacon ID and sensor values and the bracelet can be configured to "listen" for these periodically (e.g., at 0.1Hz).

The bracelet stores any signals received from the beacon with a timestamp. Signals from up to 10 beacons can be recorded. The transmission range of the beacons varies depending on the layout and structure of the home but is typically 5-10m. The bracelet also contains sensors shown in Table 1 and stores raw data (1GByte) for the data collection period without the need to recharge the bracelet. The system has the advantage that no assisted technical set-up is required, but guidance is provided to ensure the beacons are placed in optimal locations (e.g. frequently inhabited rooms, not too close together (<3m) or on adjacent sides of the same wall). The beacons receive advertising packets from each other, to

Table 1: Bracelet and Beacon Sensors					
Sensor	Bracelet	Beacon			
3 axis accelerometer	x	x			
3 axis magnetometer	X	X			
3 axis gyroscope	X				
Barometric pressure	X	X			
Temperature	X	Х			
Ambient light level		Х			
Ambient noise		Х			

detect stability of beacon networks (i.e., detect one beacon being moved relative to another from change in the values of their orientation sensors and between-beacon RSSI). The raw data stored on the bracelet undergoes 128-bit AES hardware encryption. No personal data is stored on the device, it cannot be associated with the wearer in case of loss of the device.

A. Previous Validation of Location

Kriara et al., [5] reported using a similar set-up using commercial beacons and a smart watch to determine the time spent in rooms labelled as "social". Their approach helps to validate the use of BLE beacons in a clinical trial setting, but there are some key differences in our approach. Most notably our technology can: collect data for between 2 and 4 weeks without needing to recharge devices (depending on data rate), allowing continual monitoring day and night; the beacons additionally measure temperature, light and noise levels, as well as pressure. This provides additional context about the living environment. As Kriara et al., described, BLE signal is highly dependent on the structure of the home and signal can often easily pass through floors as well as walls in a way that can confound the results. For this reason, we chose to evaluate location accuracy in multiple homes with a range of sizes and layouts. The performance of the BLE localization is influenced by the line of sight and relative speed of the transmitters and the receiver; therefore, including a wide variety of activities is required to achieve realistic results.

III. METHOD

A. Data Collection

To measure the accuracy with which the system can measure room location, we set-up beacons in 5 different homes. The bracelet was configured to collect data at the following sampling frequency: 3-axis accelerometer at 26Hz, magnetometer at 20Hz, and pressure at 25Hz. The bracelet "listened" for a beacon signal for 1s in every 10s. In each case the study participants followed instructions to place between 3 and 5 beacons in primary rooms i.e. bedroom, bathroom, living room, kitchen and other according to the layout of the home, e.g. dining room or office. Two sets of beacons were set-up in each home, in different positions, to assess sensitivity

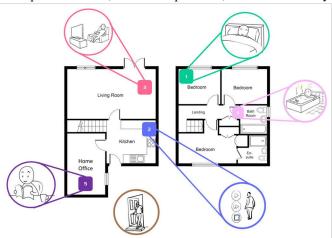


Fig. 1. Beacons should be placed in the locations in the home where the study participant spends most time. Brown (away from home) is inferred from no detectable beacon.

of location accuracy to precise beacon position. One or two test participants then wore a bracelet for 3-6 days to collect the RSSI data from the beacons. During this time the test participant kept a diary of which room they were in during waking hours, noting also when they went out to provide reference standard location data. When moving around, test participants were asked to record in which room they spent most time during each 15-minute interval of data collection. This work was carried out as part of an internal technical validation study. Data were collected according to the Declaration of Helsinki.

B. Data Analysis

Using a proprietary data annotation tool, each beacon identifier was labelled with a room identifier. For the purpose of this work only the beacon signals collected on the bracelet were analysed; the accelerometer and other sensor data on the bracelet and beacons was not included. To determine the room location of the participant, in each one minute sample, the signal from each beacon is averaged over the period and the beacon with the highest average RSSI signal is assigned. RSSI values are in the [-100, 0] range, the higher the value, the stronger the signal. If there is no beacon sample in a period, the value -100 is set. No RSSI signal represents "Out", i.e. the participant is assumed to be out of the home. For each 15minute period, the mode location is determined from the 15 one minute samples and exported from the annotation tool. Where the participant is determined to be 5 minutes in the bathroom and 10 minutes in the bedroom, the location for that 15-minute period is thus "bedroom". To compare with the values noted by the participant, the values for each 15min period were compared in Excel. Where no "truth" is recorded by the participant, this period is excluded from the analysis.

The participants also noted "Other", signifying they were at home, but not in one of the labelled locations. This was done to replicate a real-world situation and reflects that it may not be necessary or feasible to place beacons in every room.

A QC of the data was performed to exclude detected issues, e.g. charging, non-wear, movement of the beacons or technical fault. When performing QC all the sensor data listed in Table 1 is viewable, not just the RSSI data.

A confusion matrix was compiled comparing the predicted location to the diary reported location for each 15-minute period of observation. The results across experiments were then combined.

Table II. Summary of Data Collection						
	Number of	Number of 15-minute samples				
Home Description	Participants (P)	Total Collected		Included in analysis Beacon set 1/2		
A. 4 bedroom home (2 floors)	2	P1 P2	444 331	436/436 327/202		
B. 4 bedroom home (2 floors)	1	384		384		384/384
C. 3 bedroom apartment	2	P1 P2	531 530	531/531 530/530		
D. 2 bedroom apartment	1	424		424		416/416
E. Studio apartment	1	328		328/328		
Total		2972		5779		
		743	hours			

97.2% usable data: 8 periods lost due to charging bracelet, 4 lost due to no location noted in diary, 125 lost due to beacon falling to floor, 8 lost to technical issue with bracelet.

IV. RESULTS

The data files retrieved from each bracelet were around 80Mbytes. During data collection a total of 2972 location samples of 15-minutes were collected, corresponding to 743 hours (Table II). With each giving two sets of beacon data (Beacon set 1/Beacon set 2), a total of 5944 samples underwent quality control. Data were excluded for several reasons: 1. Charging the bracelet when the beacon scanning is paused, 2. Participant failed to note their location during a period, and 3. A technical issue detected with the beacon/bracelet. 5779 samples were retained for analysis corresponding to 97.3% of collected data.

Overall agreement between the predicted location from the beacon analysis and the location described in the diary kept by the participant was 94.0% (range 88.8-98.8%). If we were to group the locations to just distinguish the bedroom, out of the home and all other locations within the home, the agreement increases to 96.2 %.

Table III additionally suggests the location agreement by room may be higher the more time a participant spends in that location. Table IV breaks down the agreement by home layouts, beacon set and participant.



Fig. 2. Extract of beacon RSSI data collection in 3-bed apartment. Annotated with location from the diary entry and automated analysis of Beacon sets 1 & 2 in 15min samples. Dots represent RSSI of received advertising packet, with colour indicting beacon location. Beacon RSSI data corresponds to Beacon set 1.

Table III: Summary of location agreement results

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Predicted Actual	Bedroom	Kitchen	Living	Office /Dining	Bathroom	Out	Overall location agreement (%)	% of time reported in location
Bedroom	2424	15	16	4	83	18	94.7%	44.3%
Kitchen	23	344	16	7	2	7	86.2%	6.9%
Living	12	62	427	6	6	1	83.1%	8.9%
Office/ Dining	4	7	0	184	2	0	93.4%	3.4%
Bathroom	13	2	1	0	92	0	85.2%	1.9%
Out	6	4	10	3	2	1964	98.7%	34.4%
Other	0	9	1	2	0	0	NA	0.2%
Overall		·				•	94.0%	100%

Table IV: Overall location agreement results by home layout, participant (P) and beacon set.

Description	Beacon 1	Beacon 2	Combined		
A. 4-bed	P1 90.8% P2 97.2%	88.8% 93.6%	89.8% 95.8%		
B. 4-bed	97.1%	91.1%	94.1%		
C. 3-bed	P1 94.9% P2 95.3%	97.9% 91.1%	96.4% 93.2%		
D. 2 -bed	98.8%	92.1%	95.4%		
E. Studio	94.8%	93.0%	93.9%		
Overall	94.0% (88.8-98.8%)				

V. CONCLUSION

This study showed that BLE beacons can be used with a bracelet to accurately determine the room location of a participant and the time they spend out of the home. Data collection was conducted in real-world scenarios with over 31 days of data collected. Some limitations of the approach include that there were only 5 home layouts, and 7 separate data collections, that the diary record of location is subject to error, and that the location was assessed in 15-minute periods. Thus, more brief location occupancy would not be detected within the time interval, e.g., trips to the bathroom.

There was variation in the location agreement for the different home layouts, between the two sets of beacons and between participants. Somewhat surprisingly there was greater variability between the two beacon sets than between different home layouts. For example, in the 2-bedroom apartment (D) the highest location agreement with beacon setup 1 of 98.8% was observed but this reduced to 92.1% with beacon set-up 2. This may be because the bed was adjacent to the kitchen and positioning of one bedroom beacon away from the bed, led to the RSSI signal from the kitchen beacon sometimes being higher than that from the bedroom beacon.

In some experiments the rooms were open plan spaces, not physically separated by walls e.g.: home A had a single space containing kitchen and living areas. This led to errors in the location labelling of home A. Participant 1 recorded considerable time in the living while participant 2 did not record time there, explaining the difference in agreement for the 2 participants. Open plan spaces were not always problematic, with the studio apartment (E) showing good agreement despite there being no physical walls between the bedroom, kitchen and living. Overall, an improvement in agreement was observed when all rooms except the bedroom are combined (agreement increases from 94.0% to 96.2%).

VI. DISCUSSION

The use of BLE beacons to determine a participant's location while wearing an actigraphy bracelet can be achieved with good accuracy and a low burden to the participant. The information has the potential to transform how we look at activity data. The system is now being deployed in remote

clinical trials, with beacons and bracelet shipped to participants, and set-up over video link.

There remain technical improvements that can be made. While study participants can place their own beacons, clear instructions are important as the careful placement of the beacons can optimise the accuracy of location data. Furthermore, the addition of a calibration stage in which the participant spends time in key locations in their home to collect a reference signal during a few minutes at the start of data collection, could help improve accuracy. It is also worth considering when to combine open-plan rooms, using one beacon unless there is a compelling reason to try and differentiate the wearers' location precisely.

In further work, we are processing RSSI data using clustering with optional pre-calibration and integrating activity and location analysis to improve location accuracy.

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