Beat-to-Beat Intervals (BBI) Product Validation

February 2021

How is LifeQ Beat-to-Beat Intervals (BBI) validated?

LifeQ compares our BBI solution to the gold standard for BBI measurement, an electrocardiograph (ECG). LifeQ uses the Bitium Faros™ 180 ECG device as the reference device of choice.

This device is an ambulatory ECG device that is attached to the participant's chest through a 3-electrode single channel configuration. The BBI data obtained from both the LifeQ powered wrist-worn device and ECG reference device is analyzed statistically to assess the accuracy of the LifeQ HR solution.

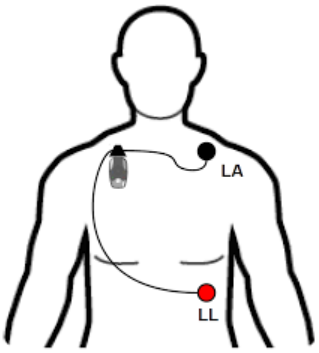


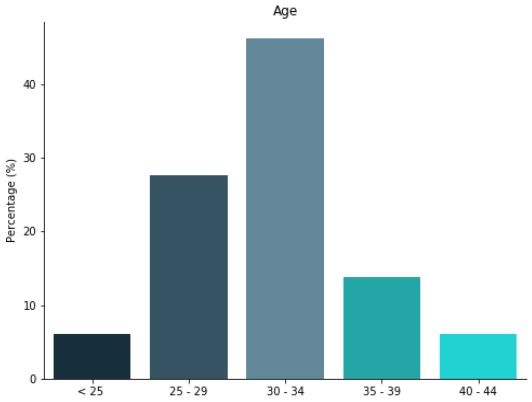
Figure 1: Placement of the Bittium Faros™ device.

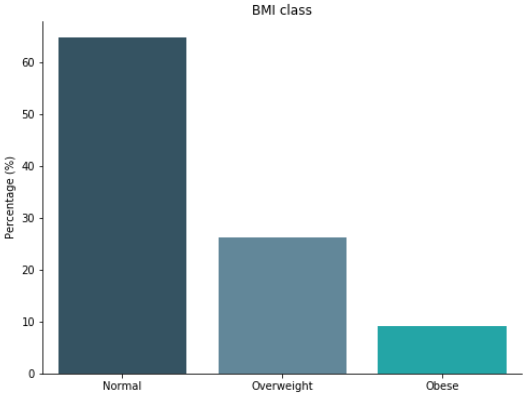
What testing Protocol does LifeQ follow?

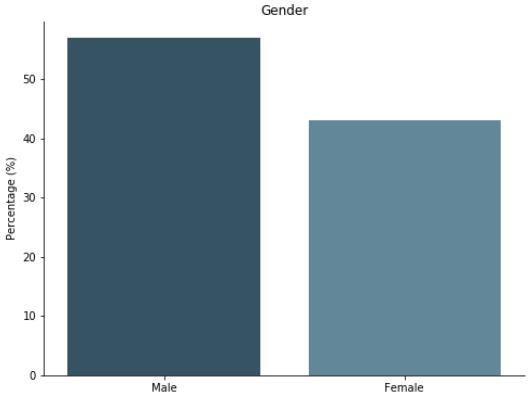
LifeQ uses both controlled (a 'free living' protocol) and uncontrolled (24-hour continuous monitoring) data to validate our continuous RR solution.

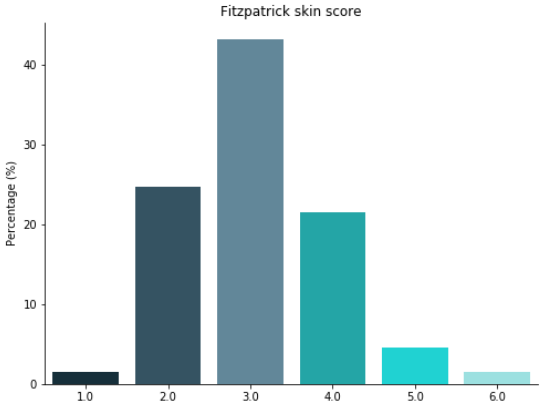
A wide range of participants are included to ensure we have varying age, ethnicity, gender and levels of physical fitness. A summary of the participants is shown below.

Controlled Setting: LifeQ Standard Free-Living Protocol

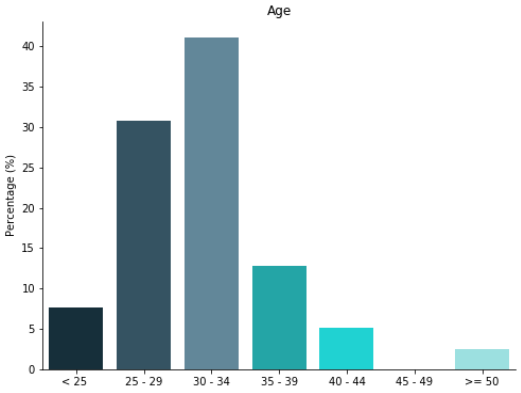


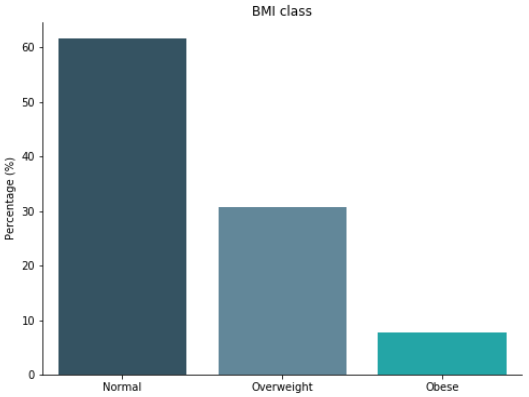


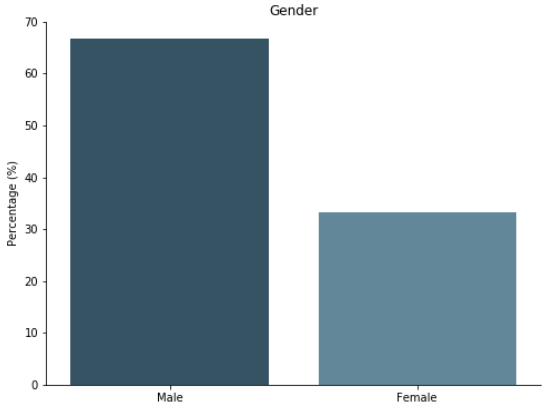


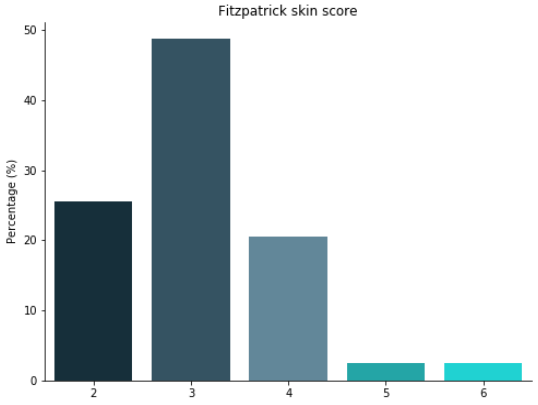


Uncontrolled Setting: 24-Hour Continuous Monitoring









Controlled Setting: LifeQ Standard Free-Living protocol

It is important to control as many variables as possible to ensure a consistent and replicable testing environment. The temperature of the testing room is maintained constant during all testing and participants are instructed to only talk if absolutely necessary, such as to raise concerns about safety or device movement during testing. The protocol starts with a verbal briefing with emphasis on keeping completely still during the designated rest periods and to not perform any unusual gestures with the hand that is fitted with a wrist-worn device.

The LifeQ Standard Free-Living protocol is designed to simulate low motion with limited wrist movement (similar to rest and sleep), low motion with lots of wrist motion (working at a desk) and higher motion such as walking and jogging to get a sense of how the solution would perform during normal periods when a user is awake and active.

LifeQ Free-Living Protocol

1. 5 minutes rest lying down
2. 2 minutes rest standing up
3. 2 minutes walking around (treadmill, 5 km/h)
4. 2 minutes rest sitting down
5. 2 minutes typing
6. 2 minutes rest sitting down
7. 2 minutes sorting
8. 5 minutes fast walk / slow jog (6 km/h)
9. 2 minutes rest standing up
10. 3 minutes slow cycle (60 rpm)
11. 3 minutes rest lying down

Uncontrolled: 24-hour Continuous Monitoring

This is a 24 hour data collection where the participants do not follow a specific protocol or set of instructions. The participant is fitted with a LifeQ-enabled wrist-worn device and the reference ECG device (Bitium Faros™ 180) for data collection. The participant is instructed to go about their normal routine and to annotate activities such as exercise and sleep times, while wearing the devices constantly.

Accuracy

Device-Based

The tables below show the best and worst range of expected performance of the LifeQ solution found on different devices and sensors. These results are based on tests with more than ten LifeQ-enabled commercially available devices using the LifeQ Free-Living protocol.

Table 1: The average error for all participants (including a range of skin colours) performing the LifeQ Free-Living protocol.

Device	# of participants	Mean Absolute Error (ms)	Standard deviation (ms)
All Devices - 24 hours*	144	17.17	42.35
All Devices - Sleep only*	144	10.64	26.87
All Devices - LQ BBI Protocol	214	20.97	40.51

*The 24-hour and sleep statistics has no predictable reproducibility for contractual purposes

Table 2: The distribution the average error for all participants who have completed either the 24 hour or LifeQ BBI protocol

Device	Coverage (%)	MAPE <=5 %	MAPE 5-10 %	MAPE 10-20 %	MAPE >20 %
All Devices - 24 hour	46	91.3	5.4	2.3	1.1
All Devices - Sleep	89	96.7	2.4	0.7	0.2
All Devices - LQ BBI Protocol	35	89.1	7.7	4.6	1.1

MAPE - Mean Absolute Percentage Error | Coverage (%) - The percentage of the data set, where LifeQ can calculate RR intervals. 50% in a 24 hour day equates to 12 hours of RR intervals in a day.
Coverage - Shows the amount of time that a "good enough" signal was available, which is governed by environmental conditions most importantly motion (if a person is moving the signal is excluded) and to a lesser extent temperature, device fit and participant perfusion).

Table 3: The distribution of error on a sample of no less than 20 random participants (including a range of skin colours) performing the LifeQ BBI protocol. The results for the best and worst performing LifeQ-enabled devices launched to date are shown.

(A)

Device	Mean Absolute Error (ms)	Standard deviation (ms)	Coverage % (when BBI is available)
Best Performing Device	12.5	33.0	36.0
Worst Performing Device	35.0	55.0	41.0

(B)

Device	Coverage (%)	MAPE <=5 %	MAPE 5-10 %	MAPE 10-20 %	MAPE >20 %
Best Performing Device	36	97	2	1	1
Worst Performing Device	41	71	21	6	2