PHILIPS

Patient monitoring

Biosensor BX100

Philips Biosensor BX100 respiration rate computation and validation summary

The Philips Biosensor BX100 is a single use chest-worn sensor that is intended to periodically collect, store, and transmit physiological data to a backend system for use by healthcare professionals. The physiological data measured by the biosensor includes respiration rate and heart rate. The BX100 is also intended to measure and wirelessly transmit contextual parameters such as activity level, activity type, and posture.

Philips Biosensor BX100

Respiration rate computation (RR and RR-SQI)

Respiration rate (RR) is computed from bio-impedance signals acquired from the device's two ECG electrodes. Thoracic movements during respiration cause chest wall movements that are translated to variations in the body's bio-impedance signal. The BX100 uses two ECG short-lead electrodes to spot changes in bio-impedance signal which represent respiration activity. The BX100 is carefully designed to optimize the signal-to-noise ratio of the impedance waveform. The RR estimation model used in the BX100 is fine-tuned for wearable application.

Each minute, the Biosensor BX100 counts the waveform cycles to calculate the respiration rate, and the associated respiration rate-signal quality index (RR-SQI). RR-SQI describes the quality of the signal used to calculate that minute's respiration rate. Only values with a valid signal quality are transmitted to the backend system.

Respiration rate validation study

A clinical study was conducted to validate the ability of the Biosensor BX100 to accurately measure respiration rate when subjects are stationary.

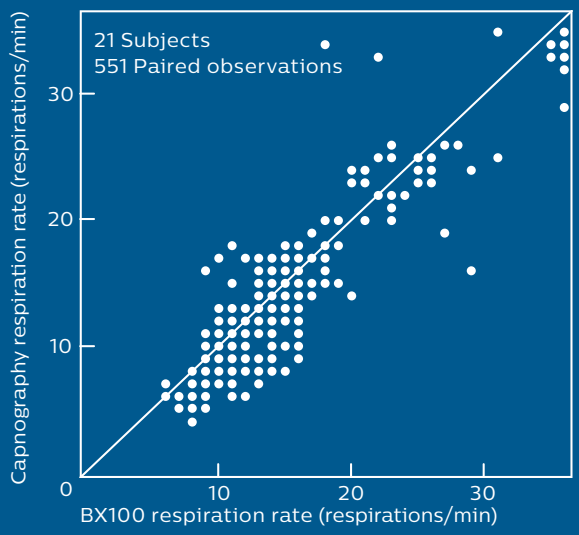
The study enrolled 24 healthy normal volunteers, 18 years of age or older. Enrollment was targeted to a mix of approximately 50% male and 50% female participants.

The Philips Respironics NM3 Respiratory Profile Monitor with nasal cannula was used as a reference device. Subjects were asked to complete a series of controlled breathing activities (breathing at a metronome rate for a predetermined period of time) to ensure the full range of respiration rates was captured. Subsequently, subjects were asked to "sit quietly" for fifteen minutes; the data from this period was used to capture their spontaneous respiration rate. The analysis was conducted across the entire period.

Twenty-one subjects were included in the final analysis, which showed that 90% of valid BX100 measurements were within ±3 rpm of capnography. The mean absolute error was 1.3 respirations per minute.

The overall results indicate that the Philips Biosensor BX100 is a reliable method of measuring respiration rate.

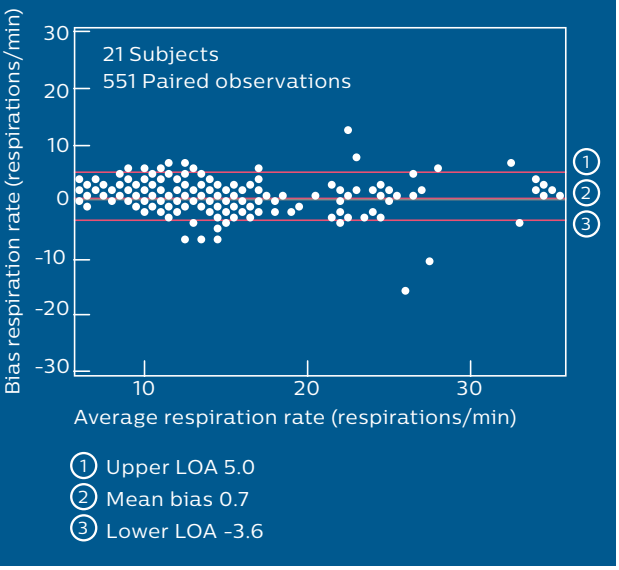
Figure 1: Scatter plot with reference line (Philips Biosensor BX100 and capnography)



	21 subjects paired observation N=551
Proportion of BX100 RR valid measurements within ±3 rpm of the reference device	90%
Absolute error of BX100 RR measurements as compared to reference device	1.3 respirations/minute (SD = 2.3)

Table 1: Respiration rate validation results

Figure 2 Bland-Altman figure with bias and limits (BX100 – capnography)



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