CARDIOSENSE

PCWP Analysis Software™

Instructions For Use

Overview

This instructions for use is intended as a guide for trained healthcare professionals for safe and effective use of the PCWP Analysis Software. It is important to read and understand the information in this document before operating the software, including cautions.

Indications For Use

PCWP Analysis Software is intended to noninvasively provide a pulmonary capillary wedge pressure (PCWP) estimate and to assess if the PCWP is above or below 18mmHg. The PCWP Analysis Software is indicated for adult patients diagnosed with heart failure with reduced ejection fraction (HFrEF), a Left Ventricle Ejection Fraction (LVEF) ≤ 40%, and New York Heart Association (NYHA) Functional Class II, III, IV symptoms.

The hemodynamic data will be used by qualified healthcare professionals in conjunction with other standard of care parameters to evaluate heart failure patients.

The results of PCWP Analysis Software are intended to be used under the supervision of a qualified healthcare professional in conjunction with the patient's clinical history, symptoms, and other diagnostic tests, as well as the qualified healthcare professional's judgment. Patient management decisions should not be made solely on the results of the PCWP Analysis Software. The device is only for prescription use.

Device Description & Clinical Benefits

PCWP Analysis Software is a standalone software as a medical device (SaMD) capable of estimating pulmonary capillary wedge pressure (PCWP) from non-invasively measured time-synchronized signals such as electrocardiogram (ECG), seismocardiogram (SCG), and photoplethysmogram (PPG). It is also capable of identifying patients with PCWP < 18 mmHg or ≥ 18mmHg. The SaMD is meant to provide access to estimates of PCWP without the need for an invasive catheter, thus providing adjunctive information to the qualified healthcare professionals that can be used to assist in the management of patients with heart failure with reduced ejection fraction (HFrEF).

NOTE: The output is not a diagnosis; it is only a potential finding to aid healthcare providers in decision-making and should be used in parallel to traditional diagnostic tests**.**

NOTE: The PCWP Analysis Software is not intended for pediatric use, patients who do not have a known diagnosis of LVEF ≤40%, patients who do not have NYHA class II-IV symptoms.

Technical Specification

To generate an output, the software receives input signals (e.g. ECG, PPG, SCG) and patient biological sex. The software will perform a signal quality check on the input data, and will return an error message if the signals are low quality or if too much motion is detected. Otherwise, the software uses the input data to estimate PCWP using an AI/ML algorithm. The PCWP Analysis Software can accept cardiac signals generated by the validated CardioTag device.

Device Usage

The PCWP Analysis Software is intended to be a tool to be used alongside current standards of care. **The PCWP Analysis Software is not intended to be used solely in clinical decision-making; rather, it is to be used as an adjunctive aid for healthcare providers when making their clinical decisions.** Data analysis and interpretation is restricted to qualified medical professionals.

To generate a PCWP estimate, high-quality signals with low motion artifacts must be provided. The PCWP Analysis Software will assess signal quality on the input signals and will determine the amount of motion. If a data recording has poor input signal quality or too much motion is detected, the software will not analyze the input data recording, and will return an error message.

The software provides a PCWP classification and a PCWP value with the following specifications:

- PCWP Classification
  - Output: <18 mmHg or ≥18 mmHg
- PCWP Value:
  - Output: Estimated PCWP in mmHg
  - Operational Range: 4 mmHg to 42 mmHg

An example of the device output and a sample report is provided below:

Cardiac Assessment:

Heart Rate (HR): 78 bpm

Pulmonary Capillary Wedge Pressure (PCWP): 11 mmHg (Non-Elevated)

Comment:
Non-Elevated: PCWP < 18 mmHg
Elevated: PCWP >= 18mmHg

This assessment is only intended for use for patients with Heart Failure with Reduced Ejection Fraction. Use in conjunction with standard of care to make patient management decisions.

Cautions

- This tool should be used under the supervision of a trained medical professional for clinical decision-making.
- Any estimated value should be used in context with individual patient clinical symptoms, medical condition and physical findings.

Cardiosense makes no warranty for any data or information that is collected erroneously, or misuse or malfunction as a result of misuse or failure to maintain the software as instructed in this document.

Troubleshooting

If difficulties in operating the product are experienced, refer to the quick troubleshooting guide below or, for further assistance, contact technical support. Additionally Cardiosense will provide assistance as needed to ensure cybersecurity measures are in place for further assistance, contact technical support.

Problem: A Poor Signal Quality error occurs	**Solution** Ensure that the input sensor placement is correct, and the individual remains as still as possible during the recording. Repeat the input device recording and try the PCWP Analysis Software again using the new recording. If the issue persists, contact the support team.
Problem: An error other than poor signal quality occurs	**Solution** Repeat the input device recording and try again to see if the problem persists. If the problem persists, contact the support team.

Contact Information

For additional support, contact Cardiosense support at support@cardiosense.com.

Performance

Performance of the PCWP Analysis Software classifier output indicating elevated PCWP (≥18mmHg) was tested against a reference Swan-Ganz PCWP and was found to be comparable, with a sensitivity of 78% [95% CI: 65%-87%] and specificity of 80% [95% CI: 70%-88%]. The PCWP Analysis Software demonstrated a positive predictive value of 73% [95% CI: 60%-83%] and a negative predictive value of 84% [95% CI: 74%-91%]. When compared to the reference Swan-Ganz PCWP, the PCWP Analysis Software's estimated PCWP value demonstrated a comparable accuracy.

While the PCWP Analysis Software was found to have comparable accuracy, there will be variability with the output. Healthcare professionals must consider this variability when interpreting results and making clinical decisions. Importantly, when the output pressure is further from the center point of 18mmHg, there is greater confidence regarding whether the output is truly above or below 18mmHg. For instance, an output of 12 mmHg would have an approximately 90% confidence of being below 18 mmHg, and a 15 mmHg output would have an approximately 70% confidence of being below 18 mmHg. The PCWP Analysis Software output is intended only as an adjunctive aid and should not be the sole basis for patient management decisions. Particular caution is advised for outputs near the "wet" and "dry" threshold (e.g., between 16-20 mmHg).

In the validation study, 119 subjects with PCWP values between 6-25 mmHg measured by Swan-Ganz catheter underwent PCWP assessment using the Cardiosense Software. The PCWP values obtained from each method were averaged and compared. The mean difference ± standard deviation between the two methods (Swan-Ganz vs. Cardiosense) was 0.50 ± 4.74 mmHg. The Limits of Agreement (LOA) between the two methods ranged from -8.79 to +9.79 mmHg [95% CI: -10.01 to -7.56 mmHg for lower LoA; 95% CI: 8.57 to 11.02 mmHg for upper LoA] (see Figure 1).

Therefore, when using the Cardiosense device, it is expected that 95% of measurements will fall within approximately 8.8 mmHg below to 9.8 mmHg above the corresponding Swan-Ganz measurement.

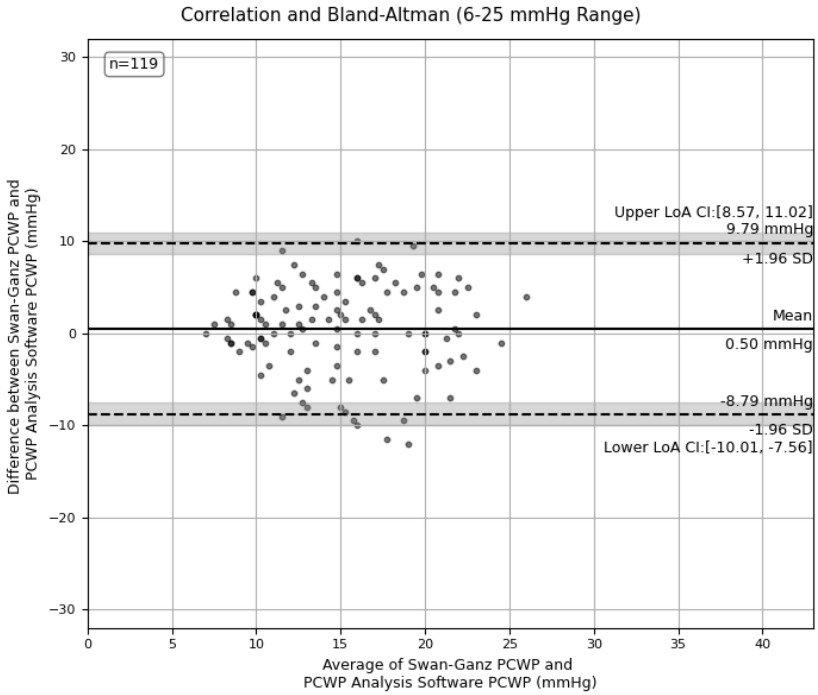

Figure 1. Bland-Altman plot showing agreement between the PCWP Analysis Software PCWP and the gold-standard Swan-Ganz PCWP for subjects with a Swan-Ganz PCWP in the clinically relevant range of 6-25 mmHg.

Symbols

The following symbols apply to the PCWP Analysis Software:

	Read instructions before use	UDI	Unique Device Identifier
	Manufacturer	**Rx Only**	For prescription use only
MD	Medical Device		

Legal

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