



APPENDIX B: SUMMARY OF LABELING AND SUPPLEMENTAL INFORMATION RELATED TO CARDIOMEMS™ PA SENSOR OPERATION

SENSOR OPERATION

- The CardioMEMS™ Hospital Electronics System Instructions for Use include the following Guidelines for Management of Hemodynamic Parameters:

The PA pressure readings should be used in addition to weights, signs and symptoms, laboratory values and other traditional markers of volume in the management of heart failure. It is important to review the trend of PA pressures. As with all other diagnostic information physicians should consider the entire medical history of each patient when initiating or modifying therapies.

- The System Instructions for Use note that “The mean pressure measurement accuracy of the system may be affected by various factors.” Additional detail includes:
 - Sensor Instructions for Use:
 - An accurate right heart catheterization is required to set system baseline (mean pressure).
 - Mean pressure measurement error has been observed when the sensor was deployed in a vessel which had an inner diameter of less than 7 mm, and in cases where there was an acute bend in the vessel of >30 degrees at the location of the sensor.
 - Accuracy of the CardioMEMS HF System is slightly affected by large changes in elevation between the initial baseline calibration and subsequent measurements. (+2 mmHg/305 meters elevation change).
 - Accuracy of the CardioMEMS™ HF System is affected by a change in body temperature (-1 mm Hg/Δ°C).
 - Signs of mean pressure measurement error include the following: (1) Gradual mean pressure changes without a corresponding proportional change in the pulse pressure (systolic-diastolic pressure) and (2) Negative mean pressures. If either feature is observed, temporarily suspend use of the pressure information for management of the patient and contact Technical Support for further assistance. A right heart catheterization may be needed to recalibrate the Baseline (mean pressure) in order to continue use of the system.
 - Hospital Electronics Systems and Patient Electronics System Instructions for Use
 - Accuracy (under typical environmental conditions): +/- 2 mmHg at baseline and +/-3% of difference between measured pressure and baseline.
 - System Accuracy: +/-4 mmHg over the range of environmental conditions.
 - Hospital Electronics Systems Instructions for Use
 - There are minimum amplitudes for the system to measure physiological signals. Operation of the equipment below the minimum amplitudes may cause inaccurate results.
 - All sensors have a unique calibration. Ensure you enter the correct sensor serial number and calibration code for each patient. Use of the incorrect calibration code information may result in an inaccurate baseline calibration and readings.
 - The serial number on the antenna and on the console must match to ensure accurate measurements.
 - A pulmonary artery or Swan-Ganz™ catheter is used to calibrate the sensor. For an accurate sensor measurement, it is important to set up the pulmonary artery or Swan-Ganz™ catheter properly.

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- Abbott is reinforcing existing labeling and providing supplemental information in this Field Notification:
 - Environmental and Operating Conditions:
 - When readings are taken above ~2,000 feet (610 meters) above sea level, operation outside of the intended radiofrequency range has the potential to result in inaccurate readings or sensor signal acquisition difficulties.
 - Not all sensors interrogated at these elevations will operate outside the intended radiofrequency range.
 - While an increase in measurement inaccuracy is possible at elevations ~2,000 feet above sea level, testing has demonstrated that when readings are taken under consistent conditions (elevation, atmospheric, etc.), readings are stable and repeatable within 3.3 mmHg.
 - Sensor implant procedure:
 - Setup of patient and sensor information in the Hospital System should be done BEFORE venipuncture and right heart catheterization during a sensor implant procedure. Sensor information includes the sensor's calibration code.
 - Reviewing Pulmonary Artery (PA) Pressure Readings:
 - **Pulmonary Artery Pressure Readings** should be used in addition to weights, signs and symptoms, laboratory values and other traditional markers of volume in the management of heart failure. It is important to review the trend of PA pressures. As with all other diagnostic information, physicians should consider the entire medical history of each patient when initiating or modifying therapies.
 - **Pulmonary Artery Pressure (PAP) Changes** should be further reviewed if the pressure changes are significantly different from expected values.
 - Pressure Changes can occur due to multiple reasons, including: elevation changes, large weather changes, and physiologic PA pressure changes (e.g., PA pressure optimization). All contribute to the total pressure change and may cause operation above 37.5 MHz in some sensors.
 - If readings appear inconsistent with prior pressure trends, the health care provider should consider whether the patient is or was at a significantly different elevation than where readings are typically taken.
 - Contact Technical support for unexpected variation in PAP readings at elevations above 2000 feet.
 - Review the current CardioMEMS System Precautions and Warnings for more information on evaluation of PA pressures.
 - When inaccurate readings are suspected, it is important to evaluate all available information prior to making treatment decisions. If inaccurate readings are suspected, you may request additional insight by contacting Technical Support.

Note: Instructions For Use are available to physicians on the Abbott CardioMEMS™ HF System website under Manuals & Technical Resources. [CardioMEMS HF System Manuals & Technical Resources | Abbott \(https://www.cardiovascular.abbott/int/en/home.html\)](https://www.cardiovascular.abbott/int/en/home.html)