



APPENDIX A: CARDIOMEMS™ PA SENSOR SETUP AND RESPONSE TO ERROR #8 MESSAGES

Please retain the following **important** information with the CardioMEMS™ Hospital Systems (Models CM3000).

Abbott recommends healthcare facilities ensure all personnel who are preparing the CardioMEMS PA Monitoring Sensor (Model CM2000) for implant are trained to these instructions, which supplement the Instructions for Use.

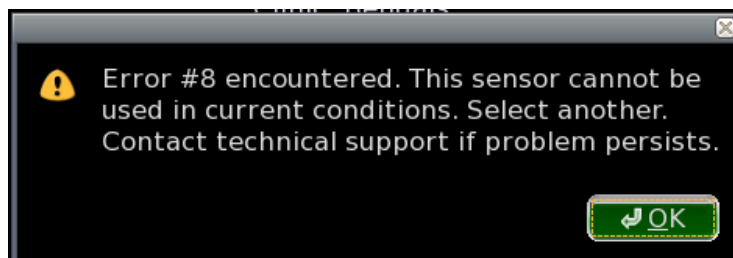
OVERVIEW

CardioMEMS™ Hospital Electronics System Model CM3000 with software version I2.2018.1105-r8829 includes an important software feature to identify CardioMEMS PA Sensors that are likely to operate above the intended radiofrequency range (between 30 and 37.5 MHz) as a result of internal sensor characteristics and current atmospheric conditions **pre-implant**. This software feature and the appropriate setup process is described below.

It is important to enter the data for CardioMEMS™ PA Sensors into the Hospital System prior to venipuncture during a sensor implant procedure.

PROCESS FOR CARDIOMEMS HOSPITAL ELECTRONICS SYSTEM MODEL CM3000 (software version I2.2018.1105-r8829)

- Initiate a new implant session.
- Sensor and patient setup must be done on the Hospital System **prior to venipuncture and right heart catheterization** during a sensor implant procedure.
 - Setup consists of selecting the patient or entering patient name and Date of Birth, entering the Sensor Serial Number and calibration code and selecting “OK.”
 - A screen will display, asking “Is this information correct”? If yes is selected, the software process to evaluate the sensor is executed.
- If the sensor is not compatible with the current environmental conditions (i.e., the sensor may operate outside of the intended frequency range of 30 to 37.5 MHz), Error #8 will be displayed at this time.



- If an Error #8 message occurs, the sensor is not compatible with the environmental pressure conditions and **should not be implanted**. Users must **select and set up another sensor** in order to complete the implant procedure.
- Once the Error #8 message is acknowledged by selecting “OK,” the user is returned to the main system screen.
- Repeat patient and sensor information entry **prior to venipuncture and right heart catheterization**, using the **new sensor** serial number and calibration code
- Proceed to the next screen by selecting “Yes” on the “Is this information correct?” screen. This will restart the process as detailed above.

If assistance is needed with entering a new sensor, please contact Technical Support or your Abbott representative.