

Virtual Case for IMDRF Adverse Event Terminology Training

Case serial: SCH-2023-01-03

Title: Anesthesia Deepness Brain Monitoring (ABDM) system & ABDM electrode sensor

Patient Condition

- An 80-year-old female patient with acute cholangitis.
- The patient was in preparation for general anesthesia.

Events

- Before starting general anesthesia, the ADBM electrode sensor (the sensor) was applied to the patient's forehead.
- The ADBM system failed to display the EEG signal on its monitor.
- The nurse confirmed that the expiration date of the sensor had not passed.

Select the most appropriate IMDRF code for the above description.	
Annex A. Medical Device Problem	Annex G. Medical Device Component

Post-event management & Health effects

- The electrode sensor was replaced with another sensor of the same lot and it worked properly.
- Nurses are experiencing frequent sensor detection errors, especially in older patients. They assume that the skin condition may have an impact, so particular attention is paid when attaching the sensor to elderly patients.

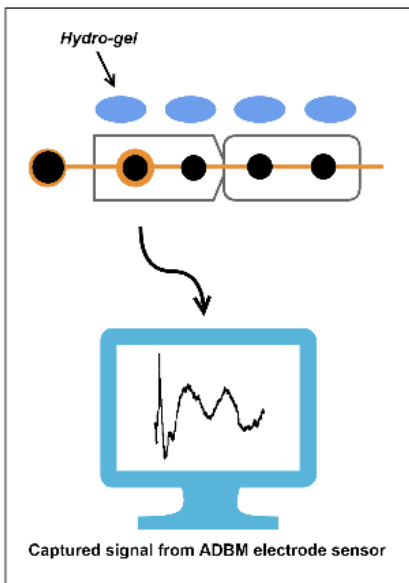
Select the most appropriate IMDRF code for the above description.	
Annex E. Clinical Signs and Symptoms	Annex F. Health Impact

Investigation (Cause, Improvements)

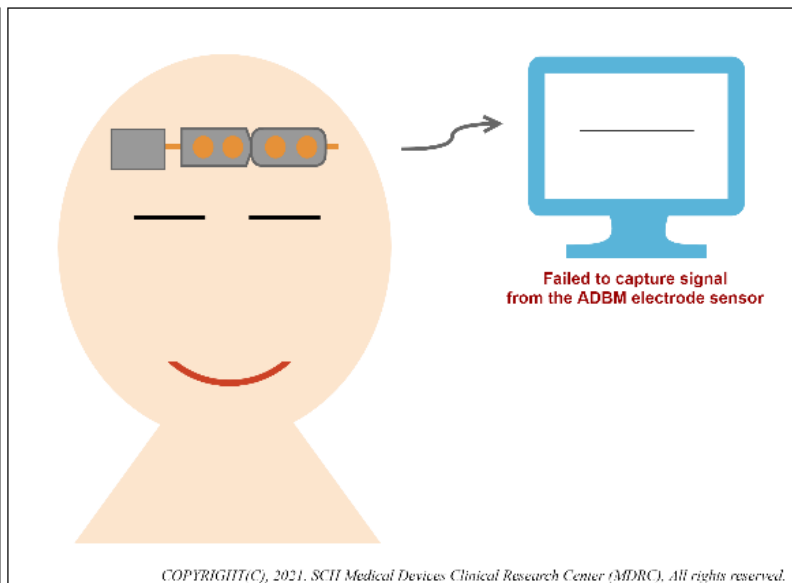
- The quality manager of the manufacturer received the problematic sensor from the user.
- When the problematic sensor was tested by connecting it to an ADBM system by the manufacturer, the system detected the signal normally.
- The quality manager checked the hydro-gel status of other products in the same lot and found that it conformed to the manufacturer's manufacturing standards.

Select the most appropriate IMDRF code for the above description.		
Annex B. Type of Investigation	Annex C. Investigation Findings	Annex D. Investigation Conclusion

Image



Schematic diagram of ADBM system and ADBM electrode sensor



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Schematic diagram of the event