Xeridiem Proactive with Connection Standard for Improved Medical Devices

Xeridiem actively working on new connection designs to improve patient care and prevent misconnections with enteral feeding devices.

July 2010, the Food and Drug Administration (FDA) issued a guidance document intended to prevent misconnections in the hospital environment. The guidance document outlines product requirements for tube-based delivery systems so they aren't accidentally misconnected. Xeridiem is actively working on connector designs to meet product requirements and prevent misconnections.

Hospitalized patients could have a wide variety of tube-based systems designed to deliver therapy, pharmaceuticals, nutrition, fluids, gases or blood to various organs. Many of the tubes are inter-connectable and mistakes happen, some with serious outcomes. For example, if an intravenous solution is mistakenly connected to an air intake tube the misconnection could result in patient injury or in extreme instances, death.

The FDA guidance follows the conformity standard of the International Standards Organization (ISO) 80369-1:2010; Small-bore connectors for liquids and gases in healthcare applications, which provides directive for the connections design. ISO is working with manufacturers worldwide to develop specific designs to insure devices for different physiological functions can't connect. The complete guidance standard is expected to go into effect January 1, 2015.

Xeridiem is working with customers to improve patient safety by proactively incorporating the new enteral feeding requirements into designs and products. The objective is to have ISO standard compliant connectors on all enteral feeding devices prior to the guidance deadline. Early collaboration will provide a smooth and effective transition to the new connections standard. Patients will also benefit from the early distribution of new enteral feeding devices into hospitals, nursing homes, and patients worldwide by preventing disruption of patient care as manufactures change the device connections simultaneously.

About Xeridiem
Xeridiem designs, develops, and manufactures single-use medical devices focused in gastroenterology, cardiology, and urology for established healthcare companies and venture-backed entrepreneurs. Services comprise full design and development including risk management, design history files, technical files, verification/validation testing, regulatory and supply chain management. Since 1986, as a silent partner, Xeridiem has enabled major medical device companies and venture-backed entrepreneurs to deliver over 22 million medical devices used worldwide and intended to reduce cost of patient care.

In recognition of design and development capabilities, Xeridiem was awarded the Medical Device Excellence Award in General Surgical Equipment and the R&D 100 for Life Sciences in 2011. ISO 13485:2003 certified, FDA registered and compliant to Code of Federal Regulations 21 Part 820.

Source URL (retrieved on *03/10/2014 - 3:31pm*):
http://www.mdtmag.com/news/2012/11/xeridiem-proactive-connection-standard-improved-medical-devices