



**U.S. Food and Drug Administration (FDA)
Center for Devices and Radiological Health (CDRH)
Patient Engagement Advisory Committee (PEAC) Meeting
Virtual**

FDA DISCUSSION QUESTIONS

July 12-13, 2022

Augmented reality (AR) and virtual reality (VR) medical devices have promise to improve patient outcomes and access to care. AR/VR devices rely on a variety of technical considerations related to how the information and data are presented to the user, sensing and feedback capabilities, and specific network and infrastructure requirements (e.g., internet, physical environment) for optimum performance.

1. AR devices are used to display navigational information as an adjunct to standard surgical procedures and provide information such as computer-generated, anatomical images to help guide surgical procedures. Other uses of AR devices include presurgical planning and surgical training and education. The role of AR devices across various types of surgical procedures is currently evolving, as the related benefits and risks of these devices are more clearly understood. While data from AR devices may benefit patients, such as through improving surgical accuracy, reliance on AR may produce new risks due to the interaction between real and virtual information. To use the AR device appropriately, users should have accurate information regarding the benefits and risks of these devices. Future research is needed to assess surgical outcomes related to use of these devices, and surgeons may need specific training on how to optimize the use of this technology.
 - a. What information would you want your surgeon to share with you during the informed consent process prior to a surgery that will involve an AR device?
 - b. What would assure you that the surgeon is appropriately trained to use a specific AR device?

2. VR devices may be prescribed by doctors for patients to use at home for diagnostic and treatment purposes. These devices may have different benefits such as helping to reduce pain and anxiety and involve a risk of side effects like nausea and dizziness. These devices are generally meant to be used for specific time periods as part of a care plan and to reduce the risk of experiencing side effects. There may also be additional information that is critical to the use of the device, including information about internet requirements, physical environment, etc. What information should be available to the patient or caregiver prior to use, for example, in an onboarding tutorial through the device itself, in addition to the device labeling to help patients and caregivers safely and effectively use these devices at home?



AR/VR medical devices may improve the diagnosis and treatment of various medical conditions in children and in people living with cognitive and mental health conditions. To safely and effectively use AR/VR technology, the user should be familiar with how to use the technology and have the appropriate strength, motor, mental, and sensory capabilities. In the pediatric population, AR/VR devices may have unknown and unanticipated long-term effects on mental health and neurological development.

3. Some AR/VR medical devices are developed specifically for a medical purpose, meaning the headset hardware is regulated by FDA. However, some AR/VR medical devices use headsets that are consumer products that are generally marketed for people over the age of 13. During FDA review of the AR/VR medical device, FDA may assess the impact of the consumer product hardware on the safety and effectiveness of the medical device. What factors do you believe FDA should consider when an AR/VR medical device for children under 13 relies on consumer product hardware intended for individuals over the age of 13 (e.g., equipment sizing, useability)?
4. The long-term effects of using the AR/VR devices, including how long they can be used safely in an individual session and over what timeframe the devices should be used, may not be well known for certain patient groups and for certain medical conditions. To assure timely access to safe and effective technology and facilitate medical device innovation, FDA balances the amount of information collected before the device can be marketed with the information that could be collected after the device is on the US market. Typically for longer studies, patients may stop participating in the study (i.e. loss of follow up or missing data) that may impact the quality of the long term studies.
 - a. Balancing the public interest for long term data and study quality, what factors should FDA use to determine the duration of a clinical study for AR/VR devices used in the treatment of cognitively impaired persons and children?
 - b. In addition to safety and effectiveness data, what information would be helpful to patients and caregivers to help inform their decision to use an AR/VR device after a device is on the US market and when it is used in children and people who are cognitively impaired?



Patient and providers need information on the benefits and risks as well as how to appropriately use AR/VR devices whether used at home or in a clinical setting by providers. To ensure that patients and providers are able to use AR/VR medical devices as intended, the FDA and industry have a variety of communication mechanisms. Some examples of FDA's current communication tools for medical devices include safety communications, website updates, social media posts, and FDA press announcements.

5. Information about the side effects, intended use and instructions for use of the AR/VR devices is available in the device labeling.
 - a. What other methods should FDA, industry, and other stakeholders, like patient groups and healthcare professional organizations, consider when communicating to patients the intended use of AR/VR medical devices?
 - b. How should FDA communicate risks to caregivers of vulnerable patients (someone who may not be wearing the device and is not the intended user) but who may be tasked with supporting in-home device use as part of a care plan beyond the product labeling?
 - c. How should FDA and industry inform patients about effective usage of AR/VR devices in communities where internet access and other connectivity issues may impact use?
 - d. As we learn more about the impacts of AR/VR devices over time, what approaches should FDA and industry use to share with patients any added benefits and/or changes in performance?

6. Manufacturers, device user facilities, and importers are required to submit to the FDA certain types of reports for adverse events and product problems about medical devices. FDA encourages health care professionals, patients, caregivers, and consumers to submit voluntary reports about serious adverse events that may be associated with a medical device, as well as use errors, product quality issues, and therapeutic failures, but such reporting is not required. How should the FDA communicate about how or where to report issues with AR/VR medical device systems, including when there are issues with the consumer product headset?