

AUGMENTED REALITY & VIRTUAL REALITY 7 IN MEDICAL DEVICES

Questions to Consider When Talking to Your Health Care Professional About Using Augmented Reality and Virtual Reality in Your Care

Medical extended reality (XR), which includes Augmented Reality (AR) and Virtual Reality (VR), has the potential to improve your health care. Medical XR devices deliver new types of treatments and tools for diagnosis and are changing how and where health care is delivered.

As information on the benefits, risks, and long-term effects of medical XR continues to be studied, the FDA recommends reviewing the device labeling and talking through these questions with your health care professional when considering possible use of XR technology in your care.



1 Is there clinical evidence for using XR in health care?

- ➔ The FDA has published a list of XR devices that incorporate AR or VR and that have been authorized for marketing based on data and information to demonstrate their safety and effectiveness.
- ➔ Ask your health care professional why they recommend one method over another.

2 Are there benefits to using XR?

- ➔ XR devices may be more portable, convenient, and accessible.
- ➔ XR devices may help increase patient compliance and adherence to therapy.
- ➔ XR may provide benefits for training health care professionals.

3 Who can use XR?

- ➔ XR devices may be used by health care professionals, and some XR types may be appropriate for use by patients.
- ➔ Medical XR devices may be different in size and weight and may not be comfortable for all body types or used in a specific position such as while seated or lying down.
- ➔ The risks and long-term effects of AR/VR on children are unknown and are still being studied.
- ➔ Treatments other than XR may be a better fit for some patients, especially children. As with any medical device, XR may not be effective in certain situations.
- ➔ Use by anyone other than the patient or health care professional (for example, untrained professionals or untrained family members) may present unknown risks and could adversely impact patient treatment.

4 What is my health care professional's experience with using XR?

- ➔ Each health care professional may have different experience or training in AR/VR. Talk to your health care professional about the benefits, risks, potential side effects, restrictions, and their comfort level and experience using AR/VR devices.

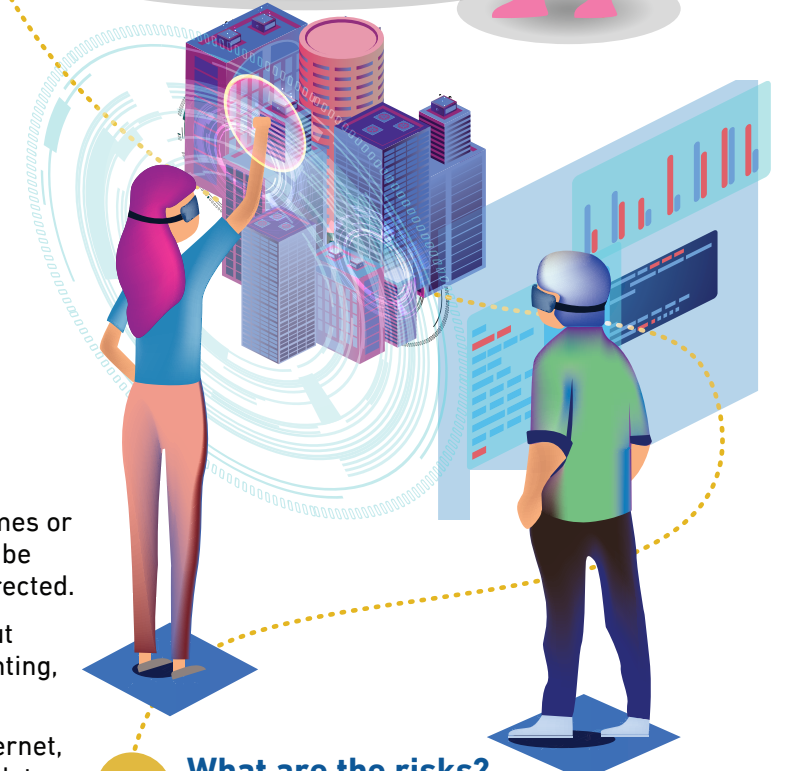


5 What is needed to use XR safely and effectively?

- ➔ Medical XR devices are not games or toys. They have been shown to be effective only when used as directed.
- ➔ XR works best in places without items in the way, with good lighting, and without background noise.
- ➔ XR may require high speed internet, charging, ongoing software updates, or physical changes. Otherwise, the device may not work or may not work as intended, or may need to be fixed.

6 How can I be sure XR is helping me?

- ➔ The time it takes to benefit from an XR treatment may vary. Do not increase or decrease use without talking to your health care professional.



7 What are the risks?

- ➔ It is important to use XR devices as prescribed or directed. Too much or too little use may result in harm or make the technology less effective.
- ➔ Health risks may include, but are not limited to headaches, neck pain, eye strain, motion sickness, and fatigue.
- ➔ Some users of XR devices may notice a change in the effectiveness of treatment over time or experience feelings like restlessness or anxiousness when not using the device.
- ➔ If you experience any harm from the device, you should report it to the FDA's Medical Device Reporting tool, MedWatch.
- ➔ XR devices may collect data that is personal and private in nature. Types of information gathered may include, but are not limited to, location, and data about the user and their medical conditions. Check the labeling on privacy risks and ask your health care team for resources on how your data and privacy are protected.

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