Health Technology Review	
Technology Ref.:	HTA21059
Technology Name:	RemMed
Approvals by International Bodies:	FDA 510k exempt, CE class 1
Company name:	RemMed VR
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Short Description of the Technology:	It's a telemedicine vision therapy service using virtual reality technology to treat the vision disorder – Amblyopia. RemmedVR training is performed using a telemedical system consisting of head mounted display (HMD) headsets with a pre-installed training app, hand-held controller, and a tablet with a Parental Control Dashboard. The solution aids in the treatment of eye issues in children with a daily exercise of few minutes, enabling doctors to supervise VR vision therapy and treat children suffering from visual impairments.

Health Technology Assessment Team Recommendation:	**Approved for Testing / Pilot Phase**

Summary of Review:

RemMed is virtual reality-based treatment for children with the visual disorder amblyopia, or lazy eye, offer an innovative interactive solution especially for these kids. Usually the conventional treatments for amblyopia include using a corrective eyeglass, contact lenses, eyepatches, Bangerter filter, blurring eye drops and surgery. We believe that utilizing VR in treating lazy eyes will be a useful therapeutic option for achieving a successful visual rehabilitation in amblyopic patients. The technology is new and not yet introduced in UAE. It has been used in Europe. The applicant intended to launch a pilot phase to prove the efficacy of this product.

Advantages	Disadvantages
Accessibility/Flexibility: The patient could utilize this technology in the comfort of his/her house or office.	The promising results of VR-based training in amblyopia should be confirmed in more studies, including randomised clinical trials
Attractive tool that promotes treatment compliance: Interactive Tool that could be helpful and appealing for younger ages in comparison to the conventional methods (example: eye patch)	Further investigations required to ensure the safety of utilizing the VR technology on the long term
Customization digital therapeutic Tool & the	Lack of international & local cost effectiveness

ability for management content (Parental Control Dashboard)	study
Efficacy: Available studies show the effect of utilizing VR in the treatment plan for amblyopia, or lazy eye.	The device is not yet approved by FDA, there is similar technology approved; Luminopia One.

We recommend an **approval for Testing / Pilot Phase for this technology the** following conditions:

1. Approval for Testing / Pilot Phase to conduct (PoC) trial to evaluate the efficiency & benefits of VR-based training in amblyopia over conventional approaches.
2. The compliance with Abu Dhabi Healthcare Information Security committee approval for the period between (19/01/2022 till 18/07/2022)
3. Obtain Abu Dhabi Health Research and Technology Ethics Committee approval in case the conducting PoC will involve a human subject
4. Establishing a proper quality monitoring process and reporting of any adverse events or unwarranted consequences including safety issues of employees and Patients
5. Provision of regular updates and reports about the product to DOH upon request.
6. Any other documents or information requested regarding the product and cost to finalize the approval process.

Moreover, DOH has the right to stop the product at any stage if deemed necessary, initial conditions and any subsequent conditions must be satisfied before obtaining final approval. Failure to do so will reflect in provoking the approval.

Technology Image

Population, setting and intended user for Technology "RemMed"

- **Population/ Intended User**;
  - Home Vision therapy for children (over 4 years old) with the visual disorder amblyopia, or lazy eye.
- **To be performed by**:
  - To be prescribed by ophthalmologist, optometrist, or orthoptist
- **Clinical Setting:**
  - Not require a clinical setting, its Home Vision therapy
- **Condition of use:**
  - To comply with the manufacturer terms of use
- **Exclusion criteria:**
  - Any other vision disorder, lack of the availability of virtual reality technology requirement.
  - Contraindications for the use
    - Epilepsy or lowered seizure threshold,
    - anxiety,