











Intended use of **Kinesix VR**: To favour motor and/or cognitive functions on impaired human patients through functional and immersive training in virtual reality, allowing progression and results follow-up during the training process.

Intended users of **Kinesix VR**:


- Adult and adolescent patients with motor and/or cognitive impairment.
- Healthcare professionals and qualified caregivers

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	<p>Medical device manufactured in Canada. Publication date: 2023-10</p>
	<p>Medical device software.</p>
	<p>(01)NYYYYYYYYYXXC(20)nn(8012)vvvvvv</p>
	<p>Read the instructions for use before using this product.</p>
	<p>Kinesix VR</p>

	<p>Kinesix VR</p>
	<p>Precautions and warnings</p> <ul style="list-style-type: none"> ● If the device label is not correctly visualized, please notify the manufacturer immediately and do not use the device until indicated by NeuroGroup XR Inc. ● The medical device software Kinesix VR has been validated for its use in combination with mobile and tablet platforms, whose minimum requirements to obtain a safe and effective combination are: <ul style="list-style-type: none"> ○ Operating system for mobile and tablet: Android 4.4 or higher. ○ Meta quest 2 or higher with operating system v56 or higher. ● The medical device software Kinesix VR has been validated for its use in combination with the virtual reality platform Oculus Meta Quest 2, whose minimum requirements to obtain a safe and effective combination are: <ul style="list-style-type: none"> ○ Panel type: fast-switch LCD ○ LCD screen resolution: 1832 X 1920 (per eye) ○ Supported refresh rate: 72 Hz; 90 Hz in future release ○ Default SDK color space: Rec.2020 gamut, 2.2 gamma, D65 white point ○ USB connector: 1x USB 3.0 ○ Tracking: inside out, 6DOF ○ Audio: integrated, in-strap ○ SoC: Qualcomm® Snapdragon™ XR2 Platform ○ RAM memory: 6 GB total ○ Lens distance: adjustable IAD with three settings for 58, 63 and 68 mm ○ View field (horizontal): 90° ○ Battery: 3640 mAh ○ Operating system: Android 10.0 or higher. ● The device should be used under the supervision of a rehabilitation professional or qualified caregiver. ● Keep out of reach of children under 12 years old (hardware limitation). ● Adolescents over 12 years old may use the device. ● Adolescents ages 12-18 require direct supervision by a rehabilitation professional or qualified caregiver. ● Do not perform the exercises without supervision at home. Always perform the session under the supervision of a rehabilitation professional or qualified caregiver. ● The use of Kinesix VR in home environments is only recommended for patients with a degree of mild (Fugl Meyer Assessment-Upper Extremity > 43/66 points) and moderate (Fugl Meyer Assessment-

Upper Extremity 29-42/66 points) motor impairment of the upper extremity for stroke, and mild-moderate (Box and Block Test >1 and less than normative data by age according to Mathiowetz et al., 1985) impairment of the upper extremity for other conditions.

- Do not train if you are very tired or sleep deprived.
- When using the device, place a table, stretcher or handrail in front of you for safety and support.
- Train in a room with adequate lighting that favors a good contrast between hands and background.
- Rest at least 5-10 minutes every 30 minutes of training.
- Use with caution when using this device if a patient has a history of vestibular issues, motion sickness or other medical condition predisposing to nausea or dizziness.
- In upper limbs with extreme weakness and/or sensory impairment, prefer weight-bearing or closed-chain exercises.
- Avoid compulsive or excessive use of the device as it may interfere with daily life.
- Avoid the use of the device by patients with significantly cognitive or behavioral disorder that prevents the patient from following simple instructions.
- Avoid the use of the device if patients have severe visual impairment (unilateral neglect, hemianopsia, non-corrected visual acuity) does not allow treatment to be carried out through immersive virtual reality glasses.
- Avoid the use of the device if patients have medical conditions precluding exercise or bone instability or other musculoskeletal alteration that does not allow the use of the device.
- Cybersickness: the sensation of dizziness, visual disturbance, nausea or headache during or after immersion and/or movement with virtual reality. While training in 3D environments or viewing videos some people may experience cybersickness. If you experience any of the symptoms, stop using the device and try again later. If the sensation persists, consult your physician.
- Epilepsy: a very small percentage of the population has a condition that could lead to seizures or blackouts when exposed to certain light patterns or flashing lights from using backgrounds or playing video games. This condition can trigger previously undetected epileptic symptoms or seizures in people with no history of seizures or epilepsy. If you or anyone in your family has epilepsy or has had an epileptic seizure of any kind, consult your physician before training.
- If you experience other symptoms such as loss of consciousness, disorientation, tics, other involuntary movement or discomfort in any part of your body, stop using the device immediately and consult your physician before resuming the training.
- Risk of falling: it is suggested that the user be seated. If you train standing, ask for assessment and authorization from your rehabilitation

	<p>professional and make sure to minimize the risk of falling by prioritizing the necessary support (e.g., standing frame, safety harness, table, bar or railing) and clearing the area of obstacles, children and/or pets.</p> <ul style="list-style-type: none">● Risk of injury: patients should perform the movements shown by the rehabilitation professional to minimize the risk of injury due to incorrect or new movements. You must follow the prescribed exercises and need for support indicated by the rehabilitation professional.● Muscle or joint pain: muscle or joint pain is an expected complaint as most patients have more repetitions and train longer compared with regular rehabilitation. To prevent pain due to over-training, a ramp-up period of time in the beginning of the training is recommended.● Fatigue: fatigue is an expected complaint after physical activity and can be resolved with rest. To prevent excessive fatigue, a strongly recommended approach is to implement a gradual increase in training time at the beginning of the training.● Euphoria: excessive motivation in patients may lead to euphoria. In this situation, ensure that the duration of training does not exceed what is considered clinically relevant, in order to prevent possible undesirable side effects.
	Software medical device in compliance with the requirements established by the European Regulation (EU) MDR 2017/745.