



REAL® SYSTEM 2 User Manual

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WARNING! CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE. OBSERVE ALL WARNINGS AND PRECAUTIONS NOTED THROUGHOUT THESE INSTRUCTIONS. FAILURE TO DO SO MAY RESULT IN COMPLICATIONS.

DEVICE DESCRIPTION

The REAL® System 2 is a digital hardware and software medical device platform utilizing virtual reality technology designed for use in residential or rehabilitation setting that focuses on physical, neurorehabilitation and/or wellness needs.

REAL System 2 consists of following components:

- All-In-One Headset with Software Application
- Headset Controller
- Large Sensor
- Small Sensors
- Sensor Charger (charging station)
- REAL Sensor Bands

The headset contains a power button that turns the component on or off and a charger/accessory port. The headset also provides visual feedback of virtual reality applications in concert with the REAL System 2 small and large sensors.

Large and small sensors are equipped with mechanical and electrical components that measure motion and direction in physical space and then translate that information into a virtual environment.

The sensor charger powers the sensors.

Headset controller can be used to perform administrative tasks such as connect to network, select therapy activity, access settings, etc.

At full charge, the entire system can last at a minimum of 60 minutes and it is recommended that a therapy session does not exceed 60 minutes. The expected amount of time to charge the system to last the recommended therapy session time is 60 minutes.

In the event of Electromagnetic disturbances, the performance of the REAL System 2 may be affected.

The REAL System 2 is a Type BF Applied Part.

Frequently used features and functions:

Headset

- Plug the headset power cord into wall outlet and the headset to charge device.
- Press power button to power on or off headset. The power button is on top of the headset.

Headset Controller

- Buttons on the controller are used to access settings.

Sensor Charger

- Plug sensor charger power cord into wall outlet and sensor charger to power on device to charge sensors.

Large Sensor and Small Sensors

- Activate or charge sensor devices by removing or placing back into the sensor charging station.
- Place sensor devices into the sensor bands.

Sensor Bands

- See Section 3 in Operating Procedures on instructions to put on sensor bands.

User Portals

- Access the **User Portal** through the Headset to perform the following:
 - Logging in
 - Selecting the activity
 - Initializing and syncing to sensors
 - Starting, modifying, or ending therapy session
 - Viewing data
 - Logging out
- **HCP Portal**
 - Selecting the application
 - Logging in
 - Adding or selecting patient
 - Initializing and syncing to sensors
 - Selecting, starting, modifying, or ending therapy session
 - Viewing data
 - Logging out

There is no preventive inspection, calibration, and maintenance necessary for the REAL System 2 besides the initial set up procedure. During the three-year product lifespan of the REAL System 2, the device will continue to perform safely without any routine maintenance. No parts within the REAL System 2 will require inspection nor maintenance by a service personnel to ensure basic safety during the three-year product lifespan. Circuit diagrams and calibration instructions are not provided because service in parts repair is not necessary.

If the system no longer stays powered on and connected through the entire recommended duration of a therapy session, dispose of the device through an environmentally safe electronic waste recycle system.

If the sensor bands no longer adequately hold the sensors nor stay strapped to your body, dispose of the sensor bands and reorder through the REAL website.

Supply mains are electrically isolated in medical equipment to maintain basic safety.

The full expected latency of the device, including movement detection, processing, and visual representation is 35 milliseconds or less. This value is considered minimal and sufficiently low enough so that movement can be quickly detected.

INDICATION FOR USE

The REAL System 2 is an immersive virtual reality and display system that interactively displays and tracks rehabilitation exercises using a combination of virtual environments and full presence tracked avatars for visual feedback. These rehabilitation exercises are intended to be conducted in a seated position in a residential environment, or any other facility that may facilitate rehabilitation.

CONTRAINDICATIONS

There are no known contraindications.

WARNINGS

If motion sickness, dizziness, headache, eye strain, or fatigue is experienced when using the device, stop use of device immediately.

Use caution when using this device if you have a history of vestibular issues or motion sickness.

Precautions

Ensure a safe environment while performing activities with the device (e.g. remove any surrounding obstacles that may lead to injuries caused by trips and falls). As this device is to be used for upper body rehabilitation, it is required to remain seated to avoid a fall.

Be aware of the limitations in range of motion and avoid device or program use that could lead to excessive gestures that could result in injuries.

Extended use of the headset can cause discomfort or eye strain.

Incorrect placement of the sensors may result in the avatar appearing incorrectly or distorted on the headset.

Damage (mechanical and electrical) may result if the headset, sensors, and/or sensor charger are dropped or struck against another object. Device is not intended for continued use if dropped from higher than 1 meter.

Surface temperature around the headset exhaust may reach 46°C if operating above nominal room temperature.

Sensors will transmit inaccurate position data if used near metal including, but not limited to, wheelchairs, walkers, and utility carts.

Headset tracking can be lost or compromised if large objects obscure the headset.

At no time should liquid products be allowed near any device component.

No modification of this equipment is allowed.

Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the REAL System 2, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Accessories such as power adapters and cords should not be replaced by the end user and should only be replaced by Penumbra. Any changes or replacements of accessories will likely impact compliance of REAL System 2.

Use of this device should be in a secure information technology environment. Outbound https communication channels must be open.

POTENTIAL ADVERSE EFFECTS/EVENTS

Visual stimulation through head-mounted displays have a small possibility of provoking an epileptic seizure. Should this occur, stop using the device immediately. Other possible complications include, but are not limited to, the following:

- | | |
|--|----------------------------|
| • claustrophobia | • light-headedness |
| • discomfort or pain in the head or eyes | • motion sickness |
| • disorientation/vertigo/dizziness | • nausea |
| • drowsiness | • pain |
| • eye strain | • repetitive strain injury |
| • falls or fractures | • seizure |
| • headache/migraine | • skin irritation |
| • insomnia | • vision problems |

Should any of the above occur, stop using the device immediately.

OPERATOR PROFILE

Intended users for this device are those with physical, neurorehabilitation and/or wellness needs. A caregiver may be optionally present to help operate the system.

Healthcare provider (HCP) of the REAL™ System 2 prescribing rehabilitation activities should be trained in rehabilitation therapy.

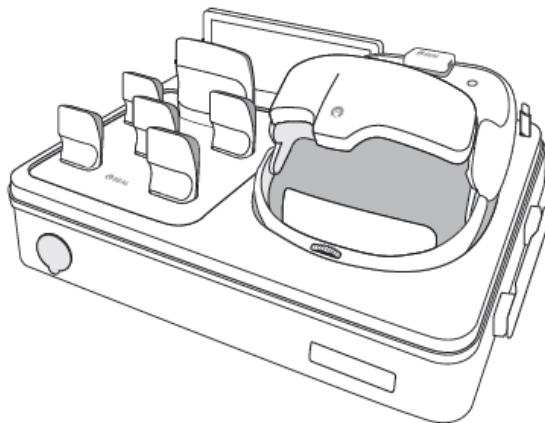
OPERATING PROCEDURE

Note: These rehabilitation exercises are intended to be conducted in a seated position. Be seated at all times when the system is in use.

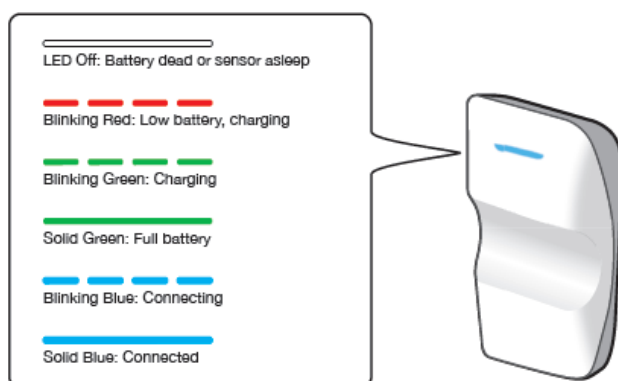
Commented [PG1]: Images in this section will be changed to reflect REAL2 (Xavier 2) configuration.

SECTION 1: GETTING STARTED AND CHARGING COMPONENTS

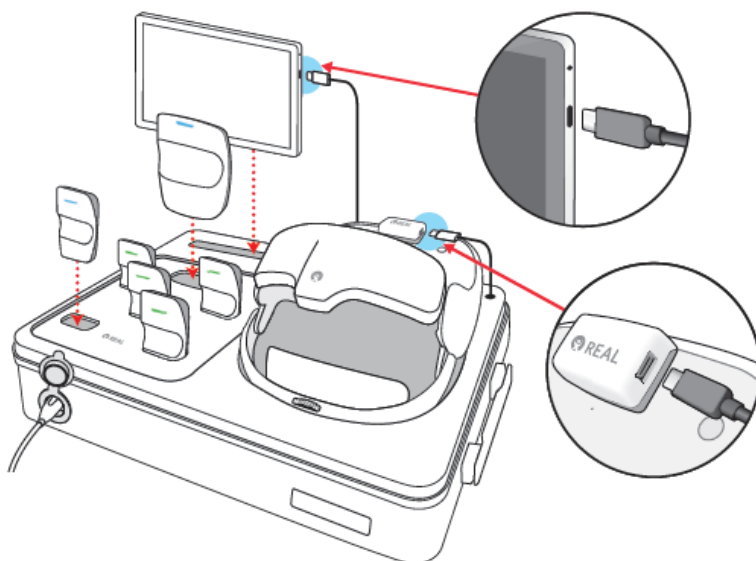
1. Remove REAL System 2 components from the product box.



2. Connect sensor charger base to its power cable supplied in the Accessories box. The wire will go through the grommet hole supplied in the box. Plug into a wall outlet. Ensure sensors with white sides facing forward are in their corresponding size slots on the sensor charger. LED lights on sensors will show the following.



3. Connect the headset to its power cord supplied in the Accessories box and plug into a wall outlet. LED lights on top of headset will show either blinking green or solid green to indicate charging status.



SECTION 2: Internet Connectivity

User:

1. Unplug power cords from headset when ready for use.
2. Turn on headset by pressing and holding power button for approximately 2 seconds.



3. Turn on the headset controller by pressing the small circular button. The controller will vibrate once it has been turned on.
Note: If the headset controller does not vibrate, press and hold both the headset controller's small circular button and the headset's Volume Down button – the singular dot on the left underside of the headset. Hold both buttons down at the same time until the controller vibrates.
4. Once the headset and headset controller are on, hold the controller's Volume Down button on the right side and the headset controller's trigger at the top of the backside. This will decrease the headset's volume as well as switch the headset to the HTC Vive environment.
5. In the Vive environment, an Android Settings (AS) menu will be viewable. If the AS menu is not visible, slowly turn your body around until the menu appears in the headset viewer.
6. The headset controller is used to navigate the menu.
 - i. Pressing the small circular button will cause the controller to vibrate and bring the pointer into view.
 - ii. Using the controller, point the pointer at the desired menu item, then press the circular trackpad at the top of the headset controller to select it.
Note: If the pointer disappears, repeat the process until the pointer reappears.
 - iii. If the trackpad button causes the menu to scroll undesirably, use the controller's trigger to open the menu instead. Hold down the trigger, then press and move trigger to select. Make sure the controller pointer is pointed at the desired text in the menu.
7. Using the headset controller's pointer and trackpad, select 'Wi-Fi' in the headset's Android Menu.
8. Connect your headset to your desired wireless home network. You may be prompted to enter your password.

9. Once connected, the headset will display your home Wi-Fi at the top of the WLAN list and the status will read 'Connected'.
10. To exit, power off the headset before starting a session.
11. Ensure patient's personal device such as computer, tablet or smartphone is connected to desired Wi-Fi
12. Reset password to log into patient portal using the login information provided in the welcome email

HCP:

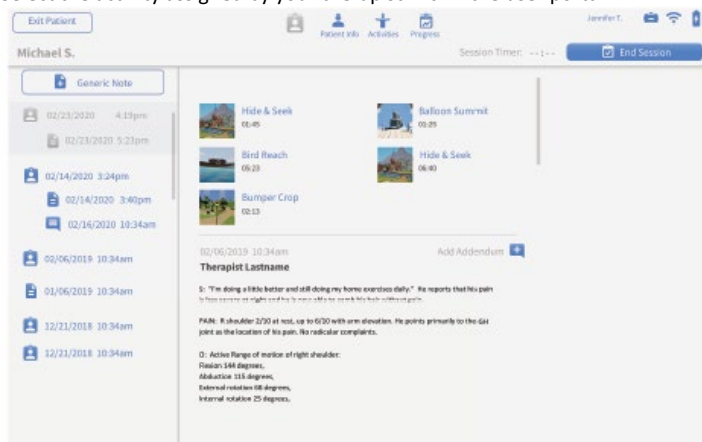
1. Ensure your personal device is connected to the internet to access the portal and assign activities to patients
2. Reset password to log into HCP portal using the log in information provided in the welcome email

Continue to Section 3 when the components are sufficiently charged, and the system has secure internet connectivity.

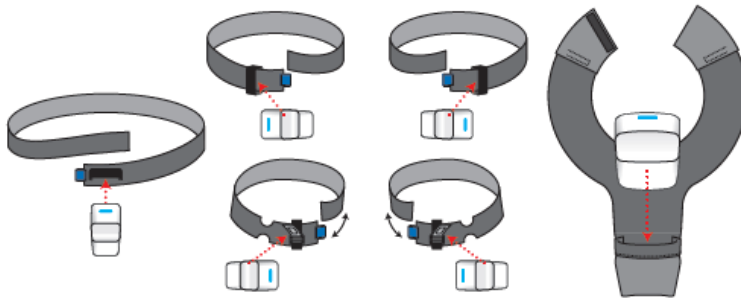
SECTION 3: START UP

USER:

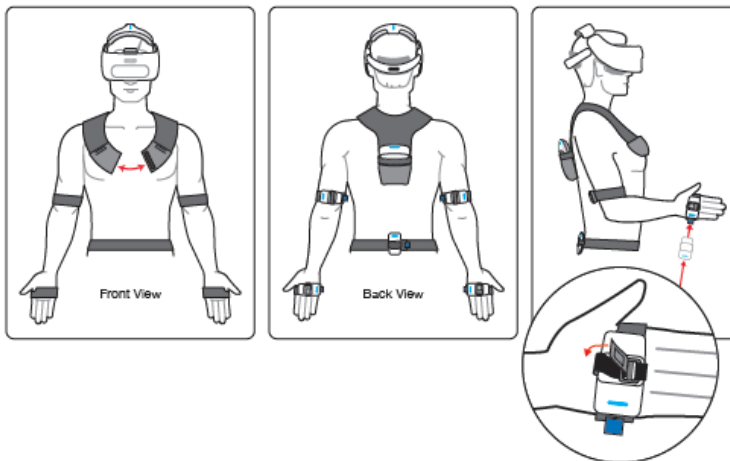
1. Using a personal device, log into the user portal using your username and password.
2. Select the activity assigned by your therapist within the user portal



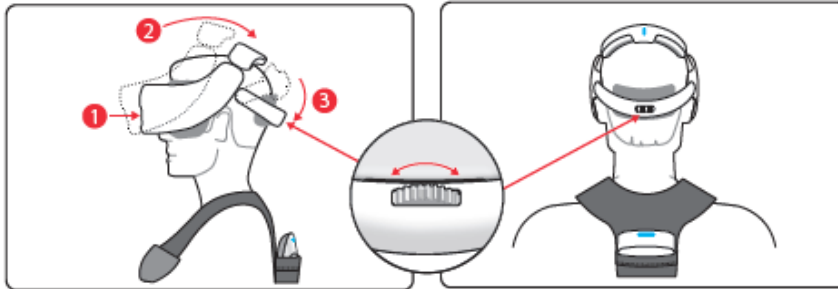
3. Remove sensor bands from the Real Sensor Bands box.
4. Remove all sensors from sensor charger.
5. Place the small sensors onto bands by sliding them into elasticized loops. For the hand sensor bands, tighten elasticized loop using the buckle. Place large sensor into pocket of the torso band.



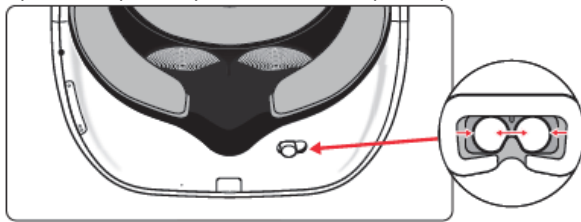
4. Once sensors are placed in the bands, put each band onto its corresponding body part (see image below). Connect hook and loop fasteners of the torso band if desired. Adjust bands for comfortable fit, if necessary.



5. Be in a seated position away from metal components and remain seated at all times for the duration of the therapy session.
6. Initiate the session by pressing "Start Session".
7. Put on the headset per in the sequence numbered below and begin visually interacting with the environment.

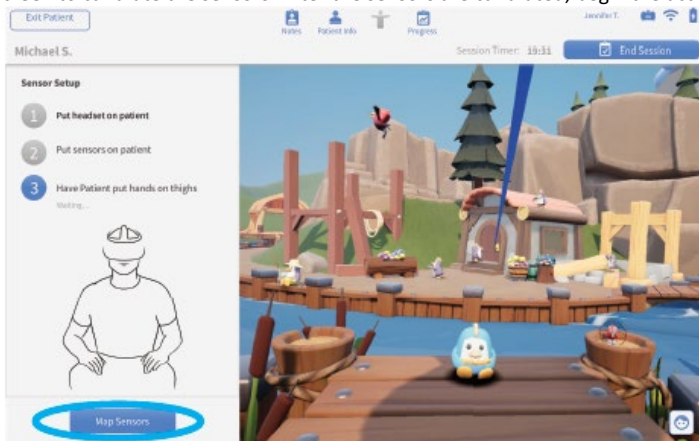


Note: Size of headset strap and interpupillary distance can be adjusted for fit. Top of head pad may be removed temporarily for better fit on larger heads.



Note: Eyeglasses may be worn during device use.

8. Sit in a neutral position, facing forward with hands on knees or thighs. Press the button on the screen to calibrate the sensors. After the sensors are calibrated, begin the activity.



HCP:

Patient Rehabilitation Activities:

1. Log into the HCP Portal and locate the patient profile.
2. Select the designated activity and click “Start Session”.

Patient Wellness Activities:

1. Log into the HCP Portal and locate the patient profile.
2. Review patient’s session results.

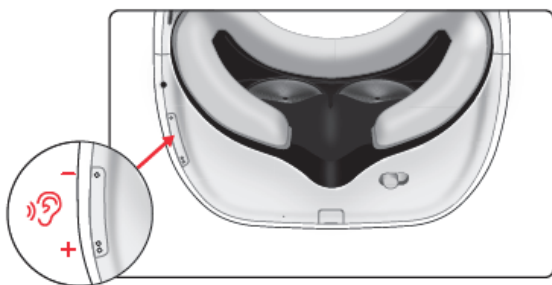
See Section 4 and 6 for more information.

Section 4: ACTIVITY NAVIGATION

User

1. Conduct rehabilitation session as planned. (See Section 6 which includes a software description for details of therapeutic activities).

Note: If sensors lose synchronization or headset loses tracking, turn off headset then turn back on to reset. Headset is turned off and on using the power button. Sensors are turned off and on by placing them in the powered charging station (while the REAL System 2 is plugged in) and then removing them again.

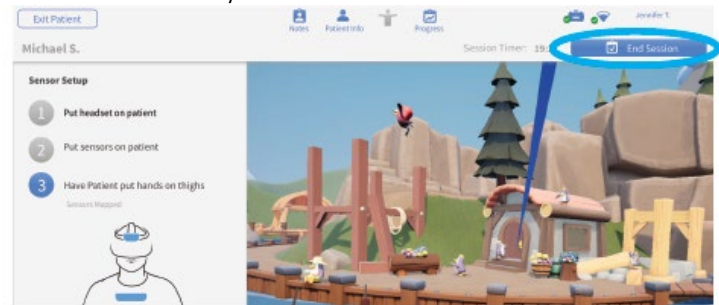


HCP

1. Conduct rehabilitation session as planned. (See Section 6 which includes a software description for details of therapeutic activities).
2. Navigate to additional therapy activities by selecting the corresponding icon from the HCP Portal. Once the activity is loaded, the HCP can press the “Start Activity” button to begin the activity.
3. Always remain with the patient throughout therapy session to provide direct supervision.
4. Monitor patient view on the HCP portal; select and change activities as desired.

Note: If sensors lose synchronization or headset loses tracking, turn off entire system then back on to reset. Headset is turned off and on using the power button. App should be relaunched on the tablet. Sensors are turned off and on by placing them in the powered charging station (while the REAL System 2 is plugged in) and then removing them again.

- When planned therapy activities are complete, press “End session”. Patient will be returned to the Hide and Seek activity.



- View patient results. You may also switch to the Notes tab for a summary of session activity times.

The screenshot shows the 'Notes' tab of the app interface. The top navigation bar includes 'Exit Patient', 'Notes', 'Patient Info', 'Activities', and 'Start Session'. The 'Notes' tab is selected. Below the navigation bar, there is a table of patient results for Michael S. The table has columns for 'Left', 'Proprioception', and 'Right'. The data is organized by body part and movement type.

		Left	Proprioception	Right
Cervical	Rotation	72°		39°
	Flexion		74°	
	Extension		56°	
Shoulder	Flexion	156°		138°
	Extension	67°		64°
	External Rotation	81°		77°
	Abduction	165°		161°
Elbow	Flexion	145°		140°
	Extension	1°		-4°
Forearm	Pronation	84°		68°
	Supination	77°		70°
Wrist	Flexion	73°		49°
	Extension	65°		59°

Data From Session:
5/24
10:34am - 11:16am

Section 5: SYSTEM REMOVAL

- Remove sensors and bands.
- Remove headset.

3. Power off headset by pressing and holding onto the power button for approximately 2 seconds.
4. Clean headset and sensors with institutional approved sanitizing wipes*.
5. Connect headset to the power cord.
6. Ensure REAL System 2 sensor charger is plugged in.
7. Return all sensors to sensor charger. Red or green LEDs should be noted on sensors when placed correctly in the charging station.
8. Store and label bands for future use.
9. Sufficiently charge all components after each use and prior to next use for 60 minutes.

NOTE: Standard operation is to power cycle and relaunch application between therapy sessions to reestablish system connections.

*Handle the lenses on the headset carefully to avoid smears or scratches. Wipe lenses with a soft cloth for cleaning as needed. Clean outer and inner plastic components of headset with institutionally approved sanitizing wipe. Do not use petroleum-based compounds, acids, caustics, or chlorinated solvents to clean or lubricate any parts. Use only water-based solvents for cleaning.

Section 6: THERAPY EXPERIENCE

The REAL™ Immersive System contains a variety of activities that incorporate clinically recognized, existing therapeutic and functional exercises to facilitate motor and cognitive rehabilitation. Settings for each activity will involve parameters such as turning on and off avatar features and environmental factors. While using the REAL Immersive System, the HCP remains responsible for the patient's safety and the appropriateness of individual exercises including range of motion (ROM) attempted and any other limb or joint limitations unique to that patient.

Therapy Activity 1: Hide and Seek



Hide and Seek can be used with or without a displayed avatar tracking the patient's upper body as it primarily relies on head movement and visual scanning ability. Hide and Seek puts the patient in a pastoral setting with a number of animated animals that react to the patient's acknowledgement of them. This is both the first and last experience for the patient. At the end of the patient's session, the patient can visualize overall progress they made during the session in the form of virtual "rewards." Patients "find" a little penguin by hovering a blue "gaze pointer" on the penguin by turning and rotating their head to exercise their cervical range of motion. The penguin will then disappear and reappear in a different location. The pointer is positioned to represent the patient's upper body vertical midline and is itself a useful tool as some patients in neurorehabilitation have lost their sense of body position resulting in "midline shift." The blue pointer provides a visual, external cue to their true body midline helping them relearn centering themselves. The Hide and Seek exercise encourages visual scanning of their environment, an important functional ability, and cognitive recognition of nameable animals, objects, and environmental locations in their immediate surrounding. HCPs may adjust various activity parameters through the tablet.

Therapy Activity 2: Hot Air Balloon



Hot Air Balloon is an introductory activity to help the patient work on core control and strength as well as centering and postural proprioception. By leaning their torso from a sitting position in a certain direction, and holding it there against gravity, they fly a hot air balloon in that same direction. There are a number of objectives the patient can achieve by flying the balloon around. To fly the balloon away and towards them, the patient uses thoracolumbar flexion and extension, and to fly from left to right involves thoracolumbar flexion to the left or right. This set of activities provide a range of challenges focusing on enhancement of trunk control, postural stability, and dynamic balance, all of which are foundational to upper extremity function. HCPs may adjust various activity parameters through the tablet.

Sub-Activity 1: Balloon Pilot

This sub-activity takes place near the ground. The patient-controlled balloon is tethered to the ground to limit balloon travel and encourage simple torso centering, trunk mobility, and dynamic weight shifting. The patient can pilot the balloon on-tether to nearby interactive objects.

Sub-Activity 2: Bumper Band

This sub-activity takes place halfway up the mountainside. The patient uses trunk extension, flexion, as well as lateral flexion to drive the balloon in an untethered mode to bump other balloons with characters in them, back to the performance stage.

Sub-Activity 3: Summit Rescue

This sub-activity takes place at the peak of the mountain where the player has to steer the balloon to bring hikers which made it to the summit. The patient has to counteract different obstacles using cognitive planning, problem solving, and trunk control movements.

Therapy Activity 3: Sunrise



This activity is based on simple shoulder flexion. The patient holds their arms out straight in front of them and raises their arms up and over their head in a motion that ideally, is pure shoulder flexion with a maximum, healthy ROM of 180 degrees. This exercise may be done passively with HCP assistance or actively by the patient themselves. This exercise encourages postural alignment and symmetrical seated shoulder flexion.

When this motion is initiated, a Sun character rises up from beyond the horizon in proportion to the patient's shoulder flexion ROM. The sun also rotates in the sky and translates side to side, depending on the patient's postural symmetry. When the patient's arms are horizontally and vertically symmetric, and their torso is in vertical alignment with their pelvis and head, the sun will be smiling broadly and high in the sky straight ahead of the patient.

If the patient's posture exhibits asymmetry or other compensating characteristics, the sun's position and the expression on its face will alter from the "ideal" state, thereby providing the patient an external visual cue as to their posture, and allowing them to learn via alternative references, what is proper, non-compensating posture. Maximum shoulder flexion ROM achieved during this activity will be stored as a session output for the HCP's record. HCPs may adjust various activity parameters through the tablet.

Sub-Activity 1: Sunrise

As the patient fully lowers and fully raises their arms to the best of their ability, the lighting in the virtual world will exhibit night-time or daytime according to the sun's position, thus greatly accentuating the activity and feedback of a simple coordinated arm raise.

Sub-Activity 2: Harvest

The Harvest sub-activity involves growing a variety of vegetables by raising and lowering one's arms a number of times in order to trigger the appearance of day-night cycles. This activity creates an incentive for the patient to do multiple repetitions of this exercise if called for by the patient's rehabilitation plan.

Sub-Activity 3: Ice Cave

The Ice Cave sub-activity involves freeing a variety of Cave Penguins from ice blocks by raising and lowering one's arms a number of times in order to trigger the appearance of day-night cycles. This activity creates an incentive for the patient to do multiple repetitions of this exercise if called for by the patient's rehabilitation plan.

Therapy Activity 4: Bird Forest



The Bird Forest activity incorporates standard functional exercises including dynamic reaching and pronation/supination into a virtual reality activity by requiring the patient to reach out with one or both hands to allow a bird to jump into their hand. Patients have opportunities to reach from low to high, high to low, from left to right and vice versa to practice functional reach. These exercises mimic standard functional exercises that would be practiced during rehabilitation to help the patient regain skills necessary to live at home with a degree of functional independence, and perform activities such as unpacking groceries, cooking, unloading a dishwasher, self-care, etc. HCPs may adjust various activity parameters through the tablet.

Sub-Activity 1: Free Birds

The patient must use their hand(s) to pick up a bird and then move their hand(s) to a nest, also within arm's reach, and maintain that position in order to deposit the bird into the nest. Filling all nests with a bird will reset the activity so it can be played again.

Sub-Activity 2: Nest Hop

The patient should use their hand(s) to pick up a bird and move it to a colored target nest in a specific order under time pressure. This sub-activity will exercise both the patient's functional and cognitive ability. When a target nest has been filled, a new target nest will appear, and the patient will have to move the bird from the previous nest to the new target.

Sub-Activity 3: Bird Match

A bird will need to be picked up and matched to the corresponding colored nest. When all nests have been filled, the exercise will reset.

Therapy Activity 5: Penguin Sports Park



In these activities, the patient must move their upper extremities to intercept an object coming at them, in a time dependent manner. These activities require quick cognitive processing and visual-motor integration to succeed, and thus are more advanced activities for a neurorehabilitation patient. Other primary skills being challenged are reflective movements, dynamic postural control, visual recognition, and motor control. HCPs may adjust various activity parameters through the tablet.

Sub-Activity 1: Chuckleball™

The patient fends off approaching Chuckleballs by deflecting them with their head or hands. The Chuckleballs will be kicked continually until a new activity is started.

Sub-Activity 2: Chuckleball Arena

Chuckleball Arena requires the patient to protect the goal from kicked Chuckleballs coming from the penguin in front of them. Chuckleballs can be deflected by either hand or the head. Depending on the plane of contact of the hand or head, the Chuckleball will deflect in specific directions and advance patients can learn to deflect the Chuckleball into the opposing goal. Other objects and animals in the

environment can also serve as targets. The HCP can control how fast the ball travels towards the patient, the distance the patient must reach to block the ball, and the number of balls to be kicked at the patients.

Sub-Activity 3: Flying Fish

Flying fish is similar to Chuckleball where the patient must deflect a fish being pitched at them with their head or hands. This may elicit a defensive response movement from the patient in VR. Fish may turn from “good” blue fish which are supposed to be deflected to “bad” red spiky fish, which need to be avoided. This requires extra cognitive processing to decide, under time pressure, which fish should be contacted, and which should be avoided, in addition to predicting where the fish are coming and integrating proper movement to accomplish the task.

TECHNICAL SPECIFICATIONS

Sensor Accuracy*	± 2 cm at a max distance of 75 cm
Sensor Precision*	2 cm or less
Latency	≤35 milliseconds
Operating Temperature	15 °C to 30 °C
Operating Pressure	102 kPa or less
Operating Relative Humidity	15% to 90%
Operating Elevation	2,500 meters or less
Transportation and Storage Temperature	0°C to 30 °C
Transportation and Storage Pressure	102 kPa or less
Transportation and Storage Relative Humidity	15% to 90%
Radio Module	Output power (EIRP**): 6.31 mW (8 dBm) max Frequency Band: ISM (Industrial, Scientific, and Medical) Typical Center frequency: 2.44 GHz Channel: 77 channels Bandwidth: 2 MHz per channel Modulation: GFSK (Gaussian frequency-shift keying) Data flow: Bi-directional **EIRP = Equivalent Isotropic Radiated Power

*REAL System 2 is calibrated appropriately to detect movement in virtual reality space in relation to real space accurately and precisely. Sensors will compute and display position at an accuracy of a 2 cm radius with respect to real space at a max distance of 75 cm relative to the headset. Sensors will also reproducibly compute position at a maximum deviation of a 2 cm radius for repeated movements at a max distance of 75 cm relative to the headset. Please note that accuracy and precision specifications contain limitations and are dependent on certain factors such as the amount of metal near the system. For example, if the patient is in a metal wheelchair and cannot move to a non-metal chair, reduction in accuracy and precision may occur.

SYMBOL GLOSSARY

	Refer to User Guide (Instruction manual)
	Type BF Applied Part
	WEEE
	Manufacturer
	Catalog Number
	Lot Number
	Date of Manufacture
	Both Direct and Alternating Current
	Class II Equipment
	Serial Number
	US and Canada Certification
	Medical Device
	Keep Dry
IP21	Protection against ingress of solid foreign objects level 2 and water level 1
IP22	Protection against ingress of solid foreign objects level 2 and water level 2

TECHNICAL INFORMATION

REAL™ System 2 is intended for use in the electromagnetic environment specified below. The customer or the user of REAL System 2 should assure that it is used in such an environment.

Emissions Test	Compliance	
RF emissions CISPR 11	Group 1	REAL System 2 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	REAL Immersive System is suitable for use in all establishments other than domestic and those directly connected to the public mains.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/ Flicker emissions	Complies	

REAL System 2 is intended for use in the electromagnetic environment specified below. The customer or the user of REAL System 2 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical residential or rehabilitation environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical residential or rehabilitation environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Voltage Dips 30% reduction, 25/30 periods At 0°	Voltage Dips 30% reduction, 25/30 periods At 0°	Mains power quality should be that of a typical residential or rehabilitation environment. If the user of the EQUIPMENT requires continued operation during power mains interruptions, it is recommended that REAL System 2 be powered from an uninterruptible power supply or a battery.
	Voltage Dips > 95% reduction, 0.5 period At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	Voltage Dips > 95% reduction, 0.5 period At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	
	Voltage Dips > 95% reduction, 1 period At 0°	Voltage Dips > 95% reduction, 1 period At 0°	

	Voltage Interruptions > 95% reduction, 250/300 periods	Voltage Interruptions > 95% reduction, 250/300 periods	
(50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical residential or rehabilitation environment.

REAL™ System 2 is intended for use in the electromagnetic environment specified below. The customer or the user of REAL System 2 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz (6 Vrms in ISM and amateur radio Bands within 150kHz – 80MHz)	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of REAL System 2, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m	Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = 2.3\sqrt{P} \quad 800 \text{ MHz to } 2.7 \text{ GHz}$ where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey^a, should be less than the compliance level in each frequency range.^b
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.			
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which REAL System 2 is used exceeds the applicable RF compliance level above, REAL System 2 should be observed to verify normal			

operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating REAL System 2.

^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

**Recommended separation distances between
portable and mobile RF communications equipment and REAL System 2**

REAL System 2 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of REAL System 2 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and REAL System 2 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.7 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Immunity to RF Wireless Communications Equipment

Test Frequency (MHz)	Band ^{a)} (MHz)	Service ^{a)}	Modulation ^{b)}	Maximum Power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380 – 390	TETRA 400	Pulse modulation ^{b)} 18 Hz	1.8	0.3	27
450	430 – 470	GMRS 460, FRS 460	FM ^{c)} ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704 – 787	LTE Band 13, 17	Pulse	0.2	0.3	9

745			modulation ^{b)} 217 Hz			
780						
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation ^{b)} 18 Hz	2	0.3	28
870						
930						
1720	1700 – 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation ^{b)} 217 Hz	2	0.3	28
1845						
1970						
2450	2400 – 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation ^{b)} 217 Hz	2	0.3	28
5240	5100 – 5800	WLAN 802.11 a/n	Pulse modulation ^{b)} 217 Hz	0.2	0.3	9
5500						
5785						
a) For some services, only the uplink frequencies are included. b) The carrier shall be modulated using a 50 % duty cycle square wave signal. c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.						

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

(1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

This device contains license-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's license-exempt RSS(s). Operation is subject to the following two conditions:

1. This device may not cause interference.
2. This device must accept any interference, including interference that may cause undesired operation of the device.

L'émetteur/récepteur exempt de licence contenu dans le présent appareil est conforme aux CNR d'Innovation, Sciences et Développement économique Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes :

1. L'appareil ne doit pas produire de brouillage;

2. L'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Les changements ou les modifications qui n'ont pas été expressément approuvés par la partie responsable de la conformité peuvent faire perdre à l'utilisateur son droit d'utiliser l'appareil.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a residential setting. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Mode of Operation:

Charging mode and battery mode

Mode of Transportation:

Devices should be transported in provided packaging.

Highest Clock Frequency:

HMD: 32 MHz

WSM: 32 MHz

WTM: 24.576 MHz

Frequency Range:

2402MHz - 2479MHz

Transmitting Frequency and Modulation:

Gaussian Frequency-shift Keying (GFSK) modulation. 2 Mbps modulation for all transmitter frequencies.

Antenna Make, Model, and Gain:

Device	Antenna Make	Antenna Model	Antenna Gain	
WSM	Johanson	P/N 2450AT43B100E	Peak Gain	1.3 dBi
WTM			Average Gain	-0.5 dBi
HMD	Penumbra, Inc.	P/N 17107	Peak Gain	0.7 dBi
			Average Gain	-2.6 dBi

Power Output and Data Rate:

Device	Power Output	Data Rate
WSM	Programmed by the firmware to +8dBm.	GFSK modulation, 2 Mbps data rate.
WTM	Programmed by the firmware to +4dBm.	
HMD	Programmed by the firmware to +8dBm.	

Product availability varies by country. Please see www.realsystem.com for more information. Copyright ©2020 Penumbra, Inc. All rights reserved. The REAL Hero logo, REAL, Chuckleball, and TherapyView are registered trademarks or trademarks of Penumbra, Inc. in the USA and other countries. All other trademarks are the property of their respective owners.

TROUBLESHOOTING GUIDE

*Refer to help line if troubleshooting solutions are unable to resolve the issue

- Sensors are not charging:
Make sure charging cable is properly plugged into the sensor charge base and the wall outlet.
- Headset is not charging:
Make sure charging cable is properly plugged into the headset and the wall adaptor.
- Headset is not turning on:
Charge the headset for 30 minutes and try again. Make sure the LED light on the headset blinking/solid green.
- If sensor(s) does not have an illuminating LED:
Charge the sensor(s) for 30 minutes and try again.
- Sensor(s) does not switch to blinking blue when taken out of the charger:
Put sensor(s) back in the charging station and take them out again.
- Sensor(s) does not switch from blinking red to blinking green when charging for prolonged time:
Take the sensor(s) out of the charging station and dock it back in.
- Cannot connect Headset to the WiFi:
Try again and make sure the correct password was entered.
- Damage to equipment:
Do not use the device and call the REAL help line.
- Equipment was exposed to liquid:

Remove the exposed equipment from the body. Power down the headset if possible and do not put the sensors back in the charging station. Do not use the equipment. Pat dry the wet equipment. Call the REAL help line.

10. Web application does not launch on the computing device:

Make sure the computing device is connected to internet and the URL is correct (*list URL HERE*).

11. Cannot log in to the web application:

Make sure the username and/or password is correct.

12. Component(s) is missing or damaged out of the box:

Call the REAL help line.



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