



REAL™ IMMERSIVE SYSTEM
OPERATION, MAINTENANCE, AND SERVICE 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™ Immersive System is a digital hardware and software medical device platform using a combination of virtual environments and full presence tracked avatars for visual feedback. It is designed for use in healthcare and focusing on physical and neuro rehabilitation. The use of the REAL Immersive System is intended to be in a clinical environment, supervised by a medical professional trained in rehabilitation therapy.

The REAL Immersive System consists of a clinician tablet, head-mounted display (HMD or headset), small sensors, large sensor, sensor charger, router, router battery, headset controller, power cords, and USB cables. Note: Sensor bands are required for use and are sold separately.

Tablet is fitted with a touch screen, a power/lock button that turns the component on or off, and a charger/accessory port.

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 Immersive System tablet and the small and large sensors.

The large and small sensors are equipped with mechanical and electrical components that measure position and orientation in physical space and then translate that information to construct a virtual environment.

The sensor charger acts as a dock to store and charge the sensors.

The headset controller is used to access system settings. It should only be used in certain troubleshooting and administrative tasks and not during patient therapy.

At full charge, the entire system can be operated for roughly 2 hours. However, 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. Please sufficiently charge all the components between use for a minimum of 60 minutes.

In the event of electromagnetic disturbances, the performance of the REAL Immersive System may be affected.

The REAL Immersive System is a Type B Applied Part. Type B is the least stringent classification, and is used for applied parts that are generally not conductive and can be immediately released from the patient.

Frequently used features and functions:

Headset

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

Headset Controller

- Buttons on the controller are used to control power, connect to headset, access settings, or control volume.

Large Sensor and Small Sensors

- Sensors are turned off and charging when placed in the charging station. Sensors turn on and attempt to sync when removed from the charging station.
- Sensors are placed into the sensor bands, which are sold separately.

Tablet

- Press the power button to power on tablet or restart tablet. The power button is on the edge of the device.
- User Interface:
 - Logging in
 - Adding or selecting patient
 - Initializing and syncing to sensors
 - Selecting, starting, modifying, or ending therapy session
 - Viewing data
 - Logging out

Sensor Bands

- Place or remove sensor bands on or from patient.

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

At the end of the one-year product lifespan, the user should dispose of the device through an environmentally safe electronic waste recycle system if the following event occurs:

The system no longer stays powered on and connected through the entire recommended duration of a therapy session when initially fully charged.

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 Immersive System is an immersive virtual reality and display system that interactively displays and tracks upper-extremity rehabilitation exercises for adult patients 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 clinical environment and prescribed and supervised by a medical professional trained in rehabilitation therapy.

CONTRAINDICATIONS

There are no known contraindications.

WARNINGS

If a patient experiences motion sickness, dizziness, headache, eye strain, or fatigue when using the device, stop use of device immediately.

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

PRECAUTIONS

Ensure a safe environment for the patient while performing activities with the device (e.g. remove any surrounding obstacles to prevent injury). As this device is to be used for upper body rehabilitation, the patient must remain seated to avoid a fall.

Be aware of the patient's limitations in range of motion and avoid device or program use that could lead to excessive gestures that could injure a patient.

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

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

Device should not be dropped. Device is not intended for continued use if dropped from higher than 1 meter (3 feet). Damage (mechanical and electrical) may result if the tablet, headset, sensors, router, router battery, and/or sensor charger are dropped or struck against another object.

Do not touch the router and patient at the same time. Patients using the device should not be allowed to touch the router at any time.

During use and while charging, the surface of the equipment will not exceed 41°C.

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

Headset tracking may be lost or compromised if close or low-contrast objects or surfaces obscure the tracking cameras on the front of the headset.

To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

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 centimeters (12 inches) to any part of the REAL Immersive System, 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 the manufacturer. Any changes or replacements of accessories could impact FCC compliance of REAL Immersive System.

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:

- discomfort or pain in the head or eyes
- dizziness
- drowsiness
- eye strain
- headache
- light-headedness
- migraine
- motion sickness
- nausea
- pain
- vertigo
- vision problems

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

OPERATOR PROFILE

Operators of the REAL Immersive System should be trained in rehabilitation therapy.

Note: These rehabilitation exercises are intended to be conducted in a clinical environment and prescribed and supervised by a medical professional trained in rehabilitation therapy. Rehabilitation therapy treatment and technique decisions will vary based on the clinical judgement of the treating medical professional. A medical professional must be present at all times to provide direct supervision throughout course of therapy.

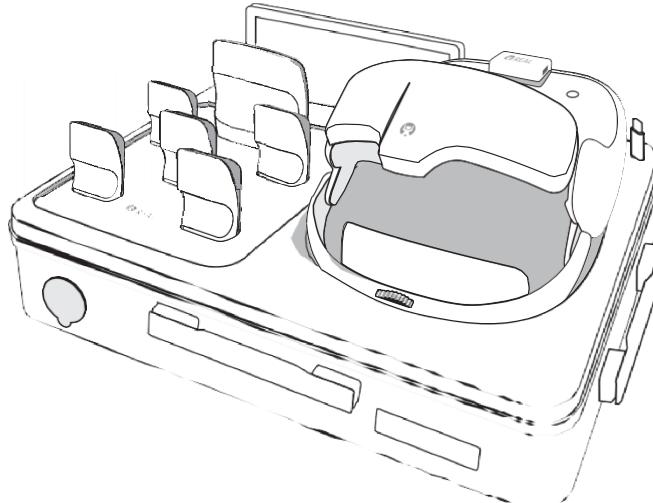
OPERATING PROCEDURE

Note: Prior to first time use, router must be configured and connected to the local internet.

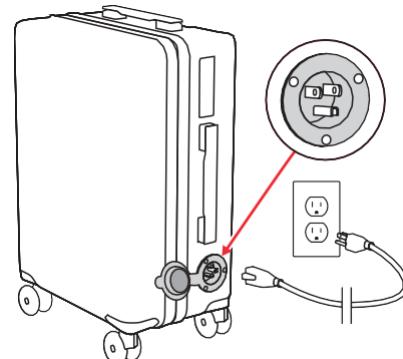
Note: These rehabilitation exercises are intended to be conducted in a seated position. The patient must be seated at all times when the system is in use.

SECTION 1: GETTING STARTED AND CHARGING COMPONENTS

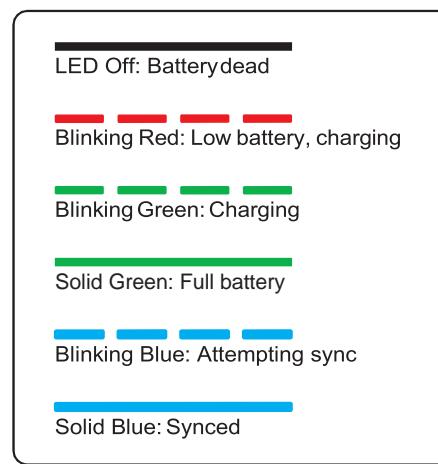
1. Remove REAL Immersive System Case from the shipping container.



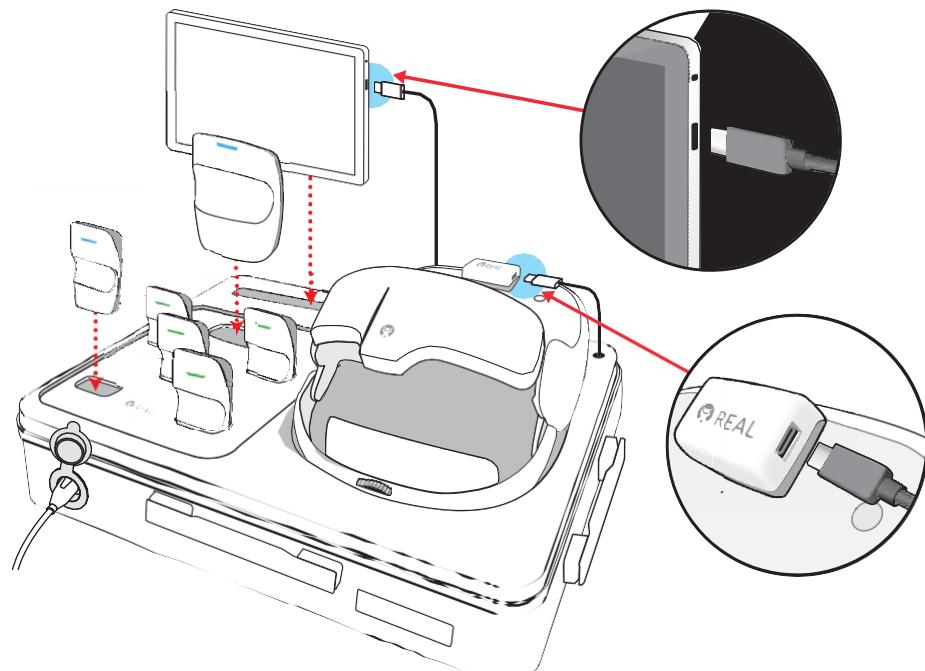
2. Connect the REAL Immersive System Case to its power cord (AC adapter power cord). Plug the power cord into a grounded electrical outlet. Ensure the power receptacle is connected to a supply mains with protective earth.



3. Ensure sensors with white sides facing forward are in their corresponding size slots on the sensor charger. LED lights on sensors will show flashing red, flashing green, or solid green to display charging status.



4. Ensure the headset is connected to its power cords (AC adapter power cord and USB-C cord). LED lights on top of headset will show blinking green or solid green to indicate charging status.
5. Ensure the tablet is connected to its power cord (USB-C cord).



SECTION 2: INTERNET CONNECTIVITY

1. Turn on tablet by pressing power button for approximately 5 seconds. (May take up to 30 seconds if tablet was fully drained of battery).
2. Open the TherapyView™ app if it is not already open.
3. On the log in page, click on the “Network Setup” button.

Network Setup

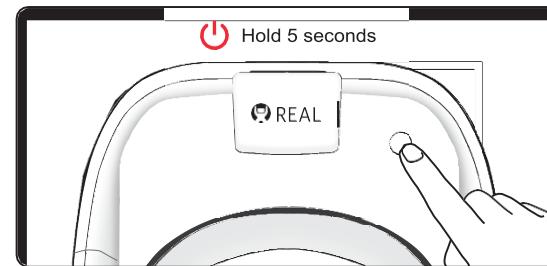
4. Enter the username and password below to login into the router:
 - a. Username: **realadmin**
 - b. Password: **realsystem**
5. Connect using your wireless network name and password OR Connect by whitelisting the device MAC address.
 - c. To connect using a network name and password:
 - i. Select “Wireless 5 GHz” from the menu. If the desired network is not a 5 GHz network, select “Wireless 2.4 GHz”. Wireless 5 GHz is preferred to Wireless 2.4 GHz.
 - ii. Select “Scan” to search for local networks.
 - iii. Select “Connect” next to the desired network.
 - iv. Enter the password into the corresponding field.
 - v. Select “Save” and exit the control panel.
 - vi. The REAL Immersive System should now be connected.
 - d. To connect by whitelisting the device MAC address:
 - i. Select “Status” from the menu.
 - ii. The device MAC address is listed under WAN.
 - iii. Whitelist the MAC address on the local network. See your IT Administrator for network support.
 - iv. Select “Wireless 5 GHz” from the menu. If the network is not a 5 GHz network, select “Wireless 2.4 GHz”.
 - v. Select “Scan” to search for local networks.
 - vi. Locate the desired network from the list.
 - vii. Select “Connect” next to the desired network.
 - viii. Select “Save” and exit the control panel.
 - ix. The REAL Immersive System should now be connected.

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

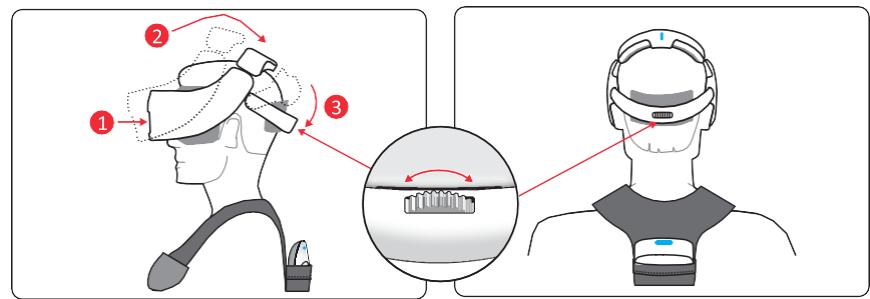
SECTION 3: START-UP SYSTEM FOR PATIENT USE

1. Unplug power cords from tablet and headset when charged and ready for use, the LED lights on the headset should be solid green when fully charged.
2. If tablet is not turned on, turn on.

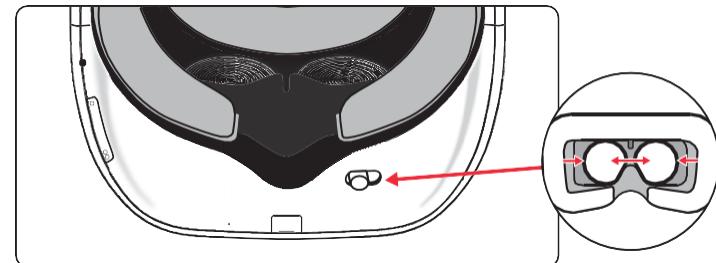
3. Turn on headset by pressing and holding power button for approximately 5 seconds.



4. Ensure the patient is in a seated position away from metal components and remains seated at all times for the duration of the therapy session.
5. Place headset on patient's head in the sequence numbered below. Patient can immediately begin visually interacting with the environment.



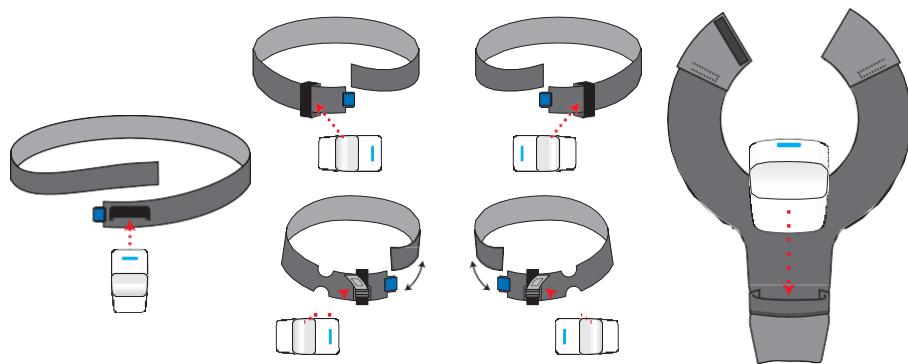
Note: Size of headset strap and interpupillary distance can be adjusted for fit. Top of head pad may be removed temporarily for better fit on larger heads.



Note: Patient may keep eyeglasses on.

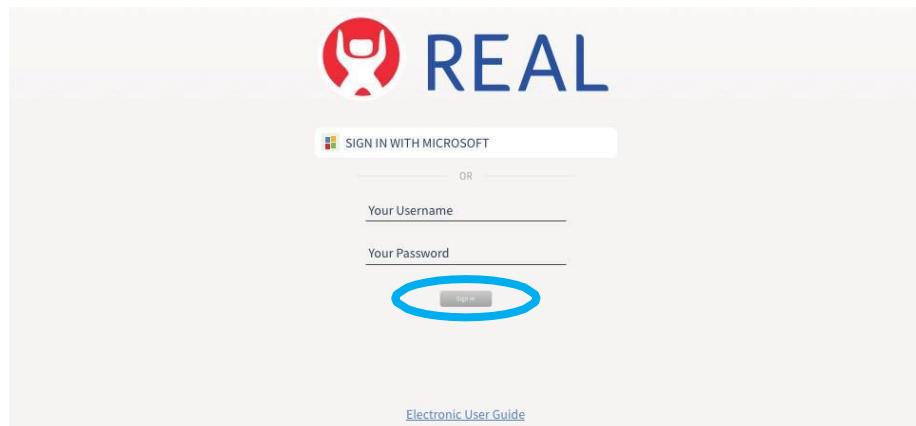
6. Remove sensor bands from reusable packaging (sold separately).
7. Remove all sensors from sensor charger.

8. Place 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 shoulder band.



9. Once sensors are placed in the bands, put each band onto its corresponding body part (see image below). Connect hook and loop fasteners of shoulder band if desired. Make sure the elbow sensor is sitting behind the patient's elbow. Adjust bands for comfortable fit, if necessary.

10. Log in on the tablet. Add new patient or select patient from directory; edit patient information as needed.

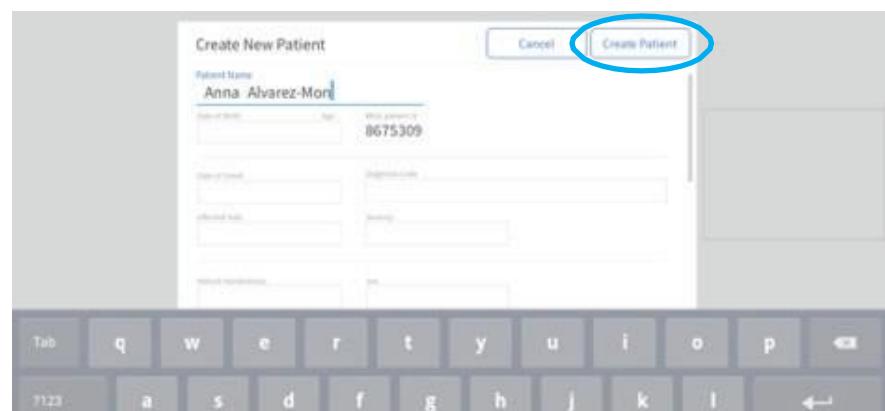
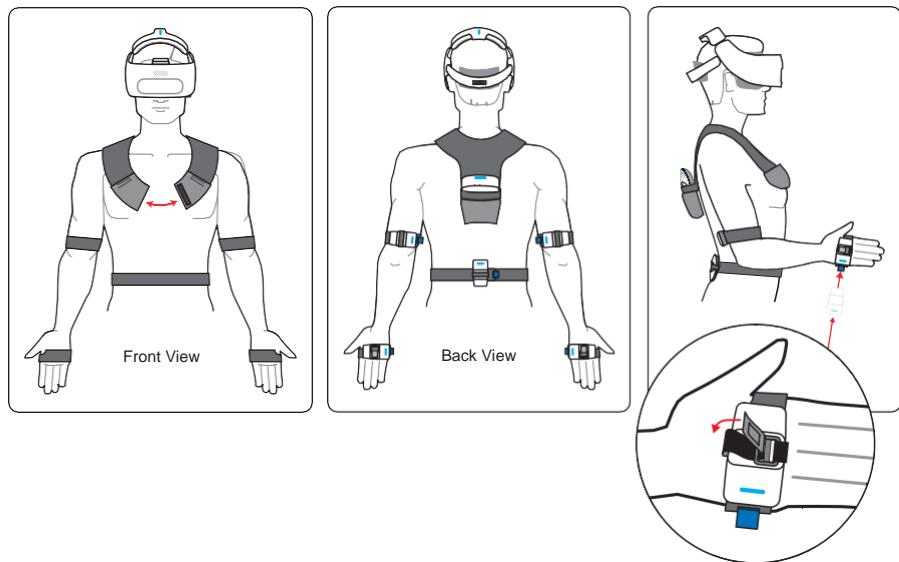


Find A Patient

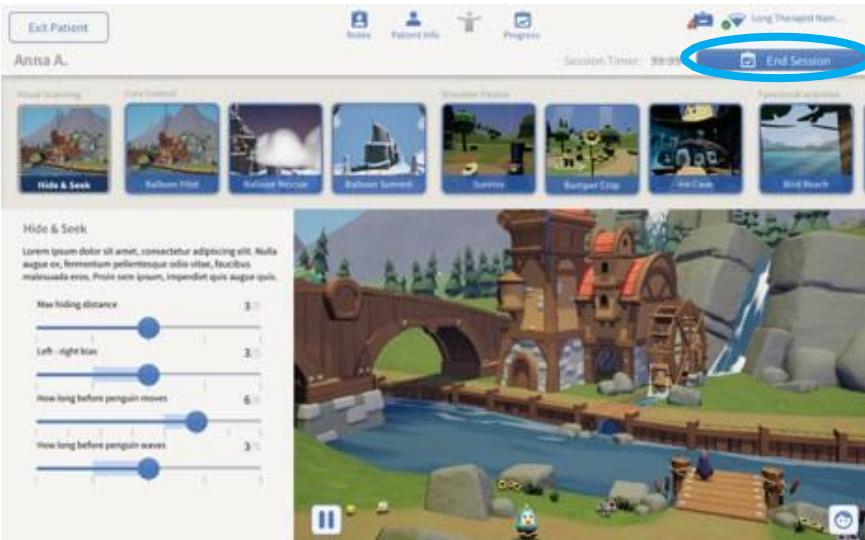
All Patients

Patient List

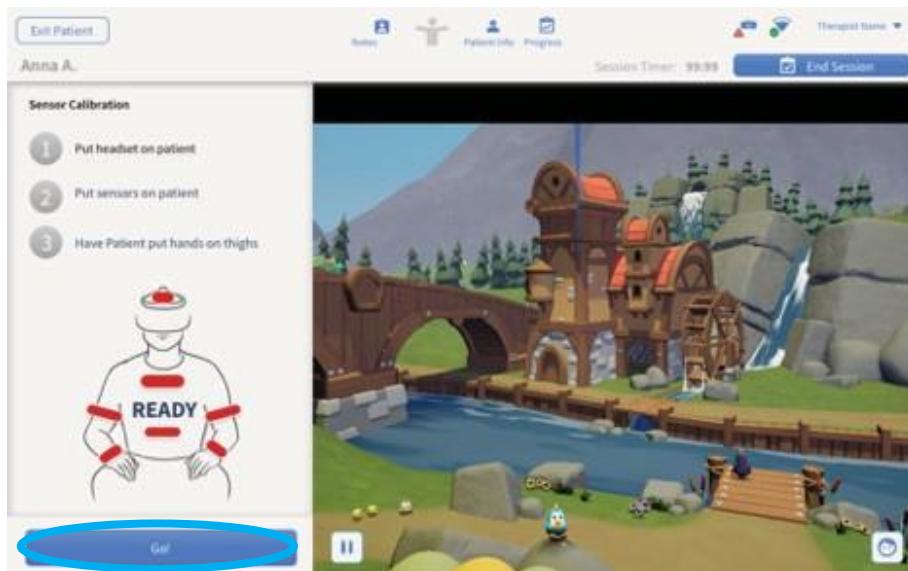
Anna Alvarez	51
Barron Arnold	58
Kenneth Leung	66
Lilith Fiorina	42
Mannie Mendoza	70
Michael Diamond	49
Trouc Nguyn	30
Sairam Suresh	80



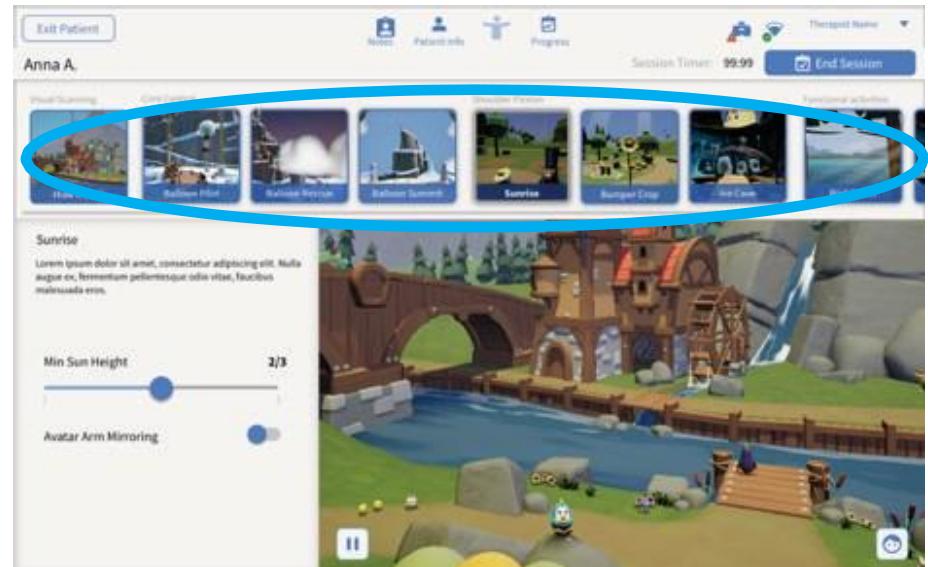
11. Once a patient is selected or created, the healthcare provider (HCP) may initiate the session by pressing "Start Session" from the header. Each session begins in the Hide and Seek game by default. See figure below



12. Orient the patient in a neutral seated position, facing forward. Press the Go button on the tablet.

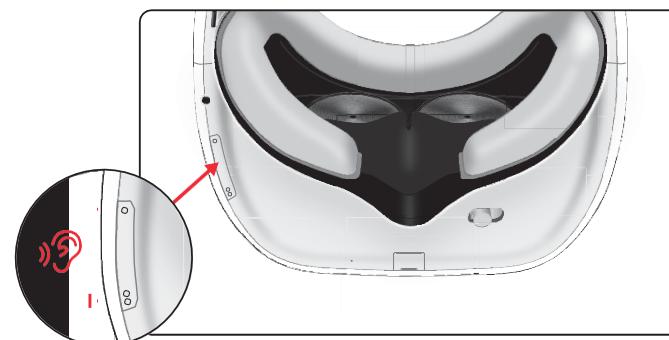


13. The HCP may navigate to additional therapy experiences by selecting the corresponding icon from the display. Once the activity has loaded, the HCP can press the "Start Activity" button to start the activity. See Section 4 for more information.



Section 4: THERAPY EXPERIENCE

1. Confirm patient's avatar in VR space corresponds to actual patient's physical movement.
2. Confirm patient's view in the VR space corresponds with patient's head movement.
3. Confirm application audio can be heard but doesn't block out HCP's communication; adjust volume on headset as needed.

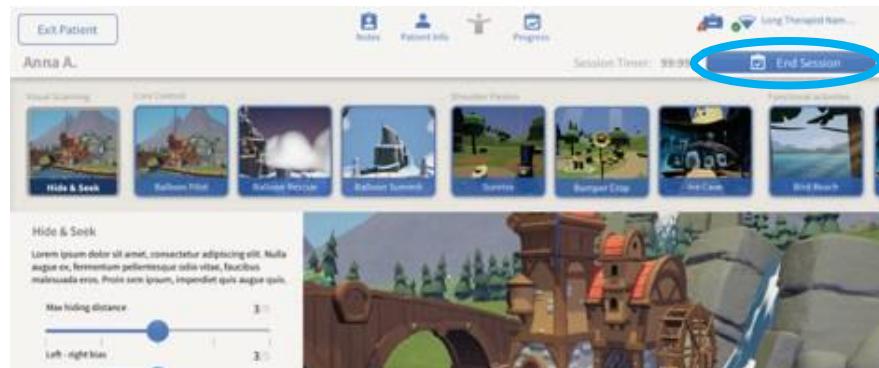


4. Conduct rehabilitation session as planned. (See Section 6 which includes a software description for details of therapeutic experiences).

- Always remain with the patient throughout therapy session to provide direct supervision.
- Monitor patient view on tablet; 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. Sensors are turned off and on by placing them in the powered charging station and removing them again.

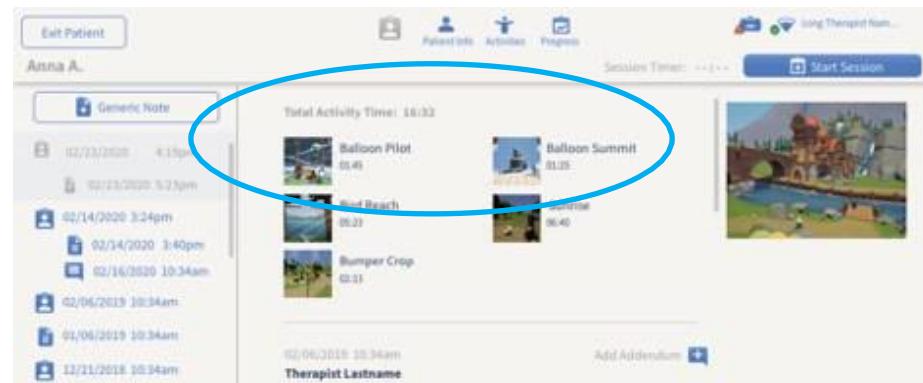
- When planned therapy experiences are complete, press "End Session" on tablet. Patient will be returned to the Hide and Seek experience without a tracked avatar. Gaze interactions will still function.



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

The screenshot shows the tablet's interface with the 'Notes' tab selected, indicated by a blue circle around the 'Notes' icon in the top navigation bar. The top bar also includes 'Exit Patient', 'Patient Info', 'Activities', and 'Progress'. The 'Session Timer' is set to 00:00. Below the timer is a blue button labeled 'Start Session'. The main content area displays a table of patient results for various joints: Cervical, Shoulder, Elbow, Forearm, and Wrist. Each joint has rows for Rotation, Flexion, Extension, Abduction, and External Rotation, with values in degrees and a plus/minus sign. To the right of the table is a small image of the 'Balloon Pilot' game. At the bottom right, there is a 'Data From Session' section with the date 3/12/2019 and a time range of 10:34am - 11:16am.

		Left	Unspecified	Right
Cervical	Rotation	80° +		80° +
	Flexion		70° -	
	Extension		70° -	
Shoulder	Flexion	55° +		54° +
	Extension	32° +		45° +
	Abduction	28° -		36° +
	External Rotation	62° +		81° +
Elbow	Flexion	110° +		150° +
	Extension	32° -		48° +
Forearm	Pronation	55° +		58° +
	Supination	41° -		82° +
Wrist	Flexion	21°		88°
	Extension	36° +		65° -



Section 5: SYSTEM REMOVAL

- Remove sensors and bands.
- Remove headset from patient's head.
- Power off headset by pressing and holding onto the power button for approximately 5 seconds.
- Log out of tablet and power off tablet.
- Clean headset and sensors with institutional approved sanitizing wipes*.
- Connect tablet and headset to their respective power cords.
- Return all sensors to sensor charger. Green LEDs should be noted on sensors when placed correctly in the charging station.
- Store and label bands for future individual patient use.
- Ensure REAL Immersive System Case is plugged in and component LED lights indicate charging.
- 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. Therefore, it may be necessary to power cycle the headset and/or restart the application on the tablet in between therapy sessions.

*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 institutional 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: SOFTWARE DESCRIPTION

The REAL Immersive System contains a variety of experiences that incorporate clinically recognized, existing therapeutic and functional exercises to facilitate motor and cognitive rehabilitation. Settings for each experience will involve parameters such as turning on and off avatar features and environmental factors as well as switching between activities. 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 Game 1: Hide and Seek



Hide and Seek can be used with or without a displayed avatar tracking the patient's upper body because it primarily relies on head movement and visual scanning ability. Once the sensors have synced, the avatar should appear. 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 the experience the patient first starts with, giving a chance for the HCP to place sensors on the patient's body and then activate visualization of the avatar. It's also the last experience prior to ending the patient's session which provides the ability for the HCP to remove the sensors and for the patient to 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. The penguin will then disappear and reappear in a different location. The pointer is positioned to represent the patient's upper body vertical midline, 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 as to their true body midline helping them relearn to position themselves in relation to it. 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 will have control over the range of locations that animals appear and wait to be found through "difficulty" settings on the tablet. Hide and Seek locations in the world will change and evolve over a number of sessions to provide an experience of logical progression and achievement as the patient continues their course of rehabilitation.

Therapy Game 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, such as knocking apples off a tree and contacting other balloons or clouds. 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.

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. 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. Objects, such as bridge components, can also be picked up and carried over to the mountain to help hikers cross gaps.

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, over to the house

stage. Wind driven clouds bump into the balloon and move the balloon arbitrarily which the patient has to counteract with trunk movements.

Therapy Game 3: Sunrise



This experience 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.

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 experience will be stored as a session output for the HCP's record.

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 experience and feedback of a simple coordinated arm raise.

Sub-Activity 2: Harvest



The Bumper Crop sub-activity involves growing a variety of vegetables by raising and lowering ones arms a number of times in order to trigger the appearance of day-night cycles. Different numbers of cycles necessary to fully grow a vegetable can be controlled by the HCP through difficulty settings. Upon full growth of each vegetable, the patient receives an award that is saved in their game record. 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 ones arms a number of times in order to trigger the appearance of day-night cycles. Different numbers of cycles necessary to fully free a penguin can be controlled by the HCP through difficulty settings. Upon each Cave Penguin's release, the patient receives an award that is saved in their game record. 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 Game 4: Bird Forest



The Bird Forest experience incorporates standard functional exercises into a virtual reality experience by requiring the patient to reach out with one or both hands to allow a bird in their immediate vicinity to jump into their hand.

Patients have opportunities to reach from low to high, high to low, from left to right crossing their midline, etc. 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.

Adjustable settings include the number of nests and their placement around the patient, whether the hand must properly pronate and supinate in order to pick up and deposit a bird, the smoothness and/or speed of movement required to get a bird to a nest before they fly away, the color of target nests and the patterns applicable to the cognitive exercises.

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 game 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 our 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 dropped off to colored target nests in a specific order. Only one target nest will be active at a time. The bird will be placed in a sequence of non-repeating colored target nests. When all nests have been filled, the exercise will reset.

Therapy Game 5: Penguin Sports Park



In this activity, the patient must move their upper extremities to intersect with 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.

Sub-Activity 1: ChuckleBall™

The patient fends off approaching Chuckleballs by deflecting them with his head or hands. There are no additional difficulty levels. The Chuckleballs will be kicked continually until a new activity is started.

Sub-Activity 2: Chuckleball Arena

Chuckleball requires the patient to protect their 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 advanced patients can learn to deflect the chuckle back 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 the hand or the head. 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	30% to 90%
Operating Elevation	2,500 meters or less
Radio Module	Output power (EIRP*): 1 mW (0 dBm) typical Frequency Band: ISM (Industrial, Scientific, and Medical) Typical Center frequency: 2.44 GHz Channel: 40 channels Bandwidth: 2 MHz per channel Modulation: GFSK (Gaussian frequency-shift keying) Data flow: Bi-directional *EIRP = Equivalent isotropically radiated power

*REAL Immersive System 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)
	Prescription only – US Federal Law restricts this device to use by or on the order of a physician
	Type B Applied Part
	WEEE
	Manufacturer
	Catalog Number
	Lot Number
	Serial Number
	Date of Manufacture
	No protection against ingress of solid and liquid
	Both Direct and Alternating Current
	Class II Equipment

REAL Immersive System is a Type B Applied Part.

TECHNICAL INFORMATION

REAL™ Immersive System Case Instructions:

The case resembles a suitcase and includes a TSA approved zipper lock.

How to reset the combination lock:

1. Set all combination dials to the following: 0-0-0.
2. Find the hole located to the right of the dials. Use a paper clip or similar device to press down on the reset button until an audible "click" is heard.
3. Set personal combination by turning the dials to display the desired set of numbers, e.g. 2-8-7.
4. Push the slide button located on the left of the dials towards the direction of the arrow and the reset button will push back up. An audible "click" will be heard.
5. Remember the personal combination and repeat the steps above to reset the personal combination, if necessary.

How to use the combination lock:

1. Turn the dials to the correct combination, and push the slide button on the left of the dial towards the direction of the arrow to unlock.
2. Put in the loop portion of the zipper into the slots of the lock, then turn the dials randomly to conceal the personal combination to lock.
3. Repeat step 1 to unlock case.

WARNING: TSA key lock must be turned to the red dot position at all times. If the TSA key lock is turned away from the red dot, it must be turned to the red dot position. Any tool which can be inserted in the TSA key lock is acceptable to use.

REAL™ Immersive System is intended for use in the electromagnetic environment specified below. The customer or the user of REAL Immersive System should assure that it is used in such an environment.		
Emissions Test	Compliance	
RF emissions CISPR 11	Group 1	REAL Immersive System 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 A	REAL Immersive System is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/ Flicker emissions	Complies	

REAL Immersive System is intended for use in the electromagnetic environment specified below. The customer or the user of REAL Immersive System 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 commercial or hospital 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 commercial or hospital 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 commercial or hospital environment. If the user of the EQUIPMENT requires continued operation during power mains interruptions, it is recommended that REAL Immersive System 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 commercial or hospital environment.

REAL Immersive System is intended for use in the electromagnetic environment specified below. The customer or the user of REAL Immersive System 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 radio Bands within 150kHz – 80MHz)	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of REAL Immersive System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m	Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.7 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.

^aField 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 Immersive System is used exceeds the applicable RF compliance level above, REAL Immersive System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating REAL Immersive System.

^bOver 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 Immersive System			
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 modulation b) 217 Hz	0.2	0.3	9
745			Pulse modulation b) 18 Hz			
780	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18 Hz	2	0.3	28
810			Pulse modulation b) 217 Hz			
870	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation b) 18 Hz	2	0.3	28
1720			Pulse modulation b) 217 Hz			
1845	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation b) 217 Hz	2	0.3	28
1970			Pulse modulation b) 18 Hz			
2450	5100-5800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	0.2	0.3	9
5240			Pulse modulation b) 217 Hz			
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 A 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 commercial environment. 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. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

Mode of Operation:
Charging mode and battery mode

Highest Clock Frequency:
HMD: 32 MHz
WSM: 24.576 MHz
WTM: 24.576 MHz

Frequency Range:
2402 MHz – 2480 MHz

Transmitting Frequency and Modulation:
Frequency-shift Keying (FSK) modulation. 2Mbps 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 Average Gain -0.5 dBi
WTM			
HMD	MVI Health Inc.	P/N 14536	Min: -1 dBi Max: 2.4 dBi

Power Output and Data Rate:

Device	Power Output	Data Rate
WSM		
WTM	Transmitter with programmable output power of +4 dBm to -20 dBm, in 4 dB steps. Programmed by the firmware to +0dBm.	GFSK modulation, 2 Mbps data rate.
HMD		

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