REAL™ IMMERSIVE SYSTEM

USER MANUAL

Table of Contents

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 DESCRIPTON

The REAL® Immersive System is a digital hardware and software medical device platform utilizing virtual reality technology designed for use in a clinical environment, or any other facility that may facilitate rehabilitation, setting that focuses on physical, neurorehabilitation and/or wellness needs.

REAL Immersive System consists of following components:

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

Tablet is fitted with a touch screen, a power/lock key 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 small and large sensors.

Large and small sensors (WTM and WSMs) 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 (Only to be used in certain troubleshooting and administrative tasks. Not used during patient therapy.)

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. Please sufficiently charge all 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 BF Applied Part.

Frequently used features and functions:

Headset

- Plug headset power cord into wall outlet and headset to charge device. • Press power button to power 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

- Components are removed or placed back into the sensor charger (charging station) to activate or charge device.
- Components are placed into the sensor bands.

Tablet

- Plug tablet power cord into wall outlet and tablet to charge device.
- Press power button to power on tablet or restart tablet. The power button is on the edge of the device.
- User Interface:
    - 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

Sensor Charger

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

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 three-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 three-year product lifespan. Circuit diagrams and calibration instructions are not provided because service or parts repair is not necessary.

At the end of the three-year product lifespan, the user should dispose of the device through an environmentally safe electronic waste recycle system. Contact the local REAL representative if the following event occurs:

- The system no longer stays powered on and connected through the entire recommended duration of a therapy session.

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 or any other facility that may facilitate rehabilitation and prescribed and supervised by a medical professional trained in rehabilitation therapy.

CONTRAINDICATIONS
There are no known contraindications.

WARNINGS
If a patient complains of 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 and ensure that the patient is unlikely to trip or fall). As this device is to be used for upper body rehabilitation, we recommend that the patient 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.

Damage (mechanical and electrical) may result if the tablet, 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.

3rd conductor of the AC cord is only a functional earth. To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

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 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 Penumbra. Any changes or replacements of accessories will likely impact compliance of REAL Immersive System.

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

AC power cord must not exceed 6 feet in length.

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

• skin irritation

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. Follow hospital guidelines for use and access to account login credentials. The same account login credentials shall not be used by more than one REAL System at any given time.

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.

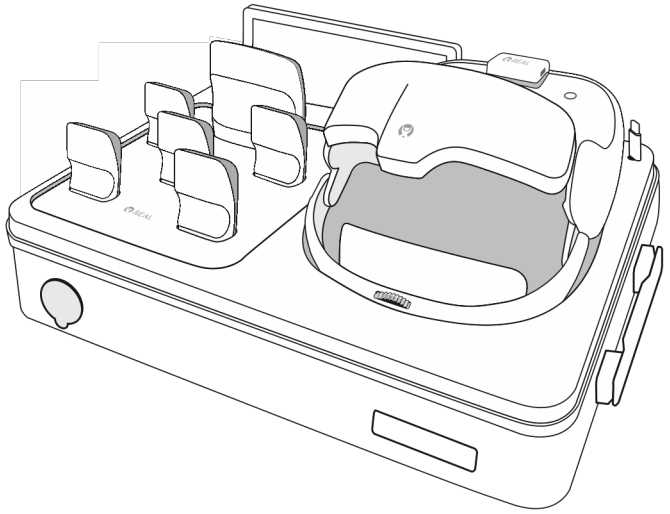
OPERATING PROCEDURE

Note: Prior to first time use, HMD and Tablet must be configured and connected to the local internet. Note: Over-the-air software updates may occur throughout the lifespan of the REAL System. User may be prompted/required to complete software updates to continue using the product.

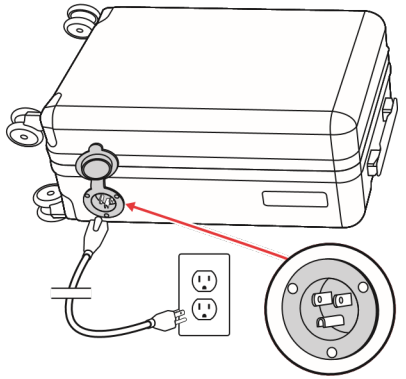
Note: These rehabilitation exercises are intended to be conducted in a seated position. The patient must be seated at all times when the system is in use.

SECTION 1: GETTING STARTED AND CHARGING COMPONENTS

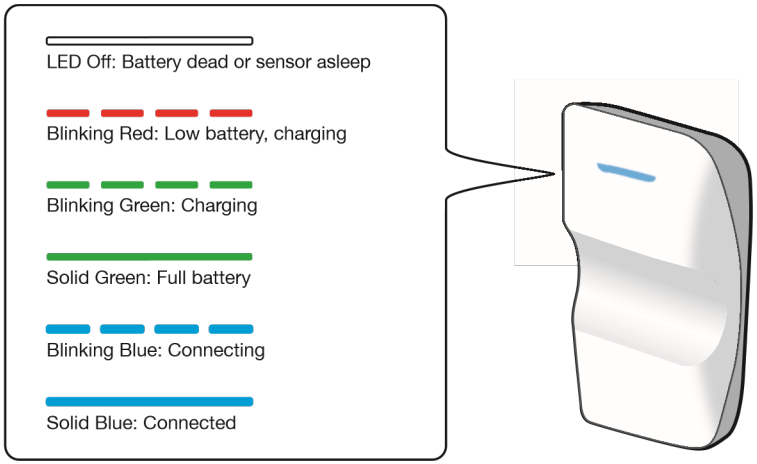
1. Remove REAL Immersive System case from the shipping container.



2. Connect the REAL Immersive System case to its power cord (AC adapter power cord). Plug the power cord into a grounded electrical outlet, making sure that it is the same voltage as indicated on the unit nameplate. Ensure the power receptacle is connected to a supply mains with protective earth.

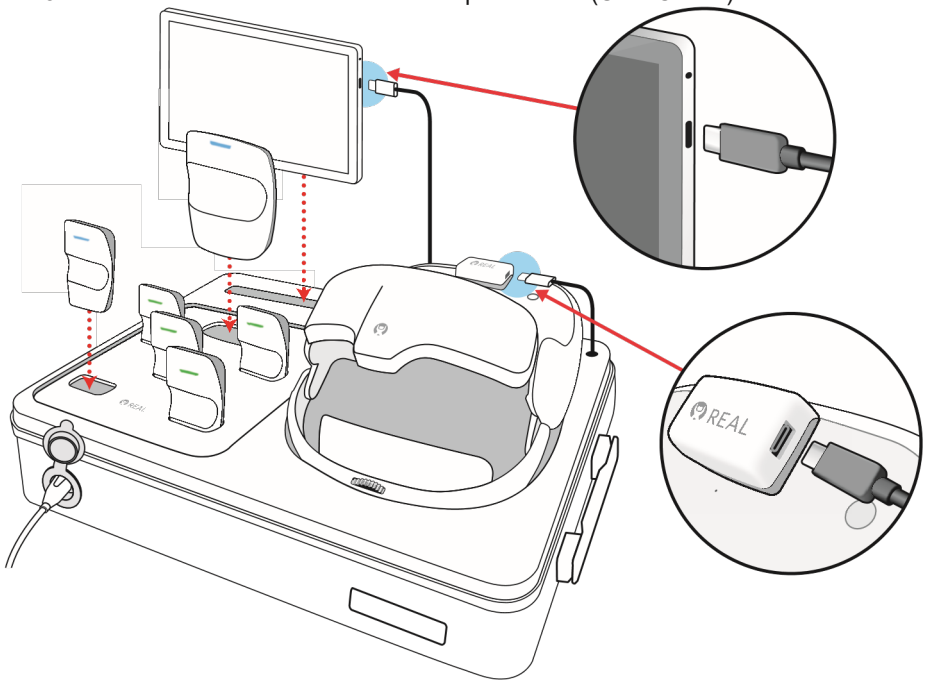


3. Ensure sensors with white sides facing forward are in their corresponding size slots on the sensor charger. LED lights on sensors will show the following:



4. Ensure the headset is connected to its power cord (USB-C cord). LED lightson top of headset will only 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

Connecting via WiFi

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.

4. Connect using the desired wireless network name and password.
5.
6. Click the button at the top left of the screen to return to the TherapyView home screen.

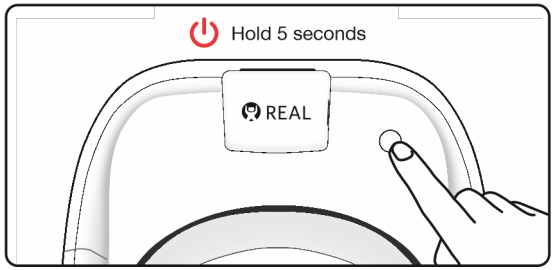
Continue to Section 3 when the components are sufficiently charged, and the system has secure internet connectivity.

SECTION 3: START-UP SYSTEM FOR PATIENT USE

1. Unplug power cords from tablet and headset when ready to use.

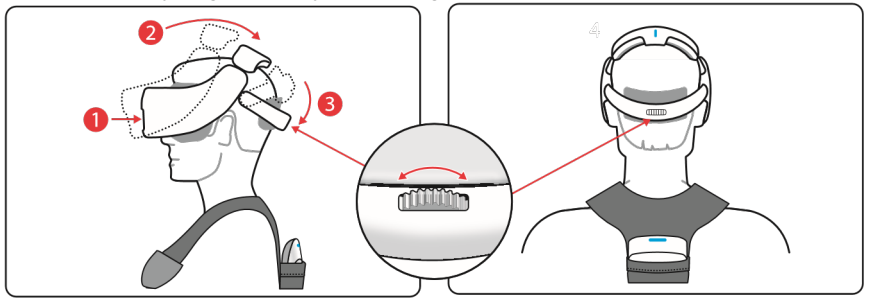
2. If tablet is not turned on, turn on.

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

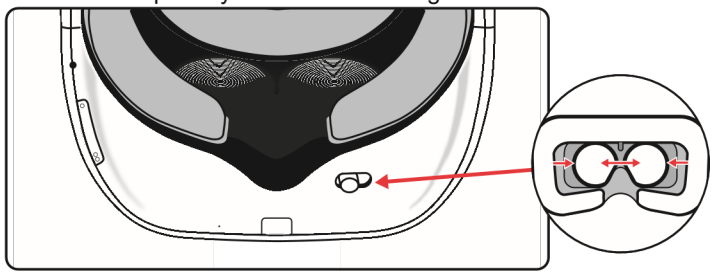


4. Ensure the patient is in a seated position away from metal components and remains seated at all times for the duration of the therapy session.

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.

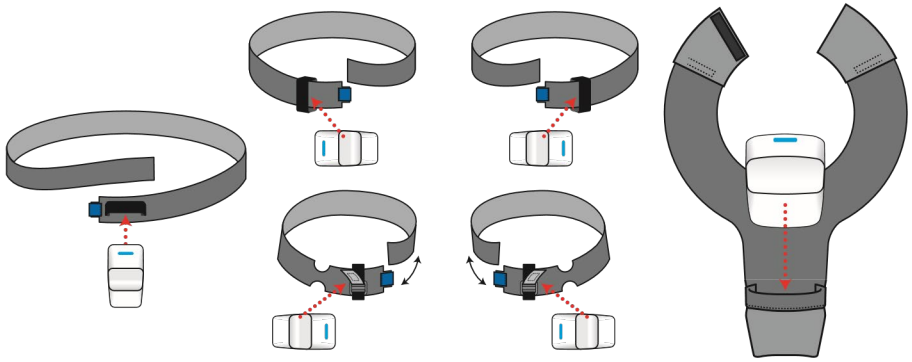


Note: Patient can keep eyeglasses on.

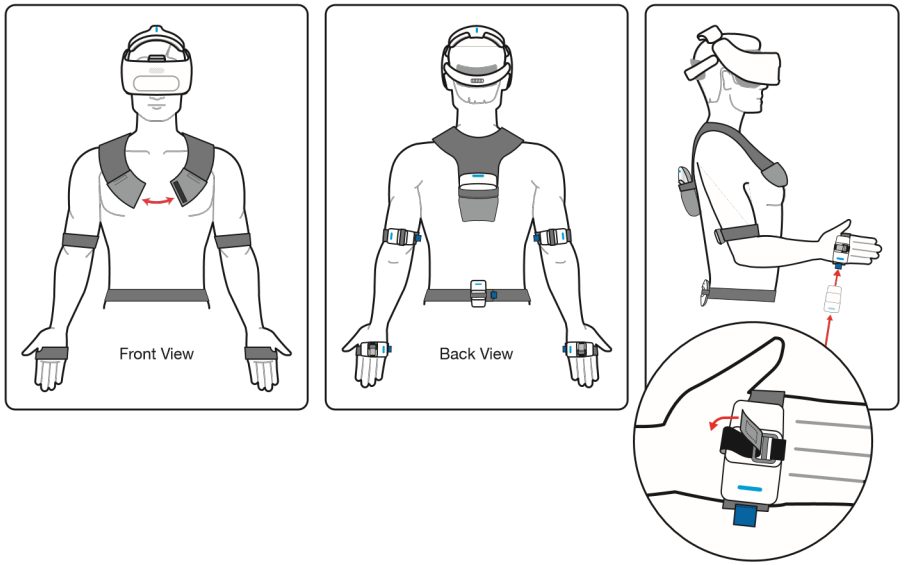
6. Remove sensor bands from reusable packaging (sold separately). Each patient should have their own sensor bands and bands should not be shared between patients.

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.

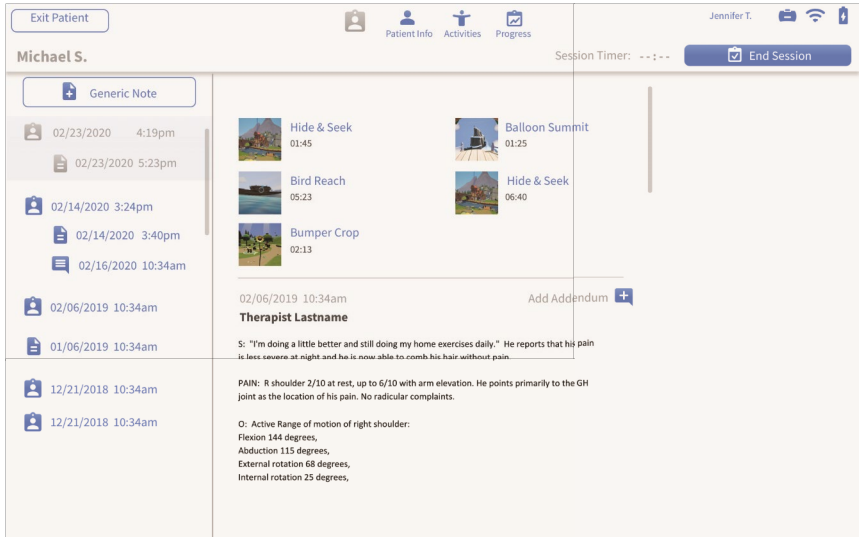


9. Once sensors are placed in the bands, put each band onto its corresponding body part (see image below). Connect hook and loop fasteners of shoulder band if desired. Make sure the elbow sensor is sitting behind the patient's elbow. Adjust bands for comfortable fi t, if necessary.

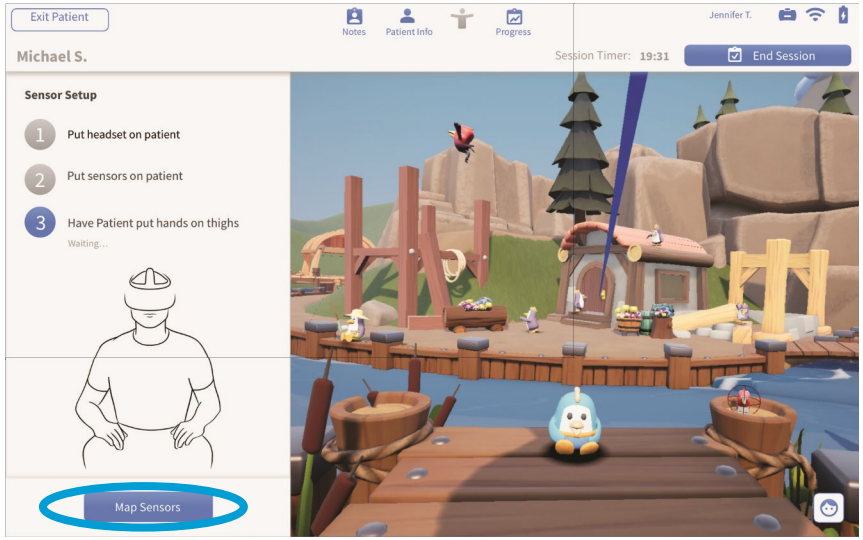


10. Log in on the tablet. Add new patient or select patient from directory; edit patient information as needed.

11. Once a patient is selected or created, the healthcare provider (HCP) may initiate the session by pressing "Start Session."



12. Have the patient sit in a neutral position, facing forward with hands on knees or thighs. Press the button on the tablet screen to calibrate the sensors.

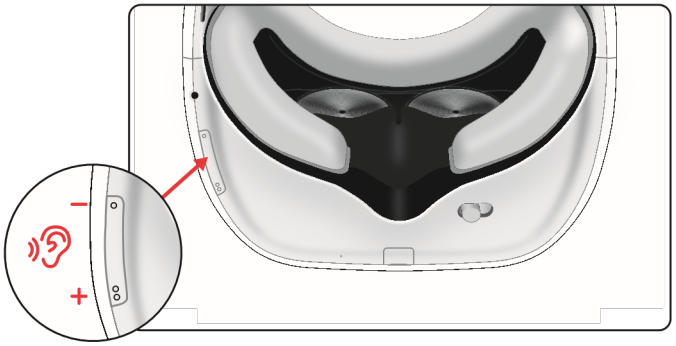


13. Confirm patient's avatar in VR space corresponds to actual patient's physical movement. Edit the default avatar settings to match your patient. If the avatar looks correct, press "Continue". If not, HCP can recalibrate the sensors by selecting the "Remap Sensors" button.
14. The HCP may navigate to additional therapy activities by selecting the corresponding icon from the display. Once the activity has loaded, the HCP can press the "Start Activity Session" button to begin the activity. See Section 6 for more information.

Section 4: THERAPY ACTIVITIES

1. Confirm patient's avatar in VR space corresponds to actual patient's physical movement.

2. Confirm application audio can be heard but doesn't block out HCP's communication; adjust volume on headset as needed.



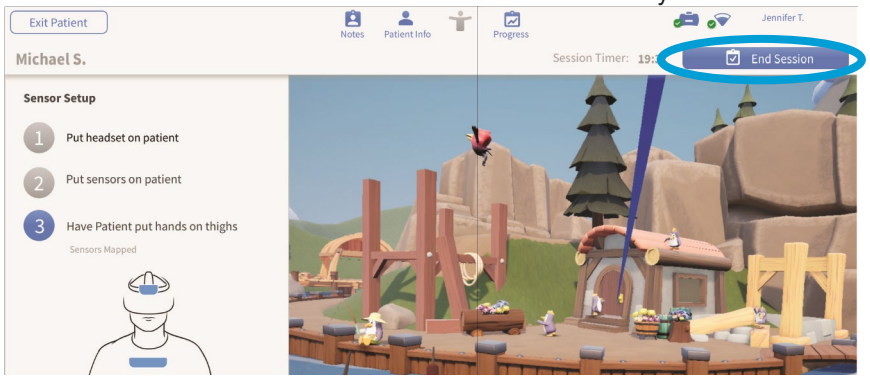
3. Conduct rehabilitation session as planned. (See Section 6 which includes a software description for details of therapeutic activities).

4. Always remain with the patient throughout therapy session to provide direct supervision.

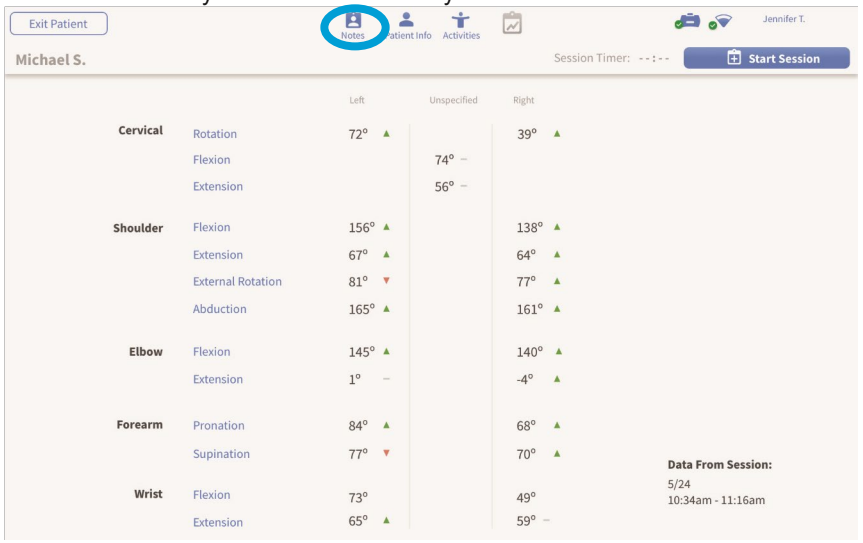
5. Monitor patient view on tablet; select and begin new activities as desired.

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™ Immersive System is plugged in) and removing them again.

6. When planned therapy activities are complete, press "End Session" on tablet. Patient will be returned to the Hide and Seek activity.



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



Section 5: SYSTEM REMOVAL

1. Remove sensors and bands.

2. Remove headset from patient's head.

3. Power off headset by pressing and holding onto the power button for approximately 5 seconds.

4. Log out of tablet.

5. Clean headset and sensors with institutional approved sanitizing wipes*.

6. Ensure REAL Immersive System Case is plugged in.

7. Connect tablet and headset to their respective power cords.

8. Return all sensors to sensor charger. Red or green LEDs should be noted on sensors when placed correctly in the charging station.

9. Store and label bands for future individual patient use.

10. 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 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.

REAL™ Immersive System Case Instructions:
The REAL Immersive System is housed in a travel case that may be locked with the attached combination lock that secures the zipper. The combination lock should be turned to the red dot position at all times. If the combination lock is turned away from the red dot, turn it to the red dot position.

How to reset the combination lock:
1. Set all combination dials to the following: (0-0-0 default)

2. Find the hole located to the right of the dials. Use a paper clip or similar tool 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. To unlock: Turn the dials to the correct combination. Push the slide button on the left of the dial towards the direction of the arrow to unlock.

2. To lock: Put the loop portion of the zipper into the slots of the lock, then turn the dials randomly to conceal the personal combination to lock.

Section 6: SOFTWARE DESCRIPTION
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 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 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 defl ect 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	30% to 90%
Operating Elevation	2,500 meters or less
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 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)
Rx Only	Prescription only – US Federal Law restricts this device to use by or on the order of a physician
	Type BF Applied Part
	WEEE
	Manufacturer
REF	Catalog Number
LOT	Lot Number
	Date of Manufacture
	Both Direct and Alternating Current
	Class II Equipment
SN	Serial Number
ETL CLASSIFIED c ETL us Intertek	US and Canada Certification
MD	Medical Device

TECHNICAL INFORMATION

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 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 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 fi eld IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fi elds 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. **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].
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m	

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 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. [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 Immersive System

REAL Immersive System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of REAL Immersive System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and REAL Immersive System 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 modulation b) 217 Hz	0.2	0.3	9
745						
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

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

Frequency Range:
2402 MHz – 2479 MHz

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 Average Gain -0.5 dBi
WTM			
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.

Manufacturer:
Penumbra Inc.
One Penumbra Place
Alameda, CA 94502 USA

Tel: 1.855.REAL-SYS
1.855.732.5759

13661.A B
2019-12 2020-10