

User Manual

Penumbra Inc.
One Penumbra Place
Alameda, CA 94502, USA
Tel: 1.888.272.4606
1.510.748.3200

DEVICE DESCRIPTION

The REAL Immersive System consists of a clinician tablet, head-mounted display (HMD) component, small sensors, large sensor, sensor charger, router, router battery, HMD controller, power cords, USB cables. *Note: Bands sold separately.*

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

Head-mounted display (HMD) provides visual feedback of virtual reality applications in concert with the REAL Immersive System tablet and small and large sensors.

Small and large 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.

HMD controller (Only to be used in certain troubleshooting and administrative tasks. Not used during patient therapy.)

In the event of EM disturbances, REAL Immersive System may not operate accordingly to what is described in device description.

The REAL Immersive System is a Type B Applied Part.

The following are frequently used functions:

HMD

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

HMD Controller

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

Large Sensor and Small Sensors (WTM and WSMs)

- Components are removed and placed back onto the Sensor Charger (charging station) to activate or charge device.
- Components are placed onto 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 side of the device.
- User Interface:

- o Selecting the application
- o Logging in
- o Adding or selecting patient
- o Initializing and syncing to sensors
- o Selecting, starting, modifying, or ending therapy session
- o Viewing data
- o Logging out

Sensor Charger

- Plug Sensor Charger power cord into wall outlet and Sensor Charger to power on device to charge WSM and WTM.

Router/Router Battery

- Power Router with Router Battery
- Plug Router Battery power cord into wall outlet and Router Battery to charge device

Sensor Bands

- Place or remove Sensor Bands onto and from patient

There are 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 such 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.

Therefore, circuit diagrams and calibration instructions are not provided because service in parts repair are not necessary.

At the end of the one-year product lifespan, the user should dispose of the device through a safe environmentally electronic waste recycle system.

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

INTENDED 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 with conditions or symptoms associated with acute pain, cerebral palsy, stroke, orthopedic, or neurodegenerative disease such as Parkinson's, dementia, and Alzheimer's, 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/PRECAUTIONS

Damage (mechanical and electrical) may result if the tablet, HMD, sensors, router, router battery, 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.

Do not touch the router and patient at the same time. Patients are not allowed to touch the router at any time.

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

Do not use sensors near metal including, but not limited to, wheelchairs, walkers, and utility carts.

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

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.

Handle the lenses on the HMD carefully to avoid smears or scratches. Wipe lenses with a soft-lens cleaning cloth as needed.

Clean outer and inner plastic components of HMD with 70% or less isopropyl alcohol (IPA) 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.

No modification of this equipment is allowed.

Keep the original box and protective packaging for transporting components between locations or shipping purposes.

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.

OPERATOR PROFILE

Operators of the REAL Immersive System should be trained in occupational or physical therapy.

INSTALLATION

1. Remove REAL Immersive System tablet, head-mounted display (HMD), small sensors, large sensor, sensor charger, router, router battery, power cords, and USB cables from container.
2. Place sensor charger on a flat, stable surface. Router should remain in reasonable proximity to patient.
3. Connect the sensor charger to its power cord. Plug the sensor charger's 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.
4. Insert sensors with white sides facing forward in their corresponding slots on the sensor charger.
5. Connect the HMD to its power cords. Plug each power cord into an electrical outlet, making sure that it is the same voltage as indicated on unit nameplate. Ensure each power receptacle is connected to a supply main with protective earth.
6. Connect the tablet to its power cord. Plug the tablet's power cord into an 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.

Note: Charging is complete when the indicator on each component is lit.

INSTRUCTION FOR USE

First-Time Use: Connect router to external internet.

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

1. Unplug power cords from tablet and HMD when charged and ready for use.
2. Power on and/or wake tablet.
Note: REAL Immersive System application launches.
3. Log in
Note: REAL Immersive System home page appears.
4. Add new patient or select patient name from directory; edit patient information as needed.
5. Turn on HMD
6. Tap “start session” on tablet to initiate user experience.
7. Place HMD on patient’s head.
Note: Size of HMD head strap and intrapupillary distance can be adjusted for fit.
8. Remove bands from packaging (sold separately).
9. Remove all sensors from sensor charger when charged and ready for use.
Note: Each sensor must be positioned on the patient according to its label and the white side of each sensor must be visible.
10. Place small sensors into elasticized loops on short, notched bands for hands, medium bands for upper arms above the elbow, and belt band for the waist. Adjust bands for comfortable fit. Sensors should be placed white side up, with indicator LED pointing outward from center torso. Waist sensor should be placed on patient’s right, with white side up and indicator LED pointing outward.
11. Place large sensor into pocket of shoulder band. Sensor should be placed white side up, with indicator LED pointing upward. Connect hook and loop fasteners of shoulder band if desired.
12. Tap “initialize” button to sync sensors. Check indicator lights on patient diagram on tablet screen to confirm all sensors are synced.
19. Select activity.
20. Confirm patient’s avatar in VR space corresponds to actual patient’s physical movement.
21. Confirm patient’s view in the VR space corresponds with patient’s head movement.
22. Confirm application audio can be heard but doesn’t block out therapist’s communication; adjust volume on HMD as needed.
23. Conduct rehabilitation session as planned.
24. Monitor patient view on tablet; select and change activities as desired.
Note: If sensors lose synchronization or HMD loses tracking system, entire system may be turned off and back on to reset.
25. End session.
26. View patient results; enter “pain rating” and notes as required.

SYSTEM REMOVAL

1. Remove sensors and bands.
2. Remove HMD from patient’s head.
3. Clean HMD and sensors with 70% or less isopropyl alcohol (IPA) wipes.
4. Connect tablet and HMD to their respective power cords.
5. Return all sensors to sensor charger.
Note: Indicator lights appear when components are charging successfully.
6. Store and label bands for future patient use.

SPECIFICATIONS

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 Protocol: Nordic Gazell *EIRP = Equivalent isotropically radiated power

SYMBOL GLOSSARY

	Refer to Instruction Manual / Booklet
	Type B Applied Part
	WEEE
	Manufacturer
	Catalog Number
	Lot Number
	Date of Manufacture
	Federal Communications Commission
IP00	No protection against ingress of solid and liquid
Intertek?	Certification?
	Direct Current

REAL Immersive System is a Type B Applied Part.

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.			
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.

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.			
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
			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

Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz (6 Vrms in ISM radio Bands within 150kHz – 80MHz)	3 Vrms	$d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m	$d = 1.2\sqrt{P}$ 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 metres (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 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.

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	1 700 – 1 990	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	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation ^{b)} 217 Hz	2	0.3	28
5240	5 100 – 5 800	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 licence-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's licence-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:

Dongle: 16MHz

WSM: 24.576MHz

WTM: 24.576MHz

Frequency Range:

2402MHz - 2479MHz

Transmitting Frequency and Modulation:

Frequency-shift Keying (FSK) modulation. 2Mbit modulation for all transmitter frequencies.

Operating Channels:

6 Channels per the following table.

Channel	F1	F2	F3
20	2402 MHz	2439 MHz	2469 MHz
21	2405 MHz	2444 MHz	2474 MHz
22	2410 MHz	2449 MHz	2479 MHz
23	2415 MHz	2454 MHz	2428 MHz
24	2420 MHz	2459 MHz	2431 MHz
25	2425 MHz	2464 MHz	2436 MHz

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
RF Dongle	NORDIC	nRF52	Peak Gain -2 dBi
			Average Gain -3.7 dBi

Power Output and Data Rate:

Device	Power Output	Data Rate
WSM	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.
WTM		
RF Dongle	Transmitter with programmable output power of 0 to -18 dBm, in 6 dB steps.	