

## IMeasureU Sensor V1 Safety and Regulatory Information

The terms "device" or "wireless device" used in this section refers to your IMeasureU Sensor V1 wearable product. **Read this information before using your device.**

### Federal Communications Commission (FCC) Part 15 Information to User

Pursuant to part 15.21 of the FCC Rules, you are cautioned that changes or modifications not expressly approved by Vicon Motion Systems Ltd could void your authority to operate the device. This device complies with part 15 of the FCC Rules. Operation is subject to the 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.

**Note:** This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15(c) of the FCC CFR47 rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency (RF) energy and, if not used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular application. 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.
- Consult the dealer or an experienced radio/TV technician for help.

### FCC Notice and Cautions

The device may cause TV or radio interference if used in close proximity to receiving equipment. The FCC can require you to stop using the equipment if such interference cannot be eliminated.

**Cautions:** Any changes or modifications to your device not expressly approved by Vicon Motion Systems Ltd could void your warranty for this equipment and void your authority to operate this equipment. Only use approved batteries. The use of any unauthorized accessories may be dangerous and void the device warranty if said accessories cause damage or a defect to the device. Although your device is quite sturdy, it is a complex piece of equipment and can be broken. Avoid dropping, hitting, bending or sitting on it.

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. End users must follow the specific operating instructions for satisfying RF exposure compliance. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

The published FCC ID is DMR-IMUAP1.

**For Canadian Customers**

Under Industry Canada regulations, this radio transmitter may only operate using an antenna of a type and maximum (or lesser) gain approved for the transmitter by Industry Canada.

To reduce potential radio interference to other users, the antenna type and its gain should be so chosen that the equivalent isotropically radiated power (e.i.r.p.) is not more than that necessary for successful communication.

This device complies with Industry Canada licence-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Conformément à la réglementation d'Industrie Canada, le présent émetteur radio peut fonctionner avec une antenne d'un type et d'un gain maximal (ou inférieur) approuvé pour l'émetteur par Industrie Canada.

Dans le but de réduire les risques de brouillage radioélectrique à l'intention des autres utilisateurs, il faut choisir le type d'antenne et son gain de sorte que la puissance isotope rayonnée équivalente (p.i.r.e.) ne dépasse pas l'intensité nécessaire à l'établissement d'une communication satisfaisante.

Le présent appareil est conforme aux CNR d'Industrie 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, et (2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

The published COMPANY NUMBER and UPN NUMBER is 11323A-IMUAP1.

**For Australian and New Zealand Customers**

The product complies with the requirements of the relevant Australian Communications and Media Authority Standards made under the following Notices:

- *Radiocommunications (Compliance Labelling - Devices) Notice 2014* made under section 182 of the *Radiocommunications Act 1992*;
- *Radiocommunications Labelling (Electromagnetic Compatibility) Notice 2008* made under section 182 of the *Radiocommunications Act 1992*;
- *Radiocommunications (Compliance Labelling – Electromagnetic Radiation) Notice 2014* made under section 182 of the *Radiocommunications Act 1992*.

Supplier's declaration of conformity available upon request.

## Other Important Safety Information

- Only qualified personnel should service the device. Faulty service may be dangerous and may invalidate any warranty applicable to the device.
- Do not store or carry flammable liquids, gases, or explosive materials in the same compartments as the device, its parts, or accessories.
- For vehicles equipped with an air bag, remember that an airbag inflates with great force. Do not place objects, including portable wireless equipment near or in the area over the air bag or in the airbag deployment area. If the wireless device is within the deployment area as an air bag inflates, serious injury could result.
- Switch off the device off before boarding an aircraft. The use of wireless devices in aircraft is illegal and may be dangerous to the aircraft's operation. Check with appropriate authorities before using any function of the device while on an aircraft.
- The primary responsibility of every driver is the safe operation of his or her vehicle. Do not engage in any activity while driving a moving vehicle which may take your eyes off the road or become absorbed in any activity that your ability to concentrate on the act of driving becomes impaired.
- Failure to observe these instructions may lead to the suspension or denial of network services, or legal action, or both.

## Battery Use and Safety

- The battery in this device is not intended to be replaced by the consumer. If you believe the battery is damaged or needs to be replaced, return the device for inspection and replacement.
- Do not let the device or battery come in contact with liquids. Liquids can get into the device's circuits, leading to corrosion. Even when the device appears dry and appears to operate normally, the circuit could slowly corrode and pose a safety hazard.
- Do not place the device in or near a heat source. Excessive heating can damage the device and battery and could cause the device or the battery to explode. Do not dry a wet or damp device with an appliance or heat source such as a microwave oven, hair dryer, iron, or radiator. Avoid leaving your device in your vehicle in high temperatures.
- Do not dispose of the device or battery in a fire. The device or battery may explode when overheated.
- Avoid dropping the device. Dropping the device, especially on a hard surface, can potentially cause damage. If you suspect damage to the device or battery, return it for inspection.
- Never use any battery that is damaged in any way.
- **Warning.** Use of a non-manufacturer approved batteries may present a risk of fire, leakage, or other hazard. Manufacturer warranty does not cover damage to the device caused by non approved batteries.
- Do not use incompatible batteries and chargers. If using a powered USB Hub always ensure that you use the manufacturer's approved or recommended power source. Some websites and second-hand dealers not associated with reputable manufacturers and carriers, might be selling incompatible or even counterfeit batteries and chargers. Please refer to Vicon Motion Systems Ltd for advice. Misuse or use of incompatible batteries and chargers could result in damage to the device and a possible risk of fire, explosion, or leakage, leading to serious injuries, damage to your device, or other serious hazard.

## Operating Environment

- Avoid temperature below 0°C/ 32°F or above 37°C/99°F.

- Do not expose your device to dust, dirt, or sand.
- Remember to follow any special regulations in force in any area, and always switch your device off whenever it is forbidden to use it, or when it may cause interference or danger. When connecting the device or any accessory to another device, read its user's guide for detailed safety instructions. Do not connect incompatible products.
- **Implantable Medical Devices.** A minimum separation of 6 inches (15.3 mm) should be maintained between the device and an implantable medical device, such as a pacemaker or implantable defibrillator, to avoid potential interference by the device. Persons who have such implantable medical devices:
  - Should ALWAYS keep the device more than 6 inches (15.3 mm) from their implantable medical device when the device is turned ON;
  - Should not carry the device in a breast pocket;
  - Should immediately turn the device OFF if there is any reason to suspect that interference is taking place;

Should read and follow the directions from the manufacturer of your implantable medical device. If you have any questions about using your wireless device with an implantable medical device, consult your health care provider.

- **Other Medical Devices.** If you use any other personal medical devices, consult the manufacturer of your device to determine if it is adequately shielded from external RF energy. Your physician may be able to assist you in obtaining this information. Immediately turn the device OFF if there is any reason to suspect that interference is taking place.

Switch your wireless device off in health care facilities when any regulation posted in these areas instructs you to do so. Hospitals or health care facilities may be using equipment that could be sensitive to external RF energy.

- **Vehicles.** RF signals may affect improperly installed or inadequately shielded electronic systems in motor vehicles. Check with the manufacturer or its representative regarding using your wireless device in a motor vehicle. You should also consult the manufacturer of any equipment that has been added to your vehicle. Immediately turn the device OFF if there is any reason to suspect that interference is taking place.

**Posted Facilities.** Switch your device off in any facility where posted notices require you to do so.

- **Potentially Explosive Environments.** Switch your wireless device off when in any area with a potential explosive atmosphere and obey all signs and instructions. Sparks in such areas could cause an explosion or fire resulting in bodily injury or even death. Users are advised to switch the wireless device off while at a refueling point (service station).

Users are reminded of the need to observe restrictions on the use of radio equipment in fuel depots (fuel storage and distribution areas), chemical plants or where blasting operations are in progress. Areas with a potentially explosive atmosphere are often but not always, clearly marked. They include below deck on boats, chemical transfer or storage facilities, vehicles using liquefied petroleum gas (such as propane or butane), areas where the air contains chemicals or particles, such as grain, dust, metal powders or anesthetic gases, and other areas where you

would normally be advised to turn off your vehicle engine. Vehicles using liquefied petroleum gas (such as propane or butane) must comply with the National Fire Protection Standard (NFPA-58). For a copy of this standard, contact the National Fire Protection Association.

- **High Magnetic Flux Environments.** The device contains ferrous components so may constitute a physical projectile hazard if brought into high magnetic flux environments such as found within Magnetic Resonance Imaging (MRI) facilities.
- **Securing Straps.** Securing straps are **Latex Free**, manufactured using **Neoprene** or polychloroprene. Allergic reaction to neoprene is generally ascribed to the accelerants used to manufacture the man-made rubber, specifically thiourea compounds and mercaptobenzothiazole (MBT). Symptoms of neoprene-related allergic contact dermatitis (ACD) include itching, skin eruptions, swelling, and hemorrhages into the skin. If you experience an ACD, please immediately desist from using the straps.

### **Restricting Children's Access to Your Device**

- Your device is not a toy. Do not allow children to play with it because they could hurt themselves and others or damage the device.
- Keep the device and all its parts and accessories out of reach of small children.

### **Restriction of the Use of certain Hazardous Substances in Electrical and Electronic Equipment –RoHS and Recast (RoHS 2)**

This device is fully RoHS (2002/95/EC provides that new electrical and electronic equipment put on the market for the first time from 1 July 2006) and RoHS 2-compliant. The European Union Directive [2011/65/EU](https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32011L0065) provides that new electrical and electronic equipment put on the market for the first time from 3<sup>rd</sup> January 2014 shall not contain more than permitted levels of lead, cadmium, mercury, hexavalent chromium, polybrominated biphenyls (PBB), or polybrominated diphenyl ethers (PBDE; PentaBDE, OctaBDE; DecaBDE), Mercury (Hg).

### **REACH Declaration of Conformity**

Vicon Motion Systems Ltd is a manufacturer of electronic hardware. We are therefore considered a "downstream user" as far as the REACH document is concerned. Vicon Motion Systems Ltd is therefore not obligated to register with the European Agency for Chemicals 'ECHA'.

Products sold by Vicon Motion Systems Ltd are "articles" as defined in REACH (Article 3 Definitions). Moreover and under normal and reasonably foreseeable circumstances of application, the articles supplied shall not release any substance. For that, Vicon Motion Systems Ltd is neither obligatory for registration nor for the creation of material safety data sheets.

In order to assure our customers the continual supply reliable and safe products, we ensure that our suppliers fulfill all requirements regarding chemical substances and prepared materials.

### Waste Electrical and Electronic Equipment (WEEE)

**(Applicable in the European Union and other European countries with separate collection systems)**



The use of the symbol as a marking on the equipment, accessories or literature indicates that this product and its electronic accessories (e.g. USB cable) may not be treated as household waste. By ensuring this product is disposed of correctly, you will help prevent potential negative consequences for the environment and human health, which could otherwise be caused by inappropriate waste handling of this product.

Household users should contact either their retailer where they purchased this device, or their local government office, for details of where and how they can take these items for environmentally safe recycling. Business users should contact their supplier and check the terms and conditions of the purchasing contract. This device and its electronic accessories should not be mixed with other commercial waste for disposal.

### Correct Disposal of Batteries in this Device

**(Applicable in the European Union and other European countries with separate battery systems)**



The use of the symbol as a marking on the battery, manual or packaging indicates that the battery in this device should not be disposed of with other household waste at the end of their working life. Where marked, the chemical symbols Hg, Cd or Pb indicate that the battery contains mercury, cadmium or lead above the reference levels in EC Directive 2006/66. If batteries are not properly disposed of, these substances can cause harm to human health or the environment.

To protect natural resources, and to promote material reuse, please separate batteries from other types of waste and recycle them through your local, free battery return system.

The rechargeable battery incorporated in this device is not user replaceable. For information on its replacement please contact Vicon Motion Systems Ltd.

**Specific Absorption Rate (SAR) Certification****For United States of American Customers (FCC)**

For Standalone SAR exclusion consideration, when SAR Exclusion Threshold requirement in KDB 447498 is satisfied, standalone SAR evaluation for general population exposure conditions by measurement or numerical simulation is not required. At 2480 MHz, equivalent isotropically radiated power of the device is 0.360mW, which will be less than the SAR Exclusion Threshold (9.53mW). For further information, please see clause 4.3 of KDB 447498 D01 General RF Exposure Guidance."

This device has been granted authorisation to be used in the United States for all equipment exhibiting DMR-IMUAP1.

**For Canadian Customers (ISED)**

SAR evaluation is required if the separation distance between the user and/or bystander and the antenna and/or radiating element of the device is less than or equal to 20 cm, except when the device operates at or below the applicable output power level (adjusted for tune-up tolerance) for the specified separation distance. At 2480 MHz, equivalent isotropically radiated power of the device is 0.360mW, which will be less than the SAR Exclusion Threshold at distance of  $\leq$  5 mm (3.94mW). For further information, please see clause 2.5.1 of RSS-102 Issue 5 March 2015.

This device has been granted authorisation to be used in Canada for all equipment exhibiting 11323A-IMUAP1.

**For European Union Customers (RED)**

Minimum Safe distance for RF exposure, based on the Reference Levels for General Public exposure of EU Council Recommendation (1999/519/EC) of 12 July 1999 on the limitation of exposure of the general public to electromagnetic fields (0 Hz to 300 GHz) was calculated:

Frequency (MHz)	EIRP (dBm)	Limit (W/m <sup>2</sup> )	Minimum safe distance (m)
2480	-8.2	10	0.001096

## CE Declaration of Conformity



## Declaration of Conformity

## (Radio Equipment Directive 2014/53/EU)

We, Vicon Motion Systems Ltd  
Unit 6, Oxford Industrial Park  
Yarnton, Oxfordshire, OX5 1QU  
UNITED KINGDOM

declare under our sole responsibility that the product

**IMEASUREU SENSOR V1**

to which the declaration relates, is in conformity with the following standards and/or other normative documents.

**SAFETY<sup>(1)</sup>** EN 60601-1:2006/A12: 2014  
Latex Free  
RF Exposure Evaluation RED 2014/53/EU Article 3(1)(a).

**EMC** EN 60601-1-2:2015 with reference to  
ETSI EN 301489-17v3.2.2 (Draft) (ETSI 301 489-1 v2.2.0 (Draft)).

**RADIO** EN300 328 V2.1.1  
Covering wide band transmission systems; data transmission equipment operating in the 2.4 GHz ISM band.

We hereby declare that all essential radio test suites have been carried out and that the above named product is in conformity to all the essential requirements of Directive 1999/5/EC. The technical documentation is kept at Vicon Motion Systems Ltd, Unit 6, Oxford Industrial Park, Yarnton, Oxfordshire, OX5 1QU, UNITED KINGDOM that will be made available on request.

T.M.L. Shannon, TD, PhD, FIE (Aust.), CPEng (Biomed.)

Director

6<sup>th</sup> November 2017

- (1) Risk analysis performed under ISO14971:2012 in compliance with Medical Devices Directive 93/42/EEC applied as amended by EU Council Directive 2007/47/EC of 5<sup>th</sup> September 2007 as the product is wearable.
- (2) For research purposes only, not a medical device. Not for use in an operating theatre, anaesthetic gas or oxygen-rich environments. Not for use where there is a risk of compromising the essential performance of medical electrical equipment. Not suitable for use in high magnetic flux, ionizing radiation, sterile, or life- or safety-critical environments.