WARRANTY & SAFETY

Improving lives through Innovation

Kinesis
Health Technologies

Important Safety Information

Read these safety messages carefully.

WARNING
The use of portable and mobile radio frequency (RF) equipment may have an impact on this and other pieces of medical equipment.

This device contains an RF transmitter. It is also an intentional RF receiver and even if other equipment complies with CISPR emissions requirements, those devices may interfere with the operation of this device.

Radio Information Transmit Characteristics: 2.4GHz Bluetooth radio using GFSK, DQPSK, and 8DPSK modulation and 75kHz bandwidth. Frequency Range in MHz: 2400-2483.5. Output Power in dBm: 5-6.

This equipment has been tested and found to comply with the EMC limits for the Medical Device Regulations 93/42/EEC (EN 55011 Class A and EN 60601-1-2).

These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. The equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference with other devices, 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 device.
- Increase the separation between the equipment.
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) is connected.
- Consult the manufacturer for help.

The use of portable and mobile RF equipment may have an impact on this and other pieces of medical equipment.

CAUTION

It is prudent to separate all electrical equipment that is very close in distance to the Kinesis system. If it is essential to use the Kinesis system very close to other electrical equipment, it is prudent to determine, by observation, if the performance of either product is affected by unintended electromagnetic coupling.

The use of accessories, cables, or transducers other than those specified in this manual can significantly increase emissions performance and degrade immunity performance of the product. Also, by using an accessory, transducer, or cable with the product, other than those specified in this manual, it becomes the responsibility of the third-party supplier or the user of the product, to determine compliance with the requirements of IEC 60601-1-2 when using this item.

WARNING

It is advised not to use equipment other than the following devices listed by manufacturer (Kinesis sensors with Bluetooth radio) stacked on or near the product, but if it is required for your location to stack or use equipment that is adjacent to the product, all must be verified to work and verification shall occur to ensure the product operates properly before conducting any procedures.

WARNING

No modification of this equipment is allowed.

Technical specifications

Specifications

Model		Shimmer2R w/450mAH Battery
Power supply	Input	100 - 240V AC 50-60Hz
	Output	7.5 VDC 15W nominal, 1.7A Max
Current consumption		700mA (7.5V input)
Weight		< 2000 grams (4.4 pound)
Operating Conditions		+5 ℃ – +40 ℃ (20% – 95% Relative Humidity)
Storage/Transport Conditions		-20 ℃ – +60 ℃ (20% – 95% Relative Humidity)
Bluetooth Transmit	Band	2.4Ghz
	Modulation	GFSK, DQPSK, and 8DPSK
	Frequency Range	2400MHz – 2483.5MHz
	Output Power	Min: 5 dBm; Typical: 6 dBm; Max: 6 dBm
Bluetooth Receiver	Bandwidth	75kHz
	Frequency Range	2400MHz – 2483.5MHz
IP Rating		None
Sterility		The device is not sterile
Re-use		The device can be reused
Essential performance		The device has no essential performance
Expected service life		3 years, dependent on battery usage
User maintainable parts		None

Symbols on sensor label

This device is authorized under part 18 of the Declaration of Conformity.

This device fulfils the provisions of EU MDR 2017/745 (EN 55011 Class A and EN 60601-1-2).

This radio device belongs to Class 2 for which restrictions or bans apply regarding its placing on the market or putting into service.

This device contains an RF transmitter and an intentional RF receiver. Interference may occur in the vicinity of equipment.

Correct disposal of this product (Waste Electrical & Electronic Equipment)

This marking shown on the product, accessories or literature indicates that it should not be disposed of, with other household wastes at the end of its working life. To prevent possible harm to the environment or human health from uncontrolled waste disposal, please separate these items other types of waste and recycle them responsibly to promote the sustainable reuse of material resources.

Users should contact their supplier and check the terms and conditions of the purchase contract. This product and its electronic accessories should not be mixed with other commercial wastes for disposal.

Warranty

12 Month Warranty

This warranty covers the Kinesis sensors, tablet and software and accessories (together referred to as the 'Product') supplied by Kinesis Health technologies. Subject to the warranty conditions below, Kinesis warrants to the original end customer purchasing (hardware) and licensing (software) the Product ('you') that, for a period of 12 months from the original date of the purchase and license of the Product by you, the Product will be free from defects in materials and workmanship.

If during the period of the warranty this Product proves defective under normal use and service, you must notify Kinesis or local distributor of the defect in the Product within 12 months of the date of the purchase and license of the Product by you and you must return the Product to Kinesis or local distributor within 30 days of notifying Kinesis or local distributor of that defect. If, having inspected the Product, Kinesis accepts the Product is defective, Kinesis will (in its sole discretion) either repair or replace the part causing the defect or replace the Product without charge.

Warranty Conditions

- This warranty does not cover the Product if it has been resold or used for rental purposes.
- This warranty does not cover defects in the Product that are caused by accidental damage, your and/or any third party's negligence or unreasonable use, use with products not supplied by Kinesis, use of Product otherwise than in accordance with Kinesis product User Guide or any other instructions provided with the Product, or any other cause unrelated to defects in material and workmanship.
- This warranty does not cover the Product if it has been modified or repaired by any person other than Kinesis or duly authorised personnel.
- Repair or replacement under the terms of this warranty does not give right to extension to or a new starting of the period of warranty.
- This warranty does not cover the following:
  - Periodic checks, maintenance, repair and replacement of parts due to normal wear and tear.
  - Upgrading of software.
  - The product has been used in conjunction with accessories and/or software not approved by Kinesis for use with this Product.
  - Accidents, Acts of God or any cause beyond the control of Kinesis caused by but not limited to lightning, water, fire, public disturbances and improper ventilation.
  - Un-authorised modifications or repairs to the Product.

Regulatory Information

Declaration of Conformity

This Kinesis Health Technologies product meets the relevant medical device regulations in EU and all other geographies in which it is made available for sale. As the legal manufacturer, Kinesis Health Technologies (and its distributors) shall comply with all applicable laws and regulations relating to medical devices, specifically the Medical Device Regulations MDR 2017/745 ('MDR') as it pertains to a Class I medical device (without a measurement function). In the United States, this product meets the Quality System Regulations ('QSR'), specifically the FDA 21 CFR part 820 for a class I medical device (exempt from 501(k) regulation). In Canada this product meets the regulations defined by Health Canada for a Class I medical device. In Australia this product is registered with the Therapeutic Goods Administration as a Class I medical device and meets appropriate regulations and standards.

Restrictions on Use

THIS KINESIS PRODUCT IS NOT INTENDED, DESIGNED OR AUTHORIZED FOR CONTINUOUS COMMUNICATION OF REAL TIME DATA. THE SOFTWARE IS NOT INTENDED, DESIGNED OR AUTHORIZED FOR PROVIDING TIME-CRITICAL MEDICAL CARE, PROVIDING MEDICAL OR OTHER EMERGENCY RESPONSE ALERTS OR ANY OTHER ANY APPLICATIONS OUTSIDE THE INTENDED USE SPECIFIED IN THE USER GUIDE, OR FOR USE IN ANY CIRCUMSTANCE IN WHICH THE FAILURE OF THE PRODUCT WOULD PRESENT AN UNREASONABLE RISK OF ILLNESS OR INJURY TO THE USER.

Medical Device Regulatory Compliance

This product, developed by Kinesis Health Technologies is intended to measure human movement. Please see product specific user guide for detailed information on intended use indications for use.

In purchasing this Kinesis product, the customer acknowledges and understands that the software is registered as a medical device under the Medical Device Regulations and that Kinesis may not put products “on sale” without first certifying to CE conformance. Similarly, for the US, the customer acknowledges and understands that the software is registered as a medical device under the Quality System Regulations. For such products, the purchase and subsequent use or resale by the customer must be with Kinesis express permission and in accordance with relevant medical device regulations.

Kinesis (or where appropriate, its local distributors) shall act as the complaint handling point of contact for any complaints relating to the product. Complaints shall be defined in accordance with the MDR.

Any complaints should be provided in English and in writing to Kinesis (or where appropriate, its local distributors). Complaints submitted shall be handled in accordance with complaint handling processes mandated by the MDR.

Representations and Warranties

Kinesis and its Distributors warrant that this product, when used in compliance with the documentation complies with the essential requirements of the MDR. Kinesis will perform its obligations in compliance with all applicable laws and regulations.

By purchasing this product, the customer acknowledges that:

i) it has been informed by Kinesis and is aware and understands that this product, specifically the Software, is a Medical Device within the meaning of the Section 2(a) of Article 1 of the MDD and further that the customer is responsible for informing its customers that this product is a Medical Device.

ii) the customer shall not in any way alter, modify, repair, attempt to repair or replace the Hardware or Software or relevant labelling except as otherwise permitted by Kinesis in writing.

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