

FCC Statements

■ Part 15.19 statement

This device complies with part 15 of the FCC Rules. Operation is subject to the condition that this device does not cause harmful interference.

■ Part 15.21 statement

Change or Modifications that are not expressly approved by the manufacturer could void the user's authority to operate the equipment

■ Part 15.105 statement

NOTE: 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 in a residential installation. This 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 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.

Warnings

Do not use any component of the Byteflies Kit before reading these warnings and the IFU:

- Do not use the Byteflies Kit if any component is damaged.
- The Byteflies Kit is provided non-sterile.
- Please verify the LED status indicators to avoid misuse.
- If a trained operator or user experiences any adverse events while using the Byteflies Kit, discontinue the use and contact us immediately.
- Skin adhesives (either provided by Byteflies as an accessory or from a compatible third party provider) should be replaced if they no longer stick firmly to the skin or as indicated in their respective manuals.
- Similar devices may cause signal interference during data transmission. Avoid operating the Byteflies Kit near interfering devices.
- Keep the Byteflies Kit away from children and pets. The Sensor Dot and accessories may present a choking hazard. Never place or let anyone place a component of the device in their mouth.
- If any component of the Byteflies Kit fails to operate after attempting all suggested troubleshooting steps, contact support as soon as possible.
- Some Byteflies Kit components contain a battery which may present a risk of fire, explosion, or chemical burn if mistreated. Do not expose the Byteflies Kit to excessive heat or fire. Do not crush, puncture, or incinerate as doing so can result in fire, explosion, or the release of toxic gasses. Do not use or charge any component of the Byteflies Kit if it appears to be leaking, discolored, deformed, or in any way abnormal.
- All components of the Byteflies Kit should be returned to the healthcare provider or study staff at the conclusion of the prescribed period of use.

- For healthcare professionals, clean Byteflies Kit components as explained in the online IFU and do not use any cleaning agents other than those listed in the instructions.
- Do not use the Byteflies Kit without first completing proper set up as described in the IFU.
- Do not use any component of the Byteflies Kit on users undergoing an MRI scan, defibrillation or who have an active implanted device, such as a pacemaker, defibrillator, or vagal nerve stimulator.
- Do not expose any component of the Byteflies Kit to strong sources of static electricity or electromagnetic fields.
- Do not leave any component of the Byteflies Kit on top of or next to other electrical equipment, or let them come into contact with conductive materials, except when following instructions on how to recharge the battery.
- Do not submerge any component of the Byteflies Kit in liquid.
- Do not damage any component of the Byteflies Kit through drops, violent shaking or crushing.
- The Byteflies Kit is not a toy. Usage on children 3 years of age and older should be under strict supervision of an adult.
- Do not alter any component of the Byteflies Kit. Any modification is strictly prohibited.
- Do not use at temperatures lower than 15°C or greater than 35°C.
- Do not use where air humidity is lower than 10% or higher than 90%.
- Do not use in environments subjected to pressure lower than 700 hPa or greater than 1080 hPa.
- Do not use a power adapter or charging cable other than the one supplied with the Byteflies Kit.

- This equipment complies with FCC/IC radiation exposure limits set forth for an uncontrolled environment. This equipment has very low levels of RF energy. However, for the Docking Station it is desirable that it should be installed and operated keeping the radiator at least 20 cm or more away from the person's body (excluding extremities: hands, wrists, feet and ankles).

Troubleshooting

We're here for you!

Learn about new features and get help when you need it:

Website: <https://www.byteflies.com> **Online IFU:** <https://www.byteflies.com/ifu>

Email support: support@byteflies.com **Phone support:** +32 (0)3 294 74 99

EU office:
Borsbeeksebrug 22, 6th floor
2600 Antwerp
Belgium

US office:
530 7th Avenue - Suite 902
New York, NY 10018
USA

- If a LED on any component of the Byteflies Kit is red, refer to the troubleshooting steps in the online IFU (www.byteflies.com/ifu). If the issue persists, contact Byteflies.
- Consult the meaning of the LED colors in the online IFU to avoid misuse.
- If a trained operator or user experiences any adverse events while using the Byteflies Kit, discontinue the use of the device and contact us.
- To restart the Byteflies Kit, unplug it from power and plug it back in.

Instructions for Use (IFU)

Byteflies Kit Legal Information

 Byteflies

Declaration of Conformity

The Byteflies Kit (Model 1) conforms to the essential requirements and provisions of the REGULATION (EU) 2017/745 on medical devices (MDR).

Manufacturer

 **Byteflies NV**
Borsbeeksebrug 22, 6th floor
2600 Antwerp
Belgium

Definition of Symbols



Manufacturer



Date of manufacture



Catalog number



Serial number



FCC marking



WEEE compliance



Consult the IFU



Type BF equipment
(IEC 60601-1)



Class II insulation



Prescription use only



Medical device



Temperature range



Humidity range



Pressure range



Ingress Protection code



Includes RF transmitter



Keep out of direct sunlight



Keep dry



Choking hazard



MR unsafe



Unique device identifier

Intended Use

The Byteflies Kit is a multisensor device intended to collect non-invasive physiological and behavioral signals to be used in the clinic and/or home for subjects who need continuous monitoring.

Intended users: The Byteflies Kit and its accessories are intended to be used by trained operators who configure it in a medical environment (e.g. hospital). Users are wearers of the Sensor Dot, not operators of the Byteflies Kit, and are 3 years of age or older. Once the correct set up is configured, the user can take the Byteflies Kit and applicable accessories home to continue recording data as instructed by the operator. The user may be required to return to the medical environment for removal or reconfiguration of Byteflies Kit components and accessories by the operator.

Clinical indications: The Byteflies Kit and its accessories are intended for prescription use in the home, healthcare facility, or clinical research environment to acquire, record, and transmit physiological and behavioral signals from users. Specifically, electroencephalogram (EEG), electrocardiogram (ECG), heart rate (HR), respiratory rate (RR), electromyogram (EMG), and/or electrooculogram (EOG) signals, with optional accelerometer (ACC), gyroscope (GYR), and activity index (AI) signals. It only acquires these signals; no diagnostic claims are made about the user's condition.

Contraindications: The Byteflies Kit and its accessories should not be used on users that have been diagnosed with, or are suspected to have, life threatening conditions that could result in immediate danger. It should not be used on users that need to undergo an MRI scan or defibrillation, or have an active implanted device such as a pacemaker or defibrillator.

Safety Information

The following is important information for using the Byteflies Kit properly and safely. Carefully read this section before operating any component. The Byteflies Kit is a biopotential and motion recording device comprised of hardware and software that has been tested to assess its safety and effectiveness, and to establish substantial equivalence with predicate devices.

- The Byteflies Kit cannot provide diagnoses. It only records physiological and behavioral signals as configured by and under the authority of the trained operator.
- The LED patterns only reflect battery status and operation mode. The LEDs do not reflect physiological status in any way and should never be interpreted as an indication of patient health.
- The Byteflies Kit is designed to be operated by a trained operator. The user should always receive proper instructions from a trained operator before using any component of the Byteflies Kit.
- Byteflies Kit components and accessories are only intended to be used by the user as instructed by the trained operator and the user cannot configure any component of the Byteflies Kit.
- The recorded data can only be used to assess heart, brain, muscle, or motion-related diseases when reviewed by a properly trained healthcare professional (e.g. cardiologist, pulmonologist, neurologist, physiologist).
- The Byteflies Kit is compatible with certain commercial biopotential (ExG) electrodes. These are not supplied as part of the Byteflies Kit. The use of any skin adhesives may cause mild skin irritation, such as redness, itching, or contact dermatitis in some users. Consult the manufacturer of the ExG electrodes for more information.


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