PulseOn Arrhythmia Monitor System
Model AMS-1

Safety Guide

for
Arrhythmia Monitor AM-1
Charging Dock CD-1
Gateway GW-1

This safety guide is delivered with physical products that are parts of the system, not standalone devices.

IMPORTANT:
Please refer to the complete PulseOn Arrhythmia Monitor System User Guide before operating any device.

Complete user guide is downloadable within the system and can also be obtained by e-mail:
support@pulseon.com

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Safety Guide

Contents

1. Introduction

This safety guide describes briefly the PulseOn Arrhythmia Monitor System, its components, and safe use.

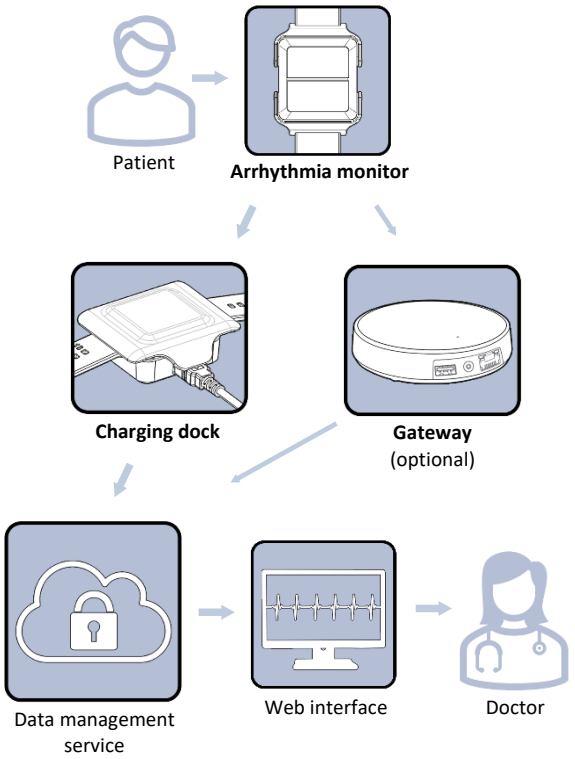
This guide is for devices:

- Arrhythmia Monitor AM-1
- Charging Dock CD-1
- Gateway GW-1

The PulseOn Arrhythmia Monitor System consists of a wrist-wearable device, its charger, a gateway device, a data management service and data transfer software. The collection of patient data is based on photoplethysmography (PPG) and electrocardiography (ECG) technologies. The system is used to assist in the diagnosis, screening and monitoring of atrial fibrillation and other cardiac arrhythmias visible in Lead I ECG.

The information in this document is subject to change without notice.

PulseOn Arrhythmia Monitor System overview



1.1. Package Contents

Package contents of the PulseOn Arrhythmia Monitor System components are described here below.

Arrhythmia Monitor package (AM-WD-EU-1) contents:

Description	Reference	UDI-DI
Wrist device	AM-1	06430054330121
Spare strap - small	ST-S-1	06430054330169
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Note: Large strap is attached to the wrist device.
Note: Arrhythmia Monitor (AM-1) incorporates a li-ion polymer rechargeable battery 350mAh, nominal voltage 3,70V with an integrated safety circuit.

Charging Dock package (AM-CD-EU-1) contents:

Description	Reference	UDI-DI
Charging dock	CD-1	06430054330138
Silicone cover	CDS-1	06430054330237
USB cable	USB-CBL-1	
USB power supply EU/UK	CD-PS-EU-1	
EU plug for USB power supply	CD-PS-P-EU-1	
UK plug for USB power supply	CD-PS-P-UK-1	
Safety guide	AMS-1-SG-EN	

Note: Charging dock power supply is made by Friwo (model: FOX6-XM-USB 5V 1400mA MEDICAL FW8002M/USB, code: 1960267). Input: 100-240 Vac, 50-60 Hz, 160-80 mA. Output: voltage 5,0 Vdc, current 1400mA.

Gateway package (GW-EU-1) contents:

Description	Reference	UDI-DI
Gateway device	GW-1	06430054330145
Gateway power supply EU/UK	GW-PS-EU-1	
EU plug for gateway power supply	GW-PS-P-EU-1	
UK plug for gateway power supply	GW-PS-P-UK-1	
Safety guide	AMS-1-SG-EN	

Note: Gateway power supply is made by GlobTek (model: GTM96180-1807-2-0). Input: 100-240 V~, 50-60 Hz. Output: voltage 5,0 V, current 3600mA.

The physical parts of the PulseOn Arrhythmia Monitor System are listed in the table below.

Item	Type	Trade name	Code	UDI-DI / GTIN
Wrist device (WD)	Device (class IIa)	Arrhythmia Monitor	AM-1	0643005 4330121
Spare strap, size S	Detachable part	Spare Strap - Small	ST-S-1	0643005 4330169
Spare strap, size L	Detachable part	Spare Strap - Large	ST-L-1	0643005 4330152
Spare strap, size XL	Detachable part	Spare Strap – Extra Large	ST-XL-1	0643005 4330251
Charging dock (CD)	Accessory (class I)	Charging Dock	CD-1	0643005 4330138
Silicone cover (for CD)	Detachable part	Silicone Cover	CDS-1	0643005 4330237
USB cable (for CD)	Detachable part	USB Cable	USB-CBL-1	
Power supply (for CD)	Device (non medical)	Power Supply EU/UK	CD-PS-EU-1	
Adapter EU (for CD)	Detachable part	EU plug for USB power supply	CD-PS-P-EU-1	
Adapter UK (for CD)	Detachable part	UK plug for USB power supply	CD-PS-P-UK-1	
Gateway device	Device (non medical)	Gateway	GW-1	0643005 4330145
Gateway power supply	Device (non medical)	Gateway Power Supply EU/UK	GW-PS-EU-1	
Adapter EU (for GW)	Detachable part	EU plug for gateway power supply	GW-PS-P-EU-1	
Adapter UK (for GW)	Detachable part	UK plug for gateway power supply	GW-PS-P-UK-1	

1.2. Software and System Requirements

Data Management Service

Data Management Service supports the following web browsers on a PC:

- o Microsoft Edge
- o Google Chrome
- o Mozilla Firefox
- o Apple Safari

Workstation Requirements

Technically, any operating system that can run supported browsers is applicable. However, it is recommended that Windows 10 (or newer) with relatively modern hardware be used with the Data Management Service. Most of the processing power required is for viewing ECG graphs. The following minimum requirements should work in most scenarios:

- Processor: 1.5 gigahertz (GHz) or faster processor
- RAM: 2 GB
- Graphics card: DirectX 9 or later with WDDM 1.0 driver
- Display: 1024x768 pixels
- USB port

2. General Safety

This safety guide gives basic information about the use and safety of the devices. Before operating any device, read the complete system user guide first

For assistance in using, maintaining, or setting up the PulseOn Arrhythmia Monitor System, or if any unexpected operation, event or incident occurs, please contact the manufacturer (local PulseOn representative).

In the event of a serious incident, immediately contact your national competent authority and the manufacturer (local PulseOn representative).

2.1. Symbols

Symbols used in equipment and in documentation:

CE 0537	CE marking and Notified Body (NB) number. The device is CE-marked according to European Regulation (EU) 2017/745 regarding medical devices.
⚠	Caution! Caution is necessary close to where the symbol is placed. The situation needs operator awareness or operator action in order to avoid undesirable consequences.

	User guide/operating instructions that should be read for additional information.
	Refer to instruction manual/booklet (mandatory).
	The device is equipped with type BF (Body Floating) applied parts fulfilling the EN 60601-1 (IEC60601-1) standard. Type BF classification is given to applied parts that are electrically connected to the patient and must be floating and separated from the earth ground.
	A Bluetooth Low Energy radio within the equipment sends radio frequency radiation at a 2.4 GHz frequency. The radiation is non-ionizing.
	Do not dispose as unsorted waste. Requires separate handling for waste disposal according to national requirements. The Waste Electrical and Electronic Equipment Directive (WEEE Directive).
	Manufacturer
	Date of manufacture
SN	Serial number
LOT	Lot/batch code. Indicates the manufacturer's batch code so that the batch or lot can be identified.
REF	Reference/catalogue number
MD	Medical device
UDI	Unique Device Identifier
	Keep away from rain / keep dry (storage and transport)
	Temperature limits (storage and transport)
	Humidity limits (storage and transport)
	Atmospheric pressure limits (storage and transport)
	For indoor use only
	Class II equipment
VI	Power-supply efficiency level VI
	Polarity marking – centre positive

2.2. Warning and Safety Notices

Warnings ⚠

- The user must be instructed to discontinue using the device in case of significant skin reactions.
- Not a toy. Not for small children. Choking hazard. The equipment may contain small parts. Keep them out of reach of small children. Strangulation may result from baby or child entanglement in power cables.
- The wrist device may give an ECG measurement notification when it is not safe to take an ECG measurement (e.g. while driving a car). In such situations, ignore the notification and do not take an ECG measurement.
- 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 it is operating normally.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) from any part of the medical equipment or medical system, including cables specified by the manufacturer. Otherwise the performance of this equipment could be adversely affected.
- Use of accessories 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 therefore result in improper operation.
- Do not position the power supply for the charging dock (or gateway) in a place or position that makes it difficult to disconnect.
- Do not use an additional multiple-socket outlet or extension cord with the system.
- The total leakage current may increase when several items of medical equipment are interconnected.
- Do not touch the recharger (charging dock) and the patient simultaneously. Do not remove the silicone cover from the charging dock as it provides IP21 protection against dripping water (vertically falling drops).

Caution ⚠

- The PulseOn Arrhythmia Monitor System provides an indication of possible arrhythmias to doctors but it does not provide diagnosis.

- The automated analysis result is not a diagnosis. The results must be reviewed by a trained professional (e.g. cardio-tech or cardiologist) in order to verify the result. Additional information may be needed before a trained professional can establish a complete diagnosis.
- The automated analysis relies on the quality of the recorded signals. Signals with disturbances may cause problems for the analysis and may result in miss-detection, mislabelling or non-detection of events.
- The automated analysis software (ECG Parser) is not complete diagnostic ECG software. Only beat and rhythm classification, HR and HRV interval measurements are validated in the ECG Parser output. Other output parameters may be used for indication only.
- It may be difficult to notice arrhythmia from the ECG signal if the heartbeat rhythm is not irregular and the heart rate is slow. For example, this can be the case with atrial flutter; it is possible that the flutter waves of the atrial contractions are not clearly visible in the Lead I ECG signal.
- It is also possible that, for some subjects, normal p-waves are not clearly visible in the Lead I ECG signal.
- If many signals are rejected as poor-quality signals by the automated analysis, then:
    - seek alternative ECG examination using other means, and/or
    - make sure the ECGs are manually reviewed, despite the signals being rejected as being of poor quality.
- According to current care guidelines, atrial fibrillation is the only cardiac arrhythmia that can be diagnosed from single-lead ECG such as the PulseOn arrhythmia monitor. If another arrhythmia is suspected, confirm the diagnosis with other methods recommended by your local care guideline, such as 12-lead ECG.
- In case of atrial fibrillation, verify that your local care guideline allows diagnosis with single-lead short-term ECG.
- Optical arrhythmia detection is based on analysis of heartbeat interval variations. Cardiac arrhythmias showing stable rhythm, such as common types of atrial flutter, are thus not recognized by the optical measurement device.
- The polarity of the ECG depends on which hand the device is worn on. ECG algorithms recognize the polarity and convert the signal if needed (the signal needs to be converted if the device is worn on the right hand). However, the polarity recognition is not always perfect and the ECG may be displayed with incorrect polarity.

- The wrist device is waterproof (IP57) up to an underwater depth of 1 metre. Nevertheless, moisture can affect measurements.
    - The device must be taken off when swimming or having a sauna.
    - The device can be worn while showering, taking a bath or doing housework such as washing dishes or doing laundry. However, it may be necessary to dry the wrist and the device afterwards in order to be able to take an ECG measurement.
    - A moist (for example, sweaty) or wet hand can prevent the initiation of an ECG measurement. Try to make measurements when the palm and wrist are dry.
    - Try to keep the space between the wrist device and the skin both clean and dry. If necessary, take the device off to clean and dry both the wrist and the bottom of the device with a soft cloth.
    - A wet environment, such as a shower, can cause accidental ECG measurements to start and the device may then the relevant notifications erroneously. These notifications should be ignored.
- If the red LED light on top of the wrist device is continuously on, the device is in unrecoverable error mode. Please contact the personnel that provided the device. Note: If the continuous red LED occurs only during charging, please ensure that you are using the power supply unit provided with the product.
- Damaged or suspected inoperative equipment must be removed from use. It must be checked and repaired by qualified service personnel prior to continuing use.
- Only the accessories and detachable parts mentioned in the user guide should be used with the PulseOn Arrhythmia Monitor. Only the supplied charger should be used to recharge the device.
- *Battery low notification*. When the wrist device battery is running low, the device will vibrate every 30 minutes and continuously – but faintly – blink red until it is placed in the charging dock. The low-battery warning does not disrupt any of the device's normal functions. To ensure prolonged proper functioning of the device, it must be recharged.
- During charging at the maximum usage temperature (38°C), the wrist device may heat up to 42°C. Once removed from the charger and taken into use, the device will cool down. During normal operation, the device does

not heat up to more than 1°C above ambient or wrist temperature.

- If for any reason the device feels hot, do not wear it.
- Motion affects the performance of the wrist device. PPG-based arrhythmia analysis is performed when the patient is stationary. When taking an ECG measurement, the patient should be still.
- A non-scheduled ECG measurement notification may sometimes be triggered due to signal artefacts or by the user having high non-pathological heart rate variation.
- The wrist device is not intended for use at the same time as the use of high frequency (HF) surgical equipment or a defibrillator. A defibrillator may break the device; the wrist device is not defibrillation-proof.
- The wrist device is not intended to be used in a magnetic resonance imaging (MRI) environment.
- The device is not intended to be used with a pacemaker.
- A healthcare professional needs to inspect the equipment for damage or excessive wear prior to each use.
- The equipment should be used by only one patient at a time.
- The wrist device and other parts of the system need to be properly cleaned after being used by one patient and before being used by another patient.
- The device needs to be configured for each patient by a healthcare professional.
- Correct tightness of the wrist band is important for optimal contact of the wrist device with the skin.
- No modification of the equipment is allowed. Do not try to disassemble, repair or modify any part of the equipment.
- The device and its accessories must not be serviced or undergo maintenance on while being worn or in use.
- The charging dock can be connected to a personal computer (PC) to download/upload wrist device data. Only a CE-approved PC complying with IEC 60950-1 or a similar safety standard should be used. The PC must be kept outside the patient environment and have restricted access. The PC should have anti-virus, firewall and operating system updates in use.
- To prevent possible damage to the equipment, maintain to the following environmental conditions:
- Operating temperature: +5°C to +38°C
    - Storage temperature: -20°C to +60°C
    - Relative humidity: 5% to 90%, non-condensing
    - Ambient air pressure: 700 hPA to 1060 hPA

Notes

- The wrist device and its LEDs do not emit harmful radiation.

- The wrist device will automatically turn off (LEDs on the bottom turn off) if the battery level gets too low.
- The wrist device vibrates when a palm is placed on top of it in order to start an ECG measurement. If there is no vibration, the device is not operational. It is possible to inspect the operation of the optical measurement by looking underneath the device. If the yellow LED lights are on, the optical measurement is operational.
- The quality of the measured ECG data may be affected by the use of other medical equipment, including but not limited to ultrasound machines.
- Tattoos, dense body hair or dark skin in the wrist area can have a negative effect on the performance of the wrist device, as can cold skin or otherwise reduced blood perfusion.
- Excessive light does not harm the device, but it can affect the optical sensors and result in false notifications.
- The wrist device is a type-BF applied part fulfilling the EN 60601-1 (IEC60601-1) standard. Wrist device electrodes should not come into contact with any other conductive parts, including the ground.
- The system is not intended for ST segment analysis.

2.3. Contraindications

- Do not use the wrist device if you suffer from hypersensitivity to silicone. In the event of significant skin reactions, do not continue using the device.
- Do not use the wrist device on a wrist with infected eczema or otherwise broken skin.
- Do not use the wrist device for life-sustaining measurements.
- The wrist device is not intended to be used by children (under 18 years old) or for assessment of cardiac arrhythmias in children (under 18 years old).
- The wrist device is not intended to be used on people who have a pacemaker.
- The wrist device is not intended for use by people without the mental capacity to react to device notifications and/or symptoms.

2.4. Residual Risks

- It is important for AMS-1 users, whether medical personnel or patients, to understand the following known risks:
- Not using AMS-1 correctly can result in no usable medical data being available after the measurement period.

- Not using AMS-1 correctly can cause bad signal quality that is not flagged correctly. Then there is a risk of the trained professional not reacting to the data correctly.
- Wearing the AM-1 wrist device too tightly can cause inconvenience and discomfort for the patient.
- Not cleaning the AM-1 wrist device properly and allergic reactions can cause skin irritation.
- If the medical professional or patient does not use the electrical device safely, electric shock may result.
- The AM-1 device can overheat if it is charged or left in a hot environment.
- AMS-1 includes small parts and cables that can cause strangulation or asphyxiation if left within reach of small children.

These issues are covered in this guide, especially in section Warning and Safety Notices.

2.4. Intended Purpose

The PulseOn Arrhythmia Monitor System is used to assist in the diagnosis, screening and monitoring of atrial fibrillation and other cardiac arrhythmias visible in Lead I ECG. The system consists of a wrist-worn device and a data management service. The wrist device optically monitors pulse rate during periods of no motion, in order to detect possible atrial fibrillation, and it is used to take intermittent single-lead electrocardiogram (ECG) measurements between the arms. The wrist device stores the measured data, which is later transferred to the data management service where the data can be analysed by medical professionals. The device is intended to be used inside or outside a hospital environment. The usage period of the system can vary from days to several weeks.

2.5. Indications for Use

The PulseOn Arrhythmia Monitor System can be used in:
1. diagnosis of atrial fibrillation that is suspected on the basis of symptoms such as shortness of breath or palpitations;
2. follow-up of the effect of treatment given for atrial fibrillation; and
3. screening of atrial fibrillation and other cardiac arrhythmias, e.g. in the general population.

The PulseOn Arrhythmia Monitor wrist device's optical heartbeat interval measurement and analysis detects atrial fibrillation episodes lasting for at least 30 seconds while the subject is stationary. Other arrhythmias causing heartbeat irregularities may be detected by the system. The wrist device

reacts to the detected arrhythmias by giving a notification that an ECG record should be taken.

The ECG signal that is measured by the device is taken between the arms and is thus comparable with Lead I ECG. Cardiac arrhythmias including atrial fibrillation can be observed with the measured Lead I ECG. Therefore, with symptom-based or pre-scheduled ECG recordings, the device can also be used in the diagnosis of cardiac arrhythmias that do not cause irregular heartbeats.

2.6. Intended Users

The intended users of the PulseOn Arrhythmia Monitor System are medical professionals, administrators (support staff) and patients. Please refer to the complete User Guide for more details.

2.7. Essential Performance

Essential Performance (EP) denotes performance which is necessary for freedom from unacceptable risks. It may be best understood by identifying an operation/performance which, when absence or degraded, leads to unacceptable risk.
No essential performance has been defined for the PulseOn Arrhythmia Monitor.

2.8. Clinical Benefits

The PulseOn Arrhythmia Monitor System has the following clinical benefits:

- enables monitoring of a patient for a prolonged period of time, e.g. for 2 weeks, which increases the probability of detecting atrial fibrillation
- is comfortable for patients, which enables long-term monitoring
- facilitates recording of symptomless arrhythmia episodes due to the built-in continuous PPG monitoring which prompts the patient to take an intermittent ECG measurement
- is easy for the patient to use and therefore suitable for people who are not technically oriented
- has been clinically validated to provide ECG data to medical professionals for diagnosis of arrhythmia

2.9. Cleaning

As it is mostly in contact with the skin, the wrist device in particular must be meticulously cleaned between patients by the operator or the operating organization.

Regularly clean and disinfect the wrist device and other parts of the system. This should be done before giving the device to a patient and after receiving the device back from a patient. The device requires no specific cleaning after having been stored suitably.

The parts can be cleaned by wiping them with an antibacterial cleaning sheet or similar. Alternatively, the parts can be cleaned with paper or linen soaked in antibacterial solution. The suggested cleaning agent is a ~70 % isopropyl alcohol (isopropanol, IPA, propan-2-ol, i-PrOH) solution.

Be careful not to rub the device too forcefully. Never use very strong solvents such as acetone (i.e. nail polish remover).

Do not submerge any other parts of the equipment than the wrist device, rinse them with liquid or leave them in touch with liquid or a wet tissue for a prolonged time.

Do not attempt to clean any parts of the equipment by autoclaving or steam cleaning them as this may damage the equipment.

Make sure that USB or power connectors are dry before use.

The wrist device must be configured for the user before handing it over to the patient using the Data Management Software.

The device and system are properly installed when the Data Management Software can start a new measurement session on the device.

2.10. Periodic Maintenance

The wrist device has a lithium-ion battery inside. If the device is not in regular use, the battery should be recharged at least once a year to maintain its condition. The expected battery life is five years.

It is advisable to conduct a visual inspection of the equipment before and after every use for any possible defects, such as:

- The PPG sensor lenses on the bottom of the wrist device having become covered in dirt (or something else that blocks the LED light) or having fully become milky opaque, and when cleaning does not help. Small scratches or blemishes on the PPG sensors do not affect the performance of the device.
- The ECG sensors on either the top or the bottom having been bent or having otherwise physically changed shape.

Scratches on the ECG sensors do not affect the performance of the device.

The wrist device ECG and PPG sensors do not require any periodic calibration or maintenance.

2.11. Interference with Medical Devices

The devices may emit radio waves, which could affect the operation of nearby electronics, including cardiac pacemakers, hearing aids and defibrillators. The PulseOn Arrhythmia Monitor is not intended to be used with a pacemaker. If you have another implanted medical device, do not use the PulseOn device without first consulting your doctor or the manufacturer of your medical device.

Maintain a safe distance between the device and your medical devices and stop using the device if you observe a persistent interference with your medical device.

Note: The gateway device does not affect the PulseOn Arrhythmia Monitor.

2.12. Device Performance

The PulseOn Arrhythmia Monitor has the following performance in detecting atrial fibrillation in Caucasian over-50-year-olds when evaluated in 5-minute segments: sensitivity > 90 %, specificity > 95 % (disregarding the segments of undetermined rhythm, ~40 %).

The ECG analysis algorithm has achieved the following performance for atrial fibrillation detection in a large-scale clinical trial with a different measurement device but based on the same approach, i.e. short Lead I ECG measurements between the hands: sensitivity 92.4%, specificity 94.4% as reported by the Possible arrhythmia label in the ECG measurement.

3. Service-life and Shelf-life

Expected service-life of the device: The wrist device's life expectancy is five (5) years in continuous use with proper care. The wrist device has a lithium-ion battery inside. It is recommended that the battery be charged at least once a year to maintain its condition.

Expected service-life of other parts and accessories shipped with the device: The life expectancy of the parts and accessories is five (5) years in continuous use with proper care.

Shelf-life of the device: The shelf-life of the wrist device is three (3) years due to the nature of lithium-ion batteries. To keep the batteries in good condition, they should be recharged at least once a year.

Shelf life of parts and accessories shipped with the equipment: No expiry date.

4. Warranty and Replacement

PulseOn Oy ("PulseOn") hereby warrants that the products are free from defects in material and workmanship that result in product failure during normal usage, for the number of years specified in the documentation accompanying the product, or for a period previously agreed between the purchaser and PulseOn, or if not otherwise stated, for a period of one (1) year from the date of shipment.

In case of product replacement needs, please contact PulseOn support: support@pulseon.com

Before returning the device to the manufacturer, the wrist device must be cleaned.

PulseOn strives to act promptly on replacement needs. However, the company is unable to provide compensation of any sort.

5. Technical Support and Maintenance

In case of a need for technical support or assistance in maintaining or setting up the equipment or system, please contact PulseOn support.

Address : PulseOn Oy, Tekniikantie 12, 02150 Espoo, Finland
Telephone : +358 44 554 0811
E-mail : support@pulseon.com
Website : https://www.pulseon.com/support

6. Recycling Information

Electrical and electronic equipment (WEEE) contains materials, parts and substances that can be dangerous to the environment and harmful to human health if the electrical waste and electronic equipment (WEEE) is not disposed of correctly.

Equipment that is marked with the WEEE logo should not be thrown away with your household waste. The product should be handed over to the applicable collection point for the recycling of electrical and electronic equipment, for proper

treatment, recovery and recycling in accordance with your national legislation.

Contact your local authority waste disposal department, as they will be able to provide details of the recycling options available in your area.

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