



Philips Axon Regulatory Notice

Introduction

This Notice contains regulatory information for the Philips Axon product and is therefore an extension of the *Philips Axon Instructions for Use*. It details the compliance statements that the product requires for its certification and approval. Philips is therefore committed to delivering products compliant with standards, laws and regulations.

Certification Marks



Australia Regulatory Compliance Mark (RCM). The Axon complies with the Radiocommunication Act 1992.



Compliance with European directives



Separate collection for electrical and electronic waste (WEEE directive)



NRTL safety mark



Compliance for products being placed in Great Britain.



Regulatory compliance and approvals

USA Federal Communications Commission

Philips Axon complies with Part 15 of the FCC Rules. Operation is subject to two conditions:

- This device may not cause harmful interference.
- 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 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.

Note: For operation within 5.180 ~ 5.250GHz / 5.500 ~5.700 GHz frequency range, the Axon is restricted to indoor environments. The band from 5600-5650 MHz will be disabled by the software during manufacturing and cannot be changed by the end user. This device meets all the other requirements specified in Part 15E, Section 15.407 of the FCC Rules.

Caution: Philips is not responsible for any radio or television interference caused by unauthorized changes or modifications to this equipment. Unauthorized changes or modifications could void the user's authority to operate the equipment.

Caution: Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

Radiation Exposure Statement

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with a minimum distance of 20 cm between the radiator and your body.

Note: The country code selection is for non-US models only and is not available on all US models. Per FCC regulation, all Wi-Fi products marketed in the USA must be fixed to US operation channels only.

Canada

Innovation, Science and Economic Development Canada (formerly Industry Canada) Statement

CAN ICES-003 B / NMB-003 B

This device contains license-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's license-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

Radiation Exposure Statement

This equipment complies with ISED radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with a minimum distance of 20 cm between the radiator & your body.

Caution: The device operates in the band 5150-5350 MHz, for indoor use only.

For further information, contact your local Industry Canada office.

European Union

CE Declaration

Philips hereby declares that this device complies with essential requirements and other relevant provisions of the Council Directive 2014/53/EU of April 16, 2014 concerning radio equipment and carries CE-marking accordingly.

This equipment may be operated in:

Austria	Greece	Norway
Belgium	Hungary	Poland
Bulgaria	Iceland	Portugal
Croatia	Ireland	Romania
Cyprus	Italy	Slovakia
Czech Republic	Latvia	Slovenia
Denmark	Liechtenstein	Spain
Estonia	Lithuania	Sweden
Finland	Luxembourg	Switzerland
France	Malta	Turkey
Germany	Netherlands	

Certain countries have specific restrictions for, or prohibitions on devices that operate in the 5 GHz band. Specifically in certain European countries, for example, some frequencies should be restricted to indoor use. The frequency and the maximum transmitted power in the EU are listed below:

2.412 – 2.472 GHz: 19.99 dBm max

5.180 – 5.700 GHz: 22.99 dBm max

You are advised to respect local requirements.



For a copy of the full RED Declaration of Conformity, contact a Philips representative.

REACH compliance

Pursuant to REACH regulation 1907/2006, Article 33, and the introduction of Lead in the list of Substances of Very High Concern (SVHC) by the European Chemical Agency (ECHA), Philips has identified components in the Philips Axon containing lead above a 0.1% weight/weight.

Lead is detected in hexagonal stands supporting the PCB. These components are internal and consequently do not expose users to the substance. In addition, lead is also detected in the DC connector. This component is made of an alloy that contains a small amount of lead and is not intended to release its substance under normal or reasonably foreseeable conditions of use.

Those parts meet exemptions in Directive RoHS 2011/65/EU, which Philips Axon complies with as explained in the section, *RoHS and WEEE compliance*.

RoHS and WEEE Compliance

This device does NOT contain any of the following substances (in concentrations exceeding legal threshold limits):

- Lead
- Mercury
- Cadmium
- Hexavalent Chromium
- Polybrominated Biphenyls (PBB)
- Polybrominated Diphenyl Ethers (PBDE)
- Bis(2-Ethylhexyl) phthalate (DEHP)
- Benzyl butyl phthalate (BBP)
- Dibutyl phthalate (DBP)
- Diisobutyl phthalate (DIBP)

In the European Union, this product and its cables should be collected separately and not disposed of with household waste. For details, refer to the section entitled *Disposal* in this document.

Chromium, lead, mercury, or cadmium are not intentionally added to packaging materials and are not present in a cumulative concentration greater than 100 ppm as incidental impurities. No halogenated plastics or polymers are used for packaging material. Packaging is compliant with the Council Directive 94/62/EC.

Great Britain

This device complies with essential requirements and other relevant provisions of the 2017 Radio Equipment Regulations, No. 2017 SI 2017/1206. This equipment may be operated in the United Kingdom.

Certain countries have specific restrictions for, or prohibitions on devices that operate in the 5 GHz band. Specifically in certain European countries, for example, some frequencies should be restricted to indoor use. You are advised to respect local requirements.

For a copy of the full UKCA Declaration of Conformity, contact your Philips representative.

RoHS and WEEE Compliance

This device does NOT contain any of the following substances (in concentrations exceeding legal threshold limits):

- Lead
- Mercury
- Cadmium
- Hexavalent Chromium
- Polybrominated Biphenyls (PBB)
- Polybrominated Diphenyl Ethers (PBDE)
- Bis(2-Ethylhexyl) phthalate (DEHP)
- Benzyl butyl phthalate (BBP)
- Dibutyl phthalate (DBP)
- Diisobutyl phthalate (DIBP)

Cables should be collected separately and not disposed of with household waste. For details, refer to the section entitled *Disposal* in this document.

Chromium, lead, mercury, or cadmium are not intentionally added to packaging materials and are not present in a cumulative concentration greater than 100 ppm as incidental impurities. No halogenated plastics or polymers are used for packaging material. Packaging is compliant with the Council Directive 94/62/EC.

Recycling and the environment

Improper disposal of IT equipment can have a negative impact on health and the environment. We recommend that you dispose of the Axon, DIM, and serial cables at an appropriate facility to enable recovery and recycling. You can also recycle packaging and guides according to your local recycling regulations.

In the European Union, for assistance with the recycling of this product, visit our customer site: <https://customers.capsuletech.com/environment>

Safety and Regulatory Compliance table

Field	Standard or regulation
Medical device safety	EN 60601-1 IEC 60601-1 3rd edition with national deviations for USA and Canada
IT safety	IEC 62368-1
Medical device usability	IEC 60601-1-6 IEC 62366
Medical device Software – Software Lifecycle Processes	IEC 62304
EMC/EMI	FCC 47 CFR Part 15 sub-part B

Field	Standard or regulation
	ICES-003 A / NMB-003 A EN 60601-1-2 CISPR 24 CISPR 32 CISPR 35 IEC 61000-3-2 IEC 61000-3-3
Radio	EN 301 489-1 EN 301 489-17 EN 301 893 EN 300 328 EN 62311 RSS-210 FCC 47 CFR 15 C FCC 47 CFR 15 E
OET65	ANSI/IEEE C95.1
Environment/Packaging	EU Directive 94/62/EC
Environment	REACH 1907/2006
RoHS	EU Directive 2011/65/EU
WEEE	EU Directive 2012/19/EU

Japan Ministry of Internal Affairs and Communications (MIC)

The Philips Axon is certified to the Technical Regulation Conformity Certification under the Japanese Radio Law.

Info-communications Media Development Authority (IMDA) Singapore

The Philips Axon is an IMDA-registered product.

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