SmartLinx Neuron 3 Regulatory Notice

Introduction

This Notice contains regulatory information for the SmartLinx Neuron 3 product and is therefore an extension of the *SmartLinx Neuron 3 Installation and Maintenance Guide*. It details the compliance statements that the product requires for its certification and approval. Capsule Technologies, Inc. is therefore committed to delivering products compliant with standards, laws and regulations.

Certification Marks

Recognized component

Underwriters' Laboratories

Compliance with FCC Regulations
Assembled from tested components
Complete system not tested

IATA Lithium Battery Mark
Hazard Warning Label (UN 3091)

IATA Lithium Battery Mark
Hazard Warning Label (UN 3481)

Regulatory compliance and approvals

USA

Federal Communications Commission

SmartLinx Neuron 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 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

Note: This device meets the requirements specified in Part 15E, Section 15.407 of the FCC Rules.

Caution: Capsule Technologies 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 minimum distance 20 cm between the radiator and your body.

Note: The country code selection is for non-US model only and is not available on all US models. Per FCC regulation, all Wi-Fi products marketed in the USA must 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 licence-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's licence-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 minimum distance 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.

Disposal

As you use the SmartLinx Neuron 3, you will accumulate solid wastes that require proper disposal or recycling. These include system components, batteries, and packaging materials.

Recycling and the Environment

Improper disposal of IT and medical equipment can have a negative impact on health and the environment. We recommend that you dispose of Capsule Technologies products, including all electronic devices, cables, batteries, and so on, at an appropriate facility to enable recovery and recycling. You can also recycle packaging and guides according to your local recycling regulations.

Components

At the end of its service life, the products described in this manual, as well as their accessories, must be disposed of in compliance with the guidelines regulating the disposal of such products. If you have questions concerning disposal of the product, contact Capsule Technologies or its representatives.

Batteries

The sealed, rechargeable batteries contain lead and can be recycled. Discharge (deplete) batteries prior to disposal. Place the battery in packaging which electrically isolates its contents. Do not puncture or place the battery in a trash compactor. Do not incinerate the battery or expose it to fire or high temperatures. Dispose in accordance with regional body-controlled guidelines and hospital protocol.

Warning: Improper disposal of batteries may create an explosion or contamination hazard. Always recycle batteries according to local regulations. Never dispose of batteries in refuse containers. Do not wrap them in metal or aluminum foil. Wrap them in newspaper before disposing of them. Do not burn them. Battery may explode if overheated.

Packaging Material

Retain original packaging materials for future use in shipping the system and its accessories. The recommendation includes corrugated shippers and inserts. Whenever possible, recycle the packaging of accessories.

Standards Compliance

Field	Standard or regulation
Safety	IEC 60950-1 UL 2054 / IEC 62133 IEC 60601-1
EMC	IEC 60601-1-2 (Class B emission) IEC 61000-3-2 IEC 61000-3-3 CISPR 22 CISPR 32 CISPR 24 CISPR 35 IEEE ANSI C63.4
Radio	IEEE ANSI C63.10

Essential Performance

- The system maintains clinical data integrity up to delivery to a third-party system. This performance does not include: data not being delivered or the delay of data delivery.
- The system does not compromise the operation of connected medical devices (vital signs monitors).

Legal Notice

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